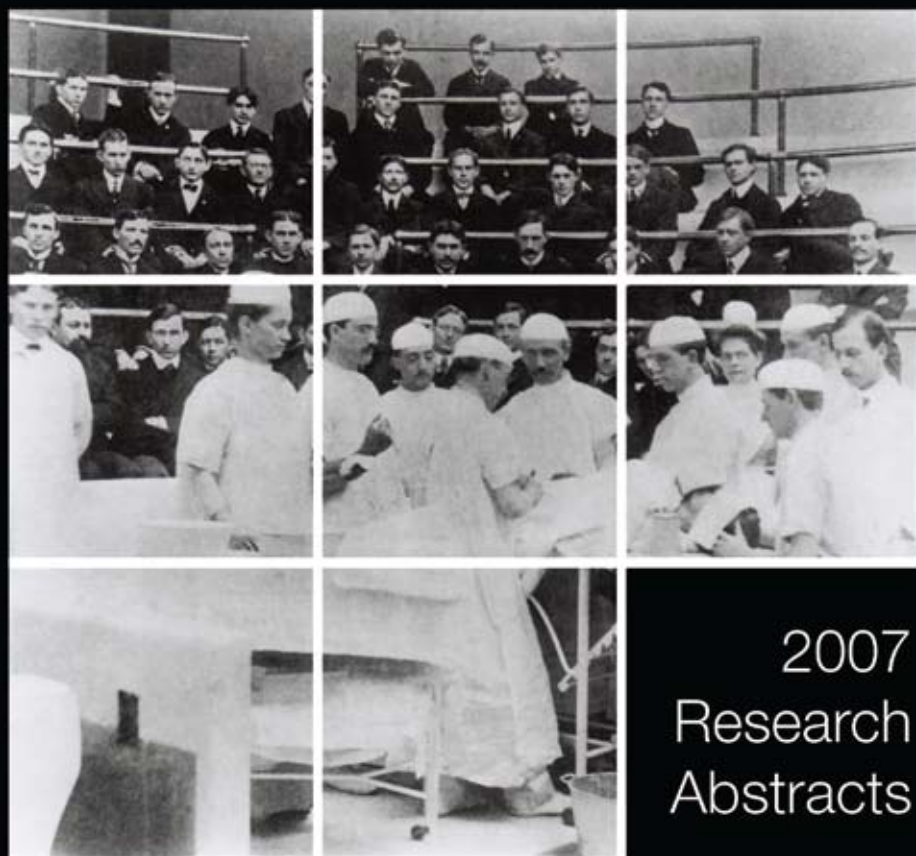




Case Western Reserve University School of Medicine

Department of Surgery



2007
Research
Abstracts

2007-2008 Research Abstracts

CASE SURGERY

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Dear Colleague:

I am pleased to share with you our 2007-2008 research abstracts. The Department of Surgery provides a unique multi-specialty academic environment where ideas are exchanged and cooperative research programs are planned.

The 2007-2008 academic year has been a fruitful and productive one for the department and it's members. The work produced has been presented at national and international forums and published in prestigious journals.

The Department of Surgery will continue to expand it's research and educational endeavors in the coming year.

We welcome your interest in our Department's research and clinical studies. If you would like additional information, please call 216.844.3209 or visit our web site at www.casesurgery.com

Sincerely,

Jeffrey L. Ponsky, MD
Oliver H. Payne Professor and Chair
Surgeon-in-Chief

Special thanks to the Case School of Medicine Biologic Research Unit for their continued support.

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Section 1

**Cardiovascular and
Cardiothoracic
Surgery**

A NOVEL PERCUTANEOUS INTRAVASCULAR REWARMING CATHETER PROTECTS AGAINST HYPOTHERMIA

A. Blitz, A.S. Aharon, S. Okada, J. Foster, S. Small, J. Andrews, S. Schomisch

INTRODUCTION: Hypothermia has been consistently linked with numerous morbidities, including shivering, wound infection, cardiovascular ischemia, coagulopathy, altered drug metabolism, and prolonged postoperative recovery. Because of extensive body surface exposure, it is particularly challenging to prevent and treat hypothermia in the burn patient.

HYPOTHESIS: The purpose of the present study is to evaluate the effectiveness of a novel rewarming catheter (Thermogard) as a protection against hypothermia during burn surgery.

METHODS: Two sets of paired adult pigs were cooled on cardiopulmonary bypass to achieve an equilibration temperature of 33 degrees Celsius. In Group C (Control), cardiopulmonary bypass was weaned at that temperature and the animal was allowed to thermoregulate on his own. Ambient temperature was kept at 21 to 23 degrees Celsius. In Group E (Experimental group) the animals underwent the exact same protocol as that described for Group C, with the addition of one intervention: the percutaneous insertion of a rewarming catheter via the right femoral vein and its subsequent activation. During the rewarming phase, nasopharyngeal temperature, ambient temperature, blood pressure, and pulse rate were recorded every 15 minutes for a period of 3 hours.

RESULTS: The mean change in temperature from the 33 degree baseline to the end of the 3-hour study period was -0.94°C for the control group and $+0.46^{\circ}\text{C}$ for the experimental group. The difference in the final mean temperatures of 1.4°C was significant ($p=0.018$) by the paired t-test. Moreover, all 5 animals (100%) in the control group demonstrated a significant drop in body temperature (defined to be $>0.3^{\circ}\text{C}$ drop in temperature) over the rewarming period in contrast to none (0%) in the experimental group. Using Fischer's exact test, this difference was highly significant ($p=0.008$).

CONCLUSIONS: Use of an intravascular rewarming catheter provides superior protection against hypothermia in an adult porcine model of hypothermia. The experimental model was designed to provide a particularly challenging barrier for rewarming. This catheter could potentially have wide application in burn patients.

A NOVEL PERIOPERATIVE HYPOTHERMIA MODEL TO TEST WARMING STRATEGIES

Arie Blitz, MD

INTRODUCTION: Perioperative hypothermia remains an obstacle to postoperative recovery. We present here an austere swine model of hypothermia, designed to provide a challenging environment for evaluating the efficacy of alternative warming strategies. (See Table)

METHODS: A pair of 100 kg swine are tested concurrently. Such pairing ensures identical ambient environments for the Control (C) and Experimental (E) groups. Each of the swine is then anesthetized and intubated. After systemic heparinization and left femoral cannulation, the swine are cooled on CPB to a core temperature of 33°C. CPB is then discontinued. In group C, no further interventions are made. In group E, a specific therapeutic intervention is employed for warming the swine. For example, in our first series of experiments, we tested an intravascular rewarming catheter (vide infra). The experiment is then continued for 3 hours post-CPB. The animals are then euthanized.

RESULTS: The following data are recorded: Every 15 minutes: core and ambient temperatures, MAP, heart rate, and CPB flow rate. Every 30 minutes: ACT and ABG. In our initial series of experiments, the model has been used to evaluate the efficacy of a percutaneous intravascular rewarming catheter (Alsius corporation). At the end of 3 hours of rewarming, the E group achieved a temperature of 1.4°C greater than that of the C group ($p=0.018$).

CONCLUSION(S): A swine model is described for the evaluation of alternative rewarming strategies. This model has been intentionally designed to provide an extremely formidable barrier to rewarming, and has been validated in our initial set of experiments.

USE OF A NOVEL PERCUTANEOUS WARMING CATHETER AS A PROTECTION AGAINST PERIOPERATIVE HYPOTHERMIA

Arie Blitz, M.D., FACC, Shoichi Okada, B.S., Jeff Foster, CCP, Sarah Small, R.N. and Steve Schomisch, B.S.

INTRODUCTION: Hypothermia has been consistently linked with numerous perioperative morbidities. Although numerous techniques exist to prevent or treat hypothermia, none is ideal.

HYPOTHESIS: The purpose of the present study is to evaluate the effectiveness of a novel rewarming catheter as a protection against hypothermia perioperatively.

METHODS: Two sets of paired 100 kg pigs (n=5 in each group) were cooled on cardiopulmonary bypass to achieve an equilibration temperature of 33 degrees Celsius. In Group C (Control), cardiopulmonary bypass was weaned at that temperature and the animal was allowed to thermoregulate on its own. The swine were left exposed to the environment, and ambient temperature was kept at 21 to 22 degrees Celsius. In Group E (Experimental group) the animals underwent the exact same protocol as that described for Group C, with the addition of one intervention: the percutaneous insertion of a rewarming catheter via the right femoral vein and its subsequent activation. During the rewarming phase, nasopharyngeal temperature, ambient temperature, blood pressure, and pulse rate were recorded every 15 minutes for a period of 3 hours.

RESULTS: The mean change in temperature from the 33 degree baseline to the end of the 3 hour study period was -0.94 C for the control group and +0.46 C for the experimental group. The difference in the final mean temperatures of 1.4 C was significant (p=0.018) by the paired t-test. See figure 1.

Moreover, all 5 animals (100%) in the control group demonstrated a significant drop in body temperature (defined to be >0.3 C drop in temperature) over the rewarming period in contrast to none (0%) in the experimental group. Using Fischer's exact test, this difference was highly significant (p=0.008). See figure 2.

CONCLUSION: Use of an intravascular rewarming catheter provides superior protection against hypothermia in an adult porcine model of hypothermia. The experimental model was designed to provide a particularly challenging barrier for rewarming.

SUMMARY: A paired swine cardiopulmonary bypass model was used to provide a challenging environment for rewarming after hypothermia. Insertion of a novel warming catheter demonstrated superior protection against hypothermia in this model.

CASE REPORT: POSTOPERATIVE THERAPEUTIC HYPOTHERMIA AFTER CARDIAC ARREST AND CARDIAC SURGERY

Blitz A*, Williams G**, Okada S*, McFarland H**, Foster J*

*Division of Cardiac Surgery and **Department of Anesthesiology, University Hospital Case Medical Center, Cleveland, Ohio

INTRODUCTION: The optimal management of patients who suffer an intraoperative cardiac arrest at the time of cardiac surgery is unclear. We report here a case of such a patient. Therapeutic hypothermia was used as an adjunct both in the intraoperative setting as well as in the postoperative care of this patient to optimize neurological outcome.

METHODS: A 56-year-old male was brought urgently to the OR with 95% left main disease, ischemic cardiomyopathy, and severe mitral regurgitation. The patient tolerated induction of anesthesia; however, during LIMA harvesting, the patient spontaneously became asystolic. Heparinization, pericardiotomy, and open cardiac massage were immediately instituted while preparations were made for CPB. CPB was initiated after 7 minutes of CPR, and the patient was immediately cooled to 28°C. On CPB the patient underwent an intraaortic balloon pump placement, CABGx5, and a mitral valve repair. Total CPB time was 224 minutes. The patient then weaned from CPB on multiple inotropes and pressors to maintain a cardiac index above 2.5 L/min/m² and a mean arterial pressure of 80mmHg. The patient remained hemodynamically stable during the initial postoperative period but failed to wake up. In addition, 6 hours following arrival in the ICU, the patient was noted to have a generalized tonic clonic (GTC) seizure approximately 15 seconds in duration. The patient was immediately given IV lorazepam followed by an IV phenytoin load. The patient was nonetheless noted to have 2 more breakthrough seizures. The patient concomitantly spiked a temperature in excess of 39 degrees at this time. Because of the intraoperative cardiac arrest, recurrent seizures, and hyperthermia, therapeutic hypothermia was initiated with a water-recirculating system (Artic Sun™). However, because cooling proceeded slowly, the water-cooling system was replaced by the Thermogard XP™ cooling system. This was accomplished by placing an intravascular cooling catheter (Quattro) in the left femoral vein.

RESULTS: Following placement of the cooling catheter, the patient was expeditiously cooled to 33.00C, and this was continued for a duration of 48 hours (see Figure 1).



This was maintained within +/- 0.10C of the target temperature. The cooling protocol was then discontinued gradually and the Thermogard XP™ catheter was removed. No further GTC seizures were noted; however, the patient remained comatose for 1 week following surgery. Continuous EEG monitoring showed global slowing without epileptiform activity. Surprisingly, On POD #9, the patient spontaneously awakened and became interactive. Over the following days, the patient's neurological status improved to the point that he was able to speak, tolerate a regular diet, and move all extremities. He was then discharged to a skilled

RADIAL ARTERIES VS SAPHENOUS VEIN BYPASS GRAFTS FOR CABG

Arie Blitz, MD and Richard F. Brodman, MD*

The benefits of unilateral and bilateral internal thoracic artery (ITA) for revascularization are well known. For more than 25 years, use of a variety of alternative arterial bypass grafts has increased because saphenous vein bypass grafts degenerate over time. The radial artery (RA) was abandoned in the 1970s because of unacceptably poor early patency of about 50%. Mechanical intimal trauma used intra-operatively doomed the RA to failure in the '70s. The advent of calcium channel blockers, better harvesting techniques, and excellent early patency of RA grafts led to a resurgence in the use of the RA in the 1990's. Nonetheless, its use still ignites some controversy.

The RA is easy to harvest, is more uniform in size than the ITA, generally has a larger internal diameter than the ITA, is easier to work with than the ITA, and is of ample length for any coronary target. However, the RA is more disposed to vasospasm than the ITA. Proper harvest technique and surgical management of the RA, though not difficult, is critical to success. The results of coronary revascularization using the RA in the present era are excellent. In a recent prospective randomized study, Desai and colleagues compared the patency of RA grafts to saphenous vein grafts. The patency rate of RA grafts at 1 year was 91.8% and saphenous vein grafts 86.4% ($p=0.009$). A finding in this study, as well as others, is that RAs are best used to graft coronary vessels that have high grade stenosis.

We will present our technique for RA harvest, a 12 year single surgeon experience using the RAs as second and third bypass grafts of choice after the LITA, and a review of the recent literature on RA and saphenous vein graft patency. We will include a brief video of ulnar artery harvest technique.

CONCLUSION: The RA plays an indispensable role in the current era of total arterial revascularization. As long as meticulous attention is paid to details of its harvesting, preparation, and target selection, it will continue to be an integral part of coronary bypass surgery.

THE USE OF A NOVEL INTRAVASCULAR TEMPERATURE MANAGEMENT CATHETER FOR HIGH RISK CARDIAC SURGERY

Arie Blitz, George Williams, Shoichi Okada, Heather McFarland, Jeff Foster, Sarah Small

OBJECTIVES: Because perioperative temperature management can be a challenge during certain types of cardiac surgery, we evaluated the use of a novel intravascular warming/cooling catheter in four patients undergoing operations of varying complexity.

METHODS: Four surgical cases were included in this evaluation. The first case is that of a 72-year-old male with severe COPD who underwent emergent repair of an aortic arch dissection requiring hypothermic circulatory arrest. The second case is that of a 58-year-old male with end-stage cardiomyopathy who underwent elective Heartmate LVAD insertion for Destination Therapy. The third case is that of a 78-year-old female who underwent salvage RVAD insertion for an acute right ventricular infarct with cardiogenic shock. The first three cases were performed with the intravascular catheter inserted during the operation so as to achieve and maintain normothermia in the early perioperative period. A fourth case is that of a 56-year-old male with bilateral severe carotid stenoses, tight left main disease, and ischemic mitral regurgitation, who underwent urgent coronary bypass surgery and mitral valve repair. Shortly after induction the patient suffered a cardiac arrest requiring cardiopulmonary resuscitation. The patient was placed on bypass and his surgery was completed. Postoperatively, the intravascular catheter was used to cool the patient to 33 degrees for a duration of 48 hours after surgery to allow recovery from his perioperative stroke and seizures.

RESULTS: All four patients in this series had tight control of their target core temperatures. Temperature curves have been generated for all four patients, and these will be presented. The figure below displays the temperature curve for the first patient described.

CONCLUSIONS: Use of an intravascular temperature control catheter facilitated the postoperative recovery of four challenging cases with expected high mortality rates. Further studies are indicated to delineate the role this temperature management system should have in cardiac surgery.

A NOVEL EXPERIMENTAL MODEL TO EVALUATE THE EFFECTIVENESS OF REWARMING STRATEGIES FOR PERIOPERATIVE HYPOTHERMIA

Arie Blitz*, Jeff Foster, Sarah Small, Steve Schomisch

OBJECTIVES: Hypothermia often complicates the postoperative course of cardiothoracic patients. A novel model, designed to provide a challenging environment for rewarming, is presented here as a tool for evaluating the efficacy of competing post-CPB rewarming strategies.

METHODS: Set-up Phase: A pair of 100 kg swine, each weighing approximately 100 kg, are tested simultaneously. Such pairing ensures identical ambient environments for the Control (C) and Experimental (E) groups. Each of the swine is then anesthetized, intubated, and left uncovered on a bare operating table. A distal esophageal temperature probe is placed transorally. The ambient temperature is kept at 21-22°C throughout the experiment.

Cooling Phase: After systemic heparinization, the left groin is cannulated for CPB, and the animal is cooled on CPB to a core T of 33°C.

Rewarming Phase: CPB is discontinued. In the C group, no further interventions are made. In the E group, a specific therapeutic intervention is employed. For example, this may consist of the placement of a Bair hugger, a circulating water mattress, or an intravascular warming catheter. The total duration of the rewarming period is 3 hours. The animals are then euthanized.

RESULTS: The following data are recorded:

1. Baseline weight.
2. Every 15 minutes: esophageal T, ambient T, MAP, heart rate, CPB flow rate (for cooling phase only).
3. Every 30 minutes: ACT and ABG.

To date, the model has been used to evaluate the efficacy of a percutaneous intravascular rewarming catheter. Our model has shown that, at the end of 3 hours of rewarming, the E group achieved a temperature of 1.4°C greater than that of the C group ($p=0.018$).

CONCLUSIONS: A novel experimental swine model is described for the evaluation of alternative rewarming methods for the prevention and treatment of perioperative hypothermia. This model has been intentionally designed to provide a formidable barrier to rewarming.

MITRAL REPAIR FOR ISCHEMIC MITRAL REGURGITATION

*Arie Blitz, MD**

Ischemic mitral regurgitation (IMR) is one of the more challenging types of insufficiency to repair. Numerous studies over the past several decades have demonstrated that—in general—successful mitral repair is preferable to replacement when it is feasible. For IMR, however, the MR may be more challenging to correct and the results may not be as durable as for other types of repair. IMR may arise acutely or chronically. In the acute scenario, patients are often very ill and unstable; mitral valve replacement may be the best alternative in this scenario. In the chronic scenario, IMR is usually due to papillary muscle mal-displacement, ventricular wall motion abnormalities, annular dilatation or some combination thereof. Correction of IMR is usually performed in conjunction with coronary bypass surgery. A variety of rings are available that are tailored to correct the altered geometry of IMR. In this presentation we will review the tailored repair techniques for IMR, as well as the clinical results of IMR repair.

BICUSPID AORTIC VALVE STENOSIS REQUIRING VALVE REPLACEMENT 10 YEARS AFTER HEART TRANSPLANTATION: CASE REPORT AND A LITERATURE REVIEW

Yakov Elgudin, Edward Lesnefsky, Ileana Pina, Jose Ortiz, Diana Whittlesey, and Brian Cmolik

This is a case report of a 59 year old patient who underwent an emergency coronary bypass surgery followed by ventricular assist device (VAD) implantation as a bridge to transplantation in 1997. VAD explantation and orthotopic heart transplantation (OHT) were performed several months later. ECHO evaluation of the donor heart revealed presence of a bicuspid aortic valve with normal opening, no transvalvar gradient, and no LV hypertrophy. At transplantation, a raphe was noted between the leaflets creating a bicuspid aortic valve but the leaflets were otherwise normal. One episode of an acute rejection occurred within the first month after transplantation but the patient otherwise made a good recovery.

Long term follow up demonstrated progressive aortic stenosis and increasing LVH in the face of a mild allograft vasculopathy. Increasingly symptomatic, the patient was evaluated at our hospital and found to have a severe aortic stenosis with a valve area of 0.7 cm sq and a peak gradient of 72 mm Hg with non-obstructive coronary allograft vasculopathy. In 2008, aortic valve replacement with a bioprosthetic valve using remote arterial and venous cannulation technique was undertaken without complication.

There have been few reports on aortic valve replacements in transplanted hearts. In a large series of over 1400 heart transplantation cases (Coskun et al., 2007) only 8 valve replacements (five- tricuspid and three – mitral) were performed, all within the first five years after the OHT. Rothenberger et al, 2005 reported "three aortic valve surgeries for an acute aortic dissection" in their group of 340 transplant recipients.

In summary, bicuspid aortic valve in a donor heart is a rare occurrence as a result of a rigorous donor selection process. When a heart with a bicuspid aortic valve is used for an OHT an increased risk of bicuspid valve stenosis should be anticipated. Aortic valve replacement can be safely performed in patients with otherwise well functioning cardiac allografts.

INCORPORATION AND RELEASE OF CYTOKINES FROM BIPHASIC POLYMERIC HEART VALVE TISSUE ENGINEERING SCAFFOLDS

M. Smith, Y. Elgudin, O. Arnoult, N. Greco, M Laughlin, S. Emancipator, B. Cmolik, and G. Wnç

PURPOSE: Electrospun polymers represent an excellent example of multi-functional biomaterials, affording a micro- or nanofibrous mechanical support for cell and tissue growth, a high surface area and controllable surface chemistry, tailored porosity to promote nutrient and waste transport, and a matrix for the delivery of bioactive molecules. Incorporation of water-soluble molecules into otherwise hydrophobic polymers represents an interesting challenge. One viable approach involves using 'biphasic' electrospinning, where dispersions of water droplets in a polymer/organic solvent are first prepared and then electrospun, encapsulating the aqueous pockets within polymer fibers. Molecules initially dissolved in the water droplets are sequestered in aqueous domains in the fibers, and can be released via a variety of mechanisms. The purpose of this study was to investigate the incorporation and release of various cytokines, including vascular endothelial growth factor (VEGF), from biodegradable polymer scaffolds, to assess and control delivery kinetics and to determine the impact of the processing and release on the activity of bioactive compounds from these heart valve tissue engineering scaffolds.

METHODS: Biphasic electrospinning was carried out with poly(ϵ -caprolactone) (PCL), a biocompatible and biodegradable polymer. PCL was dissolved in chloroform (CHCl₃) to form a viscous solution, and combined with an aqueous solution of VEGF in phosphate buffered saline (PBS, 10x). The mixture was ultrasonicated to create a suspension of the aqueous phase within the organic phase. Electrospinning was then carried out to obtain nonwoven fibrous polymer mats containing aqueous domains of the encapsulated protein. Mats were characterized via scanning electron microscopy for fiber diameters and porosity, and by dynamic mechanical analysis to evaluate thermal and mechanical properties. Fluorescent labeling and microscopy was used to locate the proteins within the fibers, to ensure complete encapsulation and isolation. ELISA was performed to quantify release rates and to assess the activity of the protein upon delivery.

RESULTS: Biphasic scaffolds containing VEGF were successfully produced from PCL and were fabricated in thicknesses ranging from fifteen to several hundred microns. VEGF was found to be fully encapsulated within aqueous pockets in the core of the fiber, providing isolation from the external environment. Release profiles for the various scaffolds were obtained, with greater than 85% of the total protein being delivered. Also, it was found that protein activity was not negatively affected by the fabrication or release.

CONCLUSION: Using biphasic electrospinning, cytokines that influence endothelial cell behavior can be readily encapsulated in aqueous domains within polymer fibers, and controlled delivery of the active protein can be achieved providing a multifunctional tissue engineering scaffold.

EVALUATION OF MECHANICAL PROPERTIES OF ELECTROSPUN SCAFFOLDS FOR HEART VALVE TISSUE ENGINEERING

M. Smith, O. Arnoult, N. Greco, M Laughlin, S. Emancipator, B. Cmolik, G. Wnç, and Y. Elgudin

PURPOSE: Stability of the tissue engineered heart valves is related to the mechanical properties of the scaffolding material. Proper mechanical evaluation is of high importance in determining a potential scaffold's applicability for engineering of the cardiac valves. Electrospun synthetic and biopolymeric scaffolding has been developed by our lab for heart valve tissue engineering. These scaffolds consist of either nano- or microfibers of poly(ϵ -caprolactone) (PCL), collagen, or biphasic PCL fibers with vascular endothelial growth factor (VEGF) encapsulated inside the core of the fiber. The objective of this work was to perform preliminary evaluation of the mechanical properties of the electrospun scaffolds. Tensile properties of the scaffolds were studied and compared to those of a commercial bovine pericardial valve treated with glutaraldäyde as well as a porcine valve and bovine pericardium stabilized with a diepoxide.

METHODS: Tensile testing was carried out using both dynamic mechanical analysis (DMA) and Instron testing with all samples loaded under identical conditions for each testing apparatus. All tissue samples were dried for 24 hours prior to testing. Electrospun samples were used in their as-produced state. For both DMA and Instron testing, small strips of the sample were prepared, and loaded in tension until failure, at constant strain rates. The elastic modulus, ultimate tensile strength (UTS) and ultimate elongation for each sample were then determined.

RESULTS: The electrospun single phase and biphasic PCL scaffolds were found to have comparable mechanical properties to the valve replacement samples tested. Elastic moduli were similar in all samples measured. Considerable variation, however, was seen in the UTS and elongation between the electrospun and tissue samples. Both types of electrospun scaffolds tested were found to have lower UTS than the bioprosthetic valve tissue. Biphasic PCL scaffold had also shown lower elastic modulus, UTS and elongation than the single phase matrix.

CONCLUSION: Mechanical properties of the electrospun scaffolds were found to be comparable to the bioprosthetic valves samples. Further investigation of the biologically relevant mechanical parameters of the scaffolding material is warranted.

CELL-FIBER COMPLEX AS A SCAFFOLD FOR THE HEART VALVES TISSUE ENGINEERING PRODUCED VIA ELECTROSTATIC PROCESSING

M. Smith, O. Arnoult, N. Greco, M Laughlin, S. Emancipator, B. Cmolik, G. Wnc, and Y. Elgudin

PURPOSE: Electrospinning is a facile technique capable of producing micro- or nanofibrous scaffolds with similar morphological characteristics to natural extracellular matrices. Incorporation of cells on these scaffolds is generally accomplished via surface seeding, followed by infiltration of the porous structure by the cells over time. Due to the small and highly tortuous pores created by the electrospinning method, dense populations of seeded cells, as well as a uniform distribution of cells throughout the scaffold can be difficult to achieve. In addition, surface seeding limits the ability to obtain localized populations of multiple cell types.

The goal of this work was to selectively position cells within the scaffold in order to manufacture a highly bio-mimetic scaffolding material. This cell-fiber construct was achieved through simultaneous and/or sequential electrospinning of polymer fibers and electro spraying of cells, to entrap the cells within select areas of the fibrous matrix.

METHODS: Initial studies were carried out using a single polymer/cell type construct. Poly(ϵ -caprolactone) (PCL), a biocompatible and biodegradable polymer, was electrospun from chloroform. Subsequently, human umbilical cord blood-derived (HUCB-derived) endothelial progenitor cells (EPCs), recovered by culturing on fibronectin-coated tissue culture plates, were electro sprayed from cell media. Both solutions were ejected from sterile stainless steel capillaries, collecting on a sterile rotating drum. Later work has focuses on developing scaffolds consisting of multiple cell types and polymers. This was accomplished using a sequential approach to construct and form various layers. To construct a biomimetic heart valve structure, outer layers consisting of collagen electrospun from HFIP were combined with electro sprayed EPCs. These collagen layers were sandwiched around an inner layer of electrospun PCL containing electro sprayed mesenchymal stem cells. This allowed for the development of a scaffold consisting of two localized cell populations in a layered multi-component polymeric scaffold. After production, mats were kept in culture conditions with DMEM media with 2% fetal bovine serum. Electrospun mats were characterized via scanning electron microscopy for fiber diameters and porosity. Cell distribution within the scaffold was identified through hematoxylin and eosin staining and visualized with light microscopy. Cells were visualized using casein-2-acetoxy methylester and cell viability was assessed using propidium iodide which labels non-viable cells.

CONCLUSION: Scaffolds consisting of integrated electrostatically processed polymer fibers and cells were successfully created by a combined electrospinning and electro spraying approach. Cell viability was maintained both through the electrospinning process and subsequent culturing of the constructs. Cells were found to be well distributed throughout the cross section of the scaffolds. Multilayered collagen-PCL-collagen scaffolds containing endothelial cells and mesenchymal stem cells were also successfully obtained, providing a highly organized construct similar in structure to the natural heart valve leaflet tissue.

1

THE USE OF A NOVEL INTRAVASCULAR TEMPERATURE MANAGEMENT SYSTEM IN CARDIAC SURGERY

Arie Blitz, George Williams, Shoichi Okada, Heather McFarland, Raymond Graber, Jeff Foster, Sarah Small

Temperature management during the perioperative period can be a challenge in cardiac surgery. We herein report the use of a novel warming/cooling catheter for a clinical series of five patients.

The first case is that of a 72-year-old male with severe COPD who underwent emergent repair of an aortic arch dissection requiring hypothermic circulatory arrest.

The second case is that of a 58-year-old male with end-stage cardiomyopathy who underwent elective Heartmate LVAD insertion for Destination Therapy.

The third case is that of a 78-year-old female who underwent salvage RVAD insertion for an acute right ventricular infarct with cardiogenic shock.

The first three cases were performed with the intravascular catheter inserted during the operation so as to achieve and maintain normothermia in the early perioperative period.

A fourth case is that of a 56-year-old male who underwent urgent coronary bypass surgery and mitral valve repair, but suffered a full cardiac arrest after induction requiring cardiopulmonary resuscitation. In this patient, the intravascular catheter was used to cool the patient to 33 degrees for 48 hours after surgery to allow recovery from his perioperative stroke and seizures.

Finally, a fifth case is that of a 62-year-old male presenting with an acute Type A dissection and paralyzed, mottled lower extremities. The patient underwent dissection repair. After his perioperative bleeding subsided, the patient underwent cooling to 33 degrees for 48 hours in an attempt to minimize his spinal cord injury. As of 4 weeks postoperatively, the patient is still recovering but is gradually recovering neurologic function of his lower extremities.

In all five cases, precise control of perioperative temperature allowed for a smoother perioperative recovery. This clinical experience has paralleled results achieved in our porcine hypothermia model. All five patients have survived, and four have been discharged home. Further studies are indicated to determine under which clinical circumstances this temperature regulation system would be of most benefit

Section 2

Colorectal Surgery

ENDOSCOPIC MANAGEMENT OF IATROGENIC COLON PERFORATION DURING COLONOSCOPY

Christine Gosen BS¹, Benjamin Poulouse MD MPH², Joseph Trunzo MD², Jeffrey Marks MD²

Colon perforation is a serious complication of colonoscopy associated with significant morbidity and mortality. Traditional management options have included surgical repair by laparotomy or laparoscopy, with some patients managed nonoperatively for microperforation. Ideal treatment guidelines are unclear and vary with the condition of the patient, time since injury, risk of contamination, and difficulty of the procedure. Endoscopic closure is a novel approach for the treatment of perforation with several potential benefits over current techniques. There is limited literature describing endoscopic management of iatrogenic colonic perforations during colonoscopy. Here we report a case of successful endoscopic closure of a perforation near a prior coloanal anastomosis, supporting the feasibility of endoscopic repair in selected patients.

ANALYSIS OF STAPLER MISFIRE DURING COLORECTAL SURGICAL PROCEDURES USING A NATIONAL EVENT REPORT DATABASE

E Marderstein, J Trunzo, J Stulberg, B Champagne, H Reynolds, CP Delaney

INTRODUCTION: While surgical staplers can decrease operative times and simplify surgical procedures, their use is not without the possibility for serious adverse events. The purpose of this investigation was to characterize the types of adverse events associated with stapler use and to define the resultant morbidity.

METHODS: The FDA MAUDE (Manufacturer and User Facility Device Experience Database) registry contains all reported adverse events associated with medical devices. This database was queried for all events associated with surgical stapler use for a 12 month period through June 2006. Non-colorectal surgical events were excluded and the remaining events analyzed.

RESULTS: 1188 total events were extracted and 588 (49.5%) were colorectal surgical procedures. The most common problem was failure of the staple line to form, followed by the staplers being stuck and unable to be removed from the tissue. All stapler types were represented among the reports with EEA (270) most common, followed by TA (193) and GIA (119) staplers respectively. Rectal resections were overrepresented in this cohort, comprising 45.2% of all reports. The morbidity of stapler-related adverse events was greater for rectal resections with 80 of the 266 adverse events after rectal resections deemed major versus only 60 of the other 322 operations ($p=0.0013$). This included a remarkable 23 unplanned permanent ostomies due to difficulties during surgery. For laparoscopic cases, reported stapler-related adverse events directly resulted in the need for conversion 43% of the time to fix the problem.

CONCLUSIONS: Stapler related adverse events during colorectal surgical procedures can result in considerable morbidity. This study utilizes an event reporting database to analyze the largest cohort described of stapler related malfunction during colorectal surgery. It demonstrates that rectal procedures are overrepresented and have greater associated morbidity.

COMBINED TRANS-GASTRIC AND TRANS-VAGINAL NOTES COLECTOMY IN A PORCINE MODEL

Joseph A. Trunzo MD, Michael F. McGee MD, Jeffrey M. Marks MD, Conor P. Delaney MD, PhD

Natural Orifice Endoscopic Surgery (NOTES) remains a topic for continued innovation and development. Here we present a video demonstration displaying a novel approach to sigmoid colectomy in a porcine model.

The procedure is performed with two endoscopes passed through trans-gastric (TG) and trans-vaginal (TV) access points. The TG endoscope primarily provides traction and visualization while the TV endoscope performs the dissection. Blunt dissection and needle knife cautery are used to mobilize the colon and expose the inferior mesenteric artery (IMA). Through the vaginal port, the IMA is ligated with endoscopic endo-clips, and the distal bowel is divided with an endo-GIA stapler. An extra-corporeal resection with EEA anvil placement is performed by pulling the specimen through the vaginal opening. The proximal colon and anvil are then finally returned back to the abdomen, and a standard stapled end-to-end anastomosis is completed.

We conclude that dual access NOTES colectomy is a feasible technique for further investigation and research.

PRELIMINARY EXPERIENCE WITH ENDOSCOPIC RADIOFREQUENCY ABLATION IN THE HUMAN COLONIC EPITHELIUM

Benjamin K. Poulouse, Michael F. McGee, Joseph A. Trunzo, Joseph E. Willis, Bridget Ermlich, Michelle Laughinghouse, Bradley Champagne, Conor P. Delaney, and Jeffrey M. Marks

BACKGROUND: Endoscopic planar radiofrequency ablation (RFA) has been used successfully in treating esophageal mucosal disease. This technology has potential application in treating lower gastrointestinal tract pathology such as radiation proctitis or angiodysplasia. Previous work has helped determine optimum power and energy settings for mucosal or submucosal ablation. We present our preliminary results of these optimized settings in patients.

METHODS: Patients undergoing elective left colon or rectal resection were enrolled under an IRB approved protocol. An endoscopically mounted planar RFA device (HALO-90, BARRX Medical) was advanced into the colonic segment to be resected. Normal mucosa was ablated with 2 or 4 applications at a constant energy density of 12j/cm² and power of 40W. After removal of the surgical specimen, ablation zones were sectioned, stained, and reviewed by a blinded expert pathologist. The deepest layer with any histopathologic change was recorded.

RESULTS: Six patients underwent a total of 23 ablations. Overall, 17 ablations (74%) penetrated deep to the submucosal layer with 2 ablations (9%) extending to the serosa. Fifty percent of ablations penetrated into the muscularis propria when 2 applications were performed compared to 100% with 4 applications ($p < 0.05$). Serosal changes were only observed with 4 applications of the RFA device.

CONCLUSIONS: These results support our preliminary work in identifying RFA treatment parameters for use in the human colon. Two applications are sufficient to produce histologic change in the mucosa and submucosa, while limiting deeper penetration. These results can be used in protocol design evaluating this technology for treatment of lower gastrointestinal tract pathology.

A NEW TECHNIQUE USING TRANSANAL ENDOSCOPIC MICROSURGERY: RECTAL SLEEVE RESECTION WITH EEA STAPLED ANASTOMOSIS

Joseph A. Trunzo, MD, Conor P. Delaney, MD, PhD

BACKGROUND: Transanal endoscopic microsurgery (TEMS) is an accepted means of resecting benign neoplasms of the rectum though remains controversial in regards to application in malignant disease. Lesion size and clear margin length remain an important concern for those utilizing TEMS in their practice. Here a new method is described that may improve resection size as well as provide a simple and safe means for defect closure.

METHODS: A 40kg porcine non-survival model was utilized for this investigative procedure. A circumferential rectal sleeve resection was performed using TEMS by mobilizing rectum through to the intra-peritoneal cavity. The rectum was delivered through the anus, resected, and an end-to-end stapled anastomosis was performed.

CONCLUSION: The method described provides a potential procedural advancement to already utilized techniques performed by TEMS. Though further investigation is required, this technique could prove useful in addressing the issues surrounding malignant rectal tumor resection via TEMS.

RESULTS OF A STANDARDIZED OPERATIVE TECHNIQUE AND PERIOPERATIVE CARE PROTOCOL FOR LAPAROSCOPIC RECTAL RESECTIONS

Lindsetmo Rolv-Ole, PhD¹, Champagne B MD², Delaney Conor P, PhD²

BACKGROUND: Laparoscopic rectal resection (LRR) has not gained the same acceptance as laparoscopic segmental colonic resection because of technical challenges, increased operating time and costs and concerns about the oncological outcome.

METHODS: Patients undergoing laparoscopic rectal resections with total or partial mesorectal excision (TME, PME) were identified from a prospectively maintained, IRB-approved database.

Collected data included age, body mass index, type of procedure, length of operation, estimated blood loss (EBL), complications, length of stay (LOS), re-operations, mortality, discharge disposition, and re-admittance within 30 days. Resection margins, TME grading and number of detected lymph nodes were recorded by retrospective review of the pathology reports. The perioperative fast track care and the laparoscopic operations were performed according to a standardized system.

RESULTS: 37 procedures were performed: 17 (46%) for malignancy; 4 (11%) for rectal polyp; 14 (38%) for inflammatory disease (diverticulitis with phlegmon, abscess or fistula) and two were operated for Crohn's proctitis and left colonic ischemia, respectively. 7 (19%) patients had a protective loop ileostomy. Conversion was performed in two males (5%). The mean operative time was 184 minutes (range 109-410 minutes). The mean hospital stay was 3.0 days (range 1-8 days) overall and 2.8 days for completed cases, with 90 % of patients discharged less than 5 days after surgery. No anastomotic leaks or mortality occurred and in hospital complications rate was 8 %. Unplanned readmissions within 30 days occurred in 3 (8%) patients. No specimen had involved distal or circumferential resection margins.

CONCLUSION: These data show that laparoscopic rectal resections can be performed safely and effectively for rectal pathology. Laparoscopy in conjunction with modern perioperative care provides rapid recovery with efficient use of hospital resources.

STANDARDIZED ALGORITHMS FOR MANAGEMENT OF ANASTOMOTIC LEAKS AND RELATED ABDOMINAL AND PELVIC ABSCESES AFTER COLORECTAL SURGERY

Phitayakorn R, Delaney CP, Reynolds HL, Champagne BJ, Heriot AG, Neary P, Senagore AJ; International Anastomotic Leak Study Group.

BACKGROUND: The risk factors and incidence of anastomotic leak following colorectal surgery are well reported in the literature. However, the management of the multiple clinical scenarios that may be encountered has not been standardized.

METHODS: The medical literature from 1973 to 2007 was reviewed using PubMed for papers relating to anastomotic leaks and abdominal abscess, with a specific emphasis on predisposing factors, prevention strategies, and treatment approaches. A six-round modified Delphi research method was utilized to find consensus among a group of expert colorectal surgeons and interventional radiologists regarding standardized management algorithms for anastomotic leaks.

RESULTS: Management scenarios were divided into those for intraperitoneal anastomoses, extraperitoneal (low pelvic) anastomoses, and anastomoses with proximal diverting stomas. Management options were then based on the clinical presentation and radiographic findings and organized into three interconnected algorithms.

CONCLUSIONS: This process was a useful first step toward establishing guidelines for the management of anastomotic leak.

EMERGENCY LAPAROSCOPIC COLECTOMY: DOES IT MEASURE UP TO OPEN?

Jonah Stulberg, MPH, Brad Champagne, MD, Zhen Fan, MD, Mike Horan DDS, PhD, Vincent Obias, MD, Eric Marderstein, MD, Harry Reynolds, MD, Conor P Delaney, MD, PhD

PURPOSE: Laparoscopic colectomy (LC) is slowly becoming a standard of care for elective resections, however the possible benefit of laparoscopy in the emergency setting is essentially unstudied. We present a case-control study of emergent LC cases compared to emergent open colectomy (OC) controls.

METHODS: We reviewed the charts of 44 patients, who had an emergent colectomy between August, 2005 and October, 2007. Laparoscopic operations were performed in 22 consecutive patients, and were matched to 22 patients from a similar time period who received OC. Patient demographics, indications for surgery, operative details, and postoperative complications were collected. A committee of laparoscopic and open surgeons collectively reviewed the medical record of each OC patient and deemed them suitable for laparoscopic exploration.

RESULTS: LC and OC patients had similar demographics with no difference in age, gender or surgical indications. Mean operative time was similar (155 min LC vs. 191 min OC, $p=0.09$). Mean hospital stay was shorter in LC patients (7 days vs. 12 days, $P=0.02$). Major complication rates were less in LC patients (25% vs. 59%, $P=0.03$) and perioperative mortality rates were similar between the two groups (0 vs. 3, $P=0.27$).

CONCLUSIONS: This is the first comparison series of an open versus laparoscopic approach in emergency colectomy patients. With increasing experience, laparoscopic colectomy is a feasible option in certain emergent situations. It is associated with shorter hospital stay, less morbidity and similar mortality to that of open operation.

HAND-ASSIST VS STRAIGHT LAPAROSCOPIC COLECTOMY: IS THERE REALLY A DIFFERENCE?

Champagne B¹, Lee E², Valerian B², Armstrong D³, Ambroze W³, Orangio G³

Case Medical Center, Albany Medical Center, Georgia Colorectal Clinic

BACKGROUND: It has been suggested that hand-assisted colectomy (HAC) may help residents progress along the learning curve but there is currently no evidence to support this claim. Previous studies include procedures performed by staff surgeons or residents at various skill levels and report operative times and conversion rates as their primary endpoints. We measured the percentage of cases completed by a resident as the operating surgeon as the primary endpoint to determine the most effective approach for teaching laparoscopic colectomy.

METHODS: All patients who underwent left-sided HAC or SLC by a single resident, starting as the primary surgeon, were included. If the assisting attending assumed the role of the operating surgeon during the case it was recorded as an incomplete case for the resident. Operative times and conversions were included as secondary endpoints.

RESULTS: A single resident started 147 laparoscopic colectomies as the primary surgeon during residency and colorectal fellowship including 81 left sided procedures. There were 44 patients in the HAC group and 37 SLC patients. Cases done by straight laparoscopy were more likely to be completed by the resident than those done by HAC (SLC 88%, HAC 72%; $p=.06$). There were also differences in operative time favoring SLC (HAC 142 min (100-170) vs. SLC 133 min (95-195); $p = 0.04$). Complications were similar in the two groups (HAC 19% vs. SLC 21%) as were conversions (HAC 5.6% vs. SLC 4.5%).

CONCLUSION: Both hand-assisted and straight laparoscopic techniques for left colectomy can be applied to successfully train surgical residents with the assistance of a staff surgeon outside of their learning curve. Residents and colorectal fellows may have more success completing straight laparoscopic colectomy than adjusting to the novel hand-assisted approach during training.

CLINICAL RESULTS OF INTRAOPERATIVE RADIATION THERAPY FOR PATIENTS WITH LOCALLY RECURRENT AND ADVANCED TUMORS HAVING COLORECTAL INVOLVEMENT

Williams CP, Reynolds HL, Delaney CP, Champagne B, Obias V, Joh YG, Merlino J, Kinsella TJ

BACKGROUND: Intraoperative radiation therapy (IORT) may be useful in the treatment of patients who have a locally advanced primary and recurrent abdominopelvic neoplasm with colorectal involvement.

METHODS: A retrospective review of colorectal cancer patients treated since 1999 with IORT using the Mobetron device.

RESULTS: Forty patients underwent colectomy or proctectomy with IORT. All patients had evidence of local extension to contiguous structures and based on preoperative staging were deemed by the operating surgeon as being likely to have incomplete resection. IORT was selected as an alternative to sacrectomy or exenteration for an expected close margin in 10 patients. Mean survival was 35 +/- 26 months, and 1 patient had local recurrence.

CONCLUSIONS: The introduction of IORT has allowed a selective treatment approach to locally advanced primary and recurrent neoplasms, which traditionally would have been deemed unresectable. Using IORT, extended resections may be avoided in selected high-risk patients with low risk of local recurrence and minimal morbidity.

A SINGLE TRAINING CENTER'S EXPERIENCE WITH 200 CONSECUTIVE CASES OF DIVERTICULITIS: CAN ALL PATIENTS BE APPROACHED LAPAROSCOPICALLY?

Garrett KA, Champagne BJ, Valerian BT, Peterson D, Lee EC.

Department of General Surgery, Albany Medical Center, 47 New Scotland Avenue, MC-61, Albany, NY, 12208, USA, garretk@mail.amc.edu.

BACKGROUND: This study aimed to evaluate the outcomes for consecutive patients with diverticular disease who underwent elective laparoscopic sigmoid colectomy.

METHODS: Data for this patient population were collected by chart review and analyzed retrospectively.

RESULTS: Between December 2001 and March 2007, 200 consecutive patients (93 men and 107 women) with an average age of 55 years were identified. All cases were managed by one of two colorectal surgeons. Of the 200 patients, 158 had recurrent diverticulitis, 20 had fistulas, 12 had abscesses, 8 had strictures, 1 had a mass, and 1 had a bleed. The mean operative time was 159 min, and the conversion rate was 8%. A total of 30 early postoperative complications occurred for 26 patients including wound infection (n = 9), ileus (n = 8), Clostridium difficile colitis (n = 3), urinary retention (n = 3), pelvic abscess (n = 2), deep vein thrombosis and pulmonary embolism (n = 1), pneumonia (n = 1) urinary tract infection (n = 1), anastomotic leak (n = 1), and small bowel obstruction (n = 1). Late complications experienced by 11 patients included Clostridium difficile colitis (n = 3), incisional hernia (n = 3), wound infection (n = 3), wound hematoma (n = 1), and intraabdominal hemorrhage (n = 1).

