Department of Surgery

Case Western Reserve University School of Medicine

2011 RESEARCH ABSTRACTS

CASE Surgery

2011-2012
Research Abstracts

CASE SURGERY

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

CASE Surgery

Dear Colleague:

I am pleased to share with you our 2011-2012 research abstracts. The Department of Surgery provides a multi-specialty academic environment where ideas are exchanged and cooperative research programs are planned.

The 2011-12 academic year has been a 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 website 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
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IDENTIFICATION OF THE "SITES OF ENTRY" IN AORTIC DISSECTIONS AND "THROMBI" IN LEFT VENTRICULAR ASSIST DEVICES USING THREE-DIMENSIONAL VIRTUAL ANGIOSCOPY (3DVA) WITH NAVIGATION

Muhammad J. Ansari, MD and Arie Blitz, MD

Conventional Computed Tomography (CT), Transesophageal Echocardiography and Magnetic Resonance Imaging, although sensitive to diagnose Type A aortic dissections, but lack the capability to identify endoluminal intimal tears or sites of entry. The number, location and size of these sites of entry have important therapeutic and prognostic implications. This information is useful in surgical planning, need for hybrid procedures or post-operative endovascular therapies if the site of entry has an active flow, if there is continuous aneurysmal dilatation of the false lumen and compression of the true lumen causing ischemia to organs or limbs. Thus we can refine on the conventional surgical treatment of type A dissections to prevent those complications.

With the increased use of Left Ventricular Assist Devices (LVAD) for class IV heart failure. There is an unmet clinical need among the available imaging modalities to be able to see the endoluminal thrombi in these devices. With the conventional non-contrast CT, it is extremely difficult to see through these platinum devices, but 3DVA can make it possible to visualize endoluminal data, with color coding the Housfield Units of thrombi to depict these structures with a greater sensitivity.

We reviewed 20 consecutive cases of type A aortic dissections at our institute with a mean age of 61 years. We were able to visualize the site of entry in 4/20 (20%) of the cases using 3DVA. Two of those sites of entry were not seen during the surgery. We were able to see 3 /19 fenestrations on the postoperative CT after the surgical repair of aortic dissections. We also reviewed 17 cases of LVAD patients, who underwent CT imaging for their clinical conditions. We were able to identify 2 thrombi in the devices, which were not evident using the CT imaging. One of this was confirmed on the autopsy of the patient.

We conclude that identification of sites of entry using 3DVA may be a "game-changer" in the way we conventionally manage type A dissections. This technology also helps to identify thrombi in LVADs and identify their exact location in the compartments to plan surgical replacement of a part rather than the entire device versus using thrombolytic agents depending on the clinical scenario.

CURRENT STATUS OF MECHANICAL CIRCULATORY SUPPORT (MCS) ABSTRACT PRESENTED AT CLINICAL UPDATE IN ANESTHESIOLOGY CONFERENCE 2012

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MCS continues to play an increasing important role in the management of the class D heart failure patient. This past year has seen the emergence of competing devices for both long-term and short-term support. Continuous flow devices have assumed center stage in the chronic HF population, while the displacement pump has all but vanished from the scene.

In addition to these technological advances, there have been refinements in the selection criteria as well as the perioperative care of VAD patients. As patient selection moves away from the initial skew towards the high-risk INTERMACS I and II levels, patient outcomes continue to improve.1,2 Some centers are even reporting 1-year survival rates comparable to that achieved with heart transplantation.

This past year, numerous articles were published addressing concomitant surgical issues at the time of LVAD surgery. These include how to manage the regurgitant tricuspid valve3, as well as the regurgitant aortic valve.4,5 Persistent driveline infection rates have led to modifications in the technique for bringing the driveline out of the skin.

Improvements in postoperative care continue to evolve. Most patients with the HMII device are no longer bridged to coumadin therapy with heparin. Nitric oxide and other pulmonary vasodilators are used liberally to prevent or treat right ventricular dysfunction. Hospital stays are shortening.

The Heartware HVAD BTT trial results were presented at ISHLT in 2011. Although the clinical results of the trial were competitive with those of the Heartmate II, a surprisingly high rate of pump thrombosis was reported. More recently, with modifications in the anticoagulation regimen, more acceptable thrombosis rates were observed.

With such improving clinical outcomes, the paradigm of destination therapy as a mode of therapy only for transplant-ineligible patients has been challenged. With intermediate-term outcomes approaching that achieved with transplantation, it may be time in the near future to evaluate LVAD therapy as a true alternative to heart transplantation. Some have even proposed that heart transplantation might one day be a back-up mode of therapy for LVAD patients suffering complications from device therapy.

A recent publication6 examined the cost-effectiveness of destination therapy, a particularly important consideration given the background of health care reform. Data indicate that, although cost-effectiveness has been improving, DT still falls short of the $50K to $100K spent per quality-adjusted life year (QALY). As more competing LVADs hit the market, the cost of the device is expected to decrease. In addition, as less severely ill patients are referred for surgery, outcomes will continue to improve, as will hospital stays. These will all impact the ultimate cost-effectiveness of DT.

References

1. Meyns et al: Clinical Benefits of Partial Circulatory Support in New York Heart Association Class IIIB and Early Class IV Patients. Eur J Cardiothorac Surg 2011; 39:693-698

2. John et al: Continuous Flow Left Ventricular Assist Device Outcomes in Commercial Use Compared with the Prior Clinical Trial. Ann Thorac Surg 2011; 92:1406-1413

3. Piacentino et al: Clinical Impact of Tricuspid Valve Procedures During Left Ventricular Assist Device Implantation. Annals Thorac Surg 2011; 92:1414-1419

4. Goda et al: Aortic Valve Procedures at the Time of Ventricular Assist Device Placement. Ann Thorac Surg 2011; 91:750-754

5. Toda et al: Late Aortic Insufficiency Related to Poor Prognosis During Left Ventricular Assist Device Support. Ann Thorac Surg 2011; 92:929-934

6. Rogers et al: Cost-Effectiveness Analysis of Continuous Flow Left Ventricular Assist Devices as Destination Therapy. Circ Heart Failure. 2011

ECHOCARDIOGRAPHY EVALUATION OF A NOVEL STABLE OVINE HEART FAILURE MODEL SUITABLE FOR CARDIOVASCULAR DEVICE TESTING

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INTRODUCTION: Numerous large animal models of chronic cardiac ischemia have been developed to explore either pathological mechanisms and or device interventions in developed heart failure models. Traditionally chronic heart failure in large animal models such as sheep or pigs has been induced by either coronary ligation with or without reperfusion. Coronary ligation is often attempted in the open chest surgical model or more recently in the closed chest animal via angiography (1). Both techniques can be challenging and also induce high mortality with the risk of myocardial stunning and resultant shock and or lethal arrhythmias. There is also difficulty in developing stable heart failure across cases where infarct sizes can be variable. One strategy to overcome this variability has been via rapid ventricular pacing, however heart failure does not induce sustained heart failure in many cases if the pacing is switched off, and additionally pacing does not induce some of the underlying pathology seen in the development of heart failure (1).

Therefore, new large animal models of heart failure are required. In particular, models that simulated clinical conditions that are robust in producing stable heart failure and that are not labor intensive or technically challenging are desirable. With this in mond we investigated using a nitric oxide synthase (NOS) inhibitor N-Nitro-L-Arginine Methyl Ester (LNAME) to induce hypertension and subsequent development of heart failure in a large ovine animal model. LNAME to date has only been studied chronically in small animal models using rats and mice to induce significant cardiac hypertrophy and subsequent ventricular dilation (2). Hence this is the first report of using LNAME in a large animal model to determine its ability to reduce cardiac output and ejection fraction over a 4 week period of dosing.

Methods: All experiments were approved by the University of Melbourne Animal Ethics Committee, Melbourne, Australia and conformed to the international care of animals and to NHMRC institutional guidelines.

Three adult sheep of mixed breed of either sex (2 females, 1 male) were used in these studies with a mean weight of 50kg. LNAME was administered intravenously via an in-dwelling venous catheter using 2 half dosages per day according to Table 1.

