



Case Western Reserve University
School of Medicine

Department of Surgery

2008
Research
Abstracts



CASE
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2008-2009 Research Abstracts

CASE SURGERY

A compilation of investigations made by Case Surgery Physicians, research scientists and distinguished colleagues.



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Dear Colleague:

I am pleased to share with you our 2008-2009 research abstracts. The Department of Surgery provides a unique multi-specialty academic environment where ideas are exchanged and cooperative research programs are planned.

The 2008-2009 academic year has been a fruitful and productive one for the department and its 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 its 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

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**

CONTEMPORARY EXPERIENCE WITH RVAD BRIDGE TO RECOVERY AFTER ISOLATED RIGHT VENTRICULAR INFARCTION AND SHOCK

Arie Blitz¹, Paul Coletta¹, John Coletta², Chen Chow², Alan Markowitz¹, Ilke Sipahi², James Fang²,

PURPOSE: To date there are no published clinical series reporting exclusively on patients who have undergone isolated RVAD support for right ventricular myocardial infarction (RVMI). We report here on our series of four patients over a 3-year span (2006-2008) who underwent salvage RVAD placement for RVMI.

METHODS: The records of all patients were retrospectively reviewed.

RESULTS: Four patients underwent salvage RVAD placement for RV shock. All patients had an occluded RCA as their culprit lesion. The RVAD was ultimately weaned in all four patients, but 1 died shortly after explantation. Follow-up echocardiogram revealed moderate RV dysfunction in all 3 survivors. Further details for each patient are listed in table 1.

Patient	Age	Type of Surgery	Duration of Support	Outcome	Duration of Follow-Up	NYHA Class
A	62	RVAD/CABG	4 days	Explanted, alive, at home	3 years	2
B	71	RVAD/CABG/PFO Closure	10 days	Explanted, hospital mortality	NA	NA
C	78	RVAD/CABG, off-pump	28 days	Explanted, alive, at home	8 months	3
D	62	RVAD/CABG, off-pump	21 days	Explanted, alive, at home	2 months	2

CONCLUSION: Patients with RVMI complicated by medically refractory cardiogenic shock can be successfully bridged to RV recovery with surgically implanted RVADs. Most patients return to a reasonable functional capacity despite persistent postoperative right ventricular dysfunction.

THE USE OF A NOVEL INTRAVASCULAR TEMPERATURE MODULATION CATHETER FOR PERIOPERATIVE CARE IN CARDIAC SURGERY

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

Case Presentations

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. This patient's temperature curve is depicted in figure 1. 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.

The final three cases illustrate the use of the percutaneous catheter for cooling purposes. 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. 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 3 months postoperatively, the patient is still recovering but is gradually recovering neurologic function of his lower extremities. The sixth case is that of a 74-year-old female with numerous comorbidities who underwent an uneventful CABG. On postoperative day 1, the patient suffered a dense focal stroke. She immediately underwent therapeutic hypothermia for 48 hours and then recovered completely.

See figure 2 below.

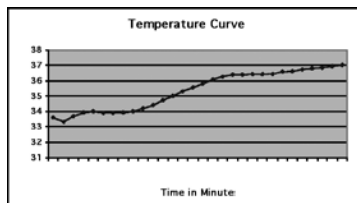


Figure 1. Case Number 3

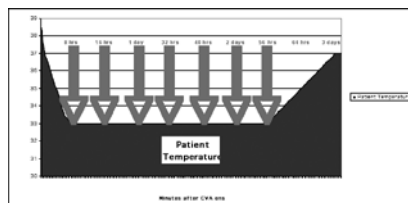


Figure 2. Case Number 6

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

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.

TECHNIQUE FOR THE INSERTION AND MINIMALLY INVASIVE REMOVAL OF THE IMPELLA DEVICES FOR USE AS A TEMPORARY RVAD

A. Blitz, MD

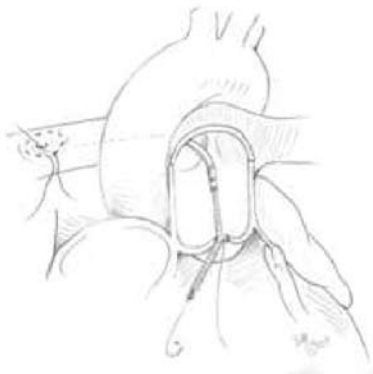
PURPOSE: Despite advances in VAD surgery, a technique for the insertion and minimally invasive removal of a temporary RVAD has been elusive. The advantage of such a technique would be to allow a smoother perioperative course for patients undergoing LVAD therapy who are at high risk for RV dysfunction.

METHODS: A Porcine animal model was used to develop a technique for the insertion and minimally invasive removal of the Impella devices on the right side. The technique for insertion is as follows: Creation of a subcutaneous pocket in the right pectoral region; Passage of the Impella catheter percutaneously through the skin adjacent to the pocket and into the right pulmonary artery; Placement of two prolene purse strings around the catheter entry site in RPA; Confirmation of appropriate Impella position in RV with either TEE or fluoroscopy; Positioning the ends of the snared prolene purse string sutures in the pocket; Securing snares with multiple clips to maintain tension; Placement of Blake drains adjacent to RPA entry site; Closure of chest and pocket.

The technique for removal: Monitoring removal with TEE; Opening of snare pocket; Removal of silk snare; Loosening of 4.0 prolene snares; Removal of Impella catheter; Snaring and securing both prolene snares; Monitoring hemodynamics, TEE, and output of Blake drains to confirm absence of bleeding; Close pocket.

RESULTS: Direct PA pressure measurements confirmed the maintenance of low PA pressures (<30 mmHg systolic) in the presence of flows in excess of 2 LPM with the 2.5 device, and in excess of 4 LPM with the 5.0 device. No complications were observed.

CONCLUSIONS: A technique is described for the placement of an Impella device as a temporary RVAD at the time of LVAD surgery, as well as a technique for its removal without sternotomy following RV recovery. These techniques would be useful for the perioperative recovery of patients undergoing LVAD placement who are at risk for perioperative RV dysfunction.



Section 2

Colorectal Surgery

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

Stulberg J, Champagne BJ, Marderstein E, Reynolds H, Ermlich B, Senagore AJ, Delaney CP

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.

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 ($R^2 = 0.08$). Stratification by preoperative patient and disease characteristics was similarly ineffective at reducing control limits suggesting outliers are based on systems inefficiencies. Grouped analysis reduced LOS outliers from 50 to 2 patients, and system improvements such as minimally invasive and standardized enhanced recovery protocol decreased variance.

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.

A NATIONAL COMPARISON OF LAPAROSCOPIC VS OPEN COLECTOMY USING THE NON-VA NSQIP DATABASE

Senagore AJ, Delaney CP, Stulberg J, Byrnes J.

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%).

2

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.

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

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

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.

ASSESSMENT OF POSTOPERATIVE AMBULATION WITH THE USE OF A Pedometer: Does Walking Really Help?

Obias V, Champagne B, Reynolds H, Joh Y, Delaney C.

PURPOSE: Although multiple studies have stressed the importance of ambulation after major abdominal surgery for accelerating recovery, this has not been demonstrated in a quantitative manner. This study prospectively assesses ambulation in the postoperative period after laparoscopic and open colorectal surgery in patients on a standardized postoperative care plan.

METHODS: After IRB approval, 44 patients undergoing a variety of colorectal procedures from 12/06 to 10/07 were evaluated. Digital pedometers were positioned in the recovery room and the number of steps taken and number of walks attempted measured on each postoperative day (POD). Demographic, operative, and postoperative data including length of stay (LOS), complications, and readmissions were documented.

RESULTS: Average age was 58.9 years, ASA was 2.5, and BMI was 29.2 kg/m². Average hospital stay was 5.2 +/- 2.8 days, with no mortality. 25% of patients developed postoperative ileus (absent BM or flatus or tolerance of diet by POD 4). Mean number of steps per patient increased daily with a peak at POD 3 (1,407 +/- 3131 steps). Subset analysis comparing ileus to non-ileus patients, showed no significant difference in age, ASA, BMI, EBL, or operative time. Patients with ileus had increased LOS than non-ileus (8.7 vs 4.0 days; p=0.0001), and significantly less ambulation between POD1-4 (196.4 vs 888.3 steps; p=0.0366). Patients without ileus were more likely to have undergone a laparoscopic procedure (p<0.01).

CONCLUSIONS: These are the first data to quantify ambulation in the postoperative period after major abdominal surgery. The results provide evidence supporting the importance of ambulation as a potential means of reducing ileus and shortening LOS. Laparoscopy facilitates early ambulation and is less likely to be associated with ileus. Future studies assessing postoperative outcomes should incorporate pedometers to better quantify ambulation after surgery.

EMERGENCY LAPAROSCOPIC COLECTOMY: DOES IT MEASURE UP TO OPEN?

Stulberg J, Champagne BJ, Fan Z, Horan M, Obias V, Marderstein E, Reynolds H, Delaney CP.

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.

2

ENDOGENOUS MORPHINE LEVELS DO NOT RISE AFTER LAPAROSCOPIC COLECTOMY: A POSSIBLE MECHANISM FOR DECREASED POST-OPERATIVE ILEUS.

Madbouly K, Senagore A, Delaney C.

INTRODUCTION: Although the negative effects of exogenous narcotics on recovery after open (OSC) and laparoscopic colectomy (LSC) have been defined, the impact of endogenous morphine (EM) on inflammatory response and gastrointestinal function has not been well defined.

PURPOSE: To assess the responses of EM, stress hormones (ACTH, cortisol) and cytokines(IL-6, IL-1ra, and IL-10 following LSC and OSC

METHODS: 20 consecutive laparoscopic segmental colectomy (LSC) patients were compared with 9 open segmental colectomy (OSC) patients. All patients received identical non-morphine analgesia post-operatively and followed a standard enhanced recovery program. Data collected included age, sex, EBL, OR time, time of return of peristalsis, time to pass flatus. Plasma EM was measured preoperatively, immediately postoperatively and at 3, 24, and 48 hours after wound closure.

RESULTS: LSC and OSC patients were of similar age (54.8 v 52.3), however the OR time (92.2 vs 61.1 min), time to regular diet (14.8 v 32.6 hrs), and hospital stay (2.9 v 5.6 days) were all significantly different between the groups, respectively ($p < 0.05$). EM levels rose significantly in the postoperative period compared to baseline only for OSC and these levels were higher when compared to LSC patients immediately after surgery (8.69 v 1.97 ng/ml), at 3 h (10.36 v 0.52), and at 24 h (2.62 v 0.81 ng/ml). At 48 hours the levels were similar for LSC and OSC (see Table).

	Group	Pre-op	Immediate Post-Op	3 hours	24 hours	48 hours
Cortisol (ug/ml) LSC	Lap	17.16± 19.58	39.34± 25.54	23.51± 16.38	16.85± 10.49	5.83± 3.22
OSC	Open	31.89±4.09	91.05± 22.56	43.56± 19.74	21.34± 12.05	7.67± 0.98
ACTH (pg/ml) LSC	Lap	55.79±45.64	138.21±79.32	46.84± 14.45	33.60±8.16	31.08± 18.71
OSC	Open	53.94±8.84	32.14± 5.53	71.52± 14.94	114.33± 167.14	40.16± 6.87
IL1ra (pg/ml) LSC	Lap	1410.23± 1631.78	1923.09± 1647.50	1954.06± 1792.00	416.1 ± 204.34	752.69 ± 774.00
OSC	Open	2729.9 ± 1411.72	1461.05± 1555.55	2383.85 ± 1890.22	441.45 ± 611.78	490.53± 215.35
IL-6 (pg/ml) LSC	Lap	13.47 ± 18.96	31.55 ± 36.26	27.54 ± 50.85	18.2 ± 23.31	9.842+ 13.688
OSC	Open	19.7 ± 17.78	28.02 ± 32.87	103.38 ± 91.16	23.12 ± 22.65	14.11 ± 18.24
IL- 10 (pg/ml) LSC	Lap	187.75 ±125.97	247.66 ±187.19	167.14 ± 105.15	177.05 ±153.62	166.4 ± 172.34
OSC	Open	79.96± 15.27	83.93± 37.81	244.43 ± 21.46	100.74 ± 49.89	206.05 ± 182.91

CONCLUSION: These novel findings demonstrate a greater degree of EM synthesis following OSC compared to LSC. The results are consistent with the concept that EM may contribute to increased post-operative ileus after OSC but not LSC. These data may indicate a different role for newly developed receptor antagonists in LSC and OSC in an enhanced recovery program

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

Elmunzer BJ, Schomisch SJ, Trunzo JA, Poulouse BK, McGee MF, Faulx AL, Delaney CP, Marks JM, Ponsky JP, Chak A.

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.

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

Trunzo JA, Marks JM, Willis JE, Poulouse BK, McGee MF, Chak A, Ermlich B, Briehl M, Elmunzer J, Champagne B, Ponsky J, Delaney CP.

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.

FACTORS AFFECTING PRIMARY POSTOPERATIVE ILEUS AFTER LAPAROSCOPIC COLORECTAL RESECTION.

Joh Y, Delaney C, Chung C, Stulberg J.

PURPOSE: Postoperative ileus (POI) is the most common reason for delayed hospital discharge after abdominal surgery and is also associated with an increased risk of readmission. As there are no known predictors of POI or delayed recovery, fast-track pathways and laparoscopic surgery are increasingly used to help standardize outcomes. This study looks for predictors of POI or adverse outcome after laparoscopic right (LRC) and left colectomy (LLC).

METHODS: Data for 76 LRC and 60 LLC patients of a single surgeon, following fast-track postoperative pathways over 24 months were recorded prospectively in an IRB-approved database. Demographics, operation time, blood loss, complications including POI, hospital stay, and readmission rate were compared between the two groups.

RESULTS: There was a significant differences in indication for surgery with 84.2% of LRC for neoplasia or polyp, and 60% of LLC for inflammatory disease ($p < 0.001$). Hospital stay after LRC and LLC was 4.5 (median 3) days and 3.2 days (median 2), respectively ($p = 0.039$), and the incidence of POI was 14.5 % in LRC and 1.7% in LLC ($p = 0.019$). LRC patients were older than LLC (65.1 vs 56.3 years, $p = 0.002$). Operative time and blood loss in LRC and LLC were 115 and 164 minutes ($p < 0.0001$) and 30 and 94 ml ($p = 0.007$), respectively. The complication rate was 31.2 % for LRC and 11.5 % for LLC ($p = 0.007$) and the readmission rate was 11.8% in LRC and 3.3% in LLC ($p = 0.112$) with no difference in reoperation rates.

CONCLUSIONS: Patients undergoing LRC were significantly more likely to develop POI, prolonged hospital stay, or readmission, even though inflammatory disease, operative time and blood loss were greater in LLC patients. These novel results show a distinct difference in outcome for patients undergoing LRC versus LLC.

GASTROINTESTINAL RECOVERY AFTER LAPAROSCOPIC PARTIAL LARGE BOWEL RESECTION: RESULTS OF A PROSPECTIVE, OBSERVATIONAL, MULTICENTER STUDY

Conor Delaney,¹ Peter Marcello,² Toyooki Sonoda,³ Paul Wise,⁴ Joel Bauer,⁵ Lee Techner⁶

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INTRODUCTION: A prospective, multicenter, observational study (14CL401) investigated gastrointestinal (GI) recovery, length of hospital stay (LOS), and postoperative ileus (POI)-related morbidity after laparoscopic bowel resection (LBR).

METHODS: Adult patients undergoing LBR with primary anastomosis performed by straight (SL) or hand-assisted (HAL) laparoscopy with scheduled postoperative intravenous patient-controlled analgesia were enrolled. The study design was similar to alvimopan phase III open laparotomy BR studies, including the use of a standardized accelerated care pathway; in this study, >80% of sites participated in ≥ 1 phase III open BR trials. Primary endpoints were GI-2 recovery (first bowel movement and tolerating solid food) and postoperative LOS (hospital discharge day minus day of surgery). Secondary endpoints included POI-related morbidity (postoperative nasogastric tube insertion and POI resulting in prolonged hospital stay or readmission), conversion-to-open (CTO) rate, and investigator-assessed prolonged POI.

RESULTS: Of 148 patients enrolled (mean, 58.3 years old), 67 patients received a right partial colectomy by SL, 42 received a left partial colectomy by SL, and 39 received a left partial colectomy by HAL. The CTO rate was 18.8%, with approach-specific CTO rates of 25.4% (SL left), 17.3% (HAL left), and 15.0% (SL right). Mean time to GI-2 recovery was 4.4 days and mean postoperative LOS was 4.9 days (range, 2-41 days), neither of which varied substantially by surgical approach. Postoperative nasogastric tube insertion was reported in 7 (4.7%) patients, and POI resulting in prolonged stay was reported in 15 (10.1%) patients. Three patients (2%) were readmitted for all causes; no patients were readmitted because of POI.

CONCLUSIONS: Mean LOS after LBR was 4.9 days, with 10% of patients experiencing delayed discharge because of POI. GI recovery and LOS were accelerated by 0.7 and 1.7 days, respectively, versus the pooled open BR placebo population in the phase III alvimopan POI trials. POI-related morbidity was similar across the LBR and open BR populations. In conclusion, the laparoscopic technique may only marginally speed GI recovery compared with an open approach, and POI remains an important morbidity after LBR.

RESULTS OF A STANDARDIZED OPERATIVE TECHNIQUE AND PERI-OPERATIVE CARE PROTOCOLS FOR LAPAROSCOPIC RECTAL RESECTIONS

Lindsetmo RO, Champagne BJ, Delaney CP.

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.

TEACHING LAPAROSCOPIC COLECTOMY TO RESIDENTS: A COMPARISON OF A HIGH-FIDELITY SYNTHETIC MODEL AND A LIVE PORCINE MODEL.

Delaney CP, Senagore AJ, Stulberg J, Champagne B, Sarker S, Zeinali F, 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

TISSUE APPPOSITION SYSTEM (TAS) – NEW TECHNOLOGY TO MINIMIZE SURGERY FOR ENDOSCOPICALLY UNRESECTABLE COLONIC POLYPS

CP Delaney, BJ Champagne, JM Marks, V Obias, L Sanuk, B Ermlich, A Chak.*

OBJECTIVE: This study reports the first clinical series using the TAS device in a feasibility study of endoscopic polypectomy as an alternative to laparoscopic colectomy (LC) for endoscopically unresectable polyps. TAS is a novel T-tag system for endoscopic placement of sutures which facilitates closure of larger defects from advanced endoluminal or transluminal endoscopic procedures. Such novel instrumentation may reduce patient risk and accelerate recovery.

METHODS: After IRB approval, patients with endoscopically unresectable polyps who would otherwise require LC were enrolled. The polyp site was visualized by colonoscopy and resected with laparoscopic assistance, if necessary taking some muscularis during endoscopic mucosal resection (EMR) or submucosal dissection. After confirming benign disease by frozen section, the polypectomy site was closed by TAS (Ethicon Endo-Surgery) under laparoscopic control to avoid injury to surrounding structures. Check colonoscopy was done at 3 months.

RESULTS: Seven patients were recruited (five male; mean age 66 years). Polyps were from 20 to 50mm in diameter (mean 30mm), six were in the right colon, and three were on the mesenteric border of the bowel. Final pathology was benign in all cases. Mean EMR time was 29 minutes, mean time taken for TAS was 37 minutes, and mean total operative time was 129 minutes. Two TAS procedures required conversion to LC (one unresectable polyp and one device failure). Five TAS procedures were completed, with a mean hospital stay of 1.2 days, and no complications. Follow-up colonoscopy revealed complete healing in all cases, with no recurrence of polyp to the current time. One patient (initial 5cm sigmoid polyp) had a very mild asymptomatic stricture in the sigmoid colon.

CONCLUSION: This initial human experience demonstrates that TAS can be used safely in the colon under laparoscopic control. TAS permits safe closure of defects after endoscopic polypectomy of selected and otherwise unresectable polyps, thereby avoiding the need for LC, and permitting rapid recovery with short hospital stay.

VALIDATION OF A NOVEL POST-OPERATIVE QUALITY OF LIFE 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.

THE EFFECT OF ILEOSTOMY CREATION AND CLOSURE ON PREEXISTING HYPERTENSION

Peter A. Knoll, Jonah J. Stulberg, Brad Champagne, Harry Reynolds, Conor P. Delaney and Eric L. Marderstein

INTRODUCTION: Ileostomy creation is associated with chronic electrolyte changes and salt and water deficiencies that persist long after the body adapts to this new physiologic state. However, no study has investigated the effect of these changes on blood pressure regulation. The purpose of this study was to determine if ileostomy creation resulted in lower blood pressure among hypertensive patients.

METHODS: A proprietary Case Department of Surgery database was queried for patients undergoing ileostomy closure from 2005-8. Electronic medical record review was then used to obtain the date of ileostomy creation in addition to data regarding blood pressure recordings and antihypertensive medication use.

RESULTS: 113 patients had ileostomy formation and closure, 64 of which met the criteria for hypertension. Following ileostomy formation, 48 (75%) of these subjects had a decrease in their antihypertensive medications and/or a decrease in their mean arterial pressure (MAP)>5mmHg without an increase in either parameter. The mean decrease in systolic blood pressure was 12.7 mmHg ($p<.001$). This effect was not seen among the non-hypertensive patients. Following ileostomy closure, 28 (50%) of the 56 subjects had a worsening of their hypertension. Steroid usage, anemia and weight loss did not confound these effects.

CONCLUSIONS: Ileostomy formation resulted in improvement of hypertension in of hypertensive patients. After ileostomy closure, of these patients had a rebound hypertensive effect. This study demonstrates a previously unrecognized effect of ileostomy creation on hypertension that has the potential to affect the way these patients are clinically managed.

2

Section 3

General Surgery

MOST LIKELY LEVEL OF IMPAIRED BOLUS TRANSIT MEASURED BY MULTICHANNEL INTRALUMENAL IMPEDANCE

Faiz Tuma, MD, Leena Khaitan, MD, MPH

INTRODUCTION: Although multiple esophageal motility disorders have been defined manometrically, the underlying esophageal pathology is not always clear. Esophageal function testing (EFT), which combines manometry and multichannel intraluminal impedance (MII), has been increasingly useful in assessment of the Esophageal Motility disorders. MII allows the assessment of bolus transit. Impairments in bolus transit remain poorly understood. This study assesses the most likely level of impaired bolus transit when abnormalities are noted by impedance which can help to further characterize esophageal motility disorders.

METHODS: Consecutive EFTs done between September 2007 to August 2008 were reviewed retrospectively. Patients underwent 10 liquid and 10 viscous swallows. Data was collected including diagnosis, medication use, symptoms, and EFT results of liquid and viscous swallows. Bolus transit is measured at 5, 10, 15 and 20 cm above the gastroesophageal junction (GEJ). The initial level of impaired bolus exit for each swallow was recorded. Data is reported as mean \pm SD.

RESULTS: One hundred and nineteen patients (48% male) underwent EFTs. One patient could not tolerate catheter insertion therefore is excluded. The most common presenting symptoms were dysphagia (47%); heartburn (44%); chest pain (24.6%) and GERD (18%). The most commonly reported diagnoses were normal manometry (54.2%); ineffective esophageal motility, (11.9%); and achalasia (10.2%). Mean LES pressure was 24 \pm 13.9 mmHg. Mean peristalsis was 81 \pm 27.5%. Mean contraction amplitude was 84 \pm 46.6 mmHg. Of 2358 swallows, 837 (35.5%) were incompletely transmitted. Of these, 39%, 41%, 15.6%, 4.4% did not exit at 20 cm, 15 cm, 10 cm, and 5 cm above the GEJ respectively. Of 118 patients, 64 had normal liquid bolus transit (group A), and 54 had abnormal liquid bolus transit (bolus transit < 70%) (group B). Group A had 79 liquid bolus exit abnormalities at channels 15 and 20 cm, and only 17 exit failures at channels 5 and 10 cm; while group B had 230 abnormal exits at the higher level, and 80 at the distal esophagus. Only 117 of the 118 patients had viscous swallows; of those, 55 had normal viscous bolus transit (group C), while 62 had abnormal viscous bolus transit (group D). Group C had 65 abnormal bolus exits at channels 15 and 20 cm, and 13 at channels 5 and 10 cm; while group D had 303, and 46 abnormal bolus exits, respectively.

CONCLUSION: When patients have abnormalities in bolus transit, the most likely level is 15 to 20 cm above the GEJ. Those with abnormal esophageal clearance are more likely to have abnormalities in this portion of the esophagus. This is at the level of the transition zone of striated to smooth muscle. This level of the esophagus should be the focus of future evaluation of the pathophysiology of esophageal motility disorders.

INACCURACY OF ENDOSCOPIC ANASTOMOTIC MEASURING TECHNIQUES.

Faiz Tuma¹, Leena Khaitan¹

INTRODUCTION: One of the major reasons identified for failure to lose weight in gastric bypass surgery is size of the anastomosis at the gastrojejunostomy. There is no standard technique for measurement of this anastomosis by endoscopy. Therefore, many treatment regimens may lead to ineffective intervention. This study was performed to identify the most accurate method to endoscopically measure the lumen diameter at the anastomosis to allow better management of these patients.

METHOD: Subjects were asked to endoscopically measure a ring of known diameter in a standardized plastic model of the esophagus and gastric pouch using 4 commonly used endoscopic measuring techniques and a double channel endoscope. Subjects used visual estimation (VE), instrument reference (IR) to a biopsy forceps, an 18 mm esophageal dilating balloon (DB) as reference, and a 30 mm endoscopic ruler (ER) made from an ERCP guide wire tip. The 5 models (33, 27, 24, 18 and 13 mm) were presented in random order. Data was collected and maintained in a database.

RESULTS: Ten (9 surgeons, 1 gastroenterologist) subjects participated. Endoscopic experience was >1000 scopes for 4 subjects; 250-500 for 3; <100 for 3. The VE was the least accurate with an average diversion (AD) from the actual diameter of 6.25 ± 4.95 mm (24.20 %); followed by IR, 3.89 ± 3.05 mm (14.80 %); then the ER, 2.4 ± 1.9 mm (9.20 %). The DB was the most accurate with AD of 1.46 ± 0.9 mm (7.20 %). Of the 200 total measurements, only 8 (4%) were accurate, 142 (71%) underestimated the size, and 50 (25%) overestimated. Underestimation was noted in 82.5% (33/40) of VE and IR measurements; ER had only 60% (24/40) underestimation; DB underestimated only 40% (16/40) of the time. Overestimation was highest using DB 55% (22/40), followed by ER method 45% (14/40), then IR 15% (6/40); and lowest in VE 12.5% (5/40). Measurements of the largest model diameter (33 mm) were underestimated 98% of the time. In the smallest diameter model (13 mm), 16% of the measurements were underestimated; 2% were accurate; and 82% were overestimated.

CONCLUSION: Endoscopic measurement of lumen diameter is very inaccurate. Underestimation is the most likely error in measurement. The larger the diameter the more likely it will be underestimated; and the smaller the diameter the more likely it will be overestimated. Endoscopists should avoid visual estimation and use a standard reference tool (dilating balloon) to measure anastomotic diameter. This will allow more effective intervention for clinical problems related to anastomotic size.

TOTAL THYROIDECTOMY IS SUPERIOR TO SUBTOTAL THYROIDECTOMY FOR MANAGEMENT OF GRAVES' DISEASE IN THE UNITED STATES

SM Wilhelm, and CR McHenry

INTRODUCTION: In the United States, Graves' disease is most commonly treated with radioiodine, yet thyroidectomy remains an important option for correcting hyperthyroidism. In many countries, limited access to thyroid hormone makes subtotal thyroidectomy the procedure of choice. In the U.S., where levothyroxine is inexpensive and widely available, we hypothesized that total (TT) or near-total thyroidectomy (NT) is superior to subtotal thyroidectomy (ST) for

MATERIALS AND METHODS: We conducted a retrospective review of patients who underwent ST, NT, or TT for Graves' disease between 1990 and 2008. Bilateral 3 gram remnants and a < 1 gram remnant remained following ST and NT, respectively. Differences in rates of recurrence were assessed using ANOVA. Rates of parathyroid autotransplantation, complications, gland weight and final pathology were also determined.

RESULTS: 136 patients with Graves' disease were treated with thyroidectomy. Average age was 36.4 ± 11.3 yrs (range 16-81) and 88% were female. Between 1990 and April 1994, 10 pts underwent ST and 6 pts had NT. Since then, all patients underwent TT (n=120). There was a significantly higher rate of recurrence for ST(30%) compared to NT (0%) ($p = 0.15$) and TT(0%) ($p < 0.0000001$). Parathyroid autotransplantation was performed in 36 (26.5%) patients, only 2 of whom underwent ST or NT. Temporary postoperative hypocalcemia was more common after TT ($p = 0.04$). However, no patient in any group had permanent hypoparathyroidism. Two TT pts had a temporary recurrent laryngeal nerve palsy. One patient in the TT group required re-exploration for postoperative neck hematoma. Final pathology revealed concomitant thyroid cancer in 3.6% of patients and thyroiditis in 26%. Average gland weight was 67.4 ± 57.3 grams.

CONCLUSIONS: ST resulted in 30% long-term failure to correct Graves' hyperthyroidism. We saw no increase in permanent RLN injury or hypoparathyroidism in the TT group despite the need for a more extensive surgical resection and higher rate of parathyroid autotransplantation. As thyroid hormone replacement is widely available, we feel that TT is safe and superior to ST for management of Graves' disease in the United States.

PANCREATICODUODENECTOMY IN PATIENTS WITH A HISTORY OF ROUX-EN Y GASTRIC BYPASS SURGERY

Merdad Nikfarjam^{1,2}, Kevin F Staveley-O'Carroll², Eric T Kimchi², Jeffrey M Hardacre¹

CONTEXT: Roux-en Y gastric bypass surgery is the most common operation for treatment of morbid obesity. The approach to pancreaticoduodenal resection in patients with a history of Roux-en Y gastric bypass is not well described.