CONCLUSIONS: The authors believe it is feasible to offer elective laparoscopic sigmoid colectomy to all patients with symptomatic diverticular disease despite preoperative risk factors.

LAPAROSCOPY AND RECTAL CANCER

Champagne BC, Delaney CP,

Laparoscopic colectomy has been proven oncologically equivalent to conventional surgery and is now generally agreed to offer patients a reduced length of stay, shorter recovery times and improved cosmesis. In contrast, acceptance of laparoscopic proctectomy for rectal cancer has been very delayed and the enthusiasm of early studies has met considerable skepticism. For rectal cancer, it has been demonstrated that there is considerable variation between surgeons in disease-free survival and local pelvic recurrence after open proctectomy for rectal cancer. These differences are likely to be magnified when the technical challenge of laparoscopy is added to proctectomy. Minimally invasive approaches to rectal cancer need to demonstrate equivalent oncologic outcomes and maintenance or improvement in quality of life. This review will outline the current evidence for laparoscopy as a treatment option for patients with rectal cancer, emphasize the need for standardized approaches amongst multi-disciplinary teams, and highlight the technical details of different laparoscopic operations for rectal cancer.

SURGISIS FISTULA PLUG: THE AMERICAN EXPERIENCE

McGee M, Champagne BC

Anorectal fistulae are heterogeneous group of disorders which can cause significant pain, social impairment, hygienic disdain and rarely sepsis. Surgery is the mainstay of treatment for anorectal fistulae, yet no one procedure is universally efficacious and safe. Simple fistulae can often be treated by simple fistulotomy, but complex fistulae present a more complicated scenario - effective surgical treatment options are compromised by increased risk of incontinence. Likewise, safe treatment alternatives have low risk of post-operative incontinence but low success rates. The Surgasis AFP is appears to be an effective and safe treatment alternative for complex fistula, including Crohn's fistula, based on initial reports. Future work should seq to include prospective randomized studies to more conclusively determine the future role of the AFP as well as better determination of indications and contraindications, as well as technical concerns related to implantation and fixation. Lastly, the economic implications of the device need to be compared to traditional low-cost techniques in separate cost-benefit analyses.

LAPAROSCOPY FOR METASTATIC COLORECTAL CANCER

Champagne BJ, Delaney CP.

Patients with metastatic disease from colorectal cancer are now living twice as long as they were one decade ago. With this increasing life expectancy, we are beginning to see these patients strive for an acceptable and improved quality of life. Medical advances have led to unanswered questions regarding the role of surgery in metastatic colorectal cancer. Despite the increasing application of laparoscopy for primary treatment of colorectal cancer, the appropriate role for laparoscopy in patients with stage IV disease has yet to be defined. This review addresses this topic and suggests treatment algorithms for patients with metastatic colorectal cancer. While unresectable, metastatic colorectal cancer remains incurable at the current time, continued advances will inevitably challenge this presumption and it is crucial to outline the role of laparoscopy in this patient population.

TEACHING LAPAROSCOPIC PROCTOSIGMOIDECTOMY (LS) TO RESIDENTS: A COMPARISON OF A HIGH FIDELITY SYNTHETIC MODEL AND LIVE PORCINE MODEL

CP Delaney, Senagore AJ, J Stulberg, B Champagne, S Sarker, F Zeinali, Efron J, Franklin M, S Lee, Obias V, Rivadeneira D, Weiss E.

PURPOSE: The technical challenge of laparoscopic proctosigmoidectomy (LS) and resulting prolonged learning curve have made effective teaching of the procedure difficult. This is particularly problematic in the era of the 80 hour work week and with the cost and complexity of using cadaver or animal models. We explored the effectiveness of a high fidelity synthetic model for use in resident training.

METHODS: PGY 4 and 5 general surgery residents received a series of technical lectures on LS. Residents then performed LS using a high fidelity synthetic plastic model under faculty supervision. The residents then performed LS in a live, step-based porcine model. Residents were scored using one validated and one novel error scoring systems which utilize structured technical skills assessment to breakdown the procedure into a series of discrete steps for performance evaluation. Faculty and residents also provided global scores for each model.

RESULTS: Residents gave the plastic model (PM) and live model (LM) significantly higher global scores than faculty (PM: 6.0 vs 4.2 ($p=0.02$); LM: 9.2 vs 7.7 ($p=0.005$)), and both residents and faculty gave higher global scores to the porcine model (8.70 vs 5.44 ($p<0.001$)). 100% of residents felt the models were of sufficient complexity for an adequate educational experience, and this was supported by the lack of a significant difference in the number of intraoperative errors during LM vs PM colectomy (mean 1.9 vs 2.1 per case ($p=0.83$)). However, summarized task specific analysis scores showed improved task completion and effectiveness when comparing LM to PM (7.5 vs. 5.1 ($p=0.05$)).

CONCLUSIONS: A high fidelity synthetic plastic model provides a potential adjunctive training aid for teaching residents laparoscopic colectomy. Although plastic models have less apparent face validity than cadaver or porcine models, they provide an additional training process that does not require the cost and complexities of laboratory based training with animal or cadaver models. This may become an important component of the LS training curriculum.

A NATIONAL COMPARISON OF LAPAROSCOPIC VERSUS OPEN COLECTOMY USING THE NON-VA NSQIP DATA

Anthony Senagore¹ M.D., Conor Delaney² M.D., Jonah Stulberg², John Byrnes¹, MD

¹ Spectrum Health and Michigan State University, Grand Rapids, MI

² Case Western Reserve University, Department of Surgery, Cleveland, OH

PURPOSE: The recent introduction of the National Surgical Quality Improvement Project (NSQIP) outside of the Veterans Administration (VA) provides a consistent sampling process to evaluate the relative benefits of LC and OC. We assess the preoperative risk factors and the postoperative complication rates in non-VA general hospitals in the United States using the standardized NSQIP data elements and a sampling process with 30 day follow-up.

METHODS: All patients included in the nationally reported NSQIP database from 12/1/05 thru 9/1/2007 undergoing segmental colectomy via LC approach (44204) and OC (44140) were evaluated. The data collected was defined by the NSQIP audit process.

RESULTS: We analyzed a total of 4719 OC procedures and 2728 LC procedures. The BMI's were similar for LC and OC groups (27.9 ± 5.8 ; 28.0 ± 7.2). The OC group had significantly higher rate of diabetes (16% v 12%), smoking (18% v 15%), dyspnea (14% v 9%), COPD (7% v 4%), CHF (2% v .6%); MI <6 mos (.9% v .4%) and hypertension (54% v 50%). The rate of all perioperative complications were higher in the OC group: mortality (4.9% v .8%), SSI (12% v 8%), wound disruption (2% v .8%), pneumonia (5% v 2%), ventilator >48 hrs (6% v 1%), ARF (1% v .3%), UTI (4% v 3%), MI (.5% v .1%), DVT (2% v .9%), and PE (.7% v .4%).

CONCLUSION: This is the first data reported from the NSQIP audit process outside of a VA hospital system and enables OC and LC as defined by the specific CPT codes for the procedures. The data confirm that the incidence rates for all commonly identified complications following colectomy are higher for OC compared to LC. However, analysis of the preoperative risk factors suggests that LC is still being reserved for a population with fewer of these risks despite a multitude of data that suggest that operative mortality, cardiopulmonary, and wound complications occur at a lower rate with LC. This newly available, audited, data sampling process may allow for the development of better formulas for colectomy risk adjustment. Ultimately, this data should provide a more accurate method of assessing the optimal role of LC and OC in specific populations.

TISSUE APPPOSITION SYSTEM (TAS) – FIRST CLINICAL EVALUATION FOR COLONIC CLOSURE

Conor P. Delaney, Vincent Obias, Bridget Ermlich, Bradley Champagne, Jeffrey M. Marks, Amitabh Chak

INTRODUCTION: Engineering sophistication in endoscopic surgery provides a growing array of novel instrumentation for minimally-invasive surgery, sparing patients risk and protracted recovery times. The TAS device (Ethicon Endo-Surgery) is a novel T-tag system for endoscopic placement of suture(s) and approximation of soft tissue. Closure of larger defects generated in advanced endolumenal endoscopic procedures can be accomplished with this device. We describe the first human use of the TAS device as part of a feasibility study, here applied to full thickness endoscopic colon lesion resection as a potential alternate to laparoscopic colectomy.

METHODS: Patients with endoscopically unresectable polyps who would require laparoscopic colectomy are being enrolled to a feasibility trial under an IRB-approved protocol. Under general anesthesia, laparoscopy is performed and the polyp site visualized. If possible, polyps will be resected, if necessary taking part of the muscularis with endoscopic polypectomy. Frozen section will document benign disease. The polypectomy site will be closed using the TAS device under laparoscopic control to avoid injury to surrounding structures.

RESULTS: The first patient was enrolled, and the 5cm cecal polyp partly excised under laparoscopic control. There was penetration to subserosa. Although the polyp could not be completely resected, the muscular defect was closed with the TAS device. A laparoscopic right colectomy was then performed, and the specimen examined. The muscular closure was complete. The patient was discharged uneventfully on post-operative day two.

CONCLUSIONS: This initial human experience demonstrates that under laparoscopic control, the TAS device can be used in the right colon, to close muscularis. Video segments and still photographs will be used to demonstrate the technology and outcome.

ASSESSING OPERATIVE TECHNICAL SKILLS PERFORMANCE IN COLORECTAL SURGERY

Sudip Sarker, Conor P Delaney

AIMS: Assessing surgical technical skills (TS) in a structured manner is a topical issue in the current changing surgical training environment. To date there has been little attempt to comprãensively assess both generic and operation specific TS in live advanced open and laparoscopic colorectal surgery. In this study we develop and validate a new tool which assesses generic and operation specific TS in colorectal surgery.

METHODS: After discussions with experts, hierarchical task analysis was constructed for three key colorectal operations: right hemicolectomy, sigmoid colectomy and anterior resection. Weighted Likert scales were individually constructed for generic and operation specific TS for each operation. Two experienced surgeons assessed each fundamental part of the operation according to the weighted Likert scoring system.

RESULTS: 68 live (45 open and 23 laparoscopic) operations were assessed, performed by 7 Consultants and 10 Trainees. Inter class correlation coefficient between the two observers were 0.83, $p < 0.05$ for generic technical skills and 0.89, $p < 0.05$ for the operation specific technical skills. Construct validity for both generic and operation specific TS for Consultants and Trainees were significant using ANOVA, $p < 0.05$.

CONCLUSIONS: This new assessment tool of TS in open and laparoscopic colorectal surgery is reliable, has face, content, concurrent and construct validities. The tool has the potential to be a reliable and useful tool for assessment of surgical skills and training.

2

A NOVEL RATING SYSTEM EFFECTIVELY DIFFERENTIATES RESIDENT SURGICAL PERFORMANCE ON AN OPEN COLECTOMY ANIMAL MODEL

E Marderstein, F Zeinali, R Phitayakorn, S Schomisch, M Rosen, J Marks, J Ponsky, B Champagne, CP Delaney

INTRODUCTION: Current evaluation of trainee operative performance is based on overall impressions and rarely involves objective rating systems. We hypothesized that a new rating system would objectively differentiate between residents of variable surgical skill performing a series of standardized operative steps.

METHODS: General surgery residents were instructed using an open porcine colectomy model. The procedure was deconstructed into a series of discrete steps and a standardized reporting form was developed for performance evaluation of each step by a trained observer using Likert scales for each procedural component.

RESULTS: Resident task performance was divided into thirds for analysis. There were significant differences in scores between Top, Middle and Bottom performing residents ($p < 0.001$, see Table). Time to completion and performance level correlated, (63 min for Bottom and 50 min for Top), but did not reach significance ($p = 0.093$). PGY2 residents had lower scores than PGY4 residents ($p = 0.007$) but there were no differences comparing either group to PGY3 residents. Staff physicians blinded to these experimental results rated resident operative performance on the basis of previous clinical evaluations and correctly predicted resident group assignments with 80% accuracy.

Group Name	Mean Score	p Value
Bottom third	8.3 ± 1.5	<0.001 v. Top, 0.0015 v. Middle
Middle third	14.6 ± 2.1	0.0002 v. Top
Top third	21.5 ± 1.6	

CONCLUSIONS: Using an open colectomy operative training model, this novel operative-step based rating system effectively differentiated resident operative performance into Top, Middle and Bottom groups, and correlated with prior clinical assessment by attending surgeons. This rating system enhances the assessment of resident operative skills, and is an ideal instrument to evaluate the effectiveness of future operative skills-training curricula.

DOSIMETRIC EVALUATION OF ENDOSCOPIC RADIOFREQUENCY ABLATION IN A TREAT AND RESECT HUMAN COLON TRIAL

Joseph A. Trunzo,, Michael F. McGee, Benjamin K. Poulouse, Joseph E. Willis, Bridget Ermlich, Michelle Laughinghouse, Bradley Champagne, Conor P. Delaney, and Jeffrey M. Marks

BACKGROUND: An endoscope-mounted planar radiofrequency ablation (RFA) device has been used effectively for the focal ablation of esophageal Barrett's epithelium. This technology may additionally have a role in the treatment of bleeding or neoplasia in the lower gastrointestinal (GI) tract. The goal of this study was to determine the optimal combination of RFA treatment parameters to maximize efficacy in achieving hemostasis and ablation while safely avoiding transmural colonic injury.

METHODS: After IRB approval, patients undergoing elective left colon or rectal resection were enrolled. Once margins of resection were determined intra-operatively, a colonoscope mounted with an RFA device (HALO90, BARRX Medical) was advanced to the segment of resection. Areas of normal mucosa within the planned resection specimen were ablated in situ with 2 or 4 applications (APP) and varying energy densities (12, 15, or 20 J/cm²). Ablation zones and untreated normal adjacent sites were sectioned and stained with H&E. An expert GI pathologist, blinded to the treatment parameters evaluated all specimens.

RESULTS: Sixteen patients underwent 51 separate ablations. When comparing 2 vs. 4 APP, regardless of energy density, serosal penetration occurred in 0% (0/24) vs. 15% (4/27) (P=0.11), whereas muscularis propria (MP) or deeper penetration was seen in 25% (6/24) vs. 63% (17/27) (P<0.05) of sites respectively. Of the MP involved specimens with 2 APP, all were at the lowest energy setting (12 J/cm²) and none reached the serosal surface. When comparing 12, 15, and 20 J/cm² of energy, regardless of APP, 74% (17/23), 35% (6/17), and 0% (0/11) penetrated to MP or deeper, respectively (P<0.05); whereas serosal penetration occurred in 9% (2/23), 12% (2/17), and 0% (0/11), P=0.517. All serosal involvement, however, was associated with 4 APP.

CONCLUSIONS: No direct correlation between energy and mural penetration depth was demonstrated. This variability may be inherent to this technique, resulting from inconsistent operator force or catheter approximation against the mucosa, variable colonic wall thickness, and possible acute eschar formation protecting the deeper layers. No transmural penetrations were observed when reserving treatment to 2 APP, regardless of energy level. The number of RFA applications, as opposed to the degree of energy, was directly associated with the depth of burn in the colon wall. Identification of safe treatment parameters with avoidance of transmural colonic injury, will guide future clinical trials utilizing RFA in the treatment of lower GI diseases.

INTRAOPERATIVE RADIATION THERAPY INTRODUCTION AND UTILIZATION IN A COLORECTAL UNIT

C Williams, H Reynolds, C Delaney, B Champagne, V Obias, Y Joh, J Merlino, T Kinsella

PURPOSE: The introduction of an intraoperative electron beam radiation therapy unit(IORT) offers the colorectal surgeon more extensive treatment options for locally advanced primary and recurrent neoplasms.

METHODS: We retrospectively review the subset of colorectal patients treated with IORT following introduction of the Mobetron unit in 1999, examining both indications and outcomes. This unit permits radiation of a cone of tissue up to 10cm in diameter using an electron accelerator with excellent tissue penetration.

RESULTS: A review of all patients treated with IORT since 1999 revealed 40 patients who underwent colectomy or proctectomy. All patients had evidence of local extension to contiguous structures and based on preoperative staging were deemed likely to have incomplete resection by the operating surgeon. 14 underwent abdominal perineal resection, 10 low anterior resection, 5 low anterior resections with low Hartmann's, 5 segmental colectomy, 2 pelvic exenteration, 1 colostomy, 1 colectomy and duodenectomy, and 2 underwent local excision of recurrences. 26 out of the 40 underwent adjacent organ, abdominal wall or pelvic sidewall excision. IORT was selected as an alternative to sacrectomy or exenteration for a close margin in 10 patients. IORT dose ranged from 9 to 12Gy.

	n	Stage***				Number with Positive margins (%)	Median Follow up after Surgery in months (range)	Number with local Recurrence	Number Surviving to Date (%)
		4	3	2	1				
Primary Rectal	14	6	4	3	1	4 (29)	25 (1-79)	0	7 (50)
Recurrent Rectal	12	4	3	5	0	5 (42)	26 (1-85)	1*	8 (67)
Recurrent Colon	6	2	2	1	1	1 (17)	49 (22-78)	0	5 (83)
Primary Colon	2	1	1	0	0	0	23 (11-34)	0	2 (100)
Appendiceal	2	0	0	2	0	0	20 (8-32)	0	2 (100)
Other**	4	1	3	0	0	2 (50)	11 (1-31)	0	4 (100)
Totals	40	14	13	11	2	12 (30)	29 months	2 (5)	28 (70)

* IORT to gross Tumor, ** Other includes colon and duodenal primaries, 2 ovarian cancers with rectal involvement, & 1 endometrial cancer recurrence with rectal involvement.

*** Pathologic stage post Pre-operative chemo and radiation

CONCLUSIONS: The introduction of IORT has allowed us to selectively approach locally advanced primary and recurrent neoplasms which traditionally would have been deemed unresectable. One local recurrence occurred in a patient who received IORT to gross tumor; the other recurrence occurred where a metastatic lesion had been resected. Sacrectomy and other extended resections may be avoided in selected patients with low local recurrence rates and good median survival for such a high risk group of patients.

OUTCOME OF DISCHARGE WITHIN 24-72 HOURS OF LAPAROSCOPIC COLORECTAL SURGERY

Conor P Delaney MD, Brad Champagne MD, Harry L Reynolds MD

Although laparoscopic colorectal surgery (LC) may permit early recovery and discharge from hospital, short lengths of stay are not routinely achieved. This is partly because accelerated recovery programs with early discharge are associated with high readmission and complication rates, especially after open colorectal surgery. This study examines safety and outcomes after LC in cases discharged within 72 hours of surgery.

118 consecutive patients (mean age 60 years) underwent elective LC by a single surgeon over a 12 month period, and were followed in a prospective IRB-approved database. Patients were managed with an accelerated recovery program using an intravenous PCA overnight, and diet and oral analgesia on postoperative day 1. Standardized discharge criteria were used.

Operations included: segmental colectomy (n=64), proctosigmoidectomy/APR (n=27), total colectomy/ileal pouch (n=10), rectopexy/reversal of Hartmans (n=8), adhesiolysis/stoma (10). Mean BMI was 28.5 (range 20-45). Mean operative time was 142 minutes with no mortality, and median stay of 3 days. 20% had a complication within 30 days, but only 2.5% had a serious complication. LC permitted 82 (70%) of patients to be discharged within 72 hours of surgery (10 day 1; 46 day 2; 26 day 3). Patients were grouped and analyzed by day of discharge. Discharge on day 1-2 was associated with significantly lower complication rates than seen for all patients. Although patients discharged on day 1-2 had the lowest readmission rate, this was not statistically significant.

	Mean stay (days)	Complications (%)	Readmissions (%)
All (n=118)	3.7	20	8.5
Day 1-2 (56)	1.8	7*	5.4
Day 3 (26)	3.0	15	7.7

* p<0.05 vs all patients

Readmission and complication rates are low in patients discharged on day 1, 2 or 3 after laparoscopic colorectal surgery. Patients who fulfill standardized discharge criteria and have adequate support at home, can safely be discharged early after laparoscopic colorectal surgery.

ASSESSMENT OF POSTOPERATIVE AMBULATION WITH THE USE OF A Pedometer: DOES WALKING REALLY HELP?

Vincent Obias, MD, Brad Champagne, MD, Harry Reynolds, MD, Yong-Geul Joh, MD, Conor Delaney, MD.

PURPOSE: Multiple studies have cited early ambulation after major abdominal surgery as key in reducing postoperative ileus. No papers to date have demonstrated this in a quantitative manner. Our study prospectively assesses ambulation in the postoperative period after both laparoscopic and open colorectal surgery by utilizing a novel technology—the pedometer.

METHODS: We examined 44 patients undergoing a variety of colorectal procedures from 12/06 to 10/07. Digital pedometers were placed on patients in the recovery room and the number of steps taken and number of walks attempted were measured daily. Demographic, operative, and postoperative data such as length of stay, complications, and readmissions were tracked in an IRB approved fashion.

RESULTS: Average age=58.9, ASA=2.5, and BMI=29.2. Average LOS=5.2 days and 25% of our patients experienced a postoperative ileus (no BM or flatus by POD 4). There were no mortalities. The average number of steps per patient gradually increased daily with a peak at POD 3 (1,407 steps). In subset analysis comparing ileus versus non-ileus patients, no significant difference was seen in Age, ASA, BMI, EBL, or operative time. LOS was significantly increased in the ileus group (8.7 days) versus the non-ileus group (4 days; $p=0.0001$). Average ambulation in the non-ileus group during POD 1 thru 4 was significantly higher than the ileus group ($p=0.0366$).

CONCLUSIONS: This is the first study to quantify ambulation in the postoperative period after major abdominal surgery. Our study confirms previously held beliefs that lack of ambulation is associated with a prolonged postoperative ileus and increased LOS. Future studies assessing postoperative outcomes should incorporate pedometers to better quantify ambulation after surgery.

SURGICAL MANAGEMENT OF RECTAL PROLAPSE

Marderstein EL, Delaney CP

This article reviews the pathogenesis, clinical presentation and surgical management of rectal prolapse. Full-thickness prolapse of the rectum causes significant discomfort because of the sensation of the prolapse itself, the mucus that it secretes, and because it tends to stretch the anal sphincters and cause incontinence. Treatment of rectal prolapse is primarily surgical. Perineal surgical repairs are well tolerated, but are generally associated with higher recurrence rates. Abdominal repairs involve fixing the rectum to the sacrum by using either mesh or sutures, and tend to have the lowest recurrence rates. If significant preoperative constipation is present, a sigmoid resection can be performed at the time of rectopexy. For many patients, diarrhea and incontinence improve after surgery. Laparoscopic repair of rectal prolapse has similar morbidity and recurrence rates to open surgery, with attendant benefits of reduced length of hospital stay, postoperative pain and wound complications.

ALVIMOPAN FOR POSTOPERATIVE ILEUS FOLLOWING BOWEL RESECTION: A POOLED ANALYSIS OF PHASE III STUDIES

Delaney CP, Wolff BG, Viscusi E, Senagore AJ, Fort JG, Du W, Techner L, Wallin B.

OBJECTIVE: To obtain further analysis regarding specific outcomes and alvimopan doses in bowel resection (BR) patients.

SUMMARY BACKGROUND DATA: Although postoperative ileus (POI) is common after BR, there is currently no recognized treatment or prevention available. Alvimopan, a novel, peripherally active mu-opioid receptor antagonist, accelerated GI recovery after BR or hysterectomy in 3 phase III trials.

METHODS: A pooled retrospective subset analysis of BR patients in alvimopan phase III trials was performed. Randomized BR patients received alvimopan 6 mg (n = 397), 12 mg (n = 413), or placebo (n = 402) \geq 2 hours before surgery and twice daily until hospital discharge for \leq 7 days. The primary endpoint of each trial was time to recovery of GI function. Hospital discharge order (DCO) written, readmission, and morbidities were also assessed. Cox proportional hazard models were used to analyze treatment effects on time-to-event endpoints.

RESULTS: Alvimopan (6 or 12 mg) significantly accelerated GI recovery (GI-3; hazard ratio = 1.28 and 1.38, respectively; $P \leq 0.001$ for both). Alvimopan significantly accelerated time to DCO written by 16 hours for 6 mg and 18 hours for 12 mg ($P < 0.001$ for both) from a mean of 147 hours for placebo. Alvimopan-treated patients had reduced postoperative morbidity compared with placebo, and incidence of prolonged hospital stay or readmission was significantly reduced ($P < 0.001$). Tolerability profiles were similar among groups.

CONCLUSIONS: Alvimopan significantly accelerated GI recovery in BR patients. A 12-mg dose provided more consistent benefits across both sexes and all ages. Postoperative morbidity rates, prolonged hospital stay, and rates of hospital readmission were significantly reduced. Alvimopan reduces the consequences of POI after BR.

PATTERNS OF GASTROINTESTINAL RECOVERY AFTER BOWEL RESECTION AND TOTAL ABDOMINAL HYSTERECTOMY: POOLED RESULTS FROM THE PLACEBO ARMS OF ALVIMOPAN PHASE III NORTH AMERICAN CLINICAL TRIALS

Wolff BG, Viscusi ER, Delaney CP, Du W, Techner L.

BACKGROUND: Postoperative ileus (POI), a transient cessation of coordinated bowel motility, occurs to some extent after all major abdominal operations. This analysis examines gastrointestinal (GI) recovery and hospital discharge history in patients undergoing partial bowel resection (BR) or total abdominal hysterectomy (TAH) by laparotomy in the placebo arms of recent phase III alvimopan trials.

STUDY DESIGN: This was a pooled post hoc analysis of placebo groups from randomized, double-blind, parallel-group, multicenter trials. All patients were uniformly managed with a standardized accelerated postoperative care pathway to facilitate GI recovery.

RESULTS: Of the 727 BR patients and 140 TAH patients included in this analysis, POI as an adverse event was reported in approximately 14.7% of BR patients and 2.9% of TAH patients, and postoperative nasogastric tube insertion was required in 11.5% of BR patients and 0.8% of TAH patients. Time to first toleration of solid food was almost 2 days longer for BR patients than for TAH patients (BR, 4.1 days; TAH, 2.5 days). Approximately 34.4% of BR patients and 4.2% of TAH patients had discharge orders written 7 days or more after operation. Nearly half (40%) of patients undergoing TAH were discharged from the hospital before GI recovery was complete. Mean postoperative lengths of hospital stay after BR and TAH were 6.6 days and 3.4 days, respectively.

CONCLUSIONS: Despite the relatively fast recovery observed with standardized accelerated postoperative care pathway use, POI as an adverse event was still reported in approximately 15% of BR patients and 3% of TAH patients. This analysis provides important clinical insight into the differences in GI recovery patterns and the incidence and impact of POI after BR and TAH.

A RANDOMIZED CONTROLLED TRIAL COMPARING SIMULTANEOUS INTRA-OPERATIVE VS SEQUENTIAL PROPHYLACTIC URETERIC STENT INSERTION IN RE-OPERATIVE COLORECTAL SURGERY

Pokala N, Delaney CP, Kiran R, Bast J, Angermeier K, Fazio VW.

OBJECTIVES: Prophylactic insertion of ureteric stents aids intra-operative identification of ureters and may allow easier visualization of any direct ureteric injury. Traditionally, ureteric catheters are inserted sequentially, before starting the abdominal part of the operation. This study determines the safety and efficacy of simultaneous intra-operative ureteric catheter insertion during complicated and re-operative colorectal surgery.

MATERIALS AND METHODS: After institutional review board (IRB) approval, 24 patients were randomized into two groups, sequential (SEQ) and simultaneous (SIM) depending upon the timing of stent placement relative to abdominal incision. Time taken from induction to abdominal incision (AIT), induction to peritoneal entry (PET), catheter insertion time (CIT), and urinary tract infection rates were recorded. Degree of difficulty for stent insertion was graded on a scale of 1-10.

RESULT: Demographics were similar between groups. Mean AIT (22 +/- 4 vs 41 +/- 7; $p = 0.0001$) and mean PET (26 +/- 4.2 vs 44 +/- 7.6; $p = 0.0001$) were shorter in the SIM group. There was no significant difference in mean CIT in SIM and SEQ groups (17.9 +/- 4.9 vs 17.6 +/- 5.9 min, $p = 0.8$). The stents were unsuccessful bilaterally in one patient in the SEQ group and unilaterally in two other patients, one in each group. The median difficulty score for catheter insertion was 3 (1-10) and 2 (1-10), ($p = 0.12$), respectively, in SIM and SEQ groups. There were no ureteric injuries in either group. One patient in SIM developed a urinary tract infection.

CONCLUSION: Simultaneous ureteric catheter insertion during abdominal procedures reduces operating times without a significant increase in morbidity. Furthermore, this permits a policy of selective stent insertion as required by the intra-abdominal findings after laparotomy.

PREDICTORS AND OUTCOME OF READMISSION AFTER LAPAROSCOPIC COLORECTAL SURGERY

O'Brien DP, Senagore AJ, Merlino JJ, Brady KM, Delaney CP

BACKGROUND: Previous studies have failed to identify predictors of early readmission after major intestinal operations. The objectives of this study were to determine readmission rates, outcomes, and predictors of readmission for patients undergoing laparoscopic colon and rectal operations.

METHODS: Patients readmitted (PR) to the hospital within 30 days of discharge after laparoscopic colon and rectal operations were identified from a prospectively maintained database. The PR group was compared with patients that were not readmitted (NR). Outcomes and variables related to readmission were evaluated.

RESULTS: There were 820 consecutive elective laparoscopic colon and rectal operations performed over a 5-year period, with adequate follow-up data for 787 cases. Seventy-nine (10%) patients were readmitted. There was no difference in the age, sex, surgeon, or type of operation between the PR and NR groups. The most common causes for readmission were bowel obstruction (19%), ileus (18%), intra-abdominal abscess (14%), and anastomotic leak (9%). Overall mean (median) length of stay (LOS) for the index admission was 3.7 +/- 4.3 (3.0) days. Patients in the PR group had a trend toward a longer index admission LOS than the NR group (5.4 +/- 8.8 [3.0] versus 3.5 +/- 3.3 [3.0], $p = 0.068$). Univariate analysis demonstrated that patients with inflammatory bowel disease, pulmonary comorbidities, and steroid use were more likely to be readmitted. Multivariate analysis confirmed that inflammatory bowel disease and pulmonary comorbidity are independent risk factors for readmission.

CONCLUSIONS: Early readmission after laparoscopic colon and rectal operations is not associated with early discharge. Identification of specific patient characteristics indicating risk for early readmission may allow for selective changes in perioperative care or discharge criteria to avoid unexpected readmission.

THE INPATIENT ECONOMIC BURDEN OF POSTOPERATIVE ILEUS ASSOCIATED WITH MAJOR ABDOMINAL SURGERY IN THE US

Goldstein JL, Matuszewski KA, Delaney CP, Senagore AJ, Chiao E, Shah M, Meyer K, Bramley T.

A study was conducted to estimate the economic burden of postoperative ileus (POI) to the U.S. hospital system. Using national data projected from a large, inpatient, service-level,

comparative database and applying hospitalization costs, we determined direct inpatient costs attributable to POI. Our results indicated that hospitalization for coded POI, according to the

International Classification of Diseases, ninth revision (ICD-9), was substantially more costly (\$18,877 vs. \$9,460) and longer (11.5 vs. 5.5 days) than hospitalization for non-coded POI. Total annual costs attributed to managing POI were \$1.46 billion, a situation thus warranting increased attention.

CLINICAL OUTCOMES AND RESOURCE UTILIZATION ASSOCIATED WITH LAPAROSCOPIC AND OPEN COLECTOMY USING A LARGE NATIONAL DATABASE

Delaney CP, Chang E, Senagore AJ, Broder M.

OBJECTIVES: To clarify national clinical and economic laparoscopic colectomy outcomes, we conducted a study of patients who underwent colectomy by laparoscopic or open approaches.

BACKGROUND: Laparoscopy is becoming the preferred approach for colectomy in benign and malignant diseases. Although it is associated with significant clinical benefits, economic outcomes have varied.

METHODS: We analyzed cohorts of patient-level data from Premier Inc.'s Perspective Rx Comparative Database, which collects data from more than 500 hospitals throughout the United States. By reviewing hospital charge data, patients who underwent elective colectomies from July 1, 2004, through June 30, 2006, were identified using International Classification of Diseases, 9th Revision, Clinical Modification procedure codes. The colectomy had to be listed as the primary or secondary procedure of the hospitalization. Primary outcomes included transfusion rates, in-hospital complications, readmissions within 30 days, reoperations, length of stay, total hospitalization costs, and discharge dispositions and services.

RESULTS: We identified 32,733 patients who had elective colectomies throughout 402 hospitals; 11,044 (33.7%) were laparoscopic and 21,689 (66.3%) were open colectomies. The mean age was 64.2 +/- 13.9 years and 53.8% were women. Laparoscopic colectomy patients had a longer mean operative time (195 +/- 76 vs. 178 +/- 80 minutes; $P < 0.0001$) and higher total hospital costs (\$8076 vs. \$7678; $P = 0.0002$). Laparoscopic patients had shorter mean length of stay (7.0 vs. 8.1; $P < 0.0001$) and fewer mean intensive care unit days (0.7 +/- 3.8 vs. 1.3 +/- 5.2 days; $P < 0.0001$). The laparoscopic cohort also had lower rates of transfusions (odds ratio [OR] = 0.68; $P < 0.0001$), in-hospital complications (OR = 0.89; $P < 0.0001$), and readmissions within 30 days (OR = 0.89; $P = 0.0051$), although reoperation rates were slightly, but significantly increased (OR = 1.78; $P = 0.002$). Laparoscopic colectomy patients were more likely to be discharged home without nursing care (OR = 0.70; $P < 0.0001$).

CONCLUSION: Evaluation of a national administrative data set showed that patients who underwent laparoscopic colectomy had shorter intensive care unit and total hospital stays, fewer complications, lower mortality, fewer readmissions, and less use of skilled nursing facilities after discharge. There was a small but significant increase in reoperation rates and in-hospital costs with laparoscopic colectomy. Improved application of enhanced recovery programs and operative efficiencies may further improve resource utilization associated with laparoscopic colectomy.

GASTROINTESTINAL RECOVERY IN PATIENTS UNDERGOING BOWEL RESECTION: RESULTS OF A RANDOMIZED TRIAL OF ALVIMOPAN AND PLACEBO WITH A STANDARDIZED ACCELERATED POSTOPERATIVE CARE PATHWAY

Ludwig K, Enker W, Delaney CP, Wolff BG, Du W, Fort JG, Cherubini M, Cucinotta J, Techner L.

PURPOSE: A pooled post hoc responder analysis was performed to investigate the clinical benefit of alvimopan, a peripherally acting mu-opioid receptor (PAM-OR) antagonist, for the management of postoperative ileus.

METHODS: Adult patients undergoing laparotomy for bowel resection scheduled for opioid-based intravenous patient-controlled analgesia received oral alvimopan 12 mg or placebo preoperatively and twice daily postoperatively until hospital discharge or for 7 postoperative days (PODs). The proportion of responders and numbers needed to treat (NNT) were examined on PODs 3-8 for GI-2 recovery (first bowel movement, toleration of solid food) and hospital discharge order (DCO) written.

RESULTS: Alvimopan significantly increased the proportion of patients with GI-2 recovery and DCO written by each POD ($P < 0.001$ for all). More patients who received alvimopan achieved GI-2 recovery (alvimopan, 80%; placebo, 66%) and DCO written (alvimopan, 61%; placebo, 77%) before POD 6 versus patients who received placebo. The NNT for GI-2 recovery before POD 6 ranged from 6-7.

CONCLUSIONS: On each POD analyzed, alvimopan 12 mg significantly increased the proportion of patients who achieved GI-2 recovery and DCO written versus placebo and was associated with relatively low NNTs. These data provide additional support for the overall clinical benefit of alvimopan in patients undergoing bowel resection.

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DEVELOPMENT OF A CLINICALLY FEASIBLE MOLECULAR ASSAY TO PREDICT RECURRENCE OF DUKES' B COLON CANCER

Jiang Y, Delaney CP, Lavery IC, Zhang Y, Talantov D, McGreevey M, Chowdary D, Skacel M, Manilich E, Mazumder A, Atkins D, Casey G, Wang Y.

PURPOSE: The 5 year survival rate of Dukes' B colon cancer patients is approximately 75%. Identification of the patients at high risk of recurrence in this group would allow better staging and more informed use of adjuvant chemotherapy. Although a number of molecular prognostic factors have been evaluated in their association with recurrence, clinical and pathological factors are preferably used to determine tumor stages in present medical practice for colon cancer. In this study, we used DNA chip technology to systematically identify new prognostic markers for tumor relapse in Dukes' B colon cancer patients.

PATIENTS AND METHODS: Using Affymetrix U133a GeneChip containing approximately 22,000 transcripts from the human genome, RNA samples from 74 Dukes' B colon cancer patients were analyzed. Thirty-one of these patients were selected because they developed tumor relapse in less than 3 years while 43 patients remained disease-free for more than 3 years after surgery. An unsupervised hierarchical clustering method was used to identify subgroups in the patients based on their gene expression profiles. The probability of recurrence of the subgroups was then determined. Cox proportional hazards regression and t-test methods were applied to further select genes whose expression levels are significantly correlated to patient disease-free time in each patient subgroup. A multivariate Cox proportional hazards model was built to predict recurrence.

RESULTS: Gene expression profiling of 74 Dukes' B patients identified 2 distinct patient subgroups. The first subgroup contained 54 patients with 18 relapse patients (33%) and the second subgroup contained 20 patients with 13 relapse patients (65%). Next, each patient subgroup was divided into a training set and a testing set with approximately equal number of patients. By applying Cox proportional hazards regression and re-sampling based t-test to the training set, we identified 7 genes from the first subgroup and 15 genes from the second subgroup whose gene expression levels were significantly correlated to disease-free time of the patients. Together, a 23-gene signature was built and validated in the testing set of 36 independent patients, 13 of 18 relapse patients and 15 of 18 disease-free patients were predicted correctly giving an odds ratio of 13 (95% CI: 2.6, 65; $p=0.003$). The Kaplan-Meier survival analysis indicated a significant difference in disease-free time between the predicted relapse and disease-free patients ($P=0.0001$).

CONCLUSION: This study suggests that gene expression profiling provides a successful strategy to identify a combination of molecular markers that can be used to build a classification model of colon cancer disease recurrence. The described model has utility in identifying patients who would otherwise relapse. The clinical value of these markers is that the patients at a high predicted risk of relapse (13-fold risk) could be up-staged to receive adjuvant therapy, similar to Dukes' C patients. Our data highlights the feasibility of a prognostic assay that could help to focus more intensive treatment for localized colon cancer.

FAST TRACK PATHWAYS – ACCELERATING RECOVERY AFTER ILEOSTOMY CLOSURE

Joh JG, Lindsetmo RO, Stulberg J, Obias V, B Champagne, Delaney CP

PURPOSE: Hospital stay after ileostomy closure (IC) is variable and can be as long as 8 days. Although multimodal care paths have been used to reduce hospital stay after abdominal surgery, there has been minimal use of these pathways after IC. This study evaluated the outcome of standardized care paths in patients undergoing IC in a unit experienced with care paths.

METHODS: Forty two patients underwent IC by a single surgeon over two years and were managed by a standardized postoperative care pathway. On the first postoperative day, patients received oral analgesia, and a soft diet. Discharge was based on standard criteria developed for laparoscopic colectomy patients, including recovery of lower gastrointestinal function and tolerance of adequate oral intake. Results were recorded prospectively in an IRB-approved database, including demographics, operative time, blood loss, complications, length of stay, and readmission data.

RESULTS: The median operative time and blood loss were 60 minutes and 17.5 ml, respectively, and median hospital stay was 2 days (mean 2.4 days, range 1-8). 29 patients (69%) were discharged by postoperative day two. The complication rate was 23%: 3 prolonged postoperative ileus (POI, 7.1%), 1 early postoperative small bowel obstruction (SBO), 1 mortality not related to ileostomy closure, 1 minor bleeding, 1 wound infection, 3 other. The readmission rate was 9.5% and reasons for readmission included SBO (n=1), POI (n=1), wound infection (n=1) and dehydration (n=1). Two patients had reoperation with 30 days for SBO and wound infection.

CONCLUSIONS: Ileostomy closure patients managed with postoperative care pathways can have a short hospital stay with acceptable morbidity and readmission rates. Although IC is not considered to be a major procedure, readmission and complication rates approximate those seen with intestinal resection.

VALIDATION OF A NOVEL POSTOPERATIVE QUALITY OF LIFE (PQL) SCORING SYSTEM

Delaney CP, O'Brien-Ermlich B, Cheruvu V, Laughinghouse M, Champagne B, Marderstein E, Obias V, Reynolds H, Debanne SM.

INTRODUCTION: No specific scoring system exists for the assessment of quality of life (QOL) after major abdominal surgery. QOL systems in existence are non-specific, insensitive, and often cumbersome and difficult to use, particularly relating to post-surgical evaluation. This study prospectively validates PQL, a novel prospective scoring system in patients having laparoscopic or open major abdominal colorectal surgery.

METHODS: A group of six experienced surgeons developed a questionnaire, encompassing the previously validated Cleveland Global QOL score. These questions were reviewed with 20 patients to select the most relevant questions, yielding a 14 question questionnaire with grades assessing global QOL, nausea, pain (at rest and maximal activity), bowel function and return to normal health. After IRB approval, patients completed the questionnaire pre-operatively, and on post-op days (POD) 1, 2, 4, 8, 12, 30 and 60. The internal consistency aspect of reliability was determined at each time-point using Cronbach's alpha. Factor analysis (a data reduction technique) was used to group items into factors using key underlying attributes.

RESULTS: 100 patients who had a variety of colorectal procedures entered the study. Average age was 60.5 years and 46% were female. Cronbach's alpha revealed excellent internal consistency over time, ranging from 0.84 to 0.94 at all time points, even at POD 1 when Cronbach's alpha was 0.79, demonstrating that the items in the questionnaire are measuring the same underlying construct. Factor analysis was performed for each follow-up time, and consistently loaded on two factors. One factor contained scores for symptoms including pain, nausea and fatigue (labeled PQL Symptom Score). The other factor contained scores for overall and gastrointestinal function satisfaction with outcomes (labeled PQL Recovery Score).

CONCLUSIONS: PQL is a novel, easy to use post-operative quality of life scoring system with high internal consistency. PQL provides scores for 14 different variables which can be grouped into a Global QOL score (CGQL), PQL Recovery Score and PQL Symptom Score, to facilitate and standardize assessment of recovery after major surgery.

ENDOSCOPIC ULTRASOUND FOR LOCALIZING SAFE ALTERNATE ACCESS SITES FOR NOTES: INITIAL EXPERIENCE IN A PORCINE MODEL

B. Joseph Elmunzer MD, Steve J. Schomisch, Joseph A. Trunzo MD, Benjamin K. Poulouse MD, Michael F. McGee MD, Ashley L. Faulx MD (), Conor P. Delaney, MD, PhD, Jeffrey M. Marks MD, Jeffrey L. Ponsky MD, Amitabh Chak MD ()

INTRODUCTION: Most natural orifice transluminal endoscopic surgery (NOTES) has been performed through an anterior transgastric approach, based on the established safety of PEG placement. This approach precludes mechanically efficient access to many anatomic areas, such as the upper abdomen and retroperitoneum. This study assesses endoscopic ultrasound (EUS) to identify safe alternate gastrointestinal access sites for NOTES.

METHODS: 32 EUS-guided access procedures were performed in 12 pigs; 11 through the antrum, 9 through the posterior stomach wall, and 12 transrectal. 16 safe access procedures (SAP) used sonographic guidance to achieve safe intraperitoneal access by avoiding extraluminal organs and vessels during the initial puncture. Sixteen unsafe access procedures (UAP) evaluated complications of blind access by performing a standard NOTES puncture at sites adjacent to critical extraluminal structures identified by EUS. 25/32 procedures were performed with a prototype forward-viewing echoendoscope (Olympus; Tokyo, Japan). After initial EUS, peritoneal access was achieved with a needle knife or FNA needle. UAP targeted the liver, gallbladder, spleen, pancreas, kidney, iliac vessels, and urinary bladder. Baseline and completion laparotomy was performed to evaluate for pre-existing abnormalities and assess for complications.

RESULTS: All 16 UAP resulted in clinically relevant damage to target structures, such as liver laceration, gallbladder puncture, and external iliac arteriotomy. Thirteen SAP were without complication. The three SAP complications occurred with transrectal access (superficial incision through pelvic sidewall peritoneum; left mesosalpinx injury; small bowel perforation). Small bowel perforations were subsequently avoided by using the Trendelenberg position.

CONCLUSIONS: This study confirms that blind NOTES access through the antrum, posterior stomach wall, and rectum may result in serious complications. EUS-guided access substantially reduces, but does not eliminate the risk. EUS is a promising adjunct to NOTES access, particularly as more experience is gained with the forward-viewing echoendoscope.

DOSIMETRIC EVALUATION OF ENDOSCOPIC RADIOFREQUENCY ABLATION IN THE HUMAN COLONIC EPITHELIUM IN A TREAT AND RESECT TRIAL

Joseph A. Trunzo, Michael F. McGee, Benjamin K. Poulouse, Joseph E. Willis, Bridget Ermlich, Michelle Laughinghouse, Bradley Champagne, Conor P. Delaney, and Jeffrey M. Marks

BACKGROUND: Radiofrequency ablation (RFA) has been used effectively for the treatment of Barrett's esophagus. This technology may additionally have a role in the treatment of bleeding or neoplasia in the lower GI tract. The goal of this study was to determine the optimal treatment parameters to create ablative effect to the colonic mucosa/submucosa, without deeper transmural colonic injury.