Animals underwent ultrasound measurements to measure cardiovascular performance at study commencement (baseline) and again at 4 weeks of treatment.

Transthoracic conventional echocardiography examinations were performed with continuous ECG monitoring using a Vingmed system 5 (General Electric medical system, Waukesha, WI, USA) equipped with a 2.2 to 3.5 MHz phased-array transducer. Sheep were sedated with an intravenous injection of 0.5 mg/kg midazolam and 10 mg/kg ketamine via a 20G needle placed into the external jugular vein. All transthoracic echocardiographic and TDI measurements included a minimum of 5 consecutive beats. Left ventricular echo dimension measurements were performed with 2D-guided M-mode on the right parasternal ventricular short-axis view, according to the recommendations of the American Society of Echocardiography. Ejection fraction and cardiac output were then calculated.

Results and Discussion: Clinical observations show that the sheep at 4 weeks were hypotensive, losing weight and fatigued, indicative of developed heart failure. These observations of heart failure were supported by a change in ejection fraction where ejection fraction significantly declined from a mean of 46-48% at baseline to 31-36% at 4 weeks post LNAME dosing ($p<0.005$).

Mean cardiac output also declined at 4 weeks at 1.8 +/- 0.1 L/min compared to a baseline of 3.4 +/- 0.6 L/min. Stroke volume also decreased over the 4 week period by 42%

In previous studies in the rat, chronic LNAME resulted in a dose-dependent increase in tail cuff pressure and a reduction in body weight with increases in left ventricular hypertrophy, elevation of aortic pressure with decreases in cardiac output, and reduced arterial compliance (3). These findings parallel what was observed in our sheep model: a loss of body weight and a decrease in cardiac output and stroke volume.

In summary this ovine model of chronic LNAME, mimics physiological heamodynamic observations made in the rodent counterpart. This sheep LNAME model deserves more attention as it is technically easy and the procedure had a 0% mortality rate and all cases developed heart failure. This model will be useful for testing biomedical devices that target cardiac remodeling at various stages of heart failure.

TABLE 1: LNAME Dosage Protocol

Week	Total Daily LNAME Dosage (mg/kg/day)
1	10
2	10
3	20
4	20

[1] Dixon JA, Spinale FG. Large animal models of heart failure: a critical link in the translation of basic science to clinical practice. Circ Heart Fail. 2009 May;2(3):262-71.

[2] Pereira LM, Mandarim-De-Lacerda CA. "Quantitative study of myocardial microcirculation in arterial hypertension due to progressive inhibition of NO synthesis". Arq Bras Cardiol. 1999 Nov;73(5):407-18.

[3] CT Hu, HR Chang, YH Hsu, CJ Liu et al. Ventricular hypertrophy and arterial hemodynamics following deprivation of nitric oxide in rats. Life Sciences, Volume 78, Issue 2 2005, 164-173

COST ANALYSIS OF ISOLATED MITRAL VALVE SURGERY IN THE UNITED STATES VASSILEVA ET AL ATS / 2012/ 359356

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Invited Commentary for Annals of Thoracic Surgery

The authors evaluated cost differences between mitral valve repair and replacement. Cost efficacy was observed in mitral repair. 1, 2

The National Inpatient Sample (NIS), an administrative database, was interrogated for patients undergoing mitral surgery between 2004 and 2008.. Sixty six per cent of hospitals had one year data. Emergent status and race data were incomplete as well. 1,3

Isolated mitral valve surgery was performed in 7365 patients, 46.8% (3452) had mitral repair while 53.2% (3919) had replacement, consistent with previous reports of variable application of mitral repair 4,5

Myocardial infarction, heart failure , emergency operation and post operative complications increased cost in both mitral cohorts. Neither teaching hospitals, hospital size , annual mitral volume, nor geographic region affected cost . 1,6,7

Patient selection , route of access, mitral pathology, types of repair , and prostheses were not available. Mitral repair in dilated cardiomyopathy may increase risk and thereby cost. Robotic repair may impact cost. 8-10 These and other patient specific factors may contribute to the variability of costs observed both within hospitals as well as between hospitals in the same region.1

This statistical analysis has identified interesting trends in mitral valve surgery and has affirmed that mitral repair, in addition to being clinically superior, is variable in application, variable in cost and cost effective. 1

Quality conclusions are reached with caution while interpreting administrative data. Clinical databases are optimum for quality measurement and performance improvement while administrative data allow readily available information for trend analysis and further investigation. 3

Finally, mitral valve reparative techniques continue to be refined, allowing expanded, but not uniform utilization. 4,5,11

1) Vassileva C. et al .Cost Analysis of Isolated Mitral Valve Surgery in the Unites States. Ann. Thoracic Surg 2012; accepted for publication

2) Iribarne A. et al . Quantifying the incremental cost of complications associated with

mitral valve surgery in the United States J Thorac Cardiovasc Surg 2012;143:864-7

3) Torchiana D. et al . Use of administrative data for clinical quality measurement The Journal of Thoracic and Cardiovascular Surgery; 129, Number 6 1223 – 1227

4) Bolling S. et al . Predictors of Mitral Valve Repair: Clinical and Surgeon Factors The Annals of Thoracic Surgery 2010;90, 1904-1912

5) Gammie JS, Sheng S, Griffith BP, et al. Trends in mitral valve surgery in the United States: results from The Society of Thoracic Surgeons adult cardiac database. Ann Thorac Surg 2009;87:1431–9.

6) Dewey T. et al Influence of Surgeon Volume on Outcomes With Aortic Valve Replacement Ann Thorac Surg 2012;93:1107–13

7) Brown P. et al . Comparing Clinical Outcomes in High-Volume and Low-Volume Off-Pump Coronary Bypass Operation Programs Ann Thorac Surg 2001;72:S1009–15

8) von Oppell UO, Mohr FW. Chordal replacement for both minimally invasive and conventional mitral valve surgery using premeasured Gore-Tex loops. Ann Thorac Surg 2000; 70:2166–8.

9) Rankin JS, Alfery DD, Orozco R, et al. Techniques of artificial chordal replacement for mitral valve repair: use in multiple pathologic disorders. Op Tech Thorac Cardiovasc Surg 2008; 13:74–83.

10) Brunsting LA III, Orozco RE, Rankin JS, et al. Robotic artificial chordal replacement for repair of mitral valve prolapse. Innovations 2009;4:229–32.

11) Bortolotti U. et al Mitral Valve Repair With Artificial Chordae: A Review of Its History, Technical Details, Long-Term Results, and Pathology Ann Thorac Surg 2012;93:684–91

INTRA-OPERATIVE EXTUBATION IN OFF PUMP CORONARY ARTERY BYPASS

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Purpose: Reduced ventilation time is associated with lower morbidity and mortality in cardiac surgery. The purpose of this review was to evaluate the practice of immediate extubation in the operating room (OR) after off-pump coronary artery bypass (OPCAB) and attempt to identify patients who are likely to tolerate intra-operative extubation after OPCAB.

Materials and methods: 214 consecutive patients undergoing OPCAB from July 2004 – Dec 2007 were studied retrospectively. These constitute approximately 95% of coronary bypass surgeries performed during the study period. All OPCAB patients received an ultra fast-track general anesthesia intended to extubate patients immediately after surgery. Patients who were successfully extubated immediately in OR constitute Group A (N = 172, 80.37%), and those transferred to ICU intubated constitute Group B (N = 42, 19.62%).

Results: Group A patients had a mean STS mortality risk of 2.39% versus 9.78% in Group B patients. Group A patients were younger, had lower weight and pre-op creatinine, and lower prevalence of diabetes and congestive heart failure. There was no significant difference in revascularization procedures between group A and group B including mean number of distal anatomizes (3.13 v/s 2.79, p=0.055), use of internal mammary artery grafts (1.26 v/s 1.12, p=0.114) or total surgery time (4.02 v/s 3.75, p=0.086). Total operative mortality for the entire study group was 1.86%; 1.16% in Group A and 4.76% in Group B (p=0.17). Observed to expected mortality ratio was 0.48 in both groups. There was a lower incidence of reintubation (4.07 vs. 19.05%, p=0.0026), permanent stroke (1.16 v/s 11.9%, p=0.003) and cardiac arrest (0.58 v/s 7.14%, p=0.02) in Group A patients compared to Group B. Mean postoperative length of stay (7.11 v/s 12 days, p<0.0001) and total ICU time (68.07 v/s 176.83 hrs, p=0.002) were also lower in group A compared to B.