CASE REPORTS: Pancreaticoduodenal resection was performed in two patients with distal bile duct strictures, with a past history of Roux-en Y gastric bypass. In both cases the remnant stomach, distal bile duct, duodenum and pancreas were excised. The biliopancreatic limb was divided close to the ligament of Treitz and brought up into the supracolic compartment in a retromesenteric manner and pancreatic and biliary anastomoses performed. The previous enteroenterostomy and gastrojejunal anastomoses were left intact. Both patients had an uncompleted post-operative recovery. The mean operating time was 6.5 hours and mean estimated blood loss was 525 mL. They were discharged home by days 6 and 7 post-operatively.

CONCLUSIONS: Pancreaticoduodenal resection can be successfully performed following Roux-en Y gastric bypass with *en-bloc* excision of the remnant stomach, with the pancreas and bile duct anastomosed to the divided biliopancreatic limb.

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SM Wilhelm, and CR McHenry

INTRODUCTION: In the United States, Graves' disease is most commonly treated with radioiodine, yet thyroidectomy remains an important option for correcting hyperthyroidism. In many countries, limited access to thyroid hormone makes subtotal thyroidectomy the procedure of choice. In the U.S., where levothyroxine is inexpensive and widely available, we hypothesized that total (TT) or near-total thyroidectomy (NT) is superior to subtotal thyroidectomy (ST) for

MATERIALS AND METHODS: We conducted a retrospective review of patients who underwent ST, NT, or TT for Graves' disease between 1990 and 2008. Bilateral 3 gram remnants and a < 1 gram remnant remained following ST and NT, respectively. Differences in rates of recurrence were assessed using ANOVA. Rates of parathyroid autotransplantation, complications, gland weight and final pathology were also determined.

RESULTS: 136 patients with Graves' disease were treated with thyroidectomy. Average age was 36.4 ± 11.3 yrs (range 16-81) and 88% were female. Between 1990 and April 1994, 10 pts underwent ST and 6 pts had NT. Since then, all patients underwent TT (n=120). There was a significantly higher rate of recurrence for ST(30%) compared to NT (0%) ($p = 0.15$) and TT(0%) ($p < 0.0000001$). Parathyroid autotransplantation was performed in 36 (26.5%) patients, only 2 of whom underwent ST or NT. Temporary postoperative hypocalcemia was more common after TT ($p = 0.04$). However, no patient in any group had permanent hypoparathyroidism. Two TT pts had a temporary recurrent laryngeal nerve palsy. One patient in the TT group required re-exploration for postoperative neck hematoma. Final pathology revealed concomitant thyroid cancer in 3.6% of patients and thyroiditis in 26%. Average gland weight was 67.4 ± 57.3 grams.

CONCLUSIONS: ST resulted in 30% long-term failure to correct Graves' hyperthyroidism. We saw no increase in permanent RLN injury or hypoparathyroidism in the TT group despite the need for a more extensive surgical resection and higher rate of parathyroid autotransplantation. As thyroid hormone replacement is widely available, we feel that TT is safe and superior to ST for management of Graves' disease in the United States.

QUILL SRS SUTURES-A RETROSPECTIVE AND PROSPECTIVE LOOK AT THEIR USE IN CLOSURE OF BREAST AND ABDOMEN INCISIONS

Daniel Medalie, M.D.

PURPOSE: This study consisted of two parts. The first part was a prospective use of Quill SRS (trademark) suture for the closure of breast and body contouring incisions. This suture is a bi-directional barbed suture designed to prevent slippage through tissues. The goal was to evaluate the speed of closure, complications and final scar outcome. The second part of the study was a prospective trial using patients as their own controls. One side of the patient was sutured in a conventional manner, and the other side was sutured using Quill sutures. The goal of this study was to perform a side-by-side comparison of the two different suture types in regard to speed of closure as well as complications and scar appearance.

METHODS: 40 patients undergoing abdominoplasty or breast reduction procedures had their wounds closed with Quill sutures as opposed to standard closure. The author performed all surgeries with the assistance of either a PA or resident. The outcomes were compared to the author's previous closures (retrospective control). In the author's standard abdominoplasty, Scarpa's fascia was closed with 2-0 Maxon, and the dermis was closed with interrupted and then sub-cuticular 4-0 monocryl sutures. In the author's standard breast reduction, the dermis was closed with interrupted and then sub-cuticular 3-0 monocryl sutures for the IM fold incision, and 4-0 Monocryl for the peri-areolar incision. In the Quills closure of the abdomen, Scarpa's layer was closed with running 2-0 barbed PDS, and the dermis was closed with a single layer of running 3-0 barbed PDS. No interrupted sutures were used. For the breast reduction surgery, the IM fold was closed with a single layer of running 3-0 barbed PDS, and the peri-areolar incision was closed with the same. Follow-up was from 3-12 months with notation of stitch abscess, wound healing complications and overall scar quality compared to historic controls.

The next study was performed on fifteen consecutive breast and abdomen patients. In each of these patients either the right or left side was closed in the conventional manner (as described above), and the opposite side was closed with the Quill suture. This was a more recent study and follow-up for the patients was only three-six months. Wound healing complications and scar appearance was evaluated for these patients with the opposite side serving as the perfectly matched control.

RESULTS: In the first study, use of the Quill suture resulted in an average time saved of 20 minutes for both the abdominoplasty and breast reduction surgeries. Initially there were a few instances of tracking suture abscesses along the Quill suture in the 2-4 week post-operative period. The author then modified his technique to dip the suture in Betadine and never allow it to touch drapes or sponge material. Subsequent to that there were no more suture abscesses. It is hypothesized that the barbed suture is much more prone to pick up small particles or bacteria from the drapes and should thus be handled meticulously. Scar results revealed no difference in the Quill versus standard closure.

In the second study there were no statistical differences in suture extrusion or wound dehiscence in the Quill side versus the standard side. There was a slight trend favoring the Quill. The early appearance of the scar was identical on both sides, and the Quill side could not be differentiated from the standard repair side by a blinded observer. Figure 1 shows an abdominoplasty incision at one month with the right side closed by Quill sutures and left side conventional sutures. Figure 2 shows a bilateral Wise-pattern breast reduction (1500 gram reduction) with the right side closed by Quill sutures and the left by conventional sutures.

CONCLUSION: Quill SRS sutures (trademark) are a rapid and effective way to close long skin and subcutaneous tissue incisions. They decrease operative time and appear to have no increased incidence of wound healing complications if they are handled in the appropriate fashion. The scar appearance is identical between Quill and conventional closure. The author thus recommends the use of the Quill suture for standard closure of breast and abdomen incisions.

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

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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.

A PROPOSED ALGORITHM FOR THE SELECTIVE MANAGEMENT OF COMPLEX VENTRAL HERNIAS

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 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.

PREDICTIVE FACTORS FOR CONVERSION OF LAPAROSCOPIC VENTRAL HERNIA REPAIRS

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

INTRODUCTION: Laparoscopic ventral hernia repair reduces length of hospital stay and postoperative wound complications. However, certain patients require conversion to an open procedure for various reasons. Identifying those patients with a high risk for conversion to open repair is important for preoperative counseling and reasonable patient and surgeon expectations. This study identifies those risk factors that predict conversion to an open repair.

METHODS: All patients undergoing attempted laparoscopic ventral hernia repair by a single surgeon between August 2005 and August 2007 were identified from a prospectively collected database. Nine preoperative factors were analyzed using R commander statistical program to predict recurrence.

RESULTS: 85 patients underwent attempted laparoscopic ventral hernia repair during the study period. The mean age was 59 ± 14 years and 52% were women. The median number of prior laparotomies was 1 (range 0-6) and 23% of the patients had prior intraperitoneal mesh. Nine patients (11%) required conversion to an open procedure for dense adhesions ($n=8$) and inadvertent enterotomy ($n=1$). There was no difference between the two groups based on age ($p=0.63$), ASA ($p=0.17$), BMI ($p=0.68$) and pre-operative albumin ($p=0.29$). The converted group had significantly more prior laparotomies (3 vs 1, $p=0.001$), more incarcerated hernias (56% vs 44%, $p=0.047$) and higher incidence of prior intraperitoneal mesh (33% vs 18%, $p=0.01$). A logistic regression model identified the number of prior laparotomies as the only factor independently predicting conversion ($p=0.006$).

CONCLUSION: While patients with prior intraperitoneal mesh placement and those with incarcerated hernias tended to have an increased chance of conversion during laparoscopic ventral hernia repair, the number of prior laparotomies was the only significant predictive factor. These results can help the surgeon counsel patients undergoing lap ventral hernia repair with regards to the probability of conversion to an open procedure.

HUMAN PERITONEAL MEMBRANE CONTROLS ADHESION FORMATION AND HOST TISSUE RESPONSE FOLLOWING INTRA-ABDOMINAL PLACEMENT IN A PORCINE MODEL

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BACKGROUND: Even with the advent of bioresorbable barriers, complications due to visceral adhesions following surgery continue to occur. The use of a homologous adhesive barrier such as human peritoneal membrane (HPM) could prevent adhesions formation and enhance wound healing. This study evaluates HPM as an effective adhesive barrier in a porcine model simulating a ventral hernia procedure.

MATERIALS AND METHODS: Through a midline laparotomy, meshes (10cm x10cm) were sewn onto the intact peritoneum of a pig, on each side of a midline incision in superior and inferior positions (4 randomized meshes/pig, n=9 pigs). The pigs were survived for 90 days. The meshes used were: HPM, compressed polytetrafluoro-ethylene (cPTFE), cPTFE+HPM, and polyester-collagen composite (PX). Exploratory laparoscopy was performed at 30 and 90 days to evaluate the extent of visceral adhesions. At necropsy, the extent and tenacity of visceral adhesions as well as material-abdominal wall integration were evaluated. Finally, host tissue response was assessed through scoring of inflammation, foreign body reaction, and mesothelialization.

RESULTS: HPM and PX led to the least extent and tenacity of visceral adhesions compared to cPTFE and cPTFE+HPM, but integrated less strongly within the adjacent abdominal wall. PX displayed the most robust foreign body reaction among all prosthetic materials, while HPM scored similarly to the native peritoneum. The extent of mesothelialization was similar throughout the materials tested.

CONCLUSIONS: The HPM barrier which promotes long-term peritoneal remodelling could diminish postsurgical intraperitoneal adhesions following hernia repair.

HUMAN PERITONEAL MEMBRANE REDUCES THE FORMATION OF INTRA-ABDOMINAL ADHESIONS IN VENTRAL HERNIA REPAIR: EXPERIMENTAL STUDY IN A CHRONIC HERNIA RAT MODEL

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BACKGROUND: Intra-abdominal adhesions leading to intestinal obstructions and fistulae are severe complications related to the intraperitoneal placement of synthetic meshes. This study evaluated human peritoneal membrane (HPM) in a chronic hernia repair rat model as an anti-adhesive solution for preventing the development of intraabdominal adhesions.

MATERIALS AND METHODS: The mechanical properties of HPM and human fascia Lata (HFL) were evaluated prior to in vivo implantation. Twenty rats underwent Midline laparotomy, which led to the development of chronic hernias 28 days later. Then, animals underwent incisional hernia repair in an underlay fashion (n=5/mesh group) with compressed poly(tetra-fluoro-ethylene) (cPTFE), onto which HPM or HFL were affixed pre-repair, along with two additional controls. The extent and tenacity of intra-abdominal adhesions were determined through qualitative gross evaluations and quantitative tensiometry at thirty days post-repair. The host tissue response was evaluated histologically.

RESULTS: In hydrated state, the elastic properties of HPM were superior to HFL. Repairs with HPM had significantly less surface area covered by adhesions, with significantly lower tenacity compared to all other groups. Further, intra-abdominal adhesions developed in the presence of HPM were associated with omentum only, and were distributed around the perimeter of the exposed cPTFE. HPM served as an active tissue remodelling template, replacing the traditional foreign body encapsulation with an anatomically and physiologically superior outcome.

CONCLUSIONS: HPM significantly reduces the extent and tenacity of intra-abdominal adhesion formation, and represents a bioprosthetic template which encourages structural and functional neoperitonealization.

USE OF ABDOMINAL WALL ALLOTRANSPLANTATION AS AN ALTERNATIVE FOR THE MANAGEMENT OF END STAGE ABDOMINAL WALL FAILURE IN A PORCINE MODEL

Judy Jin¹ MD, Christina P. Williams¹ MD, Hooman Soltanian² MD, Molly K. Smith³ MD, Jonathan Pearl¹ MD, Juan Sanabria¹ MD MSc FRCSC FACS, Michael J. Rosen¹ MD FACS

INTRODUCTION: We describe a novel approach for treating end stage abdominal wall failure using isolated abdominal wall allotransplantation in a porcine model.

METHODS: Full thickness abdominal wall transplants were performed in 13 pairs of genetically mismatched pigs. All recipients received daily immunosuppression after transplantation. Rejection was assessed by visual inspection and skin biopsies. At the end of the 28 day study period, thickness, stiffness and tensile strength of the transplanted rectus muscle was measured and compared with native rectus muscle.

RESULTS: Eight grafts were viable and showed no signs of herniation. Four grafts failed within the first week secondary to vascular thrombosis. One animal had viable graft but was euthanized due to an incarcerated inguinal hernia. Rejection was minimal in six of the eight recipients. At necropsy, the gross thickness of the transplanted muscle flap was reduced compared to the native muscle (4.3 mm versus 7.7 mm, $p < 0.001$). Histologically, the diameter of the muscle fiber decreased from 0.15 mm to 0.09 mm ($p < 0.0001$). While the stiffness measurements between the transplanted and native muscles were comparable, the transplanted muscles had significantly lower tensile strength than the native muscles.

CONCLUSION: This study demonstrates the feasibility of isolated abdominal wall allotransplantation to provide a potential solution for end stage abdominal wall failure. Based on the model set forth, future work will evaluate the biomechanical properties of the composite allograft to provide a suitable dynamic abdominal wall replacement.

DOES MESH CONSTRUCT AFFECT BIOFILM FORMATION ON PROSTHETIC MESH FOR VENTRAL HERNIA REPAIR?

Halaweish, I, Harth, K, Broome A-M, Voskerician, G, Jacobs, M, Rosen, M.

INTRODUCTION: Mesh infection in hernia repair is a major cause of patient morbidity and results in significant health care expenditures. Bacterial attachment and biofilm formation on the prosthetic is an essential step in the pathogenesis of mesh infections. The varying constructs of prosthetic mesh may alter the ability of bacteria to attach and form a biofilm. Little data exists evaluating biofilm formation on prosthetic mesh due to inherent characteristics of prosthesis preventing adequate differentiation of living bacteria and biofilm formation. Using a novel technique of Maestro In Vivo Imaging System (Cri, Inc., Woburn, MA) and GFP-expressing *Staphylococcus aureus*, this study evaluates four common meshes' ability to withstand bacterial biofilm formation in an in vitro model.

METHODS: We included four meshes in this study: Polypropylene (PP), Polypropylene/expanded PTFE (PX), compressedPTFE (cPTFE), and polyester/polyethylene glycol and collagen hydrogel (PE). Five samples of each mesh were exposed to 1×10^7 CFU of GFP-expressing biofilm producing *S. aureus* (Seattle 1945 strain) in 24 well plates and incubated for 18 hours at 37°C. Five samples of each mesh were placed in a 24 well plate in NaCl to serve as controls. The infected mesh underwent five washes in NaCl in preparation for Maestro analysis. Each infected mesh was evaluated, and the green fluorescence levels obtained with Maestro were subtracted from control fluorescence of uninfected mesh. On Maestro analysis, increased fluorescent signaling correlates with higher concentrations of biofilm producing *S. aureus*. Next, each mesh underwent sonication using the Fisher Scientific FS-74 system and the wash was collected. Serial dilutions of the sonicate wash were plated in blood agar dishes and evaluated at 24 hours for number of colony forming units. ANOVA analysis was performed to compare mean values across mesh.

LAPAROSCOPIC GRYNFELTT HERNIA REPAIR

Karem Harth, MD, Michael J Rosen, MD

BACKGROUND: Lumbar hernias are rare. Burick and Parascandola first described laparoscopic hernia repair in 1996. In 2005, Moreno-Egea of Spain published the first publication comparing open versus laparoscopic lumbar hernia repair. Most of these cases were secondary acquired lumbar hernias. Various repair techniques have been described since their identification. Given their posterior nature and relationship to critical vascular, neurologic and urologic structures, repair of these hernias can be challenging. This video demonstrates a case of laparoscopic Grynfeltt hernia repair.

TECHNIQUE: Our right lateral abdominal dissection extended from the right triangular ligament near the diaphragm down to the cecum following the line of Toldt (cephalad to caudal orientation). The right kidney was dissected out of the retroperitoneal space. A medial visceral rotation of the right colon, hepatic flexure and right kidney were performed. A large 15x15cm mesh was placed over a 5x3cm defect. This was secured in place by use of two PTFE sutures, titanium tacks and fibrin glue.

RESULTS: Operative time was 120 minutes with an estimated blood loss of 25cc. The intra-operative course was uncomplicated.

DISCUSSION: Our video demonstrates the technical feasibility of laparoscopic Grynfeltt hernia repair.

A NOVEL ANTIBIOTIC RELEASING SYNTHETIC MESH TO REDUCE PROSTHETIC SEPSIS: AN IN VIVO STUDY

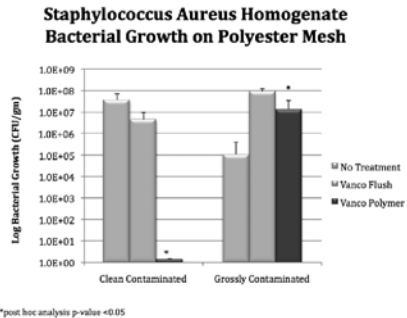
Harth, K, Halaweish, I, vonRecum, H, Rosen, M

BACKGROUND: Mesh related infections are a source of major patient morbidity and health-related costs. Despite use of aseptic technique and prophylactic use of antibiotics, mesh infections are reported to occur up to 30% of the time depending on technique and case complexity. Drug delivery devices have been implemented in other fields but to date there is no mesh available with the capacity to release antibiotics over a prolonged duration. We evaluate an antibiotic drug delivery platform in the setting of varying staphylococcus aureus mesh infections using an in vivo model.

STUDY DESIGN: Mice with subcutaneously placed mesh were randomly assigned to varying levels of Staphylococcus Aureus (SA) exposure and treatment regimens (Vancomycin = VN) followed by a two-week survival period. All mice underwent creation of a dorsal subcutaneous pocket, mesh placement (polyester = POL, 0.7x0.7cm), introduction of assigned level of bacteria prior to skin closure (clean=sterile saline, clean-contaminated=104 CFU/ml SA and grossly-infected=108 CFU/ml SA) and received an assigned type of treatment (a=no treatment (trt), b=VN flush and c=VN polymer coated mesh). Animals receiving the antibiotic polymer, the POL mesh was pre-coated with the VN delivering polymer (POLP). Bacterial inoculum and sterile saline introduction consisted of a 100 μ l volume. VN flush was given in a standard dose of 100 μ l of 7mg/1ml (0.7mg). A clinical isolate of SA labeled with green fluorescent protein was used. Our groups were as follows: one clean scenario [POL + saline (n=3)], three clean contaminated scenarios [(no trt) POL + 104 CFU/ml SA (n=4), (VN flush) POL + VN flush + 104 CFU/ml SA (n=4), (VN polymer) POLP + 104 CFU/ml SA (n=5)], and three grossly infected scenarios [(no trt) POL + 108 CFU/ml SA (n=3), (VN flush) POL + VN flush, 108 CFU/ml SA (n=5), (VN polymer) POLP + 108 CFU/ml SA (n=5)]. At 2-week necropsy, tissue was homogenized and cultured for quantitative analysis. Statistical software STATA ver 10.1 was performed. ANOVA testing was performed followed by post-hoc analysis when significant.

RESULTS: Average bacterial growth from homogenates were as follows: Clean group: no bacterial growth (0 CFU/gm). Clean contaminated group: (No trt) 3×10^7 CFU/gm (SD 3×10^7); (VN flush) 4×10^6 CFU/gm (SD 5×10^6); (VN polymer) no bacterial growth (0 CFU/gm) [p-value 0.03]. Grossly infected group: (No trt) 1×10^5 CFU/gm (SD 1×10^5); (VN flush) 9×10^7 CFU/gm (SD 3×10^7); (VN polymer) 1×10^7 CFU/gm (SD 2×10^7) [p-value <0.001]. All animals in the grossly infected group receiving 108 CFU/ml SA with no treatment were unable to tolerate infection and subsequently extruded their mesh.

CONCLUSIONS: Under a clean contaminated scenario, the drug delivery polymer was effective at treating and clearing a staphylococcus aureus mesh related infection. While there was an improved and statistically significant decrease in bacterial count under the grossly infected setting when the polymer was used, bacterial clearance was not achieved. Clinical application of this drug delivery polymer may be important in a select group of patients with risk factors for mesh related infection. Long-term studies are needed and ongoing at our institution.



MAJOR COMPLICATIONS ASSOCIATED WITH HETEROGRAFT BIOLOGIC MESH IMPLANTATION IN ABDOMINAL WALL RECONSTRUCTION

Harth, K, Rosen, M

BACKGROUND: There is limited to no human or animal data available on heterograft biologic mesh performance in the setting of infection despite their widespread utilization and significant associated costs. We reviewed an FDA database for reported adverse events.

STUDY DESIGN: Retrospective database review of heterograft biologic mesh used in the setting of abdominal wall reconstruction from 1997-2008.

RESULTS: One hundred and fifty adverse events (AE) were identified. Permacol™ and Collamend comprised 75% (n=112) of reported cases. Main adverse events included acute mechanical failure (AMF) (42%; n=63), mesh disintegration (MD) (32%; n=48) and poor mesh integration (PMI) (13%; n=20). Eighty percent of cases were described as infected and nearly 90% of AE required reoperation. No difference was found among mesh for AMF (p-value 0.39). A difference was found for MD (p-value 0.02) and PMI (p-value 0.001). Crosslinking status was not statistically associated with any of the three main outcomes. However, crosslinking status appeared to trend towards increased odds of PMI (OR 2.0; CI 0.55 - 7.43). Presence of infection at the time of mesh placement had fourfold odds of MD (OR 4.0; CI 1.28 - 12.6). No association was found between presence of infection and AMF (p-value 0.09) or PMI (p-value 0.37).

CONCLUSIONS: There are major complications reported for varied heterograft biologic mesh. The intrinsic properties of each mesh and how they relate to infection related outcomes are poorly understood. The findings from this FDA database review in conjunction with the lack of available literature point towards a significant need to carefully evaluate these products prior to widespread utilization.

ENDOSCOPIC VERSUS OPEN COMPONENT SEPARATION IN COMPLEX ABDOMINAL WALL RECONSTRUCTION

Karem C Harth, MD MHS, Michael J Rosen, MD

BACKGROUND: The component separation technique (CST) releases the lateral abdominal wall muscles to facilitate closure of complex midline defects. Open techniques often involve large lipocutaneous flaps with extensive perforator vessel division to gain access to the lateral abdominal compartment. Endoscopic approaches provide direct access to the lateral abdominal wall utilizing balloon dissectors and laparoscopic visualization. To date, no comparative trials exist evaluating these two methods of complex abdominal wall reconstruction.

METHODS: All patients undergoing open and endoscopic CST between 2005 and 2009 performed by a single surgeon at Case Medical Center were retrospective identified. Perioperative variables included: age, gender, ASA, BMI, comorbidities (COPD, diabetes), smoking status, hernia defect size, operative time, intraoperative and postoperative complications, length of stay, and hernia recurrence. Fisher's exact and t-test statistics were performed with a p-value of <0.05 considered significant.

RESULTS: During the study period, 44 cases of component separation were performed, 22 open and 22 endoscopic. The open component separation group was older (65 versus 55 years; $p=0.01$) than the endoscopic group. Both groups were similar on all other demographics including ASA (3.2 v 3; $p=0.11$), BMI (39 v 36 kg/m²; $p=0.45$), prior abdominal surgeries (4 v 4; $p=0.59$), and prior hernia repairs (2 v 2; $p=0.59$). The patients had similar sized defects (392 v 324 cm²; $p=0.44$), mesh utilized (382 v 415 cm²; $p=0.82$) and operative times (277 v 242min; $p=0.12$). The open group had a significantly longer postoperative length of stay as compared to the endoscopic group (11.6 days v 7.2 days; $p=0.04$). Wound complications were similar between the two groups open 32% (n=7) versus endoscopic 23% (n=5) $p=0.73$, although 4/5 major wound complications requiring operative debridement occurred in the open group. With a mean follow up of 9 months overall hernia recurrence rate was 18%. There was no significant difference between the open and endoscopic groups with respect to hernia recurrence (10% versus 27%; $p=0.24$).

CONCLUSION: The use of component separation for reconstructing complex abdominal wall defects results in medialization of the rectus muscle and an improved functional outcome. This can be achieved using either an open or endoscopic approach. Our study shows that the endoscopic release results in a comparable advancement of the myofascial unit in this complicated population by achieving rectus muscle reapproximation in all cases with no difference in long-term hernia recurrence rates. Using an endoscopic approach, length of stay was significantly reduced and much fewer major wound complications occurred. Given the absence of subcutaneous skin flaps, and avoidance of perforator vessel division, the endoscopic approach to component separation might be the ideal technique for complex abdominal wall reconstruction.

LAPAROSCOPIC GASTROPEXY COMBINED WITH LOCAL GASTRIC SEROSAL AND PERITONEAL IRRITATION FOR TREATMENT OF GASTRIC VOLVULUS

*Karem C. Harth, MD, MHS, Mehrdad Nikfarjam MD, PhD, Michael J. Rosen, MD, FACS**

BACKGROUND: Gastric volvulus is traditionally treated by laparotomy and stomach fixation. Consensus regarding the best methodology of stomach fixation has not been reached. We describe a simple and effective laparoscopic approach to gastric volvulus of the organo-axial type.

METHODS: Standard laparoscopic equipment was utilized for this case. This included a 10mm port for the camera, another 10 mm port in the left subcostal region (where a PEG would normally be placed), and two additional 5 mm ports. Anterior gastropexy was performed onto the abdominal wall near our 10mm port site. Prior to fixation of the sutures onto the abdominal wall, a cautery scratch pad was placed intra-abdominally and used to induce serosal irritation between the sutures on the anterior stomach and on the peritoneum near the 10mm port site.

RESULTS: There were no post-operative complications. Following a 1-month follow up, the patient is asymptomatic. Post-operative UGI revealed normal anatomical fixation of the stomach with no evidence of organo-axial volvulus.

CONCLUSIONS: Gastric volvulus can be safely and successfully managed by laparoscopic gastropexy in conjunction with serosal and peritoneal irritations for enhanced fixation. We describe a simple and effective technique.

SIGNIFICANT REDUCTION IN INCIDENCE OF WOUND CONTAMINATION BY SKIN FLORA THROUGH USE OF MICROBIAL SEALANT

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HYPOTHESIS: Application of skin sealant prior to incision reduces microbial contamination of the wound.

DESIGN: Prospective, randomized, multicenter clinical trial.

SETTING: Six teaching hospitals.

PATIENTS: A total of 177 adult patients undergoing elective open inguinal hernia repair were randomized to either standard skin preparation with 10% povidone-iodine or skin preparation followed by cyanoacrylate-based liquid microbial sealant.

INTERVENTIONS: Wound contamination was assessed during surgery by microbial sampling inside the wound at initiation of skin incision and prior to skin closure.

MAIN OUTCOME MEASURES: The primary outcome measures were the safety and effectiveness of cyanoacrylate-based microbial sealant to reduce bacterial contamination during surgery. The secondary outcome measure was reduction of postoperative surgical site infections using microbial sealant.

RESULTS: Demographics were similar. Patients treated with sealant were more likely to have no bacterial cells found in the wound than control participants (47% vs 31%; $P=.04$). Three patients developed surgical site infections; all were in the control group ($P=.25$). Independent factors that reduced wound contamination were use of microbial sealant (odds ratio, 0.45; confidence interval, 0.23-0.88; $P=.02$) and perioperative antibiotics (odds ratio 0.24; confidence interval, 0.10-0.58; $P=.001$).

CONCLUSION: Cyanoacrylate-based microbial sealant may be an important tool to reduce wound contamination and potentially prevent surgical site infections.

PREDICTIVE FACTORS FOR SURGICAL SITE INFECTION IN GENERAL SURGERY

Manjunath Haridas, MD, and Mark A. Malangoni, MD

BACKGROUND: Global parameters, such as wound class, the American Society of Anesthesiologists' physical classification score, and prolonged operative time, have been associated with the risk of surgical site infection (SSI). We hypothesized that additional risk factors for SSI would be identified by controlling for these parameters and that deep and organ/space SSI may have different risk factors for occurrence.

METHODS: A retrospective review was performed on general and vascular surgical patients who underwent an operation between June 2000 and June 2006 at a single institution. Patients with SSI were matched with a case-control cohort of patients without infection (no SSI) according to age, sex, ASA score, wound class, and type of operative procedure. Data were analyzed using bivariate and regression analyses.

RESULTS: Overall, 10,253 general surgical procedures were performed during the 6-year period; 316 patients (3.1%) developed SSI. In all, 300 patients with 251 superficial (83.6%), 22 deep (7.3%), and 27 organ/space (9%) SSIs were matched for comparison. Multivariate logistic regression analysis identified previous operation [odds ratio (OR), 2.4; 95% confidence interval (CI) = 1.6-3.71, duration of operation \geq 75th percentile (OR, 1.8; 95% CI = 1.2-2.8), hypoalbuminemia (OR, 1.8; 95% CI = 1.1-2.8), and a history of chronic obstructive pulmonary disease (OR, 1.7; 95% CI = 1.0-2.8) as independent risk factors for SSI. Only hypoalbuminemia (OR, 2.9; 95% CI = 1.4-6.3) and a previous operation (OR, 2.0; 95% CI = 1.0-4.4) were significantly associated with deep or organ/space infections.