METHODS: In this IRB approved protocol, patients undergoing elective left colon or rectal resection were enrolled. Once margins of resection were determined intra-operatively, a colonoscope mounted with a planar RFA device (HALO90, BARRX Medical) with a 13mm by 20mm bipolar array was advanced to the resection segment. Areas of normal mucosa were ablated in situ with 2 or 4 applications (APP) while varying energy density (12, 15, or 20 J/cm²). After removal with the surgical specimen, ablation zones and untreated normal adjacent tissue were multiply sectioned and stained with H&E. An expert GI pathologist, blinded to the treatment parameters, assessed the deepest histological layer with any histopathological change (inflammation, ablation, abnormal pattern, necrosis.)

RESULTS: We created 51 ablation zones in 16 patients. When comparing max depth of histological change in 2 vs. 4 APP, regardless of energy density, evidence of serosal change occurred in 0% (0/24) vs. 15% (4/27) of zones ($p=0.11$), whereas changes to the muscularis propria (MP) occurred in 25% (6/24) vs. 63% (17/27) of zones ($p<0.05$).

Comparing energy density settings of 12, 15, and 20 J/cm², regardless of APP, we observed an unexpected inverse relationship of energy vs depth, in that changes were present in MP in 74% (17/23), 35% (6/17), and 0% (0/11), respectively ($P<0.05$); and in serosa in 9% (2/23), 12% (2/17), and 0% (0/11) ($P=0.517$). No changes in serosa were seen in any 2 APP ablation zone at any energy density.

CONCLUSIONS: We observed a direct correlation between APP and ablation effect depth for this device in the colon. All ablation zones at 2 APP demonstrated no changes to the serosa and only a 25% incidence of MP changes. We observed an unexpected inverse relationship between energy and ablation depth, counter to reports in similar trials involving the esophagus. This observed variability may be due to inconsistent electrode approximation to mucosa,

21ST CENTURY HOSPITAL MANAGEMENT: USING INDUSTRIAL PROCESS CONTROL TECHNIQUES TO IMPROVE EFFICIENCY OF SURGICAL CARE

Jonah J Stulberg, MPH, Bradley J Champagne, MD, Eric Marderstein, MD, MPH, Harry J Reynolds, MD, Bridget Ermlich RN, Anthony J Senagore, MD, Conor P Delaney, MD, MCh, PhD

Case Western Reserve University, Department of Surgery, Cleveland, OH. Spectrum Health and Michigan State University, Grand Rapids, MI

PURPOSE: Manufacturing industries use statistical process control (SPC) to decrease variation and improve quality. Although SPC might improve health care efficiency, it is minimally used in health care and particularly general surgery. We used SPC to assess common patient and process level characteristics as determinants of postoperative length of stay (LOS) as a key outcome measure.

METHODS: An IRB-approved prospective database containing 921 consecutive care episodes including 514 major abdominal surgeries, was used to assess variables potentially affecting LOS. Regression analysis (RA) evaluated patient and process variables related to LOS. SPC outlier status (control limit) was defined as LOS greater than 2 standard deviations from the mean. Initial analysis defined outliers using individual variables, and the model was refined by grouping specific variables.

RESULTS: Although type of admission, age, diagnosis, procedure, race, gender and operative time significantly correlated ($P < 0.05$) with LOS, saturated model analysis showed independent variables did not explain variance. Stratification by preoperative patient and disease characteristics was similarly ineffective at reducing control limits suggesting outliers are based on systems inefficiencies. Analysis by surgical approach (minimally invasive and standardized enhanced recovery protocol) reduced LOS outliers from 50 to 2 patients.

CONCLUSION: This unique application of SPC analysis challenges the constructs currently used for surgical quality improvement, and demonstrates the benefit of new methods of identifying variation in outcomes. SPC analysis based upon specific process measures (surgical technique and standardized care plans), may provide a superior approach to real-time detection of outliers to focus clinical efforts for rescue and improved outcomes.

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Section 3

General Surgery

CHANGING THE “FEVER WORKUP” UTILIZING A MULTI-MODELING TECHNIQUE APPROACH TO MORE ACCURATELY DIAGNOSE INFECTIONS

Fadlalla A, Golob JF, Claridge JA.

BACKGROUND: We have previously demonstrated that fever and/or leukocytosis are not significantly associated with urinary tract infections (UTI), bacteremia, or respiratory tract infections (RTI) in critically ill trauma patients during their initial 14 hospital days. Unfortunately, the actual clinical parameters to trigger an “infection workup” remain illusive. Advanced mathematical modeling techniques in combination with quality data and computerized clinical decision support may help discover a more accurate “infection workup”. The purpose of this study was to determine the accuracy of various modeling techniques to identify infectious complications in critically ill trauma patients and compare the performance of these models to the current “fever workup” practice.

METHODS: An 18-month retrospective analysis was conducted using critically ill trauma patients who were admitted to the surgical and trauma intensive care unit (STICU) at a level I trauma center for 2 or more days. Utilizing variables previously shown to be associated with infectious complications; three mathematical models were created to predict the presence of UTI, bacteremia, or RTI. Decision trees, neural networks, and logistic regression analysis models were created after the data sample was split into 70% for a training set and 30% for a testing set. The independent variables used for model creation were age, gender, body temperature, leukocyte count, requirement for mechanical ventilation, presence of a central line, penetrating or blunt injury, day in the STICU, antibiotic use, and injury severity score. Models were compared to each other by calculating sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, and area under the ROC curve.

RESULTS: 510 critically ill trauma patients met inclusion criteria, and 3839 patient-days of data were collected. A total of 2191 different microbiologic cultures were obtained which identified 184 infections. Infected-days (184) were defined as the day the infectious complication was identified with a confirmatory positive culture. These infected-days were matched with 184 non-infected days, randomly selected from patient days of non-infected patients; hence a sample size of 368 patient-days was used for modeling. The results reported in the table are for the testing set.

	Overall Accuracy (%)	AUC	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Decision tree	79	84	85	72	74	84
Neural net	74	82	84	65	69	81
Logistic regression	67	81	75	58	63	72

CONCLUSIONS: These results demonstrate that using modeling techniques other than logistic regression analysis, we are able to improve the robustness and accuracy of predicting infections. Thus, to continue to work towards the goal of creating an “infection workup” we have demonstrated that using advanced modeling techniques beyond the presence of fever and leukocytosis should be considered for designing computerized clinical decision support.

IMPROVING THE MONITORING OF NOSOCOMIAL INFECTIONS IN THE INTENSIVE CARE UNIT WITH REAL-TIME MEDICAL INFORMATICS

Golob JF, Claridge JA, Kan JA, Patel NP, Yowler CJ, Fadlalla A.

BACKGROUND: We developed a prototype electronic clinical information system called the Surgical Intensive Care – Infection Registry (SIC-IR), to prospectively study infectious complications and monitor quality of care improvement programs in the surgical and trauma intensive care unit (STICU). The objective of this study was to validate SIC-IR as a successful health information technology with an accurate clinical data repository.

STUDY DESIGN: Utilizing the DeLone and McLean Model of Information Systems Success as a framework, we evaluated SIC-IR in a three month prospective crossover study of physician use in one of our two STICUs (SIC-IR unit vs. non SIC-IR unit). Three simultaneous research methodologies were employed: a user survey study, a pair of time-motion studies, and an accuracy study of SIC-IR's clinical data repository.

RESULTS: The SIC-IR user survey results were positive for system reliability, graphical user interface, efficiency, and overall benefit to patient care. There was a significant decrease in pre-rounding time of nearly four minutes per patient on the SIC-IR unit compared to the non SIC-IR unit. The SIC-IR documentation and data archiving was accurate 74-100% of the time depending on the data entry method utilized. This accuracy was significantly improved compared to normal hand-written documentation on the non SIC-IR unit.

CONCLUSIONS: SIC-IR proved to be a useful application both at an individual user and organizational level, and will serve as an accurate tool to conduct prospective research and monitor quality of care improvement programs.

WHO IS MONITORING YOUR INFECTIONS: SHOULDN'T YOU BE?

Claridge JA, Golob JF, Fadlalla A, D'AMico B, Peerless JR, Yowler CJ, Malangoni MA.

BACKGROUND: In the era of pay for performance and outcome comparisons between institutions, it is imperative to have a reliable and accurate surveillance methodology for infectious complications. The current monitoring standard often involves a combination of prospective and retrospective analysis by trained infection control (IC) teams. We have developed a medical informatics application, the Surgical Intensive Care - Infection Registry (SIC-IR), to assist with this process. The objectives of this study were to 1) evaluate for differences in data gathered between the current IC practices and SIC-IR and 2) determine which method has the best sensitivity and specificity for identifying ventilator associated pneumonia (VAP).

METHODS: A 12 month prospective analysis was conducted in two surgical and trauma intensive care units (STICU) at a level I trauma center (Unit 1 - 8 months, Unit 2 - 4 months). Data was simultaneously collected by the SIC-IR system at the point of patient care and by IC utilizing multiple different administrative and clinical modalities. Data collected by both systems included patient-days, ventilator-days, central line-days, number of VAPs, and catheter related blood stream infections (CRBSIs). VAPs and CRBSIs were defined using the Centers for Disease Control definitions. Central line and ventilator use as well as VAP and CRBSI rates were calculated using the National Nosocomial Infection Surveillance methodology. VAP discrepancies between SIC-IR and IC were individually analyzed and true infections were identified by a physician panel. Using these true infections as a gold standard, sensitivity and specificity for both SIC-IR and IC were determined.

	SIC-IR	IC	p value
Patient-days/month	396	356	<0.001
Vent-days/month	225	237	0.005
Central line-days/month	202	198	NS
Vent use (%)/month	57%	67%	<0.001
Central line use (%)/month	51%	55%	0.003
VAPs/month	3.6	2.0	0.002
CRBSIs /month	0.1	0.3	NS
VAP rate/1000 vent-days/ month	15.5	8.0	0.002
CRBSI rate/1000 line-days/month	0.4	1.5	NS

RESULTS: 769 patients were evaluated by both systems in this analysis; 40 patients (5%) had 43 VAPs. The table compares SIC-IR and IC. SIC-IR identified 39 and IC recognized 22 of the 40 patients with VAP. SIC-IR had a sensitivity and specificity of 97% and 100%, respectively for identifying VAP. This compared to an IC sensitivity of 56% and a specificity of 99%.

CONCLUSIONS: Utilizing SIC-IR at the point of patient care by a multidisciplinary STICU team offers more accurate infection surveillance with a high sensitivity and specificity. This can be accomplished without additional resources and engages the physicians treating the patient. In addition, SIC-IR, unlike IC, comprehensively collects data on all infected and uninfected STICU patients to allow accurate prospective research and quality of care improvement program monitoring.

COMPLICATED SKIN AND SOFT-TISSUE INFECTIONS: DIAGNOSTIC APPROACH AND EMPIRIC TREATMENT OPTIONS

James I. Merlino MD, Mark A. Malangoni MI

Skin and soft-tissue infections are common and generally are uncomplicated at the time of initial presentation. However, these infections can worsen quickly when there are delays in presentation and treatment. Upon encountering these infections, physicians must respond quickly with an appropriate therapeutic plan and be aware of trends in microbial resistance in order to optimize patient care.

PREOPERATIVE FINDINGS PREDICT CONVERSION FROM LAPAROSCOPIC TO OPEN CHOLECYSTECTOMY

Jeremy M. Lipman MD, Jeffrey A. Claridge MD, Manjunath Haridas MBBS, Matthew D. Martin BS, David C. Yao BS, Kevin L. Grimes BS and Mark A. Malangoni MD

BACKGROUND: Previous studies evaluating predictive factors for conversion from laparoscopic to open cholecystectomy have drawn conflicting conclusions. We evaluated objective preoperative variables to create an accurate, accessible risk score to predict conversion.

METHODS: A retrospective review was performed of laparoscopic cholecystectomy patients at an urban tertiary care center. Seventy characteristics were subjected to bivariate and multivariate logistic regression analysis to identify parameters that independently predict conversion to open cholecystectomy. A model was created based on this analysis.

RESULTS: Laparoscopic cholecystectomy was performed on 1377 patients for benign gallbladder disease over a 71-month period. There were 112 (8.1%) conversions to open cholecystectomy. The correlation between the preoperative clinical diagnosis and pathologic diagnosis for acute and chronic cholecystitis was 48.6% and 94.6%, respectively. Multivariate analysis identified male gender, elevated white blood cell count, low serum albumin, ultrasound finding of pericholecystic fluid, diabetes mellitus, and elevated total bilirubin as independent predictors of conversion. These 6 factors were also associated with the pathologic diagnosis of acute cholecystitis. A model to calculate the risk for conversion was created with an area under the receiver operator curve of 0.83. The risk for conversion also can be estimated based on the number of factors identified present and ranged from 2% when 1 factor was present to 89% with 6 factors.

CONCLUSIONS: These results demonstrate that conversion to open cholecystectomy can be predicted based on parameters available preoperatively. Conversion is more likely in patients who have acute cholecystitis; however, the correlation between its clinical and pathologic diagnosis is poor. Improvements in the ability to determine the risk for conversion have important implications for surgical care.

BACTERIOLOGICAL EFFICACY OF SEQUENTIAL INTRAVENOUS (IV) TO ORAL (PO) MOXIFLOXACIN FOR POLYMICROBIAL COMPLICATED INTRA-ABDOMINAL INFECTIONS (cIAI)

H. Lippert¹, G. Weiss¹, M. Malangoni², S.H. Choudhri³, P. Pertel³, J. Herrington³, J-M. Breilmann³

¹Universitaetsklinikum Otto-von-Guericke-Universitaet Magdeburg, Germany

²MetroHealth Medical Center, Case Western University, Cleveland, OH, USA

³Bayer HealthCare Pharmaceuticals, West Haven, CT, USA

OBJECTIVES: Complicated intra-abdominal infections are typically polymicrobial (2 or more bacterial species), and are caused by bacterial species normally present within the gastrointestinal tract. The microbiology of cIAI varies according to the site of the primary process and if the infection is community- or hospital-acquired. Pooled data from 2 cIAI trials were used to compare the microbiological efficacy of sequential IV/PO moxifloxacin (MXF) with comparator (COMP) therapy among patients with polymicrobial infections.

METHODS: Data were pooled from 2 trials of sequential MXF (400 mg once daily IV/PO) in the treatment of cIAI. Comparator therapy consisted of IV piperacillin/tazobactam followed by PO amoxicillin/clavulanate and IV ceftriaxone and metronidazole followed by PO amoxicillin/clavulanate.

RESULTS: The 2 trials enrolled 1276 patients (632 MXF, 644 COMP) of which 656 were per protocol and microbiologically valid (316 MXF, 340 COMP). For valid patients, the majority of infections were polymicrobial (69.0% MXF, 68.2% COMP). Among those with polymicrobial infections, the mean numbers of organisms per patient in the MXF- and COMP-treated groups were 3.4 (750 from 218 patients) and 3.6 (827 from 232 patients), respectively. The overall bacteriological success rates at test-of-cure among valid patients were 248/316 (78.5%) and 270/340 (79.4%) for MXF- and COMP-treated patients, respectively. The success rates among patients with polymicrobial infections were 168/218 (77.1%) and 180/232 (77.6%) for MXF- and COMP-treated patients, respectively.

CONCLUSIONS: Monotherapy therapy with IV/PO MXF had similar bacteriological efficacy to the standard treatment regimens in the management of polymicrobial cIAI.

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REDUCTION OF SURGICAL SITE CONTAMINATION IN INGUINAL HERNIA REPAIR USING A MICROBIAL SEALANT

Shirin Towfigh, M.D.(a), William G. Cheadle, M.D. (b), Stephen F. Lowry, M.D. (c), Samuel E. Wilson, M.D.(d) and Mark A. Malangoni, M.D. (e)

a) LA County-USC Medical Center, Los Angeles, CA 90033.

b) Veterans Affairs Medical Center, Louisville, KY 40206.

c) Robert Wood Johnson Medical School, New Brunswick, NJ 08901.

d) Veterans Affairs Long Beach Healthcare System, Long Beach, CA 90822.

e) MetroHealth Medical Center, Cleveland, OH 44109.

BACKGROUND: Contamination of surgical wounds with endogenous skin flora is a known risk factor for surgical site infection. Standard pre-operative skin preparation does not completely mitigate the risk of wound contamination. The novel application of a microbial sealant may reduce peri-operative wound contamination from skin flora.

METHODS: A prospective, randomized, multi-center clinical study was conducted on patients undergoing clean open inguinal hernia repair. InteguSEAL* Microbial Sealant (Kimberly-Clark), a liquid cyanoacrylate, was used to immobilize the skin flora after standard skin preparation with 10% povidone iodine. This was compared to control: 10% povidone iodine alone. Wound contamination was measured using a nylon filter placed in the wound for 30 seconds at 1) the beginning of surgery, immediately after skin incision, and 2) the end of surgery, prior to skin and soft tissue closure. The filters were then transferred to a blood agar plate. Total colony forming unit (CFU) counts on each filter were analyzed at a core lab within 24 hours of sampling. Gram positive organisms underwent specific identification procedures for *Staphylococcus aureus*.

RESULTS: Of 177 enrolled patients, 166 (95%) were evaluable. At the beginning of surgery, 21/83 (25%) control wounds and 12/83 (15%) of InteguSEAL* wounds were contaminated with at least 1 CFU ($p=0.08$). At the end of surgery, contamination rates were 52/83 (63%) in control wounds and 42/83 (51%) in InteguSEAL* wounds ($p=0.12$). Combining time points as an indicator of total exposure provided a difference of 57/83 (69%) for control wounds and 44/83 (53%) for InteguSEAL wounds ($p=0.04$). No *S. aureus* were cultured in either group.

CONCLUSIONS: InteguSEAL* Microbial Sealant significantly reduces surgical wound bacterial contamination when used in conjunction with 10% povidone iodine skin preparation, as compared to povidone iodine alone. This reduction in contamination is evident at the start of surgery and persists through the length of the operation. Further study of the effects of InteguSEAL* on surgical site contamination and infection is indicated.

EFFECT OF PARATHYROIDECTOMY ON ANEMIA IN END-STAGE RENAL DISEASE PATIENTS WITH HYPERPARATYROIDISM

Joseph A. Trunzo MD, Christopher R McHenry MD, James A. Schulak MD, Scott M. Wilhelm MD

INTRODUCTION: Development of secondary and tertiary hyperparathyroidism (HPT) is a well known sequela of end-stage renal disease (ESRD). It has been suggested that parathyroidectomy for HPT in ESRD patients may result in improvement in anemia and improved response to erythropoietic stimulating drugs. Our goal was to examine the effect of parathyroidectomy on EPO dosing requirements and anemia in our ESRD patients.

METHODS: A retrospective review was conducted using electronic hospital and local dialysis unit database records to obtain pre-operative and post-operative laboratory values. Patients were included if pre-operative and 1 year post-operative hemoglobin (HB) and hematocrit (HCT) levels were available and excluded if they received a kidney transplant or had failure of parathyroidectomy during the 1 year follow up. Lab values were obtained pre-operatively and at 1, 2, and 12 months post-operatively. HB and HCT levels were averaged over 3 months prior to surgery and again at 9 to 12 month post surgery. Erythropoietin (EPO) dose, calcium (CA), phosphorus (PH), alkaline phosphatase (AP), albumin (ALB), and parathyroid hormone (PTH) were also obtained during these times.

RESULTS: Thirty-seven patients met inclusion criteria. Surgical therapy resulted in decreased PTH from 1871 ± 236 (mean \pm SEM) to 167 ± 29 pg/mL ($P < 0.001$) at 1 year. EPO dosing requirement showed a profound decline from $10,086 \pm 1721$ to $3,514 \pm 620$ units/treatment ($p = 0.004$). HB and HCT levels showed an upward trend at 1 year (11.4 ± 0.3 to 12.1 ± 0.2 g/dL and 35.7 ± 1.0 to $37.1 \pm 0.6\%$, respectively), though neither were statistically significant. AP levels dropped from 476 ± 65 to 103 ± 51 U/L ($p < 0.001$). CA, PH, and ALB levels showed no difference.

CONCLUSION: In ESRD, parathyroidectomy for HPT improves anemia of chronic disease and statistically lowers exogenous erythropoietin requirements. This suggests either increased endogenous EPO production or improved response at lower dosing levels. As a result, we propose refractory renal anemia as a secondary indication for surgical resection in this population.

ENDOSCOPIC FULL THICKNESS RESECTION OF GASTRIC TUMORS USING A NOVEL GRASP-AND-SNARE TECHNIQUE: FEASIBILITY IN EX VIVO AND IN VIVO PORCINE MODELS

B. Joseph Elmunzer MD, Joseph A. Trunzo MD, Jeffrey M. Marks MD, Steve J. Schomisch, Amitabh Chak MD (), Benjamin K. Poulouse MD, Jessica J. Bailey, Jeffrey L. Ponsky MD.

INTRODUCTION: Endoscopic full thickness resection (EFTR) may provide a non-surgical method of removing tumors of the gastrointestinal tract. A variety of EFTR techniques are under development. The aim of this study was to evaluate the feasibility of a grasp-and-snare EFTR technique using a novel grasping device that provides more secure tissue anchoring and manipulation.

METHODS: EFTR of "artificial" gastric subepithelial tumors was performed 11 times, 7 in explanted swine stomachs and 4 in live pigs. In 8 cases, the tumors were created by externally injecting a mixture of methylene blue and surgical lubricant into the gastric submucosa. In the remainder, a piece of styrofoam was surgically implanted into the gastric submucosa and anchored in place with sutures to the serosa. All model tumors were between 1 and 2.5 cm in greatest dimension. Resection was performed using a double channel therapeutic endoscope with a prototype hook grasping device (Olympus Tokyo, Japan) through one channel and a prototype hexagonal snare (US Endoscopy, Mentor, OH) through the other. The grasper was advanced through the open snare loop and anchored to the gastric wall immediately adjacent the model tumor. The grasper was then partially retracted into the endoscope, causing the target tissue, including tumor, to evert into the gastric lumen. The entire endoscope-grasper apparatus was then pulled back to move the target tissue into an en face position, allowing placement of the open snare distal to the tumor around uninvolved gastric tissue. Resection was performed with a blended current through the snare. In the live pigs, tumor resection was followed by laparotomy and necropsy to assess for extraluminal organ injury.

RESULTS: Successful EFTR was achieved in all cases as evidenced by full thickness gastric wall defects and presence of serosa in all resected specimens. Model tumor specimens measured up to 4.2 cm when stretched and pinned on a histology stage. Gross margins were negative in 8/10 resections; in 2 cases methylene blue remained along the gastric margin, presumably due to inadvertent tracking of surgical lubricant within the submucosa beyond the intended tumor margin during injection. All 4 resections in live pigs had clear gross margins and no complications.

CONCLUSIONS: EFTR of gastric tumors using the aforementioned grasp-and-snare technique is feasible in pigs. This technique is advantageous in that eversion of the gastric wall avoids injury to external organs and the involved techniques are quite familiar to therapeutic endoscopists. Additional research is necessary to further evaluate safety, optimal electrosurgical settings, and reliable closure.

A NOVEL APPROACH TO ENDOSCOPIC FULL THICKNESS GASTRIC RESECTION USING A PROTOTYPE HOOK GRASPER

Joseph A. Trunzo, B. Joseph Elmunzer, Jeffrey M. Marks

Performing an endoscopic full-thickness resection (EFTR) safely has proven a difficult task with the current endoscopy equipment available. Current grasping devices are not able to elevate the tissue beyond the mucosa, and cutting blindly into the abdomen has clear drawbacks. This presentation demonstrates a prototype hook grasper's (Olympus, Inc) ability to grip deep muscle layers and invert the external serosa, providing a safe means for snaring a full-thickness section of gastric tissue in a porcine model. This is followed with a gastrotomy closure using the TAS system (Ethicon, Inc.).

ENDOSCOPIC ULTRASOUND FOR LOCALIZING SAFE ALTERNATE ACCESS SITES FOR NOTES: INITIAL EXPERIENCE IN A PORCINE MODEL

B. Joseph Elmunzer MD, Steve J. Schomisch, Joseph A. Trunzo MD, Benjamin K. Poulouse MD, Michael F. McGee MD, Ashley L. Faulx MD (), Conor P. Delaney, MD, PhD, Jeffrey M. Marks MD, Jeffrey L. Ponsky MD, Amitabh Chak MD ()

INTRODUCTION: Most natural orifice transluminal endoscopic surgery (NOTES) has been performed through an anterior transgastric approach, based on the established safety of PEG placement. This approach precludes mechanically efficient access to many anatomic areas, such as the upper abdomen and retroperitoneum. This study assesses endoscopic ultrasound (EUS) to identify safe alternate gastrointestinal access sites for NOTES.

METHODS: 32 EUS-guided access procedures were performed in 12 pigs; 11 through the antrum, 9 through the posterior stomach wall, and 12 transrectal. 16 safe access procedures (SAP) used sonographic guidance to achieve safe intraperitoneal access by avoiding extraluminal organs and vessels during the initial puncture. Sixteen unsafe access procedures (UAP) evaluated complications of blind access by performing a standard NOTES puncture at sites adjacent to critical extraluminal structures identified by EUS. 25/32 procedures were performed with a prototype forward-viewing echoendoscope (Olympus; Tokyo, Japan). After initial EUS, peritoneal access was achieved with a needle knife or FNA needle. UAP targeted the liver, gallbladder, spleen, pancreas, kidney, iliac vessels, and urinary bladder. Baseline and completion laparotomy was performed to evaluate for pre-existing abnormalities and assess for complications.

RESULTS: All 16 UAP resulted in clinically relevant damage to target structures, such as liver laceration, gallbladder puncture, and external iliac arteriotomy. Thirteen SAP were without complication. The three SAP complications occurred with transrectal access (superficial incision through pelvic sidewall peritoneum; left mesosalpinx injury; small bowel perforation). Small bowel perforations were subsequently avoided by using the Trendelenberg position.

CONCLUSIONS: This study confirms that blind NOTES access through the antrum, posterior stomach wall, and rectum may result in serious complications. EUS-guided access substantially reduces, but does not eliminate the risk. EUS is a promising adjunct to NOTES access, particularly as more experience is gained with the forward-viewing echoendoscope.

INITIAL EVALUATION OF A NOVEL PROTOTYPE FORWARD-VIEWING ECHOENDOSCOPE IN A PORCINE ARTERIAL BLEEDING MODEL

Pollack MJ, Elmunzer BJ, Trunzo JA, McGee M, Ponsky JL, Marks JM, Wong RC, Schomisch SJ, Chak A.

BACKGROUND: Currently accepted endoscopic stigmata for peptic ulcer bleeding are secondary mucosal indicators of submucosal arteries. Interpretation of these stigmata has limited interobserver variability and endoscopic therapy has to be delivered blindly to the presumptive submucosal vessel. Real-time visualization of submucosal arterial flow at the base of an ulcer would permit more accurate assessment of the vessel and precise targeting for endoscopic therapy. Moreover, visualized cessation of blood flow would provide definitive evaluation for adequacy of endoscopic therapy.

METHODS: A prototype therapeutic ultrasound (US) endoscope (XGiF-UCT160), Olympus Inc., Tokyo, Japan contains forward viewing optics, an US scanner with 90 degrees scanning range with color Doppler, and a 3.7 mm working channel in alignment with the endoscopic shaft. This geometry may allow endoscopic visualization of a submucosal artery in peptic ulcer with the ability to perform and assess real-time targeted therapy. A previously described live porcine model for peptic ulcer hemorrhage was created by isolating the gastroepiploic and/or short gastric artery and tunneling it into the subserosal space at laparotomy. The prototype endoscope was introduced into the gastric lumen and attempts were made to image submucosal arterial flow and deliver endoscopic therapy.

RESULTS: Three cases were performed. The tunneled artery with color Doppler flow could be imaged from the luminal surface using the prototype forward viewing device. Direct contact with the gastric wall with the endoscope tip was necessary for imaging since the sonographic transducer on the prototype does not have a water balloon.

TRANSGASTRIC NATURAL ORIFICE TRANSLUMENAL ENDOSCOPIC SURGERY (NOTES) PERITONEOSCOPY: A PILOT STUDY IN EFFICACY AND GASTROTOMY SITE SELECTION

Joseph A. Trunzo, Michael F. McGee, Raymond P. Onders, Jonathan P. Pearl, Benjamin K. Poulouse, Jeffrey L. Ponsky, Jeffrey M. Marks

BACKGROUND: Diagnostic NOTES peritoneoscopy can be easily performed with standard endoscopic equipment and by virtue of its minimal technological requirements may represent a popular application of NOTES. The efficacy and optimal transgastric access site for NOTES peritoneoscopy has not been determined. The goal of this pilot study was to characterize the efficacy of various anterior gastric access sites for diagnostic transgastric NOTES peritoneoscopy in patients undergoing hybridized laparoscopy-NOTES procedures.

METHODS: Patients undergoing planned laparoscopic gastrotomy for gastric neoplasm excision or foreign body (FB) retrieval were eligible for intra-operative transgastric NOTES peritoneoscopy. Following laparoscopic abdominal exploration, the laparoscopist chose an anterior gastric site for NOTES gastrotomy appropriate for neoplasm excision or FB removal. At the chosen site, transgastric NOTES access was established independently through endoscopic means and standardized NOTES peritoneoscopy was performed. The gastric site and the ability to visualize abdominopelvic organs were graded. Patients were evaluated post-operatively for complications.

RESULTS: Eight patients requiring 9 procedures were included (Neoplasm = 7, FB=2). Gastrotomy sites were classified as body (n=3), lesser curvature (n=3), greater curvature (n=1), fundus (n=1), and antrum (n=1). Satisfactory navigation to all quadrants was performed. The spleen was visualized only once, when a greater curvature site was chosen. No major complications, readmissions, or mortalities occurred. One patient developed a surgical site infection at a laparoscopic port site requiring oral antibiotic therapy. Following NOTES exploration, median length of stay was 2 days (range 0 to 3 days).

CONCLUSIONS: The preliminary findings of this limited pilot study demonstrate tolerable effects of intraperitoneal gastric contamination and adequate visualization of the majority of the abdominal cavity from transgastric NOTES peritoneoscopy. All abdominal quadrants were adequately visualized regardless of the location of the anterior transgastric access site; however visualization of the spleen proved elusive. Based on these encouraging results, future controlled trials will compare efficacy and outcomes of diagnostic laparoscopy with NOTES peritoneoscopy and better determine optimal site location for specific NOTES procedures.

IMPACT OF REPAIR TYPE AND FISTULIZING DISEASE ON LENGTH OF STAY IN INFLAMMATORY BOWEL DISEASE PATIENTS UNDERGOING INCISIONAL HERNIA REPAIR

Benjamin K. Poulouse MD, MPH, Joe Trunzo, MD, Jeff Marks, MD, Jeff Ponsky, MD, Michael J. Rosen MD

INTRODUCTION: Inflammatory bowel disease (IBD) patients with incisional hernia present a challenging management problem to the surgeon. The aim of this study was to characterize the IBD patient population undergoing incisional hernia repair (IHR) and evaluate factors that impact length of stay (LOS) during initial hospitalization.

METHODS: Adult patients with IBD undergoing IHR in non-federal United States hospitals were identified by ICD-9 diagnostic and procedural codes using the 2005 Nationwide Inpatient Sample. Patient demographics and inpatient LOS were calculated.

RESULTS: A population of 814 patients was identified with mean age 54.5 ± 1.2 years (mean \pm SE) and 64% female. No difference in LOS was observed between ulcerative colitis patients or patients with Crohn's disease. Patients undergoing repair with mesh had reduced LOS (5.4 ± 0.5 days) compared to those undergoing primary repair (8.9 ± 1.3 days, $p < 0.05$). Patients with fistulizing disease had a markedly prolonged LOS (12.7 ± 2.1 days) compared to those without fistulizing disease (6.3 ± 0.6 days, $p < 0.05$).

CONCLUSION: Primary repair of incisional hernia in the IBD population is associated with a significantly longer LOS compared to the use of prosthetic material. Fistulizing disease also prolongs LOS during the initial hospitalization for IHR in IBD patients.

A NOVEL APPROACH FOR SALVAGING INFECTED PROSTHETIC MESH AFTER VENTRAL HERNIA REPAIR

Joseph A. Trunzo MD, Jeffrey Ponsky MD, Judy Jin MD, Christina Williams MD, Michael J. Rosen MD

BACKGROUND: Salvaging infected prosthetic material after ventral hernia repair is rarely successful. Most cases require mesh excision and complex abdominal wall reconstruction with variable success rates. We report two cases of mesh salvage with a novel use of percutaneous drainage and antibiotic irrigation.

CASES: Two patients developed infected seromas after laparoscopic ventral hernia repair. One patient had a 32x33cm piece of Gore-tex Dual Mesh Plus placed for repair. He subsequently developed a massive seroma requiring repeated aspirations. Ten months following the repair, he developed an infected seroma with Klebsiella pneumonia. Another patient with a remote history of MRSA mesh infection underwent laparoscopic ventral hernia repair with a 20x23cm piece of Parietex mesh. Two weeks post-operatively he developed fevers and MRSA was aspirated from the seroma. Each patient underwent percutaneous drainage of their abscesses with a 6 French pigtail catheter under ultrasound guidance. After two weeks of parenteral antibiotics and clinical resolution, the patients were placed on four weeks of gentamicin irrigations (80mg in 20cc solution) via the drain three times per day. Once therapy was completed the drains were removed. The second patient also remains on daily oral doxycycline for suppression. Both patients have remained free of clinical signs of infection at 9 and 3 months respectively, following completion of therapy.

CONCLUSION: Percutaneous drainage followed by antibiotic irrigation is a potential alternative to prosthetic removal when treating infected mesh in carefully selected patients.

NATIONAL ANALYSIS OF PARAESOPHAGEAL HERNIA REPAIR IN OCTOGENARIANS

Benjamin Poulouse, Christine Gosen, Leena Khaitan, Michael Rosen, Joseph Trunzo, Jeffrey Ponsky, Jeffrey Marks

INTRODUCTION: Paraesophageal hernia (PEH) repair is often performed in an elderly population. No large study has evaluated perioperative mortality in this high risk group. We examine outcomes of patients undergoing PEH repair and identify predictors of inpatient mortality.

METHODS: Patients 80 years of age or older undergoing PEH repair from an abdominal approach were identified in the 2005 Nationwide Inpatient Sample (NIS). A coding algorithm was developed to include patients with type II, III, and IV hiatal hernias while excluding those with congenital diaphragmatic defects or traumatic injuries. Complex-sample data analysis methods were used to analyze the NIS accounting for its stratified sampling structure.

RESULTS: 1005 patients with mean age of 84.7 years met inclusion criteria for analysis including 738 women (73%) and 266 men (27%). Overall inpatient mortality was 8.2% with mean length of stay 10.1 days (95% confidence interval (CI) 8.9-11.3 days). Emergent or urgent repair was performed in 43% of patients with mortality of 16% compared to 2.5% for elective patients ($p < 0.05$). A 7.1 increase in odds of death was observed for non-elective patients in univariate analysis (95% CI of 2.1-24.9, $p < 0.05$). Chronically symptomatic patients admitted electively were not associated with increased odds for death. When controlling for gender, hospital characteristics and comorbidities, emergent or urgent repair remained the sole predictor of inpatient mortality (odds ratio 6.2, 95% CI 1.8-21.3, $p < 0.05$).

CONCLUSION: This study establishes baseline characteristics and quantifies risk in elderly patients undergoing PEH. Emergent or urgent repair contributed greatly to overall inpatient mortality, increasing the odds of death 6 to 7 fold. However, chronically symptomatic patients who underwent elective repair were not at increased odds for inpatient mortality. These data provide important information for patient selection and for the design of large studies to evaluate long-term survival after intervention.

NATURAL ORIFICE TRANSLUMENAL ENDOSCOPIC SURGERY (NOTES) PERITONEOSCOPY VERSUS LAPAROSCOPY TO EVALUATE INTRA-ABDOMINAL PATHOLOGY IN A PORCINE MODEL

Joseph A. Trunzo, Jeffrey M. Marks, Michael F. McGee, Benjamin K. Poulouse, Judy Jin, Steve J. Schomisch, Raymond Onders, Amitabh Chak, and Jeffrey Ponsky

BACKGROUND: The decision to operate on the intensive care patient with a questionable abdominal source of sepsis continues to prove difficult despite advancements in radiographic imaging. We believe a bedside trans-gastric NOTES exploration could be a valuable diagnostic tool in this setting.

METHODS: An acute, non-survival, study of 8 pigs was performed. Pigs were randomized to demonstrate from 0 to 4 common intra-abdominal lesions: small bowel ischemia (SBI), Small bowel perforation (SBP), Recto-sigmoid colon perforation (CP), and gangrenous cholecystitis (GC). Two blinded surgeons were allowed 60 minutes to perform NOTES or laparoscopy to locate lesions and identify their presence or absence correctly.

RESULTS: Laparoscopy was more sensitive for detecting SBI and SBP. NOTES was consistently more specific with 100% positive predictive value for all lesions. It, however, was found to be weakest in identifying SBP with a poor negative predictive value of 57.1%.

Lesion	Sens. (N/L)	Spec. (N/L)	PPV
SBI	50%/100%	100%/100%	100/100
SBP	25%/75%	100%/75%	100/75
CP	75%/75%	100%/100%	100/100
GC	75%/75%	100%/75%	100/75

N=NOTES L=Laparoscopy

PPV=positive predictive value

CONCLUSION: Our findings suggest identification of common life threatening lesions as seen in an ICU setting can be accomplished by NOTES techniques in a porcine model. Identification of gall bladder disease and colonic perforation was comparable to laparoscopy. NOTES, however, was found to be weakest in identifying small bowel lesions where laparoscopy was routinely successful. Further studies will be warranted, though initial data are promising.

USE OF TISSUE ANCHORS FOR GASTROTOMY CLOSURE AFTER NATURAL ORIFICE TRANSLUMENAL ENDOSCOPIC SURGERY

Leandro Cavazzola, Joseph A. Trunzo, Benjamin Poulouse, Jeffrey L. Ponsky, Jeffrey M. Marks

BACKGROUND: Closure of the gastrotomy after natural orifice transluminal endoscopic surgery (NOTES) remains a critical step for its widespread acceptance and use. One of the major problems after NOTES is the ability to maintain insufflation after gastrotomy. We evaluated the use of endoscopic tissue anchors (t-tags) as a means of gastrotomy closure.

METHODS: A standard upper endoscopy and wire placement as used for percutaneous endoscopic gastrostomy placement was performed in 5 pigs. Prior to gastrotomy, 4 tissue anchors were placed in 4 quadrants (1 cm away from the wire), making sure to pair sutures in opposite quadrants, with the final result being a figure of an "X". A 12-mm gastrotomy was created endoscopically using a combination of needle knife cautery and balloon dilation, and the abdomen was entered. After a brief intrabdominal peritoneoscopy, the sutures were approximated using the tissue knotting element. One additional pair of sutures was placed after evaluation of the gastric closure. The animals underwent in vivo contrast fluoroscopy and methylene blue testing studies for assessment of leakage at the closure site.

RESULTS: All of the animals studied showed complete sealing of the gastrotomy site without evidence of leak on in vivo multiplanar fluoroscopic imaging or post mortem methylene blue instillation.

CONCLUSION: This study supports the use of the tissue anchors for the closure of standardized gastric defects in a porcine model. One of the most important findings of the model was that the first transgastric suture can be placed safely without visualization of the peritoneal cavity, even without gastric insufflation. Sufficient air is retained into the stomach to have good visualization for the next steps of the closure. Future applications of this technology that warrant evaluation include closure of gastric perforations, anastomotic leaks, and stomal reduction after gastric bypass procedures. Animal studies with longer-term evaluation are necessary before human trials are performed.

UTILITY OF A PROTOTYPE DUAL CHANNEL ENDOSCOPE FOR ORGAN EXPOSURE AND SERIAL EVALUATION OF THE SMALL BOWEL DURING NOTES PERITONEOSCOPY IN A PORCINE MODEL (VIDEO)

Joseph A. Trunzo MD, Jeffrey M. Marks MD, Steve J. Schomisch BS, Amitabh Chak, Gary Coffey, and Jeffrey Ponsky MD

INTRODUCTION: The advancement of natural orifice surgery hinges on improvements in current endoscopic tools. Our inability to manipulate tissues free from alterations in optical view and light source has proved to be a recurrent barrier in many previous studies. This video presentation exhibits a prototype dual-channel endoscope and how it can improve our ability to perform more technically challenging maneuvers.

METHODS: The prototype is known as the R-scope (Olympus, Inc.) Its design incorporates two working channels that allow for instruments passed through them to be manipulated independent of the fixed view and light. One channel can be raised distally in a vertical pattern as a standard ERCP elevator. The opposing channel moves in a horizontal direction via an independent control wheel. This demonstration display how this endoscope is controlled while applying it to a technically rigorous procedure: running the small bowel. We also display our ability to reflect various tissues (i.e. rectum, gall bladder, and bladder) endoscopically.

RESULTS: The R-scope maintained a consistent direct view of the targeted tissue by moving the channels only to reflect surrounding structures.

CONCLUSIONS: We found this endoscope significantly improved our endoscopic abilities and believe it could be adapted to numerous other NOTES or endoluminal interventions in the future.

POLYESTER BASED MESH: IS IT SAFE FOR VENTRAL HERNIA REPAIR?

Michael J. Rosen MD FACS

INTRODUCTION: The ideal prosthetic material for ventral hernia repair has yet to be described. Each prosthetic material has unique advantages and disadvantages in terms of tissue ingrowth, adhesion formation and shrinkage profiles. Polyester based mesh has shown minimal shrinkage and excellent tissue ingrowth in animal models. However, the macroporous, braided nature of this material has raised several concerns regarding the incidence of infections, fistulas, and bowel obstructions. We have reviewed our experience with polyester based mesh for the repair of ventral hernias.

METHODS: All patients undergoing ventral hernia repair at the Case Comprehensive Hernia Center from January 2006 to January 2008 were included. Laparoscopic cases underwent intraperitoneal mesh placement of a polyester based mesh with a collagen hydrogel anti-adhesive barrier. The mesh was sized for at least 4 cm of fascial overlap, and transfascial fixation sutures and titanium spiral tacks were routinely used to secure the mesh to the abdominal wall. Those cases deemed inappropriate for laparoscopic ventral hernia repair underwent open repair. Open ventral hernia repairs were performed using a retrorectus repair, placing the mesh in an extraperitoneal position. Unprotected polyester mesh was utilized in these cases. Pertinent data included patient demographics, operative details, postoperative outcomes and long term follow up.

RESULTS: During the study period 95 patients underwent ventral hernia repair with polyester mesh. Seventy two patients had a laparoscopic repair (LR), and 23 patients had an open repair (OR). The mean age was 57 years, BMI 34 kg/m², and ASA 2.6. The patients had undergone 2.1 prior abdominal surgical procedures, and 39 patients had recurrent hernias. Operative details for the LR and OR were as follows: mean defect size 108 v 454 cm², mesh size 355 v 1018 cm², and operative times of 138 v 170 min respectively. Average hospital stay was 3.9 days for the LR and 5.1 days for the OR. With a mean follow up of 13 months (2-27) in the LR, one patient (1.4%) developed a mesh infection (with a history of a prior MRSA mesh infection), one patient (1.4%) developed a small bowel obstruction remote to the mesh on re-exploration, and there were no fistulas. With a mean follow up of 10 months (3-20) in the OR, 3 wound infections (13%) occurred, 2 involved the mesh which was salvaged with local wound care, and there were no bowel obstructions or fistulas during follow up.

CONCLUSIONS: This study demonstrates that in this complex group of patients polyester mesh placed during ventral hernia repair results in acceptable infection rates, and no direct bowel complications or fistulas. Given the macroporous nature of the mesh, each case of infection.

A PROPOSED ALGORITHM FOR THE SELECTIVE MANAGEMENT OF COMPLEX VENTRAL HERNIA

Judy Jin MD, Christina P. Williams MD, Michael J. Rosen MD

INTRODUCTION: The repair of large, complex ventral hernias can lead to significant post operative morbidity and mortality, especially when infections are present. To optimize outcomes, we developed a management algorithm at our institution for these hernias.

METHODS: Patients undergoing complex ventral hernia repairs between August 2005 and August 2007 were reviewed from a prospectively collected database. Our management strategy for complex ventral hernias includes an open retrorectus repair for large, non infected hernias. In the presence of infection/contamination, we perform lateral component separation with biologic underlay reinforcement. All massive hernias with loss of abdominal domain are approached using a staged ePTFE mesh excision technique until fascia can be reapproximated with biologic reinforcement.

RESULTS: 38 patients (OP=17, OB=13, SE=8) were identified during the period and 74% of the patients were female. Patient demographic information was similar in these groups in terms of mean age ($p=0.30$), BMI ($p=0.33$), albumin ($p=0.84$) and the number of prior laparotomies ($p=0.34$). The SE group had significantly larger defect size than the OB group (SE=584 cm², OP=450 cm², OB=253 cm², $p=0.03$) as well as longer length of hospital stay than both OB and OP group (OP=5 d, OB=9 d, SE=40 d, $p<0.001$). There was no perioperative mortality in any group. The most common complication was wound infection (OP=29%, OB=46%, SE=50%, 2 test $p=0.006$) and all patients responded with debridement and local wound care. The subgroup of OP patients who underwent concurrent panniculectomy had the highest rate of wound infection (67%, $p<0.0001$). Two hernia recurrences (OB=1, SE=1) were noted in the follow up period.

CONCLUSION: While perioperative morbidity and mortality of large, complex ventral hernias can be high, with selective management strategy, perioperative mortality was avoided. The wound infection rate, while higher compared to uncomplicated hernia repairs, were amenable to local wound management and did not require mesh resection.

IN VIVO EVALUATION OF THE SUSCEPTIBILITY OF PROSTHETIC MESHES TO STAPHYLOCOCCUS EPIDERMIDIS INFECTION

Judy Jin MD, Michael White, Christina P. Williams MD, Christopher Hofman BS, Gabriela Voskerician PhD, Michael J Rosen MD. ¹University Hospitals Case Medical Center, Cleveland, Ohio. ²Proxy Biomedical Limited, Galway, Ireland. ³Department of Biomedical Engineering, Case Western Reserve University, Cleveland, Ohio

INTRODUCTION: Infected prosthetic mesh placed intra-abdominally often necessitates removal. This can result in significant patient morbidity and mortality. We evaluated three types of prosthetic meshes and their susceptibility to *Staphylococcus epidermidis* in a rat model.