Conclusions: Selected patients can be safely extubated in the operating room after off-pump coronary artery bypass surgery. Continued mechanical ventilation in such patients is not necessary. In our study, patients with low STS mortality risk were able to be extubated immediately after OPCAB without increased morbidity or mortality while advanced risk patients were more likely to remain intubated post-operatively and to experience post-operative complications.

TRANSIT TIME FLOW MEASUREMENTS IN OFF-PUMP CORONARY ARTERY BYPASS SURGERY

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Purpose: Measurement of graft flow is important to determine the quality of coronary bypass grafts and assists in predicting graft patency. Transit time flow measurement (TTFM) is available but not uniformly utilized. In an effort to enhance familiarity with the modality, we studied variations of TTF measurements in off-pump coronary artery bypass (OPCAB). Identification of expected flow characteristics in different graft types and configurations may contribute to our knowledge base and ability to project graft patency and longevity.

Methods: TTF measurements for 1,102 distal anastomoses constructed with 878 bypass conduits in 357 consecutive patients undergoing isolated primary OPCAB from April 2004 – May 2009 were evaluated retrospectively. Mean number of grafts and distal anastomoses per patient were 2.45 and 3.06 respectively. Grafts were grouped based on anastomotic types - straight vs. sequential; conduit types - arterial vs. venous; and target system - left vs. right coronary system. Groups were analyzed for variations in mean flow (MF), diastolic filling (DF), pulsatility index (PI) and insufficiency percent (IP). Body mass index (BMI), body surface area (BSA), age and gender were analyzed for effects on TTF measurements in LIMA to LAD grafts.

Results:
1) Sequential grafts had higher MF compared to straight grafts in both venous (55.14 ± 32.8 ml/min v/s 33 ± 19.7 ml/min, p=0.0001) and radial artery (41.63 ± 18.5 ml/min v/s 28.38 ± 18.5ml/min, p=0.0021) subgroups. DF, PI and IP were similar.

2) Venous grafts had higher MF compared to arterial grafts but failed to reach statistical significance, while arterial grafts had higher DF (66.3% ± 11.6 v/s 61.33% ± 14.0, p=0.0032) and lower PI (2.4 ± 0.8 v/s 3.5 ± 2.7, p=0.0001).

3) There were no significant differences in MF in grafts to left vs. right coronary systems. DF was lower in grafts directed to right coronary system in saphenous vein (58.37% ± 14.8 v/s 63.8% ± 12.9, p=0.012) as well as arterial subgroups (56.44 ± 15.3 v/s 68.16 ± 11.7, p=0.0001)

4) Graft flow parameters were not affected by BMI, BSA, age nor gender.

Conclusions: Higher flows in sequential grafts and a tendency towards higher flows in venous grafts can be expected. Lower DF in grafts directed to right coronary system may be related to lower right ventricular mass. Flow characteristics were not influenced by patient size, age or gender for LIMA to LAD grafts, the most common graft. Due to wide variability in graft flows measurements, all four parameters should be considered while evaluating coronary bypass grafts using TTFM.

PROOF OF CONCEPT: EXCELLENT DESTINATION THERAPY SURVIVAL CAN BE ACHIEVED IN A LOW VOLUME VAD PROGRAM

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Purpose: As VAD programs continue to flourish, and stand-alone programs are being established, a natural skepticism exists as to whether a low-volume VAD program can achieve results comparable to high-volume centers. In this retrospective study, we analyze our results with our Destination Therapy (DT) program since FDA approval of a continuous flow (CF) VAD for DT.

Methods: We retrospectively reviewed the charts of all patients undergoing CF LVAD implantation for DT at our center over a 3-year period since FDA approval for that indication. Follow-up was 100% complete. Definitions of all terms are identical to those established by INTERMACS.

Results: Our center has implanted CF LVADs for DT in 18 patients. Mean age at implantation was 59 years (range 22-72). Primary reasons for transplant non-candidacy are as listed in the table below. INTERMACS levels were as follows: No patients were level 1, 9 patients were level 2, 8 patients were level 3, and 1 patient was level 4. Hence, 17 of 18 patients were inotrope-dependent at the time of surgery. All LVAD implantations were performed on cardiopulmonary bypass (CPB), with a mean CPB time of 59 minutes (range 44-90 minutes). Operative and hospital survival were 100%, and median postoperative length of stay was 28 days (range 14-60 days). Early postoperative complications included reexploration for bleeding in 1 patient, CVVH requirement in 1 patient, and CVA in 1 patient. Long-term complications (at a mean follow-up of 1 year) included CVA's in 2 additional patients (all have resolved), driveline infections in 4 patients, GI bleeding in 5 patients, pump pocket infection requiring omental flap coverage in 1 patient, and pump thrombosis requiring VAD replacement in 1 patient. At the time of abstract submission, all DT patients are alive and are in NYHA 1 or 2.

Conclusions: Destination Therapy can be performed at low volume centers with excellent survival and clinical results.

Reasons for Transplant Non-Candidacy in DT Patients	
Reason	**Number of Patients**
Advanced Age	6
Severe COPD	5
Severe PVD	1
Renal Dysfunction	5
Psychosocial	11
Obesity	3
Cardiac cachexia	2
Hepatitis C	1
HIV	1
Solid Organ Cancer	1

Section 2
Colorectal Surgery

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COMBINING REAL-TIME ADMINISTRATIVE DATA ANALYSIS AND STANDARDIZED ENHANCED CARE PATHWAYS TO DOCUMENT IMPROVEMENTS IN QUALITY AND COST EFFICIENCY OF HEALTHCARE

Conor P Delaney, Justin K Lawrence

DESCRIPTION: Evaluation of healthcare outcomes has become increasingly important as we strive to improve quality and efficiency while controlling cost. Many groups feel that analysis of large datasets will be useful in optimizing resource utilization, however the ideal blend of clinical and administrative data points has not been developed. Enhanced recovery pathways have been shown to reduce hospital stay and costs for certain disease processes. However, many of the efforts designed to enhance the utilization of healthcare resources are made without details of patient outcomes, or data to support their implementation. Consequently, many centers, specialties and societies have established databases to track clinical outcomes. These are usually specific to certain surgical specialties, and can provide an opportunity to perform quality improvement.

Hospitals and health care systems have several tools to measure cost and resource utilization of care as they strive to improve outcomes and efficiency, but the data is often housed in disparate systems that are not integrated and do not permit multi-system analysis. SOCRATES is a novel data merging, warehousing, analysis and reporting technology, which will merge disparate hospital administrative systems (billing, operating room and financial/administrative), generating automated or customizable risk-adjusted reports. These allow real-time identification of outliers by cost or resource utilization to permit root cause analysis, and allow measurement of efficiency of care and process control. After 5 years of development, SOCRATES is currently in use at the main campus. The system is ready to permit immediate analysis and results, and is ready to be evaluated in varied institutions across multiple sites in different states, and different size health care institutions. Used in combination with standardized enhanced care pathways, SOCRATES provides a unique opportunity to improve the quality and efficiency of care, with the ability to measure real-time changes in outcomes.

GOALS: Based on the development of SOCRATES, which provides, accurate, real-time data that is prospectively collated and organized to permit risk-adjusted reporting, this project will use SOCRATES in combination with standardized and enhanced care pathways to improve the quality and cost profile of healthcare. This technology provides a unique opportunity to improve the quality of care across multiple disciplines.

TOTAL BUDGET: $4,070,786

PARTICIPANTS: 5 initial institutions serving 86,000 patients to be expanded to 10 institutions and almost 172,000 patients by year 3.

PROJECTED TOTAL COST OF CARE SAVINGS: 5% reduction in cost of care at each institution, potentially $10.2 million reduction in total affected spend by year 3.

FUND DISTRIBUTION: Albany Medical Center $649,053, University of Southern California $568,071 and St John Westshore Medical Center $458,693. At all sites, total requested fund is 99% Personnel costs and 1% supplies.