CONCLUSIONS: These results demonstrate additional factors that increase the risk of developing SSI. Deep and organ/space infections have a different risk profile. This information should guide clinicians in their assessment of SSI risk and should identify targets for intervention to decrease the incidence of SSI.

A NOVEL APPROACH FOR THE SIMULTANEOUS REPAIR OF LARGE MIDLINE INCISIONAL AND PARASTOMAL HERNIAS WITH BIOLOGIC MESH AND RETRORECTUS RECONSTRUCTION

Michael J. Rosen, Harry L. Reynolds, Bradley Champagne, Conor P. Delaney

INTRODUCTION: Patients with concomitant large midline incisional and parastomal hernias present many unique challenges to the reconstructive surgeon. Local approaches, laparoscopic repairs, and open synthetic mesh reconstructions have high failure rates, and major morbidity including mesh erosions, sepsis, and obstruction. We describe a novel approach of simultaneously repairing the midline incisional and parastomal defect, while prophylactically reinforcing the resited stoma site with a retrorectus biologic graft.

METHODS: Between March 2006 and January 2009 all patients undergoing simultaneous repair of midline incisional and parastomal defects were retrospectively identified. Standard patient demographics, operative details and postoperative outcomes were analyzed. Surgical technique involved a midline incision, adhesiolysis, takedown and reciting of the stoma, component separation when indicated, midline closure, and retrorectus placement of a biologic graft to reinforce the old stoma site, buttress the midline, with a keyhole at the new stoma.

RESULTS: During the study period 13 patients underwent simultaneous repair of both a midline incisional and parastomal defect. There were 9 men, and 4 women with a mean age of 63 years, BMI 34 kg/m², and ASA 3. Patients had undergone an average of 4 (range 2-9) prior abdominal surgical procedures, and 2 (range 0-8) prior hernia repairs. Hernia defects averaged 359 cm² (range 150-506) and typically a 20x20 cm sheet of biologic mesh was utilized. Two patients required simultaneous resection of a piece of infected prosthetic mesh. The midline fascia was reapproximated in all patients utilizing a component separation in 7 cases. Mean operative times were 282 min (range 165-420). Postoperative complications occurred in 3 patients (23%) and included transient renal failure, deep venous thrombosis, and one patient died suddenly on postoperative day 3 of unknown causes. After a mean follow up of 11 months (2-24) no midline incisional hernias have recurred and one patient has a small asymptomatic parastomal recurrence.

CONCLUSIONS: Simultaneous parastomal and midline incisional hernia repair is a technically demanding procedure with little data available evaluating its results. The utilization of various abdominal wall reconstructive techniques including, component separation, biologic grafts, and retrorectus graft positioning may offer an acceptable approach to repairing these challenging defects.

PROSPECTIVE RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL OF POSTOPERATIVE ELASTOMERIC PAIN PUMP DEVICES FOLLOWING LAPAROSCOPIC VENTRAL HERNIA REPAIR

Michael J. Rosen MD, Trieve Duperier MD, Jeffrey Marks MD, Raymond Onders MD, Jeffrey Hardacre MD, Bridget Ermlich RN, Michelle Laughinghouse RN

INTRODUCTION: The laparoscopic repair of ventral hernias can result in significant postoperative pain resulting in prolonged length of hospital stay, increased narcotic utilization, and patient dissatisfaction. Elastomeric pain pump devices with local analgesics may result in a significant reduction in postoperative discomfort after laparoscopic ventral hernia repair. We evaluated the effect of continuous infusion of local anesthetic with an elastomeric pain pump device to reduce postoperative pain in a prospective randomized double blind placebo controlled study.

METHODS: After IRB approval, all patients undergoing laparoscopic ventral hernia repair were consented to participate in the study. Standardized technique included routine transfascial fixation sutures and titanium spiral tacks. Elastomeric pain pumps were placed percutaneously just above the mesh, in the hernia sac. 100cc's of continuous 0.5% marcaine or normal saline at 2 ml/hr were utilized for 48 hours postoperatively. Postoperatively, patients were evaluated every 8 hours for the first 72 hours, then 2 weeks, 6 weeks, and 3 months for pain scores, narcotic usage (both PO and IV), return of flatus, length of hospital stay, and postoperative complications.

RESULTS: 73 patients were enrolled in the study, 37 received 0.5% marcaine and 36 received placebo. Despite randomization, the control group had significantly more obese patients (mean BMI 39 v 33 kg/m²; p=0.005), more recurrent hernias (40% v 19%; p=0.05), and tended to have more prior hernia repairs (0.8 v 0.3; p=0.06). There were no significant differences between the two groups based on operative times (p=0.7), hernia size (p=0.9), mesh size (p=0.6), number of transfascial fixation sutures (p=0.4), or spiral tacks (p=0.13). Postoperative visual analog pain scores, usage of oral or intravenous narcotics, and morphine equivalents were similar between the two groups at all study points (p>0.05). There were no significant differences between the two groups based on return of bowel function, tolerating a regular diet, or length of stay. No postoperative complications occurred directly related to the catheter.

CONCLUSIONS: This prospective randomized double blind placebo controlled trial shows no advantage of an elastomeric pain pump device to provide a measurable reduction in postoperative pain scores, narcotic utilization, return of bowel function, or hospital stay after laparoscopic ventral hernia repair. Further studies are warranted to determine other alternatives for reducing postoperative pain after laparoscopic ventral hernia repair.

DIAPHRAGM PACING STIMULATION (DPS) SYSTEM: PROVIDING VENTILATION OPTIONS FOR TETRAPLEGICS

Raymond P. Onders M.D.1; Mary Jo Elmo ACNP; Bashar Katirji M.D.

BACKGROUND: For tetraplegics with chronic respiratory insufficiency, the diaphragm pacing stimulation (DPS) system is an alternative to long-term mechanical ventilation. This report summarizes the largest single site experience with DPS.

RESEARCH DESIGN: Prospective FDA trial of the DPS System (NeuRx RA/4, Synapse Biomedical, Ohio) for electrical activation of the diaphragm for ventilatory assist in tetraplegics from March 2000 to December 2007.

METHODS: Patients underwent laparoscopic diaphragm motor point mapping with electrode implantation. Patients were progressively weaned from their ventilator as the diaphragm strengthened. The implanted electrodes were also utilized to assess for recovery of diaphragm EMG activity.

RESULTS: A total of 39 patients were implanted with failure only in the second patient due to a false positive phrenic nerve study. There was no peri-operative mortality with average hospitalization of less than one day. 98% of the patients had DPS stimulated tidal volumes above 5-7cc/Kg for 4 or more continuous hours with 50% utilizing DPS for continuous 24 hour ventilation. Age and time from injury directly affects conditioning time with younger and more recently injured patients weaning from the ventilator faster. During long term follow-up, there have been three unrelated deaths (1 sepsis, 2 cardiac). In analyzing 7 patients with pre-existing cardiac pacemakers there was no cardiac or device to device interaction. Six patients were assessed utilizing DPS simultaneously with a ventilator showing a 20% increase in respiratory compliance, a 21 % decrease in peak airway pressure and a 24% increase in tidal volumes. Two implanted patients recovered volitional and automatic diaphragm EMG activity and with training were able to wean off of DPS.

CONCLUSION: The results show that DPS is a low risk effective procedure to replace chronic ventilator use for tetraplegics. Also DPS can be used in conjunction with a ventilator to increase respiratory compliance by decreasing atelectasis and this may decrease the typical high initial pneumonia rates for tetraplegics. Most importantly was the use in two patients of DPS in recovering their own natural breathing outlining how acute DPS use in SCI injury could be used as a bridge to extubation.

DIAPHRAGM PACING AND THE ART OF LONG DISTANCE PATIENT MANAGEMENT

MaryJo Elmo, Raymond P. Onders M.D.

Tetraplegia requiring mechanical ventilation fortunately occurs rarely comprising less than 500 new cases yearly. These patients frequently have difficulty finding local quality care. The Diaphragm Pacing Stimulation (DPS) System (Synapse Biomedical, Ohio) is an alternative method of breathing for this population and has many reported benefits by its users and their primary caregivers. DPS has a home based conditioning program that has proven to be beneficial to the patient and manageable by the health care team.

Conditioning is the process of increasing diaphragm muscle strength and begins 10-14 days post implantation. The increase in muscle strength is required to sustain ventilation and can take up to 12 weeks. In the home based program patients and caregivers are instructed on care and use of the device and an individualized plan is developed to transition the patient from the ventilator to DPS.

Patients choosing to undergo DPS may travel a great distance to the implantation site. Currently, UHCMC site has implanted and manages 39 SCI persons from 12 states and 3 countries. We have been able to successfully oversee the conditioning of patients regardless of their physical distance from Cleveland by utilizing telephones, faxes and the internet.

SURGERY IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS: THE MIDWESTERN SURGICAL EXPERIENCE WITH THE DIAPHRAGM PACING STIMULATION (DPS) SYSTEM SHOWS THAT GENERAL ANESTHESIA CAN BE SAFELY PERFORMED

Raymond P. Onders MD, Cleveland, OH; Arthur M. Carlin, Detroit MI

BACKGROUND: There is a paucity of literature concerning general anesthesia and surgery in patients with amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). Historically surgery has been considered high risk because of the significant and progressive respiratory insufficiency in ALS patients. Thirty day mortality rates are reported to be as high as 30% for gastrostomy tubes alone. The laparoscopic diaphragm pacing stimulation (DPS) is being placed under general anesthesia in prospective trials. Preliminary results show that the DPS system has significantly decreased the decline of forced vital capacity (FVC) from 2.4% pre-implant to .9% per month post implant extrapolating to a 24 month improvement in survival. Other finding showed improved respiratory compliance and overcoming central sleep apnea. This report outlines the peri-operative management utilized at the two Midwestern implantation sites to dispel the beliefs that surgery in patients with ALS can not be performed safely.

METHOD: Under FDA and IRB approvals patients underwent laparoscopic diaphragm motor point mapping with electrode implantations. Because muscle stimulation has to be performed to identify optimal implantation site of electrodes no neuromuscular relaxants (paralyzing agents) are used. Pre-emptive local anesthetic is placed in all planned incision. The overall strategy was to use rapid reversible short acting analgesic and amnestic agents. The following regimen was used: midazolam (anxiolytic and decreases intraoperative muscle spasms); remifentanyl (intravenous ultrashort acting narcotic used for induction and maintenance of anesthesia. This agent being a potent narcotic depresses the respiratory drive which facilitates diaphragm mapping.); sevoflurane (inhalational amnestic agent with low lipid solubility) and propofol (intravenous amnestic agent). 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. In several cases DPS was utilized to stimulate respirations immediately post-operatively.

RESULTS: Fifty-one patients were implanted from March 2005 to March 2008 under three different research protocols at these 2 sites (9 sites worldwide). Their ages ranged from 42 to 73 and the percent predicted FVC at the time of implant ranged from 20% to 87%. On pre-operative blood gases the pCO₂ was as high as 60. Using this protocol there were no failures to extubate or 30 day mortalities. There were no prolonged hospitalizations with most patients being discharged in less than one day. Three patients returned for second operations- two gastrostomies and one colon resection for colon cancer with no morbidity. The DPS system was utilized during the second operation to not only monitor diaphragm respirations but to also stimulate respirations in the now identified central sleep apnea these patients develop.

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. 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.

DIAPHRAGM PACING STIMULATION (DPS) SYSTEM IN AMYOTROPHIC LATERAL SCLEROSIS: SURGICAL EXPERIENCE IN A PROSPECTIVE PIVOTAL MULTI-CENTER TRIAL

Raymond P. Onders MD, Cleveland, OH; John M. Morton MD, Stanford CA; Arthur M. Carlin, Detroit MI; Gregg H. Jossart MD, San Francisco CA; C. Daniel Smith MD, Jacksonville FL; Brian J. Dunkin MD, Houston TX

BACKGROUND: Respiratory insufficiency is the major cause of mortality in patients with amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). The pilot trial of the diaphragm pacing stimulation (DPS) system in patients with ALS significantly decreased the decline of forced vital capacity (FVC) from 2.4% pre-implant to .9% per month post implant extrapolating to a 24 month improvement in survival. Other significant finding showed improved respiratory compliance and overcoming central sleep apnea. This is the initial report of the surgical and peri-operative experience of the pivotal multi-center trial.

METHOD: Under FDA and IRB approvals patients underwent laparoscopic diaphragm motor point mapping with electrode implantations. Surgical and peri-operative adverse events were recorded prospectively.

RESULTS: Forty-six patients of the planned 100 patient trial have been implanted at 6 sites between March 2007 and March 2008. Average age was 56(range 42-73). The average FVC of the time of implantation was 60% predicted (range 45-87%) with average pCO₂ of 40(range 38-60). In all patients mapping and electrode implantation was done successfully and during post-operative electrode characterization all electrodes functioned with appropriate resistance, stimulus and output characteristics. All electrodes were able to assess diaphragm electromyographic (EMG) activity. All patients were successfully extubated with no peri-operative mortality. No perioperative wound infections occurred even with simultaneous gastrostomy tubes. Non-device peri-operative morbidity included: one extended hospitalization from a pre-existing cardiomyopathy and one post-operative gastrostomy tube dislodgement requiring re-hospitalization.

CONCLUSIONS: The DPS system implantation can be safely duplicated at multiple sites in a high risk ALS population suffering from respiratory insufficiency.

DIAPHRAGM PACING IN ALS: EXPERIENCE AT THE FIRST AND LARGEST IMPLANT SITE

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

BACKGROUND: Respiratory failure is the major cause of mortality in patients with ALS/MND. The Diaphragm Pacing Stimulation (DPS) system provides electrical stimulation to the motor points causing diaphragm contraction. DPS requires a minimally invasive laparoscopic implantation procedure and is currently utilized world wide to maintain diaphragm breathing. DPS therapy offers a specific therapy for diaphragm dysfunction in ALS.

OBJECTIVE: To describe our experience with our 47 implanted ALS patients. Analyze and discuss what we have learned about the diaphragm, affects on the ALS diaphragm and how patients have utilized DPS. .

CLINICAL OUTCOMES: From 2005-2008, 47 patients tolerated the surgical implantation of the DPS with 18 receiving simultaneous feeding tube placement. No significant perioperative adverse events occurred even with forced vital capacity(FVC) as low as 20%. Fluoroscopic evaluation of is extremely beneficial in determining function with patients having more visualized diaphragm movement of the diaphragm with stimulation than under maximal voluntary effort. Utilization of DPS to overcome night time sleep dysfunction has been used by almost 50% of patients with or without non invasive positive pressure ventilation. DPS can also continuously assess diaphragm EMG activity and this has become a key marker to follow patients diaphragm function. Increase usage of DPS has corrected hypercarbia. With DPS, there has been maintenance of the respiratory sub-score on the ALSFRS_r scale. DPS has been shown to decrease the rate of decline of FVC from a pre-implantation rate of 2.4% per month to 0.87% per month after DPS conditioning of the diaphragm. This extrapolates to an additional 24 ventilator free months. Presently now have had patients stop DPS when they lose their ability to communicate allowing dignified death without the need and stress of mechanical ventilator choice. For 26 patients implanted greater than 12 months there is a mean survival from diagnosis of 45 months. For patients with simultaneous PEG and DPS the one year survival is 75% with no 30 day deaths which is much improved over historical reports of up to 30% 30 day mortality rate.

PROGRAM DESCRIPTION: The effects of DPS in the management of the ALS/MND patient will be discussed. Results and case reports will be described. Utilization in research and future practice will be analyzed.

RECOMMENDATION TO THE FIELD: DPS positively affects diaphragm function in patient with ALS. It offers another therapy to improve respiratory dysfunction and decreases the decline in respiratory failure delaying the need for mechanical ventilation.

RESULTS OF PROSPECTIVE PILOT AND MULTI-CENTER PIVOTAL TRIALS OF DIAPHRAGM PACING IN AMYOTROPHIC LATERAL SCLEROSIS: MAINTAINING DIAPHRAGM FUNCTION AND IMPROVING SURVIVAL

R Onders, B Katirji, M Elmo(University Hospitals Case Medical Center, Cleveland, OH); Y So, C Cho, H Katzberg (Stanford University Medical Center, Palo Alto, CA); J Katz, R Miller(California Pacific Medical Center, San Francisco, CA); D Newman, X Arcila-Londono (Henry Ford Hospital, Detroit, MI); E Simpson, S Appel (Methodist Neurological Institute, Houston, TX); K Boylan (Mayo Clinic, Jacksonville, FL); N Maragakis, J Rothstein (John Hopkins Medical Center, Baltimore, MD); M Sivak (Mt. Sinai, New York, NY); M Wiedau-Pazos (UCLA Medical Center, Los Angeles, CA); T Heiman-Patterson (Drexel Medical Center, Philadelphia, PA); V Meininger, F Salachas, J Gonzalez-Bermejo, T Similowski (Pitie Salpetriere, Paris, France)

BACKGROUND: Respiratory insufficiency is the major cause of mortality in patients with ALS/MND. Present therapies in ALS do not address diaphragm dysfunction. The diaphragm pacing system (DPS) is a standardized minimally invasive laparoscopic technique that is being utilized worldwide to maintain and provide natural diaphragm ventilation.

Objective: Analyze safety and efficacy of DPS in ALS.

METHODS: At 11 worldwide sites, a prospective lead-in design study obtaining a battery of three initial data sets were collected prior to treatment by laparoscopic placement of intramuscular diaphragm pacing electrodes. Subjects utilized DPS to condition their diaphragm with additional utilization depending on respiratory condition. Data was collected for another nine months post implant and until death.

RESULTS: Total recruitment will be completed with 140 subjects (20 in pilot and 120 in pivotal with 20 European subjects being enrolled while the US enrolment is completed). Of these 140 patients 73 have been implanted with 40 patients still in the lead in and 27 patients falling out after consenting but prior to implantation(most commonly from FVC not meeting inclusion criteria- 13 patients). Patient demographics at implantation was 70% male, 60% NIPPV use, 34% use of gastrostomy, FVC 60+/- 12 % predicted with decline rate of -1.81% per month and ALSFRS-r score of 28+/- 7.5. There were no perioperative mortalities with over 25% having FVC below 50 and over 30% having elevated pCO₂. Non-device peri-operative morbidity included: one extended hospitalization from a pre-existing cardiomyopathy and one post-operative gastrostomy tube dislodgement requiring re-hospitalization. Total cumulative use of DPS is over 600 months with longest implants over 2 years with no non-tolerance of pacing post implantation. Subjects with declining FVC during the lead-in period showed a significant ($p < 0.05$) improvement in paired comparison to rate of decline with treatment with an average improvement of $1.33 \pm 2.45\%$ per month. Overall there have been 19 patients that have reached the endpoint of death or tracheostomy with only 4 being the result of respiratory failure. The probability of survival is at a mean of 60.9 +/- 6.7 months for all patients. In patients undergoing DPS and gastrostomy (n=18) the 30 day survival was 100% and the 1 year survival 75%. The ALSFRS-R score showed that while the overall symptoms of ALS progressed the respiratory subscore did not decline. Prior to implant the respiratory subscore represented 32% of the total and following treatment it was 41%. In paired comparison of pre- and post-treatment, the respiratory subscore increased by $8 \pm 12\%$ of the total ALSFRS-R score ($p < 0.001$). DPS can continuously assess diaphragm EMG activity which has allowed the identification of instability of respiratory control and central hypoventilation. Sleep assessments performed at one site showed 23 of 47 patients utilize DPS during sleep. Greater fluoroscopic diaphragm movement is visualized with DPS stimulation in patients with more upper motor neuron diaphragm involvement. DPS has been able to lower pCO₂ levels with increased daily use.

CONCLUSION: The DPS system can be safely implanted and utilized in ALS patients with a positive effect on diaphragm function. DPS minimizes the impact of NIPPV on diaphragm dysfunction and positively impacts patients with identified instability of respiratory control.

IDENTIFYING THE ROLE OF DIAPHRAGM PACING STIMULATION (DPS) IN AMYOTROPHIC LATERAL SCLEROSIS/MOTOR NEURON DISEASE: RESULTS FROM OVER 50 CONSECUTIVE IMPLANTS

Raymond P. Onders MD, MaryJo Elmo ACNP, Anthony Ignagni MD, Bashar Katirji MD

BACKGROUND: Respiratory failure is a major cause of mortality in amyotrophic lateral sclerosis/motor neuron disease patients. Mechanical ventilation with attendant limitations is the only current therapeutic option for patients developing respiratory compromise. Diaphragm pacing stimulation (DPS) is being utilized to assist in ventilation in patients with ALS/MND and this reports the experience at the worlds largest implant site.

Aim: Review of results from the initial site implanting DPS in ALS patients.

METHODS: From 2005 to 2008, patients were evaluated prospectively and then underwent diaphragm motor point mapping with percutaneous intra-muscular electrode implantation. Diaphragm conditioning ensued.

RESULTS: 51 patients were implanted with DPS with a predicted Forced Vital Capacity (FVC) at implantation ranging from 20% predicted to 88% predicted. Only one significant peri-operative adverse events occurred in a patient with an FVC below 20% and extreme malnutrition requiring both a feeding tube and DPS. Feeding tubes were safely implanted simultaneously with DPS with a 12 month survival of 83% compared to reported historical 30 day mortality rate for gastrostomy alone of up to 40%. DPS patients with FVC below 50% at implantation have a mean survival of 16 months compared to the historical one year mortality rate of 100%. Additional findings include: DPS increases diaphragm muscle thickness as measured by ultrasound; DPS improved diaphragm movement under fluoroscopy; DPS maintains the respiratory sub-score of ALSFRS-r; DPS can convert fast twitch glycolytic (Type IIb) to functional slow twitch oxidative muscle (Type 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. It was found that ALS patients develop instability of respiratory control and even acquired central hypoventilation. Over 50% of patients utilized DPS during sleep. DPS was used to overcome hypoventilation and hypercarbia.

CONCLUSION: Diaphragm pacing can be safely implanted in ALS patients positively affecting diaphragm physiology to improve both peri-operative and long term survival. DPS overcomes upper motor neuron involvement and the instability of respiratory control.

DIAPHRAGM PACING STIMULATION (DPS) SYSTEM: PROVIDING VENTILATION OPTIONS FOR TETRAPLEGICS

Raymond P. Onders M.D.1; Mary Jo Elmo ACNP; Bashar Katirji M.D.

BACKGROUND: For tetraplegics with chronic respiratory insufficiency, the diaphragm pacing stimulation (DPS) system is an alternative to long-term mechanical ventilation. This report summarizes the largest single site experience with DPS.

RESEARCH DESIGN: Prospective FDA trial of the DPS System (NeuRx RA/4, Synapse Biomedical, Ohio) for electrical activation of the diaphragm for ventilatory assist in tetraplegics from March 2000 to December 2007.

METHODS: Patients underwent laparoscopic diaphragm motor point mapping with electrode implantation. Patients were progressively weaned from their ventilator as the diaphragm strengthened. The implanted electrodes were also utilized to assess for recovery of diaphragm EMG activity.

RESULTS: A total of 39 patients were implanted with failure only in the second patient due to a false positive phrenic nerve study. There was no peri-operative mortality with average hospitalization of less than one day. 98% of the patients had DPS stimulated tidal volumes above 5-7cc/Kg for 4 or more continuous hours with 50% utilizing DPS for continuous 24 hour ventilation. Age and time from injury directly affects conditioning time with younger and more recently injured patients weaning from the ventilator faster. During long term follow-up, there have been three unrelated deaths (1 sepsis, 2 cardiac). In analyzing 7 patients with pre-existing cardiac pacemakers there was no cardiac or device to device interaction. Six patients were assessed utilizing DPS simultaneously with a ventilator showing a 20% increase in respiratory compliance, a 21 % decrease in peak airway pressure and a 24% increase in tidal volumes. Two implanted patients recovered volitional and automatic diaphragm EMG activity and with training were able to wean off of DPS.

CONCLUSION: The results show that DPS is a low risk effective procedure to replace chronic ventilator use for tetraplegics. Also DPS can be used in conjunction with a ventilator to increase respiratory compliance by decreasing atelectasis and this may decrease the typical high initial pneumonia rates for tetraplegics. Most importantly was the use in two patients of DPS in recovering their own natural breathing outlining how acute DPS use in SCI injury could be used as a bridge to extubation.

THE DIAPHRAGM PACING SYSTEM AS A NEW THERAPEUTIC OPTION FOR CENTRAL SLEEP APNEA

Raymond P. Onders MD; Mary Jo Elmo ACNP; Anthony Ignagni MS

BACKGROUND: The rate of sleep-disordered breathing is high in patients with neuromuscular diseases. Diaphragm pacing stimulation (DPS) can successfully treat central apnea in complete tetraplegics, replacing mechanical ventilation. This reports a single site experience of using DPS to treat acquired central sleep apnea in incomplete tetraplegia and in patients with amyotrophic lateral sclerosis or motor neuron disease (ALS/MND).

DESIGN: Prospective trial database of diaphragm pacing patients at a single institution.

Participants/methods: Patients with tetraplegia with documented central sleep apnea but volitional diaphragm movement underwent laparoscopic diaphragm motor point mapping with electrode implantation. After conditioning the diaphragm during daytime, patients utilized DPS for sleep instead of positive pressure ventilation. ALS patients who were involved in trials of DPS and developed sleep-disordered breathing began using DPS at night.

RESULTS: Four tetraplegic patients with central sleep apnea were implanted from 2006-2008 (three males, one female). Average age was 38 years (range 18-59) with implantation an average of 10 years post injury (range 3-24). All patients were able to utilize DPS for nighttime ventilation alone with discontinuation of positive pressure mechanical ventilation. One patient who was completely dependent on ventilation was successfully weaned. One patient was able to undergo tracheostomy tube decannulation after 24 years. Out of a population of 51 ALS patients implanted with DPS, 50% (25) utilize DPS with or without non-invasive positive pressure (NIPPV) ventilation at night to improve their sleep disordered breathing or acquired central sleep apnea. Continuous diaphragm electro-myographic recordings in ALS/MND patients show suppression of diaphragm activity with NIPPV. The combination of NIPPV and DPS can optimize ventilation while maintaining diaphragm strength and reduce the deconditioning effects of NIPPV and resulting rapid dependence.

CONCLUSION: This experience shows that diaphragm pacing can be used to treat acquired central sleep apnea. Recent reports describe the rapid deconditioning of the diaphragm when utilizing positive pressure ventilation without diaphragm activity. DPS maintains Type 1 muscle fibers and improves respiratory compliance by ventilating posterior lobes. These factors improve daytime ventilation and can decrease the work of breathing in patients with compromised strength. Aggressive use of polysomnography can identify patients that have developed acquired central sleep apnea allowing this new option in ventilation.

DIAPHRAGM PACING IN AMYOTROPHIC LATERAL SCLEROSIS (ALS) – LONG TERM FOLLOW UP OF THE COMPLETED PILOT STUDY

MaryJo Elmo, Raymond P. Onders MD

BACKGROUND: Respiratory failure is the major cause of death in ALS. The Diaphragm Pacing Stimulation system (DPS) utilizes motor point stimulation of the diaphragm to replace mechanical ventilation in tetraplegics. We hypothesized that DPS can maintain diaphragm muscle strength in ALS therefore delaying respiratory failure.

PURPOSE: The purpose of the pilot study was to evaluate safety and tolerability of DPS in ALS. The secondary objective was to evaluate the effects of DPS on the diaphragm muscle and pulmonary function. The purpose of this presentation is to share our results and to share what we have learned about the ALS diaphragm.

METHODOLOGY: In an FDA trial, 16 patients underwent outpatient laparoscopic implantation of Diaphragm Pacing Stimulation (DPS) system. The patients then used electrical stimulation to condition their diaphragm. Each patient had three extensive lead-in assessments that were continued post implantation.

RESULTS: Sixteen patients have been safely implanted with no adverse events. Patients had improved fluoroscopic movement of their diaphragm with stimulation. DPS increased muscle thickness when assessed with ultrasound. With DPS, the 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: conversion of fast twitch glycolytic (IIb) to functional slow twitch oxidative muscle (I) fibers; improved posterior lobe lung ventilation; increased lung compliance leading to decreased work of breathing; and improved nighttime ventilation.

CLINICAL SIGNIFICANCE: Improving diaphragm function with DPS in ALS patients will increase therapeutic options.

DIAPHRAGM PACING – A SUPERIOR METHOD OF RESPIRATORY SUPPORT IN CERVICAL SPINAL CORD INJURED PATIENTS.

MaryJo Elmo, Raymond P. Onders M.D.

Cervical spinal cord injury (SCI) persons typically require respiratory support via mechanical ventilation. The Diaphragm Pacing Stimulation (DPS) system is now an FDA approved mode of ventilation in SCI persons. Electrodes are implanted in the diaphragm muscle; an electrical stimulus is delivered stimulating the motor points of the phrenic nerves causing diaphragm contraction, which results in respiration. Unlike mechanical ventilation, DPS is negative pressure breathing which alleviates many of the complication associated with ventilators. Breathing with the DPS system is quiet, it allows for sense of smell, a more natural speaking pattern, increases mobility, and eases transfers. Between 2000 and 2008 over 50 cervical SCI persons were implanted with DPS with 50% achieving full time pacing and the remaining patients replacing their ventilators between 8 and 18 hours a day. This presentation will review the implantation procedure, results from the clinical trial and the benefits of DPS.

Section 4

**Oral and Maxillofacial
Surgery**

UTILIZATION OF CONE BEAM CT IMAGING TO VOLUMETRICALLY ASSESS ALVEOLAR CLEFT DEFECTS

Quereshy,F; Barnum,G; Palomo,M; Demko,C; Horan,M

STATEMENT OF PROBLEM: There is currently no method available to preoperatively determine the amount of bone needed to graft an alveolar cleft. The purpose of the current study was to determine the utility of Cone Beam CT imaging in assessing the volume of alveolar cleft defects in patients undergoing secondary cleft repair.