METHODS: A chronic hernia model was used to first induce abdominal wall hernias in rats. The animals then underwent midline incisional hernia repair in an underlay fashion with 0.5 cm overlap of the mesh using polypropylene (n=6) (PP, Marlex, CR Bard Inc), expanded PTFE (n=6) (ePTFE, DualMesh, WL Gore Inc), compressed PTFE (n=6) (cPTFE, MotifMESH, Proxy Medical Ltd). 1 mL of 108 cfu/mL of *Staphylococcus epidermidis* (S. epi) was then released onto the mesh. The animals were allowed to survive for 5 days and each mesh was retrieved for bacterial analysis, histology and the mesh surfaces viewed using a scanning electron microscope (SEM). Each surface of the mesh was graded as having none (0), minimal (1), moderate (2), or extensive (3) S. epi colonization (SEC).

RESULTS: All animals survived to the end of study period and there was no overt sign of infection. Histology review showed cPTFE as having early collagen deposition around the mesh at 5 days that was not seen with ePTFE or PP. Mesh surfaces examined using SEM showed sparse bacterial colonization on cPTFE with a SEC grade of 0.5. This grade was significantly lower when compared with PP (SEC=1) and ePTFE (SEC=2) ($p=0.002$). PP exhibited more bacterial colonization at the knot surfaces while the dual surfaces of ePTFE did not result in difference in bacterial adherence.

CONCLUSION: Based on this preliminary rodent infectious study, cPTFE exhibited lower susceptibility to *Staphylococcus epidermidis* colonization while having earlier collagen deposition around the mesh than ePTFE and PP.

NUMBER OF PRIOR LAPAROTOMIES PREDICTS THE PROBABILITY OF INTRA-OPERATIVE CONVERSION OF LAPAROSCOPIC VENTRAL HERNIA TO OPEN PROCEDURE

Judy Jin MD, Christina P. Williams MD, Michael J. Rosen MD

INTRODUCTION: The practice of laparoscopic ventral hernia repair has been documented to decrease length of hospital stay as well as post operative wound complications. However, in cases where conversion to open procedures are unavoidable, the patients may incur additional morbidities due to the longer than intended procedures. We intended to identify patient factors that will increase the risk of conversion during a laparoscopic ventral hernia repair.

METHODS: Patients who underwent laparoscopic ventral hernia repairs by a single surgeon between August 2005 and August 2007 were reviewed from a prospectively collected database.

RESULTS: 85 patients were identified from the database. The mean age for the group was 59 ± 14 years and included 52% women. The median number of prior laparotomies was 1 (range 0-6) and of the patients who had prior surgeries 23% had prior placement of intraperitoneal mesh. The rate of conversion to open procedure in this case was 11%. The two groups (laparoscopic vs. conversion) had similar patient characteristics in terms of age ($p=0.63$), ASA ($p=0.17$), BMI ($p=0.68$) and pre-operative albumin ($p=0.29$). However, the conversion group also had significantly more number of prior laparotomies (3 vs 1, $p=0.001$), more incarcerated hernias (56% vs 44%, $p=0.047$) and higher percent of patients with prior intraperitoneal mesh (33% vs 18%, $p=0.01$). A logistic regression model was used to predict conversion rate and the number of prior laparotomies appeared to be the only significant patient factor ($p=0.006$). The conversion group has longer length of hospital stay (7 vs 4 day, $p=0.001$) and higher post operative wound complication (11% vs 4%, $p=0.06$) compared to the laparoscopic group.

CONCLUSIONS: While we have verified that open ventral hernia repair results in longer length of hospital stay and higher wound complication rate, we have also identified the number of prior laparotomies to be a significant contributor for conversion for which we believe can aid in future decision making for the mode of ventral hernia repair.

EVALUATION OF THE PERMEABILITY OF PROSTHETIC MESHES AS THE POSSIBLE CAUSE OF POST OPERATIVE SEROMA FORMATION

Judy Jin MD, Steve Schomish BS, Michael J. Rosen MD

INTRODUCTION: Seroma formation is one of the most common post operative complications related to abdominal wall hernia repairs with mesh. We hypothesized that the different biomaterials used to construct commonly used prosthetic mesh may influence permeability to fluid and effect seroma formation rates.

METHODS: We designed an in vitro study where a 5 cm piece of mesh was placed in a closed system where normal saline was forced across the mesh and the pressure required for a constant stream of fluid was recorded. Pre-soaking of the mesh was performed when indicated. Seven prosthetic materials were studied including: intraperitoneally placed mesh polyester/hyaluronic acid (PC, Parietex Composite, Covidien), expanded PTFE (DM, DualMesh, WL Gore Inc), polypropylene/ePTFE (BC, Bard Composix, CR Bard Inc), polypropylene/oxidized cellulose (PR, PROCEED, Ethicon Inc) and compressed PTFE (MM, MotifMESH, Proxy Biomedical Inc) and polypropylene (PP, Marlex, CR Bard Inc), polyester (P, Parietex, Covidien).

RESULTS: Each mesh was tested five times and results averaged. The 3 meshes without antiadhesive barriers (MM, PP, P) had fluid move across with minimally pressure (<1 mmHg). For the intraperitoneal mesh, there was a significant difference in pressure necessary for fluid movement (PR=3.6 ± 1.1 mmHg, PC=56.6 ± 14.3 mmHg, DM>350 mmHg, BC>350mmHg, p<0.001). However, the fenestrations at the suture lines necessary to combine the PP and ePTFE in the BC mesh permitted fluid transport at low pressures (<1mmHg).

CONCLUSION: Based on our in vitro study, each mesh exhibited different fluid permeability, especially in the case of meshes with anti-adhesive barriers. The ePTFE surface prevented fluid movement across the mesh even at high pressure, and may possibly contribute to seroma formation when used clinically. This study also infers that methods to create pressure gradients across mesh, such as an abdominal binder, may reduce seroma formation of certain meshes.

THE USE OF ABDOMINAL WALL ALLOTRANSPLANTATION AS AN ALTERNATIVE FOR THE MANAGEMENT OF END STAGE ABDOMINAL WALL FAILURE

Judy Jin¹ MD, Christina P. Williams¹ MD, Molly K. Smith² MD, Hooman Soltanian MD³, Juan Sanabria⁴ MD, Jonathan Pearl MD¹, Michael F. McGee¹ MD, Michael Rosen¹ MD.¹

INTRODUCTION: The management of massive abdominal wall defects with loss of abdominal domain is a formidable challenge to the general surgeon. Current options including the staged repair, native tissue flap transfer or prosthetic mesh repair have limited success due to the size of the defects and lack of adequate local tissue. Additionally, post operative morbidity related to skin breakdown, mesh infection and hernia recurrence have limited the widespread acceptance of these techniques. We proposed the use of full thickness abdominal wall allotransplantation as an alternative solution for these patients and report our initial experience with this novel approach in a porcine model.

METHODS: Ten genetically mismatched pigs (~20 kg) underwent transplantation. A full thickness portion of the donor abdominal wall was harvested. The graft was based on the inferior epigastric vascular pedicle which was left in continuity with the donor aorta and vena cava. Simultaneously, the recipient received a matching, full thickness abdominal wall defect and underwent repair with the donor allograft. The allograft pedicle was anastomosed to the recipient external iliac vessels and the tissue was reapproximated to the native abdominal wall. Recipients received daily immunosuppressive therapy. Rejection was assessed by visual inspection and histologic review of skin biopsies. Euthanasia, angiography and histological evaluation of the allograft were performed following the 28 day survival period.

RESULTS: All recipient animals survived the procedure and had no evidence of herniation or bulging at the completion of the study. There was good tissue ingrowth into the donor graft. Angiograms revealed intact anastomosis in all animals. While mild degree of histologic rejections was present, visual inspection showed minimal rejection of the skin flap.

CONCLUSIONS: Based on our initial experience, composite abdominal wall allotransplantation may provide a potential solution to massive ventral hernia repairs. Further work is necessary to determine the functional outcome of these grafts.

LAPAROSCOPIC VERSUS OPEN COMPONENT SEPARATION FOR COMPLEX ABDOMINAL WALL RECONSTRUCTIONS

Christina P. Williams M.D., Judy Jin M.D., Michael J. Rosen M.D.

INTRODUCTION: Traditional open component separation involves elevation of large lipocutaneous flaps predisposing to significant postoperative wound morbidity. We have developed a minimally invasive component separation technique to theoretically reduce these wound complications while providing adequate myofascial advancement. In this study we compare perioperative outcomes and hernia recurrence rates between open and laparoscopic component separation techniques during complex ventral hernia repairs.

METHODS: We retrospectively identified all patients undergoing component separation procedures between August 2005 and August 2007. Information collected included patient demographics, technique of component separation, and postoperative outcomes. Hernia recurrence was determined by physical exam or abdominal imaging.

RESULTS: Eleven patients underwent open component separation (5 males), and 11 patients underwent laparoscopic component separation (4 males) during the study period. There was no significant difference between the groups in terms of age (open 66 ± 13 yrs and lap 56 ± 14 , $p=0.09$), albumin prior to surgery (open 3.1 ± 0.8 and lap 3.38 ± 0.8 , $p=0.45$), size of the defect (open $325\text{cm}^2\pm 194$ and lap $424\text{cm}^2\pm 328$, $p=0.39$), number of prior hernia repairs (open 1.0 ± 0.9 and lap 1.55 ± 1.3 , $p=0.2$), or presence of infection/bowel resection during surgery (open 6/11 and lap 8/11, $p=0.66$). All patients underwent biologic mesh reinforcement and achieved primary fascial apposition after the component separation. The laparoscopic component separation resulted in significantly fewer postoperative wound complications when compared with the open approach (18% versus 82%; $p=0.03$). The average length of stay was shorter in the laparoscopic group (6 days versus 14 days). One patient developed a hernia recurrence in each group during follow-up.

CONCLUSIONS: Laparoscopic component separation results in significantly less postoperative morbidity and earlier hospital discharge. Given these advantages along with the comparable myofascial advancement and equivalent hernia recurrence rates, laparoscopic component separation may be the procedure of choice for myofascial advancement in complex ventral hernia repair.

UTILIZATION OF PRE-OPERATIVE PATIENT FACTORS TO PREDICT POST-OPERATIVE VITAMIN D DEFICIENCY FOR PATIENTS UNDERGOING GASTRIC BYPASS

Judy Jin MD, Thomas A. Stellato MD, Peter T. Hallowell MD, John J. Jasper MD,

Scott M. Wilhelm MD

INTRODUCTION: Vitamin D deficiency occurring after gastric bypass procedures can predispose patients to calcium and parathyroid hormone (PTH) level abnormalities. The aim of the study is to identify pre-operative patient risk factors for post operative vitamin D deficiency.

METHODS: We retrospectively reviewed patients who underwent Roux-en-Y gastric bypass (short limb= 75 cm, long limb= 165 cm) procedures at our institution from January 2005-October 2006. Patient demographics, laboratory values of calcium, vitamin D and PTH were followed at quarterly intervals for one year. Statistical analysis included paired t-test for continuous variables and Fisher's exact test (FET) for categorical variables. A backward stepwise logistic regression model was used to predict probability of post operative vitamin D deficiency.

RESULTS: 145 patients were included in the study after 50 patients were eliminated for incomplete follow up. The mean age for the group was 44 ± 10 years with an average body mass index (BMI) of 49.5 kg/m². 86% of patients were female and 23% of the population was African American. Forty two percent of the patients had vitamin D deficiency (<20 ng/mL) either pre-operatively or at year one, with minimal change in mean values over the one year (25.7 \rightarrow 25.0 ng/mL, $p=0.54$). However, the mean calcium levels decreased significantly from 9.39 to 9.16 mg/dL ($p<0.001$) while the mean PTH levels increased significantly from 25.7 to 43.9 ng/mL ($p<0.001$) over the same period. On univariate analysis, post operative vitamin D deficiency was associated with higher pre-operative BMI (51.1 vs 48.4 kg/m², $p=0.037$), African American race (FET, $p=0.0002$), long limb bypass (FET, $p= 0.017$), lower pre-operative calcium levels (9.27 vs 9.47 mg/dL, $p=0.018$) and lower pre-operative vitamin D levels (19.9 vs 30.0 ng/mL, $p<0.0001$). Age, sex, reduction in BMI and pre-operative PTH levels did not appear to affect post operative vitamin D values. A logistic regression model used to predict post operative vitamin D levels recognized pre-operative vitamin D levels, race and bypass limb length to be the only significant factors ($p<0.05$).

CONCLUSION: Our study identified several characteristics that predispose patients for vitamin D deficiency after the bypass procedures. However, only pre-operative vitamin D values, race and limb length were significant for predicting post operative vitamin D values. It is important to recognize these patients who are at risk before surgery so that early intervention could be in place to minimize further post operative deficiency.

ISOLATED COMPOSITE FULL THICKNESS ABDOMINAL WALL ALLOTRANSPLANTATION FOR TREATING ABDOMINAL WALL FAILURE IN A PORCINE MODEL

Judy Jin¹ MD, Christina P. Williams¹ MD, Molly K. Smith² MD, Hooman Soltanian MD³, Juan Sanabria⁴ MD, Jonathan Pearl MD¹, Michael F. McGee¹ MD, Michael Rosen¹ MD

BACKGROUND: There are few successful surgical solutions for treating end stage abdominal wall failure secondary to traumatic tissue loss or massive ventral herniation. We describe a novel approach for repairing these defects using isolated abdominal wall allotransplantation in a porcine model.

METHODS: Twenty two genetically mismatched (20 kg) pigs were included in the study. Eleven donor animals had a portion of their full thickness abdominal walls harvested. The graft was based on the inferior epigastric vascular pedicle which was left in continuity with the aorta and vena cava. In the 11 recipient animals a similar full thickness defect was created in the abdominal wall and the vascular anastomosis was completed to the recipient common iliac vessels and the tissue was reapproximated to the native abdominal wall. All pigs received daily cyclosporine/mycophenolate mofetil/prednisone regimen for immunosuppression. Rejection was assessed by visual inspection of the flap skin and correlated with daily cyclosporine levels, as well as histopathologic review of skin biopsies (grade I = mild rejection, grade IV = severe rejection). After 28 days the animals were euthanized. An angiogram was performed and the grafts were harvested and underwent standard biomechanical testing and histologic evaluation.

RESULTS: A mean surface area of 47 ± 19 cm² of donor full thickness abdominal wall was harvested. Two grafts failed within the first week secondary to arterial (1) and venous (1) thrombosis. One animal developed a small bowel obstruction on POD#6 secondary to an incarcerated inguinal hernia at the vascular access site remote to the transplanted tissue which remained viable. The remaining 8 animals survived the study period and had normal complete blood counts, serum creatinine and liver function tests. The mean daily cyclosporine level was 595 ± 280 ng/ml. Some degree of histopathologic rejection was present in all animals at 28 days (Grade I N=3, Grade II N=4, Grade III N=1). Visual inspection of the graft did not correlate with histopathologic rejection. At necropsy, the thickness of the transplanted muscle flap was reduced compared to the native rectus (4.3 mm vs 7.7 mm, $p < 0.0001$). The diameter of the muscle fibril under histological examination decreased from 0.15 mm to 0.09 mm ($p < 0.0001$) at 40x magnification. While the elasticity between the transplanted and native muscles were comparable (0.5 ± 0.27 N/mm vs 0.40 ± 0.10 N/mm, $p = 0.12$), the transplanted muscles had significantly lower tensile strength than the native muscles (5.48 ± 2.38 N vs 11.3 ± 1.34 N, $p < 0.0001$).

CONCLUSION: This study demonstrates the feasibility of isolated abdominal wall allotransplantation to provide a potential solution to end stage abdominal wall failure. There were no hernias associated with the surviving allografts during short term follow up. Further work is ongoing to determine the functional outcomes of composite allografts to provide a suitable dynamic abdominal wall replacement.

PARASTOMAL HERNIA: NATIONAL ANALYSIS OF A SURICAL DILEMMA

Judy Jin MD, Benjamin K. Poulouse MD, MPH, Conor Delaney MD, PhD, Brad Champagne MD, Jeff Marks, MD, Jeff Ponsky, MD, Michael J, Rosen MD

INTRODUCTION: Parastomal hernia management presents a challenge to the surgeon. No large study has characterized the patient population undergoing repair or has described the factors associated with adverse outcomes. We examined these outcomes on a national level.

METHODS: Using the 2005 Nationwide Inpatient Sample, adult patients undergoing parastomal hernia repair in non-federal hospitals in the United States were identified by ICD-9 procedural codes. Characteristics including demographics and comorbid conditions were determined. In-hospital length of stay (LOS) and mortality were calculated and risk factors for mortality were identified.

RESULTS: A national population of 4,880 patients was identified, aged 65 ± 0.5 years (mean \pm SE) and 63% female. 7% of the population was obese. Non-elective repair was performed in 35%. Stoma revision was performed in 16%, while 32% underwent stoma closure. In-hospital mortality was 0.3%, and LOS 9.4 ± 0.3 days. LOS for non-elective repair was 13.7 ± 0.7 years compared to 7.1 ± 0.3 days for elective repair ($p < 0.05$). Non-elective repair was associated with increased mortality (odds ratio (OR) 5.1, 95% confidence interval (CI) 2.3-11.4, $p < 0.05$) compared to elective repair. Increased mortality was also observed with a history of congestive heart failure (OR 6.9, CI 3.3-14.4, $p < 0.05$), and renal failure (OR 3.7, CI 1.1-12.8, $p < 0.05$).

CONCLUSION: Parastomal hernia repair is performed in older patients and many require non-elective repair. Non-elective repair is associated with increased mortality and hospital stay. Early intervention for these complex hernias may be warranted. Further investigation into the relationship between comorbid conditions and mortality in this complex surgical population is needed.

DIAPHRAGM PACING STIMULATION (DPS) SYSTEM PATIENTS VARIABLES AFFECTING INITIAL DIAPHRAGM CONDITION AND SUBSEQUENT FUNCTION WITH ELECTRICAL STIMULATION

Onders RP, Elmo MJ, Ignagni AR

INTRODUCTION: Minimally invasive motor point stimulation of the diaphragm has demonstrated 100% success rate in providing adequate tidal volumes for ventilation of tetraplegics with intact phrenic nerves. This study analyzes patient variables affecting the initial function of the deconditioned diaphragm and the length of time needed to reach 4 continuous hours of DPS ventilation.

DESIGN: Prospective FDA trial of the DPS System for electrical activation of the diaphragm for ventilatory assist in tetraplegics.

PARTICIPANTS/METHODS: Patients underwent laparoscopic mapping of the diaphragm to locate phrenic nerve motor points for electrode implantation. Two weeks after surgery stimulation of each electrode was set to provide tidal volume for ventilation and patients underwent conditioning of the diaphragm. Pre-operative variables were assessed in relation to when patients met the criteria of 5-7cc/Kg tidal volume for 4 or more continuous hours of ventilation with the DPS system.

RESULTS: A total of 28 patients were implanted, there was a failure to pace in the second patient due to a false positive phrenic nerve study. The amount of time and daily episodes of conditioning the diaphragm affect speed to DPS ventilation. Age and time from injury directly affects conditioning time to achieve 4 continuous hours with DPS from less than 1 week for 18 to 20 year olds on a ventilator for less than one year to 14 weeks for 40 to 50 year olds on ventilators for greater than 5 years. Both patients over 65 years took 21 weeks. Two patients requiring surgical correction of scoliosis prior to implantation have required prolonged conditioning to achieve adequate tidal volumes.

CONCLUSION: DPS has been demonstrated to work in all innervated diaphragms. Earlier implantation facilitates weaning from the ventilator and should decrease the complications from positive pressure ventilation. Geriatric tetraplegics and patients with significant scoliosis require increased diaphragm conditioning.

PATIENT AND CAREGIVER PERCEPTIONS OF THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM

Elmo MJ, Onders RP, Nagy L, Bell S.

INTRODUCTION: Spinal cord injury is an overwhelming, devastating experience and the addition of a ventilator adds to the complexity of daily care. Motor point stimulation of the diaphragm is a low-risk, cost-effective outpatient system for ventilatory support. This study analyzes how patients and caregivers perceive the effects of DPS on activities.

DESIGN: Prospective FDA trial of the DPS System for electrical activation of the diaphragm for ventilatory assist in tetraplegics.

PARTICIPANTS/METHODS: After successful implantation and conditioning of the diaphragm to provide at least 4 continuous hours of DPS ventilation, a survey was sent to patients and caregivers to assess DPS effect on their activities. This survey was repeated one year later and the answers analyzed.

RESULTS: The response rate was 92% (22/24). All patients are presently living at home with the primary caregiver being the mother in 14 patients. 64% of patients report fewer secretions with 68% of caregivers reporting less suctioning. 82% of patients report "more normal breathing". 77% of caregivers state caring for the paced patient is less work than the mechanical ventilator. 91% of caregivers say the pacer is easy to use. Other comments included: DPS as life saving during hurricanes and power outages (3); the silence of pacing enabled sleeping well for the first time since their injury (2); attending classes or church easier; traveling for the first time ever since injury (1); transfer from ventilator ward to assisted living or home(2) and air travel now possible(4). 100% of patients describe an increase in mobility. 95% of patients report more freedom and feeling of independence. 100% of patients would recommend it to other tetraplegics.

CONCLUSIONS: DPS stimulation provides natural negative pressure ventilation utilizing the patient's own diaphragm but the most important benefit is allowing patients greater integration into society without the stigma of the ventilator.

IMPROVEMENTS OF RESPIRATORY MUSCLE DETERIORATION USING THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Onders R, Schilz R, Katirji B, Elmo M, Sivashankaran S, Ignagni A.

PURPOSE: Respiratory insufficiency is the major cause of mortality in patients with ALS. Ventilators, although life-saving, are inconvenient and associated with significant risks and alternate therapies to prevent or manage respiratory muscle decline in ALS is needed. The motor point diaphragm pacing stimulation (DPS) system has become a standardized minimally invasive laparoscopic technique that can provide ventilation in spinal cord injured patients. We postulate that therapeutic DPS will delay respiratory failure in ALS patient.

METHODS: As part of an FDA trial, patients underwent outpatient laparoscopic diaphragm motor point mapping with electrode implantations. Stimulus/output characteristics of each electrode were determined and diaphragm conditioning initiated. ALS patients conditioned their diaphragms with 5 daily stimulation sessions of 30 minutes each. Each patient had three extensive lead-in assessments that were continued post implantation of the DPS system.

RESULTS: Sixteen patients have been safely implanted with no adverse events. Feeding tubes were safely simultaneously placed in 7 patients. In all patients, more fluoroscopically observed diaphragm excursion occurred with diaphragm stimulation than under maximal voluntary effort. DPS significantly increases muscle thickness when assessed with ultrasound (p -value 0.02). After conditioning the diaphragm with the DPS, preliminary results show an average rate of decline in FVC of 1.3% per month from the pre-implantation decline of 3.1% a month, which extrapolates to an additional 15 months of ventilator free survival. Additional findings include: DPS can convert fast twitch glycolytic (IIb) to functional slow twitch oxidative muscle (I) fibers; DPS improves posterior lobe lung ventilation; DPS increases lung compliance leading to decreased work of breathing; and patients have started utilizing DPS to improve nighttime ventilation.

CONCLUSION: The DPS system can be safely implanted and utilized in ALS patients, with a documented decrease in the decline of respiratory failure leading to increased survival. A multi-center pivotal trial is now enrolling patients and collecting data.

CLINICAL IMPLICATIONS: The ability to specifically target and improve diaphragm function with the DPS system will increase therapeutic options in these patients.

LIBERATING TETRAPLEGICS FROM MECHANICAL VENTILATION USING MOTOR POINT DIAPHRAGM PACING

Onders R, Elmo M, Schilz R, Katirji B, Sivashankaran S, Ignagni A.

PURPOSE: Patients with high spinal cord injury (SCI) face death or life with mechanical ventilation. Ventilators, although life-saving, are inconvenient and associated with significant risks. This report outlines a single institution experience with the diaphragm pacing stimulation (DPS) system since the first implantation 7 years ago.

METHODS: In a prospective FDA trial, patients underwent outpatient laparoscopic diaphragm motor point mapping with electrode implantations. Stimulus/output characteristics of each electrode were determined and diaphragm conditioning initiated. Patients were weaned from their ventilators at home.

RESULTS: A total of 34 patients were implanted, there was a failure to pace in the second patient due to a false positive phrenic nerve study. The amount of time and daily episodes of conditioning the diaphragm affects speed to DPS ventilation. Age and time from injury directly affects conditioning time to achieve 4 continuous hours with DPS from less than 1 weç for 18 to 20 year olds on a ventilator for less than one year to 14 weçs for 40 to 50 year olds on ventilators for great than 5 years. Both patients over 65 years took 21 weçs. Two patients requiring surgical correction of scoliosis prior to implantation have required prolonged conditioning to achieve adequate tidal volumes. Additional findings of DPS use include: reduction of airway pressure decreasing risks of barotrauma with a return of negative chest pressure; conversion of fast twitch glycolytic (IIB) to functional slow twitch oxidative muscle (I) fibers; increased diaphragm muscle thickness; improved posterior lobe lung ventilation with over 60% reduction in secretions and need for suctioning and increased measured respiratory compliance.

CONCLUSIONS: The DPS system is safe with a 97% success rate and should replace the ventilator for SCI patients providing them more natural negative pressure ventilation. Ongoing results are being evaluated in a multi-center trial.

CLINICAL IMPLICATIONS: With the safety shown in this trial earlier implantation in tetraplegics would shorten initial implantation and possibly decrease the high rate of ventilator associated pneumonia in this population.

CONTINUOUS AMBULATORY DIAPHRAGM EMG MEASUREMENTS: ASSESSING RESPIRATORY CONTROL AND FUNCTION UTILIZING THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM

Onders R, Katirji B, Schilz R, Elmo M, Sivashankaran S, Ignagni A.

BACKGROUND: Diaphragm contraction is necessary for ventilation although respiratory control is incompletely understood. Important structures likely include: the special somatic respiratory nuclei of the brainstem, the cerebral cortex and the carotid body among others. Output from these centers is transmitted through the phrenic nerve to the diaphragm but muscle electrical activity cannot be easily measured further limiting investigations of neuromuscular control of breathing. Ongoing work from our group has led to the development of intramuscular electrode pacing of the diaphragm in patients with respiratory failure. An interesting by-product of this research is to have a continuously available electrode in the diaphragm that could theoretically be used to monitor EMG activity.

OBJECTIVE: This report analyzes initial feasibility and applications of continuous EMG assessment of the diaphragm in ALS/MND patients implanted with the diaphragm pacing stimulation (DPS) system (Synapse Biomedical, Ohio).

METHODS: Amyotrophic lateral sclerosis (ALS) patients who were implanted with electrodes at the motor point with DPS system were analyzed utilizing a home polysomnography system (CleveMed, Ohio). Continuous EMG was recorded from the implanted diaphragm electrodes.

RESULTS: Four implanted patients were studied. The ALS patients studied showed that diaphragms with less volitional or stimulated movement under fluoroscopy also had a reduction in the generated motor response demonstrated by the EMG tracings. Diaphragm EMG activity correlated with the appropriate thoracic and abdominal movements during sleep. Stronger EMG activity correlated with larger chest and abdomen movements along with visualized diaphragm movement under fluoroscopy. Sleep EMG obtained in one ALS patient receiving non-invasive positive pressure ventilation (NIPPV), showed significant periods of absent diaphragm EMG activity which led to lower subsequent SpO₂ which in turn led to increased EMG activity. The home based study in this patient showed unsuspected oxygen desaturations 33% of the time which necessitated changes in NIPPV. Another patient showed that decreasing rhythmic EMG activity and decreasing O₂ saturations caused a subsequent increased EMG activity that corrected the desaturation. Correction of O₂ desaturations in the second patient with NIPPV resulted in a stable but decreased diaphragm EMG activity.

CONCLUSIONS: We show the initial feasibility of continuous EMG assessment of the diaphragm in ALS/MND patients implanted with the DPS system and its use in analysis of sleep dysfunction. EMG activity correlated with progression of disease. Because the electrodes are implanted at a standardized point (diaphragm motor point-the point where stimulation causes maximal contraction), serial diaphragm EMGs may be a viable biomarker for disease progression. The ability to follow serially with EMG at a well described reproducible motor point the most important muscle of respiration may also allow rapid assessment of new therapies. Also as other directed therapies are developed, the ability to utilize the bilateral DPS system to monitor unilateral or bilateral therapy and then help with ventilation when needed may hold promise.

DIAPHRAGM PACING AS A SHORT-TERM ASSIST TO POSITIVE PRESSURE MECHANICAL VENTILATION IN CRITICAL CARE PATIENTS

Onders R, Schilz R, Sivashankara s, Karirji B, Elmo M, Ignagni A.

BACKGROUND: Diaphragm Pacing Stimulation (DPS), using intramuscular electrodes implanted at the diaphragm motor points, is effective in replacing mechanical ventilation (MV) for tetraplegics. DPS has also demonstrated safety and preliminary efficacy in a pilot study to maintain diaphragm strength in patients with ALS.

METHODS: The effect of DPS on respiratory system compliance (CRS), peak airway pressure (PAW), and ability to trigger positive pressure MV in pressure support mode was conducted during intra-operative testing in SCI and ALS patients. DPS was synchronized with MV and the change in CRS was viewed qualitatively on the volume-pressure tracing and recorded numerically. PAW was recorded with and without DPS to determine the ability of DPS to reduce pressures while maintaining or increasing tidal volumes.

RESULTS: Ten patients (six SCI and four ALS) were studied. Without stimulation $CRS = 58 \pm 5.7$ ml / cm H₂O and increased with stimulation to $CRS = 69 \pm 5.7$ ml / cm H₂O, a 19% increase. Depending on the timing of synchronization between the DPS and mechanical ventilation the resulting volume-pressure tracing was viewed as progressing to negative pressure ventilation initially or reducing the pressure when the DPS commenced. Peak pressures were substantially decreased with the addition of DPS. Without DPS $PAW = 20 \pm 4.2$ cm H₂O and $VT = 747 \pm 125$ ml. With DPS $PAW = 15 \pm 4.3$ cm H₂O and $VT = 916 \pm 194$ ml, a 21% decrease in PAW with a 24% increase in VT. DPS was able to trigger the ventilator in all 10 patients. No adverse hemodynamic effects were observed.

CONCLUSIONS: These findings suggest a potential role for DPS in critically ill ventilator dependent ICU patients with atelectasis, pneumonia, barotrauma or diaphragm dysfunction which could theoretically benefit from the effects shown in this study. The addition of negative pressure ventilation with DPS increases the respiratory system compliance, decreases peak airway pressures and increases tidal volumes. Further studies to examine these potential benefits are planned.

MOTOR POINT DIAPHRAGM PACING IN PATIENTS WITH MND/ALS: LONG-TERM FOLLOW-UP OF COMPLETED SAFETY AND FEASIBILITY STUDY

Onders R, Katirji B, Schilz R, Elmo M, Sivashankaran S, Ignagni A.

BACKGROUND: Respiratory insufficiency is the major cause of mortality in patients with ALS. Ventilators, although life-saving, are inconvenient and associated with significant risks and alternate therapies to prevent or manage respiratory muscle decline in ALS is needed. The motor point diaphragm pacing stimulation (DPS) system has become a standardized minimally invasive laparoscopic technique providing ventilation in spinal cord injured patients. This report outlines the results of the application of DPS in ALS since the first implantation in 2005.

OBJECTIVE: Analyze safety, utility and long term use of the DPS system from the initial FDA single site study.

METHODS: Patients underwent outpatient laparoscopic diaphragm motor point mapping with electrode implantations. Stimulus/output characteristics of each electrode were determined and diaphragm conditioning initiated. Patients conditioned their diaphragms with 5 daily stimulation sessions of 30 minutes each but were allowed to increase usage. Each patient had three extensive lead-in assessments that were continued post implantation of the DPS system and included pulmonary function tests, fluoroscopic evaluation of diaphragm movement, speech phonation times, ultrasound analysis of diaphragm thickness, and quality of life tests.

RESULTS: Sixteen patients were implanted with no adverse events with 7 undergoing simultaneous feeding tubes placement. Average age was 50(range 32-70) with 13 males. Average of 35 months of symptoms until enrolment with an ALSFRr of 26 at surgery. The average predicated forced vital capacity (FVC) at surgery was 52% with 12 patients eventually having bulbar symptoms. In all patients, more fluoroscopically observed diaphragm excursion occurred with diaphragm stimulation than under maximal voluntary effort. DPS significantly increases muscle thickness when assessed with ultrasound (p-value 0.02). In a subgroup analysis, those patients with declining FVC and bulbar symptoms pre-operatively reached statistical significance going from pre-implant slope of -2.9 to -1.4(%FVC /month with p<0.05) The first four implanted patients expired 16.5 months post implantation. Given that their average FVC was only 49% predicted at surgery this is an improved survival compared to historical data. The cause of death was secondary to a fall, aspiration, peri-operatively from a cervical spinal fixation with only one being respiratory after a brief trial of mechanical ventilation. Additional study findings include: DPS can convert fast twitch glycolytic (IIB) to functional slow twitch oxidative muscle (I) fibers; DPS improves posterior lobe lung ventilation; DPS increases lung compliance leading to decreased work of breathing; and 7 patients utilize DPS to improve night-time ventilation.

CONCLUSION: The diaphragm pacing system can be safely implanted and utilized in patients with ALS with over 15 years of cumulative use. There has been a documented decrease in the decline of respiratory failure which leads to an increased survival. The ability to specifically target and improve diaphragm function with the DPS system will increase therapeutic options in these patients with specific focus on night-time sleep dysfunction. A multi-center pivotal trial is now enrolling patients and collecting data.

GENERAL ANESTHESIA IN PATIENTS WITH ALS/MND CAN BE SAFE: LESSONS LEARNED FROM THE TECHNIQUES USED IN THE DIAPHRAGM PACING STIMULATION TRIAL

Onders R, Schilz R, Katirji B, Elmo M, Sivashankaran S, Ignagni A.

BACKGROUND: There is a paucity of literature and no standard for the conduct of general anesthesia in patients with MND/ALS. Management has historically paralleled recommendations of non-ALS patients undergoing similar procedures but this has led to hemodynamic and neuromuscular complications in some patients. The current trial of the laparoscopic diaphragm pacing stimulation system (DPS) necessitated general anesthesia without compromise of diaphragmatic or neuromuscular function either intraoperatively or postoperatively. This report describes the anesthesia management in 18 ALS patients undergoing DPS implantation as an outpatient laparoscopic surgery.

OBJECTIVES: Identify the optimum techniques of applying general anesthesia to patients with ALS/MND.

METHODS: Our overall strategy was to use rapid reversible short acting analgesic and amnestic agents without neuromuscular relaxants to minimize side effects in patient with neuromuscular diseases. The following regimen was used in all patients: midazolam[anxiolytic and decreases intraoperative muscle spasms];remifentanil[intravenous ultrashort acting narcotic with rapid on and off capabilities, used for induction and maintenance of anesthesia. This agent being a potent narcotic, depresses the respiratory drive which facilitates our mapping technique of diaphragm pacing because the patient during the operation will not be trying to breathe which may interfere with surgery. Because of its ultra short action, the patient resumes their normal respiration minutes after discontinuation of the drug.]; sevoflurane[inhalational amnestic agent with low lipid solubility allowing rapid on and off.] and propofol[a short acting intravenous amnestic agent with rapid on/off capabilities]. At the end of each procedure the DPS system is also utilized to increase the respiratory system compliance by decreasing posterior lobe atelectasis. If a patient was on non-invasive positive pressure ventilation pre-operatively they are placed on it in the recovery room. We can now also measure continuous diaphragm electromyography(EMG) via the implanted electrodes to assess diaphragm function immediately post-operatively.

RESULTS: To date we have used this in 17 patients and have found no adverse problems with general anesthesia. The average predicated forced vital capacity(FVC) at surgery was 52% with 5 patients below 50%. All patients were extubated uneventfully at the completion of surgery. No reintubations were needed. All patients were discharged from the hospital with no respiratory problems.

CONCLUSIONS: Patients with ALS may require surgical procedures during the course of their disease(for example appendicitis, cholecystitis) and an understanding that general anesthesia can be safely given to patients will increase the quality of their life. General anesthesia consisting of remifentanil, sevoflurane and propofol was effective in facilitating neuromuscular evaluation and laparoscopic surgery in ALS patients without adverse perioperative effects. This strategy may be useful more widely in surgery on patients with ALS. Consideration should be given for implantation of the DPS system at the time of surgery for peri-operative management and increasing peri-operative respiratory compliance.

LAPAROSCOPIC DIAPHRAGM MOTOR POINT PACING: COMPLETE WORLDWIDE EXPERIENCE OF ALL IMPLANTED PATIENTS

Onders R, Khansarinia S, Dunkin B, Bass B, Yee J, Oddsdottir M.

BACKGROUND: Diaphragm movement is essential for adequate ventilation and when the diaphragm is adversely affected patients face life long positive pressure mechanical ventilation or death. This report summarizes the complete world wide multi-center experience with the diaphragm pacing stimulation (DPS) system to maintain and provide diaphragm function for ventilation.

METHODS: In prospective FDA trials, patients underwent laparoscopic diaphragm motor point mapping to identify the area where maximum diaphragm contraction occurs when the implanted electrode is stimulated. The adverse events and operative experience were recorded and analyzed.

RESULTS: From March of 2000 to September of 2007, a total of 88 patients(44 in 2007 alone) were implanted with the DPS system at 5 sites for the following indications spinal cord injury (SCI) (48), Amyotrophic Lateral Sclerosis (ALS) (38), and transverse myelitis (2). Patient age ranged from 18-74 and time from SCI to implantation ranging from 3 months to 27 years. In 87 patients the diaphragm motor point was mapped with successful implantation of electrodes with the only failure the second patient due to a false positive phrenic nerve study. There was no peri-operative mortality even in ALS patients with forced vital capacity (FVC) below 50% predicted. The most common tracked adverse event (42% of SCI patients) was a capno-thorax were the CO2 tracked to the pleural space from electrode implantation in the thinned deconditioned diaphragm. Average time in the operating room was less than 120 minutes with no differences between sites. There was no cardiac involvement from diaphragm pacing even when analyzed in 10 of the patients who had pre-existing cardiac pacemakers. No infections occurred even with simultaneous gastrostomy tube placements for ALS patients with bulbar symptoms and dysphasia. Average hospital stay was less than 24 hours. In the SCI patients 96% were able to use the DPS system to provide ventilation and in the ALS studies patients have been able to delay the need for mechanical ventilation up to 20 months.

CONCLUSION: This multi-center experience has shown that laparoscopic diaphragm motor point mapping, electrode implantation and pacing can be safely performed. The ability to move the diaphragm for ventilation or maintain diaphragm function has significant patient benefit and is the basis for continued multi-center trials for additional indications.

DIAPHRAGM PACING IN TETRAPLEGIS: LIVING BETTER WITHOUT THE VENTILATOR

Mary Jo Elmo, MSN, RN

PROBLEM: Cervical spinal cord injury often results in the need for mechanical ventilation. This therapy may be life saving, however it is associated with multiple complications such as impaired speech and barotraumas. In addition, ventilators are loud, cumbersome and decrease life expectancy. The diaphragm pacing system (DPS) is an excellent alternative to the ventilator. DPS requires a low risk implantation and is associated with numerous benefits including physiologic breathing pattern which is silent.

METHODOLOGY: Diaphragm pacing patients and their primary caregivers were interviewed.

MAJOR FINDINGS: Twenty three patients and caregivers were surveyed. All surveyed reported an increase in independence and mobility. Seventy-five percent reported a decrease in suctioning. Several patients shared positive experiences of traveling with the pacer and four patients shared stories of DPS being "life-saving" during major long term power outages. All patients/caregivers discussed "the quiet" of the device which was especially beneficial when attending church, school or the theatre. All patients preferred the DPS to the ventilator.

IMPLICATIONS FOR NURSING: There are now three implantation sites. As this procedure increases in popularity, nursing will be greatly impacted. Nurses will need the knowledge and skill to care for patients using the DPS as well as for patient education.

PROVIDING AND MAINTAINING VENTILATION WITH THE MOTOR POINT DIAPHRAGM PACING STIMULATION (DPS) SYSTEM: CAN MECHANICAL VENTILATORS BE REPLACED WITH NATURAL DIAPHRAGM VENTILATION?

Raymond Onders MD, Mary Jo Elmo RN, Bashar Katirji MD, Robert Schilz DO, PhD, Anthony Ignagni

BACKGROUND: Patients with tetraplegia or amyotrophic lateral sclerosis (ALS) face death or life with mechanical ventilation. Ventilators, although life-saving, are inconvenient and associated with significant risks. This report outlines the experience with the diaphragm pacing stimulation (DPS) system and ramifications for anyone on positive pressure ventilation.

METHOD: In FDA trials, patients underwent outpatient laparoscopic diaphragm motor point mapping with electrode implantations. Stimulus/output characteristics of each electrode were determined and diaphragm conditioning initiated. Spinal cord injured (SCI) patients were weaned from their ventilators at home and ALS patients conditioned their diaphragms.

RESULTS: Fifty patients were successfully implanted (35 SCI and 15 ALS patients). DPS provided tidal volumes to free 97% of tetraplegics from ventilators. ALS results showed a decrease in the decline of forced vital capacity (3.1% to 1.3% per month) to provide a 15 month improvement in ventilator free survival. Additional findings of DPS use include: reduction of airway pressure decreasing risks of barotrauma with a return of negative chest pressure; conversion of fast twitch glycolytic (Ib) to functional slow twitch oxidative muscle (I) fibers; increased diaphragm muscle thickness; improved posterior lobe lung ventilation with over 60% reduction in secretions and need for suctioning; increased lung compliance leading to decreased work of breathing; and ALS patients have started utilizing DPS to improve nighttime ventilation.

CONCLUSION: The DPS system is safe and should replace the ventilator for SCI patients and prolong natural ventilation of ALS patients. Results provide the basis for ongoing research to decrease ventilator time and reduce risks for any ventilated patient.

DIAPHRAGM PACING FOR PHRENIC NERVE DYSFUNCTION: RESULTS IN THE FIRST IMPLANTED ACUTE TRANSVERSE MYELITIS PATIENTS AND IDENTIFYING THE FUTURE ROLE FOR ACUTE MANAGEMENT OF DIAPHRAGM DYSFUNCTION IN THE INTENSIVE CARE UNIT

Raymond Onders MD, Saeid Khansarinia MD, Anthony Ignagni MS, University Hospitals Case Medical Center, Cleveland; Piedmont Hospital, Atlanta; Synapse Biomedical, Oberlin

BACKGROUND: Phrenic nerve injury occurs in up to 20% of patients undergoing cardiac or thoracic procedures. This leads to diaphragm dysfunction and subsequent respiratory problems of atelectasis, effusions, pneumonia and even need for prolonged mechanical ventilation (MV). Electromyography shows an absence of nerve conduction in these cases, but the nerve is usually not transected, just injured with inflammation causing the inability to transmit impulses to the diaphragm to contract for ventilation. Acute transverse myelitis (ATM) is a rare focal inflammatory disorder of the spinal cord leading to motor and sensory dysfunction. Cervical lesions can lead to MV dependence for reasons similar to the problems acutely post-surgery. We report the first two patients with ATM being implanted with the diaphragm pacing stimulation (DPS) system to provide natural negative pressure ventilation.

METHODS: Two patients with acute transverse myelitis, under IRB and FDA approval, underwent laparoscopic diaphragm motor point mapping to identify the area where maximum diaphragm contraction occurs when the implanted electrode is stimulated. Electrodes were implanted and DPS conditioning of the diaphragm started.

RESULTS: The first patient presented within 3 months of tracheostomy and MV and was implanted with DPS. Using pressure support and DPS the patient was able to be weaned off of MV. The second patient was on MV through a tracheostomy for 2 years since her presentation at age 16. She was implanted and within 2 months was able to be free of MV through DPS use. The more interesting aspect is that she also recovered volitional diaphragm EMG and spontaneous diaphragm ventilation without DPS.

CONCLUSION: This is the first report of DPS being successfully used to replace mechanical ventilation in patients with ATM. The trophic effect of DPS also helped recovery of spontaneous ventilation even two years after acute presentation. The use of DPS with pressure support also decreased the peak airway pressures by preferentially ventilating the posterior lobes decreasing the likelihood of atelectasis and subsequent pneumonia. These findings support the early use of DPS for patients with acute phrenic nerve dysfunction decreasing the significant morbidity of respiratory problems and potentially decreasing the usual year long process of phrenic nerve recovery.

DIAPHRAGM EMG MEASUREMENTS UTILIZING IMPLANTED ELECTRODES OF THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM: ADVANCING OUR UNDERSTANDING OF RESPIRATION IN ALS

Hans D Katzberg, Stanford, California, United States, Charles Cho, Stanford, California, United States, Bashar Katirji, Cleveland, Ohio, United States, Yuen So, Stanford, California, United States, Daniel S Newman, Detroit, Michigan, United States, John Morton, Stanford, California, United States and Raymond P Onders, Cleveland, Ohio, United States

OBJECTIVE: To assess the utility of EMG measured from implanted diaphragm electrodes as a potential biomarker of respiratory disease in ALS

BACKGROUND: Preliminary data from a feasibility and safety trial demonstrated that patients implanted with DPS slowed forced vital capacity (FVC) decline to 0.9% per month compared to a baseline decline of 2.4% per month, which extrapolates to an additional 24 months of ventilator free survival. During this study, we assessed EMG data collected continuously from the implanted diaphragm electrodes.

DESIGNS/METHODS: Respiratory EMG data was collected from ALS patients implanted with DPS electrodes in three stages: immediately following implantation, follow-up clinic visits, and overnight continuous diaphragm analysis utilizing a home polysomnography system.