COMPARATIVE EFFECTIVENESS OF LAPAROSCOPIC VS. ROBOT-ASSISTED COLORECTAL RESECTION

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Background: Laparoscopic colorectal surgery has been increasingly accepted over the last 20 years, and there is a general consensus that patients experience less pain, shorter hospital stay and fewer complications. Having achieved market dominance in the field of prostate surgery, robots are now being used more frequently for other procedures, including colorectal surgery. We therefore evaluated a national database to evaluate the effectiveness of robotic technology as an addition to the laparoscopic approach for colorectal surgery.

Methods: A national inpatient database was evaluated for colorectal resections performed over a 30-month period. Length of hospital stay (LOS), surgical time, complications and costs were compared between traditional laparoscopic resection (TLR) and robot-assisted laparoscopic resection (RALR) cases.

Results: 17265 TLR and 744 RALR procedures were identified. Not including the cost of acquisition or maintenance of the robot, RALR cases were associated with a $4,432 increase in direct costs ($p<.001$). RALR patients also had a 39-minute increase in operating time ($p<.001$), and were more likely to develop post-operative bleeding (OR 1.5: $p=0.014$). Hospital stay, complications and discharge disposition were similar.

Conclusions: Patients undergoing RALR mirrored clinical outcomes of TLR patients, but consumed significantly more resources, while hospital costs were dramatically increased and operative times were longer. These results support abandoning the use of robotics for colorectal surgery, outside of funded trials to evaluate specific clinical questions.

TAP BLOCKS AND ENHANCED RECOVERY PATHWAYS: MAKING 23 HOUR STAY A REALISTIC GOAL AFTER LAPAROSCOPIC COLECTOMY

Favuzza J, Samia H, Brady K, Sivashankaran S, Delaney CP

Although enhanced recovery pathways (ERP) may permit early recovery and discharge after laparoscopic colorectal surgery (LC), most publications report mean length of stay to be between four and six days. We have optimized an ERP and obtained mean length of stay of 3.7 days in series up to 1000 consecutive procedures. In this study we evaluate the addition of a transversus abdominus plane block (TAP) to our standard ERP.

Twenty-seven consecutive elective patients received a TAP block at the end of LC. One patient was excluded during the study period, requiring expected ICU stay and intubation for severe COPD and cardiac disease. Patients were matched by operation, diagnosis, age, gender and BMI to 27 recent cases, and followed in a prospective, IRB approved database. All patients were managed with a standardized ERP, including diet and oral analgesia on the day after surgery, gabapentin, acetaminophen and ketoralac, overnight PCA and standardized discharge criteria. TAP blocks were placed by the surgeon using a regional anesthesia needle under laparoscopic guidance without ultrasound, infiltrating 15ml of 0.5% marcaine on left and right sides of the abdomen.

Cases included 18 low pelvic anastomoses, 10 sigmoid/left colectomies, 16 ileocolic/right colectomies, two total colectomies, two reversal of end stomas, and six others. Mean age was 62.9 years, BMI 30.4, blood loss 38ml, and operative time 159 minutes. Muscle splitting or ostomy site extraction incisions were favored for left side cases. Mean (SD) hospital stay was 2.1 (1.0) days in TAP patients, compared to 3.2 (1.3) days in non-TAP cases, p=0.0003. Median stay dropped from 3 days in non-TAP to 2 days in TAP patients. Nine TAP patients went home on post-operative day 1 (33%), 9 on POD2 (33%), and 7 on POD3 (26%). One non-TAP patient went home on POD 1 (4%), 5 on POD2 (19%), 11 on POD 4 (41%), and 9 on POD 4 (33%). There were two readmissions in the ERP group, and none in the TAP group.

A bilateral TAP block significantly improved the results of an established ERP for patients undergoing LC. One third of patients were ready for discharge on the first day after surgery, and an additional 33% on day two. Readmission rates were low. Surgeon-administered TAP blocks may be an economical and efficient method for further improving the results of LC.

CURRENT STATE OF THE ART IN LAPAROSCOPIC COLORECTAL SURGERY FOR CANCER: UPDATE ON THE MULTI-CENTRIC INTERNATIONAL TRIALS

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Laparoscopic colectomy is now widely applied to cases of malignancy, supported by early data from several large randomized controlled trials. Long-term follow-up is now available from those trials, supporting equivalency of cancer-free and overall survival for open and laparoscopic resections. This promising data has inspired further exploration of other applications of laparoscopic techniques, including use of single incision laparoscopy. This article reviews recent reports of long-term data for colorectal cancer resection from four randomized, prospective international trials.

DEVELOPMENT OF A SAFETY CHECKLIST FOR BOWEL RESECTION: AN EXPERT PANEL APPROACH

E. Viscusi, M. Broder, M. Aeder, R. Chard, T. Gan, N. Hyman, M. Maggard-Gibbons, J. Rowbottom, P. Seifert, A. Senagore, S. Wren, C. Delaney

Introduction: Many potentially preventable complications may occur with bowel resection surgery (BR). Use of the World Health Organization Safe Surgery Checklist increases adherence with best practices and reduces preventable complications and deaths. Despite the utility of this checklist, it is very general, and experts recommend checklists optimized for procedure-specific tasks. Our objective was to develop an evidence-based checklist for BR to improve perioperative safety and clinical outcomes.

Methods: A RAND/UCLA Delphi process was used to develop a bowel surgery specific checklist. A nationally representative, multidisciplinary group of experts (colorectal and general surgery, anesthesiology, perioperative nursing) reviewed 149 surgical safety measures ("checkpoints"). Checkpoints were grouped into 6 pause points [pre-op, preinduction, time out, intra-op, debriefing, post-anesthesia care unit (PACU) hand-off]. The panelists completed a pre-meeting rating of the individual checkpoints. At a 2 day meeting, they discussed areas of disagreement and re-rated the checkpoints. Checkpoints for which there was a high or moderate level of agreement were included in the final checklist.

Results: In the final round of ratings there was high agreement to include 23 (22.1%) of the checkpoints and moderate agreement to include 13 (12.5%). Of these 36 checkpoints, 14 were at pre-op, 6 at preinduction, 10 at time out, 2 at intra-op, 3 at debriefing, and 1 at PACU hand-off. Checkpoints were formatted into a checklist. Panelists reviewed the checklist and their comments were incorporated into the final version. The panel enumerated additional items considered "best practices" but not needed as part of a checklist.

Conclusion: The Delphi process was used to derive a 36 item checklist specific to bowel surgery. The checklist was organized around natural breaks in workflow, and was designed to improve communication and detect errors at a time when they can still be corrected. The panel refrained from assigning responsibility to a team member for each checkpoint or from providing detailed implementation advice since institutional practices vary. The panel recommended pilot testing before final implementation. An expert panel and Delphi process is highly recommended when developing procedure specific surgical checklists.

EARLY DISCHARGE WITH ENHANCED RECOVERY PATHWAYS FOR COLORECTAL SURGERY IS ASSOCIATED WITH LOW READMISSION RATES

Lawrence JK. MD, Samia H. MD, Ermlich B., Brady K, Nobel T, Delaney CP

Introduction: Enhanced Recovery Pathways (ERP) have been shown to reduce hospital length of stay (LOS) after major colorectal surgery (CRS) and can therefore improve outcomes and patient Quality of Life (QOL). Laparoscopic CRS permits earlier discharge without a compromise in safety.

Methods: This study retrospectively reviews a prospectively collated database of major colorectal surgical procedures for a single surgeon. 969 (mean age 58.7 years) cases identified as major in a 64 month period between 2005 and 2012 were included: 806=Elective, 163=Emergency. Patients were categorized by their day of discharge (DoD) up to 7 days. The remainders were grouped as 7+ days. Mean LOS and readmission rates (RR) were analyzed.