MATERIALS AND METHODS: 14 patients with unilateral clefts were enrolled in the study. Preoperative Cone Beam CT imaging was obtained for all patients preparing to undergo secondary repair of alveolar clefts. Cone Beam CT imaging was evaluated using InVivo, an image analysis software. Using anatomical landmarks, three measurements were obtained from the Cone Beam CT image for each patient. These measurements including Facial width (F), Height (H), and Facial-Lingual length (FL). These values were used to calculate the Estimated Volume (EV) of the cleft and the amount of bone graft material that would be needed to fill the defect.

METHODS OF DATA ANALYSIS: Measurements were taken by one student rater at three different times, approximately two weeks apart, on a random sample of 14 images from patients with alveolar clefts. The mean, standard deviation, and standard error was calculated for each measurement. Data as expressed as the mean \pm standard deviation. Intra-rater reliability was estimated using the intraclass correlation coefficient (ICC) computed from a two-way mixed model of reliability specifying absolute agreement. Ratings based on both single and average measure reliability were examined. ICCs ranged between 0 and 1; ICCs approached one when the values of the repeated measures on an individual subject show less variation than the variability between different subjects. All statistical analysis was conducted on a PC using SPSS v16.0 for Windows XP.

RESULTS OF INVESTIGATION: The mean of F, H, and FL was calculated to be 9.68mm(\pm 3.07), 14.07mm(\pm 2.7), and 5.57mm(\pm 0.78), respectively. Mean EV was 489.0 mm³(\pm 151.6). For F, third measurements were slightly larger than first measurements but this variability was not significant. The single (.879) and average (.956) measure ICC for F were very good to excellent. Similar data was observed for H, with single (.827) and average (.935) measure ICC, again very good to excellent. For FL, a clear decreasing trend in both the mean and variability over the three measurement times were reflected in a low single (.305) and moderate average (.569) measure ICC. Therefore, the rater was more successful at repeating the same measurements for each image except for the FL measurement. For the set of images, the EVs tended to increase slightly over the three measurements.

CONCLUSION: Measures of F and H by one student rater were reliable across all three measurements. In contrast, the low-moderate reliability of FL with a clear trend toward decreasing variability suggests that the rater's reliability was low but increasing over time. Thus, Cone Beam CT imaging can be used to reliably measure F, H, and FL and to calculate the EV of the cleft. These data can be utilized by oral and maxillofacial surgeons to quantitatively assess the volume of an alveolar cleft and aid in preoperative determination of the amount of bone that will be needed to adequately graft the cleft. This will aid in appropriate selection of an autogenous graft donor site prior to surgery.

IDENTIFICATION OF BODY DYSMORPHIC DISORDER IN ADULT PATIENTS SEEKING ORTHOGNATHIC AND FACIAL COSMETIC SURGERY FROM ORAL AND MAXILLOFACIAL SURGEONS

Horan, MP, Quereshy, FA, Choi, S, Baur, DA

STATEMENT OF PROBLEM: Traditionally, Oral and Maxillofacial Surgeons have aided orthodontists in alignment of teeth by performing orthognathic surgery to correct misalignment of the jaws due to dentofacial deformities. While studies indicate that 90% of individuals who undergo orthognathic surgery are satisfied with their outcome and 80% would chose to do it again given the same circumstances and outcomes, approximately 10-15% of individuals are dissatisfied regardless of outcomes (Proffit et al, 1999). These patients have typically been referred to as being "high maintenance" and dismissed. However, it is plausible that some of these individuals suffer from body dysmorphic disorder (BDD). No assessment tool is currently in place to screen patients seeking orthognathic surgery for BDD. Furthermore, as Oral and Maxillofacial Surgeons expand the scope of their practice to include more cosmetic facial surgery, it will be important to screen this population of patients in order to identify individuals that have BDD. The purpose of the present study was to identify adult patients with BDD seeking orthognathic or facial cosmetic surgery procedures by utilizing a well documented, "user friendly" BDD screening tool, the BDD Questionnarre (BDDQ) (Dufresne et al, 2001).

MATERIALS AND METHODS: The current study was designed as a cross-sectional cohort study consisting of three groups: 1) patients seeking orthognathic surgery, 2) patients seeking facial cosmetic surgery, and 3) patients seeking dentoalveolar surgery. Each potential patient participant received information describing the study. If interested, the patient was asked to fill out a consent form. Patients were subsequently given the BDDQ at the initial consultation appointment. Demographic information including age, gender, diagnosis and any preexisting psychiatric diagnosis was also solicited from the patient. The study was performed at the Case Western Reserve University School of Dental Medicine, Department of Oral and Maxillofacial Surgery. Approval for the study was obtained from the Case Western Reserve University Institutional Review Board for Social and Behavioral Science (IRB#20080104).

METHODS OF DATA ANALYSIS: 46 patients, 18 years of age or older, seeking care in the department of Oral and Maxillofacial Surgery at the Case Western Reserve University School of Dental Medicine were enrolled in the study. Of the 46 patients enrolled, 5 were unable to complete the BDDQ due to time constraints. Of the 41 patients that completed the BDDQ, 4 patients presented for orthognathic, 12 patients for cosmetic, and 25 patients for dentoalveolar consultations. The mean BDDQ score was calculated for each group and data was presented as mean \pm standard error. Intergroup differences were analyzed using ANOVA and Tukey-Kramer post-hoc analysis. Data analysis were performed on NCSS/PASS '04 for Windows XP.

RESULTS OF INVESTIGATION: BDDQ revealed a mean score of 1.250(\pm 0.342), 1.833(\pm 0.197), and 1.160(\pm 0.136) for patients presenting for orthognathic, cosmetic and dentoalveolar surgery consultations, respectively. A significant difference was noted between patients seeking facial cosmetic and those seeking dentoalveolar surgery ($P < 0.05$). No significant difference was noted between patients seeking orthognathic and dentoalveolar surgery ($P > 0.05$). Patients with previously diagnosed psychiatric conditions tended to score higher on the BDDQ. Interestingly, only one patient scored above the BDDQ threshold for clinical suspicion of BDD, and that patient was seeking dentoalveolar surgery.

CONCLUSION: The results of this study indicate that patients seeking facial cosmetic surgery from Oral and Maxillofacial Surgeons score significantly higher on the BDDQ than do patients seeking dentoalveolar surgery, whereas those seeking orthognathic surgery do not. The BDDQ is a fast and efficient way to screen patients seeking either orthognathic or facial cosmetic surgery for BDD. By doing this preemptively, unnecessary surgery and medicolegal issues can be avoided and patients can be referred to the appropriate specialists for treatment of their psychiatric condition.

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

Faisal Quereshey, M.D., D.D.S., F.A.C.S., Jonathan T. Williams, D.M.D., Dale Baur, D.D.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 +/-6mm for MPH and PAS of 10 +/-3mm (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.

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ENDOSCOPY ASSISTED MANDIBULAR SAGITTAL SPLIT RAMUS OSTEOTOMY

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PURPOSE: The prevalence of inferior alveolar nerve (IAN) parasthesia/dyesthesia following a sagittal split osteotomy (SSO) ranges from 9% to 85%^{1,2}. Over zealous retraction and inappropriate positioning of surgical instrumentation often results in excess manipulation/damage of the soft tissues surrounding the IAN thereby inadvertently causing damage to the nerve^{2,3,4}. Intraoperative identification of the IAN has traditionally relied upon utilization of plain films and radiographic landmarks, tactile identification of the antilingula and IAN foramen utilizing a nerve hook, and direct visualization if possible. Unfortunately, in the absence of direct visualization, these methods lack the necessary precision and accuracy for reliable identification of IAN position. Radiographic determination of the position of the IAN foramen at best only provides a rough estimate of the nerve location. Aziz and coworkers demonstrated that tactile identification of the antilingula to infer position of the lingula is not always reliable⁵. Thus, direct visualization is the most reliable way to identify IAN position. In the present study, a 30° Stryker endoscope was used to visualize the medial aspect of the ramus in order to determine IAN location following the initial dissection. We hypothesized that utilization of endoscopy to identifying the IAN prior to creation of the medial horizontal osteotomy would limit manipulation of the soft tissues surrounding the IAN, preventing inappropriate positioning of surgical instrumentation, thereby reducing the incidence of parasthesia/dyesthesia following an SSO.

MATERIALS AND METHODS: Endoscopy-assisted SSO was performed on 8 patients (16 rami) and compared to 8 patients (16 rami) that underwent SSOs without benefit of endoscopy assistance. In the endoscopy-assisted SSO, a 300 endoscope (Lightsource: Stryker 220-190-000 - X7000 XENON LIGHTSOURCE; Fiberoptic cord: Luxatec cord UH275540n; Camera: Stryker 21F, Monitor: Sony 988, Scope: Stryker 30 degree scope 502-477-031) was used to perform cavity endoscopy to visually assess the position of the IAN on the medial aspect of the ramus just superior to the IAN foramen and to confirm vertical positioning of the reciprocating saw prior to osteotomy. The reciprocating saw was then used to score the medial aspect of the mandible to a depth of 0.5 mm. The position of the incomplete osteotomy was endoscopically confirmed to be above the IAN foramen with the nerve intact. The SSO was then completed in the normal fashion.

METHODS OF DATA ANALYSIS: IAN parasthesia/dyesthesia was used as the final outcome measure. A qualitative, discontinuous grading scale was used to analyze clinical parameters including ease of endoscope placement, soft tissue manipulation, soft tissue edema post-operatively, and short/long term IAN parasthesia/dyesthesia. Data were reported as Mean ± SEM and analyzed using Student's t-test with significance at $p < 0.05$.

RESULTS: Use of the endoscope added approximately 15-20 minutes to operating room time. The endoscope allowed for direct visualization of the IAN and confirmation of medial osteotomy in all endoscopy-assisted cases. Although not clinically significant, there was a trend shown towards reduced post-operative parasthesia with endoscopy-assisted SSO as compares to SSO completed without benefit of endoscopy assistance. No significant differences were noted in post-operative tissue edema regardless of technique used.

CONCLUSION: Establishing the IAN position is frequently challenging and often results in excess manipulation of the soft tissues surrounding the nerve. The use of an endoscope allows the operator to easily determine the location of the IAN without excess soft tissue manipulation, thereby minimizing potential damage to the IAN and possibly improving patients' post-operative outcomes.

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

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

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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ANALYSIS OF OROFACIAL CLEFT BIRTHS IN OHIO

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.

CORRELATION OF BLOOD LOSS AND OPERATING TIME DURING ORTHOGNATHIC SURGERY

Keith M. Schneider, DMD, Catherine Demko, Dale Baur, Faisal A. Quereshy, MD, DDS, FACS

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.

Section 5

Pediatric Surgery

LONG-TERM OUTCOME FOLLOWING PARTIAL EXTERNAL BILIARY DIVERSION FOR PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS

Ihab Halaweish, Walter J. Chwals

BACKGROUND: Though patients with Progressive Familial Intrahepatic Cholestasis (PFIC), or Byler disease, typically require liver transplantation, initial surgical treatment includes partial biliary diversion to relieve jaundice-associated pruritis. This study was undertaken to describe long-term PFIC outcome data which are currently sparsely reported.

METHODS: Retrospective review of 7 patients diagnosed with PFIC who underwent partial biliary diversion between 2004 and 2008 was directed towards long-term postoperative outcome including resolution of jaundice/pruritis, ostomy complications, interval to transplant, and death.

RESULTS: Six patients who underwent partial biliary diversion experienced complete resolution of jaundice and pruritus. Four patients experienced persistent ostomy-related complications requiring a total of 14 revisions. Three symptom-free patients have not yet required liver transplantation post-PFIC (average 70 mo.; range 59-78 mo.). Two patients underwent orthotopic liver transplantation (average 44±18 mo. post-PFIC). Two patients died at home due to gastroenteritis-associated dehydration prior to transplantation.

CONCLUSION: Partial biliary diversion for PFIC is effective as a bridge to liver transplantation in improving jaundice and pruritis and can result in long-term transplant-free intervals but may be associated with a high incidence of ostomy-related complications and dehydration-related mortality.

TUBO-OVARIAN ABSCESS FOLLOWING PERFORATED APPENDICITIS IN AN ADOLESCENT

Sahannon Acker and Todd A. Ponsky

ABSTRACT: Common complications of perforated appendicitis wound infection, intra-abdominal abscess, and prolonged ileus. Other rare complications include pleural effusion, urinary tract infection or urinary retention, bleeding, wound dehiscence, pneumonia and intestinal obstruction. Here we present the case of a 17-year-old, non-sexually active, female who developed bilateral tubo-ovarian abscesses (TOA) following perforated appendicitis. We discuss the prevention, diagnosis, and treatment of TOA resulting from perforated appendicitis. This case is only the second reported case of TOA following perforated appendicitis.

BACKGROUND: Appendicitis is the most common cause of emergency abdominal surgery in children. Delay in diagnosis correlates strongly with the rate of perforation (1). Complications of perforated appendicitis include pleural effusion, wound infection, prolonged ileus, urinary tract infection or urinary retention, intra-abdominal abscess, gastrointestinal bleeding, wound dehiscence, pneumonia and intestinal obstruction (2,3). The proximity of the fallopian tubes to the appendix and the parastaltic nature of the tube makes it reasonable to believe that there would be a risk of tubo-ovarian abscess (TOA) following perforation of the appendix. Only one such case has been reported in the literature (4). Here we present the case of a 17-year-old female who developed bilateral TOA following perforated appendicitis.

CASE REPORT: A 17-year-old female, who was not sexually active, presented in September 2008 with severe right lower quadrant pain associated with fever, nausea, and vomiting. An abdominal CT scan revealed evidence of perforated appendicitis. She was taken to the operating room for laparoscopic appendectomy. Intra operative findings included an entirely gangrenous and necrotic perforated appendix. Her postoperative course was complicated by persistent abdominal pain with distention, fever and an elevated CRP, that peaked at 23.3. She was treated with ertapenem throughout her hospital course. Her abdominal pain failed to resolve within three weeks and a repeat abdominal CT was obtained, which revealed a loculated fluid collection in the left pelvis and fluid in the endometrial cavity. A pelvic ultrasound obtained at this time detected a left ovarian cyst. She continued to have abdominal pain that was exacerbated by her menstrual cycles. She was followed by a gynecologist that started treatment with the Ortho Evra patch followed by repeat imaging of the ovarian cyst. An ultrasound obtained in November 2008 showed an increase in the size of the left ovarian cyst which was concerning for a tubo-ovarian abscess versus a hemorrhagic cyst. The ultrasound study also revealed fluid in the right fallopian tube. Three weeks later she presented with sharp abdominal pain and a white blood cell count of 13.4. A pelvic ultra sound at that time revealed bilateral tubular structures concerning for TOAs. She was admitted and started on doxycycline and cefoxitin. A gonorrhea and Chlamydia swab were both negative. On hospital day two she continued to have sharp abdominal pain and her antibiotics were changed to ampicillin, gentamicin and metronidazole. She was discharged on hospital day six with continued antibiotic treatment. Despite this treatment she continued to have left sided and periumbilical abdominal pain. An abdominal and pelvic CT scan in February 2009 revealed a complex left pelvic cyst and an increased amount of fluid in the right adnexa. In April 2009 she was taken to the operating room for a diagnostic laparoscopy, which revealed multiple pelvic inclusion cysts and multiple bands of thin adhesive disease, common findings after TOA.

DISCUSSION: Tubo-ovarian abscess (TOA) occurs as a complication of pelvic inflammatory disease in almost all cases. However, less common causes should be considered in the differential diagnosis of TOA in children, including inflammatory bowel disease, bowel perforation, and as a complication of perforated appendicitis, as presented here. We are confident that this reliable patient has no history of sexual activity making it unlikely that this case of bilateral TOA was caused by pelvic inflammatory disease (PID). Although not very sensitive, negative screening tests for gonorrhea and chlamydia infection provide further evidence arguing against a sexually transmitted cause of the bilateral TOA.

Techniques to reduce the occurrence of intra abdominal abscess following perforated appendicitis are also likely to be effective at reducing the risk of TOA following perforated

appendicitis. Hussain and colleagues showed that by copiously irrigating the peritoneal cavity including the right and left paracolic, supra and subhepatic, perisplenic, pelvic and interloop areas with at least 3L of saline they could decrease the incidence of postoperative abscess and infectious complications. In addition to the irrigation, they advocate leaving 300-500ml of saline inside the peritoneal cavity with a drain in order to further dilute the infection foci (5). In addition to intraoperative irrigation, others have promoted the use of a scoring system to identify patients at high risk of developing intraabdominal abscess following perforated appendicitis and then treating these patients with broad spectrum antibiotics postoperatively (imipenem plus cilastatin until 48hrs of afebrile, followed by 7 days of amoxicillin plus clavulanate). Factors included in the scoring system include: clinical findings of peritonitis, leukocytes >15,000, axillary-rectal temperature difference >1 degree C, intraoperative findings of gangrenous or perforated appendicitis, and iatrogenic perforation secondary to inflammation of the appendix (6).

The classic presentation of TOA includes abdominal pain and fever, pelvic mass on examination, and leukocytosis, although women can be afebrile with a normal white blood cell count (7). The possibility of TOA should be considered in a female patient with persistent abdominal pain following appendectomy for perforated appendicitis without evidence of intra-abdominal abscess. As in the present case, persistent pain exacerbated by the menstrual cycle should be concerning for TOA. TOA can be diagnosed by a number of screening modalities including CT, ultrasound, scintigraphy, and radionuclide scanning. CT and ultrasound are the most accepted and readily available modalities (7). CT has a higher sensitivity (78%-100%) than ultrasound (75%-82%) (7). CT findings that may be suggestive of TOA include a peripherally enhancing low-density pelvic mass, anterior displacement of the round ligament, and the presence of satellite lesions adjacent to main masses (8). Other findings include a thick, uniform, enhancing abscess wall, multi-loculated, with an increased fluid density (7). Ultrasound findings reveal a complex adnexal mass or a cystic-type mass with multiple internal echoes (7).

TOAs tend to be polymicrobial including anaerobic, aerobic, and facultative organisms and may include *E. coli*, *Prevotella*, *Bacterioides*, and *Peptostreptococcus* species. *N. gonorrhoeae* is often isolated from the endocervix. TOA is usually managed with antimicrobial therapy however ruptured TOA is a surgical emergency (7). Selection of an appropriate antibiotic is dependent upon choosing an agent with anaerobic, gram-positive and gram-negative aerobic coverage. Metronidazole or clindamycin are often used as they have broad anaerobic spectra and are able to penetrate the abscess wall (7). Patients with TOA should be hospitalized and treated with antibiotic therapy until pain and tenderness has resolved, the patient has defervesced, leukocytosis has normalized, and the mass has either decreased or stabilized in size (7). Ultrasound or CT can be used to guide minimally invasive drainage of pelvic abscesses. A review of 302 cases of TOA that underwent transvaginal ultrasound guided drainage showed that the treatment was successful in 93.4% of women. However, no large-scale randomized trials addressing the role of image-guided drainage have been conducted (7,9).

Although TOA is a rare complication of perforated appendicitis surgeons should be aware of this as a possible postoperative complication. Care should be taken intraoperatively to decrease the risk of postoperative abscess formation. In female patients with persistent postoperative abdominal pain, fever, and leukocytosis, the possibility of TOA should be considered.

PRELIMINARY EXPERIENCE WITH SINGLE INCISION LAPAROSCOPIC SURGERY IN CHILDREN

Todd A. Ponsky, M.D., Robert Parry, M.D., Walter Chwals, M.D., Edward Barksdale, M.D., Scott Boulanger, M.D., PhD

INTRODUCTION: The current paradigm in laparoscopic surgery is for each instrument to enter the abdomen through its own separate incision. The advent of newer laparoscopic trocars and instruments now allow for all instruments to enter through a single incision. This may lead to less pain and improved cosmetic outcome. Single incision laparoscopic surgery (SILS) has recently been described in adults. Here we report our preliminary experience of SILS in children.

METHODS: A retrospective review was performed of the operative database at Rainbow Babies and Children's Hospital in Cleveland, Ohio from 3/2008 to 11/2008 looking for all cases that were performed through a single laparoscopic incision.

RESULTS: A total of 38 SILS cases were performed. These included: cholecystectomy, splenectomy, intussusception reduction, gastrostomy tube placement, and appendectomy. Two appendectomies were converted to traditional 3-port laparoscopy for mesoappendix bleeding and a long appendiceal stump. There was one umbilical wound infection after an appendectomy (erythema that responded to antibiotics). There were no other complications.

CONCLUSION: Preliminary experience with single incision laparoscopic surgery in children appears to be safe and effective. Greater numbers and a prospective trial will be necessary to assess the true benefit of this approach.

Procedure	Number	Mean Age (yrs)	Mean Weight (kg)	Mean OR time
Cholecystectomy	5	13.3	59	1:48
Splenectomy	1	16	53	3:53
Intussusception	1	1.67	12	0:35
Gastrostomy	7	1.51	7.05	0:35
Appendectomy	22	10.6	45.8	0:43

SINGLE PORT LAPAROSCOPIC SPLENECTOMY IN A CHILD: A CASE REPORT AND REVIEW OF TECHNIQUE

Todd A. Ponsky, M.D., Scott Boulanger, M.D.

BACKGROUND: Pediatric laparoscopic splenectomy was described in 1993 by Tulman et al. This has become the preferred technique for spleen removal as it leads to less pain, better cosmetic outcome, and shorter hospital stay than the open approach. Here we describe a single-site laparoscopic splenectomy in a child.

CASE: This patient is a 12 year old male with idiopathic thrombocytopenic purpura (ITP) that has been refractory to 6 months of aggressive medical therapy. The decision was made to perform a laparoscopic splenectomy through a single incision in the umbilicus. One umbilical skin incision was created through which two 5mm and 1 12mm ports were placed through the fascia. The splenectomy was performed using flexible, reticulating instruments. At the completion of the case the three incisions were connected to create one 15mm fascial incision. There was minimal blood loss and no intra-operative or post-operative complications. The patient is doing well with no visible scar 1 months post-operatively.

CONCLUSION: Single Site Splenectomy is feasible. A larger series will be necessary to assess safety, pain reduction, and cost-efficiency.

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THE ENDOSCOPIC U-STITCH TECHNIQUE FOR PRIMARY BUTTON PLACEMENT: AN INSTITUTION'S EXPERIENCE

Neil Nixdorff MA, MPH, Jennifer Diluciano MSN, Todd Ponsky MD, Walter Chwals MD, Robert Parry MD, Scott Boulanger MD, PhD

BACKGROUND: Various gastrostomy tube placement techniques have been reported in the literature. The endoscopic U-stitch technique allows for primary button placement without the need for laparoscopy. The purpose of this study was to quantify the completion rate and the occurrence of complications with this procedure at one academic teaching hospital.

MATERIALS AND METHODS: All gastrostomy procedures between February 2001 and September 2008 were reviewed. Data was collected from paper and electronic records for endoscopic U-stitch procedures.

RESULTS: Endoscopic U-stitch gastrostomies were attempted in 121 patients with primary button placement in 115 (95%) and conversion to an open procedure in 6. No procedure related deaths occurred, and 7% of patients experienced postoperative complications that included hematemesis, cellulitis, colonic perforation, granulation tissue requiring operative excision, and surgical fistula closure. Average operative time was 18 minutes.

CONCLUSION: The endoscopic U-stitch technique is safe and allows for primary button placement in infants and children. Its complication rate compares favorably with other laparoscopic and open techniques described in the literature.

Section 6

Surgical Oncology

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

Wilhelm, Scott M. MD, FACS, Lynch, Melanie MD, and Kim, Julian A. 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: 22 patients with thyroid nodules confirmed as PTC (n=10) or suspicious for PTC (n=12) underwent thyroidectomy with SLNB utilizing peritumoral injection with isosulfan blue dye. Blue nodes were considered SLN and sent for frozen section. Patients with a SLN positive for metastatic PTC underwent completion CNLD. Post-operatively, patients were evaluated with thyroglobulin (TG) levels and I131 scans to look for residual disease. Rates of postoperative hypocalcemia were also examined. T-tests compared TG levels. Fisher's exact test was used for continuous variables to examine hypocalcemia and I131 scan results. Finally, Pearson's correlation identified factors linked to the rate of identifying a SLN (e.g. tumor and SLN size, tumor location, and presence of multifocal PTC).

RESULTS: Final pathology was PTC in 20/22 patients (91%). SLN were identified in 15/20 (75%) of patients with PTC. SLN size ranged from 3-20 mm (mean= 5.8 +/- 3.2mm), with 60% of SLN \leq 5mm. Seven patients had positive SLN and had additional PTC positive nodes found in the CNLD specimen. Post-operative thyroglobulin levels were 14.1 +/- 35.2 (range 0-114) in the SLNB group and 21.3 +/- 35.1 (range 0-90) in the CNLD group (p =0.67). Similarly, postoperative I131scans were positive in 90% of pts undergoing SLNB vs. 75% of CLND patients (p= 0.55). Hypocalcemia was not different between SLNB vs. CLND groups (75% vs. 88%, p= 0.61). Finally, only the presence of multifocal PTC predicted a higher likelihood of no SLN being found.

CONCLUSIONS: These data do confirm the feasibility of SLNB technique for patients with PTC. All patients with a SLN positive for PTC had other positive central compartment nodes. 60% of PTC positive SLN were 5mm or less, which altered the surgical management and did guide our operation. However, SLNB did not decrease the need for initial postoperative I131 therapy nor did it decrease the rate of positive postop scans. Postop TG levels were similar between groups perhaps indicating that CLND guided by + SLN reduced regional lymph node tumor burden. This preliminary report indicates that further study is needed for utilizing a SLNB technique for patients with PTC.

ANALYSIS OF RISK FACTORS FOR HYPOCALCEMIA FOLLOWING MINIMALLY INVASIVE PARATHYROIDECTOMY FOR PRIMARY HYPERPARATHYROIDISM

Joseph A. Trunzo, Karem Harth, Matthew Strohacker, Scott M. Wilhelm

BACKGROUND: With the emergence of minimally invasive parathyroidectomy (MIP), outpatient surgery for primary hyperparathyroidism (HPT) has become more common. The concern for post-operative hypocalcemia, however, remains a potential limiting factor. We observed our experience for peri-operative factors to predict who would require post-operative calcium therapy.

METHODS: A retrospective review of 125 consecutive primary HPT patients who underwent parathyroidectomy was conducted. Those with hyperplasia requiring subtotal parathyroidectomy were excluded resulting in 121 for investigation. Peri-operative factors were collected to identify an association with need for post-operative calcium therapy. Variable factors included: age, gender, race, pre-operative DEXA scan results, pre-operative calcium and PTH levels, presence of a solitary or double adenoma, gland weight, low intra-operative parathyroid hormone (IOPTH) level (<10), and percent decline of IOPTH. Mann-Whitney U, Student's T, and Fisher's exact tests were used for association analysis. The final model was chosen from multiple logistic regression analysis (p-value of < 0.05).

RESULTS: Hypocalcemia requiring calcium therapy was observed in 14 of 121 patients (11.6%) and, of them, only 5 (35.7%) were symptomatic. All were effectively treated with temporary calcium supplementation. A strong predictor of hypocalcemia for both symptomatic and asymptomatic patients was resection of a double adenoma with an odds ratio of 6.0 (p=0.009) compared to a solitary adenoma. Double adenoma was present in 15 of 121 patients (12.3%), and of them, 5 (33.3%) required therapy. Overall risk of hypocalcemia was independent of age, gender, and IOPTH levels. Other variables investigated including race, pre-operative DEXA results, and gland weight also did not show significant association for predicting this outcome.

CONCLUSION: Despite numerous peri-operative variables including final IOPTH <10, which has been shown to predict hypocalcemia after total thyroidectomy, most patients undergoing MIP for primary HPT are at low risk for hypocalcemia requiring calcium treatment. An outpatient approach for this population can be considered safe. However, when a double adenoma is present we observed a strong predictive association for hypocalcemia. Inpatient admission for calcium monitoring and supplementation may be warranted in these patients.

CHARACTERIZATION OF HUMAN SKELETAL MUSCLE IN WEIGHT-LOSING PANCREATIC CANCER PATIENTS

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BACKGROUND: Decreased body mass (cachexia) is a common cause of functional decline in pancreas carcinoma (PC) and other malignancies. The etiology is unknown. Characterization of human PC skeletal muscle, in regard to proteolysis and gene expression, compared to control muscle may reveal information about pathophysiology.

METHODS: Biopsies of rectus abdominus muscle were performed in weight-losing PC patients all stages (A) during cancer-related surgery and in cancer-free controls undergoing ventral hernia repair (B). Caspase-3, pAkt, and urinary 3-methylhistidine (u3-MH) were assessed by Western blot and high-performance liquid chromatography. Fat-free mass (FFM), body mass index (BMI), and time to progression were recorded. Muscle from five patients (median weight loss 21%) and five controls were analyzed for gene expression patterns using Affymetrix Human Genome U133 A 2.0 array chip. Two hundred differentially over- and under-expressed genes were examined in group A for potential association with cachexia. RT-PCR confirmation of six candidate genes was performed.

RESULTS: Thirty-eight patients were enrolled. Median weight loss in group A (N=27) was 14.5% (5%-34%). No differences were noted between groups in caspase-3 and pAkt expression. Baseline u3-MH ($p=0.86$) and FFM ($p=0.28$) did not differ; baseline BMI was lower in group A ($p=0.04$). BMI follow-up measurements (N=17) were significantly decreased ($p=0.0005$). In 65% patients, progressive disease was noted within median time of 3 months. RT-PCR established up-regulation of CHRNA1 and LMO7, but not GDF8. mRNA down-regulation for TRIM63, IGF-BP6, and MYH-1 was confirmed.