RESULTS: Of 43 patients implanted at 3 sites, 36 patients had bilateral diaphragm EMG (dEMG) assessments, 18 had continuous overnight EMG analysis with pulse oximetry, 19 had serial dEMG assessments. Findings include: implanted electrodes give reproducible EMG recording, diaphragm motor unit amplitudes correlate with movement on fluoroscopy, EMG recruitment and amplitude correlate with strength of abdominal/chest excursions and intraoperative diaphragm measurements. After 3 months of diaphragm conditioning post implantation, the mean amplitude of rectified EMG signal increased from 49 microvolts to 62 microvolts.

Reduced recruitment on dEMG can identify hypoventilation leading to nocturnal desaturation and improves along with oxygenation after conditioning of the diaphragm.

CONCLUSIONS/RELEVANCE: Continuous dEMG assessment in ALS patients reproducibly identified abnormalities of diaphragm control. Further experience with Demg may reveal features that could serve as a biomarker of respiratory disease in ALS.

UTILIZING THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM FOR DIAPHRAGM FOR EMG ASSESSMENT: FINDINGS AND FUTURE ROLE IN SPINAL CORD INJURIES

Raymond P. Onders M.D.¹; Mary Jo Elmo ACNP¹; Brock Bowman M.D.²; Greg Nemunaitis M.D.³, ¹University Hospitals Case Medical Center, Cleveland, OH; ²Shepherd Center, Atlanta, GA; ³MetroHealth Medical Center, Cleveland, OH

INTRODUCTION: Many spinal cord injured patients require temporary mechanical ventilation (MV) until they are able to be weaned and for some the diaphragm pacing stimulation (DPS) system (Synapse Biomedical, Ohio) is necessary to allow natural diaphragm breathing. This report outlines the use of the DPS system to assess for diaphragm electromyography (EMG) activity.

DESIGN: Tetraplegics implanted with the DPS System were assessed for EMG activity utilizing the implanted electrodes and a polysomnography system (CleveMed, Ohio).

PARTICIPANTS/METHODS: Patients underwent laparoscopic diaphragm motor point mapping with electrode implantations. During electrode characterization the diaphragm EMG activity was assessed both volitionally, without mechanical ventilation and with stimulation of only one diaphragm. All patients were completely dependent on mechanical ventilation at time of implantation.

RESULTS: Eleven of the total 50 implanted patients were assessed. Two patients although dependent on MV had volitional EMG activity of the diaphragm and are presently being conditioned with DPS. Two patients had documented recovered diaphragm EMG activity after DPS was used to wean from the ventilator and subsequently weaned from the DPS system to breathe spontaneously. Two patients with transverse myelitis although dependent on MV had diaphragm EMG activity. One patient when removed from MV for over a minute had diaphragm EMG activity develop although not enough to provide tidal volumes. The DPS system also allows documentation of the crossed phrenic pathway in humans, so that when one diaphragm is stimulated the afferent effect caused EMG activity in the other diaphragm.

CONCLUSION: This preliminary study shows that the DPS system can also be utilized for continuous diaphragm EMG and not only will help maintain diaphragm strength early after injury but help in assessing recovery. DPS may also help recovery of ventilatory function after injury with the concept of neuroplasticity and the multiple pathways of ventilatory drive.

IDENTIFYING THE ROLE OF THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM IN AMYOTROPHIC LATERAL SCLEROSIS (ALS): RESULTS AND EXPERIENCE FROM OVER 40 CUMULATIVE YEARS OF UTILIZATION

RP Onders, MJ Elmo, B Katirji, R Schilz, AR Ignagni

BACKGROUND: Respiratory insufficiency is the major cause of mortality in patients with ALS. The motor point diaphragm pacing stimulation (DPS) system is a standardized minimally invasive laparoscopic technique that is being utilized worldwide to maintain and provide natural diaphragm ventilation.

AIM: To review the experience and results from the initial and largest site implanting the DPS system in ALS patients.

METHODS: In three separate prospective trials from January of 2005 to March of 2008, ALS patients were evaluated pre-implantation and then underwent diaphragm motor point mapping to identify the optimum site where stimulation will cause maximum diaphragm contraction. Two percutaneous intra-muscular electrodes were implanted in each hemidiaphragm and diaphragm conditioning initiated.

RESULTS: 48 patients have been implanted and begun on diaphragm conditioning with the DPS system with no significant peri-operative adverse events even with forced vital capacity(FVC) as low as 20% predicted. Feeding tubes can be safely implanted simultaneously. The mean time from implant was 10 months (range 1-26 months). After conditioning the diaphragm with the DPS, preliminary results show an average rate of decline in FVC of 0.87 % per month from the pre-implantation decline of 2.4% a month, which extrapolates to an additional 24 months of ventilator free survival. For 26 patients that have been implanted greater than 12 months there is a mean survival from diagnosis of 45+/- 4 months using Kaplan-Meier statistics. The DPS system was also used to continuously assess diaphragm EMG activity. It was found that ALS patients develop instability of respiratory control with some having complete acquired central hypoventilation syndrome. Overall ___ of 48 patients utilized the DPS system at night with or replacing their noninvasive positive pressure system. Additional findings include: increased muscle thickness via ultrasound; increase of respiratory compliance by 20%; maintenance of diaphragm Type I slow twitch oxidative muscle fibers; and in more fluoroscopically observed diaphragm excursion occurs with diaphragm stimulation than under maximal voluntary effort in patients with more upper motor neuron diaphragm involvement.

CONCLUSION: The DPS system can be safely implanted and utilized in ALS patients, with a documented decrease in the decline of respiratory failure leading to increased survival. ALS patients with more upper motor neuron involvement of the diaphragm and those with instability of respiratory control are especially good candidates.

LATE PHASE TNF-ALPHA DEPRESSION IN NATURAL ORIFICE TRANSLUMENAL ENDOSCOPIC SURGERY (NOTES) PERITONEOSCOPY

McGee MF, Schomisch SJ, Marks JM, Delaney CP, Jin J, Williams C, Chak A, Matteson DT, Andrews J, Ponsky JL

BACKGROUND: Natural orifice transluminal endoscopic surgery (NOTES) allows access to the peritoneal cavity without skin incisions. Contamination of the peritoneal cavity by enteric contents may render NOTES more physiologically and immunologically invasive than previously thought. Measurement of interleukin-1 (IL-1), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-alpha) is a validated method to quantify surgical stress. The physiologic and immunologic impact of NOTES is unknown.

METHODS: A total of 37 swine underwent abdominal exploration via transgastric NOTES peritoneoscopy, laparoscopy (LX), laparotomy (OPEN), or sham surgery (CONTROL) and were allowed to survive. TNF-alpha, IL-1beta, and IL-6 plasma levels were determined at the start and completion of surgery, and at 1 hour, 2 days, and 14 days postoperatively.

RESULTS: At surgical completion, OPEN animals demonstrated higher TNF-alpha levels than all groups. TNF-alpha levels were similar for all groups at 1 hour and 2 days. NOTES animals had significantly reduced plasma levels of TNF-alpha than all other groups on postoperative days 7 and 14. Controlling for baseline cytokine variability, analysis was repeated using normalized data, which confirmed significantly reduced TNF-alpha levels for NOTES compared with all groups at 14 days. Subset analysis excluding LX and OPEN complications revealed lower NOTES TNF-alpha levels at 7 and 14 days compared with all groups. IL-1beta and IL-6 levels were undetectable in 66.8% and 70.5% of samples, respectively, without significant trends.

CONCLUSIONS: Diagnostic NOTES peritoneoscopy demonstrated similar levels of systemic proinflammatory cytokine TNF-alpha compared with diagnostic laparoscopy and exploratory laparotomy in the immediate postoperative period despite gross intraperitoneal contamination. None of the surgical groups, however, produced a measurable, consistent trend in IL-1beta or IL-6. Consistently reduced levels of TNF-alpha in NOTES animals in the late postoperative period indicates an immunomodulatory effect of the NOTES surgical technique not present in laparoscopy or laparotomy.

LAPAROSCOPIC TREATMENT OF SMALL BOWEL OBSTRUCTION: IS IT SAFE?

Pearl JP, Marks JM, Hardacre JM, Ponsky JL, Delaney CP, Rosen MJ.

Laparoscopic treatment of small bowel obstruction has many reported advantages, yet it is infrequently performed. Criticisms include reduced working space, difficult abdominal access, and bowel injury. The experience with laparoscopic treatment of small bowel obstruction to determine its safety has been reviewed. Nineteen patients underwent laparoscopic treatment of small bowel obstruction. A cut-down technique was used for abdominal access and avoided manipulation of dilated bowel. The average number of prior operations was 1.4. The average size of maximally dilated bowel was 3.5 cm, including 6 patients whose diameter was greater than 4 cm. Laparoscopic treatment was successful in 16 patients; 3 patients required laparotomy. There were no complications from abdominal access and no iatrogenic bowel injuries. This series demonstrated that abdominal access and relief of bowel obstruction can be safely performed laparoscopically in patients with complex small bowel obstruction. Neither massively dilated bowel nor multiple previous abdominal operations precluded safe conduct of the operation laparoscopically.

SELF REPORTED HEIGHT AND WEIGHT IN BARIATRIC PATIENTS

Peter T. Hallowell, M.D.* , Thomas A. Stellato, M.D., Margaret Schuster, RN, BSN,

Kristen Graf, RN, BSN, Ann Robinson, B.A., and John J. Jasper, M.D.

BACKGROUND: The inability of patients to accurately assess their own height and weight can lead to inappropriate allocation of medical resources. This problem was identified in a recent report in trauma patients showing a significant misjudgment by patients of their own height and weight (ref). Using this information would lead to an erroneous calculation of body mass index (BMI). Consequently we undertook this study to assess the accuracy of self reported height and weight in a select population of morbidly obese candidates for bariatric surgery. We hypothesized that the misjudgment of height and weight would be amplified in the bariatric patient.

METHODS: During the intake process of an initial consultation for bariatric surgery, the patient is asked to provide the best estimate of their current height and weight. Actual height and weight is then subsequently measured and recorded by the clinic nurse and used to calculate BMI. We reviewed the last 120 prospectively entered consecutive patients from January 2007 to May 2007. Statistics were performed with GraphPad Prism (GraphPad software Inc, San Diego Ca.). Student's T test was used for parametric data.

RESULTS: The table below shows the estimated height and weight compared to the actual measure height and weight. There were 86% females and 14 % males.

	Est. Height (inches)	Act. Height (inches)	Est. Weight (Lbs.)	Act. Weight (Lbs.)
Mean \pm Std. Error	65.4 \pm 0.3	64.6 \pm 0.4	289.0 \pm 5.1	290.5 \pm 5.2
range	59 - 74	57.5 - 74.5	176 - 425	180.7 - 467.8

There was no statistically significant difference between estimated and actual values

DISCUSSION: Our results demonstrate that morbidly obese patients who present for surgical evaluation do not overestimate their height or underestimate their weight. Thus our hypothesis is not supported in this specific patient population. Our data indicates that bariatric patients are accurate in estimating height and weight prior to direct contact with physicians and nurses in a bariatric program. However the likelihood of the same results occurring with remote contact such as a phone or mail survey remains to be proven.

ANALYSIS OF IRON LEVELS IN MALE BARIATRIC PATIENTS

PT Hollowell, TA Stellato, JJ Jasper, K Graf, M Schuster, and A Robinson*

INTRODUCTION: Limited data exists concerning iron status in male patients undergoing Roux en Y gastric bypass. The need for iron supplementation in male patients is undefined. Consequently we reviewed our experience with morbidly obese male patients who underwent gastric bypass at our institution to evaluate adequacy of iron levels pre and post bypass.

METHODS: A retrospective review was performed of our prospectively maintained bariatric database from 1998 until the present encompassing over 1000 patients. 140 male patients were identified. Of these, 83 patients had data adequate to analyze pre and postoperative iron levels. Patients with BMI < 50 had a short limb gastric bypass (SL); for BMI 50 or greater a long limb bypass (LL) was performed. Serum iron data for preoperative and at defined intervals extending out to five years following gastric bypass, were analyzed. The table below represents only preoperative and 1 year postoperative data.

RESULTS: There were 41 male patients with a short limb gastric bypass and 42 patients with a long limb gastric bypass. The mean BMI in the short limb group was 44.9 and in the long limb group 57.6.

	Iron		% sat		Ferritin		Hct	
	Pre op	1yr	Pre op	1yr	Pre op	1 yr	Pre op	1 yr
Short limb	89.1	86.3	25.9	37.1	214.9	127.2	45.1	42.0
n	41	31	41	31	41	29	44	32
SL % below nl	14.6	12.9	46.3	32.3	0	0	2.3	3.1
Long Limb	80.7	78.7	24.3	27.4	228.6	177.3	44.5	43.2
n	42	36	42	35	42	34	46	37
LL % below nl	16.7	30.6	64.3	45.7	2.4	2.9	0	2.7

Levels represent mean values for each group, (nl) normal

CONCLUSIONS: Iron abnormalities are not uncommon in male bariatric patients both preoperatively and postoperatively. These abnormalities are aggravated in super morbidly obese male patients with long limb gastric bypass. Ferritin, which is a reflection of iron storage, is in the normal range preoperatively and postoperatively. However, average ferritin values decrease over the postoperative period. Hematocrit appears to be unaffected by these changes. Iron abnormalities are well known in to occur in female bariatric patients. Our data shows iron abnormalities are similarly common in male bariatric patients mandating evaluation, surveillance, and appropriate supplementation in all patients undergoing Roux en Y gastric bypass.

SHOULD BARIATRIC REVISION SURGERY BE AVOIDED SECONDARY TO INCREASED MORBIDITY AND MORTALITY?

D Yao, PT Hallowell, TA Stellato, A Robinson, M Schuster, K Graf

BACKGROUND: Revision bariatric surgery is often necessary due to inadequate weight loss or post-op complications of the primary bariatric surgery. In many cases, revision surgeries are technically challenging and thus yield undesirable outcomes. Some bariatric programs avoid this challenging patient population. Here, the goal of this study is to identify the reasons for revision, characteristics of the surgery, and outcomes of the surgery at our institution. We hypothesize that revision surgery, although technically challenging can be performed with care in order to produce desirable outcomes with relatively acceptable complications.

METHODS: Patients undergoing bariatric surgery at our institution between 1998 and 2007 were retrospectively reviewed from a prospective database. Patients who had revision surgery were compared to those who had primary.

RESULTS: We have identified a total of 1038 patients in our bariatric surgery program. 46 patients underwent revision surgery and 13 of which had the primary surgery performed at our institution. In this cohort, reasons for revision are summarized below.

Reasons for Revision (n=46)	
Primary Surgery Type	Number of patients
Roux-en-Y	19
VBG	15
Jejunioleal bypass	5
Horizontal gastric stapling	4
Others	3

When comparing to the primary bariatric surgery patients, the characteristics and the outcomes of the revision surgery are summarized below. The revision patients successfully lost weight, their BMI dropped 12 points from 45.5 ± 10 to 33.5 ± 5.7 Kg/m² 1 year post op ($p < 0.001$)

Variables	Revision (n=46)	Non-Revision (n=992)	p-value
Length of Surgery	221 ± 61	164 ± 54	$p < 0.0001$
Length of Stay	5 ± 3.1	3.2 ± 3.7	$P < 0.049$
Post-op Complications			
Leaks	10.9%	1.2%	$p < 0.0006$
Re admit under 30 days	24.4%	6.5%	$p < 0.0004$
ICU Stays	11%	4.4%	$P < 0.06$
Death	0	0.3%	ns
PE	0.0%	0.7%	ns

CONCLUSIONS: At our institution we have attained a sizeable experience in bariatric revision surgery. Although we saw a 9 fold increase in leaks, a 2.5 fold increase in ICU utilization and 1.5 fold increase in length of stay our mortality rate was the same. In experienced hands bariatric revision surgery can be performed to produce desirable outcomes with relatively acceptable complications.

LAPAROSCOPIC TREATMENT OF COMPLEX SMALL BOWEL OBSTRUCTION: IS IT SAFE?

Jonathan P Pearl MD, Jeffrey M Marks MD, Jeffrey M Hardacre MD,

Jeffrey L Ponsky MD, Conor P Delaney MD, and Michael J Rosen MD

Laparoscopic treatment of small bowel obstruction (SBO) has many reported advantages, yet it is infrequently performed. Critics cite concerns about reduced working space, difficult abdominal access, and iatrogenic bowel injury. Our outcomes have been favorable, even in patients with massively dilated bowel and multiple previous operations. We retrospectively reviewed our experience with laparoscopic treatment of acute SBO to help determine its safety. Over 20 months 19 patients underwent laparoscopic treatment of SBO. We used a cut-down technique to obtain abdominal access and avoided direct manipulation of dilated bowel. The average age was 55 years. Fourteen of the patients had previously operated abdomens; the average number of prior operations was 1.4. All patients had preoperative CT scans. The average size of maximally dilated bowel was 3.5 cm including 6 patients whose diameter was greater than 4 cm. Laparoscopic treatment was successful in 16 patients, while 3 patients required laparotomy. There was no difficulty in obtaining abdominal access and no iatrogenic bowel injuries. The average length of post-operative hospital stay was 5 days. Resumption of diet began within 3.6 days of the operation, on average. In this series we have shown that abdominal access and relief of bowel obstruction can be safely performed laparoscopically in patients with complex SBO. Neither massively dilated bowel nor multiple previous abdominal operations precluded safe conduct of the operation laparoscopically.

Section 4

**Oral and Maxillofacial
Surgery**

A NEW SURGICAL TECHNIQUE – ENDOSCOPICALLY ASSISTED MANDIBULAR SAGITTAL SPLIT RAMUS OSTEOTOMY

Faisal Quereshy MD, FACS, Hardeep S. Dhaliwal, DMD

STATEMENT OF THE PROBLEM: Postoperative inferior alveolar (IA) nerve deficits after sagittal split ramus osteotomy are a prevalent post-operative complication^{3,4}. Some have suggested that manipulation of the nerve and surrounding soft tissues are related to the incidence of this complication^{2,4,5}. It has also been suggested that inappropriate positioning of osteotomy instruments can result in direct nerve damage. Methods of determining the position of the IA foramen include tactile (using a nerve hook), radiographic, palpation (antilingula) and direct visualization of the nerve. Most clinicians appreciate that tactile sensation with a nerve hook can result in false positives. Radiographic determination is often difficult to translate clinically. Relying on the position of the antilingula to infer position of the lingual has been shown to great variation¹. Direct visualization of the nerve on the medial aspect of the mandible is not always possible without excess manipulation of the nerve and its associated soft tissues. In this study, an endoscope was used to visualize the medial aspect of the mandibular ramus to determine the IA nerve position before and during the osteotomy. Our hypothesis is that use of the endoscope will allow greater accuracy of determining the position of the IA nerve while limiting manipulation of the nerve and the surrounding tissues.

MATERIAL METHODS: A sinus endoscope need to input brand info was used to visually assess the position of the inferior alveolar nerve entrance into the mandible and confirm positing of the reciprocating saw. Upon endoscopic confirmation the IA nerve position, a reciprocating saw was positioned above the nerve and the osteotomy was initiated to a depth of 0.5-1mm. Thereafter, the position of the incomplete osteotomy was endoscopically confirmed to be above the IA nerve. Next the osteotomy was completed in normal fashion.

DATA ANALYSIS: Qualitative analysis via clinician experience was initiated to compare the endoscopically assisted osteotomy with the non-endoscopically assisted osteotomies. Visualization of the IA nerve via the endoscope was easily performed w/o excessive manipulation in the area. Confirmation of reciprocating saw position was easily assessed and confirmed after initiation of the osteotomy.

RESULTS: All cases resulted in direct visualization of the IA nerve. All cases resulted in confirmation of saw and osteotomy position. All cases resulted in clinically intact IA nerve continuity. In no case was assessment of nerve position inaccurate. Use of the endoscope added approximately 15-20 minutes to operating room time.

CONCLUSIONS: Establishing the IA nerve position on the medial aspect of the mandibular ramus has sometimes proven to be difficult or require excess manipulation of the nerve. The use of an endoscope to determine the position of the IA nerve was very successful in the current study. Endoscopic evaluation of the IA nerve, will likely aid in a surgeon's confidence of IA nerve position. However, clinical correlation with incidence of IA neurosensory defecits still needs to be studied.

ALVEOLAR CLEFT BONE VOLUME DEFECT MEASUREMENT USING CONE BEAM CT IMAGING

Faculty Mentor: Faisal Quereshy, MD

Co-Investigator: Geoffrey Barnum

OBJECTIVES AND SPECIFIC AIMS: The purpose of this research project is to explore the necessity of Cone Beam CT scan versus conventional radiographic technique in predicting the amount of grafted bone needed for alveolar cleft surgery. This will be a retroactive study looking at CBCT scans taken from the Imaging Center at the School of Dental Medicine on the Campus of Case Western Reserve University. As to date, the amount of grafted bone needed to fill an alveolar cleft has been estimated. By taking Cone Beam CT scans of patients, we hope to be able to calculate the amount of grafted bone needed in order to fill the cleft volume. Conventional radiographs are not sufficient for calculation because they are only two-dimensional images and give no information as to the depth or thickness of the cleft. However, with advances in Cone Beam CT technology, a three-dimensional view of the cleft can be obtained and the volume missing can be calculated.

BACKGROUND AND SIGNIFICANCE: As to date, there has been very little research done directly relating to this objective. Some clefts have been rudimentarily measured. Others have used expensive software programs. However, the common practice is to estimate the amount of bone needed for the bone graft. By finding a way to actually measure the missing void with the CBCT scan, physicians will be more prepared to accomplish the surgery with more precise success.

METHODS: This project will be a retrospective in nature by using pre-operative Cone Beam CT scans of randomly selected patients between the ages of 8-11. By looking at the CBCT scans, the computer software will be able to measure distances from one point to another. An alveolar cleft has certain points that can be identified with every patient and these points will be used for every patient. It will be vital to the validity of the study that the same points are picked on every patient. The same patients will be measured numerous times until intra-rater reliability has been reached. We will determine this reliability by comparing measurements with that of a CBCT scanner expert. Then we will determine the missing volume by taking the measurements and calculating the missing volume of the cleft.

ANALYSIS OF OROFACIAL CLEFT BIRTHS IN OHIO: 1990-2004

J. Curtis, C.A. Demko, J.A. Lalumandier, M. Halley, and F. Quereshy

BACKGROUND: Orofacial clefting represents a significant cause of morbidity among infants. It ranks second to cardiovascular disease as the most common human congenital malformation, with incidence rates from 0.18 to 3.74 per 1,000 live births reported, varying strongly according to race.¹ Indeed, genetics are a major cause in orofacial clefting. There are more than 300 congenital or hereditary syndromes that include cleft lip with or without cleft palate or cleft palate alone. In addition to major genetic factors, minor genetic factors and environmental factors probably combine to some "threshold" level of risk, at which point there will be clefting (reference this). Risk factors and indicators that have been previously associated with orofacial clefting include maternal smoking and alcohol use, sex of infant, parental race and ethnicity, various maternal systemic diseases, maternal nutrition, season of birth, and maternal age. In addition, recent research links imperfect expression of genes involved in detoxification of tobacco smoke with increased clefts in children of smoking parents.²

Our work reports on the incidence of cleft lip and palate births in Ohio over the years 1990-2004 and analyzes risk factors among these Ohio population-based data. Our goal is to compare our Ohio findings with published risk factors and indicators and their associated odds ratios. In addition to testing for risk factors, we compare incidence of cleft lip and cleft palate with incidence of spina bifida. In 1996, folic acid was added into the fortified grain supply and rates of neural tube defects were shown to decrease nationwide.³ We look for a similar trend in both spina bifida and cleft lip and cleft palate.

We include analysis of cleft lip births as a whole group in this initial poster, without regard to other congenital anomalies. Our future work will separate non-syndromic (isolated) cleft lip and cleft palate cases from those associated with other congenital syndromes. It will report separate analysis for isolated CLP and for both isolated and non-isolated CLP. (Matching based on the field "other malformation" in the birth record seems meaningless in the context of matching similar, non-isolated CLP cases)

CONCLUSIONS: This is the first report analyzing CLP malformations from Ohio birth records. Observed incidence rates are consistent with previous reports. We saw a decrease in spina bifida rates, but we did not see the same change in clefting incidence following changes to the folic acid supplementation protocol. Tobacco use and certain maternal co-morbidities are associated with increased risk of CLP birth. Higher educational levels appear to confer protection, but only beyond high school education. This implies that more effective secondary education programs regarding optimal early prenatal care or the effects of tobacco use on an unborn fetus may help reduce the risk of CLP births.

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APPLICATIONS OF CONE BEAM CT IN THE PRACTICE OF ORAL AND MAXILLOFACIAL SURGERY

Faisal A. Quereshy, M.D., D.D.S., F.A.C.S. , J. Martin Palomo, D.D.S., M.S.D. , Truitt A. Savell, D.D.S., M.D.

Over the past thirty years computerized tomography (CT) has revolutionized the practice of medicine, however it has yet to be truly applied to the practice of dentistry. Through the recent development of the cone beam computerized tomography (CBCT) for dentomaxillofacial imaging this might change. With a small fraction of the radiation dose of conventional CT, superior resolution and lower cost, CBCT technology may find it's way into multiple aspects of dental practice. The purpose of this paper is to explore possible uses of CBCT technology in the field of oral and maxillofacial surgery.

CORRELATION OF BLOOD LOSS AND OPERATING TIME DURING ORTHOGNATHIC SURGERY

Faisal A. Quereshy, MD, FACS, Keith Schneider, DDS, MS

PURPOSE: The purpose of this study was to correlate different orthognathic surgery procedures with operating time and blood loss. Previous studies have evaluated similar comparisons, however little data has been reported from accredited resident training institutions. This data will help to better inform our patients of risks and benefits to these procedures.

METHODS: 55 patient records were evaluated retrospectively in an ongoing study of orthognathic procedures from years 2005-2007. Patients were divided into 5 categories based on number and type of procedures performed under hypotensive anesthesia. Height and weight of each patient was recorded for quantification of individual blood volume. Percent blood volume lost, unlike previous studies reported, was calculated and reported along with estimated blood loss for each patient. These values were compared against operating time and number and type of orthognathic procedures performed. We examined single procedures (e.g. Le Forte I osteotomy, bilateral sagittal split osteotomy (BSSO) alone) or in combinations of 2 or more, including genioplasty. Analytic methods included independent t-tests, one way analysis of variance and linear regression

RESULTS: 28 females and 27 males with a mean age 21.6yrs (\pm 8.2yrs, range 15-49yrs) were compared. The mean operating time for all procedure was 214.8 minutes and the mean blood loss was found to be 481.8ml. Mean estimated blood loss (EBL) for males was 562ml (\pm 377ml) versus 404ml (\pm 359ml) for females. To adjust for this difference, we examined percent blood volume loss (BVL) for each individual. BVL for males was 11.1% compared to 9.8% for females. For a single orthognathic procedure (n=25) the mean operating time (OT) was 167.2min. (\pm 54.8min.), mean EBL 414.6ml (\pm 312ml), mean BVL 8.6% (\pm 6%); for 2 procedures, mean OT was 217.6min. (\pm 82.1min.), mean EBL was 436.5ml (\pm 347.0ml), mean BVL 10.1% (\pm 7.9%); and for 3 procedures the mean OT was 402.0min. (\pm 118.3min.), mean EBL 943.3ml (\pm 442.1ml), mean BVL was 19.6% (\pm 13.6%). As the number of procedures increased from 1 to 3, operating times (p for trend $<$.001), EBL and BVL (p for trend=.014) all increased. In this dataset, patients receiving 3 procedures tended to be younger (17.3yrs) than other groups (22.1yrs, p=.001). Simple linear regression of blood loss on operating time revealed a significant positive correlation (zero-order correlation=.517) and an adjusted R-squared of .253 (p<.001). A preliminary examination of individual procedures from the 5 categories (e.g., Le Forte I \pm BSSO) suggested a shorter operating time for Le Forte I procedures but with slightly greater blood loss.

CONCLUSION: Our observations agree with previous reports that concomitant orthognathic procedures are associated with greater operating times and blood loss. Operating time explains 25% of the variance in blood loss before adjustment for other factors, suggesting the importance of surgical practices that could shorten operating times. We also demonstrated that calculating percent blood volume lost accounts for the effect of sex on estimated blood loss that was previously reported^{1,2}. Blood volume should be calculated based on height and weight for male and female patients separately. Further research will include greater numbers of subjects in each of the 5 procedural categories. This and future data will be used to better inform our patients of the risks and benefits to undergoing orthognathic surgery at our institutions.

INTERRADICULAR RADIOLUCENCY IN THE MANDIBULAR MOLAR REGION

John Dudek D.D.S., M.D.; Faisal A. Quereshey, M.D., D.D.S.**; John Kalmar, D.M.D.****

Case Presentation

A 41-year-old caucasian male with a noncontributory medical history, presented to his general dental practitioner with the complaints of pain and swelling in the left posterior mandible for the past 2 months. Initially, the lesion was assumed to be of infectious etiology and was treated with incision, drainage and a course of antibiotics. However, the pain and swelling continued and the patient was referred to an endodontist, who determined that both teeth # 18 and 19 were vital. The patient was subsequently referred to an oral and maxillofacial surgeon (FAQ). Clinical examination, at that time, revealed a firm slight swelling of the lingual alveolus adjacent to teeth # 18 and 19. No buccal swelling was detected and the mucosa overlying the area appeared normal (Fig 1). The buccal and lingual aspects of the alveolus were both mildly tender to palpation, however, there was no evidence of either erythema or purulence in the region. Periapical and panoramic radiographs revealed a well demarcated interradicular and periapical unilocular radiolucency involving teeth # 18 and 19 (Fig 2).

INTRAOSSEOUS ANGIOLIPOMA OF THE MANDIBLE IN A 15-YEAR OLD PATIENT: A CASE REPORT

Brijesh J. Patel, DDS, MD† and Faisal A. Quereshy, MD, DDS, FACS‡

Lipomas are the most common mesenchymal neoplasms, the majority of which occur on the trunk, shoulder, neck, and proximal portions of the extremities. Their occurrence in the oral and maxillofacial region, however, is much less frequent.¹ Lipomas occurring within bone are a very rare entity, with an incidence of approximately one per thousand bone tumors.² Angiolipomas are a microscopic variant of lipomas. This article describes a case of an intraosseous angiolipoma occurring in the mandible. There have been a total of three other cases of intraosseous angiolipomas of the mandible reported in the literature.^{3,5,7}

(Endnotes)

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MEASURING CROSS SECTIONAL AIRWAY SURFACE AREA USING CONE BEAM COMPUTED TECHNOLOGY (A PRE-STUDY)

Faisal Quereshy, M.D., D.D.S., F.A.C.S., Dale Baur, D.D.S., Jonathan T. Williams, B.S.

STUDY QUESTION: The cross sectional area of the posterior airway space (PAS) and the level of the hyoid bone in relation to the inferior border of the mandible are two anatomic parameters used in the prediction and diagnosis of obstructive sleep apnea (OSA). A decreased PAS and an inferiorly positioned hyoid bone have been associated with an increased likelihood of OSA. Up until recently, these parameters were measured in only two dimensions using traditional cephalometric radiographs. With the advent and increased utilization of CBCT technology, the ability now exists to measure the aforementioned parameters as well as other anatomic relationships in a third dimension. The purpose of this study is to retrospectively collect cross sectional airway surface area measurements using CBCT in patients eighteen years and older that already have images in the CBCT data base. We will measure cross sectional surface area in the plane defined from point B to the gonion. In the same patient, the distance from the inferior border of the mandible to the hyoid will be measured. Although these patients have not been screened or been specifically diagnosed with OSA, in this preliminary study, we hope to collect enough data to better define the relationship between these parameters. In a future prospective study, we hope to pre-screen patients with a sleepiness scale and then compare the anatomic findings.

With this data, we hope to compile standards for cross sectional surface area that will serve as an additional reference to the standard length measurements from cephalometric studies.

LITERATURE REVIEW: Recent literature has explored the cross sectional surface area and volumetric analysis in patients using CBCT (1,4). However, a study looking specifically at the point B to gonion (PAS) and inferior border of the mandible to the hyoid surface area is lacking in the number of patients used. Studies have shown that patients with OSA have altered position of the hyoid bone and smaller cross sectional surface airway than the general population. The altered position of the hyoid has been shown to be lower in patients with obstructive sleep apnea. Cross sectional surface area is usually less in areas below the occlusal plane. We hope to gain additional references for normal patients for MPH and PAS cross sectional surface area in addition to the distance measurements of 17 ± 6 mm for MPH and PAS of 10 ± 3 mm (1). From compiling data from a large patient base, we can then make comparisons in the future to patients with obstructive sleep apnea. If CBCT can accurately identify the specific alterations causing OSA in a particular patient, the method of intervention can be applied earlier in treatment. This data may also serve in the future as a tool to identify OSA patients from non-OSA patients.

DATA SOURCE: Retrospectively study patients who had CBCT imaging at the School of Dental Medicine (through the graduate orthodontics program) who are 18 years and older. We are not attempting to separate patients with diagnosed OSA versus the normal population at this time.

REPORT OF A UNIQUE CASE OF CERVICOTHORACIC NECROTIZING FASCITIS ALONG WITH A CURRENT REVIEW OF REPORTED CASES

Faisal A. Quereshy[§] MD, DDS, FACS, Marc A. Zechel^{}, MD, DDS, MSc; Sunwoong Choi, MD, DDS; Jonathan Baskin[†], MD; Anca M. Barbu[‡], MD*

PURPOSE: This article presents a uniquely severe case of cervicothoracic necrotizing fasciitis as well as a literature review of recent articles reporting this entity. Predisposing factors, diagnosis, and treatment strategies is also reviewed.

PATIENTS AND METHODS: A single case is presented along with a review of six other recent studies of CNF.

RESULTS: Our patient developed CNF secondary to an infection of tooth #32. Despite being placed on antibiotic therapy by her primary care physician, she developed fulminate CNF which involved the thorax, mediastinum and great vessels of the heart. Review of the literature suggests there a number of predisposing factors such as diabetes, alcoholism, and advanced age.

CONCLUSION: Odontogenic infections, particularly in a compromised host require aggressive management.

RESORBABLE SCREW FIXATION FOR CORTICAL ONLAY BONE GRAFTING: A PRELIMINARY REPORT

Sukhdeep S. Dhaliwal, DDS, MD; Faisal A. Quereshy, DDS, MD, FACS; and Michael P. Horan, DDS, PhD.

PURPOSE: The current “gold standard” in alveolar ridge augmentation is autogenous bone grafting. Autologous cortical onlay grafts provide predictable increases in bone volume when used for alveolar ridge augmentation. However, rigid fixation of the graft to the recipient site is essential. Phillips and Rahn showed increased graft survivability in rigidly fixated onlay grafts compared to grafts that were not rigidly fixated.¹ Titanium screws are commonly used to provide rigid fixation for onlay grafting, but have potential drawbacks including the need for second surgery for removal prior to implant placement and screw fracture during removal. Chacon et al. demonstrated equal onlay graft integration and survivability using either resorbable or titanium screw fixation in a rabbit model.² However, to the best of our knowledge, studies on resorbable screw fixation of onlay grafts in humans have not been performed. The purpose of the present study was to investigate the efficacy of using 2.0mm resorbable fixation screws to secure autologous cortical onlay grafts to either the maxilla or mandible to augment alveolar bone height and/or width prior to implant placement. It was hypothesized that equal onlay graft integration and survivability is attained using either resorbable or titanium screw fixation.

MATERIALS AND METHODS: Eleven patients requiring alveolar ridge augmentation were enrolled in this study. All patients received autologous cortical onlay grafts. Patients were randomly assigned to two groups, grafts fixated with either 2.0mm resorbable (experimental) or 1.5mm titanium (control) screws. Integration and survivability of the graft was assessed using Cone-Beam Computed Tomography (CBCT). Graft resorption was calculated at 5-7 months post-op and used as a quantitative outcome measure.

METHODS OF DATA ANALYSIS: Statistical analysis was performed using NCSS/PASS Dawson Edition for Windows XP. Data presented as Mean±SEM. Inter-group differences were assessed using Students t-test.

RESULTS: Nine of the 11 patients initially enrolled completed the study. In these patients, 12 bone graft were placed, four being fixated with 2.0mm resorbable and eight fixated with 1.5mm titanium screws. Integration and survivability of the grafts was 100% regardless of fixation type. CBCT data indicated that all grafts integrated regardless of fixation type. At 5-7 months post-op, CBCT analysis indicated there was 28.07 ± 3.15 and 40.03 ± 3.67 percent bone resorption in grafts fixated with 2.0mm resorbable and 1.5mm titanium screws, respectively ($P>0.05$).

CONCLUSION: These data suggest that cortical onlay graft integration and survivability is similar using either 2.0mm resorbable or 1.5mm titanium screw fixation. Therefore, use of resorbable fixation devices in alveolar ridge augmentation will obviate the need for removal prior to implant placement. Further studies need to be performed with increased sample size to confirm these data.

(Endnotes)

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- ² Chacon GE, Ellis JP, Kalmar JR, McGlumphy EA: Using resorbable screws for fixation of cortical onlay bone grafts: An in vivo study in rabbits, *J Oral and Maxillofac Surg*. 2004 Nov; 62(11): 1396-1402

THE EFFICACY OF BIORESORBABLE FIXATION IN THE REPAIR OF ORBITAL FLOOR FRACTURES: AN ANIMAL PILOT STUDY

Lucas R. Beatty, DDS, MD and Faisal A. Quereshy, MD, DDS

PURPOSE: The late sequelae following orbital trauma may include enophthalmos, telecanthus, and diplopia. Treatment options range from the use of metallic rigid fixation to the placement of implantable autogenous and alloplastic materials. To date, no known studies exist regarding the use of resorbable rigid fixation materials in the stability of repairing orbital floor defects, as well as assessing new bone formation over the defect. The purpose of this study is to analyze the treatment of orbital floor "blow-out" fractures using a bioresorbable fixation system in a feline model.

METHODS: Five adult cats comprised the experimental group (A) and underwent left iatrogenic infraorbital osteotomies to remove the orbital floor, followed by fixation with bioresorbable mesh spanning the floor defect and stabilized to the infraorbital rim. The control group (B) included three cats, all with similar fractures. Two of the cats were treated using a standard titanium mesh and screw fixation, and the other was closed without treatment of the defect. All animals were allowed to function immediately without the use of an ocular patch. Direct coronal and axial computerized tomography (CT) scans were obtained preoperatively and prior to sacrifice at 3 and 6 months to assess bone ingrowth/replacement, orbital levels, and position of the globe within the orbit. At the three month interval, one specimen from the experimental group was sacrificed, and at six months the entire sample was sacrificed.

RESULTS: Regions of the fractured site were assessed morphologically, radiographically, and histologically. Perioperative complications included postoperative seroma in four specimens: two experimental, one with titanium, and one with defect only. The cats were treated for three weeks with intramuscular amoxicillin/duracef antibiotics. All cultures obtained were negative as the areas resolved. There were no other complications. Morphologically, both groups did not show clinical evidence of (i) entropion/ectropion, (ii) incisional dehiscence, (iii) wound infection or foreign body reaction, (iii) intra/extraorbital palpability of the device, or (iv) enophthalmos as visualized at the time of sacrifice. Remnants of the bioresorbable mesh was present at 3 months, but was clinically absent at 6 months with gross evidence of fibrosis spanning the defect. Radiographically at three months, periorbital thickening was noted with increased radiodensities. The globe was also noted to be further projected in both antero-posterior and supero-inferior dimension as compared to the contralateral orbit. The defect was noted to be present without evidence of radiographic bone regeneration. At six months, all specimens, treated with both fixation systems, showed excellent globe position within the orbital vault. Rigid fixation material was absent in the experimental group, whereas radiographic scatter and interference persisted in the control titanium group. All animals showed lack of bone formation across an open defect at 6 months. Histologic evidence at three months revealed activity mainly at the bony edges of the defect with focal patches of fibrosis, inflammation, and minimal new bone growth. Marked remnants of bioresorbable material was present across the defect. At six months, moderate fibrosis spanned the defect and there was minimal inflammation/bioresorbable material. Of the control group, the cat with titanium had marked fibrosis spanning the defect with minimal inflammation and the cat without repair revealed a persistent defect without spanning fibrosis.

CONCLUSIONS: Bioresorbable fixation systems are efficacious in orbital trauma, specifically "blow-out" fractures, in the cat model. They have been shown to be comparable to traditional fixation systems albeit in a pilot study with a small sample size and short term follow-up period. Functional enophthalmos was not directly assessed but was clinically absent on gross observation of the animals.

UTILIZATION OF THE TYMPANOMASTOID FISSURE FOR INTRAOPERATIVE IDENTIFICATION OF THE FACIAL NERVE

Andrew W. Bushey, DMD, Landers, MA; Boice, JG; Baur, DA.

Intraoperative identification of the facial nerve is an essential component of parotid gland surgery. Failure to visualize the facial nerve during the procedure can result in significant complications such as facial palsy. Several anatomic landmarks are used clinically to identify the facial nerve trunk; however the majority of these structures have variable locations with respect to the nerve. The tympanomastoid fissure is the closest and least variable of the anatomic landmarks utilized in parotid gland surgery. The aim of this study was to evaluate the distance between the tympanomastoid fissure and the facial nerve trunk. Thirty cadaver sides were dissected. A pre-auricular incision exposed the facial nerve trunk and the dissection was extended to the stylomastoid foramen and adjacent mastoid process. The distance between the most lateral aspect of the tympanomastoid fissure and facial nerve trunk was obtained using a digital caliper. The distance from the tympanomastoid fissure to the facial nerve trunk ranged from 3.3mm to 9.2mm with a mean of 4.9mm. The results demonstrated that the tympanomastoid fissure is a close and predictable anatomic landmark that can be used to identify the facial nerve trunk intraoperatively.

EVALUATION OF THE EFFECT OF SILDENAFIL AND VASCULAR ENDOTHELIUM GROWTH FACTOR COMBINATION TREATMENT ON SKIN FLAP SURVIVAL IN RATS

John W. Tsai, Farhan S. Ayubi, Kristopher L. Hart, Dale A. Baur, Mary A. Parham, Jay K. Moon, Raymond Vazquez, Arthur B. Chasen, Zhuo Zhang, Jose M. Pizarro

BACKGROUND: Distal ischemic necrosis of surgical flaps remains a challenging problem for the reconstructive surgeon. Recent studies have shown that either sildenafil or vascular endothelium growth factor (VEGF) treatment significantly improves ischemic skin flap viability. In this study, the effect of the combination of sildenafil and VEGF 165 was evaluated on a rat skin flap model using orthogonal polarization spectral imaging and histologic analysis.

METHODS: Rats were assigned to either a sham (n = 31), vehicle (n = 24), sildenafil (n = 24), VEGF (n = 23), or sildenafil and VEGF combination treatment (n = 21) groups. Distances from the distal end of the flap to avascular, stasis, and normal capillary blood flow zones were

determined using orthogonal polarization spectral imaging on a skin flap model. Vessel density assessment was done at 7 days post surgery.

RESULTS: Imaging analysis showed significant reduction in avascular and stasis areas in sildenafil and VEGF combination -treated groups at 7 days post surgery (p<0.05). The combination-treated group, however, was not significantly different when compared to the group treated with sildenafil only. The sildenafil-treated group showed a significant (p<0.05) reduction in both areas at day 7 compared to the VEGF and control groups. Histologic analysis showed no significant differences in vessel density between the groups.

CONCLUSION: The combination of sildenafil and VEGF decreases the extent of avascular and stasis zones in skin flaps. The skin flap improvement seen with the combination treatment was similar to the sildenafil treatment alone suggesting that enhanced flap survival was due solely to the effect of sildenafil.

EVALUATION OF POSTERIOR AIRWAY SPACE USING CONE BEAM CT TECHNOLOGY

Faisal Quereshy, M.D., D.D.S., F.A.C.S., Dale Baur, D.D.S., Jonathan T. Williams, B.S.

STUDY QUESTION: The cross sectional area of the posterior airway space (PAS) and the level of the hyoid bone in relation to the inferior border of the mandible are two anatomic parameters used in the prediction and diagnosis of obstructive sleep apnea (OSA). A decreased PAS and an inferiorly positioned hyoid bone have been associated with an increased likelihood of OSA. Up until recently, these parameters were measured in only two dimensions using traditional cephalometric radiographs. With the advent and increased utilization of CBCT technology, the ability now exists to measure the aforementioned parameters as well as other anatomic relationships in a third dimension. The purpose of this study is to retrospectively collect cross sectional airway surface area measurements using CBCT in patients eighteen years and older that already have images in the CBCT data base. We will measure cross sectional surface area in the plane defined from point B to the gonion. In the same patient, the distance from the inferior border of the mandible to the hyoid will be measured. Although these patients have not been screened or been specifically diagnosed with OSA, in this preliminary study, we hope to collect enough data to better define the relationship between these parameters. In a future prospective study, we hope to pre-screen patients with a sleepiness scale and then compare the anatomic findings.

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LITERATURE REVIEW: Recent literature has explored the cross sectional surface area and volumetric analysis in patients using CBCT (1,4). However, a study looking specifically at the point B to gonion (PAS) and inferior border of the mandible to the hyoid surface area is lacking in the number of patients used. Studies have shown that patients with OSA have altered position of the hyoid bone and smaller cross sectional surface airway than the general population. The altered position of the hyoid has been shown to be lower in patients with obstructive sleep apnea. Cross sectional surface area is usually less in areas below the occlusal plane. We hope to gain additional references for normal patients for MPH and PAS cross sectional surface area in addition to the distance measurements of 17 ± 6 mm for MPH and PAS of 10 ± 3 mm (1). From compiling data from a large patient base, we can then make comparisons in the future to patients with obstructive sleep apnea. If CBCT can accurately identify the specific alterations causing OSA in a particular patient, the method of intervention can be applied earlier in treatment. This data may also serve in the future as a tool to identify OSA patients from non-OSA patients.