Results: Mean LOS (±SD) was 4.2 (4.3) days for the laparoscopic (N=659) group and 10.4 (8.7) days for open (N=310) cases. The mean ages for the groups were comparable (laparoscopic=58.6, open=59.0). Of the 609 elective laparoscopic cases, 62% were discharged within 72h, with a 3.4% cumulative RR. 74% of cases were colectomies (partial/total/APR). The percentage of elective laparoscopic cases with DoD 0, 1, 2 and 3 (and their respective cumulative RR) were 1.3% (0%), 7.7% (0.2%), 27.1% (1.6%) and 25.9% (3.4%).

Conclusion: At most centers, major colorectal procedures are predominantly performed laparoscopically. The benefits of which include less postoperative pain, better compliance with ERP and earlier discharge compared with those offered by open surgery. ERP and a laparoscopic approach in major colorectal surgery are safe and efficient.

	LAP	OPEN	ALL
N (%)	659 (68%)	310 (32%)	969
AGE AV. (SD)	58.6 (18.7)	59.0 (16.4)	58.7 (18.0)
LOS AV (SD)	4.2 (4.3)	10.4 (8.7)	6.2 (6.7)
elective	3.9 (3.3)	8.4 (6.8)	
emergency	8.8 (9.6)	13.7 (10.5)	
ALL READMIT N (%)	50 (7.6%)	34 (11%)	84 (8.7%)
EL RR: of <72h grp	3.4%	2.0%	**3.0%**
EM RR: of <72h grp	6%	0%	**1.8%**
ALL	**3.6%**	**1.3%**	**-**
EL RR: of >72h grp	3.8%	12.2%	**5.8%**
EM RR: of >72h grp	6.0%	5.3%	**5.5%**
	3.9%	**9.7%**	
EL RR OVERALL	7.2%	14.2%	
EM RR OVERALL	12.0%	5.4%	
CASES:			
COLECTOMY			
segmental	319 (33%)	99 (10%)	418 (43%)
total	75 (8%)	34 (4%)	109 (11%)
LAR	83 (9%)	15 (2%)	98 (10%)
APR/POUCH	55 (6%)	33 (3%)	88 (9%)
LAPAROTOMY/EXENT	2 (0%)	41 (4%)	43 (4%)
STOMAS	38 (4%)	37 (4%)	75 (8%)
LOA	34 (4%)	1 (0%)	35 (4%)
OTHER	53 (5%)	50 (5%)	103 (11%)

ELECTIVE			
	LAP	OPEN	
DoD	N (%)	CUMUL. RR	N (%)
0	8 (1.3%)	0.0%	1 (0.5%)
1	47 (7.7%)	0.2%	1 (0.5%)
2	165 (27.1)	1.6%	7 (3.6%)
3	158 (25.9%)	3.4%	12 (6.1%)
4	90 (14.8%)	3.9%	24 (12.2%)
5	38 (6.2%)	4.8%	21 (10.7%)
6	27 (4.4%)	5.6%	28 (14.2%)
7	23 (3.8%)	6.2%	23 (11.7%)
7+	53 (8.8%)	7.2%	80 (40.6%)
OVERALL	**609 (76%)**	**-**	**197 (24%)**

EMERGENCY			
	LAP	OPEN	
DoD	N (%)	CUMUL. RR	N (%)
0	0 (0%)	0.0%	0 (0%)
1	3 (6%)	0.0%	0 (0%)
2	3 (6%)	2.0%	1 (0.9%)
3	6 (12%)	6.0%	2 (1.8%)
4	5 (10%)	8.0%	8 (7.1%)
5	6 (12%)	8.0%	12 (10.6%)
6	5 (10%)	8.0%	15 (13.3%)
7	6 (12%)	12.0%	4 (3.5%)
7+	16 (32%)	12.0%	71 (62.8%)
OVERALL	**50 (31%)**	**-**	**113 (69%)**
			163

EFFECT OF LOCAL ANESTHETICS ON POSTOPERATIVE PAIN AND OPIOID CONSUMPTION IN LAPAROSCOPIC COLORECTAL SURGERY

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BACKGROUND: Several studies have evaluated use of local anesthetic, specifically, administration of intraperitoneal anesthetic, during laparoscopic general surgery and gynecologic operations, with varying results. There have been no studies to determine the role of local anesthetic in laparoscopic colorectal surgery. This study evaluates the efficacy of subcutaneous and intraperitoneal anesthetic in reducing postoperative pain following common laparoscopic colorectal procedures, in patients managed with enhanced recovery care pathways.

METHODS: A single-institution retrospective cohort analysis of 172 patients who underwent common elective laparoscopic colorectal procedures was carried out. Over three consecutive time periods, patients were divided into three study arms, based on administration of local anesthetic. The first group received no local anesthetic (n = 66), the next received only subcutaneous bupivacaine (n = 67), and the final group received both subcutaneous bupivacaine and intraperitoneal lidocaine (n = 44). Pain scores, time in the postoperative care unit, and the amount of opioid pain medication consumed in the immediate postoperative period were quantified.

RESULTS: There was no difference in pain scores reported between the three study arms, including upon arrival and upon leaving the recovery unit ($P \leq 0.086$, $P \leq 0.166$), and at 3, 6, 9, and 12 h postoperatively ($P \leq 0.332$, $P \leq 0.142$, $P \leq 0.155$, $P \leq 0.872$). There was no significant difference in the amount of postoperative opioid analgesia consumed between the three study arms on postoperative day 0 and on postoperative day 1 ($P \leq 0.365$, $P \leq 0.458$). There were no significant differences in the amount of time spent in the postoperative care unit, hospital stay, 30 day morbidity, or 30 day mortality between the three study arms.

CONCLUSIONS: Use of local anesthetic does not influence postoperative opioid requirements or patients' subjective report of pain following laparoscopic colorectal procedures managed within enhanced recovery care pathways.

EVALUATION OF INFLAMMATORY MARKERS AS PREDICTORS OF HOSPITAL STAY AND UNPLANNED READMISSION AFTER COLORECTAL SURGERY

David M. Krpata MD, Hoda Samia MD, Justin Lawrence MD, Izi Obokhare MD, Karen M. Brady RN, Conor P. Delaney, MD, PhD

Background: Hospital stay and readmission continue to be unpredictable events following colorectal surgery whether patients follow enhanced recovery pathways or traditional care. In this study, we evaluate white blood cell count and C-reactive protein level as potential predictors of early recovery or hospital readmission following colorectal surgery.

Methods: Patients undergoing laparoscopic or open abdominal colorectal surgery were managed using standardized enhanced recovery pathways. Those with post-operative day 2 C-reactive protein and white blood cell values were evaluated. Primary outcomes included 30-day hospital readmission rates and postoperative length of hospital stay.

Results: C-reactive protein values were available for 193 patients (86 Male, mean age 58.6 years). Ninety-nine patients had surgery for colon cancer, 23 Crohn's disease, 19 ulcerative colitis, 31 diverticulitis and 18 for other reasons. Twenty patients (10.4%) were readmitted to the hospital within 30 days of surgery. Post-operative day 2 C-reactive protein accurately predicted short length of hospital stay ($p< 0.01$). Mean C-reactive protein was 6.3 in patients with a length of stay of 3 days or less, and 11.7 in patients with a length of stay of 4 days or longer. The average C-reactive protein of the readmission and non-readmission groups was 11.8 and 9.9 respectively ($p=0.29$).

Conclusions: A low post-operative day 2 C-reactive protein level was associated with a short hospital stay. In contrast, post-operative day 2 white blood cell count, and the absolute difference in white blood cell count from baseline predicted readmission. Evaluation of inflammatory markers on post-operative day 2 with comparison to baseline may be useful indicators of suitability for early discharge in patients following enhanced recovery pathways and warrants further investigation in larger prospective studies.

EXTRACTION SITE LOCATION AND INCISIONAL HERNIAS AFTER LAPAROSCOPIC COLORECTAL SURGERY: SHOULD WE BE AVOIDING THE MIDLINE?

Samia H. MD, Lawrence J. MD, Nobel T. MS, Stein S MD, Champagne BJ MD, Delaney CP MD

BACKGROUND: Laparoscopic colorectal procedures generally require an incision for specimen extraction. Few studies evaluate how extraction site impacts the incidence of incisional hernia (IH) in laparoscopic surgery. In order to define the long term consequences of extraction site, this study evaluates the incidence and location of IH after laparoscopic colorectal resection (LC).