CONCLUSIONS: Muscle proteolysis in human PC skeletal muscle was not demonstrated, perhaps due to unmeasurable proteolysis or use of non-informative endpoints. BMI decreased in group A with PD; further studies need tight control of BMI variables. New hypotheses about cachexia include neuromuscular junction dysfunction, as CHRNA 1 has specific role in ion channel gating; this is disrupted in the paraneoplastic Eaton-Lambert syndrome. This is first study analyzing human muscle in weight-losing PC and proves symptom management multidisciplinary research is feasible in academic setting. Supported by American Cancer Society pilot grant.

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DRAMATIC RESPONSE OF A GASTROINTESTINAL STROMAL TUMOR TO NEADJUVANT IMATINIB THERAPY

Shohrat Annaberdyev BA 1, Joseph Gibbons MD 1,2, Jeffrey M. Hardacre MD 1,3

Gastrointestinal stromal tumors (GISTs) are the most common sarcoma of the alimentary tract and are believed to derive from the interstitial Cell of Cajal. Imatinib mesylate (Gleevec; Novartis, Basel, Switzerland) has revolutionized the treatment of GISTs and is generally used in the metastatic and adjuvant settings. We report the case of a 61-year old man who was treated with neoadjuvant imatinib for a massive gastric GIST with the hope of avoiding a potential multi-visceral resection.

TOTAL THYROIDECTOMY IS SUPERIOR TO SUBTOTAL THYROIDECTOMY FOR MANAGEMENT OF GRAVES' DISEASE IN THE UNITED STATES

SM Wilhelm, and CR McHenry.

INTRODUCTION: In the United States, Graves' disease is most commonly treated with radioiodine, yet thyroidectomy remains an important option for correcting hyperthyroidism. In many countries, limited access to thyroid hormone makes subtotal thyroidectomy the procedure of choice. In the U.S., where levothyroxine is inexpensive and widely available, we hypothesized that total (TT) or near-total thyroidectomy (NT) is superior to subtotal thyroidectomy (ST) for long-term control of Graves' disease.

MATERIALS AND METHODS: We conducted a retrospective review of patients who underwent ST, NT, or TT for Graves' disease between 1990 and 2008. Bilateral 3 gram remnants and a < 1 gram remnant remained following ST and NT, respectively. Differences in rates of recurrence were assessed using ANOVA. Rates of parathyroid autotransplantation, complications, gland weight and final pathology were also determined.

RESULTS: 136 patients with Graves' disease were treated with thyroidectomy. Average age was 36.4 ± 11.3 yrs (range 16-81) and 88% were female. Between 1990 and April 1994, 10 pts underwent ST and 6 pts had NT. Since then, all patients underwent TT (n=120). There was a significantly higher rate of recurrence for ST(30%) compared to NT (0%) ($p = 0.15$) and TT(0%) ($p < 0.0000001$). Parathyroid autotransplantation was performed in 36 (26.5%) patients, only 2 of whom underwent ST or NT. Temporary postoperative hypocalcemia was more common after TT ($p = 0.04$). However, no patient in any group had permanent hypoparathyroidism. Two TT pts had a temporary recurrent laryngeal nerve palsy. One patient in the TT group required re-exploration for postoperative neck hematoma. Final pathology revealed concomitant thyroid cancer in 3.6% of patients and thyroiditis in 26%. Average gland weight was 67.4 ± 57.3 grams.

CONCLUSIONS: ST resulted in 30% long-term failure to correct Graves' hyperthyroidism. We saw no increase in permanent RLN injury or hypoparathyroidism in the TT group despite the need for a more extensive surgical resection and higher rate of parathyroid autotransplantation. As thyroid hormone replacement is widely available, we feel that TT is safe and superior to ST for management of Graves' disease in the United States.

LAPAROSCOPIC AND HAND-ASSISTED DISTAL PANCREATECTOMY

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With the increased use of CT, 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 years (range, 23-83 years) and mean body mass index was 29.9 kg/m² (range, 19.9-44.7 kg/m²). Technique was laparoscopic (25) or hand-assisted (seven) with one conversion in each group. The spleen was preserved in six patients (18.8%). Mean operative time overall was 238 minutes (range, 140-515 minutes); hand-assisted was 222 minutes and laparoscopic was 254 minutes. Estimated blood loss averaged 221 mL (range, 50-1800 mL). Mean tumor size was 2.7 cm (range, 0.6-7 cm). Tumor pathology was serous cystadenoma (10), neuroendocrine tumor (six), mucinous cystic neoplasm (four), intrapapillary mucinous neoplasm (four), adenocarcinoma (three), other (four), and solid pseudopapillary neoplasm (one). Mean length of stay was 5 days (range, 3-11 days). Complications were pancreatic fistula (six), wound infection (two), pulmonary embolism (one), pancreatitis (one), myocardial infarction (one), postoperative bleed from combined laparoscopic bilateral oophorectomy (one), and pancreatic stump staple line bleed requiring reoperation (one). There were no perioperative deaths. All pancreatic fistulas resolved with conservative management.

PANCREATIC RESECTION IN OCTOGENARIANS

Jeffrey M. Hardacre, MD, Kerri Simo, MD, Michael F. McGee, MD, Thomas A. Stellato, MD, James A. Schulak, MD

BACKGROUND: Few studies exist that evaluate outcomes of pancreatectomy in patients ≥ 80 years of age, an age group increasing in size in the United States. This study analyzes the outcomes of pancreatectomy in patients ≥ 80 years of age.

METHODS: The medical records of 32 patients ≥ 80 years of age undergoing pancreatectomy at our institution from April 1995 through October 2008 were reviewed and outcomes analyzed.

RESULTS: The median patient age was 82 years, and 75% were ASA Class 3. Eighty-one percent of the resections were pancreaticoduodenectomies. There were no operative deaths. Sixty-six percent of patients suffered at least one complication. The median length of stay was 11 days. Eighty-one percent of the resections were performed for cancer. Median survival for all patients was 14.4 months. Median survival for patients with cancer was 12 months versus 103 months for patients without cancer, $p = 0.017$.

CONCLUSIONS: Pancreatectomy in patients ≥ 80 years of age can be performed with a low risk of mortality but with significant morbidity.

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

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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 (+ 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 (+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.

FIRST ANALYSIS OF AN INTERNATIONAL PEDIATRIC MELANOMA AND ATYPICAL MELANOCYTIC NEOPLASM DATABASE

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BACKGROUND: Pediatric melanoma (PM) care has been extrapolated from adult melanoma data. PM and atypical melanocytic neoplasms (AMNs) appear to have different biology. An international database (DB) was developed to clarify their behavior.

METHODS: IRB approval was obtained at 12 institutions. An SQL-DB was developed for web entry of de-identified demographic and pathologic data for PM and AMN patients (pts) < 21yr through an honest broker system at the University of Pittsburgh. Institutions retained a key of pts entered with assigned numbers for quality assurance and updates. Statistical analysis used Kaplan-Meier survival curves, univariate linear trends and log rank tests. In situ melanoma was excluded from PM survival analysis.

RESULTS: 828 pts were registered as of 31 Oct 2008 (ages 11mo-23; median 15yr). 34 pts 21-23 yr entered were left in the DB for statistical comparison. Diagnosis years ranged from 1936-2008. 455 pts had complete follow-up. Too few AMN pts had complete follow-up for analysis (18/208). After excluding 32 in situ and 40 with other incomplete data, 365 PM out of 415 total PM were evaluable for OS and 351 for DFS (Stage IV removed). Mean/median age for evaluable PM pts was 16.44/17-yrs (range 1-21yr). 591 pts were age 10-20 while 203 were < 10. Sentinel lymph node (SLN) biopsy showed spread in 30.1 % PM pts (compared to 50% [4/8] of AMN SLN pts). 10-yr PM OS was 80.6%, and pts 0-10yr had 100% 10-yr OS compared to 69.6% for pts age 10-15 and 79.49% for age 15-20 ($p=0.1473$). OS did not differ significantly by gender. Stage predicted OS ($p<0.0001$). 10-yr OS was 94.13% for Stage I ($n=174$), 79.62% for stage II ($n=67$) & 77.14% for stage III ($n=75$). Thickness affected 10-yr OS: 0-1mm=97% ($n=147$), 1.1-2mm 70% ($n=84$), 2.01-4mm 78% ($n=71$) & >4mm 81% ($n=25$), $p=0.0099$. Survival was similar for pts with PM > 1mm of the several T stage groupings. Ulceration adversely affected OS ($p=0.022$). Mitosis, defined as present/absent did not alter survival. Nodal metastasis correlated with worse OS ($p=0.170$).

CONCLUSIONS: Stage, thickness, ulceration, and nodal status are significant predictors of OS for PM. Further study will focus on multivariable analysis of PM and AMNs after updating pts, increasing accrual, and cleaning data.

LAPAROSCOPIC AND SELECTIVE OPEN RESECTION FOR ADRENAL AND EXTRAADRENAL NEUROENDOCRINE TUMORS

Phitayakorn R, McHenry CR.

Laparoscopic resection is preferred for most adrenal tumors. From 1996 to 2007, 54 consecutive patients who underwent resection of an adrenal tumor or extraadrenal pheochromocytoma were reviewed to determine the outcome of laparoscopic resection and the rate of conversion and indications for open resection. Adrenalectomy was performed in 51 patients and resection of a pheochromocytoma of the organs of Zuckerkindl in three patients. Laparoscopic adrenalectomy was initiated in 42 patients, three (7.3%) of whom underwent conversion to an open approach because of bleeding from an accessory vein (one), tumor invasion (one), or adhesions (one) (median American Society of Anesthesiologists score = 2, estimated blood loss = 186 ± 235 mL, size = 5 ± 3 cm). Open resection was performed in 12 patients, six at the time of another procedure, three for pheochromocytoma of the organs of Zuckerkindl, two for bilateral adrenalectomy, and one for tumor invasion (median American Society of Anesthesiologists score = 3, estimated blood loss = 1525 ± 978 mL, size = 8 ± 4 cm). With proper patient selection, laparoscopic adrenalectomy can be successfully performed with a low conversion rate. When unrecognized, an accessory right adrenal vein may be a source of significant bleeding requiring conversion to an open approach. Open resection is indicated for tumor invasion, for extraadrenal pheochromocytoma, when laparoscopic resection cannot be performed safely, and for concomitant open procedures.

INCIDENCE OF THYROID CARCINOMA IN PATIENTS WITH GRAVES' DISEASE

Roy Phitayakorn, M.D. Christopher R. McHenry, M.D.

BACKGROUND: The clinical significance of incidental thyroid carcinoma to patients with Graves' disease is uncertain.

METHODS: The prevalence of incidental thyroid carcinoma was determined in patients with Graves' disease who underwent surgery from 1990 to 2007 and was compared with patients with nontoxic nodular goiter or toxic multinodular goiter who underwent surgery during the same time period.

RESULTS: Of the 93 patients who underwent thyroidectomy for Graves' disease, 2 patients (2.2%) had an incidental papillary carcinoma: .4 and .5 cm in size. Neither patient developed recurrence disease after 3 and 13 years of follow-up evaluation. The prevalence of incidental thyroid cancer was 3.6% and 6.2% in patients with nontoxic nodular goiter and toxic multinodular goiter, respectively (P = not significant).

CONCLUSIONS: The prevalence of incidental thyroid carcinoma in patients with Graves' disease is comparable with patients with nontoxic or toxic goiter. Incidental thyroid carcinomas in patients with Graves' disease were papillary microcarcinoma of no clinical consequence.

LIFE-THREATENING NECK HEMATOMA COMPLICATING THYROID AND PARATHYROID SURGERY

Michael A. Rosenbaum, M.D., Manjunath Haridas, M.D., Christopher R. McHenry, M.D.

BACKGROUND: Observation following thyroidectomy and parathyroidectomy has been progressively shortened. The challenge has been to reduce the duration of postoperative observation without jeopardizing patient safety.

METHODS: A retrospective review of patients who underwent thyroidectomy and/or parathyroidectomy between July 1990 and March 2007 was completed to determine the frequency of life-threatening hematoma and hospital readmission and their impact on postoperative observation.

RESULTS: Of 1,050 patients, life-threatening hematoma developed in 6 (.6%) patients, 5 following bilateral and 1 following unilateral thyroidectomy. Hematoma developed 10 minutes to 7 days postoperatively, four within 4 hours, one at 21 hours, and one at 7 days. Twelve patients were readmitted an average of 5 days postoperatively for hypocalcemia, hematoma, infection, or respiratory distress.

CONCLUSION: Without factors contributing to bleeding, unilateral thyroidectomy and parathyroidectomy can be performed as an ambulatory procedure. To maximize safety, we recommend 4-hour and 23-hour observation following unilateral and bilateral thyroidectomy, respectively.

HYPERPARATHYROID CRISIS: USE OF BISPSPHONATES AS A BRIDGE TO PARATHYROIDECTOMY

Roy Phitayakorn, M.D., Christopher R. McHenry, M.D., FACS

BACKGROUND: Hyperparathyroid crisis is an uncommon, potentially lethal condition for which emergent parathyroidectomy has been advocated.

STUDY DESIGN: The manifestations of hyperparathyroid crisis and outcomes of bisphosphonate-based therapy and delayed parathyroidectomy were determined and compared with cases from a review of the literature. Laboratory indices and gland weights were compared with those from patients with primary hyperparathyroidism without crisis.

RESULTS: Of the 292 patients operated on for hyperparathyroidism, 8 (2.8%) had hyperparathyroid crisis, consistent with rates of 1.6% to 6% reported in the literature. Hyperparathyroid crisis was manifested by vomiting, nausea, or both (n = 6); abdominal pain (n = 3); mental status changes (n = 3); pancreatitis (n = 2); bone pain, osteolytic lesions, or both (n = 2); electrocardiogram changes (n = 1); and acute conversion disorder (n = 1).

Isotonic sodium chloride and furosemide, in combination with a bisphosphonate drug in 7 of 8 patients, resulted in a calcium decline from 16.2 ± 1.6 mg/dL to 11.8 ± 1.6 mg/dL, with resolution of electrocardiogram and mental status changes, and pancreatitis before resection of an adenoma (n = 7) or carcinoma (n = 1). Patients with hyperparathyroid crisis had higher parathyroid hormone levels (691.7 ± 662.4 pg/mL versus 172.6 ± 147.5 pg/mL; $p = 0.062$), larger tumor weights (7.5 ± 8.4 g versus 1.6 ± 2.1 g; $p = 0.085$), and lower postoperative calcium levels (7.3 ± 1.6 mg/dL versus 8.7 ± 0.9 mg/dL; $p = 0.035$) than patients without crisis. Four (50%) of the 8 tumors were found in ectopic locations. There was no mortality from hyperparathyroid crisis, compared with a 7% mortality rate for cases reported in the literature since 1978.

CONCLUSIONS: Rehydration, calciuresis, and bisphosphonate therapy are effective in correcting life-threatening manifestations of hyperparathyroid crisis, providing an effective bridge to parathyroidectomy.

FOLLOW-UP AFTER SURGERY FOR BENIGN NODULAR THYROID DISEASE: AN EVIDENCE-BASED APPROACH

Roy Phitayakorn R, Christopher R. McHenry

BACKGROUND: There is no consensus on what constitutes appropriate methodology and timing for follow-up of patients after surgery for benign nodular disease.

METHODS: A systematic review of the medical literature using evidence-based criteria was used to address the following four issues: (1) How often should patients who have undergone thyroidectomy for the treatment of benign nodular goiter be followed, and what constitutes appropriate follow-up? (2) What is the most appropriate method for detecting recurrent nodular thyroid disease? (3) Does thyroid hormone administration prevent recurrent nodular thyroid disease? (4) Does iodine administration prevent recurrent nodular thyroid disease?

RESULTS: Altogether, 727 articles were found in MEDLINE using a keyword search strategy; we then narrowed them to 23 articles. There were a total of four articles with Level I data, five articles with Level II data, one article with Level III data, and 13 articles with Level IV or retrospective data.

CONCLUSIONS: Based on the available data, it is our recommendation that patients undergoing thyroid lobectomy for benign nodular thyroid disease should be followed with an annual physical examination, neck ultrasonography, and serum thyroid-stimulating hormone (TSH) measurement. Patients undergoing total thyroidectomy should be followed with an annual physical examination and a serum TSH measurement. Routine thyroxine and/or iodine supplementation may be useful for preventing recurrence in patients from iodine-deficient regions.

IS NODULE SIZE AN INDEPENDENT PREDICTOR OF THYROID MALIGNANCY?

Christopher R. McHenry, M.D., Eun S. Huh, BS, and Rhoderick N. Machenko, Ph.D.

BACKGROUND: A decision to proceed with thyroidectomy or to perform more extensive thyroidectomy based on nodule size is controversial. It was our hypothesis that larger nodules are more likely to be malignant, and, as a result, nodule size may be useful for guiding operative decision making.

METHODS: Data was obtained from a prospectively maintained database for patients with nodular thyroid disease evaluated from 1990 to 2007. Logistic regression analysis was performed to determine if there was a significant relationship between nodule size and malignancy based on final pathology. The relationship of nodule size and malignancy was further evaluated for specific diagnostic categories of fine needle aspiration biopsy (FNAB).

RESULTS: 1023 patients were evaluated for nodular thyroid disease and 676 underwent thyroidectomy. Mean size was 4.4 ± 2.4 cm for benign and 3.3 ± 2.2 cm for malignant nodules ($P < .05$). The size of benign and malignant nodules, as a function of FNAB, was not significantly different.

CONCLUSION: Increasing nodule size was not predictive of thyroid malignancy suggesting that it should not be used in lieu of FNAB for therapeutic decision making.

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

Trunzo JA, McHenry CR, Schulak JA, Wilhelm SM.

BACKGROUND: It has been suggested that parathyroidectomy for hyperparathyroidism (HPT) in end-stage renal disease (ESRD) may result in improvement in anemia and the response to erythropoiesis stimulating drugs. This study examines the effect parathyroidectomy had on erythropoietin (EPO) dosing requirements and anemia in ESRD.

METHODS: A retrospective review was conducted. Patients were included if pre-operative and 12 month post-operative hemoglobin (Hg) and hematocrit (Hct) levels were available and they did not receive a kidney transplant or have failure of parathyroidectomy during the follow-up. Erythropoietin (EPO) dose, calcium, phosphorous, alkaline phosphatase, albumin, and parathyroid hormone (PTH) were also obtained. Other data collections were at 1 and 2 months post-operatively.

RESULTS: Thirty-seven patients met inclusion criteria. Parathyroidectomy resulted in decreased PTH from 1871 ± 236 (mean \pm SEM) to 172 ± 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/week ($p < 0.05$). Hb and Hct levels followed an upward trend at 12 months (11.4 ± 0.3 to 12.1 ± 0.2 g/dL and 35.7 ± 1.0 to $37.1 \pm 0.6\%$, respectively).

CONCLUSIONS: In ESRD, parathyroidectomy for HPT improves anemia and statistically lowers exogenous erythropoietin requirements suggesting either increased endogenous EPO production or improved response. As a result, we propose refractory ESRD associated anemia as a secondary indication for surgical resection in this population.

INCIDENTAL THYROID NODULE: PATTERNS OF DIAGNOSIS AND RATE OF MALIGNANCY

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

BACKGROUND: The clinical significance of thyroid incidentalomas is controversial.

METHODS: The rate of malignancy was determined for patients with an incidentally-discovered thyroid nodule and the results were stratified according to imaging modality and the presence and type of pre-existing malignancy.

RESULTS: 150 patients were identified, 88 with a known malignancy who were screened for metastases. 23 (15%) patients were diagnosed with thyroid malignancy. Incidental nodules identified on PET scan were malignant in 33% of the patients as compared to 11% for those identified on CT ($p=0.016$). The rate of thyroid malignancy in patients with pre-existing non-thyroid malignancy (18%) was not significantly different from patients without a history of malignancy (11%, $p=0.36$).

CONCLUSION: Thyroid incidentalomas are associated with a high rate of malignancy. The rate of malignancy is higher for nodules discovered on PET scan and is no different in patients with or without pre-existing malignancy.

WHAT CONSTITUTES ADEQUATE SURGICAL THERAPY FOR BENIGN NODULAR GOITER?

Phitayakorn R, Narendra D, Bell S, McHenry C

BACKGROUND: It is our hypothesis that the extent of thyroid resection for benign nodular thyroid disease (NTD) should be based on the extent of disease.

METHODS: Patients operated on for benign NTD from 1990 through 2007 were divided into three groups, those who underwent lobectomy for unilateral NTD (Group 1), near-total or total thyroidectomy for bilateral NTD (Group 2), and reoperation for NTD initially treated at other institutions (Group 3). The incidence of recurrence was determined for Groups 1 and 2 and the timing of diagnosis was compared to Group 3. Potential risk factors for recurrent disease were examined.

RESULTS: 545 patients were operated on for benign NTD. Contralateral disease was excluded in Group 1 patients using ultrasound (47.7%) and/or intraoperative palpation (100%). Five (1.9%) of 260 patients in Group 1 and one (0.4%) of 248 patients in Group 2 developed recurrent NTD after 7 ± 4 (median=8) and 4 years compared to a mean 19 ± 11 (mean=20) years for the 37 patients in Group 3 following one to three previous thyroidectomies. Recurrent disease was diagnosed by physical exam in 24 (55.8%) and imaging in 19 (44.2%) patients. Thyroid hormone was required for post-surgical hypothyroidism in 70 (26.9%) patients in Group 1.

CONCLUSION: Thyroid lobectomy is optimal therapy when benign NTD is limited to one lobe, as evidenced by a 2% recurrence rate and maintenance of euthyroidism in 73% of patients. When NTD is bilateral, total thyroidectomy is indicated to eliminate recurrence, underscoring the importance of routine preoperative ultrasound.

ACUTE SUPPURATIVE THYROIDITIS: A CLINICAL REVIEW AND GUIDE FOR FUTURE CLINICAL INVESTIGATION

John E. Paesa, DO, Kenneth D. Burmanb, MD, James Cohen, MDc, PhD, Jayne Franklyn, MDd, Christopher R. McHenry, MDe, Shmuel Shoham, MDf, and Richard T. Kloos, MDg.

BACKGROUND: Acute suppurative thyroiditis (AST) is an infrequent but potentially life threatening endocrine emergency. The prevailing management of this disease is surgery in conjunction with targeted antibiotic therapy. Although case reports describe individual experiences, there is reporting bias, and few reports provide decision analysis for clinical guidance. Furthermore, there are no randomized clinical trials to derive high level evidence. Here we provide an approach to this problem based on existing evidence, clinical experience, and expert opinion.

METHODS: The literature was reviewed utilizing Pub Med and a representative case of AST was presented to a panel of experts. Endocrinology, surgery, and infectious diseases experts responded to a series of questions regarding diagnosis, management, prognosis, and harm.

RESULTS: Combining a broad spectrum of clinical expertise and best-evidence practices, the authors define a clinical algorithm as a guide to management, addressing both diagnosis and acute long term management.

CONCLUSIONS: Published studies indicate a trend toward less invasive management during active inflammation and infection. Remaining questions are presented to engender an evidence-based approach to this disease. Ideally, future randomized, controlled trials will provide data to improve the therapy and outcome of AST.

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MANAGEMENT OF THYROID NODULES

Elizabeth A. Mittendorf, MD, and Christopher R. McHenry, M.D.

A thyroid nodule is a discrete lesion within the thyroid gland. Such lesions are common in the United States, with a prevalence of 4% to 7% for palpable nodules. However, nonpalpable nodules discovered incidentally on ultrasound or at autopsy suggest an overall prevalence of 19% to 67%. With an estimated annual incidence rate of 0.1%, approximately 3000,000 new nodules are identified yearly. Thyroid nodules are four times more common in women than in men, and the incidence increases with age, radiation exposure, and reduced iodine intake. The prevalence of nodular thyroid disease has been reported to be 15% in areas of iodine deficiency.

The majority of thyroid nodules are benign. Colloid nodules, cysts, and thyroiditis account for approximately 80%, and benign follicular and Hurthle cell adenomas account for 10% to 15% of all thyroid nodules. Only 5% of thyroid nodules are malignant. In 2008, an estimated 33,550 new cases of thyroid cancer are expected to occur in the United States, and approximately 1530 patients are expected to die from thyroid cancer. The challenge for a clinician is to distinguish patients with malignancy, who are treated surgically, from patients with benign disease, who are followed clinically. This is accomplished by a diagnostic approach that consists of routine fine needle aspiration biopsy (FNAB), a routine screening third-generation thyrotropin (thyroid-stimulating hormone [TSH]) level, and selective use of high-resolution ultrasound (US) and iodine-123 (I-123) thyroid scintigraphy.

OPHTHALMIC ACID AND GLUTATHIONE CONCENTRATIONS 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 oxido-reductive status of the liver and its metabolite as surrogates of tumor subsistence and growth.

EXPERIMENTAL DESIGN: Ophthalmic acid and Gluthatione concentrations 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.

MATERIALS 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 8.4 +5.96 (Mean+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 vs status after tumor implantation, $p < 0.01$, paired t-test). Similar values were found in the Glutathione concentration between the healthy status and the status after tumor implantation (see Table 1).

TABLE 1

Ophthalmic acid and Glutathione concentrations in the Rabbit VX2 model before and after tumor implantation and growth.

Time(h) (n=6)	Ophthalmic BTI *	Ophthalmic ATI *	GSH BTI	GSH ATI	GSSG BTI	GSSG ATI
24 hours (M±SD)	1.203+0.80	2.338+0.68	9.1	10.66	9.66	10.51
48 hours	1.064+0.29	5.161+1.60	13.08	13.24	13.39	13.74
72 hours	1.363+0.37	5.57+2.51	14.25	13.48	13.55	14.91

* $p < 0.01$ by paired t-test.

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

CONCLUSIONS: Ophthalmic acid concentration significantly differed in rabbits before and after tumor implantation and growth. Changes in the oxido-reductive state of livers with subsequent increase in the Ophthalmic acid concentration is a reliable surrogate of tumor subsistence and growth.

THE RISE IN OPHTHALMIC ACID CONCENTRATION AND GLUTATHIONE TURNOVER: MARKERS OF LIVER TUMOR EXISTENCE AND GROWTH

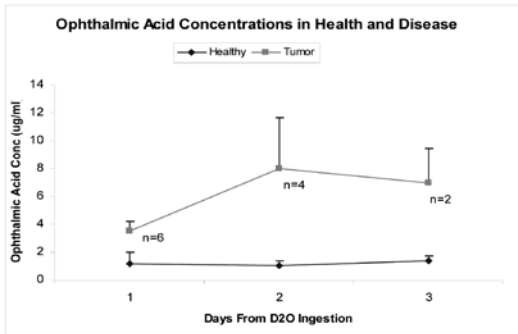
R. Abbas, MD¹; K. Subramanian, MS²; H. Brunengraber MD PhD²; and J. Sanabria, MD, MSc¹.

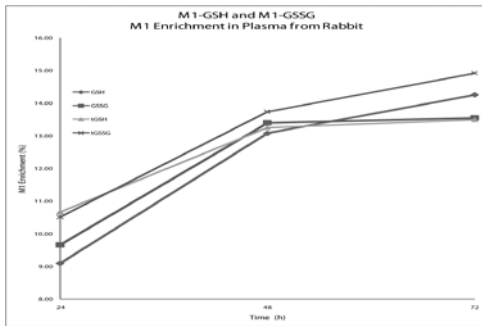
Neoplastic cells differ from normal ones by their metabolism due to a focus on cell division thus resulting in an increased need for lipid and protein synthesis especially in presence of a higher oxidative stress. The purpose of this study was to evaluate the oxido-reductive status of the liver before and after implantation of a VX2 tumor by measurement of glutathione (GSSG/GSH) turnover rate and ophthalmic acid concentration.

EXPERIMENTAL DESIGN: An animal model with liver tumor has been established with the use of the VX2 carcinoma, an anaplastic squamous cell carcinoma derived from a virus-induced papilloma in the wild rabbit. Glutathione and ophthalmic acid levels were checked in rabbits in their healthy stage then when they were tumor carrying.

MATERIALS AND METHODS: 6 healthy rabbits were loaded with Deuterated water (D2O or 2H2O) at 2.5% (Body Water) through an intraperitoneal injection, followed by maintenance by oral ingestion at 4%. As plasma enrichment is reached, daily blood draws (1 ml) are taken through the marginal ear veins. Those same rabbits (n=6) and after a period of 4 weeks to ensure the clearance of the primary dose of D2O, then received VX2 tumor implant into their livers. The implant was cut to a volume of (1x1x1) mm³, deposited in a well within the liver parenchyma, and finally fixed to the organ by a surgifoam section. The tumor growth was allowed for a period of 14 days reaching a tumor size of 1-2 cm. Rabbits with liver cancer are loaded and maintained again with D2O treatment over a 72 hour period, during which time, the tumor growth and its metabolic effect on the liver function could be identified. On the 14th day, the animals undergo an open RFA of the liver tumor. After ablation, healthy liver tissue as well as ablated are collected for metabolic comparison.

RESULTS: The metabolic assays are processed by way of Gas Chromatography- Mass spectrometry.





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.

CHARACTERIZATION OF HUMAN SKELETAL MUSCLE IN WEIGHT-LOSING PANCREATIC CANCER PATIENTS

J. M. Brell, J. Hardacre, J. Schulak, R. Onders, T. Stellato, J. Sanabria, M. Schulchter, L. Strickland, R. Sprosty, J. Pink;

BACKGROUND: Decreased body mass (cachexia) is a common cause of functional decline in pancreas carcinoma (PC) and other malignancies. The etiology is unknown. Characterization of human PC skeletal muscle, in regard to proteolysis and gene expression, compared to control muscle may reveal information about pathophysiology.