Section 5

Pediatric Surgery

CEREBRAL REGIONAL OXYGENATION DURING AORTIC COARCTATION REPAIR IN PEDIATRIC POPULATION

Ahmed Farouk, Mohsen Karimi, Mark Henderson, Jacob Ostrowsky, Ernest Siwik, Hani Hennein

Rainbow Babies and Children's Hospital, Case Western Reserve University Hospitals, Cleveland, Ohio, United States

Presented at the Congenital Forum, 21st Annual Meeting of the European Association for Cardio-Thoracic Surgery, 15-19th September, Geneva, Switzerland

OBJECTIVES: During repair of aortic coarctation, clamping of the transverse aortic arch proximal to the left common carotid artery occludes blood flow to the left carotid and vertebral arteries. The objective of the present study is to determine whether blood flow through the right carotid and vertebral arteries provides adequate cerebral blood flow during aortic cross-clamping, as assessed by near-infrared spectroscopy.

METHODS: In 11 consecutive children undergoing aortic coarctation repair through a standard posterolateral thoracotomy, regional cerebral oxygen saturation (cSO₂) was measured using near-infrared spectroscopy. Six patients underwent an extended end-to-end repair, in which the aortic cross-clamp was placed in between the innominate and left common carotid arteries (extended repair group). Five patients underwent a standard end-to-end repair in which the cross-clamp was placed between the left common carotid and subclavian arteries (standard repair group).

RESULTS: After aortic clamping, there was a significant decrease in cSO₂ in the extended repair group, whereas the cSO₂ increased in the standard repair group (-9.2 ± 12.2 vs. 6.0 ± 5.1 %, extended vs. standard repair groups, $p = 0.03$). In the extended repair group, the cSO₂ decreased linearly during the aortic cross-clamping period ($r_s = -0.842$, $p < 0.001$), while in the standard repair group, the cSO₂ increased during the same time period ($r_s = 0.786$, $p < 0.001$). Regression analysis identified the site of aortic cross-clamping as the sole independently significant variable explaining changes in the cSO₂ during aortic cross-clamping ($p < 0.03$), whereas neither age nor duration of aortic cross-clamping were statistically significant. There were no postoperative neurological impairments in either group of patients.

CONCLUSION: During aortic coarctation repair, aortic cross-clamping proximal, as compared to distal, to the left carotid artery is associated with significantly decreased regional cerebral oxygen saturation, as measured by near-infrared spectroscopy. Although no short-term clinical impairments were identified, long-term follow-up in a larger cohort is needed to study the effects of unbalanced cerebral oxygenation during clamping of the transverse arch. These data suggest that cerebral saturation monitoring is warranted, and may be indicative of cerebral hypoperfusion.

INTER-OBSERVER VARIATION IN THE ASSESSMENT OF APPENDICITIS

Todd A. Ponsky, M.D., Muhannad Hafi, M.D., Kurt Heiss, M.D., John Dinsmore, M.D., Kurt D. Newman, M.D., James Gilbert, M.D.

BACKGROUND: Following appendectomy, surgeons define appendicitis, for treatment and billing purposes, into one of four categories: normal appendix, acute appendicitis, gangrenous appendicitis, and perforated appendicitis. Treatment of appendicitis is predicated upon classification at the time of visual inspection. Furthermore, this classification often plays a role in the assessment of hospital outcomes. The currently accepted classification system is based solely upon intraoperative surgeon opinion and not objective data. Inconsistent surgeon grading of the severity of appendicitis may have implications in both management and outcomes.

OBJECTIVE: To assess the inter-observer and intra-observer variation amongst surgeons in grading of the inflammatory severity of acute appendicitis as recognized on visual findings at operation.

METHODS: A cross-sectional study design. 110 surgeons and surgical residents were randomly selected. Surgeons were shown images of intraoperative appendicitis, and asked to evaluate the severity of the appendicitis (normal, inflamed, gangrenous, and perforated). Demographic information regarding the type of practice, hospital setting, and the number of encounters with patients with acute appendicitis were assessed.

RESULTS: The study group consisted of 100 surgeons, 62 practicing surgeons and 48 surgical trainees. 79% of the surgeons treated predominately adults with appendicitis, 18% treated primarily children, and 3% treated both children and adults. Hospital practices included University Hospitals (47%), Community Hospitals (33%), Children's Hospitals (14%), and other (6%). Overall there was poor agreement amongst surgeons in assessing the severity of appendicitis. The kappa score was used to assess agreement with $k=0.25$ being random chance. Specifically, when choosing to apply the descriptor "normal" the kappa score was ($k=0.22$), less than random chance alone, inflamed ($k=0.30$), perforated ($k=0.27$); and gangrenous ($k=0.20$). Completion of a general surgery residency did improve the intra-observer agreement when compared with trainees ($k=0.33$ vs 0.20); although there was a trend toward substantial intra-observer agreement amongst pediatric surgeons in the study group ($k=0.63$). Evidence of fecal spillage (32%), walled off purulent fluid collection (28%), green-black lesions of the appendix (14%), and iatrogenic disruption of the appendix (9.5%) were the most frequent operative findings used in determining whether the appendix was perforated. The majority of surgeons in the study group did not use the duration of symptoms as a factor in determining whether they would diagnosis (80% vs 20%) or treat (85% vs 15%) appendicitis as perforated.

CONCLUSION: There is poor agreement amongst surgeons in describing the severity of appendicitis. Treatment protocols based on more accurate assessment and categorization could potentially lead to more favorable and cost effective outcomes. Furthermore, studies determining efficacy in the diagnosis and treatment of appendicitis should consider observer variability. Future work must attempt to define critical objective assessment points, such as visible discontinuity of the appendix or fecal soilage, to assure better correlation of findings with prognosis.

Keywords: Appendicitis, Children, Outcomes, Management, Variation

CONGENITAL EPENDYMOBLASTOMA ARISING IN THE SACROCOCCYGEAL SOFT TISSUE: CASE STUDY OF THE LITERATURE

Mariarita Santi¹, Bulas Dorothy, Burger C. Peter, Fasano Ross, Ponsky Todd, Sandler Antony, and Elisabeth J. Rushing⁴

Divisions of Pathology¹, Radiology², General Surgery, Hematology Oncology Children's National Medical Center, Washington, D.C., Department of Pathology³, Johns Hopkins School of Medicine, Baltimore, Maryland, and Department of Neuropathology and Ophthalmic Pathology⁴, Armed Forces Institute of Pathology, Washington, D.C.

Ependyoblastomas are distinct small cell, embryonal tumors of the central nervous system reported only rarely in the literature. Most examples arise in the supratentorial compartment, and may or may not be related to the ventricular system. We report the case of a 1 day-old infant who presented with a 5cm x 5cm ruptured skin covered buttock mass. Findings on ultrasound (US) demonstrated a solid mass at the base of the spine with an internal component deviating the bladder anteriorly with resultant hydronephrosis. Magnetic resonance imaging confirmed the presence of a solid mass surrounding the lower sacrum with an internal component partially encircling and deviating the rectum. Histopathological evaluation revealed a highly cellular neoplasm containing densely packed rosettes composed of multilayered, mitotically active cells. The authors describe their experience and review the literature, emphasizing that ependyoblastomas need to be differentiated from other ependymal neoplasms and that they should be considered in the differential diagnosis of sacral masses in the newborn.

DIVISION OF THE MESOAPPENDIX WITH ELECTROCAUTERY IN CHILDREN IS SAFE, EFFECTIVE, AND COST-EFFICIENT

Todd A. Ponsky, M.D. and Steven S. Rothenberg, M.D.

Rocky Mountain Hospital for Children

INTRODUCTION: Laparoscopic appendectomy is one of the most common procedures performed in children. There are several techniques available for dividing the mesoappendix including the using an endo-stapler, a ligasure (Valley Lab, Denver, CO), a harmonic scalpel (Ethicon Endosurgery, Cincinnati, OH), or electrocautery. Although it is the least expensive approach, many feel that electrocautery is an unsafe method of dividing the mesoappendix. Here we present our experience with the use of solely electrocautery to divide the mesoappendix.

METHODS: Over a period of 6 years, a total of 442 laparoscopic appendectomies were logged into our database. Each appendectomy was performed by coagulating and dividing the mesoappendix with a Maryland dissector or in some cases a hook electrocautery. Three 0-PDS Endoloops were then used to ligate the base of the appendix, 2 proximal and one distal. The total number of cases of post-operative bleeding and time of procedure were queried.

RESULTS: Of the 442 cases, 71 were perforated (16%). The mean time for non-perforated appendectomies was 26 min. and 38 min. for perforated. There was one case of post-operative bleeding managed non-operatively in a patient with previously undiagnosed Factor VIII deficiency. The cost of each Endoloop was \$22.

CONCLUSION: Although some have questioned the safety of using electrocautery alone to divide the mesoappendix for fear that it may not be adequate to seal the appendiceal artery, takes excessive time, or cause collateral tissue injury, this has not been our experience. Therefore the use of more costly instruments to divide the mesoappendix such as the endo-stapler, ligasure, or harmonic scalpel seems unwarranted. This study clearly show that electrocautery for the mesoappendix and Endoloops for the appendix is safe, effective, and cost efficient.

EXPERIENCE WITH A NEW ENERGY SOURCE FOR TISSUE FUSION IN PEDIATRIC PATIENTS

Todd A. Ponsky, M.D. and Steven S. Rothenberg, M.D.

Rocky Mountain Hospital for Children, Denver, CO, USA

INTRODUCTION: Options for effective techniques for vessel and tissue sealing in infants and children are limited because of the size and limited intracorporeal space of many pediatric patients. We evaluated a new energy source, The ForceTriad™ (Tyco Health, West Windsor, NJ) Ligasure which delivers both monopolar and bipolar energy in a 5mm format, that allows for tissue fusion and vessel sealing and division. This report documents our experience with this device

METHODS: A database review was performed looking for all cases that were performed in children using the ForceTriad Ligasure as the main source of hemostasis and tissue fusion. Two different handpieces were used a fine Maryland dissector type instrument with no cutting blade, and a sealer / cutter, both in a 5mm format.

RESULTS: A total of 60 cases were performed in children from September, 2006 to September, 2007 using the ForceTriad. The two most common cases were Nissen fundoplication (40 cases, Weight: 8.5-95kg (avg 40.7kg), OR time: (15-70min) Avg 32min, Avg days to full feeds: 2), and lung lobectomy (11 cases, Weight: 4.6-63kg (avg 27.3kg), OR time: (60-180min) Avg 123min, Avg hospital days: 3.1). Other procedures included, excision of choledochal cyst (3), aortopexy, closure of bronchopleural fistula, resection of a giant thymic cyst (1), thymectomy (1), parathyroid adenoma excision (1), total colectomy (2), and intestinal duplication resection (2). There were no failures of vessel or tissue fusion and no operative complications. A delayed hydropneumothorax developed in one lung resection and spontaneously resolved.

CONCLUSION: The ForceTriad provides a safe and effective energy source in a 5mm format. As compared to previous versions of the Ligasure there is less sticking, a quicker seal, and no tissue fusion failures.

MINIMALLY INVASIVE SURGERY IN INFANTS LESS THAN 5 KG: EXPERIENCE OF 649 CASES

Todd A. Ponsky, M.D. and Steven S. Rothenberg, M.D.

INTRODUCTION: With the development of advanced skills and the introduction of miniature laparoscopic tools, endoscopic procedures in infants and small children have become possible. This report documents our experience in minimally invasive surgery (MIS) in infants under 5kg.

METHODS: A retrospective database review was performed from September, 1993 to September, 2007. All children weighing 5kg or less that underwent a laparoscopic or thoracoscopic procedure were included.

RESULTS: A total of 649 cases were attempted. 43 different procedures were performed. The most common were Nissen fundoplication (310 cases, avg. OR time: 43min, avg. time to full feeds 2 days), pyloromyotomy (104 cases, avg. OR time 12.5min, avg. hosp days <1), PDA ligation (26 cases, avg. OR time: 31min, avg. hospital days: <1), TEF repair (22 cases, avg. OR time: 83min, avg. time to full feeds: 7.8days), duodenoduodenostomy (20 cases, avg. OR time: 76min, avg. time to full feeds: 8.6 days), colonic pull-through for Hirschsprung's Disease (18 cases, avg. OR time:109.6, avg. time to full feeds 3 days), colonic pull-through for imperforate anus (10 cases, avg. OR time:103, avg. hospital days:2), lung resection (12 cases, avg. OR time:66.8, avg. hospital days 1.75), congenital diaphragmatic hernia repair (10 cases, avg. OR time: 62.5, avg. time to full feeds: 4.75). There were no surgery related deaths. The conversion rate to open was 1.2% (#8). There were 6 intraoperative complication rate (0.9%) and the overall complication rate was 3% (20 complications overall).

CONCLUSION: The development of modern low flow CO2 insufflators, smaller, instruments and telescopes, as well as advanced techniques, has made MIS in neonates feasible and safe. The greatest challenge remains performing intestinal anastomosis in these confine space and further technical advances will be required to make these techniques universally adopted

THORACOSCOPIC LUNG BIOPSY IN CHILDREN: IS A CHEST TUBE ALWAYS NECESSARY?

Todd A. Ponsky, MD¹, Steven S. Rothenberg, MD¹, KuoJen Tsao, MD², Daniel Ostlie, MD², Shawn St Peter, MD², G Whit Holcomb, II, MD².

¹Rocky Mountain Hospital for Children, Denver, CO, USA, ²Children's Mercy Hospital, Kansas City, MO, USA.

PURPOSE: Surgical dogma has dictated that a chest drain be left following lung biopsy in children to prevent a tension pneumothorax in the event of an air leak from the biopsy site. However, the drain is often the greatest source of pain post-operatively. We propose that the incidence of a clinically significant air leak following a thoracoscopic lung biopsy in children is so low that a chest tube (CT) is not always necessary.

METHODS: Over a period of 14 years, from 1993 to 2007, a total of 196 patients from two institutions underwent thoracoscopic lung biopsy utilizing either an endosurgical stapler or endosurgical loops. Ages ranged from 2 months to 28 years. Weight ranged from 2 to 117 kg. Biopsies were obtained for Interstitial Lung Disease, metastatic disease, and infiltrates of unknown origin. All biopsies were performed using a 3 port technique. A CT was placed through a cannula site in each child and then removed at the end of the case if no air leak was present in 182 patients. A CT was left in place in 14 patients who were either on positive pressure ventilation postoperatively or had large effusions which needed drainage. All patients had a chest radiograph in the recovery room.

RESULTS: Of the 196 patients, none had an air leak at the end of the case. Of the 182 patients without chest drainage, only one developed a postoperative pneumothorax which developed on postoperative day 2 following reintubation for respiratory failure. A chest tube was then inserted. In this patient, repeat thoracoscopy on day 7 demonstrated a bleb blowout separate from the biopsy site.

CONCLUSIONS: The use of routine CTs following thoracoscopic lung biopsy appears to be unnecessary. Eliminating the CT removes much of the morbidity of the thoracoscopy, primarily the pain associated with the CT.

THORACOSCOPY IN CHILDREN: IS A CHEST TUBE NECESSARY?

Todd A. Ponsky, MD^{1,3}, Steven S. Rothenberg, MD¹, KuoJen Tsao, MD², Daniel J. Ostlie, MD², Shawn D. St Peter, MD², G Whit Holcomb, III, MD².

¹Rocky Mountain Hospital for Children, Denver, CO

²Children's Mercy Hospital, Kansas City, MO

³Rainbow Babies and Children's Hospital, Cleveland, OH

PURPOSE: Historically, a chest tube or drain has been left following a thoracic operation to allow drainage of air or fluid in the postoperative period. However, in patients undergoing thoracoscopy, the tube is often the greatest source of postoperative pain. We began excluding chest tubes several years ago and therefore are reviewing our experience to evaluate the safety and efficacy of this approach.

METHODS: A retrospective review of the medical record was performed on patients undergoing thoracoscopy at two centers from 1993 to 2007. Patients who left the operating room without a chest tube (CT) were included in this series. Patient demographics, type of operation and outcome were recorded.

RESULTS: A total of 319 thorascopic procedures were performed at the two institutions without the use of a CT. Ages ranged from 1 week to 39 years. Weight ranged from 1.3 kg to 117 kg. The cases performed included aortopexy, congenital diaphragmatic repair, excision of a bronchogenic cyst, exploratory thoracoscopy, lung biopsy, resection extralobar sequestration, Nuss procedure, patent ductus arteriosus ligation, resection/biopsy of mediastinal lesions, resection of esophageal duplication, excision of parathyroid adenoma, hiatal hernia repair, esophagomyotomy, and thymectomy. Within this group of thoracic operations, 182 patients underwent either lung biopsy or resection of an extralobar sequestration. Pulmonary lobectomy or segmentectomy patients were excluded. All patients had a chest radiograph in the recovery room. Only one developed a postoperative pneumothorax which occurred on postoperative day 2 following reintubation for respiratory failure. A chest tube was then inserted.

CONCLUSIONS: The use of routine CTs following thoracoscopy in children appears to be unnecessary as the absence of a chest tube in our series resulted in an intervention in 1 patient (0.3%). Elimination of the CT will allow for a much more tolerable post-operative course in most children.

THOROSCOPIC LUNG BIOPSY IN CHILDREN WITH ENDOLOOP ALLOWS SMALLER TROCAR SITES

Todd A. Ponsky and Steven S. Rothenberg

BACKGROUND: Thoracoscopy is replacing open lung biopsies because it is less invasive. However, most surgeons divide the lung with an endostapler which requires a 12mm trocar. Also the smallest endostapler requires a minimum of 4.5cm of intrathoracic space to open, making its use in patients less than 10kg impractical. This report describes the use of the Endoloop in small pediatric patients undergoing thoracoscopic lung biopsies.

MATERIALS AND METHODS: From 1993 to Feb 2007 69 patients underwent thoracoscopic lung biopsy for diagnosis and therapy. Ages ranged from 2 weeks to 4 years and weight from 2 kg to 22 kg. One 5mm and two 3mm trocars were used in all cases. In all cases two Endoloops were placed proximal to the segment of lung being biopsied and the lung was divided sharply distal to the Endoloops. The specimen was removed through the 5mm trocar site. The lung was re-expanded and no chest drains were left in post-operatively.

RESULTS: All 69 procedures were completed successfully thoracoscopically. Two biopsy specimens were obtained in most cases. Operative time ranged from 10- 35 minutes (average 20). There were no intra-operative complications. One patient required re-intubation and ventilator support on post-operative day 1 and developed a pneumothorax on post-operative day 2 requiring a chest tube. There were no other complications.

CONCLUSIONS: The thoracoscopic approach to lung biopsy is the preferred method of obtaining lung tissue for diagnosis. The use of the Endoloop technique is a safe and effective technique in small pediatric patients avoiding problems with the limited size of the chest cavity in patients less than 10kg and avoids the use of large incisions in a small child.

ANOMALOUS ORIGIN OF THE LEFT CORONARY ARTERY FROM THE RIGHT PULMONARY ARTERY

Ahmed Farouk, MD, Kenneth Zahka, MD, Ernest Siwik, MD, Alex Golden, MD, Mohsen Karimi, MD, Minhaz Uddin, MD, Hani Hennein, MD

Anomalous origin of the left coronary artery from the pulmonary artery (ALCAPA) is a rare congenital anomaly, one which requires a high index of suspicion in order to be diagnosed promptly and managed accurately. ALCAPA from the right branch pulmonary artery is a small subset of ALCAPA in general, with only few reported cases in the world literature. We report two cases of ALCAPA from the right pulmonary artery: the first case, an infant, presented in severe cardiac failure requiring preoperative extracorporeal membrane oxygenation for stabilization; and the second, a neonate, who presented with severe aortic coarctation. Both patients underwent successful complete surgical repair using a modified surgical technique, and are doing well in midterm follow up. We describe our operative technique and review the literature of this rare congenital anomaly.

RIGHT VENTRICULAR ANEURYSM FOLLOWING MODIFIED NORWOOD-SANO OPERATION FOR HYPOPLASTIC LEFT HEART SYNDROME

Mohsen Karimi, Ahmed Farouk, John Stork, Hani Hennein

Hypoplastic left heart syndrome is a rare congenital heart defect characterized by underdevelopment of left-sided heart structures, including the aortic arch. The contemporary surgical management of this anomaly includes the Norwood procedure and provision of pulmonary blood flow by either a modified Blalock-Taussig shunt or a right ventricle-to-pulmonary artery conduit, commonly referred to as the Sano shunt. We report on an unusual complication of the Sano shunt, that of a giant right ventricular pseudoaneurysm occurring at the shunt insertion site.

TEN-YEAR EXPERIENCE IN THE USE OF AORTIC HOMOGRIFT CONDUITS TO CONSTRUCT AN EXTRACARDIAC TOTAL CAVOPULMONARY CONNECTION

Hani Hennein, Ahmed Farouk, Mohsen Karimi, Francine Erenberg, Yasser Al-Khatib, Alex Golden, Ernest Siwik, Kenneth Zahka

BACKGROUND: Arrhythmias, pleural effusions, and thromboembolism remain major reasons for morbidity and mortality following the Fontan-Kreutzer operation. Use of an extracardiac homograft conduit to construct a total cavopulmonary connection may have advantages over intracardiac palliations by eliminating intra-atrial suture lines, frequently avoiding the use of pump-oxygenators, and minimizing the use of long-term warfarin anticoagulants.

METHODS: Over a ten-year period ending in 2007, 128 consecutive patients (mean age of 4.4 ± 3.2 yrs) underwent an extracardiac total cavopulmonary connection using an aortic homograft for a conduit. Cardiopulmonary bypass with a pump-oxygenator was used in 84 patients (66%), veno-venous bypass without an oxygenator in 9 (7%), and no extracorporeal support in 35 (27%). 117 patients (91%) were discharged on aspirin, and 4 (5%) on warfarin, the latter for supraventricular arrhythmias (N=2), heparin-induced thrombocytopenia (N=1), or use of a mechanical atrioventricular valve (N=1). Atrioventricular valvular regurgitation was graded qualitatively from 0 to 4+. Arrhythmias were defined as either supraventricular brady- or tachyarrhythmias, documented during the postoperative period. Prolonged pleural effusions were defined as those that lasted > 10 days. The pulmonary artery index (mm^2/m^2) was calculated as the cross-sectional area of the branch pulmonary arteries at the hilum, divided by the body surface area. Multiple regression analysis (SAS Institute, Cary, N.C., U.S.A.) was used to test for independent risk factors, and a probability value of ≤ 0.05 was considered to be statistically significant.

RESULTS: Over time, there has been a clear trend towards less use of mechanical circulatory support to perform the operation. 124 patients (97%) survived to hospital discharge and at 4.9 ± 2.1 years follow-up, there have been no late deaths, circuit revisions, conduit replacements, or documented thromboembolic events. Statistically significant independent risk factors for prolonged pleural effusions included the lack of a fenestration (36/102 vs. 2/26, $p < 0.001$) and a low pulmonary artery index (187 ± 25 vs. 218 ± 24 mm^2/m^2 , $p = 0.03$). Independent risk factors for arrhythmias were a right (vs. left) univentricular morphology (18/40 vs. 2/68, $p < 0.0001$), a low pulmonary artery index (176 ± 16 vs. 213 ± 26 mm^2/m^2 , $p = 0.0002$), and increased atrioventricular valvular regurgitation (1.50 ± 0.75 vs. 0.29 ± 0.53 , $p < 0.0001$). Independent risk factors for death included increased atrioventricular valvar regurgitation (2.5 ± 0.6 vs. 0.6 ± 0.4 , $p < 0.0001$) and a low pulmonary artery index (159 ± 10 vs. 210 ± 27 mm^2/m^2 , $p = 0.0004$).

CONCLUSIONS: Use of a homograft conduit to construct an extracardiac total cavopulmonary connection is a safe and effective procedure – applicable to most forms of univentricular morphologies. The operation can frequently be performed without a pump-oxygenator, and eliminates the need for long-term anticoagulation in most patients. Whereas a fenestration can decrease the duration of pleural effusions, significant risk factors for morbidity and mortality include $\geq 2+$ atrioventricular valvular regurgitation, right (vs. left) univentricular morphology, and a pulmonary artery index ≤ 180 mm^2/m^2 .

Section 6

Surgical Oncology

USING SENTINEL LYMPH NODE BIOPSY TECHNIQUE TO GUIDE SELECTIVE NECK DISSECTION IN PAPILLARY THYROID CARCINOMA

Scott Wilhelm, MD, FACS, Melanie Lynch, MD, Julian Kim, MD, FACS

BACKGROUND: The role of routine central compartment lymphadenectomy (CNLD) in the treatment of papillary thyroid carcinoma (PTC) is debated. We sought to use sentinel lymph node biopsy (SLNB) to guide CNLD.

METHODS: 18 patients with thyroid nodules confirmed as PTC (8 pts) or suspicious for PTC (10 pts) by biopsy underwent thyroidectomy with SLNB. Thyroid nodules were injected peritumorally with isosulfan blue dye. All blue lymph nodes were considered SLN and sent for frozen section. Patients with SLN positive for metastatic PTC underwent CNLD.

RESULTS: Final thyroid pathology was PTC in 16/18 patients (89%). SLN were identified in 12/18 patients (67%). Of 6 patients with no SLN identified, 4/6 had multifocal PTC. Comparing patients with unifocal and multifocal PTC, SLN was identified in 8/11 (73%) versus 2/5 (40%) patients respectively. 8 PTC positive SLN were identified in six patients, sized 4-20mm (7.1 +/- 5.3mm). All six patients had additional PTC positive nodes in the CNLD. 56% of SLN were <5mm.

CONCLUSIONS: SLNB technique for selective lymphadenectomy for patients with PTC is feasible. All patients with a SLN positive for PTC had other positive central compartment nodes. Most PTC positive SLN were 5mm or less, which altered the surgical management of these patients. In regard to non-identification of a SLN, only multifocal PTC, not tumor size or location was significant. Current practice ranges from routine CNLD (associated with increased operative morbidity) to selective CNLD based upon random intra-operative node biopsy. SLNB can guide CNLD for patients with PTC.

EFFECT OF PARATHYROIDECTOMY ON ANEMIA IN END-STAGE RENAL DISEASE PATIENTS WITH HYPERPARATHYROIDISM

Joseph A. Trunzo MD, Christopher R. McHenry MD*, James A. Schulak MD, Scott M. Wilhelm MD*

INTRODUCTION: Development of secondary and tertiary hyperparathyroidism (HPT) is a well known sequela of end-stage renal disease (ESRD). It has been suggested that parathyroidectomy for HPT in ESRD patients may result in improvement in anemia and improved response to erythropoietic stimulating drugs. Our goal was to examine the effect of parathyroidectomy on EPO dosing requirements and anemia in our ESRD patients.

METHODS: A retrospective review was conducted using electronic hospital and local dialysis unit database records to obtain pre-operative and post-operative laboratory values. Patients were included if pre-operative and 1 year post-operative hemoglobin (HB) and hematocrit (HCT) levels were available and excluded if they received a kidney transplant or had failure of parathyroidectomy during the 1 year follow up. Lab values were obtained pre-operatively and at 1, 2, and 12 months post-operatively. HB and HCT levels were averaged over 3 months prior to surgery and again at 9 to 12 month post surgery. Erythropoietin (EPO) dose, calcium (CA), phosphorus (PH), alkaline phosphatase (AP), albumin (ALB), and parathyroid hormone (PTH) were also obtained during these times.

6 RESULTS: Thirty-seven patients met inclusion criteria. Surgical therapy resulted in decreased PTH from 1871 ± 236 (mean \pm SEM) to 167 ± 29 pg/mL ($P < 0.001$) at 1 year. EPO dosing requirement showed a profound decline from $10,086 \pm 1721$ to $3,514 \pm 620$ units/treatment ($p = 0.004$). HB and HCT levels showed an upward trend at 1 year (11.4 ± 0.3 to 12.1 ± 0.2 g/dL and 35.7 ± 1.0 to $37.1 \pm 0.6\%$, respectively), though neither were statistically significant. AP levels dropped from 476 ± 65 to 103 ± 51 U/L ($p < 0.001$). CA, PH, and ALB levels showed no difference.

CONCLUSIONS: In ESRD, parathyroidectomy for HPT improves anemia of chronic disease and statistically lowers exogenous erythropoietin requirements. This suggests either increased endogenous EPO production or improved response at lower dosing levels. As a result, we propose refractory renal anemia as a secondary indication for surgical resection in this population.

INCIDENTAL THYROID NODULE: PATTERNS OF DIAGNOSIS AND MALIGNANCY RATE

Judy Jin MD¹, Scott M. Wilhelm MD, FACS¹, Christopher R. McHenry MD, FACS²

BACKGROUND: Incidental thyroid nodules are often found in patients during screening for medical conditions and follow up and staging for non-thyroid malignancies. The radiologic modality which led diagnosis of an incidental thyroid nodule and the rate of malignancy were determined.

METHODS: Between January 2001 and January 2008, we identified patients from a prospectively collected database who were referred for evaluation of incidental thyroid nodules. The rate of malignancy was determined for incidental thyroid nodules based on the imaging modality of detection and the presence and type of pre-existing malignancy. Fisher's exact test (FET) was used to compare categorical data; and a p-value less than 0.05 was considered statistically significant.

RESULTS: 156 patients with incidental thyroid nodules were identified, 105 (67%) as a result of screening for metastases from a primary malignancy. These included gastrointestinal (n=46) and non-gastrointestinal (n=59) tumors (breast=20, genitourinary=14, melanoma=9, lung=8 and blood=8). The two most frequent radiologic modalities which detected incidental nodules were CT (54%) and PET (13%) scans. Mean nodule size was 2.1 ± 1.1 cm. 136 patients (87%) underwent fine needle biopsy (FNB) of the thyroid nodules; 62 were benign, 56 were indeterminate (follicular=39, Hurthle cell=6, non-diagnostic=11), and 9 were malignant. FNB revealed a thyroid neoplasm in 44% of patients with a non-thyroid malignancy and 49% of patients without a pre-existing malignancy. Patients with gastrointestinal malignancy had a significantly lower rate of thyroid neoplasm when compared with non-gastrointestinal malignancy (31% versus 49%, $p=0.01$). Of the patients who underwent surgical resection based on biopsy results (n=67), 22 (14%) of the study population had thyroid malignancy. This represented an 11% malignancy rate in patients without pre-existing malignancy versus 15% in a patient with a known pre-existing malignancy. Of the 19 patients with a hypermetabolic nodule identified on PET scan, 32% had a thyroid cancer. In patients whose initial diagnostic modality was CT, the rate of malignancy was only 12% ($p<0.001$).

CONCLUSION: In selected patients with incidental thyroid nodules, the rate of malignancy is higher than the rates traditionally reported for nodules found during physical exam. There was no overall difference in thyroid malignancy in patients with or without pre-existing malignancy. However, patients with a history of a non-gastrointestinal malignancy do appear to have a higher likelihood of harboring a malignant thyroid nodule than patients with gastrointestinal malignancies. Nodules identified on PET scan have a higher rate of malignancy than nodules identified by CT scan, which warrants more aggressive management.

HOW MANY DIAGNOSTIC ROADS MUST AN ADRENAL TUMOR WALK DOWN?

Roy Phityakorn and Scott Wilhelm

OBJECTIVE: Present the diagnostic evaluation of a patient with human immunodeficiency virus (HIV) and an adrenal mass.

METHODS: We reviewed the laboratory, radiographic, and microscopic findings of a patient with HIV and an adrenal mass. We reviewed the medical literature regarding adrenal tumors in HIV patients and adrenal adenomatoid tumors (AAT).

RESULTS: A 22 year-old male with HIV complained of dyspnea. Computed tomographic (CT) scan of his chest was normal, but noted an incidental right adrenal mass. A subsequent abdominal/pelvic CT scan, adrenal hormonal work-up, MRI, and PET scan were performed by his physician. The patient was also scheduled for adrenal biopsy, but was referred to our endocrine surgery service for a second opinion. The differential diagnosis included: adrenal adenoma, adrenalitis secondary to cytomegalovirus or mycobacterium, or malignancy. We performed a laparoscopic right adrenalectomy. Final pathology was consistent with an AAT (only 25 total described cases). This is the second case in the literature of an AAT in a patient with HIV.

6 CONCLUSION: The work-up of an adrenal mass in HIV patients represents a diagnostic challenge. Surgeons must be willing to lead a multi-disciplinary team to focus the diagnostic work-up and prevent unnecessary testing.

A MIXED PANCREATIC ENDOCRINE TUMOR AND CLEAR CELL CARCINOMA MIMICKING RENAL CELL CARCINOMA

Amber A. Petrolla, MD; Jeffrey M. Hardacre, MD; Joseph E. Willis, MD; Gregory T. MacLennan, MD; Wei Xin, MD, PhD

We report a case of a mixed pancreatic tumor consisting of endocrine tumor and clear cell carcinoma in a 76-year-old man. The patient was originally evaluated for hematuria and subsequently diagnosed with urinary bladder infection. During the initial workup, the computed tomography scan revealed a 2-cm solid mass in the pancreatic body. Endoscopic ultrasound showed a 2.2-cm round, sharply demarcated mass consistent with an endocrine tumor. The patient had no medical history of von Hippel-Lindau disease or renal cell carcinoma. A distal pancreatectomy was performed. Grossly, we found a solitary 2.18 x 1.6-cm yellow-brown well-circumscribed pancreatic mass with central hemorrhage. Microscopic findings revealed a mixed pancreatic tumor with 2 distinct areas of endocrine tumor and clear cell carcinoma components. The 2 components had different immunohistochemical staining patterns, consistent with neuroendocrine tumor and renal cell carcinoma, respectively, as summarized in the Table. Extensive workup did not show any evidence of primary renal cell carcinoma or other malignant neoplasm (up to 8 months after surgery). The molecular analysis performed on clear cell carcinoma derived from laser microdissection did not reveal K-ras mutation. To our knowledge, this is a new entity of mixed pancreatic endocrine tumor and clear cell carcinoma, which has never been reported. The clear cell carcinoma component mimics the histology and immunohistochemical profile of renal cell carcinoma, and it does not express the neuroendocrine markers as clear cell endocrine tumor does. It also does not express HMB-45, which differentiates it from sugar cell tumor.

Immunohistochemical Profile of Components of Mixed Pancreatic Tumor		
Immunohistochemical Stain	Endocrine Tumor Component	Clear Cell Carcioma Component
Chromogranin	Positive	Negative
Synaptophysin	Positive	Negative
Cytokeratin	Positive	Positive
HMB-45	Negative	Negative
Renal cell carcinoma antigen	Negative	Positive
CD10	Negative	Positive

OPTIMAL NUMBER OF RADIOACTIVE SENTINEL LYMPH NODES TO REMOVE FOR ACCURATE AXILLARY STAGING OF BREAST CANCER

Melanie A Lynch, MD, Jashaun Jackson, Rosemary A Leeming, MD, Julian A Kim, MD

BACKGROUND: Although sentinel lymph node (SLN) biopsy is the standard technique for staging the axilla of clinically node negative breast cancer, the optimal number of radioactive SLN to remove to ensure accuracy and minimize morbidity is still actively debated. The purpose of this study was to determine the minimum number of SLNs to excise to ensure accurate axillary staging of SLN positive patients.

METHODS: One hundred twenty six patients with invasive breast cancer underwent SLN biopsy by periareolar injection of radiolabeled technetium sulfur colloid on the day of surgery. The sequence in which SLNs were removed and the corresponding ex vivo radioactive counts were recorded. SLNs were removed until radioactive counts in the axilla were <10% the ex vivo counts of the hottest SLN.

RESULTS: A radioactive SLN was identified in every patient. The mean number of SLNs identified was 2.86 (range: 1-8). Clinicopathologic features associated with a positive SLN included a palpable tumor ($p=0.0035$), increasing tumor size ($p=0.0039$), increasing histologic grade ($p=0.0234$), and angiolymphatic invasion ($p<0.001$). The highest radioactive counts were found in the first node in 100 patients (79.4%), the second node in 15 (11.9%) and the third or later node in 11 patients (8.7%). Among the 38 patients with a positive SLN (30.2%), the hottest node was the first positive SLN in 27 patients (71.1%). The first positive SLN was the first node removed in 31 patients (81.6%), following the second node in 37 patients (97.4%) and was removed in all patients by the third SLN.

CONCLUSION: These data support the trend of limiting SLN biopsy to 2-3 lymph nodes. Removing all SLN with radioactive counts > 10% of the ex vivo counts of the hottest SLN did not increase accuracy.

UTILITY OF I-123 THYROID UPTAKE SCAN IN INCIDENTAL THYROID NODULES: AN OLD TEST WITH A NEW ROLE

Scott Wilhelm, MD

BACKGROUND: Incidentally discovered thyroid nodules are being seen more frequently. Biopsy is warranted for nodules ≥ 1 cm. In a multinodular thyroid, determining which nodule to biopsy may be challenging. The aims of this study were to determine: 1) if an I-123 Thyroid Uptake Scan (TUS) could help guide fine needle aspiration biopsy (FNABx) of incidental thyroid nodules and 2) how well TUS findings correlate with final nodule pathology.

METHODS: This is a retrospective review of 71 patients referred for evaluation of an incidentally discovered thyroid nodule between 5/2005-8/2007. All patients underwent thyroid ultrasound. In patients with a multinodular thyroid with 2 or more non-dominant (similar appearing) nodules ≥ 1 cm, an I-123 TUS was performed to look for "cold" nodules, to help limit and guide FNABx. Sensitivity and specificity for TUS were calculated.

RESULTS: 14 of 71 (20%) patients had multinodular thyroid glands with no dominant nodule to biopsy. The average number of nodules per patient was 5.3 (range 2-12), with an average size disparity between nodules of only 0.4 cm (range 0.2-0.7 cm). TUS found an isolated "cold" nodule in 9/14 (64%) patients and a "hot" nodule in one (7%) patient. The "cold" nodules were then biopsied. "Cold" nodules were found to represent cancer by FNABx or surgical pathology in 3/9 (33%) pts. A normal or "hot" TUS corresponded to benign pathology in 5/5 (100%) pts. This gave a "cold" nodule 100% sensitivity for finding cancer in a thyroid nodule, and a specificity of 45%. Using a Bayesian Analysis model, a "cold" nodule had a positive likelihood ratio of 1.83 to be cancerous. To monitor all non-biopsied nodules, serial thyroid ultrasounds were done to look for nodule growth that might indicate malignancy. 8/11 pts with a benign biopsy have had 6-12 months of follow up with 1 or 2 ultrasounds with no growth in any nodule.

DISCUSSION: 20% of patients referred for evaluation of an incidentally discovered thyroid nodule were found to have multinodular disease, posing a question of which nodule to biopsy. I-123 TUS have generally been removed from the treatment algorithm of thyroid nodules due to the reliability of FNABx. In the setting of a non-dominant, multinodular goiter, this test demonstrated utility. It decreased unnecessary, multiple biopsies in 71% of our patients, guided biopsies to more suspicious lesions (three malignancies), and gave excellent overall sensitivity. This old test has gained a new role in the management of these challenging cases.

EARLY EXPERIENCE WITH INTRAOPERATIVE RADIOTHERAPY IN RESECTED PANCREATIC ADENOCARCINOMA

Craig Messick MD, Jeffrey M. Hardacre MD, Michael F. McGee MD, Christopher T. Siegel MD PhD, Thomas A. Stellato MD, Juan R. Sanabria MD, Timothy J. Kinsella MD, and James A. Schulak MD

BACKGROUND: The use of intraoperative radiotherapy (IORT) in patients with resected pancreatic adenocarcinoma (PA) has not been clearly defined. This study assesses complications, recurrence, and survival in patients undergoing IORT for resected PA.

METHODS: The medical records of our first 22 patients receiving IORT for resected PA (2001-2006) were reviewed and compared to a group of 27 consecutive patients not receiving IORT (2004-2006). IORT (median dose 1200cGy) was administered using a mobile linear accelerator.

RESULTS: The mean age of patients receiving IORT differed from that of patients not receiving IORT, 63 vs. 71 years, $p = 0.012$. A similar distribution of patients in both groups underwent proximal, distal, and total pancreatectomies. Mean estimated blood loss was greater in the IORT group (1159 ml) than in the no IORT group (696 ml), $p = 0.049$. Mean operative time tended to be greater in the IORT group than the no IORT group, 474 vs. 405 minutes, $p = 0.06$. There were no 30-day deaths in either group. At least one complication occurred in 50% (11/22) of patients receiving IORT and in 37% (10/27) not receiving IORT. Tumor size and resection margins were similar in both groups. Lymph node metastases were present in 95% (21/22) of patients in the IORT group but only 78% (21/27) in the no IORT group, $p = 0.06$. Of the patients available for follow-up, 88% (15/17) in the IORT group and 64% (16/25) in the no IORT group received similar adjuvant chemotherapy. Adjuvant external beam radiotherapy, median dose 6300cGy, was administered to 76% (13/17) of patients receiving IORT and to 64% (16/25) not receiving IORT. Local recurrence occurred in 18% (3/17) of patients in the IORT group and in 12% (3/25) in the no IORT group. The median time to local recurrence was 14 months in the IORT group and 7 months in the no IORT group. Distant recurrence was observed in 47% (8/17) of patients receiving IORT and in 32% (8/25) of patients not receiving IORT. The median time to distant recurrence was 11 months in the IORT group and 6.5 months in the no IORT group. Overall median survival did not significantly differ between the IORT and no IORT groups, 13 vs. 20 months. Further, stage-specific and location-specific survival did not differ between the groups.

CONCLUSIONS: Though limited in size and follow-up, our experience showed that complications, recurrence, and survival were not affected by IORT, but the time to recurrence may be longer with IORT. Further study of the role of IORT in resected PA is needed.

DOES IMATINIB MESYLATE (IM) AFFECT LONG-TERM OUTCOME IN PATIENTS WITH GASTROINTESTINAL STROMAL TUMORS (GISTS)?

Judy Jin MD, Jeffrey M. Hardacre MD FACS, Ann V. Robinson BA, Joseph E. Willis MD, Julian A. Kim MD FACS

INTRODUCTION: IM improves short-term survival in patients with metastatic GISTs. However, the long-term effect of IM on survival is not established. This study compares both short-term and long-term outcomes in case-matched patients with GISTs treated with surgery and/or IM.

METHODS: We identified 84 patients with c-KIT+ GISTs in our tumor registry from 1995 through 2005. Demographics, operative data, pathology data, systemic therapy, and survival were collected and analyzed. Survival was estimated using Kaplan-Meier and differences analyzed by log rank test.

RESULTS: The mean age of the patients was 64 years and the mean follow-up was 3.2 years. Sixty-four patients (76%) had a complete surgical resection, while the remainder had an incomplete resection or metastatic disease. IM was administered to 20 patients for primary organ-confined disease (35%), metastatic disease (25%), recurrent disease (25%), and locally-advanced disease (15%). Patients with a gastric primary demonstrated the best overall survival as compared to small intestine, colorectal or retroperitoneal ($p=0.005$). When 19 patients who received IM were case-matched for tumor size and extent of disease to patients who received surgery alone, the proportion of patients surviving 2 years was significantly higher in the IM-treated group (94% vs. 73%). However, the overall survival of patients treated with IM was not significantly improved as compared to patients treated with surgery alone ($p=0.665$).

CONCLUSION: Our data confirm that IM increases short-term survival in patients with GISTs. However, 5-year and overall survival was not improved, which emphasizes the importance of long-term follow-up of patients enrolled in prospective, randomized trials.

LAPAROSCOPIC AND HAND-ASSISTED DISTAL PANCREATECTOMY

Laxa BU, Carbonell AM, Cobb WS, Rosen MJ, Hardacre JM, Mçeel KL, Harold KL.

With the increased use of computed tomography, discovering incidental pancreatic lesions has become commonplace. Lesions in the distal pancreas lend themselves well to laparoscopic resection. We reviewed our experience with laparoscopic distal pancreatectomy. During the study period, 32 distal pancreatectomies were performed. There were 20 females. Mean patient age was 58.0 (23-83) years and mean body mass index was 29.9 (19.9-44.7) kg/m². Technique was laparoscopic (25) or hand-assisted (7), with one conversion in each group. The spleen was preserved in six patients (18.8%). Mean operative time overall was 238 (140-515) minutes; hand-assisted (222 minutes) and laparoscopic (254 minutes). Estimated blood loss averaged 221 (50-1800) ml. Mean tumor size was 2.7 (0.6-7) cm. Tumor pathology was serous cystadenoma (10), neuroendocrine tumor (6), mucinous cystic neoplasm (4), IPMN (4), adenocarcinoma (3), solid pseudopapillary neoplasm (1), other (4). Mean length of stay was 5 (3-11) days. Complications were: pancreatic fistula (6), wound infection (2), pulmonary embolism (1), pancreatitis (1), myocardial infarction (1), postoperative bleeding (2). There were no perioperative deaths. All pancreatic fistulas resolved with conservative management.

PANCREATIC RESECTION IN OCTOGENARIANS

Hardacre JM, Simo K, McGee MF, Stellato TA, Schulak JA

BACKGROUND: Pancreatectomy in patients ≥ 70 years of age is associated with acceptable rates of morbidity, mortality, and survival. Few studies exist evaluating outcomes in patients ≥ 80 years of age, an age group increasing in size the United States. This study analyzes the outcome of pancreatectomy in patients ≥ 80 years of age.

METHODS: The medical records of 27 patients ≥ 80 years of age undergoing pancreatectomy at our institution from 1995 through 2007 were reviewed. Outcomes including morbidity, mortality, and survival were analyzed.