METHODS: We retrospectively evaluated an IRB approved prospective database, and identified patients undergoing LC from August 2005 to January 2012. Pediatric cases, conversions, and natural orifice extraction cases were excluded, and outcomes between patient specific sites of specimen extraction were compared.

RESULTS: Of 480 LC cases, extraction sites were midline (n=305), muscle splitting (n=128), pfannenstiel (n=26), and ostomy (n=21), with an average follow-up of 3.5 years. Age, gender, diagnosis, extraction incision length and hospital stay were similar. Mean BMI for all patients was 28, but 31 for those with IH ($p= 0.008$). The overall IH rate was 6.7%. Midline IH accounted for 84% of all hernias, occurring in 8.9% of midline extractions ($p<0.05$ vs. non-midline). Hernia rates for muscle-splitting, pfannenstiel, and ostomy site extractions were 2.3%, 3.8% and 4.8%.

CONCLUSION: Although midline hernia rates were lower than traditionally reported with open surgery, midline extraction sites have a significantly higher chance of IH than non-midline sites.

AN OBJECTIVE STEPWISE ASSESSMENT TOOL OF OPERATIVE SKILLS (SATOS) FOR EVALUATING JUNIOR SURGICAL TRAINEES LEARNING LAPAROTOMY AND WOUND CLOSURE IN A PORCINE MODEL

Kelly KB, Zeinali F, Schomisch S, Samia H, Khan S, Ponsky J, Delaney CP

We have previously investigated a porcine model to teach laparoscopic and open approaches for colon and gastric resection. In this study, we objectively evaluate and compare the performance of junior surgical trainees learning to open and close the abdominal wall in a porcine model of laparotomy.

Twenty-six PGY-1 or PGY-2 general surgery trainees each performed two mid-line laparotomies and abdominal closures during an operative skills session using a living, non-survival porcine model. The performances of abdominal wall opening and closure were deconstructed into six and ten skills, respectively. Residents were evaluated for each skill on a three point scale (unsatisfactory- 0, needs improvement-1, or satisfactory-2). The maximum skills score for opening and closure were 12 and 20, respectively. Operative times were recorded.

Fifteen PGY-1 and eleven PGY-2 residents performed the laparotomy and wound closure on two separate occasions. PGY-1 residents had significantly longer operative times than PGY-2s on their first attempt at opening (12.1 ± 2.6 min. vs 10.0 ± 1.5 min.; $p=0.011$), a difference eliminated by training. PGY-2 residents did not demonstrate a reduction in operative times with training. No other significant differences in operative times or skills scores between the two classes were found. Both PGY-1 and PGY-2 classes improved their operative skills scores with training in opening and closure. For opening, the mean PGY-1 skills score increased from 7.0 to 11.9 ($p<0.05$) and PGY-2 skills score increased from 8.4 to 11.8 ($p<0.05$) between the two evaluations. Likewise for closure, the mean PGY-1 skills score increased from 9.1 to 16.3 ($p<0.001$) and PGY-2 skills score increased from 10.7 to 17.0 ($p<0.001$).

SATOS provided an objective assessment of junior surgical trainees' operative skills. Junior level trainees showed skills improvement using a living porcine model to teach midline laparotomy and abdominal wall closure.

LAPAROSCOPIC TREATMENT OF RECTAL CANCER

Lawrence JK MD, Delaney CP MD PhD

Introduction/Background

Approaches to the diagnosis and management of rectal cancer have changed significantly in recent years. With the advent of neoadjuvant therapy, laparoscopic and robotic-assisted surgery, attempted curative resection appears to be associated with fewer adverse outcomes, shorter hospital stays and at least comparable oncologic 1 clearance as that achieved with conventional open surgery (COS).

Over 40,000 patients are diagnosed with rectal cancer in the U.S. annually with 20% of those dying from the disease. Historically, difficulties with surgical resection arose with the position of the tumor, often deep in the pelvis (especially the narrow male pelvis) and ensuring oncological clearance whilst preserving local pelvic structures. Those difficulties persist, but with advances in laparoscopic instrumentation and technique, access to these structures under direct, magnified vision has improved curative resection potential whilst minimizing injury to adjacent structures.

Increasing evidence suggests that these techniques improve post-operative recovery time and reduce post-operative pain, reduce operative blood loss and return to normal function 2-4 but these outcomes can come at a cost. While the majority of the evidence is based on laparoscopic colectomy (LC), why could these benefits not translate to rectal surgery too? Laparoscopic surgery (LS) can involve longer operative times, uses more expensive equipment and if robotic devices are employed, requires extended setup times in the operating room. However, with similar or fewer instances of early complications including wound infection and ileus, comparable oncologic clearance and often significantly reduced hospital stay, these costs can be absorbed 5,6.

PROCESS CONTROL IN SURGERY: USING INDUSTRIAL METHODOLOGY TO EVALUATE RESOURCE UTILIZATION FOR PERIOPERATIVE COLORECTAL CARE

Lawrence J, Rose J, Jung B, Brady K, Samia H, Delaney CP.

OBJECTIVE(S): Enhanced recovery pathways (ERP) may permit early recovery and discharge after colorectal surgery (CR), but are variably interpreted and implemented. Outliers for length of stay (LOS) may exist because of case complexity/type, or complications. Statistical process control (SPC) is used by industry to measure and change processes to improve efficiency. We use SPC methodology to evaluate patients undergoing major colorectal procedures.

METHODS: Over six years, 1,531 patients undergoing CR procedures by a single surgeon were followed in a prospective, IRB approved database. Loop stoma closure and non-abdominal cases were excluded, leaving 358 open and 563 laparoscopic major cases for evaluation. Patients followed an optimized ERP with standard dietary, analgesia and discharge orders using a laparoscopic approach when possible. SPC (one standard deviation) and all-cause readmission were used to identify outliers.

RESULTS: Overall LOS was 6.1 days (4.8 elective; 12.3 emergency; 4.1 laparoscopic; 9.3 open). There were 8.7% laparoscopic outliers and 10.6% open. Open outliers were likely to be >76 years, emergency, multivisceral resections or re-operative cases, have particular physical or other co-morbidity, or have complications. Laparoscopic outliers were predominantly complicated elective cases. Patients with a primary LOS < 4 days were unlikely to become outliers.

CONCLUSIONS: SPC methodology permits the identification of specific characteristics of outliers for LOS or readmission, even while on a well established ERP. Targeting these patient cohorts could potentially reduce institutional resource utilization by 25%.

A RANDOMIZED TRIAL COMPARING COST AND EFFECTIVENESS OF BIPOLAR VESSEL SEALERS VS CLIPS AND VASCULAR STAPLERS FOR STRAIGHT LAPAROSCOPIC COLORECTAL RESECTIONS

Adamina M, Champagne BJ, Hoffman L, Ermlich B, Delaney CP

Br J Surg, 2011; 98(12): 1703-12.

Background: The widespread use of laparoscopy has resulted in a variety of instruments being used routinely for vascular control. This randomized controlled trial evaluated the cost-effectiveness of bipolar vessel sealer (BVS) compared with clips and vascular stapler (CVS) in straight laparoscopic colorectal resection.

Methods: Patients scheduled for elective colorectal resection, including benign and malignant diseases, were randomized to either BVS or CVS for vascular control. Patients whose operation was converted to an open approach before pedicle ligation were excluded. The primary endpoints were duration of operation, including time taken to control vascular pedicles, and cost of disposable instruments for vascular control.

Results: Of 114 patients randomized to BVS (60 patients) or CVS (54), 14 did not receive the allocated vascular control device, leaving 55 and 45 respectively for analysis. The BVS reduced the time spent for vascular control by a mean of 6·9 min (P = 0·031) and reduced the cost of disposable instruments for vascular control by US $ 80·7 per patient (P = 0·043). For total colectomy, the BVS reduced the operating time by 103·6 min (P = 0·023) and the time taken for vascular control by 16·8 min (P = 0·022). For left colectomy, it decreased the time to vascular control by 9·3 min (P = 0·021). In multivariable analysis, the cost of disposable instruments for vascular control was independently reduced by randomization to BVS, type of procedure, female sex and estimated blood loss. The mean cost reduction was $ 88·2 for left colectomy (P = 0·037), $ 377·7 (P = 0·005) for total colectomy and $ 366·9 (P = 0·012) for proctectomy. Conversely, use of the BVS increased the cost of instruments used for vascular control in right colectomy by $ 92·6 (P = 0·012).