METHODS: Biopsies of rectus abdominus muscle were performed in weight-losing PC patients all stages (A) during cancer-related surgery and in cancer-free controls undergoing ventral hernia repair (B). Caspase-3, pAkt, and urinary 3-methylhistidine (u3-MH) were assessed by Western blot and high-performance liquid chromatography. Fat-free mass (FFM), body mass index (BMI), and time to progression were recorded. Muscle from five patients (median weight loss 21%) and five controls were analyzed for gene expression patterns using Affymetrix Human Genome U133 A 2.0 array chip. Two hundred differentially over- and under-expressed genes were examined in group A for potential association with cachexia. RT-PCR confirmation of six candidate genes was performed.

6 RESULTS: Thirty-eight patients were enrolled. Median weight loss in group A (N=27) was 14.5% (5%-34%). No differences were noted between groups in caspase-3 and pAkt expression. Baseline u3-MH ($p=0.86$) and FFM ($p=0.28$) did not differ; baseline BMI was lower in group A ($p=0.04$). BMI follow-up measurements (N=17) were significantly decreased ($p=0.0005$). In 65% patients, progressive disease was noted within median time of 3 months. RT-PCR established up-regulation of CHRNA1 and LMO7, but not GDF8. mRNA down-regulation for TRIM63, IGF-BP6, and MYH-1 was confirmed.

CONCLUSIONS: Muscle proteolysis in human PC skeletal muscle was not demonstrated, perhaps due to unmeasurable proteolysis or use of non-informative endpoints. BMI decreased in group A with PD; further studies need tight control of BMI variables. New hypotheses about cachexia include neuromuscular junction dysfunction, as CHRNA 1 has specific role in ion channel gating; this is disrupted in the paraneoplastic Eaton-Lambert syndrome. This is first study analyzing human muscle in weight-losing PC and proves symptom management multidisciplinary research is feasible in academic setting. Supported by American Cancer Society pilot grant.

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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 $12,500 \pm 3,000$ rads (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.

CYBERKNIFE RADIOSURGERY FOR NON-RESECTABLE & NON-TRANSPLANTABLE PRIMARY TUMORS OF THE LIVER

KK Goyal¹, MD, D Einstein³, MD, PhD, C Kunos³, MD, PhD, C Siegel¹, MD, PhD, D Singh², MD, J Williams³, RN, and J Sanabria¹, MD, MSc

OBJECTIVE: More than 100,000 individuals are diagnosed with primary tumors of the liver every year in USA. Less than 20% of those lesions are amenable to definitive surgical management due to advance local disease or a medical condition. Alternative therapies, i.e. TACE, RFA have 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. 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 fiducial markers has provided a technique for locking on the neoplasm by a computer controlled Robotic arm that delivered gamma radiation (Cyberknife). We report on our initial experience with Stereotactic Radiosurgery (CK) for patients with malignant tumors of the liver who were not candidates for surgical resection or transplantation.

METHODS: Our first ten consecutive patients receiving CK as part of the treatment for non-resectable and non-transplantable hepatocellular carcinoma (HCC) or intrahepatic cholangiocarcinoma (IHC) were reviewed over a median follow-up of 6 months under an approved IRB protocol.

RESULTS: 80% of patients experienced a Grade III/IV local response to CK with a mean decrease in maximum diameter from 7.9 ± 4.9 cm to 5.5 ± 2.3 cm and a mean total tumor volume reduction of 44%. Two patients had a local recurrence distant from the radiation field. Thirty percent of patients were readmitted to the hospital for medical complications. No complications attributable to fiducial placement or CK treatment were observed.

CONCLUSION: Our initial experience shows CyberKnife radiosurgery to be a safe and effective local treatment modality for non-resectable/non-transplantable primary liver neoplasms. Further follow-up is ongoing to assess the role of CK in the downstage management of these malignancies.

THE USE OF BREAST MAGNETIC RESONANCE IMAGING (MRI) IN THE SURGICAL MANAGEMENT OF BREAST DISEASE

R. Leeming, MD, S. Ranallo, C. Holmes, CNP, N. Klein, MD, D. Plecha, MD, A. Coffey, M.D, J. Lyons, MD

BACKGROUND: The role of breast MRI in the management of breast disease continues to evolve. Breast MRI is a highly sensitive screening tool in high risk patients and can aid in diagnosis when clinical findings and standard imaging are inconclusive. The high false positive rate has prompted guidelines suggesting limiting the use of breast MRI. The purpose of this study was to evaluate the usefulness of breast MRI on patients treated within a single surgical practice.

METHODS: A retrospective review of patients undergoing breast MRI in 2006 treated by a single surgeon in 2006 was performed. 144 patients underwent breast MRI (121 records available for analysis). 44 patients underwent diagnostic breast MRI (30 following a new diagnosis of breast cancer and 14 who had inconclusive findings on exam, imaging or initial biopsy). 77 asymptomatic patients had screening breast MRI (48 with a previous diagnosis of breast cancer and 29 high risk patients based on family history or known BRCA mutation). All had routine evaluation prior to MRI, including physical exam and standard imaging (mammogram and/or ultrasound). The majority had dense breast tissue limiting the sensitivity of mammography.

RESULTS: The median age of the patients was 48 (range 18 to 81). Of the 30 patients with a new diagnosis of breast cancer, 8 (26.6%) were found to have occult lesions on MRI. This changed surgical management in 4 (13%). Three of these four patients underwent mastectomy for multicentric disease and the fourth patient chose a bilateral mastectomy after refusing contralateral core biopsy (pathology negative). One cancer patient had a benign fibroadenoma in the opposite breast, and the three additional patients underwent follow-up MRI after second look ultrasound was negative. Eight of 14 patients (57%) with inconclusive clinical or imaging findings had positive findings on breast MRI. Four of these 14 patients had a history of previous breast cancer with suspicious clinical findings, and all four were confirmed to have breast cancer on biopsy. Two young patients had large palpable masses and biopsy revealed one fibroadenoma and one phyllodes tumor. One patient had an abnormal ultrasound showing a solitary mass and was found to have multiple nodules on MRI confirmed to be atypical papillomas on biopsy. Another had a solitary palpable mass and had additional areas seen on MRI which were benign on core biopsy. Only 7 of 77 (9%) screening breast MRIs done in asymptomatic high risk women were abnormal and all lesions were negative on biopsy. One patient had a papilloma associated with ADH.

CONCLUSIONS: Breast MRI is highly sensitive in detecting occult disease. In our series, it's use changed surgical management in 13% of newly diagnosed breast cancer patients, did not reveal cancer in the high risk screening group, but was able to provide information in patients presenting with inconclusive findings. Given the expense of MRI and the cost of additional imaging and biopsies, continued evaluation is needed to clarify the situations where it is most useful.

ATYPICAL OR MULTIPLE SENTINEL LYMPH NODE DRAINAGE BASINS ARE SIGNIFICANT IN PATIENTS WITH MELANOMA

Harvey Chim, MD^{1,2}, Julian A. Kim, MD, FACS¹

BACKGROUND: The purpose of this study was to identify the proportion of patients undergoing sentinel lymph node biopsy for melanoma who had atypical or multiple drainage basins and determine the clinical significance of removal of these nodes based upon final histology.

METHODS: A retrospective analysis was performed on a cohort of patients (n=136) with primary or recurrent melanoma who were evaluated in a multidisciplinary melanoma clinic from May 2006 to Feb 2009. Univariate, followed by multivariate statistical analysis was performed in order to identify variables associated with a positive sentinel lymph node biopsy and atypical and/or multiple (A+M) sentinel nodes.

RESULTS: Mean age of patients was 58.9 years. Mean Breslow thickness of melanomas excised was 2.5 + 3.5mm, and there were no significant differences in mean Breslow thickness associated with location. Lymphatic drainage to atypical lymph node basins including periscapular, epitrochlear, popliteal and pectoral were identified in 14 patients (10%), while drainage to multiple lymph node basins was identified in 21 patients (15%). Multivariate analysis demonstrated that patients with A+M nodal drainage sites and Breslow depth demonstrated a higher rate of sentinel node positivity ($p<0.05$), while a positive sentinel node was significantly associated with A+M drainage sites ($p<0.05$). Interestingly, patients with proximal extremity melanomas were associated with lack of A+M nodal drainage sites ($p<0.05$).

CONCLUSIONS: Accepting the limitations of this retrospective analysis, the presence of atypical or multiple lymph node drainage basins should not be overlooked as the false negative rate of the procedure may be adversely affected.

CONTEMPORARY MANAGEMENT OF PAPILLARY CARCINOMA OF THE THYROID GLAND

Michael A. Rosenbaum and Christopher R. McHenry

The incidence of thyroid cancer is increasing by 4% per year. Thyroid cancer has become the eighth most common malignancy diagnosed in women. Papillary cancer accounts for 80% of all thyroid cancer. The management of papillary thyroid cancer is challenging, primarily because there have been no prospective randomized trials to help guide therapeutic decision making. The purpose of this article is to discuss the contemporary management of papillary thyroid cancer, including the diagnosis and pre-operative evaluation, surgical management, postoperative thyroid hormone and radioiodine therapy, long-term follow-up, prognosis and management of recurrent and metastatic disease. The role of molecular markers to enhance the cytologic diagnosis of papillary cancer and new molecular-based therapies will also be reviewed.

Section 7

**Thoracic and
Esophageal Surgery**

ROUTINE THORACOSCOPY IMPROVES STAGING OF PANCOAST TUMORS

Matthew O. Hubbard MD, Carsten Schroeder MD, Jason M. Robke MD, Philip A. Linden MD

PURPOSE: Non-small cell lung cancers invading the apex of the chest are best managed with preoperative radiation or combined chemoradiation. In the absence of overt radiographic evidence of first rib destruction, the definitive diagnosis of a Pancoast tumor can be difficult. In an effort to avoid unnecessary thoracotomy or the unnecessary use of neoadjuvant treatment, we review the routine use of thoracoscopy of tumors abutting the first rib without overt signs of apical invasion.

METHODS: 137 patients with upper lobe tumors who underwent thoracoscopy between July 2004 and February 2009 were reviewed. Twelve patients were identified who had a tumor abutting the first rib without overt CT scan evidence of invasion. Data collection occurred retrospectively from a single tertiary care center's Pancoast tumor experience.

RESULTS: The average patient age was 66.8 years, 58% were male, and 42% were right-sided tumors. The average diameter of the tumors was 7.4 cm, and five different histologic varieties of NSCLC were found. Eight patients underwent successful staging thoracoscopy. Four of the successful thoracoscopic evaluations found apical invasion and spared further thoracotomy, while four had no visualized invasion and were considered candidates for primary lung resection and thus spared unnecessary neoadjuvant therapies (three of the latter were primarily resected, one resection was not completed due to a highly friable tumor that resulted in hemodynamically significant bleeding upon dissection). The average diameter of tumors that were successfully evaluated by thoracoscopy was 7.0 cm. Thoracoscopy was unable to successfully evaluate four patients' tumors; one tumor had superficial invasion into apical subpleural fat and underwent primary lung and chest wall resection before proceeding to receive chemoradiation; the remaining three were referred for medical oncology for possible chemotherapy and/or radiation therapy. Of those tumors that were unable to be staged by thoracoscopy, the average tumor diameter was 8.2 cm, and two patients were converted to thoracotomy after dense adhesions did not allow staging by thoracoscopy. Of patients who were successfully staged by thoracoscopy the delay until starting adjuvant therapy was 22.3 days, the average length of stay was 1.5 days, and no major morbidity or mortality was encountered.

CONCLUSION: Routine staging thoracoscopy for suspected Pancoast tumors may lead to more accurate assignment of patients to receive primary lung resection or neoadjuvant chemoradiation than noninvasive imaging techniques. No significant morbidity or mortality was encountered, and there is only a minimal delay until neoadjuvant therapy may be started in those patients who truly have apical invasion. Thoracoscopic staging may be limited by adhesions to the chest wall, but does not seem to be limited by tumor size.

ROUTINE USE OF STAGING THORACOSCOPY FOR PANCOAST TUMORS WITHOUT OVERT RADIOGRAPHIC CHEST INVASION

Matthew O. Hubbard MD¹, Carsten Schroeder MD PhD¹, Jinsun Kim MD¹, Philip A. Linden MD¹.

OBJECTIVES: To determine the utility of thoracoscopy to accurately determine chest wall invasion in patients with malignant non small cell lung cancers abutting the first rib without overt radiographic evidence of chest wall invasion.

METHODS: All patients with CPT coded upper lobe or not otherwise specified malignant neoplasms of the lung and non small cell lung histology were reviewed. Patients with tumors abutting the first rib without overt radiographic evidence of invasion routinely underwent staging thoracoscopy. Preoperative characteristics, intraoperative findings, and postoperative events were reviewed.

RESULTS: Of the twelve patients with tumors abutting the first rib without overt radiographic invasion, thoracoscopy was able to correctly determine chest wall invasion in eight of twelve patients. There was no significant morbidity related to thoracoscopy. Four patients were found to have no invasion and proceeded to primary resection, while four patients were shown to have invasion and proceeded to radiation or chemoradiation. Thoracotomy was necessary in four patients. Large tumor size did not seem to preclude thoroscopic staging. The presence of diffuse, dense adhesions did limit the utility of staging thoracoscopy. Patients with invasion by thoracoscopy were able to begin radiation or chemoradiation much sooner (median 22.3 days) than patients requiring thoracotomy (median 60 days).

CONCLUSIONS: The routine use of staging thoracoscopy in all tumors abutting the first rib without overt radiographic evidence of invasion accurately identify apical chest wall involvement in the majority of patients. With this strategy, unnecessary neoadjuvant treatment and futile thoracotomy may be avoided

CHARACTERIZATION OF HUMAN AND MOUSE CYTOKINE PROFILES IN XENOGENEIC LUNG INJURY

Carsten Schroeder, MD, PhD¹, Nitin Sangrampurkar³, Kasper Kaledjan², Amal Laaris³, Xiangfei Cheng³, Chris Avon³, Richard N. III Pierson³ and Agnes M Azimzadeh, PhD².

¹Surgery, Case Western University, Cleveland, OH, United States, add kasper information here³ Surgery, University of Maryland Medical Center and Baltimore VAMC, Baltimore, MD, United States

BACKGROUND: Lung injury after xenotransplantation occurs despite control of galactosyl (Gal) natural antibodies. Current strategies targeting complement and coagulation cascade activation delay but do not completely prevent lung injury and blood cell activation. Pro-inflammatory cytokines, if produced, may stimulate or amplify rejection mechanisms. Cytokine profile changes during xenogenic lung injury have not yet been systematically studied. Here we characterize the production of pro-inflammatory cytokines at the protein and transcriptional level in an effort to understand Gal-independent related xenogenic lung injury.

METHODS: Wild-type (WT) C3H/HeJ mouse lungs were perfused ex vivo with human blood containing Nextran 1285 (Gal antigen control, n=5). Mouse and human cytokines were measured in the plasma by Luminex at 60 and 240 min. Mouse cytokine transcripts were assessed in the lung tissue by qRT-PCR at 240 min and expressed as fold increase over pre-perfusion expression levels.

RESULTS: All lungs survived until elective termination at 240 minutes. However, lung pulmonary vascular resistance rose above normal levels and features of lung rejection (thrombosis, hemorrhage) were detectable at 240 min. At the protein level, human IL-8 and TNF α (240 min) and mouse IL-6 (240 min) and KC (60 and 240 min) showed the greatest changes (see table). Human IL-1 β , mouse IL-1 β , IP-10 and TNF α remained unchanged. Human IP-10 levels were relatively high (999 \pm 243 ng/ml) before perfusion, and tended to be decreased at 240 min (from 664 \pm 151) delete IP-10 if you need space At the transcriptional level, tissue expression of mouse IL-6 was significantly increased (58 \pm 14 fold), while mouse TNF α (8 \pm 3) and IP-10 (6 \pm 3) were moderately increased at 240 min. Mouse IL-1 β mRNA level was essentially unchanged (1.7 \pm 0.9).

Please check units for cytokines, make sure it is ng/ml for all of them.

CONCLUSIONS: Hyperacute lung injury is associated with prolific production of pro-inflammatory cytokines at the protein and transcriptional levels. Our data suggest that human IL-8, TNF α or mouse IL-6, KC are potential therapeutic targets to prevent lung injury and sequestration of leukocytes. Alternatively, approaches modulating blood and endothelial cell activation may have a beneficial effect.

Time (minutes)	Hu. IL-8 (ng/ml)	Hu. TNF α (ng/ml)	Hu. IP-10 (ng/ml)	m. IL-6 (ng/ml)	m. KC (ng/ml)
Pre	1.9 \pm 0.2	5.1 \pm 0.5	976 \pm 48	11 \pm 0.2	15 \pm 0.2
60 min	2 \pm 0.3	5.7 \pm 0.3	664 \pm 67	13 \pm 0.3	20 \pm 0.3
240 min	185 \pm 120	64 \pm 51	694 \pm 80	143 \pm 120	90 \pm 120

Carsten, I used sem, not sd.

THE PRO-INFLAMMATORY MEDIATOR HMGB1: A POTENTIAL TARGET IN XENOGENIC LUNG INJURY?

Agnes M Azimzadeh, PhD¹, Carsten Schroeder, MD, PhD¹, Tiffany Stoddard, MD¹, Bao Nguyen, MD¹, Sean Kelishadi, MD¹, Jingping Hu¹, Xiangfei Cheng¹, Chris Avon¹, David Ayares², Richard N. III Pierson¹ and Trevor Snyder¹. ¹Surgery, University of Maryland Medical Center and Baltimore VAMC, Baltimore, MD, United States and ²Revivacor, Blacksburg, VA, United States.

BACKGROUND: Lung injury after transplantation across species (xenotransplantation) occurs despite use of organs lacking the α -galactosyl (Gal) antigen, or expressing human complement regulatory proteins. At concentrations above 5 ng/ml, high mobility group box 1 (HMGB1), which is released from activated macrophages, platelets, and endothelial cells, amplifies systemic inflammation through binding to RAGE, TLR2 and TLR4. A role for HMGB1 in xenograft injury has not previously been described.

METHODS: Wild-type (WT) C3H/HeJ mouse lungs and pig lungs (WT, galactosyl transferase knock-out (GalTKO) or GalTKO expressing human membrane complement inhibitor CD46 (GalTKO.CD46+)) were perfused ex vivo with human blood. Plasma HMGB1 levels were measured by ELISA.

RESULTS: High levels of HMGB1 were detected at failure of untreated mouse lungs (119 \pm 38 ng/ml versus 1.5 \pm 0.4 ng/ml baseline, n=5). Whereas, inhibition of Gal with NEX did not significantly decrease HMGB1 release (57 \pm 9, p=0.15, n=5), HMGB1 was less elevated with complement inhibition (C1Inh: 25 \pm 4, p=0.04 vs. untreated or NEX).

HMGB1 was substantially increased at graft failure of Gal+WT lungs (38 \pm 12 ng/ml, n=4; relative to 2.2 \pm 0.4 ng/ml baseline). Similar levels of HMGB1 were detected despite the absence of Gal (GalTKO: 41 \pm 12 at 60 min, 55 \pm 14 at graft failure) or with additional CD46 expression (GalTKO.CD46+: 43 \pm 10 at 60 min, 81 \pm 23 at graft failure).

CONCLUSIONS: Xenogenic lung rejection is associated with prolific HMGB1 elaboration. HMGB1 release is minimally attenuated by neutralization of anti-Gal antibody and/or efficient inhibition of complement. We postulate that HMGB1 release is a sensitive indicator of xenograft injury, and a potential target for therapeutic intervention to protect a pig organ xenograft from injury escaping control by approaches that target antibody and complement.

ROLE OF HMGB1 IN LUNG XENOGRAFT INJURY AND CYTOKINE PRODUCTION

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BACKGROUND: Lung injury after xenotransplantation occurs despite use of organs lacking the -galactosyl (Gal) antigen. High mobility group box 1 (HMGB1), which is released from activated neutrophils, macrophages, platelets, and endothelial cells, amplifies systemic inflammation through binding to RAGE, TLR2 and TLR4. In separate studies, we showed increased levels of HMGB1 after xenogeneic Gal-independent lung perfusion. Here we tested whether HMGB1 mediates lung xenograft injury and cytokine production.

METHODS: Wild-type (WT) C3H0uJ mouse lungs were perfused ex vivo with human blood containing Nextran 1285 (Gal antigen control) n=5 or human blood with Nextran + HMGB1 inhibitor (Glycyrrhizin 0.3mg/ml) n=5. Lung survival, PVR, complement and platelet activation, CBC, mouse and human plasma (Luminex) and tissue (qRT-PCR) cytokine levels were measured.

RESULTS: All lungs survived for the time of study and perfusion was electively terminated at 240 minutes. The pulmonary vascular resistance (PVR) rose moderately above normal levels similarly in both groups, not meeting rejection criteria. Complement (measured as plasma C3a) and platelet (-thromboglobulin, expression of CD62P) activation were not different between groups. Thrombosis and hemorrhage were evident after 4 hours of perfusion, and not prevented by HMGB1 blockade. Mouse IL-6 and KC as well as human IL-8 and TNF were consistently increased at 4hrs with or without HMGB1 blockade. Tissue expression of mouse IL-6, IP-10 and TNF transcripts was significantly up-regulated at 4hrs of perfusion, but not influenced by HMGB1 blockade.

CONCLUSIONS: The physiological and molecular phenotype of lung HAR appears essentially independent of the pro-inflammatory mediator HMGB1. While a role for HMGB1 as an amplifier of inflammation in late injury cannot be excluded, control of early blood cell activation, lung injury and NFkB-dependent gene expression will require alternative therapeutic strategies.

ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY-GUIDED FIDUCIAL PLACEMENT FOR ROBOTIC STEREOTACTIC RADIOSURGERY OF LUNG TUMORS USING COIL-SPRING FIDUCIALS UNDER MODERATE SEDATION

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BACKGROUND: Stereotactic radiosurgery (Cyberknife; Accuray Incorporated; Sunnyvale, CA) is a treatment option for patients who are medically unfit to undergo lung tumor resection. For precise tumor ablation, the Cyberknife requires fiducial marker placement in or near the target tumor. Fiducial placement under transthoracic CT guidance is associated with a high risk of iatrogenic pneumothorax. Electromagnetic navigation bronchoscopy (ENB) offers a less morbid alternative to accurately deploy fiducials to bronchoscopically invisible peripheral lung lesions. However, prior studies, in which linear markers were used, showed at least a 10% dislocation rate and required general anesthesia for placement. We propose the use of coil-spring fiducials placed under moderate sedation in an outpatient bronchoscopy suite setting to decrease these complications.

METHOD: Consecutive patients with peripheral lung tumors who were felt to be nonsurgical candidates underwent fiducial placement using ENB under moderate sedation in an outpatient bronchoscopy suite setting. Four patients received 17 linear fiducials and 17 patients with 21 tumors received 68 coil-spring fiducials. The procedures were considered successful if fiducials were placed in or near the tumors and remained in place without migration allowing radiosurgery to proceed. The need for alternative or additional intrathoracic fiducial placement was documented as procedure failure.

RESULTS: A total of 85 fiducial markers were successfully deployed in 21 patients (100%) with 25 tumor locations. Eight patients underwent simultaneous transbronchial biopsy. Of these 25 cases, four received linear fiducials and 21 cases had coil-spring fiducials placed. At Cyberknife planning, 7 to 10 days after fiducial placement, 8 of 17 linear fiducial markers (47%) and 68 of 68 coil-spring fiducials (100%) were still in place and were adequate to allow radiosurgery to proceed. One pneumothorax occurred immediately after bronchoscopic fiducial placement with concurrent transbronchial biopsy. This was treated with insertion of a pig-tail chest tube which was removed and the patient discharged within 24 hours.

CONCLUSIONS: ENB can be used to deploy fiducial markers for Cyberknife radiosurgery of lung tumors safely and accurately without the complications associated with transthoracic CT guided placement. Transbronchial biopsies can be performed in the same setting. Coil-spring fiducials do not dislocate and therefore reduce the re-procedure rate and/or Cyberknife tracking errors. The procedure can be performed safely in an outpatient bronchoscopy suite setting under moderate sedation.

Section 8

**Transplantation and
Hepatobiliary Surgery**

LIVER RESECTION IN CIRRHOTICS VS NON-CIRRHOTICS PATIENTS

Sanabria JR MD MSc FACS, Weigel K RN, NP and Siegel C MD PhD FACS.

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.

	Cirrhotic 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.

DEFINING THE METABOLOME OF SUBJECTS WITH NORMAL AND ABNORMAL LIVER FUNCTION

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Liver disease has increased significantly during the last decade mainly due to increased prevalence of HCV infection and epidemic rates of both obesity and diabetes. The overall aim of this project is to define metabolic patterns of liver disease progression and to define metabolic signatures for specific liver diseases. To answer these questions two metabolomic approaches already developed and validated in our laboratory on healthy individuals have been taken in subjects with different degree of liver dysfunction ranging from subclinical disease to patients waiting for liver transplantation, and in patients after liver transplantation. The first approach includes the use of stable isotopomer analyses for the assessment of liver oxidative stress (glutathione species and ophthalmic acid turn over), liver synthetic function (pre-albumin, albumin and Factor V concentrations) and liver regenerative state (Insulin growth factor-1=IGF-1). The second approach involves the study of the subject's metabolome sampling (210 metabolites) that may define metabolomic patterns for a specific liver disease. Plasma samples were analyzed following GC-MS and HPLC-MS/MS techniques. We observed differences in the turnover of reduced and oxidized glutathione and ophthalmic acid in subjects with liver disease as compared to healthy subjects (controls) and patients after liver transplant with normal graft function. In addition, the aminoacid profile (Figure 1) and metabolome signatures (Figure 2) were significantly different in subjects with liver disease (n=2) compared to controls (n=10) or patients after liver transplant with normal graft function (n=4).

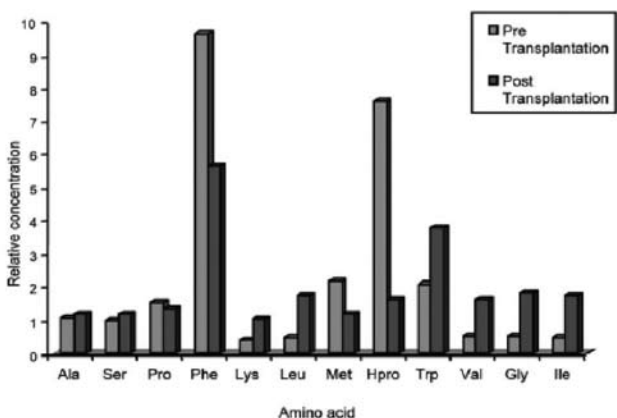


Figure 1. Relative concentration of aminoacids in plasma.

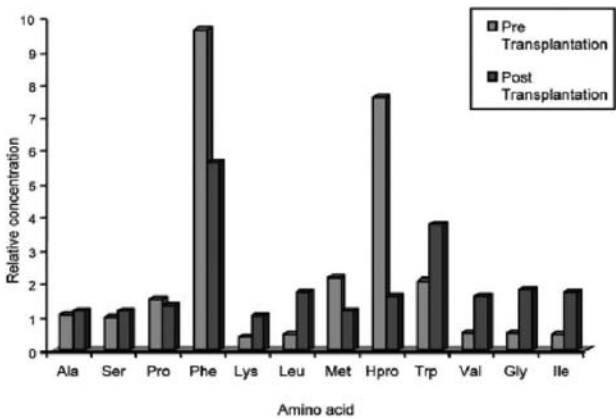


Figure 2. Relative concentration of plasma metabolites.

CONCLUSIONS: metabolic patterns of liver/ liver graft function may provide information for liver disease progression. Further analysis may find markers for early tumor detection and degree of immunosuppression.

THE ROCKY ROAD TO STEROID-FREE, CALCINEURIN INHIBITOR-FREE IMMUNOSUPPRESSION IN KIDNEY TRANSPLANTATION

A Padiyar, MD¹, J J Augustine, MD¹, K A Bodziak, MD¹, J Sanabria, MD¹, C Siegel, MD PhD¹, M Aeder, MD¹, J A Schulak, MD¹ and D E Hricik, MD¹

Corticosteroids (STR) and calcineurin inhibitors (CNIs) exhibit many toxicities that have prompted efforts to withdraw these agents. Since January 2006, we have treated primary kidney transplant recipients (KTRs) with the following regimen: induction antibody therapy (rabbit ATG for deceased-, basiliximab for live-donor KTRs), 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 between day 90 and 180, and FK stopped once SRL levels are 8-12 ng/ml. Conversion from FK to SRL is excluded in KTRs with prior acute rejection (AR), proteinuria > 500 mg/day, or severe anemia, leukopenia or thrombocytopenia. 158 KTRs (age 51 ± 13 yrs; 66 females; 68 African American; 74 live donor) have been enrolled. 6 early graft losses resulted from thrombosis (n=3), primary non-function (n=2) or death (n=1). Of the remaining 152 KTRs, 128 (81%) were withdrawn from STR. Main reasons for not withdrawing STR included delayed graft function (DGF), MMF intolerance, and prior STR therapy. AR occurred after STR withdrawal in 16 patients (12.5%) and also in 11 of the 24 patients in whom steroid withdrawal was never attempted. Of the remaining 125 rejection-free KTRs eligible for SRL conversion, only 54 (43.2%) have been converted. Mean time of conversion was 132 ± 108.6 days. Main reasons for not converting were noncompliance, leukopenia/anemia, and proteinuria. 16 of 54 (29.6%) KTRs were converted back from SLR to FK for AR (n=3) or SRL side effects. To date, 33 of 50 KTRs (66%) completing both phases of the protocol remain STR-free and CNI-free. In this cohort, 1-yr patient and graft survival are 98% and 94.3%, and mean eGFR at 1 year is 54 ± 16 ml/min. On the other hand, only 33 of 158 eligible KTRs (21%) have completed the protocol and remain STR- and CNI-free. Our large 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, bone marrow suppression and side effects of SRL 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.