RESULTS: The mean and median age of the patients was 82 years, range 80-89. Twenty-three of 27 were operated on from 2000 through 2007. Fifty-six percent (15/27) were female. Seventy-eight percent (21/27) were ASA class 3. Twenty-two (81%) underwent pancreaticoduodenectomy (PD), four (15%), underwent distal pancreatectomy/splenectomy (DPS), and one (4%) underwent total pancreatectomy. Operative time averaged 402 minutes for PD and 238 minutes for DPS. Estimated blood loss averaged 680 ml for PD and 900 ml for DPS. Fifty-four percent of patients received a blood transfusion. The overall median length of stay was 12 days, 16.5 (range 5-51) for PD and 6.5 (range 5-12) for DPS. Seventy-eight percent (21/27) underwent surgery for malignancy, 15% (4/27) for a pre-malignant condition, and seven percent (2/27) for a benign condition. Fifty percent (10/20) of patients with adenocarcinoma had a margin-positive resection and 70% (14/20) had lymph node metastases. There were no 30-day or in-hospital deaths. Seventy percent of patients suffered a post-operative complication. The most common complications were UTI (22%), bleeding (19%), wound infection (19%), delayed gastric emptying (16%), and atrial fibrillation/flutter (15%). Seven patients (26%) underwent a second operation. Overall median, one-year, two-year, and five-year survival rates were 13.5 months, 53.3%, 48.9%, and 21.9%. For patients with cancer, the median, one-year, two-year, and five-year survival rates were 11.1 months, 40.5%, 34.7%, and 11.6%. For patients without cancer, the median, one-year, two-year, and five-year survival rates were 102.5 months, 100%, 100%, and 60% ($p < 0.016$ when compared to patients with cancer).

CONCLUSIONS: Pancreatectomy in patients ≥ 80 years of age can be performed with a low risk of mortality but with significant morbidity. Long-term survival can be achieved. Patient selection will be increasingly important in offering pancreatectomy to our aging population.

THE IMPACT OF RESECTION MARGIN STATUS AND POST-OPERATIVE CA19-9 LEVELS ON SURVIVAL AND PATTERNS OF RECURRENCE FOLLOWING POST-OPERATIVE HIGH-DOSE RADIOTHERAPY WITH 5FU-BASED CONCURRENT CHEMOTHERAPY FOR RESECTABLE PANCREATIC CANCER

Timothy J. Kinsella, M.D., Yuji Seo, M.D., Joseph Willis, M.D., Thomas A. Stellato, M.D., Christopher T. Siegel, M.D., Deborah Harpp, B.S.E., B.S.N., James K. Willson, M.D., Joanna Brell, M.D., Joseph Gibbons, M.D., Smitha A. Krishnamurthi, M.D., Juan R. Sanabria, Jeffrey M. Hardacre, M.D., and James P. Schulak, M.D.

OBJECTIVES: To analyze the impact of surgical margins and other clinicopathological data on treatment outcomes on 75 consecutive patients treated from 1999-2006 by initial potentially curative surgery (\pm intraoperative radiotherapy), followed by high-dose 3-D conformal radiation therapy and concomitant fluoropyrimidine based chemotherapy (FP-CRT).

METHODS: All clinical and pathological data on this patient cohort were analyzed by actuarial Kaplan-Meier survival methodology and by univariate and multivariate Cox proportional hazards methods to measure effects on survival and patterns of failure.

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RESULTS: With a median follow-up of 28 months, the median, 2-year and 5-year overall survival (OS) rates were 18.1 months, 41% and 23.6% respectively. Disease-free survival (DFS) rates were of 11.4 months, 35% and 20%, respectively. Only 2 clinicopathological features, positive (≤ 1 mm) surgical margins ($p < 0.05$) and a 2-fold (> 70 U/ml) elevation of the post-operative serum CA19-9 ($p < 0.001$) impacted OS and DFS. In patients with negative (> 1 mm) surgical margins and a low (≤ 70 U/ml) post-operative CA19-9, the projected 2- and 5-year OS were 80% and 65%, respectively, compared to 40% and 10% with positive surgical margins and a low CA19-9 and to 10% and 0% with positive or negative surgical margins and a high (> 70 U/ml) CA19-9. Positive surgical margins ($p < 0.001$) and an elevated post-operative CA19-9 ($p < 0.001$) also predicted early development of distant metastases, while isolated loco-regional failure was less common and not affected by these or other clinicopathological features.

CONCLUSIONS: Using this FP-CRT regimen following surgical resection (\pm IORT), positive surgical margins and an elevated (2-fold) post-operative serum CA19-9 level predicted for reduced survival and early development of distant metastatic disease. This regimen was generally well tolerated and isolated loco-regional failure was uncommon.

THE DEVELOPMENT OF A SWINE MODEL OF SECONDARY LIVER TUMORS FROM A GENETICALLY INDUCED SWINE FIBROBLASTS CELL LINE.

Abbas R. MD, Robinson, A., Adam S., PhD, Okada S., Kim J. MD, Christopher Counter, PhD and Sanabria J. MD MSc. Department of Surgery, University Hospitals – Case Medical Center, Case Western Reserve University, Cleveland, OH and Department of Pharmacology, Duke University, Durham, NC

Swine models of secondary liver tumors may demonstrate to be an ideal model to study the efficacy of surgical and ablative treatment options available for liver tumors. The purpose of the present studies was to develop a secondary liver tumor in a large animal model. Fibroblasts from swine were isolated from ear lobule; cells then were transfected with amphotropic retroviruses encoded with human genetic (hTERT, p5300, cyclinD-1, CDK4R24C, Myc T58A, RASG12V) material. Transformed cell lines were inoculated into swine under tacrolimus based immunosuppression (n=4). Isolates from first pass were cultured and then inoculated as a second pass into 1) nude immunodeficient mice (n=5), 2) immune intact wild mice (n=2) and, 3) porcine animals without immunosuppression (n=2). Tumor growth was evident in 75% of immunosuppressed swines. One animal die with diarrhea and failure to thrive before the completion of experiment (3weçs). Growth of tumors was slow in two animals while in one animal tumor was larger with a peak growth of 42mm at three weçs. All growths showed to be malignant on histology. Cell morphology changed from initial cell line as compared with cell isolates after first pass. Tumor growth was evident in 100% of the nude immunodeficient mice with a peak size of 22mm (17+5mm, Mean+SD) at the time of sacrifice (3weçs). Tumor growth was evident in all wild mice with a peak size of 8.9mm at the end of the third weç. Tumor growth in swine was characterized for slow growth with a peak size of 8mm at three weçs. Characterization of new mutations in cell lines after first pass is the matter of current studies. Further changes may produce a more rapid growth of genetically induced tumorigenic cells in the immune-intact swine.

OFTALMIC ACID CONCENTRATION AND GLUTATHIONE TURN-OVER IN SECONDARY LIVER TUMORS SUBSISTENCE AND GROWTH.

R. Abbas MD¹, K. Subramanian MS², H. Brunengraber MD PhD² and J. Sanabria MD, MSc¹.

Available tumors markers have low sensitivity and specificity for the diagnosis of primary and secondary liver tumors. The purpose of the present study was to evaluate the oxidoreductive status of the liver and its metabolite as surrogates of tumor subsistence and growth.

EXPERIMENTAL DESIGN: Ophthalmic acid concentration and Glutathione turnover were measured by Gas Chromatography- Mass spectrometry in the serum of rabbits (n=6) on their healthy state and in the state of tumor growth after implantation of VX2 carcinoma on animal livers.

MATERIAL AND METHODS: animals were loaded with Deuterated water (D₂O) at 2.5% of their total body water (TBW) through an intraperitoneal injection and maintained at 4%TBW label by oral ingestion. As plasma enrichment was accomplished, daily blood draws were taken for 3days. Enrichment was performed before tumor implantation and 12days after tumor implantation. The tumor growth was allowed for a period of 14 days when animals were sacrificed. Livers were removed and slides of tissue from normal and from tumor growth were submitted for pathological studies.

RESULTS: Tumor growth was found in 100% (6/6) of the animals. Its size was XXX+XX (M±SD in mm). A significant increase in Ophthalmic acid concentration was observed in animals after tumor implantation when compared to the Ophthalmic acid concentration on same animals previous tumor implantation (healthy status, p<0.05, paired t-test for each point, and ANOVA for all points). Similar findings were found in the turn-over rate of Glutathione (see Table 1).

TABLE 1

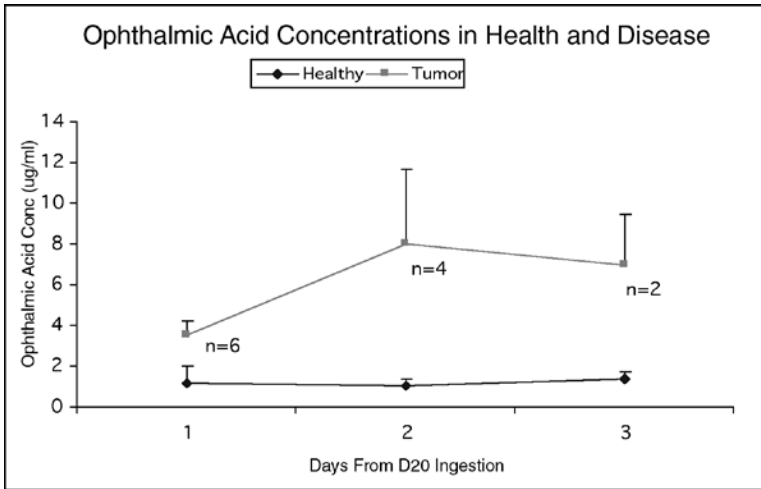
Ophthalmic acid concentration and Glutathione turn over in the Rabbit VX2 model before and after tumor implantation and growth.

Time(h) (n=6)	Ophthalmic <u>BTI</u>	Ophthalmic <u>ATI</u>	GSH/GSSG <u>BTI</u>	GSH/GSSG <u>ATI</u>
24 hours (M±SD)				
48 hours				
72 hours				
TOTAL				

*p<0.01 by t-test paired; **p<0.05 by ANOVA.

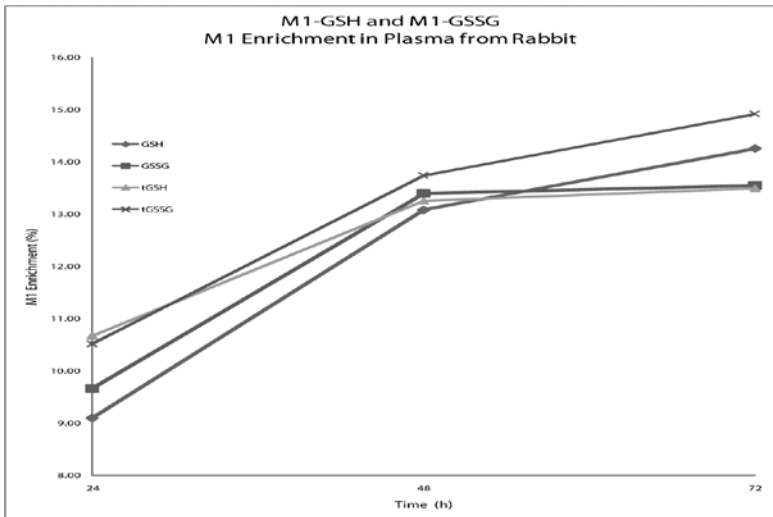
BTI= before tumor implantation; ATI= after tumor implantation.

CONCLUSIONS: Ophthalmic acid concentration and Glutathione turnover significantly differed in rabbits before and after tumor implantation and growth. Changes in the oxidative-redox state of livers with subsequent increase in Ophthalmic acid are reliable surrogates of tumor subsistence and growth.



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Glutathione turnover rates



The tumor behavior within the liver is proportionally implied by the increase in the turnover rate of the oxidized form of glutathione (GSSG) as well as by the significant rise in the concentration of ophthalmic acid (*Student's t test* p value ≤ 0.05 at 95% CI).

CONCLUSION: A higher rate metabolic oxidative stress seem to define the hallmark of liver tumor growth which gives way to the potential for ophthalmic acid levels and glutathione turnover rates to be used as liver tumor markers.

CYBERKNIFE THERAPY FOR NON-RESECTABLE TUMORS OF THE LIVER, BILIARY TREE AND PANCREAS.

Sanabria JR, MD MSc FRCSC FACS, Siegel C MD PhD FACS, Einstein D, MD

More than 120,000 individuals are diagnosed with tumors of the liver, biliary tree and pancreas every year in USA. Less than 20% of those lesions are amenable to definitive surgical management due to advance local disease or other medical condition that prohibit major surgery. Alternative therapy modalities have been developed, i.e. TACE, RFA with limited response and no significant impact on patient survival. Gamma radiation has been shown to be very effective in the treatment of brain tumors with more than 60% response rates. Nevertheless, this form of therapy has been limited, in abdominal neoplasms, due to the implicit tumor movement that occurs during the respiratory cycle. The development of a tracking system of endoscopically/laparoscopically placed fiducials has provided a technique for locking on the neoplasm by a computer controlled Robotic arm that delivered gamma radiation (Cyberknife). The purpose of the present study is to describe the preliminary results of 10 patients with non-resectable tumors of the liver, biliary tree and pancreas treated by Cyberknife. Radiation plans were developed, reviewed and implemented by a multidisciplinary team conformed by radiation oncologist, hepatobiliary surgeons, oncologist and physicist. 8 males and 2 females with the diagnoses of Cholangiocarcinoma (n=5), metastatic adenocarcinoma from colon (n=2), Hepatocellular carcinoma (n=2) and neuroendocrine tumor (n=1) underwent an average of 3 sessions with a delivery of 12,500+3,000rads (Mean+STDV) per session to previously defined target areas. Mean age of the patients were 82+7 years, with all of them having an ASA 3 risk for surgery. Patients had been followed up for 60+45 days with 100% survival rate. 80% of tumors had a response as judged by a decrease in size on two imaging modalities. Stabilization of the disease was observed in 20% of the patients. No major side effects, requiring admission to the hospital, have been observed. Cyberknife therapy is a new promising form of therapy for hepato-biliary and pancreatic neoplasms. Further studies are needed to define its role as primary and/or adjuvant form of therapy.

ABSENCE OF INTESTINAL GLUCONEOGENESIS IN RATS AND ZBD DOGS

Brunengraber, D., Sayre, C., Cendrowski, A., Sanabria, J. MDF MSc, and Previs, S. PhD

We investigated the potential for intestinal gluconeogenesis in 48 hr-fasted rats and in 48 hr-fasted hepatectomized dogs. The arterio-venous balances of concentration and labeling of [6,6-2H₂]glucose were determined across the intestine (in rats and dogs) and across the muscle and kidney (in dogs). The gas chromatography-mass spectrometry data were integrated using a recently developed method for integrating peaks that amplifies the apparent labeling while improving the precision of the measurements. In 48 hr-fasted rats receiving a constant infusion of [6,6-2H₂]glucose, we could not detect any difference in glucose enrichment across the intestine (n = 7 rats, with 4 pairs of samples per rat). To test whether deep hypoglycemia would induce intestinal glucose production, we did a series of experiments in 5 dogs acutely hepatectomized after 48 hr of fasting. When the liver was clamped, we injected a 1.1 mmol bolus of [6,6-2H₂]glucose. Over the next 2 hr, arterial glucose concentration decreased linearly from ~ 5 mM to ~ 0.5 mM. In parallel, arterial glucose enrichment decreased linearly from ~ 1.25% to ~ 0.25%. This resulted from some glucose production in the kidney, demonstrated by a small detectable difference in glucose enrichment between arterial and renal vein plasma. However, this renal glucose production did not prevent very deep hypoglycemia. In addition, there was no detectable difference in glucose enrichment or concentration between arterial and portal vein plasma (n = 5 dogs, with a minimum of 8 pairs of samples per dog). We conclude that there is no detectable intestinal gluconeogenesis in dogs and rats *in vivo*.

IMPACT OF POSTOPERATIVE RADIATION THERAPY ON POSTMASTECTOMY BREAST RECONSTRUCTION

Louis Keiler, M.D., Hooman Soltanian, M.D., Paula Silverman, M.D., Robert Shenk, M.D., Rosemary Leeming, M.D., Janice Lyons, M.D

PURPOSE: To analyze the effects of postoperative radiation therapy on breast reconstruction following modified radical mastectomy for breast cancer.

METHODS AND MATERIALS: Between 1988 and 2006, 73 women were treated with post-mastectomy radiation therapy (RT) after breast reconstruction. Their RT records were retrospectively reviewed. Information regarding comorbid conditions, systemic therapy, reconstruction method, and RT technique was obtained and correlated with acute RT toxicity, lymphedema, fat necrosis, telangiectasias, cosmetic outcome, and revision of reconstruction. Cosmesis was scored prospectively pre-RT and at follow-up using RTOG criteria.

RESULTS: The median duration of follow-up was 46 months. 37 had transverse rectus abdominus flap (TRAM), 25 had tissue expander (TE), 4 had latissimus dorsi flap (LD), and 7 had LD with a TE. 9 had revisions prior to RT and 13 had revisions following XRT. TRAM was less likely than TE to require a revision after XRT (9% vs. 35%; $p=0.016$) and overall (16% vs. 48%; $p=0.006$). Pre and post-RT cosmesis did not differ significantly between reconstruction types. Patients who received chemotherapy had worse cosmesis before RT, which persisted after RT ($p=0.037$). Moist or dry desquamation and extent of RT skin erythema did not affect cosmesis or revisions. Time between reconstruction and RT did not predict for cosmetic outcome, RT toxicity, or revisions.

CONCLUSION: Postmastectomy RT after breast reconstruction is well tolerated with 75% of patients having good or excellent cosmetic outcomes both before and after radiation. TE was more likely than TRAM reconstruction to require future surgical revision.

Section 7

**Transplantation and
Hepatobiliary Surgery**

SEQUENTIAL STEROID FREE, CALCINEURIN INHIBITOR FREE IMMUNOSUPPRESSION AFTER KIDNEY TRANSPLANTATION: OUTCOMES AND BARRIERS

Aparna Padiyar, Joshua J. Augustine, Kenneth A. Bodziak, Juan Sanabria, Christopher Siegel, Mark I. Aeder, James A. Schulak, Donald E. Hricik

Steroids (STR) and calcineurin inhibitors (CNIs) exhibit many toxicities that have prompted withdrawal trials. Since 1/06, we have treated kidney transplant recipients (KTRs) with a protocol consisting of induction antibody therapy (rabbit ATG for deceased, basiliximab for live-donor KTRs) and initial STR, tacrolimus (FK, target levels 8-10 ng/ml), and mycophenolate mofetil (MMF, 2 gm/d). STR are stopped on day 5, sirolimus (SLR) started on day 60, and FK stopped once SLR levels are 8-12 ng/ml. 50 KTRs (age 50±24 yrs; 26 males; 28 blacks; 30 live donor) have been enrolled. 3 early graft losses resulted from thrombosis (n=2) or death (n=1). Of the remaining 47 KTRs, 32 (68%) were withdrawn from STR. Reasons for not withdrawing STR included delayed graft function (DGF) (n=9), MMF intolerance (n=2), prior transplant (n=3), and prior STR therapy (n=1). Acute rejection (AR) occurred after STR withdrawal in 5 of 32 KTRs (16%). 10 KTRs are awaiting FK to SLR conversion. 23 of the remaining 37 KTRs have been converted. Timing of conversion was 91±39 days and was postponed most often because of leukopenia. In 14 KTRs, conversion was postponed indefinitely because of AR (n=5), leukopenia/anemia (n=2), wound healing problems (n=3), noncompliance (n=2), or AR in prior transplants (n=2). 4 of 23 KTRs were converted back from SLR to FK for AR (n=1) or SLR side effects (n=3). To date, 18 of 37 KTRs (49%) who have completed the protocol remain STR-free and CNI-free. Comparison of parameters before and 1 month after FK to SLR conversion show trends toward increased urine protein/creatinine ratio (.236±.12 to .417±.31; p=0.16) and increased GFR (62±14 to 65±17 ml/min; p=0.35). WBC (4,400±1700 to 3,700±1100 /mm³; p=0.031) and MMF dose (1.64±.5 to 1.44±.61 gm/d; p=0.027) decreased significantly. Our early experience indicates that STR-free, CNI-free immunosuppression can be achieved in KTRs treated with induction antibodies and maintained on SLR and MMF, with low rates of AR and good short-term graft function. However, DGF, AR, leukopenia/anemia and other side effects of SLR often prevent successful completion of the protocol. Long-term studies are needed to determine whether elimination of CNIs and MMF dose reductions driven by leukopenia/anemia will influence graft function and survival.

THE OBESE DECEASED DONOR: AN UNDERUTILIZED RESOURCE?

Mark I. Aeder, Maureen A. McBride, James A. SchulaK

Obesity has been implicated as a risk factor for multiple disease processes and the widespread use of obese donor organs has been limited by the perception that they are associated with a poorer long term outcome. It is estimated that 60-66 million adults and 5-9 million children in the US are obese, and that trend would be impacting the donor pool. We assessed the changes in donor BMI and examined the short and long term effect of obesity on graft survival (GS) in liver (LR) and pancreas recipients (PR). Methods: All 56550 deceased donors recovered from 1997-2005 were included. In 879 donors (1.6%), the BMI was not reported. Donors were stratified by BMI (<25, 25-30, 30-35 and >35), age and gender. Kaplan Meier GS results were computed for all transplanted LR and PR from 2000-4 from donors ≥ 18 years. Statistical comparisons were made using the logrank test. Results: During the 9 year span, the mean donor BMI increased from 25.6 to 26.4 and the median BMI from 24.6 to 25.7. The percentage of donors with a BMI <25 decreased from 49.4% to 44.9% while it increased in other groups: BMI 25-30 (27.4% to 31.1%), 30-35 (11.1% to 15.6%) and >35 (6.4% to 7.8%). The percentage of organs discarded was higher in the BMI 30-35 and >35 groups, indicating careful donor selection. The GS rates for LR were 79.9-81.4% at 12 mos., 71.8-72.7% at 36 mos., and 65.6-66% at 60 mos. For PR, the GS rates were 74.3-78.6% at 12 mos., 59.7-64.8% at 36 mos., and 50.2-57.9% at 60 mos. GS from adult donors was further stratified by age and BMI:

Graft Survival - Liver 5 year (%)				
AGE/BMI	<25	25-30	30-35	>35
18-34	69.3	70.2	66.7	69.5
35-44	66.2	68.0	68.6	57.5
45-54	63.1	63.6	64.8	58.6
55-64	57.3	62.5	55.7	53.6
65+	49.0	50.4	62.4	
Graft Survival - Pancreas 3 year (%)				
AGE/BMI	<25	25-30	30-35	
18-34	65.6	59.5	58.0	
35-44	58.1	56.0	65.3	
45-54	68.1	46.3		

A decreasing trend in GS by increasing donor age was observed in the LR but was not evident in the PR. There were no significant trends in liver or pancreas GS according to donor gender. Conclusion: Utilization of organs from obese donors based on BMI, regardless of gender, does not negatively impact liver or pancreas GS at 5 years. Liver graft survival is negatively impacted by rising donor age. Careful selection of donor organs is warranted but organs from the obese donors can be utilized with long term outcomes similar to non-obese donors.

IMPROVEMENT IN PROTEINURIA AND RENAL FUNCTION AFTER CONVERSION FROM TACROLIMUS/SIROLIMUS TO TACROLIMUS/ENTERIC COATED MYCOPHENOLIC SODIUM

Joshua J. Augustine, Michael S. Simonson, Kenneth A. Bodziak, Aparna Padiyar, Christopher Siegel, Juan R. Sanabria, Mark I. Aeder, James A. Schulak, Donald E. Hricik

Proteinuria has been described with sirolimus (SRL) therapy in kidney transplantation, often after late conversion from calcineurin inhibitors (CIs). In an ongoing conversion study of tacrolimus (TAC)/SRL to TAC/enteric coated mycophenolic sodium (EC-MPS), we analyzed data on proteinuria and renal function pre- and post-conversion. Six month follow-up data was available on 18 kidney recipients converted at a mean of 26 ± 16 (range: 3-57) months post-transplant. Patients abruptly stopped SRL with initiation of EC-MPS at a dose of 720 mg bid. Mean urinary albumin:creatinine ratio (ACR) fell from a baseline level of 157 ± 289 to 48 ± 81 ug/mg at six months ($p=0.001$), and fell in 16/18 patients. Nine patients had ACR levels consistent with microalbuminuria (30-300 ug/mg), and of these 7/9 converted to normal levels. Three patients had gross proteinuria by ACR (>300 ug/mg), and all converted to microalbuminuric levels post-conversion. There was no change in systolic or diastolic blood pressure after conversion, and no change in use or dose of angiotensin blocking agents. There was a trend for decreased weight after conversion (101 ± 31 to 96 ± 31 kg, $p=ns$). TAC blood levels increased significantly after conversion, from 5.1 ± 1.4 to 8.5 ± 2.7 ng/mL ($p=0.001$), and levels frequently increased despite stable TAC dosage after conversion. Decrease in ACR appeared independent of TAC levels however, as the four patients who had a drop in TAC levels at six months also had a reduction in ACR (61 ± 42 to 24 ± 20 ug/mg, $p=0.07$). There was an overall trend for a decrease in hemoglobin A1c (HbA1c), but in 6 patients with an increase in HbA1c at six months, ACR also decreased from 52 ± 32 to 8 ± 2 ug/mg ($p=0.03$). Finally, mean calculated GFR (MDRD) increased from 44 ± 12 pre- to 49 ± 13 ml/min/m³ post-conversion ($p=0.01$).

CONCLUSIONS: Conversion from TAC/SRL to TAC/EC-MPS therapy in kidney transplant recipients led to decreased albuminuria which appeared to be independent of blood pressure, TAC levels, and glycemic control, further supporting a putative role of SRL therapy in proteinuria. Conversion from SRL to EC-MPS also led to improvement in GFR by 6 months, despite an increase in TAC exposure.

HEMODIALYSIS VINTAGE, BLACK ETHNICITY, AND PRETRANSPLANTATION ANTIDONOR CELLULAR IMMUNITY IN KIDNEY TRANSPLANT RECIPIENTS

Augustine JJ, Poggio ED, Clemente M, Aeder MI, Bodziak KA, Schulak JA, Heeger PS, Hricik DE.

Prolonged exposure to dialysis before transplantation and black ethnicity are known risk factors for acute rejection and graft loss in kidney transplant recipients. Because the strength of the primed antidonor T cell repertoire before transplantation also is associated with rejection and graft dysfunction, this study sought to determine whether hemodialysis (HD) vintage and/or black ethnicity affected donor-directed T cell immunity. An enzyme-linked immunosorbent spot (ELISPOT) assay was used to measure the frequency of peripheral T cells that expressed IFN-gamma in response to donor stimulator cells before transplantation in 100 kidney recipients. Acute rejection occurred in 38% of ELISPOT (+) patients versus 14% of ELISPOT (-) patients ($P = 0.008$). The median (HD) vintage was 46 mo (0 to 125 mo) in ELISPOT (+) patients versus 24 mo (0 to 276 mo) in ELISPOT (-) patients ($P = 0.009$). Black recipients had a greater median HD vintage (55 versus 14 mo in nonblack recipients; $P < 0.001$). Black recipients with less HD exposure had a low incidence of an ELISPOT (+) test, similar to nonblack recipients. Among variables examined, only HD vintage remained a significant positive correlate with an ELISPOT (+) result (odds ratio per year of HD 1.3; $P = 0.003$). These data suggest that the risk for developing cross-reactive antidonor T cell immunity increases with longer HD vintage, providing an explanation for the previously observed relationship between increased dialysis exposure and worse posttransplantation outcome. Longer HD vintage may also explain the increased T cell alloreactivity that previously was observed in black kidney recipients.

LONG-TERM GRAFT OUTCOMES AFTER STEROID WITHDRAWAL IN AFRICAN AMERICAN KIDNEY TRANSPLANT RECIPIENTS RECEIVING SIROLIMUS AND TACROLIMUS

Hricik DE, Augustine JJ, Knauss TC, Bodziak KA, Aeder M, Siegel C, Schulak JA.

BACKGROUND: We previously reported excellent short-term outcomes in African American kidney transplant patients receiving tacrolimus/sirolimus and withdrawn from corticosteroid therapy three months after transplantation. We now report the long-term outcomes of patients subjected to this protocol.

METHODS: In all, 47 African American kidney transplant recipients were enrolled in an uncontrolled trial in which they were initially treated with sirolimus, tacrolimus, and corticosteroids, without antibody induction therapy. Eligible patients were withdrawn from prednisone between three and five months posttransplant, and followed for acute rejection and changes in renal function. Outcomes (group 1, n=32) were compared to those of patients deemed not to be candidates for steroid withdrawal (group 2, n=15).

RESULTS: After a mean follow-up of 48.5 months, 13 of 32 patients (41%) in group 1 developed acute rejection; only 13 patients (41%) remain steroid-free. Nine of 13 rejection episodes were associated with noncompliance. Graft loss occurred in 8 of 32 patients (25%) in group 1 and in 5 of 15 patients (33%) in group 2 (P=NS). Serum creatinine rose from 1.4+/-0.41 to 2.45+/-1.7 mg/dL in group 1 (P=0.004) and from 2.1+/-0.45 to 2.62+/-1.2 mg/dL (P=NS) in group 2. Among 13 patients in group 1 who remain steroid-free, creatinine concentration has risen from 1.28+/-0.37 prior to steroid withdrawal to 1.64+0.54 at last follow-up (P=0.027).

CONCLUSIONS: Late noncompliance and/or rejection in African Americans withdrawn from steroids have a negative impact on long-term graft function and survival. Steroid withdrawal may be associated with long-term deterioration of renal function, even in the absence of overt acute rejection.

NATIONAL ALLOCATION OF KIDNEYS - 2007

Mark Aeder, M.D., F.A.C.S.

Allocation of kidneys has been a controversial subject since the formation of UNOS in 1987. Originally based on the organ distribution system instituted by the Southeast Organ Procurement Network, the system has undergone modifications through the years to accommodate for the changing variables in the organ transplant process. Whereas the organ distribution of the extrarenal organs, liver, heart and lungs, has been prioritized to a "sickest first" mode, the kidney distribution has remained intact through the years with small modifications of the allocation through a tweaking of the points system. The national distribution of 6 antigen matched kidneys and then 0 antigen mismatched kidneys has been one of the cornerstones of the national sharing. The priority given to directed donation was instituted to meet the needs of a small percentage of donors that had other family members or friends in need of an organ. As the number of pediatric recipients increased and their time waiting lengthened, a priority was given to those under the age of 18. To protect the living donor and provide a safety net for their long term outcome, any living organ donor was allocated extra points so that their wait for a deceased organ would be minimized. The impact of tissue matching became less important and the allocation algorithm, which had been based on the closeness of the tissue match, was now reduced to a minor factor. With the elimination of the advantage given to antigen match, the distribution of the kidneys defaulted to time waiting on the list.

As the deceased donor waiting list has passed 70,000, the organ acceptance criteria became more liberalized. Organ donors who would not have been considered a decade earlier now became a suitable source for transplants. These older donors with vascular and metabolic difficulties were classified as expanded criteria donors and the successful utilization of these organs was a key factor in increasing the number of transplants performed. Although these organs were associated with a 70% greater risk of graft loss compared to the standard donor, in select and appropriately consented recipient populations, they provided an opportunity for dialysis independence. Owing to the increased use of these expanded donor kidneys, the number of transplanted deceased organs has reached 10,659 in 2006, and now graft failure of one of these grafts and required retransplantation has become a critical factor. It has led to the impetus to totally revamp the organ allocation process in an attempt to optimize the available organs.

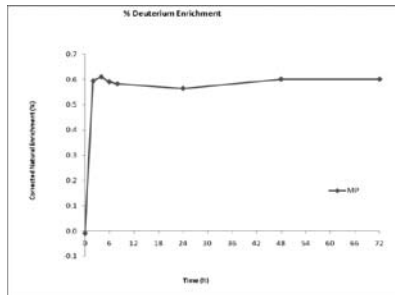
The proposed new kidney allocation system seeks to maximize the utility of each donated organ by matching the life expectancy of the recipient with an organ that should function for that length of time. Instead of time waiting, the key would be Life Years from Transplant (LYFT) and would be the measure of benefit between a candidate's estimated survival and their survival awaiting transplant on dialysis. LYFT would be calculated based on several candidate-specific factors including age, diabetes status, BMI, albumin, degree of sensitization (PRA), and degree of HLA mismatch with a potential donor. The organs would then be allocated with a greater justice to their distribution with the aim of increased utility.

GLUTATHIONE AND ALBUMIN TURN-OVER IN HUMAN LIVERS FROM NORMAL VS TRANSPLANTED GRAFTS: PRELIMINARY RESULTS

Sanabria JR MD MSc, Abbas R MD, Combo H PhD, Anderson V PhD, Pravis S PhD and Brunengraber H MD PhD

Liver disease has increased significantly during the last decade. Increasing prevalence of HCV infection and epidemic rates of both obesity and diabetes are the most contributory etiologies. Liver transplantation is an established therapy for end stage liver disease with recipient and graft survival rates above 90% at one year. Further implementation of this form of therapy to fulfill the demand is limited due to the scarcity of organs available for transplantation. Different mechanisms of hepatocyte injury involve common intercellular and intracellular pathways that render into the exhaustion of mitochondrial ATP production with membrane instability and cell termination. The present studies were designed to evaluate metabolic pathways patterns of human liver in normal and diseased organs as well as in liver grafts after implantation. 0.5%:0.05% of the total body water of 1) normal individuals, of 2) patients in the waiting list for liver transplantation and of 3) patients after liver transplantation with normal liver graft function was labeled with a mixture of Deuterium ($2H_2O$) and H_2O^{18} waters, respectively. The turn-over rates of Glutathione (GS), and Albumin (Alb) were found following Isotopomer analysis methods. Gas chromatography-mass spectrometry data were integrated using a recently developed method for consolidating peaks that amplifies the apparent labeling while improving the precision of the measurements. Protocols were IRB approved and patients were tested at the GCRC facility at Case University.

Figure 1. Deuterium enrichment in human subjects. 0.5%:0.05% of total body water form each individual was enriched with Deuterium ($2H_2O$) and H_2O^{18} waters.



Time (h)	Control - (n=3)		Waiting OLTx (n=2)		Post OLTx (n=2)	
	GSH	GSSG	GSH	GSSG	GSH	GSSG
0	0	0	0	0	0	0
2	0.45+0.09	0.26+0.18	0.09+0.1	0.54+0.12	0.49+0.04	0.23+0.08
2	0.77+0.14	0.42+0.18	0.2+0.07	0.69+0.23	0.59+0.22	0.39+0.19
6	1.01+0.07	0.61+0.30	0.29+0.11	1.07+0.08	1.21+0.1	0.54+0.21
8	1.29+0.15	0.91+0.24	0.27+0.2	1.32+0.21	1.31+0.09	0.88+0.17
24	1.40+0.14	1.12+0.27			1.27+0.11	0.98+0.22

Table 1. Glutathione reduce (GSH) and Glutathione oxidize (GSSG) turn over in healthy subjects, patients waiting for a liver transplant and patients after liver tx with normal liver graft function.

CONCLUSIONS: It appears patients waiting for liver transplant has a reduce turn over of reduce Glutathione compared with normal subjects and patients after liver transplant. Albumin turn over follow similar pattern.

LIVER RESECTION IN CIRRHOTICS VS NON-CIRRHOTICS PATIENTS

Sanabria JR MD MSc FACS, Weigel K RN, NP and Siegel C MD PhD FACS. The Division of Transplant and Hepatobiliary Surgery

The management of primary and secondary liver tumors has changed in recent years due to the development of new technical modalities of tumor control like ablation (RFA), embolization (TACE, MACE) or radiation (Cyberknife) or to the development of more effective forms of chemotherapy. One of the most frequent medical reasons for delay or avoid surgical therapy in patients with liver tumors is the presence of advanced fibrosis/cirrhosis. We hypothesized that patients with resectable liver tumors and compensate liver fibrosis may have similar mortality and morbidity that patients with no liver fibrosis. Patients who underwent liver resection of more than 2 anatomical segments from 10-2004 to 10-2007 were reviewed. Results are summarized in Table 1.

Table 1

Liver resection in patients with and without cirrhosis.

	Cirrhoic patients (n=11)	Non-cirrhotic patients (n=86)
Age (Mean+SD in years)	61+6.6	60.1+14.8
Gender (M:F)	9:2	47:39
Complications Grade 1	1	12
Grade 2	0	4
Grade 3	1	0
(Mortality) Grade 4 <30d	0	0
Grade 4 <60d	1	1
Number of lesions(Mean+SD)	2.9+3.5	3.9+3.8
Diameter of the lesions(cms)	3.0+1.9	5.6+1.0
Liver Tx	1	3

CONCLUSIONS: There were no significant differences in the rate of complications, mortality or number of liver transplant required in patients with or without cirrhosis after major liver resection. Liver resection should be offered to patients with resectable liver neoplasms as the primary approach. Liver transplantation is a complementary form of therapy in patients with resectable liver disease in selected patients.

GLUTATHIONE SPECIES CONCENTRATION IN HUMAN LIVERS FROM NON-CIRRHOTICS, CIRRHOTICS & TRANSPLANTED GRAFTS: PRELIMINARY RESULTS

Sanabria JR MD MSc^{1,2}, Abbas R.MD¹, Subramanian K. MS², Anderson V Ph¹³, Pravis S Ph,² and Brunengraber H MD PhD^{1,2}

Liver disease has increased significantly during the last decade mainly due to an increased prevalence of HCV infection and epidemic rates of both obesity and diabetes. Different mechanisms of hepatocyte injury involve common intercellular and intracellular pathways that render into the exhaustion of mitochondrial ATP production with membrane instability and cell self termination. Glutathione expresses the redox status of the mitochondria (GSH:GSSG) and since most plasma GSH and GSSG are released from the liver, the turnover of these species in plasma should reflect their metabolism inside the liver. The present studies were designed to evaluate Glutathione species concentration as a metabolic fingerprint of human liver in normal and disease and in liver grafts after implantation. 0.5% of the total body water of 1) normal individuals, of 2) patients in the waiting list for liver transplant and of 3) patients after liver transplantation with normal liver graft function was enriched with Deuterium (2H₂O). The concentrations of 2H-enriched GSH:GSSG were measured by liquid chromatography-mass spectrometry (LC-MS-MS). The assay involves the protection of the oxidizable SH of GSH (extant and derived from GSSG) by formation of thioethers. The Multi Reactions Monitoring (MRM) mode of LC-MS-MS cancels background signals and allows the measurement of very low species concentration. Results are summarized in Table 1.

Table 1

Glutathione reduce (GSH) and Glutathione oxidize (GSSG) concentrations in healthy subjects, patients waiting for a liver transplant and patients after liver transplantation with normal liver graft function.

Time (h)	Control - (n=3)		Waiting OLTx (n=1)		Post OLTx (n=2)	
	GSH	GSSG	GSH	GSSG	GSH	GSSG
0	0	0	0	0	0	0
2	0.45±0.09	0.26±0.18	0.09	0.54	0.49±0.04	0.23±0.08
2	0.77±0.14	0.42±0.18	0.2	0.69	0.59±0.22	0.39±0.19
6	1.01±0.07	0.61±0.30	0.29	1.07	1.21±0.1	0.54±0.21
8	1.29±0.15	0.91±0.24	0.27	1.32	1.31±0.09	0.88±0.17
24	1.40±0.14	1.12±0.27			1.27±0.11	0.98±0.22

CONCLUSIONS: it appears patient waiting for liver transplant has a decreased GSH:GSSG ratio and therefore liver redox balance when compared with normal subjects and patients after liver transplant. This assay may be important in the early detection of graft dysfunction or for the prediction of graft function during the evaluation of marginal donors.

METHOXYPOLYETHYLENE GLYCOL MODIFIED-ALBUMIN (PEG-ALB) ENHANCED THE COLD PRESERVATION PROPERTIES OF UW SOLUTION IN RAT LIVER GRAFTS

Abbas R. MD, Dingam D. PhD, Alo H., Malhotra D. MD PhD, Brunengraber H. MD PhD and Sanabria JR MD MSc. The Division of Transplant and Hepatobiliary Surgery, Departments of Surgery and Nutrition, University Hospitals – Case Medical Center, Case Western Reserve University, Cleveland OH and the Division of Nephrology, Department of Medicine, University of Toledo Medical Center, Toledo, OH.

Liver grafts preserved in cold undergo changes mainly manifested by morphological changes of the sinusoidal endothelium. Swollen and fragmented cytoplasm translates into poor portal blood flow, increase release of liver enzymes and low bile production upon liver reperfusion. Studies were performed to determine if the addition of higher molecular weight polyethylene glycol modified albumin to the University of Wisconsin (UW) preservation solution ameliorates the cold preservation injury of liver grafts. Mátoxypolyethylene glycol 5000 activated with cyanuric chloride was covalently coupled to human albumin (Peg-Alb) at multiple sites. The Isolated Perfused Rat Liver model was used (IPRL). Rat hepatocytes cell line was preserved in cold under similar preservation solutions. Effects were studied after rewarming of cells on Glutathione turn over by mass spectrometry. Apoptosis of SLC's on liver tissue and cell lines were evaluated by Tunel assay and flow-cytometry techniques.

Table 1. IPRL results of grafts preserved with UW solution and UW solution plus PEG- Alb. Values are given after 60minutes of perfusion with a sanguineous perfusate.

Group (n=4) *(preservation time in hours)	Portal Blood flow ml/g of liver/minute	AST Units/g of liver	Bile production l/g of liver
Control neg UW *(1h) Mean+SD	0.93+0.033**	2.1+1.08*	10.5+5.97
Control pos UW *(30h)	0.19+0.010	14.4+0.34	0+0
PEG-Alb & UW *(30h)	0.98+0.005**	28.4+1.03	3.5+7.54
Alb & UW *(30h)	0.05+0.007	26.9+2.45	0+0

** p<0.05 by ANOVA

Preliminary results showed Glutathione turnover was significantly decreased in all groups compared to negative controls. In contrast, apoptosis of SLC was similar in the PEG-Alb group when compared to the negative control group but significantly decreased in the PEG-Alb group when compared to other groups. Cell viability was similar in all experimental groups.

CONCLUSIONS: The addition of high molecular albumin to UW preservation solution appears to ameliorate endothelial injury of cold preserved liver grafts as judged by better portal vein blood flow, increased bile production and decreased SLC apoptosis. PEG-Alb appears to have no effect on hepatocyte viability.

Section 8

Trauma and Burns

RELATIONSHIP OF SERUM C-REACTIVE PROTEIN AND BLOOD GLUCOSE WITH INJURY SEVERITY AND HOSPITALIZATION IN PEDIATRIC TRAUMA CRITICAL CARE

Lisa N. Brunengraber, Ann V. Robinson, Walter J. Chwals*

INTRODUCTION: Serum markers of inflammation and of glucose production are known to reflect the acute metabolic response to injury. We hypothesized that monitoring of the early C-reactive protein (CRP) and blood glucose (BG) concentrations would correlate with clinical morbidity and outcome measures in pediatric intensive care unit (PICU) trauma patients.

METHODS: A five-year retrospective chart review of pediatric trauma patients in our PICU was conducted to establish the relationships between early (first 3 PICU days) serum CRP and BG concentrations, Injury Severity Score (ISS), and hospital length of stay (HLOS). Statistical significance ($p < 0.05$) was determined using Student's t-test.

RESULTS: Forty-two PICU trauma patients (8.0 ± 5.2 years) were evaluated. The early inflammatory response ($CRP \geq 10$ vs < 10 mg/dl) was significantly correlated to the glycemic response ($BG; 121 \pm 24$ vs 97.3 ± 14.2 mg/dl, $p < 0.05$). Severely injured patients ($ISS \geq 25$ vs < 25) were significantly more hyperglycemic ($BG; 156 \pm 56.9$ vs 125 ± 31.6 mg/dl, $p < 0.05$). Both increased inflammatory response ($CRP; 8.1 \pm 6.4$ vs 2.5 ± 3.5 mg/dl) and increased glycemic response ($BG; 111 \pm 15.9$ vs 97.4 ± 11.7 mg/dl) were independently and significantly associated with prolonged hospitalization ($HLOS > 7$ vs ≤ 7 days, $p < 0.05$).

CONCLUSIONS: This study establishes a significant relationship between the early inflammatory and glycemic injury response and the association of that response with PICU patient morbidity and outcome measures. These data may be useful in constructing a predictive clinical outcome scoring system, potentially applicable for serial assessment of critically ill pediatric populations.

COMPUTED TOMOGRAPHY BEFORE TRANSFER TO A LEVEL I PEDIATRIC TRAUMA CENTER RISKS SUBSTANTIALLY INCREASED RADIATION EXPOSURE

*Diya Alaedeen, Ann V. Robinson, Ellen Fitzenrider, Laura Cizmar, and Walter J. Chwals**

INTRODUCTION: Community hospitals commonly obtain CT imaging of pediatric trauma patients before triaging to a Level I pediatric trauma center (PTC). This practice potentially increases radiation exposure when imaging must be duplicated following transfer.

METHODS: A retrospective review of our Level 1 PTC registry from January 1, 2004 -December 31, 2006 was conducted. Level I and II trauma patients were grouped based on whether they had undergone outside CT examination (head and/or abdomen) at a referring hospital (Group 1) or received initial CT examination at our institution (Group 2). Sub-groups were analyzed based on whether duplicate CT examination was required at the PTC (Fischer's Exact Test).

RESULTS: A duplicate CT scan (within 4 hours of transfer) was required in 91% (30/33) of Group 1 transfer patients whereas no Group 2 patient required a duplicate scan (0/55 $p < 0.0001$). There was no significant difference within the groups for weight, age or ICU length of stay.

CONCLUSIONS: A significant number of pediatric trauma patients who receive CT scans at referring hospitals prior to transfer to a Level I PTC require duplicate scans of the same anatomic field(s) following transfer, exposing them to increase potential clinical risk and cost.

FEVER AND LEUKOCYTOSIS IN CRITICALLY ILL TRAUMA PATIENTS: IT'S NOT THE URINE*

Joseph F Golob Jr,¹ Jeffrey A. Claridge,¹ Mark J. Sando,¹ William R. Phipps,² Charles J. Yowler,¹ Adam M.A. Fadlalla,³ and Mark A. Malangoni¹

¹MetroHealth Medical Center Department of Surgery, Case Western Reserve University School of Medicine, Cleveland, Ohio. ²Trumbull Memorial Hospital, Department of Surgery and Critical Care, Cortland, Ohio. ³Cleveland State University, Department of Information Science, Cleveland, Ohio.