Conclusion: BVS devices are expedient and cost-efficient in proctectomy, left and total colectomy procedures.

RISK OF COLONIC NEOPLASIA AFTER PROCTECTOMY FOR RECTAL CANCER IN HEREDITARY NONPOLYPOSIS COLORECTAL CANCER

Kalady MF, Lipman J, McGannon E, Church JM

Ann Surg. 2012 Jun;255(6):1121-5.

OBJECTIVE: To define the neoplastic risk in the remaining colon after proctectomy for rectal cancer in patients with hereditary nonpolyposis colorectal cancer (HNPCC).

BACKGROUND: The extent of surgery for rectal cancer in HNPCC is controversial. In determining which operation to perform, surgeons and patients must consider cancer risk in the remaining colon as well as functional consequences of removing the entire colorectum. The natural history of colon neoplasia in this situation is understudied and is not well-defined.

METHODS: A single-institution hereditary colorectal cancer database was queried for patients meeting Amsterdam criteria and with rectal cancer. Patient demographics, surgical management, and follow-up were recorded.

RESULTS: Fifty HNPCC patients with a primary diagnosis of rectal cancer treated by proctectcomy were included. Detailed follow-up colonoscopy data were available for 33 patients. Forty-eight high-risk adenomas developed in 13 patients (39.4%). Five patients (15.2%) developed metachronous adenocarcinoma at a median of 6 years (range 3.5-16) after proctectomy, including 3 at advanced stage. One of these patients developed a high-risk adenoma before cancer. Mean interval between the last normal colonoscopy and cancer discovery was 42 months (range 23.8-62.1) with one developing within 2 years. Thus, 17 of 33 patients (51.5%) developed high-risk adenoma or cancer after proctectomy.

CONCLUSIONS: Surgeons and patients need to be aware of substantial risk for metachronousneoplasia after proctectomy. Selection of operation should be individualized, but total proctocolectomy and ileoanal pouch should be strongly considered. If patients undergo proctectomy alone, close surveillance is mandatory.

SIMULATION AND ITS ROLE IN TRAINING

Samia H, Khan S, Lawrence J, Delaney CP

Despite its short history, surgical simulation has been successfully introduced into surgical residency programs in an effort to augment training. A wide range of simulator types and levels of complexity have been proven an effective teaching method for surgical trainees. They have been used in training in areas such as general surgery, urology, gynecology, and ophthalmology among others. Coincident with the introduction of simulators, is the need for objective evaluation of skills learned on them which has led to the development and validation of multiple evaluation tools. This article evaluates the drivers for simulation, types of simulators, training, and evaluation of them especially as it pertains to laparoscopic colorectal surgery.

THE SOCRATES STORY – INTEGRATING HOSPITAL ADMINISTRATIVE DATA TO IMPROVE HEALTH CARE EFFICIENCY AND OUTCOMES

Lawrence J, Delaney CP

Evaluation of healthcare outcomes has become increasingly important as we strive to improve quality and efficiency while controlling cost. Many groups feel that analysis of large datasets will be useful in optimizing resource utilization, however the ideal blend of clinical and administrative data points has not been developed. Hospitals and health care systems have several tools to measure cost and resource utilization, but the data is often housed in disparate systems that are not integrated and do not permit multi-system analysis. Systems Outcomes and Clinical Resources AdminisTrative Efficiency Software (SOCRATES) is a novel data merging, warehousing, analysis and reporting technology, which brings together disparate hospital administrative systems generating automated or customizable risk-adjusted reports. Used in combination with standardized enhanced care pathways, SOCRATES offers a mechanism to improve the quality and efficiency of care, with the ability to measure real-time changes in outcomes.

Objectives: Following review of this article, readers should appreciate the need for information technology and sophisticated data analysis in healthcare to assess performance and optimize patient care and outcomes.

TAILORED RECTAL CANCER TREATMENT – A TIME FOR IMPLEMENTING CONTEMPORARY PROGNOSTIC FACTORS?

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Introduction: The aim of this paper was to review literature supporting the development of tailored treatment strategies for rectal cancer including available prognostic factors outside of the TNM system.

Methods: Based on a comprehensive review of the literature on rectal cancer the impact of prognostic factors currently not included in international guidelines is discussed.

Results: There is considerable variation in treatment guidelines for rectal cancer around the world, especially for stage II and III disease. Long term side effects of chemoradiotherapy are not considered in any guideline. Detailed knowledge of, and the prognostic impact of the circumferential resection margin, tumour grade, and venous invasion should be factored into the development of a treatment strategy.

Conclusions: Factors additional to the TNM system should improve decision making for contemporary rectal cancer treatment. Optimized radiological and pathological evaluations, and a focus on detailed clinical factors should be the basis for treatment decisions. International guidelines should consider all known prognostic factors, both for long-term oncological and functional outcomes.

Section 3
Education

MAKING ENDS MEET: SEEKING FINANCIAL STABILITY IN HEALTHCARE SIMULATION

M. Aeder, K. Walker, I. Cooper, M. Seropian, V. Brazil

Background: Simulation centers have multiple financial models as some are proprietary for a school, hospital or medical care system while others are educational providers at all levels, both within and outside of their service core. They may be collaborative investments of multiple entities with a common mission or be wholly owned by a sponsoring organization. While some centers are strongly supported by foundation grants, research studies, government finances or contributions, many have hybrid annual budgets which require a concrete business model. Some centers are highly specialized to a specific learner group while others provide programs for entire communities of learners at all levels and may have a regional network.

Methods and Results: We examined and evaluated the models for simulation center sustainability and the paradigms of incorporating various funding models into the financial planning. The assessment included simulation models from 3 different countries. Evaluating program specifics for educational impact balanced for resource utilization provided the basis for the models defining center viability. By assessing the learner requirements, stakeholder needs, and diversity of the educational programming and balancing the resources expended to fulfill those requirements, we developed models of pricing, utilization, subscriptions and fee for service.

Discussion and Conclusion: Given the extensive fiscal challenges within the healthcare system and the promise of further financial reductions, the value of simulation education is based on the outcomes of better and more efficient health care delivery. Additionally, previous reliance on animal and cadaver use has been modified with increasing costs and societal pressures. We examined the different business models used in simulation programs and the key drivers for fiscal accountability within three different national health systems. There was a common thread of value based purchasing of the simulation programming as it promoted the acceleration of the educational process. The major barrier to more sustained use of the simulation facilities was the cost of the process. It was concluded that the stakeholders which would benefit most from the simulation experience would have to subsidize the cost.

USING CIVILIAN SIMULATION TRAINING CENTERS FOR MILITARY PREPAREDNESS TRAINING

Mark Aeder, MD, F.A.C.S.

With increased reliance on Reserve Component Medical Units (RCMU) of the US Armed Forces (USAF) to provide combat casualty care (79%), there is an urgent need for clinical skills and team training preparation. Medical simulation can provide relevant combat casualty care skills training prior to deployment. Major barriers include limited individual RCMU accessibility to unit specific high fidelity training and limited resources/time to travel to Army Medical Simulation Training Centers (avg. dist. 278 mi). One day training events at suitable Civilian Simulation Training Centers (CSTC) can provide convenient and cost effective military preparedness training (MPT).

Design: Unit members of the 256th Combat Support Hospital. Informed consent for observation was given by all participants. Case scenarios were created by Commander Staff and programmed by the CSTC staff. The learner teams were observed as they progressed through the series of scenarios in a one day session. The trainer-facilitator observed the team interaction and the progression through key branch points of the scenario. An AAR was led by the trainer-facilitator following each scenario. Assessment of the experience was provided by the trainer –facilitator.

Analysis: Based on summary observations of the trainer facilitator, the simulation experience provided a facilitative enhancement of team training techniques and, when accomplished, improvement in clinical performance. Unit trainers and trainees gave positive ratings to the one day events conducted at the CSTC.