LABELING OF PLASMA GLUTATHIONE AND OPHTHALMATE FROM 2H-ENRICHED BODY WATER: A NONINVASIVE PROBE OF THE REDOX STATUS OF THE LIVER

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NOVEL ASPECT: A noninvasive probing of labeling pattern and redox status of liver to evaluate the performance of human liver.

INTRODUCTION: The Glutathione (GSH) and glutathione disulphide (GSSG) redox couple is one of the main defenses of cells against oxidative stress. Ophthalmate (glutamyl-aminobutyryl-glycine), a glutathione analog has been reported as an indicator of oxidative stress. To assess the oxidative status one can study the synthesis rate of these small peptides by measuring the incorporation of 2H (from 2H-enriched body water) in their constitutive aminoacids during transaminations and other reactions. Once incorporated into proteins or peptides, the 2H on aminoacids does not exchange with body water. We developed a LC-MS/MS method for measuring enrichment of constitutive aminoacids of GSH and tried to fit the labeling of plasma GSH to an equation with three exponential saturation terms.

METHODS: Plasma samples collected from the rats under stable 2H enriched body water (2.5%; 31 days) were assayed for GSH and GSSR as thioether derivatives, and ophthalmate using homo-glutathione as internal standard. Electrospray-ionization mass spectrometry of thioethers was performed on a 4000 QTrap (Applied Biosystems) mass spectrometer coupled to an Ultimate 3000 HPLC. Product ion spectra (MS/MS) were used to calculate the enrichments of fragments of the carboxymethyl-GSH derivative: from the precursor ions at m/z 366.2 and 367.2, we monitor m/z 134 (CYS), 237 (GLY-CYS) and 291 (GLU-CYS) with a mass width of 5 amu, from m/z 100 to 400. The 2H labeling of plasma water was assayed by equilibration with [¹³C₃]acetone.

PRELIMINARY RESULTS: We calculated the M1 enrichment of the constitutive aminoacids of GSH from the product ion spectra of the derivatives. The enrichment of GLY was calculated from the difference in enrichment of GLY-CYS and CYS. The enrichment of GLU was calculated from the difference in enrichment of GLU-CYS and CYS. Our long-term experiment in rats under steady state 2H enriched body water (31 days) revealed very different rates of labeling of the aminoacids making up the GSH molecule. Glycine equilibrated rapidly with body water. The equilibration of glutamate with body water was fairly slow, and was limited to 2.5 protons from water on average per molecule. These hydrogen atoms are presumably distributed on the five carbon-bound hydrogens of glutamate. The very slow labeling of cysteine results presumably from the high Km for cysteine (22 mM) of cysteine- α -ketoglutarate aminotransferase. In the same rats whose body water was 2.5% enriched, the enrichment of plasma ophthalmate plateaued at about 13%. Thus, the synthesis of ophthalmate incorporated five H from body water. Assuming that the labeling of the glycine and glutamate moieties of GSH and ophthalmate are the same, one calculates that the 2-aminobutyrate moiety of ophthalmate had incorporated two H from body water. Starting with the labeling plateau of each aminoacid, we fitted the labeling profile of each aminoacid with the general equation $MPE(t) = MPET \times (1 - e^{-kt})$. While the fitting of the glycine labeling profile was good, this was not the case for the labeling of glutamate and cysteine, as well as for the calculated total labeling of GSH. This shows that the kinetic constant of labeling is not the same for the individual carbon-bound hydrogens of glutamate and cysteine. Also, the labeling pattern of plasma GSH does not allow to compute its turnover.

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 PhD¹,

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.

SEQUENTIAL STEROID-FREE, CALCINEURIN INHIBITOR-FREE IMMUNOSUPPRESSION AFTER KIDNEY TRANSPLANTATION: OUTCOMES AND BARRIERS

Padiyar A, Augustine JJ, Bodziak KA, Siegel C, Sanabria J, Aeder M, Schulak JA, Hricik DE

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; 24 females; 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 47 KTRs (11%). 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=4), leukopenia/anemia (n=3), 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%) completing the protocol remain STR-free and CNI-free. Comparison of parameters before and 1 month after FK to SLR conversion indicate 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.

AFRICAN AMERICAN ETHNICITY AND RISK OF PROTEINURIA AFTER CONVERSION TO SIROLIMUS THERAPY IN KIDNEY TRANSPLANTATION

Joshua J. Augustine, Aparna Padiyar, Kenneth A. Bodziak, Mark I. Aeder, James A. Schulak, Donald E. Hricik

We have utilized an immunosuppressive protocol in kidney transplantation with antibody induction therapy, early steroid withdrawal, and conversion from tacrolimus (TAC) to sirolimus (SRL) after three to six months, with adjunctive mycophenolate mofetil (MMF) therapy. We sought to analyze risk factors for proteinuria on SRL therapy in a cohort of 39 patients transplanted between 1/06 and 9/07 and maintained on SRL/MMF dual therapy for at least six months. Steroids were eliminated early post-transplant in 34 (87%), and mean time to conversion from TAC to SRL was 4 months post-transplant. Patients were excluded from conversion if they had early rejection or baseline urinary protein to creatinine ratio (PCR) > 500 mg/g. Of the 39 patients, 14 (36%) were female, 17 (44%) were African American (AA), and 16 (41%) were deceased donor (DD) recipients. Post-conversion rejection occurred in 4 patients (2 AA and 2 non-AA). Late PCR measured at 6-27 months was 500 mg/g in 13 (33%), and nephrotic range proteinuria was seen in 4 (10%), (3 AA and 1 non-AA). A comparison of demographics in patients who did or did not develop a PCR > 500 mg/g is shown in Table 1.

Variable	PCR < 500 mg/g (n=26)	PCR 500 mg/g (n=13)	p Value
Age	46 15	52 11	ns
Male (%)	62	69	ns
AA (%)	27	77	0.002
DD (%)	38	46	ns
Donor age	38 16	41 16	ns
Diabetes*	23	8	ns
MAP* (mmHg)	90 10	100 10	0.004
eGFR* (MDRD, ml/min/1.73m)	59 14	62 24	ns
BMI* (kg/m)	25.6 4.4	26.6 5.5	ns
U PCR* (med, mg/g)	195 (20-430)	221 (117-490)	ns

*At time of conversion from TAC to SRL

By univariate analyses, AA ethnicity and higher baseline mean arterial pressure (MAP) correlated with a high PCR. A logistic regression analysis was performed controlling for AA ethnicity, baseline MAP, and other factors which were more common in AAs, including DD transplant, older recipient age, and AA donor race. In this model, AA ethnicity (odds ratio=20, p=0.03) and baseline MAP (odds ratio per mmHg=1.2, p=0.02) remained correlates of PCR > 500 mg/g. In conclusion, we have found a strong independent correlation with AA ethnicity and increasing proteinuria after conversion to SRL in a steroid-free, calcineurin inhibitor-free protocol in kidney transplantation.

CELLULAR OR HUMORAL PRESENSITIZATION INCREASES THE RISK OF DELAYED GRAFT FUNCTION AND ACUTE REJECTION IN RECIPIENTS OF EXPANDED CRITERIA DONOR KIDNEYS

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Although the outcomes of kidney transplants using expanded criteria donors (ECD) are generally inferior to those using standard criteria donors (SCD), it is not clear whether adverse outcomes are magnified based on recipient characteristics. We hypothesized that patients at high immune risk, defined by pretransplant donor specific ELISPOT for interferon-gamma $> 25/300K$ cells and/or current flow PRA $>80\%$, may have particularly bad outcomes after transplantation with ECD kidneys. To examine this interplay between presensitization and ECD status, we retrospectively reviewed outcomes of 93 deceased donor recipients in whom pre-transplant measurements of both ELISPOT and PRA were available. Population characteristics: age 46 ± 11 yrs, 59% male, 53% African American, HLA mismatches 3.9 ± 1.9 , time on dialysis 0-136 mos (mean 49 mos). High risk patients included 26 with high ELISPOT alone, 4 with high PRA alone, and 2 with both. The incidence of delayed graft function (DGF) and acute rejection (AR) for various combinations of immune risk and ECD or SCD are shown in the figure. DGF occurred in 56% in high risk recipients of ECD kidneys vs 19% in all other combinations ($p=0.012$). AR occurred in 56% of high risk/ECD patients v 17% in all others ($p=0.006$). eGFR 12 months posttransplant was 29 ± 9 ml/min in high risk/ECD patients v 52 ± 20 ml/min in others ($p=0.006$). In contrast, low risk recipients of ECD kidneys exhibited outcomes similar to low risk recipients of SCD kidneys: DGF 18% v 16%, AR 18% v 12%, eGFR 47 v 55 ml/min). Logistic regression showed that the combination of high risk status and ECD increased the risk of DGF (odds ratio 4.8, $p=0.038$) and AR (odds ratio 5.5, $p=0.033$) independent of age, gender, ethnicity, HLA mismatch, or time on dialysis. Results of this analysis indicate that cellular or humoral presensitization magnifies the poor outcomes of ECD kidney transplantation and suggest that caution be used in offering ECD kidneys to presensitized patients.

CLINICAL ETHICISTS AS LIVING DONOR ADVOCATES: IDENTIFICATION OF DONOR AUTO-COERCION

Mark Aeder, Barbara Daly, Cynthia Griggins, Kenneth Bodziak, Aparna Padiyar, Juan Sanabria, Christopher Siegel, Joshua Augustine, James Schulak, Donald Hricik

Living kidney donation is one of the most elective surgeries performed. The ethos was accepted originally because living donors were nearly always siblings or parents. As the need for kidneys increased and outcomes improved, 40% of living donors have no blood relationship to the recipient. While historically the same team that treated the recipient performed the donor work up, many programs now have a separate team evaluate the potential donor. The Federal Register in 2007 called for the identification of a donor advocacy team (DAT) to represent, advise and protect donor interests. At our institution, clinical ethicists were asked to be the independent donor advocates. Our 5-member DAT interviewed potential donors in isolation from the transplant team or family. The interviews were performed after the full donor educational and work up process. Our first 33 potential donors evaluated over 9 months ranged in age from 24-66 (85% < age 50), 64% were female, and 63% were white. Siblings comprised 27%, child to parent 27%, spouse 15%, other blood relative 21% and unrelated but known to recipient 9%. The DAT supported 32 of the 33 donors. In 1 circumstance, clarification of risk and additional education was needed prior to donation consideration. At the time of DAT evaluation, all potential donors had been educated and medically cleared for donation. Despite multiple educational programs (slide show, written materials, physician and surgeon discussions), almost no donors were able to demonstrate understanding of the three necessary components: the major risks of surgery, the procedure, or the long-term effects of losing a kidney. Comments expressed indicated a powerful internal norm of self-imposed expectation existed which may interfere with true informed consent. We have termed this internalized sense of duty to donate as auto-coercion. Auto-coercion raises important questions about appropriate criteria for informed consent and the difficulty in assessing the value of the DAT process.

CONCLUSION: Use of clinical ethicists as the DAT provides an independent donor assessment opportunity in compliance with CMS guidelines. The effectiveness of the program may be limited by the internalized auto-coercion imposed by the potential donor. The DAT may be more effective if the initial interview occurred at an early stage in the donor evaluation process.

IMPROVEMENT IN SCIP METRICS WITH A DEDICATED ENGAGEMENT OF PHYSICIANS, NURSES, CLINICAL ASSOCIATES AND QUALITY CENTER PERSONNEL

Mark Aeder, M.D., F.A.C.S. and Susan Semrau, R.N.

The Center for Medicare Services (CMS) records the core measures for each hospital, placing the individual institution's results on its web site for public comparison. Each hospital strives to excel in each of the reportable process metrics, and implements tools to achieve compliance with the parameters. The Surgical Care Improvement Program (SCIP) was added as a core measure group, designed to reduce surgical site infections and the incidence of deep venous thrombosis (DVT)/ pulmonary embolus (PE). Achieving compliance with the SCIP parameters requires the cooperative intervention of the treating surgeons and anesthesiologists, the nursing and clinical support staff, and the members of the hospital's quality center.

Changes in financial remuneration have places severe constraints on a physician's voluntary participation on hospital administrative committees. The success of the core measures compliance often hinges on the vital role of these physicians. The SCIP project is centered on evidence based parameters which, although known to be associated with a reduction in Perioperative morbidity, are not universally followed. Achievement of high compliance with the SCIP processes requires physician intervention and follow-up, and achieving the 90th percentile in these metrics necessitates a dedicated effort from multiple clinical and quality disciplines.

We established a multidisciplinary SCIP committee to review the data, evaluate the metric processes and develop interventions to achieve the 90th percentile in all the SCIP measures. The hospital personnel and quality center members were engaged in the project from the hospital perspective. The physician participation and commitment had historically been the most challenging aspect of this endeavor. The physician leadership was vital as the organization of the committee necessitated the participation of key members of the surgical and anesthesia departments involved with the clinical care. We have accomplished this through a cooperative committee which assayed the data monthly and implemented the changes necessary to achieve the goal. Utilizing this committee, we have maintained the committee for nearly 3 years with minimal turnover and with marked improvement in the SCIP metrics.

We believe that it is the composition of the committee, the open discussions of the barriers, the cooperative measures initiated to achieve the desired results and the shared satisfaction in the success of the process measures which provides impetus for success. Any hospital based quality initiatives require the participation of a dedicated team of clinical leaders who are dedicated to achieving improvement in patient care metrics.

INFLUENCE OF AFRICAN AMERICAN ETHNICITY ON ACUTE REJECTION AFTER EARLY STEROID WITHDRAWAL IN PRIMARY KIDNEY TRANSPLANT RECIPIENTS

Aparna Padiyar, Joshua J. Augustine, Kenneth A. Bodziak, Mark Aeder, James A. Schulak, Donald E. Hricik

The influence of ethnicity on outcomes of kidney transplant recipients subjected to early steroid withdrawal remains controversial. Even recent randomized trials that suggest no higher risk among African Americans (AAs) may be biased by patient selection, as evidenced by recruitment of relatively small numbers of AAs. Since January 2006, our center has employed an immunosuppression protocol in which steroids are withdrawn in all primary kidney transplant recipients (KTRs) on post-transplant day five. All patients receive induction antibody therapy (thymoglobulin in deceased-donor and basiliximab in living-donor transplants), tacrolimus and mycophenolate mofetil (MMF). 24 patients (11 AAs and 13 non-AAs) were excluded from the steroid withdrawal protocol and from this analysis, usually because of pretransplant steroid therapy or prolonged delayed graft function. To date, 52 AAs (age 54+11 yrs, 22 female (42%), 17 living donor (33%) and 76 non-AAs (age 49+14 yrs, 33 female (43%), 49 living donor (64%) KTRs have completed this protocol with follow-up ranging from 1 to 33 months (mean 17 months). During the first 12 months after early steroid withdrawal, AAs experienced a significantly higher incidence of acute rejection (AR) than non-AAs (19.2% versus 7.9%, $p < 0.05$). Using multivariate logistic regression, ethnicity was significantly correlated with acute rejection ($p = 0.045$) independent of recipient age, gender, PRA at time of transplant, time on dialysis, or donor source. However, when the number of HLA mismatches was added to or substituted for donor source in the regression model, HLA mismatching became the most statistically significant correlate of acute rejection (odds ratio 1.6, $p = 0.009$). Results of this single center experience with a large, consecutive series of patients suggest that AAs are at increased risk of AR following early steroid withdrawal, even when treated with induction antibody therapy, tacrolimus, and MMF. This correlation may be related more to higher degrees of HLA mismatching among AA kidney transplant recipients than to ethnicity per se. AA KTRs receiving kidneys from poorly matched donors may be suboptimal candidates for early steroid withdrawal. Longer follow-up is needed to determine whether AR in this cohort of AAs negatively influences long-term outcomes.

REDEFINING ACS-NSQIP AS A COST EFFECTIVE ADMINISTRATIVE TOOL

Mark I. Aeder, M.D., F.A.C.S., Randy Harmatz

ACS-NSQIP is an effective risk-adjusted outcomes measurement system that has been adopted by over 200 hospitals. Limitations to widespread adaptation include the large financial investment and the limited detail of key components of the entire surgical experience. As financial pressures to medical center budgets increase, the information obtained from ACS-NSQIP needs to be justified. Although benefits to the surgeons and surgical department in 30-day comparative morbidity and mortality outcome reporting are established, key administrative quality and budgetary benefits warrants examination.

METHODS: Meetings with administrative and quality leaders were conducted to assess benefits of participation and the quality information derived. A priorities list was developed outlining information believed most crucial for quality improvement using process or system modifications.

RESULTS: Limited sampling of our most frequent general and vascular CPT codes masked the ability to recognize and develop process interventions for outcome improvement. We are unable to stratify common CPT outcomes by departmental division. The lack of surgeon specific data limits the system as a maintenance of certification tool. Our administrative investment of nearly \$150,000. requires assessing not only ACS-NSQIP data but data from our other institutional initiatives.

CONCLUSION(S): As ACS-NSQIP is redefined, tracking 100% of our most frequent procedures across all specialties having the highest potential opportunity for risk-adjusted morbidity and mortality improvement is vital. We need to assess surgeon specific data both for education and maintenance of certification. A cost effective, ACS-NSQIP program must develop flexible risk-adjusted outcome and process tools that address the case mix requirements of each hospital.

SAVINGS AND INVESTMENT STRATEGIES: WHAT EVERY SURGEON NEEDS TO KNOW

Mark I. Aeder, M.D., F.A.C.S.

Surgical training requires an intensive dedication for its successful completion. With the increased pressures to achieve the necessary expertise in all the surgical aspects, attentions to the personal aspects of life are often poorly addressed. Chief among these is the time spent setting up the financial planning for short and long term goals. Often these decisions are made hastily and with limited professional input. As surgeons have a marked delay in achieving significant financial remuneration, and as they often have tens or hundreds of thousands of dollars in outstanding educational loans, it is important that they are well educated regarding the pitfalls of poor judgment. The importance of sound investment principles and life skill education needs to be emphasized.

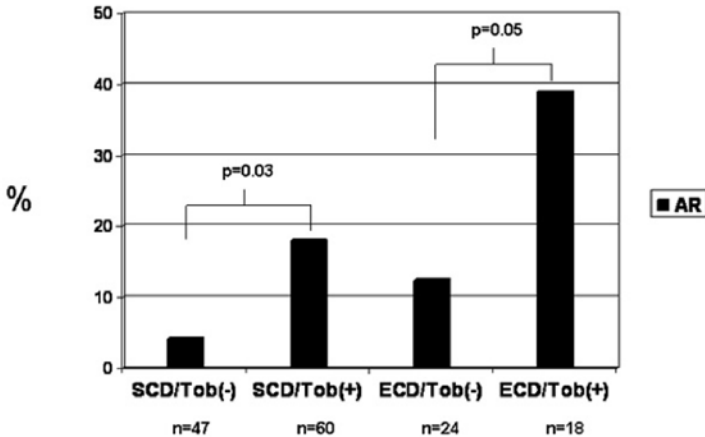
With the current market conditions and economic stresses facing the physician workforce, the need for unbiased physician education has never been more necessary. Presentation of the basic principles of financial planning and investment should be a required aspect of the life skills training that all physicians receive. As many of the educational opportunities in this area are delivered by non-physicians trying to market various products, this would place a bias on the presentation of the available products and the potential for financial missteps.

A program to educate physicians in training as well as young physicians early in their practice is presented to cover basic skills necessary for the nonmedical aspects of life. The program should be physician based with expertise provided by those unaffiliated with any financial planning product and free of any commercial support. An outline for the ample opportunity for guidance with these important decisions is also a key component of the financial education. As the potential for errors in judgments is significant at all stages of the surgical career, especially early when there is the greatest opportunity for elimination of debt and the establishment of good long term financial skills, it is important that attention to this aspect of the education process be addressed.

IMPACT OF DONOR CIGARETTE SMOKING AND EXPANDED CRITERIA DONOR STATUS ON ACUTE REJECTION IN DECEASED DONOR KIDNEY RECIPIENTS.

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Donor cigarette smoking is known to negatively impact upon long term kidney allograft survival, although no link to immune mediated injury has been established. Vascular inflammation related to smoking may stimulate an alloimmune response after transplantation via innate immune mechanisms. We sought to analyze the impact of donor smoking on acute rejection (AR) rates in a cohort of deceased donor kidney recipients. Because expanded criteria donor (ECD) kidneys have been associated with increased AR in registry analyses, we stratified patients by standard criteria donor (SCD) and ECD status. Recipients of donor with cardiac death (DCD) or multiorgan transplants were excluded from analysis. One hundred forty nine consecutive deceased donor recipients with six month follow-up were analyzed. Forty-two kidneys were from ECD donors (28%), and six month AR rates were 24% in ECD recipients vs. 12% in SCD recipients ($p=0.08$). We stratified SCD and ECD recipients by donor smoking status (>10 pack years, TOB(+)). AR rates in each group are shown in Figure 1.



TOB(+) status was associated with a significant increase in AR in both SCD and ECD cohorts. AR occurred in 39% of ECD/TOB(+) recipients vs. 13% of all other recipient types ($p=0.005$). By logistic regression analysis, ECD/TOB(+) donor status remained a significant correlate with AR after controlling for age, gender, ethnicity, time on dialysis, HLA mismatch, delayed graft function, and antibody induction therapy (odds ratio = 5.3, $p = 0.01$). Results of this analysis suggest that donor cigarette smoking conveys an immunologic risk in deceased donor kidney transplantation which is accentuated with ECD kidneys. Further research is required to analyze potential mechanisms linking age- and smoking-related kidney damage to immune mediated injury after transplant.

Section 9

Trauma and Burns

HEMOGLOBIN-BASED OXYGEN CARRIERS

John J. Como, MD, and Mark A. Malangoni, MD

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 URINE

Joseph F. Golob Jr., Jeffrey A. Claridge, Mark J. Sando, William R. Phipps, Charles J. Yowler, Adam M.A. Fadlalla, and Mark A. Malangoni

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 men, 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 a 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 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.

HUMAN POLYMERIZED HEMOGLOBIN FOR THE TREATMENT OF HEMORRHAGIC SHOCK WHEN BLOOD IS UNAVAILABLE: THE USA MULTICENTER TRIAL

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BACKGROUND: Human polymerized hemoglobin (PolyHeme, Northfield Laboratories) is a universally compatible oxygen carrier developed to treat life-threatening anemia. This multicenter phase III trial was the first US study to assess survival of patients resuscitated with a hemoglobin-based oxygen carrier starting at the scene of injury.

STUDY DESIGN: Injured patients with a systolic blood pressure ≤ 90 mmHg were randomized to receive field resuscitation with PolyHeme or crystalloid. Study patients continued to receive up to 6 U of PolyHeme during the first 12 hours postinjury before receiving blood. Control patients received blood on arrival in the trauma center. This trial was conducted as a dual superiority/noninferiority primary end point.

RESULTS: Seven hundred fourteen patients were enrolled at 29 urban Level I trauma centers (79% men; mean age 37.1 years). Injury mechanism was blunt trauma in 48%, and median transport time was 26 minutes. There was no significant difference between day 30 mortality in the as-randomized (13.4% PolyHeme versus 9.6% control) or per-protocol (11.1% PolyHeme versus 9.3% control) cohorts. Allogeneic blood use was lower in the PolyHeme group (68% versus 50% in the first 12 hours). The incidence of multiple organ failure was similar (7.4% PolyHeme vs. 5.5% control). Adverse events (93% versus 88%; $p = 0.04$) and serious adverse events (40% versus 35%; $p = 0.12$), as anticipated, were frequent in the PolyHeme and control groups, respectively. Although myocardial infarction was reported by the investigators more frequently in the PolyHeme group (3% PolyHeme versus 1% control), a blinded committee of experts reviewed records of all enrolled patients and found no discernible difference between groups.

CONCLUSIONS: Patients resuscitated with PolyHeme, without stored blood for up to 6U in 12 hours postinjury, had outcomes comparable with those for the standard of care. Although there were more adverse events in the PolyHeme group, the benefit-to-risk ratio of PolyHeme is favorable when blood is needed but not available.

THERAPUTIC ANTICOAGULATION IN THE TRAUMA PATIENT: IS IT SAFE?

Joseph F. Golob Jr, MD; Mark J. Sando, MD; Justin C. Kan, BA; Charles J. Yowler, MD; Mark A. Malangoni, MD; and Jeffrey A. Claridge, MD

PURPOSE: Trauma patients who require therapeutic anticoagulation pose a difficult treatment problem. The purpose of this study was to determine: (1) the incidence of complications using therapeutic anticoagulation in trauma patients, and (2) if any patient factors are associated with these complications.

METHODS: An 18-month retrospective review was performed on trauma patients ≥ 15 years old who received therapeutic anticoagulation using unfractionated heparin (UH) and/or fractionated heparin (FH). Forty different pre-treatment and treatment patient characteristics 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-fourteen trauma patients were initiated on therapeutic anticoagulation. The most common indication for anticoagulation was deep venous thrombosis (46%). Twenty-four patients (21%) had at least 1 anticoagulation complication. The most common complication was a sudden drop in hemoglobin concentration requiring blood transfusion (11 patients). Five patients died (4%), 3 of whom had significant hemorrhage attributed to anticoagulation. Bivariate followed by logistic regression analysis identified chronic obstructive pulmonary disease (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 laboratory values and anticoagulation indications.

CONCLUSION: Trauma patients have a significant complication rate related to anticoagulation therapy, and predicting which patients will develop a complication remains unclear. Prospective studies are needed to determine which treatment regimen, if any, is appropriate to safely anticoagulate this high risk population.

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

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Cleveland State University: Department of Computer and Information Science,
MetroHealth Medical Center: Department of Surgery

BACKGROUND: Differentiation between infectious and non-infectious etiologies of the systemic inflammatory response syndrome (SIRS) within trauma patients remains illusive. We hypothesized that mathematical modeling techniques in combination with computerized clinical decision support may assist with this differentiation process. The purpose of this study was to determine the capability of various mathematical modeling techniques to predict infectious complications in critically ill trauma patients, and compare the performance of these models to a standard “fever-workup” practice (identifying infections based on fever and/or leukocytosis).

METHODS: An 18-month retrospective database was created using data collected daily from critically ill trauma patients admitted to an academic surgical and trauma intensive care unit. Utilizing ten variables previously shown to be associated with infectious complications; decision trees, neural networks, and logistic regression analysis models were created to predict the presence of urinary tract infections (UTI), bacteremia, and respiratory tract infections (RTI). The data sample was split into a 70% training set and a 30% testing set. Models were compared to each other by calculating sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, and discrimination.

RESULTS: Two hundred forty-three non-infected patient-days were randomly chosen to combine with the 243 infected-days which created a modeling sample of 486 patient-days. Decision trees had the best modeling performance with a sensitivity of 83%, an accuracy of 82%, and a discrimination of 0.91 for identifying infections. Both neural networks and decision trees outperformed logistic regression analysis. A second analysis was performed utilizing the same 243 infected days and only those non-infected patient-days associated with a negative microbiologic culture workup (n=236). Decision trees again had the best modeling performance for infection identification with a sensitivity of 79%, an accuracy of 83%, and a discrimination of 0.87.

CONCLUSION: The use of mathematical modeling techniques beyond logistic regression has the ability to improve the robustness and accuracy of predicting infections in critically ill trauma patients. Decision tree analysis appears to have the best potential to use within computerized clinical decision support to assist physicians in differentiating infectious from non-infectious SIRS.

ISOLATED CERVICAL SPINE FRACTURES IN THE ELDERLY: A DEADLY INJURY

Golob JF Jr, Claridge JA, Yowler CJ, Como JJ, Peerless JR.

BACKGROUND: Traumatic injury in the elderly is an increasing problem and studies have shown that elderly patients ($>/=65$ years old) with cervical spine fractures and spinal cord injury (SCI) carry a mortality rate of 21% to 30%. However, little has been described with regard to outcomes for elderly patients with isolated cervical spine fractures (ICSF). **HYPOTHESIS:** Outcomes for elderly patients with ICSF will be similar to elderly patients with cervical fractures and associated traumatic injuries (ATI) 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 cervical spine fracture. 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). ICSF was defined as those fractures without ATI or SCI. Long-term mortality data were gathered using 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 men 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%. ATIs were seen in 57% of the population and 22% had SCI. Patients with SCI had a significantly higher mortality compared with patients without SCI (38% vs. 22%, $p = 0.032$). However, there was no difference in unfavorable outcomes. Patients with ICSF had no differences in unfavorable outcomes compared with patients with SCI or ATI. Long-term survival analysis after discharge (mean = 2.8 years) demonstrated that patients with a favorable outcome had a significantly improved survival compared with patients with unfavorable outcomes ($p < 0.001$).

CONCLUSION: ICSFs were associated with an unfavorable outcome in the elderly population regardless of ATI 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.

MORTALITY FOR INTRA-ABDOMINAL INFECTION IS ASSOCIATED WITH INTRINSIC RISK FACTORS RATHER THAN THE SOURCE OF INFECTION

Tazo Inui BA, Manjunath Haridas MD, Jeffrey A. Claridge, MD, MS, FACS, and Mark A. Malangoni MD, FACS

BACKGROUND: Intra-abdominal infections (IAIs) are an important cause of mortality and morbidity. Nosocomial IAIs (NIAIs) have been associated with higher mortality than community-acquired IAIs (CIAIs). We hypothesized that intrinsic risk factors were a better predictor of mortality than the type of infection.

METHODS: Patients with IAI treated at a single urban academic hospital over eight years (June 1999- June 2007) were retrospectively reviewed. Data collected included demographics, co-morbidities, source of infection, type of infection (community vs. nosocomial), type of intervention (operation vs. percutaneous drainage), and post-operative complications. Charlson Co-morbidity Index and multiple organ dysfunction (MOD) scores were evaluated at admission and POD-7.