BACKGROUND: Infectious complications are a major cause of morbidity and mortality in critically ill trauma patients. Therefore, fever and leukocytosis often trigger an extensive laboratory workup that includes a urine culture (UCx). The purposes of this study were to: 1) Define the current practice for obtaining UCxs in trauma patients admitted to the surgical and trauma intensive care unit (STICU); and 2) determine if there is an association between fever or leukocytosis and urinary tract infections (UTIs) during the initial 14 hospital days.

METHODS: An 18-month retrospective cohort analysis was performed on consecutive trauma patients admitted for at least two days to the STICU at a level I trauma center. Data collected included demographics, injuries, and daily maximal temperature (Tmax), leukocyte count, and UCx results for the first 14 days. Fever and leukocytosis were defined as Tmax $\geq 38.5^{\circ}\text{C}$ and leukocyte count $\geq 12,000/\text{mm}^3$, respectively. Urinary tract infections were diagnosed with a positive UCx ($\geq 10^5$ organisms/mL of urine).

RESULTS: Five hundred ten patients were evaluated for a total of 3,839 patient-days. Their mean age and Injury Severity Score were 49 ± 1 years and 19 ± 1 points, respectively. Seventy-two percent were man and 91% had sustained blunt injuries.

Four hundred seven UCxs were obtained; 42 patients (8%) had 60 UTIs. The cohort had an indwelling urinary catheter for 97% of the patient-days, yielding an infection density of 16 UTIs/1,000 urinary catheter-days. There was significant association between obtaining a UCx and fever and between fever and leukocytosis (both, $p < 0.001$), but no association of UTI with fever, leukocytosis, or the combination of fever and leukocytosis. Analysis using temperature and leukocyte count as continuous variables identified no temperature or leukocyte range associated with UTIs. Independent risk factors for UTI calculated by logistic regression were female sex, older age, low Injury Severity Score, and no antibiotics within 24 h before the UCx was obtained.

CONCLUSIONS: The practice of obtaining a UCx from the STICU trauma patient was related to fever and fever with leukocytosis. However, neither fever nor leukocytosis nor both were associated with the UTIs. These data suggest that there is an unnecessary emphasis on UTI as a source of fever and leukocytosis in injured patients during their first 14 STICU days. Our results suggest that the paradigm for evaluating UTI as a cause of fever needs to be reevaluated in critically ill trauma patients.

ISOLATED CERVICAL SPINE FRACTURES IN THE ELDERLY: A DEADLY INJURY

Golob JF, Peerless JR, Yowler CJ, Como JJ, Patrick PA, Claridge JA.

BACKGROUND: Traumatic injury in the elderly is an increasing problem and studies have shown that elderly patients (≥ 65 years-old) with cervical spine fractures (CSF) and spinal cord injury (SCI) carry a mortality rate of 21-30%. However, little has been described with regard to outcomes for elderly patients with isolated CSF. **HYPOTHESIS:** Outcomes for elderly patients with isolated CSF will be similar to elderly patients with CSF and associated injuries or SCI.

METHODS: A 9-year retrospective analysis was performed on all patients ≥ 65 years-old admitted to a level I trauma center with any CSF. Primary outcomes were defined as favorable (discharge to home or rehabilitation hospital) or unfavorable (death, discharge to a long term acute care facility or a skilled nursing facility). Isolated CSF was defined as those fractures without associated injuries or SCI. Long-term mortality data was gathered from the Social Security Death Index.

RESULTS: A total of 177 patients with mean age of 78 ± 1 and injury severity score of 17 ± 1 were evaluated. Fifty-six percent were male and falls were the most common mechanism (62%). An unfavorable outcome was seen in 56% of the study population with a mortality rate of 25%. Associated injuries were seen in 57% of the population and 22% had SCI. Patients with SCI had a significantly higher mortality compared to patients without SCI (38% vs. 22%, $p=0.032$). However, there was no difference in unfavorable outcomes. Patients with isolated CSF had no differences in unfavorable outcomes compared to patients with SCI or associated injuries. Long-term survival analysis after discharge (mean = 2.8 y) demonstrated that patients with a favorable outcome had a significantly improved survival compared to patients with unfavorable outcomes ($p < 0.001$).

CONCLUSION: Isolated CSF were associated with an unfavorable outcome in the elderly population regardless of additional associated injuries or SCI. These unfavorable outcomes were also associated with long term mortality. Strategies to reduce morbidity and mortality in this devastating injury will be essential to improve outcomes and maximize resource utilization.

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THE “FEVER WORKUP” AND RESPIRATORY CULTURE PRACTICE IN CRITICALLY ILL TRAUMA PATIENTS

Claridge JA, Sando MJ, Golob JF, Fadlalla AM, Peerless JR, Yowler CJ.

INTRODUCTION: Due to the morbidity of infections, fever and leukocytosis(F&L) in critically ill patients often trigger a “workup” including a respiratory secretion culture(RCx). The rationale of this practice has not been thoroughly evaluated after trauma.

HYPOTHESIS: F&L would be associated with obtaining a RCx, but would not be associated with a positive culture or treating a respiratory infection in critically injured patients during the first 14 intensive care unit (ICU) days.

METHODS: An 18-month retrospective analysis was performed on consecutive ICU trauma patients admitted for ≥ 2 days to a level I trauma center. Data collected included demographics, injuries, RCxs(bronchoalveolar lavage or tracheal aspirate), and the presence of fever ($\geq 38.5^{\circ}\text{C}$) and leukocytosis($\geq 12,000/\text{mm}^3$) over the first 14 ICU days. A diagnosis of respiratory infection was defined by the clinicians’ decision for a ≥ 7 day course of antibiotics.

RESULTS: A total of 510 patients with a mean age of 49 and injury severity score of 19 were evaluated for a total of 3839 patient-days. 211 patients had 489 RCxs obtained (2.4RCxs/patient); 94 (19%) were obtained on consecutive days. Obtaining a Rcx was associated with fever (RR=4.8 95CI=4.1-5.8) and the combination of F&L (RR=2.6 95%CI=2.2-3.1), but not leukocytosis alone. Neither fever, leukocytosis, nor F&L predicted a positive RCx. 128 patients were treated for a respiratory infection. Treatment of respiratory infections was contrary to the RCx results 24% of the time. The sensitivity and specificity of a positive RCx being associated with respiratory infection was 97% and 46%, respectively.

CONCLUSIONS: F&L were associated with the decision to obtain RCxs, but neither were associated with positive RCxs. RCx results had a low specificity and did not consistently impact treatment decisions. Factors other than F&L alone should influence the decision to obtain RCxs during the first 14 days in the ICU after trauma.

PASTORAL CARE INTERVENTIONS SIGNIFICANTLY REDUCE PAIN AND ANXIETY IN BURN PATIENTS

A.A. Snedger, MDiv, R.B. Fratianna MD, FACS, L.C. Yurko, RN, BSN, C.P. Brandt, MD, FACS, C. J. Yowler, MD, FACS

MetroHealth Medical Center Campus of Case Western Reserve University, Cleveland, OH

INTRODUCTION: We have previously presented data from a pilot study of 42 adult burn patients involving the effect of pastoral care, including guided imagery, on pain and anxiety. The results appeared to demonstrate reduced pain and anxiety levels following pastoral care, but the small number of patients combined with the varying techniques used in the study precluded statistical analysis. We present expanded data from our ongoing research into pastoral care interventions in the burn center.

METHODS: 93 adult burn patients agreed to participate in the study. Demographic data including age, gender and current involvement in a faith-based community was collected. Using the Likert Visual Analogue Scale the patients self reported their pain and anxiety levels before and after pastoral interventions including prayer (P), spiritual/pastoral counseling (PC) and guided imagery (GI) including the specific "Breath of God" (BG) technique. The specific intervention was selected after discussion with the patient and was not randomized. Prayer = an act that brings one into closer contact with a higher power; pastoral counseling = the use of spiritual as well as psychological resources for spiritual, emotional and psychological healing; guided imagery = use of relaxation, rhythmic breathing and mental visualization to improve mood and/or physical, psychological and spiritual wellbeing.

RESULTS: Results remain significant independent of age, gender or current relationship to a faith-based community.

CONCLUSIONS: Pastoral care interventions including prayer, pastoral counseling and guided imagery including the "Breath of God" technique significantly reduce pain and anxiety levels in adult burn patients. Interventions by the pastoral care service are an important component of patient care in a burn center. It remains to be determined how long this effect lasts and whether one technique or another maybe more powerful in an individual patient.

MEASUREMENT OF NURSING WORKLOAD IN AN OUTPATIENT BURN CLINIC

L.C. Yurko, RN, BSN, L. Inman-Werner, RN, MSN, C.P. Brandt, MD, FACS, C. J. Yowler, MD, FACS, MetroHealth Medical Center/Case Western Reserve University, Cleveland, OH

INTRODUCTION: It is necessary to determine the actual nursing workload in an outpatient clinic in order to establish staffing ratios and appropriate billing for direct nursing care. We have previously presented data describing the inadequacy of using outpatient professional billing code levels in describing direct nursing workload in an outpatient burn clinic. This study describes the actual nursing time spent in direct patient care during the operation of a 24 hour outpatient clinic.

METHODS: We prospectively monitored all clinic visits over an eight week period. The nursing time spent in each patient encounter was listed by the nurse immediately following the visit. Time was divided into segments corresponding with professional billing codes and description of service provided. Results were analysis for visits occurring from 7AM to 7 PM, and 7 PM to 7 AM.

RESULTS: See Table

CONCLUSIONS: Currently, at our facility, nursing care can only be billed as a Level 1 technical charge. However this study shows that most visits require direct nursing time in excess of a Level I visit. Determining the direct nursing time required in an outpatient clinic can assist in determining appropriate staffing levels. It may also be utilized in discussions concerning appropriate coding and levels of reimbursement with Medicare and other third party payors.

RISK FACTORS FOR BURN WOUND INFECTIONS IN THE OUTPATIENT BURN PATIENT

T.L. Coffee, RN, CNP, C.P. Brandt, MD, FACS, C. J. Yowler, MD, FACS

MetroHealth Medical Center/Case Western Reserve University, Cleveland, OH

INTRODUCTION: Previous research on incidence and risk factors for burn wound infections concentrated on the inpatient burn population. However, the overwhelming majority of burn injuries are small and can be treated as outpatients. We conducted a prospective study on the incidence and risk factors for burn wound infections on patients treated in our outpatient burn center.

METHODS: All patients treated in our outpatient burn center were evaluated for inclusion from July 2005 until September 2006. Exclusion criteria included presentation to our clinic more than 72 hours post burn, systemic antibiotic usage prior to evaluation, age < 18, patients who did not return for follow up after their initial burn clinic visit or were admitted to the burn center on initial visit and then treated as outpatient. Data collected on initial evaluation included demographics, etiology, TBSA burned, topical treatment applied, history of diabetes mellitus, steroid use, malnutrition, homelessness, peripheral vascular disease, and immunocompromise. Standard burn dressings were then utilized. On subsequent visits all patient were evaluated for infection by one experienced burn practitioner based on clinical criteria. Antibiotics were prescribed and wound cultures were obtained and monitored for organism growth and antibiotic sensitivity.

RESULTS: A total of 2,267 outpatients were evaluated during this 13 month period, of which 486 met inclusion criteria and were prospectively studied. Mean age was 40 (range 18-88), mean TBSA 1.6 (0.1-10.0), mean third degree burn 0.29 (0-2.0). Two thirds of patient were male. The majority of burns resulted from either scald (46.7%) or flame injuries (29.8%). The overall infection rate was 4.9%. There was no statistical difference in burn incidence based on any of the risk factors except diabetes mellitus (infection rate 15%, $p = 0.02$). No cultures were positive for pathologic bacteria. No infection required admission or surgery.

CONCLUSIONS: Acknowledging the inaccuracy in the clinical diagnosis of burn wound infection, the incidence of clinical burn wound infection in patients treated without systemic antibiotics in our outpatient burn center is 4.9%. The only risk factor identified to statistically increase the incidence of infection was the presence of diabetes mellitus. Further prospective randomized studies of antibiotic use in outpatient burned diabetics is warranted.

IS THERE AN INDICATION FOR PROPHYLACTIC ANTIBIOTICS IN THE TREATMENT OF OUTPATIENT DIABETIC BURN PATIENTS?

T.L. Coffee, RN, CNP, C.P. Brandt, MD, FACS, C. J. Yowler, MD, FACS

MetroHealth Medical Center Campus of Case Western Reserve University, Cleveland, OH

INTRODUCTION: A previous study from our center found that the incidence of wound infections in burn patients treated without the use of systemic antibiotics was 4.9%. The only risk factor identified to statistically increase the incidence of infection was the presence of diabetes mellitus. The subgroup of 24 diabetic burn patients had an infection rate of 15%. We have extended our study concentrating on outpatient diabetic burn patients to further characterize the infections in this population.

METHODS: All patients treated in our outpatient burn center with a past medical history of diabetes mellitus from July 2005 through August 2007 were evaluated for inclusion. Exclusion criteria were patients age < 18, presentation to our burn clinic more than 72 hours post burn, systemic antibiotic usage prior to evaluation, failure to follow up after initial burn clinic visit or initial admission to the burn center. Data collected on initial evaluation included demographics, source of burn, TBSA burn, and topical treatment applied. Standard dressings were utilized. On subsequent visits the patients were evaluated for infection based on clinical criteria and antibiotics were prescribed in the presence of infection.

RESULTS: A total of 76 patients presented to the burn clinic with the diagnosis of diabetes mellitus and 4 were excluded due to antibiotic usage prior to initial evaluation in our burn clinic. Mean age was 50 (range 22 – 85), mean TBSA 1.2 (0.1-6.0), third degree burn 1.5 (0.1 – 3.0). Three quarters of the patients were male. Half of the burns resulted from scald injuries and the initial dressing applied was bacitracin and xeroform. Eight (11%) developed wound infection. Seven of these patients were successfully treated as outpatients with oral antibiotics. One third of the burns occurred below the knee and two thirds (62.3%) of those wounds became infected. Four patients required outpatient skin grafting, but all had third degree burns noted on initial evaluation; no patient required grafting due to progression of burn depth secondary to infection.

CONCLUSIONS: The incidence of wound infection in outpatient diabetic burn patients is 11%. The subgroup of diabetic patients with burns below the knee have an infection rate of 62% and prophylactic oral antibiotics may be indicated in this group. Despite this increased infection rate, the overwhelming majority of diabetic patients with minor burns (71/72) can be treated as outpatients for both their burns and any subsequent infections.

THERAPEUTIC ANTICOAGULATION IN TRAUMA PATIENTS: IS IT SAFE?

Golob JF, Claridge JA, Sando MJ, Kan JC, Yowler CJ, Malangoni MA.

BACKGROUND: Indications for therapeutic anticoagulation such as deep venous thrombosis (DVT) or pulmonary embolism (PE) are common in trauma patients; however the safety of anticoagulation treatment has not been determined in this patient population. The purpose of this study was to determine: 1) the incidence of complications using therapeutic anticoagulation in trauma patients and, 2) if any pre-treatment patient factors may be associated with these complications.

METHODS: A 30 month retrospective review was performed on all trauma patients ≥ 15 years old who were admitted to a level I trauma center and received therapeutic anticoagulation using either unfractionated heparin (UH) or fractionated heparin (FH). Over 40 individual patient characteristics including demographics, comorbidities, anticoagulation indications, and laboratory values were recorded. Complications of anticoagulation were documented and defined as any unanticipated discontinuation of the anticoagulant for bleeding or other adverse events.

RESULTS: One hundred and fourteen patients met inclusion criteria; 75 patients received UH only, 34 had FH only, and 5 received combinations of both UH and FH. The mean age was 44 ± 2 years with 74% males. The population had a mean injury severity score of 17 ± 1 and 25% had a penetrating injury. The most common indications for anticoagulation were DVT (46%), the need for therapeutic anticoagulation after vascular repair (18%), PE (13%), and atrial arrhythmia (10%). Five patients died (4%), three of whom had significant hemorrhage attributed to anticoagulation. Twenty-four patients (21%) had at least one anticoagulation complication. The most common complications were a sudden drop in hemoglobin concentration requiring subsequent blood transfusions (11 patients), surgical site bleeding (5 patients), and gastrointestinal hemorrhage (4 patients). Bivariate analysis comparing patients with and without complications identified the following variables as potential risk factors of complications related to anticoagulation: chronic obstructive pulmonary disease (COPD), liver disease, presence of an artificial heart valve, post-vascular surgery anticoagulation, lower initial platelet count, and treatment with UH. Anticoagulation for DVT or PE was associated with fewer complications. Logistic regression analysis identified COPD (OR=9.2, 95%CI=1.5-54.7), UH use (OR=3.8, 95%CI=1.1-13.0), and lower initial platelet count (OR=1.004, 95%CI=1.000-1.008) as being associated with complications. Patients receiving UH vs. FH differed in several characteristics including anticoagulation indication, comorbidities, as well as laboratory values.

CONCLUSION: Trauma patients receiving therapeutic anticoagulation have a 21% complication rate, and predicting which patients will develop a complication remains obscure. UH was associated with more complications; however there were significant differences in the UH and FH populations which may contribute to the safety profile. Further prospective studies are needed to determine which trauma patients and treatment regimen, if any, is appropriate for safely anticoagulating this high risk population.

TRAUMA TEAM ACTIVATION CAN BE TAILORED BY PRE-HOSPITAL CRITERIA

Claridge JA, Golob JF, McDonald AA, Kan JA, Wilczewski P, Malangoni MA, Yowler CJ.

BACKGROUND: Responses to trauma activations are triggered by predetermined criteria at individual trauma centers and utilize a large amount of resources to provide care for injured patients. The purpose of this study was to identify and evaluate which prehospital criteria did not require full trauma team activation and resources while maintaining or improving current standards of patient care.

METHODS: A two phase prospective study was carried out at a regional urban Level I trauma center over one year. Phase I involved collecting observational data to determine which trauma criteria could potentially be used to identify patients that could be evaluated by a lower level trauma activation (LowAct). LowAct involved a smaller response team with priority access to imaging. Phase II involved implementing a LowAct and prospectively evaluating the outcomes related to resources and patient care.

RESULTS: A total of 3104 patients were evaluated with 2076 patients enrolled over 6 months in phase I and 1037 enrolled in phase II. Three criteria out of the 36 studied were most commonly identified that were not associated with admission. These criteria were pedestrian struck by vehicle, high speed vehicular crash, and Glasgow Coma Score (GCS) 12-14. These were then used as triggers for LowAct in phase II. Comparisons between phase I and II of patients with these three identified criteria demonstrated that significantly less patients were admitted and there was significant reduction in resource allocation in patients in phase II. Follow up (mean = 3.8 days) of discharged patients treated by the LowAct during phase II demonstrated that 78% of patients felt they had adequate treatment and 9% required additional unplanned health care.

CONCLUSION: LowAct is appropriate for the following three criteria: pedestrian struck by vehicle, high speed vehicular crash, and GCS 12-14. The utilization of LowAct resulted in a decrease utilization of many resources without sacrificing patient care.

MUSIC THERAPY SIGNIFICANTLY REDUCES PAIN, ANXIETY, AND MUSIC TENSION INVOLVED WITH BURN DEBRIDEMENT

X.Tan, MM, MT-BC, C.J. Yowler, M.D., FACS, D.M. Super, MD, MPH, R.B. Fratianne, MD, FACS

INTRODUCTION: The management of pain and anxiety are daily problems confronted in the treatment of burn patients. The purpose of this prospective, randomized study was to explore the effectiveness of two music therapy protocols, music-based imagery (MBI) and music alternate engagement (MAE), on patients' pain, anxiety, and muscle tension levels before, during, and after burn debridement.

METHODS: Each patient underwent two days of research. Through randomization, patients received music therapy services—either on the first or second day of research. On control days, they received no music. On music days patients practiced music-based imagery (MBI), a form of music-assisted relaxation with imagery facilitated by the music therapist before and after their dressing changes. During dressing changes, patients engage in music alternate engagement (MAE) with the music therapist to help distract them from the debridement process. Four nurses on the burn unit went through training and testing for objective ratings of patients' muscle tension. The investigators proceeded with patient recruitment after inter-rater reliability was achieved at Weighted Kappa > 0.6, which placed the nurses into the "excellent" category of agreement. The patients gave subjective ratings for their pain and anxiety levels on a 10-point Likert scale which were recorded by the research nurse. The nurse scored her observation of the patients' muscle tension levels on a 5-point scale. Data was collected seven times during the whole process for each of the research days.

RESULTS: Twenty-nine inpatients (24 males, 5 females) ranging in age from 8 to 71 years (mean 41.3 + 14.0) participated in this study. Total body surface area burn ranged from 3 to 40% (mean 11.5 + 7.6) and 62.1% had only second degree burns. Using the Wilcoxon Signed Ranks test, the investigators found significant decreases in pain levels before ($p < .025$), during ($p < .05$), and after ($p < .025$) dressing changes on days the patients received music therapy compared to control days. Decreases in anxiety levels were significant during dressing changes ($p < .05$) while decreases in muscle tension levels reached significant differences during and after dressing changes ($p < .05$ and $.025$ respectively). The Mann-Whitney U analysis showed no sequence effect ($p > .05$) in the crossover design.

CONCLUSIONS: We have found the use of music therapy during daily burn debridement significantly reduces pain, anxiety, and muscle tension levels.

COMPUTERIZED TRAINING TARGETING BURN NURSE EDUCATION

S. A. Ulrich, RN, L. C. Yurko, RN, BSN, M. L. Madej, RN, BSN, C. J. Yowler, MD, FACS, C. P. Brandt, MD, FACS

INTRODUCTION: Working in a specialized area of nursing, such as burns, requires a unique knowledge base. Our burn center has developed a computer based educational program for continuing education of the nurses and training of new staff. The purpose of this study was to evaluate the efficacy of this novel educational program.

METHODS: A series of computer based educational modules were developed to cover topics identified through performance improvement initiatives and results of previous educational programs. The modules were developed by nursing staff and consist of a CD-ROM presentation with audio narration. The modules were viewed individually by staff members at their convenience. Prior to viewing and immediately following each presentation all participants completed a six to twenty item test. Results of the scores were analyzed to determine if significant improvement occurred. Scores from pre and post tests were compared by the Student's T-test.

RESULTS: See graph.

CONCLUSIONS: Utilization of computer-based burn care modules results in a significant short term increase in knowledge of the presented topics. The development of a computer based self-directed burn educational program provides a tool to review knowledge of selected topics. This method of instruction is an effective and cost efficient method of continuing nursing education.

IS MAGNETIC RESONANCE IMAGING ESSENTIAL IN CLEARING THE CERVICAL SPINE IN OBTUNDED PATIENTS WITH BLUNT TRAUMA?

John J. Como MD, Marsha A. Thompson RN, James S. Anderson MD, Rajiv R. Shah MD, Jeffrey A. Claridge MD, Charles J. Yowler MD and Mark A. Malangoni, MD

BACKGROUND: The optimal method of clearing the cervical spine (CS) in obtunded blunt trauma patients (OBTPs) remains unclear. Computed tomography (CT) identifies most injuries but may fail to detect ligamentous and spinal cord injuries. Magnetic resonance (MR) imaging has been widely used to exclude these. The purpose of this study was to evaluate whether CT of the CS (CT-CS) alone is adequate to clear the CS in OBTPs. Our hypothesis was that MR imaging of the CS (MR-CS) does not contribute relevant information and is not necessary in this patient population.

METHODS: A prospective evaluation of OBTPs with a CT-CS negative for acute trauma and MR-CS obtained for clearance was performed at a Level I trauma center between July 1, 2004 and June 30, 2006. Data gathered included demographics, results of CT-CS and MR-CS, timing of MR-CS, Glasgow Coma Scale score at time of MR-CS, adverse events occurring while obtaining MR-CS, and cervical collar complications.

RESULTS: One hundred and fifteen patients were identified. There were 90 male patients. The mean age was $43.9 \text{ years} \pm 1.9 \text{ years}$, mean Injury Severity Score was 24.4 ± 1.0 , and mean length of stay was $23.4 \text{ days} \pm 1.2 \text{ days}$. The MR-CS was performed on hospital day 7.5 ± 0.6 and the mean Glasgow Coma Scale score at the time of MR-CS was 8.3 ± 0.3 . Six MR-CS (5.2%) subsequently identified acute injuries. Findings included microtrabecular injuries, intraspinal ligament injuries, a cord signal abnormality, and a cervical epidural hematoma. None of these findings changed management and none required continued cervical collar usage. Six cervical collar complications were identified (5.2%). No adverse events related to transport or obtaining MR-CS occurred. Eliminating MR-CS would have decreased health care costs by over \$250,000 during this period.

CONCLUSIONS: MR-CS may be unnecessary in the OBTP if the CT-CS is negative. Elimination of MR-CS in this population will lead to earlier removal of cervical collars, decreased cervical collar complications, protection of the patient from exposure to potential risks inherent to obtaining this study, and decreased health care costs.

HEMOGLOBIN-BASED OXYGEN CARRIERS

John J. Como MD and Mark A. Malangoni MD

OBJECTIVES: 1) To describe the need for and use of hemoglobin-based oxygen carriers, especially in the trauma population. 2) To describe the adverse effects of allogeneic blood transfusions. 3) To describe the method of preparation of PolyHeme and its potential clinical indications. 4) To summarize prior research done on PolyHeme in trauma patients and in other populations. 5) To describe the current phase III trial investigating PolyHeme in trauma patients with hemorrhagic shock.

There has been increasing concern about the potential adverse effects of red blood cell (RBC) transfusion. Trauma patients are very likely to receive transfusions while in the hospital and are especially prone to these adverse effects. There has consequently been a worldwide interest in the development of a clinically useful oxygen carrier that could serve as a blood substitute, particularly in the trauma population. Hemoglobin-based oxygen carriers (HBOCs), such as PolyHeme, may serve this role and decrease or potentially eliminate the need for blood transfusion. PolyHeme is a human hemoglobin-based temporary RBC substitute that is presently under clinical evaluation for the treatment of life-threatening blood loss when an oxygen-carrying fluid is required and RBCs are not available. The potential benefits of PolyHeme in clinical care are that it is immediately available, is in abundant supply, and has a prolonged shelf life. It is universally compatible with all blood types and therefore does not require time-consuming typing and cross-matching. It is also sterile and free from disease transmission, antigenic reactions, and immunologic effects. A multicenter, randomized, controlled phase III trial investigating PolyHeme in trauma patients with hemorrhagic shock was recently completed. Final results of this study are still pending but may herald the introduction of HBOCs to patient care.

FEVER AND LEUKOCYTOSIS IN CRITICALLY ILL TRAUMA PATIENTS: IT'S NOT THE BLOOD

Golob JF, Fadlalla A, Blatnik J, Yowler CJ, Claridge JA.

BACKGROUND: The diagnosis of bacteremia in critically injured patients is difficult and is often based on fever and/or leukocytosis. This inefficient practice is termed the “fever workup”. The objectives of this study were to determine 1) if our intensive care unit obtains blood cultures based on fever and/or leukocytosis over the initial 14 days of hospitalization and 2) the efficacy of this diagnostic workup for diagnosing bacteremia.

METHODS: An 18-month retrospective cohort analysis was performed on consecutive trauma patients admitted for ≥ 2 days to a level I trauma center. Data collected included demographics, injuries, and the first 14 days maximal daily temperature and leukocyte count. In addition, the results of all blood culture episodes (defined as obtaining central venous or peripheral blood cultures) and central line catheter tip quantitative cultures were recorded. Fever was defined as a maximal daily temperature of $\geq 38.5^{\circ}\text{C}$ and leukocytosis was a leukocyte count $\geq 12,000/\text{mm}^3$ of blood. All positive blood cultures were individually evaluated for the source of bacteremia and classified as either true bacteremias or contaminants.

RESULTS: Five hundred and ten patients were evaluated for a total of 3839 patient-days. The mean patient age and injury severity score (ISS) was 49 ± 1 years and 19 ± 1 , respectively. Seventy two percent were males and 91% had blunt injuries. Four hundred and twenty five blood culture episodes were obtained and 25 (6%) true bacteremias were identified in 23 patients (5%). A significant association was found between obtaining blood cultures in patients with fever (RR=7.7; 95%CI 6.3-9.5), leukocytosis (RR=1.3; 95%CI=1.1-1.5) and fever+leukocytosis (RR=3.2; 95%CI=2.7-3.8). However, no significant association was found between these clinical signs and the diagnosis of a true bacteremia. Logistic regression using gender, age, ISS, hospital day, and antibiotic use failed to identify any independent risk factors for predicting bacteremia.

CONCLUSION: Our intensive care unit follows the common “fever workup” practice. Neither fever nor leukocytosis was significantly associated with true bacteremia, suggesting inefficiency in this practice. Further prospective study will be required to identify when blood cultures in critically ill trauma patients should be obtained, but at this point we do not recommend obtaining blood cultures based on fever and leukocytosis alone.

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Section 9
Clinical Trials

CARDIOTHORACIC SURGERY

Clinical Evaluation of the Jarvik 2000 Heart Assist System

Blitz, Arie

INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support)

Blitz, Arie

Thoratec TLC-II Portable VAD Driver

Blitz, Arie

Skin Care Interventions for Patients Undergoing Cardiac Surgery

Idemoto, Bette, Blitz, Arie

Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management

Multivessel Disease (FREEDOM)

Nair, Ravi, Blitz, Arie

BLATE (AtriCure Synergy Bipolar RF Energy Lesions for Permanent Atrial Fibrillation Treatment during Concomitant On-Pump Endo/Epicardial Cardiac Surgery)

Alan Markowitz, MD, Arie Blitz, MD

Evaluation of Functional Longevity of Aortic Tissue Valves

Markowitz, Blitz, Arie

COLORECTAL SURGERY

“Quality of Life / Post-Op Ileus Discharge Criteria Study”

Conor Delaney, MD

“Follow-up phone calls after colorectal surgery to assess patient satisfaction and post-operative outcomes”

Conor Delaney, MD, PhD. Primary contact: Michelle Briál, RN.

“Enhancing the Safety of Surgical Technical Skills”

Conor Delaney, MD, PhD. Primary contact: Mary Ann Draves

“A randomized trial comparing outcomes for the Ligasure and disposable stapling instruments for laparoscopic colectomy”

Conor Delaney, MD, PhD. Primary contact: Bridget O'Brien-Ermlich, RN

Sponsor: Tyco Healthcare/Valley labs

“A Randomized, Double-blind, Placebo-controlled Study Evaluating Two Doses of Asimadoline on the Duration of Post operative Ileus in Subjects Undergoing Laparoscopic/Hand-assisted Laparoscopic Segmental Colonic Resection Secondary to Colon Cancer or Polypectomy”

Conor Delaney, MD, PhD. Primary contact: Bridget O'Brien-Ermlich, RN

“STARR Registry”

Conor Delaney, MD, PhD. Primary contact: Bridget O'Brien-Ermlich, RN

Sponsor: Ethicon Endosurgery

“A Prospective, Observational, Multicenter Study Assessing Early Postoperative Recovery Following Laparoscopic Partial Large Bowel Resection”

Conor Delaney, MD, PhD. Primary contact: Bridget O'Brien-Ermlich, RN or Michelle Briál, RN

Sponsor: Adolor Corporation

“COLOR II: A randomized Clinical Trial Comparing Laparoscopic and Open Surgery for Rectal Cancer”

Conor Delaney, MD, PhD

“Evaluation of an Endoscopic Suturing System for Tissue Apposition in Colonic Polypectomy”

Conor P. Delaney, MD., PhD, Jeffrey Marks, MD, Bradley Champagne, MD, Amitabh Chak, MD

“General Surgery Outcomes Database”

Conor Delaney, MD, PhD, Bridget Ermlich, RN, BSN

GENERAL SURGERY

Stimulation of the Diaphragm in Amyotrophic Lateral Sclerosis

Raymond Onders, MD, Bashar Katirji, MD, Robert Schilz, PhD, DO, Mary Jo Elmo, ACNP, Jane E. Prasse, MA, CCC-SLP, Robert Gilkerson, MD

Electrical Activation of the Diaphragm for Ventilatory Assist

Raymond P. Onders, MD, Mary Jo Elmo, RN, ACNP, Robert Schilz, PhD, DO, Subhalakshmi Sivashankara, MD, Bashar Katirji

Electrical Activation of the Diaphragm for Ventilatory Assist in Spinal Cord Injured Who Have a Cardiac Pacemaker

Raymond Onders, MD, Mary Joe Elmo, RN, ACNP, Robert Schilz, PhD, DO, Subhalakshmi Sivashankara, MD, Bruce S. Stambler, MD, Judith A. Mackall

NeuRx RA/4 Motor-point Stimulation for Conditioning the Diaphragm of Patients with Amyotrophic Lateral Sclerosis

Raymond Onders, MD. Primary contact: Mary Jo Elmo, RN

A Multicenter, Open-label, Randomized Comparative Study of Tigecycline vs Ceftriaxone Sodium Plus Metronidazole for the Treatment of Hospitalized Subjects with Complicated Intra-abdominal Infection

Mark A. Malangoni, MD

“Intensive Communication System for Chronically Critically Ill” NIH RO1 NR 008941

Joel Peerles, MD

“Stimulation of the Diaphragm in Amyotrophic Lateral Sclerosis”

Raymond Onders, MD, Bashar Katirji, MD, Robert Schilz, PhD, DO, Mary Jo Elmo, ACNP, Jane E. Prasse, MA, CCC-SLP, Robert Gilkerson, MD

“Electrical Activation of the Diaphragm for Ventilatory Assist”

Raymond P. Onders, MD, Mary Jo Elmo, RN, ACNP, Robert Schilz, PhD, DO, Subhalakshmi Sivashankara, MD, Bashar Katirji

“Electrical Activation of the Diaphragm for Ventilatory Assist in Spinal Cord Injured Who Have a Cardiac Pacemaker”

Raymond Onders, MD, Mary Joe Elmo, RN, ACNP, Robert Schilz, PhD, DO, Subhalakshmi Sivashankara, MD, Bruce S. Stambler, MD, Judith A. Mackall

“Ongoing Study of GISTs”

Jeffrey M. Hardacre, MD, Julian Kim, MD, Judy Jin, MD, Robert Shenk, MD, Thomas Stellato, MD, Joseph Willis, MD

“Initial Experience with IORT for Pancreatic Cancer”

Jeffrey M. Hardacre, MD, Timothy Kinsella, MD, Christoher Siegel, MD, PhD, Juan Sanabria, MD, Julian Kim, MD, James Schulak, MD, Charles Kunos, MD, Melanie Lynch, MD, Michael McGee, MD

“Hyperthyroidism Crisis Revisited”

Roy Phitayakorn, MD, Christopher McHenry, MD

“The Rate Of Conversion From a Laparoscopic to an Open Approach and Selective Open Resection for Adrenal and Extraadrenal Neuroendocrine Tumors”

Roy Phitayakorn, MD, Christopher McHenry, MD

“The Incidence of Thyroid Cancer in Patients with Graves Disease”

Roy Phitayakorn, MD, Christopher McHenry, MD

“Prospective Evaluation of the Intra-Operative use of Transluminal Flexible Endoscopes during Combined Flexible and Laparoscopic Foregut Surgery”

Jeffrey Marks, MD. Primary contact: Mike McGee, MD

“Development of An Assessment Tool to Measure Flexible Endoscopic Performance”

Jeffrey Marks, MD

“Prospective, Randomized, Double-Blind Trial of Continuous Infusion of 0.5% Bupivacaine by Elastomeric Pump for Postoperative Pain Management After Laparoscopic Ventral Hernia Repair”

Michael Rosen, MD. Primary contact: Michelle Briál, RN

“Ablation of Gastrointestinal Tissue in Patients Prior to Undergoing Planned Removal of Said Tissue-Bearing Organ Clinical Protocol B-400”

Jeff Marks, MD. Primary contact: Michelle Briál, RN

Sponsor: *BARRX*

“Quality of life evaluations in patients with abdominal wall hernias”

Michael Rosen, MD, Judy Jin, MD

“Prospective Evaluation of NOTES PEG “Rescue” Feasibility”

Jeffery Marks, MD

“Sleep Apnea in the Obese Surgical Patient”

Michael Rosen, MD, Christina Williams, MD, Judy Jin, MD, Michael McGee MD, Sanjay Patel MD, Susan Redline MD, David Yao BS

“A Multicenter, Prospective, Observational Evaluation of Repair of Infected or Contaminated Hernias (RICH) using LTM”

Michael Rosen, MD

ORAL AND MAXILLOFACIAL SURGERY**Alveolar Cleft Bone Volume Defect Measurement Using Cone Beam CT Imaging PI:**

Faisal A. Quereshy, MD, DDS, FACS; Geoffrey Barnum B.S. Approved IRB Protocol Case Western Reserve University (4-2008)

Measuring Cross Sectional Airway Surface Area Using Cone Beam Computed Technology (pre-study data collection). PI:

Faisal A. Quereshy, MD, DDS, FACS Jonathan Williams B.S. Approved IRB Protocol Number: 20080210 University Hospitals Case Medical Center 2-21-08

Correlation of Blood Loss and Operating Time during Orthognathic Surgery Procedures PI:

Faisal A. Quereshy, MD, DDS, FACS; Keith Schneider. Approved IRB University Hospitals Case Medical Center 2-21-08.

Body Dismorphic Disorder in Adult Patients Seeking Orthognathic and Facial Cosemtic Surgery from Oral and Maxillofacial Surgeons PI:

Faisal A. Quereshy, MD, DDS, FACS; Michael P. Horan, DDS, PhD. IRB Case Western Reserve University, Protocol #20080104

Bioform Medical (\$21 000) Evaluation of soft tissue augmentation with Radiesse: A pilot study to evaluate soft tissue changes utilizing CBCT PI:

Faisal Quereshy MD, DDS, FACS, Cyrus Ramsey, DMD, MD, Micheal Horan DDS, PhD, J Martin Palomo DDS, MSD. Pending IRB University Hospitals Case Medical Center

PEDIATRIC SURGERY**Use of “Contegra” Pulmonary Valve Conduit in Pediatric/Congenital Heart Surgery**

Hani Hennein, MD (Ongoing Humanitarian Use Device study)

The Right Ventricle in Congenital Heart Diseases: Risk Factors and Outcomes

A. Farouk, MD, H. Hennein, MD (Ongoing PhD Thesis Clinical Study, under joint supervision between Case Western Reserve University and Assiut University, Assiut, Egypt)

Arterio-Arterial Flow Augmentation: A Novel Approach with Particular Suitability in the Pediatric Heart Failure Population

A. Farouk, J. Ostrowsky, S. Schomisch, Y. Kamotani, J. Kadambi, J. Stork, M. Karimi, H. Hennein

Effects of Selective Antegrade Cerebral perfusion on Cerebral Oxygenation

M. Karimi, A. Farouk, J. Ostrowsky, S. Schomisch, J. LaMamma, H. Hennein

Autotransfusion of Washed Shed Mediastinal Blood after Pediatric Cardiac Surgery

A. Farouk, M. Karimi, J. Ostrowsky, H. Hennein (Pending study)

SURGICAL ONCOLOGY

A Phase II Study of HyperAcute®-Pancreatic Cancer Vaccine in Subjects with Surgically Resected Pancreatic Cancer.

Industry Sponsor: NewLink Genetics. UMCMC Primary Investigator: Jeffrey M. Hardacre MD. UHCMC

Co-Investigators:

Julian Kim MD, Joanna Brell MD, Janice Lyons MD.

Ongoing Study of Pancreatic Disease.

Jeffrey M. Hardacre, MD.

Ongoing Study of Gallbladder Disease.

Jeffrey M. Hardacre, MD.

“A Phase 3 Clinical Trial to Evaluate the Safety and Efficacy of Treatment with 2 mg Intravesical Allovectin-7® Compared to Dacarbazine (DTIC) or Temozolomide (TMZ) in Subjects with Recurrent Metastatic Melanoma”

Julian Kim, MD, Henry Koon, MD

“Using Gene Expression Profiling to Identify the Molecular Basis for Racial Disparities in Breast Cancer Survival”

Ruth Keri, PhD, Melanie Lynch, M.D., Robert Elston, PhD., and Julian Kim, M.D.

University Hospitals Case Medical Center Principal Investigator: Rosemary Leeming, MD

NSAB1101: Effects of Selective Estrogen Receptor Modulators on Cognitive Aging; Cognition in the Study of Tamoxifen and Raloxifene. (Status – closed.)

NSAB1192 A Clinical Trial to Determine the Worth of Tamoxifen for Preventing Breast Cancer. (Status – terminated)

NSAB1199 Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer. (Status – closed.)

NSABP B-32 A Randomized, Phase III Clinical Trial to Compare Sentinel Node Resection to Conventional Axillary Dissection in Clinically Node Negative Breast Cancer Patients. (Status – closed.)

NSABP B-33 A Randomized, Placebo-Controlled, Double-Blind Trial Evaluating the Effect of Exemestane in Clinical Stage T1-3, NO-1, M-O Post-Menopausal Breast Cancer Patients Completing at Least 5 Years of Tamoxifen Therapy. (Status – closed.)

NSABP B-34 A Clinical Trial Comparing Adjuvant Clodronate Therapy versus Placebo in Early Stage Breast Cancer Patients Receiving Systemic Chemotherapy and/or Tamoxifen or No Therapy. (Status – closed.)

NSABP B-35 A Clinical Trial Comparing Anastrozole with Tamoxifen in Post-Menopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy. (Status – closed.)

NSABP B-31 A Randomized Trial Comparing the Safety and Efficacy of Adriamycin and Cyclophosphamide Followed by Taxol (AC – T) to that of Adriamycin and Cyclophosphamide Followed by Taxol plus Herceptin (AC-TH) in Node Positive Breast Cancer Patients Who Have Tumors that Overexpress Her2. (Status – closed.)

NSABP B-36 A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5FU, Epirubicin, and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) with or without Celecoxib, in Patients with Node Negative Breast Cancer. (Status – open.)

NSABP B-37 A Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Local-Regional Relapse of Breast Cancer. (Status – open.)

NSABP B-38 A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node Positive Breast Cancer. Doxorubicin/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by Dose-Dense Paclitaxel (DDAC-P); DDAC Followed by DD Paclitaxel plus Gemcitabine (DDAC-PG). (Status – open.)

NSABP B-39 A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, II Breast Cancer. (Status – open.)

NSABP-B41 A Randomized Phase III Trial of Neoadjuvant Therapy for Patients With Palpable and Operable HER2-Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response. (Status - pending IRB approval.)

NSABP B-42 A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Post-Menopausal Women with Hormone Receptor Positive Breast Cancer. (Status – PRMC approved.)

NSABP FB-4 A Phase II Clinical Trial of Bevacizumab Beginning Concurrently with a Sequential Regimen of Doxorubicin and Cyclophosphamide Followed by Docetaxel and Capecitabine as Neoadjuvant Therapy Followed by Postoperative Bevacizumab Alone for Women with Locally Advanced Breast Cancer. (Status – closed)

NSABP FB-5 A Phase II Clinical Trial of Epirubicin Plus Cyclophosphamide Followed by Docetaxel Plus Trastuzumab and Bevacizumab Given as Neoadjuvant Therapy for HER2-Positive Locally Advanced Breast Cancer or Given as Adjuvant Therapy for HER2-Positive Pathologic Stage III Breast Cancer

NSABP C-08 A Phase III Clinical Trial Comparing Infusional 5FU, Leucovorin and Oxaliplatin (mFOLFOX6) Every Two Weeks with Bevacizumab to the Same Regimen Without Bevacizumab, for the Treatment of Patients with Resected Stages II and III Cancer of the Colon. (Status – closed.)

TRANSPLANTATION AND HEPATOBILIARY SURGERY

"Non-invasive markers and transplant outcomes in humans".

CCLCM PI-Peter Heeger, CWRU PI- Donald Hricik, CWRU Co-I- Mark Aeder (5% effort) 9/15/04-8/31/05, CWRU

A randomized open-label study to compare the safety and efficacy of two different sirolimus regimens with a tacrolimus + mycophenolate mofetil regimen in de novo renal allograft recipients

(protocol #0468H1-101497). Study started in January, 2005.

Sponsored by Wyeth. Mark Aeder, Subinvestigator.

An open-label; prospective, randomized, controlled, multicenter study assessing fixed dose vs concentration controlled CellCept regimens for patients following a single organ renal transplantation in combination with full dose and reduced dose calcineurin inhibitors.

Protocol #ML 17225/01265. Study started in November, 2004.

Sponsored by Roche. Mark Aeder, Subinvestigator.

A two-year extension to a one-year, multicenter, partially blinded, double-dummy, randomized study to evaluate the efficacy and safety of FTY720 combined with reduced-dose or full-dose Neoral® and corticosteroids versus mycophenolate mofetil (MMF, Cellcept®) combined with full-dose Neoral® and corticosteroids, in de novo adult renal transplant recipients.

Sponsored by Novartis. Study started July, 2004. Mark Aeder, Subinvestigator.

A one-year, multicenter, partially blinded, double-dummy, randomized study to evaluate the efficacy And safety of FTY720 combined with reduced-dose or full-dose Neoral® and corticosteroids in de novo adult renal transplant recipients.

Sponsored by Novartis. Study started September, 2003.

Mark Aeder, Subinvestigator.

An open-label, concentration-controlled, randomized, 12 month study of prograf + rapamune + corticosteroids compared to cyclosporine capsules,

USP (modified) + rapamune + corticosteroids. Study started March, 2003.

Sponsored by Wyeth. Mark Aeder, Subinvestigator.

Living Paired Donation to Benefit Incompatible Living Donor Recipients Through Registration in the Paired Donation Network.

UH IRB: 09-07-19. Mark Aeder, Principal Investigator.

Complete IVC and Bilateral Lower Extremity Thrombosis in Kidney Transplant Recipients.

UH IRB: 04-08-36. Mark Aeder, Principal Investigator.

Evaluation of Parameters Leading to NSQIP Identified Surgical Site Infections.

IRB Pending. Mark Aeder, Principal Investigator.

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Department of Surgery
Case Western Reserve University
School of Medicine
11100 Euclid Avenue
Cleveland, Ohio 44106
Telephone: 216.844.3209
Facsimile: 216.844.1350
www.casesurgery.com