RESULTS: There were 452 patients; 234 (51.8%) had CIAI and 218 (48.2%) had NIAI. The mean age was 51.3 ± 0.8 . The most common source of CIAI was the appendix ($n = 129$, 28.5%); 137 patients with NIAI had post-operative infections (30.3%). When patients with appendicitis were excluded, there was no difference in mortality or complications between patients with CIAI and NIAI. Logistic regression analysis demonstrated catheter-related bloodstream infection ($p < 0.001$, OR 7.3, 95% CI 2.5 – 22.2), cardiac event ($p < 0.001$, OR 6.0, 95% C.I. 2.3 – 16.1), and age ≥ 65 ($p = 0.009$, OR 3.8, 95% C.I. 1.4-8.8) to be independent risk factors for mortality. Among patients who failed initial therapy, non-appendiceal source of infection ($p < 0.001$, OR 4.7, 95% CI, 2.3-9.8) and a Charlson score ≥ 2 ($p = 0.033$, OR 1.6, 95% CI 1.0-2.6) were determined to be independent risk factors. Non-appendiceal source of infection ($p = 0.001$, OR 3.3, 95% CI 1.6-7.0) and POD-7 MOD score ≥ 4 ($p < 0.001$, OR 3.4, 95% CI 1.9-6.0) were found to be independent predictors for re-intervention.

CONCLUSION: These results suggest mortality from IAI is strongly related to age and organ dysfunction; however, catheter-related bloodstream infection and post-operative cardiac events have a greater effect on outcome.

FOLLOW UP DISPARITIES AFTER TRAUMA: A REAL PROBLEM FOR OUTCOMES RESEARCH

Claridge JA, Leukhardt WH, McCoy AM, Golob JF, Malangoni MA

INTRODUCTION: Improvements in trauma care will require extending research beyond outcomes at hospital discharge to include long-term follow up data. Objectives of this study included: 1) determine risk factors associated with trauma patients not following up, including data related to communities in which the patient lives; and 2) in those patients who do follow up, determine if free text discharge summaries and outpatient notes are an adequate data collection tool for outcomes research.

METHODS: A six year retrospective analysis was conducted on all trauma patients admitted to a level I trauma center. Follow up appointments were analyzed using our outpatient electronic medical record (EMR) and were defined as an outpatient visit to our hospital system within 3 months of injury. Long-term survival was determined by querying the National Death Index (NDI). Community data was obtained utilizing the 2000 census data and geocoding methodology. Bivariate and logistic regression analyses were conducted to identify which patients are less likely to follow up. A subgroup analysis was then conducted on a matched cohort of patients based on death after discharge to determine if information was documented within discharge and outpatient clinic visit notes regarding basic functional outcomes (Glasgow outcome score (GOS), diet, ambulation, and employment status).

RESULTS: A total of 14784 patients were discharged and 9141 patients (61%) had 22926 follow up appointments. Orthopedics was the most common follow up service (37%) followed by trauma surgery (19%). Logistic regression analysis of trauma registry data identified the following patient characteristics as being independently predictive of patient not following up after traumatic injury: older age, lower injury severity score, shorter intensive care and hospital stay, nonwhite race, blunt injury, death after discharge, and discharged to home. A separate evaluation of geocoded socioeconomic factors demonstrated several key differences between the patients' residential communities of those who followed up and those that did not. A subgroup analysis of 223 random patient's electronic outpatient chart found 76 patients (24%) had 315 follow up notes. Evaluation of all 223 discharge summaries identified 39% discussed ambulation, 52% discussed diet, and 0.4% mentioned employment status. Assessment of the 315 outpatient notes found 37% discussed ambulation, 20% mentioned diet, and 9% discussed employment.

CONCLUSIONS: Our institution had a 61% follow up rate within three months of injury. Furthermore, evaluation of outpatient notes demonstrated significant deficiencies in documentation regarding ambulation, diet, and employment. These deficiencies in follow-up and documentation highlight the weaknesses of data available for trauma outcomes research, even when electronic charting is utilized. Trauma process improvement programs could potentially correct these deficiencies by targeting patients at risk for not following up (older, nonwhite, after blunt injury, lower injury severity scores, shorter stays, and the communities in which the patient lives) and utilizing a structured electronic outpatient note.

PHYSICIAN DECISION MAKING IN PHYSICAL RESTRAINT USE IN HOSPITALIZED PATIENTS: PART 1. PHYSICIAN CHARACTERISTICS

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Ruth Ludwick, PhD, RN⁴, Jeffrey Claridge, MD⁵, James Pile 6, Michael Harrington⁷

OBJECTIVES: There is marked variation in restraint use among similar units and patient populations. Study objectives were to determine: 1) physician knowledge regarding restraint regulations and effectiveness; 2) the impact of physician characteristics on their decisions to order physical restraints

DESIGN: Cross-sectional, factorial research survey design

SETTING: Academic medical center:

PARTICIPANTS: 1) interns in all specialty practices 6/2007; 2) resident physicians 6-8/2007 in general internal medicine, family practice, emergency medicine, psychiatry and surgery; and 3) attendings in departments of surgery, general internal medicine, family practice and psychiatry.

MEASUREMENTS: The survey consisted of demographic items, professional items, knowledge items of physical restraint issues, and 5 distinct case vignettes. Analyses include descriptive and bivariate statistics, and exploratory multiple linear regression analysis.

RESULTS: 189/246 (77%) surveys returned. 58% male, median age 30 (range 25-63 years), median years experience 2 (range 0-33), 60% USA medical school graduates. Knowledge score: mean 7.9 (\pm 1.6), range 4-11. Judgments to order physical restraints in 906 distinct vignettes ranged from 0 (not at all) to 9 (absolutely) with a mean of 3.9 (\pm 3.0), median 4.0. Exploratory regression analysis on physicians' decisions to order restraint as the outcome (dependent) variable with independent variables of physician age, gender, restraint knowledge, judgment of likelihood of harm, years experience, US medical school, and specialty explained 33% of the variance in judgments ($F=30.4$, $p < 0.0001$). Higher appraisal of harm ($p = 0.0001$), less knowledge regarding restraint issues ($p < 0.0001$), and being male ($p < 0.0001$) were independent risk factors for greater likelihood to order restraints. Internal medicine ($p = 0.016$) and psychiatry ($p = 0.004$) specialties were independent factors for less likelihood to order restraints.

CONCLUSION: Physician characteristics influence their decisions to order physical restraints. Lack of knowledge was an independent predictor for likelihood to order physical restraint. These results will help guide further medical education initiatives to reduce restraint rates.

THE “FEVER WORKUP” AND RESPIRATORY CULTURE PRACTICE IN CRITICALLY ILL TRAUMA PATIENTS

Jeffrey A. Claridge, MD, MS; Joseph F. Golob Jr. MD*; William H. Leukhardt, MD*; Mark J. Sando BS*; Adam M.A. Fadlalla, Ph. D**; Joel R. Peerless, MD*; and Charles J. Yowler MD**

PURPOSE: Fever and leukocytosis (FAL) in critically ill patients often triggers a “workup” which includes a respiratory secretion culture (Rcx). We evaluated our respiratory culture practice associated with FAL. We hypothesized that FAL would be associated with a Rcx, but would not be associated with a positive culture or treating a respiratory infection in critically injured patients during their first 14 intensive care unit(ICU) days.

MATERIALS AND 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, Rcx(bronchoalveolar lavage or tracheal aspirate), maximum daily temperature and a daily leukocyte count during the first 14 ICU days.

RESULTS: 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 Rcx obtained (2.4Rcx/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 FAL (RR=2.6 95%CI=2.2-3.1), but not leukocytosis alone. Fever, leukocytosis, or FAL did not predict 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: FAL were associated with the decision to obtain Rcx, but were not associated with positive Rcx. Rcx results had a low specificity and did not consistently impact treatment decisions. FAL alone should influence the decision to obtain Rcx during the first 14 days in the ICU after trauma.

SIC-IR® (SURGICAL INTENSIVE CARE – INFECTION REGISTRY) DOCUMENTS SICKER PATIENTS

*Joseph F. Golob Jr MD**, *Joel R. Peerless MD**, *Charles J. Yowler MD**, *Adam M.A. Fadlalla PhD†*, and *Jeffrey A. Claridge MD**

OBJECTIVE: In the era of risk-adjusted outcome comparisons, hospitals must have a method to capture documentation that accurately reflects a patient's level of illness. We designed a novel billing/documentation module (B/DM) into our surgical and trauma intensive care unit (STICU) electronic physician charting system (SIC-IR) that provided clinical decision support to assist with documentation and billing. We hypothesized that utilizing the SIC-IR B/DM would increase the documented severity of illness, risk of mortality, number of captured diagnoses at discharge, and hospital reimbursement of a critically ill surgical and trauma patient population.

DESIGN: A 6 month prospective two phase interventional study

PATIENTS: All patients admitted to the STICU

SETTING: The STICU at a regional Level 1 Trauma center

INTERVENTIONS: A 6 month prospective two phase study was performed: P1-normal practice without SIC-IR B/DM (3 months), P2-normal practice with SIC-IR B/DM (3 months). Outcomes compared included the number of captured diagnosis codes at discharge, diagnosis related group-relative weight (DRG-RW), DRG geographic mean length of stay, and DRG estimated reimbursement. In addition, the 3M™ all patient refined-DRG-RW (APR-DRG-RW), APR-severity of illness, and APR-risk of mortality were compared between P1 and P2.

RESULTS: 436 patients (2202 patient-days) were evaluated during P1 and 378 patients (2308 patient-days) in P2. During P2, the SIC-IR B/DM created 2206 bills of which 1381 (63%) were actually billed by the intensivists. P2 had a significant increase in the number of diagnoses captured at patient discharge (12.7 vs 9.7; $p < 0.001$). Likewise, the SIC-IR D/BM significantly increased the DRG-RW by 26%, DGR geographic mean length of stay by 21%, and a DRG estimated reimbursement by 21% (\$6,665/patient). In addition, P2 had a significant increase in APR-DRG-RW by 20%, the APR-severity of illness by 7%, and the APR-risk of mortality by 14%.

CONCLUSIONS: Utilizing medical informatics techniques to accurately assist physician documentation and billing can significantly increase the documented illness burden and hospital reimbursement of a large STICU population. This will permit more accurate risk-adjustment of patient populations to allow fair comparisons between institutions.

THE EFFECTS OF SPLENIC ARTERY EMBOLIZATION ON NON-OPERATIVE MANAGEMENT OF BLUNT SPLENIC INJURY: A 16 YEAR EXPERIENCE

Ashraf A. Sabe, B.A., Jeffrey A. Claridge, M.D., David I. Rosenblum, D.O., Kevin Lie, M.D.

Mark A. Malangoni, M.D.

INTRODUCTION: Non-operative management (NOM) of blunt splenic injury has become the preferred treatment for hemodynamically stable patients. The application of splenic artery embolization (SAE) in NOM has been controversial. We hypothesized that incorporation of initial use of SAE into a practice protocol for patients at high risk for NOM failure (contrast extravasation or pseudoaneurysm on CT, grade 3 injury with large hemoperitoneum, grade 4 injuries) would improve patient outcomes.

METHODS: A retrospective analysis of three continuums of practice was performed: group I (January 1991 - June 1998) – SAE not part of routine non-operative management; group II (July 1998 - December 2001) - introduction and discretionary use of SAE; and group III (January 2002 - June 2007) – standardized use of initial SAE for patients considered at high risk of non-operative failure. The primary outcome measure was the success of NOM. Failure of NOM was defined as the need for abdominal operation. Secondary outcomes were mortality, length of stay, and splenic salvage.

RESULTS: Over 16 years, 815 patients with blunt splenic injury were treated at our Level 1 trauma center. There were 222 patients in group I, 195 in group II, and 398 in group III. There was an increase in the use of SAE over time with a significant improvement in the utilization of NOM (61% in group I; 82% in group II; 88% in group III, $p < 0.05$). This was associated with an increase in successful NOM (77%, group I; 94%, group II; 97%, group III, $p < 0.0001$ group I vs. group II and III). Mortality, length of stay, and splenic salvage were similar in groups II and III but significantly improved compared to group I.

CONCLUSIONS: The increased use of initial SAE in high-risk patients expanded the successful use of NOM, but was not associated with other incremental improvements.

THE SURGICAL INTENSIVE CARE-INFECTION REGISTRY: A RESEARCH REGISTRY WITH DAILY CLINICAL SUPPORT CAPABILITIES

Fadlalla AM, Golob JF Jr, Claridge JA.

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Infections in the surgical and trauma intensive care unit (STICU) are responsible for significant patient morbidity and mortality. Research into these infectious complications often uses administrative databases or clinical information systems designed for documenting and billing daily patient care. Neither of these sources is intended for research, and many investigators have questioned their accuracy. The Surgical Intensive Care-Infection Registry (SIC-IR) was developed as a research data repository to use to monitor STICU infections. SIC-IR is a relational database application designed to collect quality data and to integrate with daily patient care. SIC-IR prospectively collects and archives more than 100 clinical variables daily on each STICU patient to ensure completeness and correctness of the registry. Furthermore, SIC-IR aids in clinical activities by providing patient summaries and medical record documentation. SIC-IR provides accurate data for STICU infection research and enables the users to easily undertake quality-of-care improvement initiatives.

VALIDATION OF SURGICAL INTENSIVE CARE-INFECTION REGISTRY: A MEDICAL INFORMATICS SYSTEM FOR INTENSIVE CARE UNIT RESEARCH, QUALITY OF CARE IMPROVEMENT, AND DAILY PATIENT CARE

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

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. The objective of this study was to validate SIC-IR as a successful health information technology with an accurate clinical data repository.

STUDY DESIGN: Using the DeLone and McLean Model of Information Systems Success as a framework, we evaluated SIC-IR in a 3-month prospective crossover study of physician use in one of our two surgical and trauma intensive care units (SIC-IR unit versus non SIC-IR unit). Three simultaneous research methodologies were used: 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, graphic user interface, efficiency, and overall benefit to patient care. There was a significant decrease in preroounding time of nearly 4 minutes per patient on the SIC-IR unit compared with the non SIC-IR unit. The SIC-IR documentation and data archiving was accurate 74% to 100% of the time depending on the data entry method used. This accuracy was significantly improved compared with normal hand-written documentation on the non SIC-IR unit.

CONCLUSIONS: SIC-IR proved to be a useful application both at individual user and organizational levels 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 AM, D'Amico BM, Peerless JR, Yowler CJ, Malangoni MA.

BACKGROUND: In the era of pay for performance and outcome comparisons among institutions, it is imperative to have reliable and accurate surveillance methodology for monitoring 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 infection surveillance. 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 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 were collected simultaneously by the SIC-IR system at the point of patient care and by IC utilizing multiple administrative and clinical modalities. Data collected by both systems included patient days, ventilator days, central line days, number of VAPs, and number of catheter-related blood stream infections (CR-BSIs). Both VAPs and CR-BSIs were classified using the definitions of the U.S. Centers for Disease Control and Prevention. The VAPs were analyzed individually, and true infections were defined by a physician panel blinded to methodology of surveillance. Using these true infections as a reference standard, sensitivity and specificity for both SIC-IR and IC were determined.

RESULTS: A total of 769 patients were evaluated by both surveillance systems. There were statistical differences between the median number of patient days/month and ventilator-days/month when IC was compared with SIC-IR. There was no difference in the rates of CR-BSI/1,000 central line days per month. However, VAP rates were significantly different for the two surveillance methodologies (SIC-IR: 14.8/1,000 ventilator days, IC: 8.4/1,000 ventilator days; $p = 0.008$). The physician panel identified 40 patients (5%) who had 43 VAPs. The SIC-IR identified 39 and IC documented 22 of the 40 patients with VAP. The SIC-IR had a sensitivity and specificity of 97% and 100%, respectively, for identifying VAP and for IC, a 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 high sensitivity and specificity. This monitoring can be accomplished without additional resources and engages the physicians treating the patient.

CRITICAL ANALYSIS OF EMPIRIC ANTIBIOTIC UTILIZATION: ESTABLISHING BENCHMARKS

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† Cleveland State University: Department of Computer and Information Science

BACKGROUND: There is increasing interest to critically evaluate trauma centers. The NTDB, state trauma registries, and evolving Trauma Quality Improvement Project only evaluate hospital outcomes. The purpose of this study was to evaluate long-term outcomes after trauma and determine independent risk factors for mortality after discharge (MAD).

METHODS: An analysis was conducted on all patients admitted from 2000 through 2005 to a regional level I trauma center. Registry data was linked to the electronic medical record (EMR), the National Death Index (NDI) with cause of death codes (2000 through 2005), and the 2000 US census data utilizing geocoding methodology.

RESULTS: Hospital mortality of the 15,285 patients was 3.3%, and post-discharge mortality was 4.8% for an overall mortality of 8.1% with an average follow up of 2.8 years. The 1-year mortality was 5.4%. Patients were discharged to home (84%), rehab facility (8.4%), skilled nursing facility (6.5%), acute care facility (1.3%), and hospice (0.2%) with respective mortalities of 3.4%, 7.7%, 18.7%, 20.7%, and 100%. MAD was related to trauma 31%, unrelated to trauma 45%, and was unclear 24% (potentially trauma related). Logistic regression analysis demonstrated independent risk factors for hospital mortality were penetrating injury, non-vehicular injury, and increased age, ISS, and ventilator days ($p < 0.05$). Significant independent risk factors for MAD were age (OR=1.06), hospital length of stay (OR=1.04, disposition other than home (OR=1.6), fall (OR=1.7) and sobriety on admission (OR=1.4, all $p < 0.05$). Evaluation of the census data demonstrated that lower socio-economic status was associated with better hospital survival. Non-native status as associated with MAD, but no factors were independently predictive for MAD. Analysis of EMR failed to discern meaningful functional outcomes (ambulation, diet, employment).

CONCLUSIONS: Mortality rates after trauma are grossly underestimated when measured at discharge. Caution must be employed in the assessment and comparison of trauma outcomes based solely on hospital discharge.

Section 10

**Vascular Surgery &
Endovascular Therapy**

ASSESSMENT OF RENAL ARTERY DUPLEX ULTRASOUND CRITERIA

Yin Ping Liew¹, Brett Butler¹, Alaa Alahmad¹, Tingfei Hu¹, Linda M. Graham¹, Teresa L. Carman²

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BACKGROUND: The renal duplex (RD) criteria for renal artery stenosis (RAS) were established by angiographic correlation in the 1980's. Changing technology has improved RD resolution and incorporated the use of magnetic resonance (MRA) and computed tomography angiography (CTA) into practice. In addition RD is performed for indications other than suspected renovascular hypertension as initially investigated. What influence these changes have had on the accuracy of RD remains unknown.

METHODS: We reviewed RD performed between 1/2005 and 10/2007. Cases with angiographic imaging (AI) within 3 months of RD were analyzed. Two, independent, blinded staff reviewed all AI to determine % RAS. We excluded occlusions, aortic velocity ≥ 290 cm/sec, stented arteries, and poor AI.

RESULTS: 186 renal arteries were compared to 129 angiograms, 20 CTA, and 37 MRA. 70/186 (37.6%) had RAS $\geq 60\%$. Renal aortic ratio (RAR) ≥ 3.5 (aortic velocity 40-100 cm/sec, n=142), had a sensitivity of 94% and specificity of 51% for $\geq 60\%$ RAS; negative predictive value (NPV) 86% and positive predictive value 48% (Figure 1). Peak systolic velocity (PSV) ≥ 200 cm/sec (n=186) had a sensitivity and specificity of 90% and 48% respectively, for RAS $\geq 60\%$; NPV 89%.

CONCLUSIONS: The specificity of current RD criteria was lower than previously reported. Our experienced, high volume vascular laboratory performs almost 1000 RD annually. It is unlikely that inexperience contributes to our low specificity. RD was traditionally done for patients with high clinical suspicion of RAS. Expanding indications including screening in patients with concomitant vascular disease, nonspecific abdominal bruits, and pre-operative imaging may contribute to the low specificity. Using retrospective analysis it is difficult to determine whether this played a role in our results. From our data, a negative RD is likely very useful to exclude RAS, however, RD may not serve as a good screening tool to diagnose RAS due to a high false-positive rate.

ASSESSMENT OF THE DUPLEX ULTRASOUND CRITERIA FOR RENAL ARTERY STENOSIS

Yin Ping Liew; Brett Butler, Alaa Alahmad; Tingfei Hu; Linda M Graham; Teresa L. Carman

OBJECTIVES: Duplex (DU) criteria for renal artery stenosis (RAS) $\geq 60\%$, renal-aortic-ratio (RAR) ≥ 3.5 and peak systolic velocity (PSV) ≥ 200 cm/sec, were established by angiographic correlation in the 1980's. Changing technology has improved DU image resolution and incorporated the use of computed tomography angiography (CTA) and magnetic resonance angiography (MRA). We sought to correlate the DU with angiographic imaging (AI) and determine whether alternative criteria may be better suited for diagnosis of RAS.

METHODS: We reviewed renal vascular DU performed between 10/2005 to 10/2007. Cases with AI within 3 months of DU were analyzed. Two independent, blinded staff reviewed all AI to determine %RAS; simultaneous review resolved discrepancies. Occlusions (23), elevated aortic velocity ≥ 290 cm/sec (5), and poor AI were excluded (1). SAS version 8.02 was used for statistical analysis. The sensitivity and specificity of RAR and PSV cutoffs were analyzed with AI stenosis $\geq 60\%$, 70% and 80% .

RESULTS: We included 186 renal DU for analysis. AI included 129 angiograms, 20 CTA and 37 MRA; 70/186 (37.6%) had RAS $\geq 60\%$. Figure 1 illustrates the variability in RAR vs % stenosis by AI. Table 1 denotes the sensitivity and specificity for RAR values compared to AI stenosis $\geq 60-80\%$ in cases with aortic velocity 40-100 cm/sec ($n=142/186$, 76%). Table 2 provides the sensitivity and specificity for PSV values in the total population ($n=186$) when compared to AI stenosis $\geq 60-80\%$.

CONCLUSIONS: Despite improvement in DU imaging quality, the sensitivity and specificity of diagnosing RAS with the current DU criteria has not improved. The sensitivity and specificity of our DU data for diagnosis of RAS $\geq 60\%$ is not what has been previously reported. The distribution of RAR compared to % stenosis varies widely and contributes to the low specificity of this technique. Using an RAR of 3.0 improves the sensitivity for RAS $\geq 60\%$ slightly, without significant loss in specificity, compared to the current criteria of 3.5. From our results it is difficult to identify criteria which may be better suited for diagnosing $\geq 70\%$ RAS.

Section 11
Clinical Trials

2008 DEPARTMENT OF SURGERY UNIVERSITY HOSPITALS CASE MEDICAL CENTER

Sponsored Research:

Efficacy of Bioabsorbable Staple Line Reinforcement in Colorectal and Coloanal Anastomoses: a Prospective Randomized Study

Principal Investigator- Conor Delaney, MD, PhD

Sponsor: W.L. Gore & Associates

A randomized trial comparing outcomes for the LigaSure™ and disposable stapling instruments for laparoscopic colectomy

Principal Investigator- Conor Delaney, MD, PhD.

Sponsor: Covidien

The US STARR Registry: Stapled Trans-Anal Rectal Resection (STARR) for the Treatment of Obstructed Defecation Syndrome (ODS)

Principal Investigator- Conor Delaney, MD, PhD

Sponsor: Ethicon-Endosurgery

A Multicenter, Prospective, Observational Evaluation of Repair of Infected or Contaminated Hernias (RICH) using LTM

Principal Investigator- Michael Rosen

Sponsor: LifeCell

A Phase II, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety and Efficacy of Ipamorelin Compared to Placebo for the Management of Post-Operative Ileus in Patients Who have Undergone Partial Bowel Resection Surgery

Principal Investigator-Harry Reynolds, MD

Sponsor: Sapphire Pharmaceuticals

Analysis of Transgastric Cholecystectomy, Transvaginal Cholecystectomy and Laparoscopic Cholecystectomy: Projected Long Term Outcomes and Complications Evaluation

Responsible Investigator – Jeff Marks, MD

Grant: NOSCAR Grant - ASGE

Treatment of Hemorrhagic Radiation Proctitis Using the Halo System

Principal Investigator-Jeffrey Marks, MD

Sponsor: BARRX

A Phase 3 Clinical Trial to Evaluate the Safety and Efficacy of Treatment with 2mg Intravesical Allovectin-7® Compared to Dacarbazine (DTIC) or Temozolomide (TMZ) in Subjects with Recurrent Metastatic Melanoma

Principal Investigator - Julian Kim, MD

Sponsor: Vical, Inc.

A Follow-up Study of Breast Cancer and Melanoma Patients that Participated in the Phase 2 Clinical Study for Lymphoseek NEO3-03

Principal Investigator - Julian Kim, MD

Sponsor: Neoprobe Corporation

A Phase 3, Prospective, Open-Label, Multicenter Comparison Study of Lymphoseek® and Vital Blue Dye as Lymphoid Tissue Targeting Agents in Patients with Known Melanoma or Breast Cancer Who are Undergoing Lymph Node Mapping

Principal Investigator – Julian Kim, MD

Sponsor: Neoprobe Corporation

A Follow-up Study of Breast Cancer and Melanoma Patients that Participated in the Phase 3 Clinical Study for Lymphoseek®

Principal Investigator – Julian Kim, MD

Sponsor: Neoprobe Corporation

TOGA™: A Randomized, Sham-Controlled Trial to Assess the Safety and Effectiveness of Transoral Gastroplasty in the treatment of Morbid Obesity

Principal Investigator-Jeffrey Marks, MD

Sponsor: Satiety, Inc.

Observation and Analysis of Treatment Outcomes of Crohn's Fistulas Using A Porcine Intestine Submucosa Graft (Surgisis® AFP)

Principal Investigator- Brad Champagne, MD.

Sponsor: Cook Incorporated

Evaluation of an Endoscopic Suturing System for Tissue Apposition in Colonic Polypectomy

Principal Investigator- Conor Delaney, MD, PhD

Sponsor: Ethicon-Endosurgery

Compression Anastomosis using the CAR™ 27

Principal Investigator- Conor Delaney, MD, PhD

Sponsor: NiTi Surgical Solutions, Israel

A Phase III Prospective Randomized Trial Comparing Laparoscopic-assisted Resection Versus Open Resection for Rectal Cancer

Principal Investigator- Conor Delaney, MD, PhD

Sponsor: NCI-sponsored cooperative group study (ASCOG)

A Phase II Study of Hyperacute-Pancreatic Cancer Vaccine in Subjects with Surgically Resected Pancreatic Cancer.

Principal Investigator: Jeffrey Hardacre, MD

Sponsor: NewLink Genetics

Circular Anal Dilator for Transanal Hemorrhoidectomy

Principal Investigator-Brad Champagne, MD.

Sponsor: Ethicon-Endosurgery

Electrical Activation of the Diaphragm for Ventilatory Assist in Spinal Cord Injury who have a Cardiac Pacemaker

Principal Investigator –Ray Onders, MD

Sponsor: Synapse Biomedical

Muscle Stimulation of the Diaphragm in Amyotrophic Lateral Sclerosis

Principal Investigator –Ray Onders, MD

Sponsor: Synapse Biomedical

Pivotal Study of the NeuRx RA/4 for Motor Point Stimulation for Conditioning the Diaphragm of Patients with Amyotrophic Lateral Sclerosis (ALS)

Principal Investigator –Ray Onders, MD

Sponsor: Synapse Biomedical

Electrical Activation of the Diaphragm for Ventilatory Assist

Principal Investigator – Ray Onders, MD

Patients with Amyotrophic Lateral Sclerosis (ALS)

Principal Investigator – Ray Onders, MD

Investigator Initiated Research:**General Surgical Outcomes Quality Improvement Database**

Principal Investigator- Conor Delaney, MD, PhD

Funding: Fellowship Grant from Ethicon-Endosurgery, Inc.

Development of An Assessment Tool to Measure Flexible Endoscopic Performance. Principal Investigator-Jeffrey Marks, MD

Enhancing the Safety of Surgical Technical Skills

Principal Investigator- Conor Delaney, MD, PhD.

Prospective Evaluation of the Intra-Operative use of Transluminal Flexible Endoscopes during Combined Flexible and Laparoscopic Foregut Surgery.

Principal Investigator-Jeffrey Marks, MD.

Quality of life evaluations in patients with abdominal wall hernias

Principal Investigator- Mike Rosen, MD

Prospective Evaluation of Notes Peg Rescue

Principal Investigator-Jeffrey Marks, MD

Sleep Apnea in the Obese Surgical Patient

Principal Investigator: Michael Rosen, MD

Retrospective/Observational /Chart Reviews:**Inappropriate use of ICD-9 codes in surgical literature**

Principal Investigator: Jonah Stulberg, PhD candidate

Industrial outliers analyses in a colorectal surgery division

Principal Investigator: Jonah Stulberg, PhD candidate

Effect of ileostomy creation and closure on regulation of hypertension

Principal Investigator: Eric Marderstein, MD

Retrospective review of case-matched laparoscopic emergency colectomies

Principal Investigator: Bradley Champagne, MD

Practice patterns for biologic mesh use among surgeons

Principal Investigator: Michael Rosen, MD

Biochemical evaluation of incidental adrenal masses

Principal Investigator – Scott Wilhelm, MD

Evaluation of vitamin D supplementation in roux-en-Y gastric bypass patients

Principal Investigator – Scott Wilhelm, MD

Analysis of clinical parameters in National Surgical Quality Improvement Program (NSQIP) Identified Surgical Site Infections (SSIs)

Principal Investigator – Mark Aeder, MD

Living paired donation to benefit incompatible donor transplant recipients through registration in the Paired Donation Network

Principal Investigator – Mark Aeder, MD

Metabolomic, proteomic & isotopomer analysis of human liver function in health and disease

Principal Investigator – Juan Sanabria, MD

Does prior gastric bypass surgery influence the rate of hernia recurrence following ventral hernia repair

Principal Investigator – Christina Williams, MD

Epidemiology of Surgical Stapler Misfire During Colorectal Surgery

Principal Investigator: Eric Marderstein, MD

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