Findings: Effective training to achieve military learner goals in a CSTS is dependent on 6 critical factors: 1. Adequate space, center availability and on site expertise, 2. Interactive operational capabilities for medical and administration liaisons, 3. Unit specific equipment, props, moulage and resources, 4. Constant communication between center and trainer personnel, 5. Resources for AAR facilitation, video and observational, 6. Confidentiality, security and privacy. Successful training events require precise attention to scheduling, scenario rehearsals and modification for individual unit needs through feedback evaluations.

Conclusions: Combat casualty case simulations are a vital component of MPT. Weekend simulation sessions provide the opportunity for team training development in a stressful but safe learning environment. Simulation training in a CSTC provides a cost effective opportunity for MPT and the enhancement of successful field of operations outcomes.

Section 4

General and Gastrointestinal Surgery

EVALUATION OF ABDOMINAL WALL REMODELING FOLLOWING VENTRAL HERNIA FORMATION IN A RODENT MODEL

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Introduction: Mediating abdominal wall function, the linea alba is a major tendinous insertion for abdominal wall musculature. When tendons are severed in limb muscles, changes classic for disuse atrophy appear. Similarly, when a ventral hernia occurs, particularly following a midline laparotomy, the linea alba attachment is lost and abdominal wall muscles may laterally retract and potentially undergo disuse atrophic changes. The objective of this study was to evaluate in a rat model the abdominal wall remodeling that occurs after the unloading of the core abdominal wall musculature with ventral hernia formation.

Methods: The linea alba of Sprague-Dawley rats were incised and rats were survived for 30 days to represent a model of chronic ventral hernia. At 30 days, abdominal wall samples were evaluated for changes in muscle fiber type and size with histologic analysis, changes in muscle biomechanics and changes in gene expression with Affymetrix GeneChips to potentially associate downstream effects of ventral hernias with abdominal wall remodeling.

Results: In total, 10 Sprague-Dalwey rats underwent hernia formation (Hernia) and were compared 10 Sprague Dawley normal abdominal walls (Control). Mean size of the hernia defects at 30 days was 4.52 cm2 (range 2.5-6 cm2). On histologic analysis, there was no significant difference in number of Type I muscle fibers or Type I fiber total percent area in either the external abdominal oblique muscles (Control: 413 fibers ± 216; 4.62% ± 1.29: Hernia: 481 ± 297 fibers; 5.11% ± 1.56) (p=0.30; p=0.18) or internal abdominal oblique muscles (Control: 311 fibers ± 241, 5.96% ± 1.25; Hernia: 442 fibers ± 231, 6.03 ± 1.90) (p=0.06, p=0.88). The biomechanical properties of unloaded and normal abdominal walls were similar in tensile strength (Control: 1.90 N/mm2 ± 0.72; Hernia: 1.82 N/mm2 ±0.38) (p=0.71), toughness (Control: 126.37 J ± 48.18; Hernia: 105.89 J ± 25.37) (p=0.16), and stiffness (Controls: 1.05 N/mm ± 0.5; Hernia: 1.00 N/mm ± 0.30) (p= 0.77). After RNA isolation, gene expression was significantly different in only a single gene out of the over 30,000 genes analyzed.

Conclusions: Abdominal musculature of Sprague Dawley rats at 30 days following ventral hernia formation does not show significant changes in muscle typing, biomechanical properties or gene expression as would be expected with abdominal wall remodeling. Although literature supports a rat model to investigate the disuse atrophy associated with limb muscle unloading, this does not appear to hold consistent with abdominal wall musculature. Additional models should be investigated to evaluate the abdominal wall remodeling likely associated with functional changes seen in humans who have developed ventral hernias.

ABDOMINAL WALL RECONSTRUCTION UTILIZING TRANSVERSUS ABDOMINIS RELEASE (TAR) IN A PATIENT WITH MASSIVE LOSS OF DOMAIN

Eric M Pauli, David M Krpata, Michael J Rosen, Yuri W Novitsky

Case Comprehensive Hernia Center, University Hospitals Case Medical Center, Cleveland, Ohio

Obtaining midline closure in patients with large hernia defects during abdominal wall reconstruction can be challenging. Myofascial advancement flaps, such as a components separation, are utilized to achieve midline closure in these patients. The most common method of component separation employed is the release of the external oblique muscle 2 cm from the edge of the lina semilunaris. Unfortunately, significant wound morbidity occurs when large lipocutaneous flaps are created to access the external oblique muscle. An alternative approach, transversus abdominis release (TAR), has been developed to avoid the creation of skin flaps while maintaining the ability for medialization of rectus muscles and linea alba restoration. The objective of this video is to demonstrate our approach to abdominal wall reconstruction using TAR in a patient with a large hernia defect. The patient is a 60 year-old morbidly obese male who developed an incisional hernia with loss of domain. In this video, we review the retro-rectus dissection required to access the transversus abdominis, the release of the transversus abdominis and key aspects of giant prosthetic sublay reinforcement of a visceral sac following abdominal wall reconstruction with this approach.

A 5-YEAR CLINICAL EXPERIENCE WITH SINGLE-STAGED REPAIRS OF INFECTED AND CONTAMINATED ABDOMINAL WALL DEFECTS UTILIZING BIOLOGIC MESH

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Case Comprehensive Hernia Center, University Hospitals Case Medical Center, Cleveland, OH

Objective: Our objective was to evaluate the safety and durability of biologic mesh for single-staged reconstruction of contaminated fields.

Introduction: The presence of contamination during ventral hernia repair (VHR) poses a significant challenge. Some advocate for a multi-staged reconstructive approach with delayed definitive repair, while others perform definitive repair at the initial operation.

Methods: Patients undergoing single-staged VHR in a contaminated field with biologic mesh over a five year period were retrospectively reviewed from a prospectively maintained database. Outcome measures included wound complication and hernia recurrence.

Results: 128 patients (76F, 52M) were identified with a mean age of 58.2 years, mean ASA 3.1, and mean BMI 34.1 kg/m2 ± 9.7. Comorbidities included COPD (n=29), diabetes (n=65), smoker (n=29), and immunosuppression (n=8). Mean hernia defect size was 431 cm2 (range 40-2450cm2). Reasons for contamination included presence of infected mesh (n=45), stoma (n=24), concomitant GI surgery (n=17), enterocutaneous fistula (n=25), open non-healing wound(s) (n=6), enterotomy/colotomy (n=5) and chronic draining sinus (n=6). Post-operative wound complications were identified in 61 (47.7%) patients. Predictors of wound complications included ASA, diabetes, smoking, number of previous abdominal surgeries or hernia repairs, hernia defect size, and operative time. With a mean follow up time of 21.7 months, hernia recurrence was identified in 40 (31.3%) patients. The majority of recurrent hernias were asymptomatic and seven patients were repaired.

Conclusion: Despite the high rate of wound morbidity associated with single-staged reconstruction of contaminated fields it can safely be performed with biologic mesh reinforcement. While biologic mesh in these situations is safe, the long-term durability appears to be less favorable.

ACUTE KIDNEY INJURY FOLLOWING OPEN VENTRAL HERNIA REPAIR

Peter Will, David M Krpata, Emanuel E Sadava, Eric M Pauli, Jeffrey A Blatnik, Yuri W Novitsky, Michael J Rosen

Background: Acute kidney injury (AKI) following general surgery is common and significantly increases patient morbidity. Although the changes in physiology of the abdominal wall in patients undergoing open ventral hernia repairs (VHR) may significantly affect abdominal viscera, perioperative kidney function in hernia patients has not been evaluated to date. We aimed to assess the incidence and impact of AKI in a large cohort of patients undergoing open VHR.

Methods: Patients undergoing open VHR between 2008 and 2011 were examined using a prospectively maintained database. Charts were reviewed for inpatient fluid administration. Patients were assessed for AKI utilizing the Acute Kidney Injury Network criteria, defined as an increase in serum creatinine of ≥0.3 mg/dL from baseline.

Results: Of 133 patients examined, 36 (27.1%) met the criteria for AKI, with an average increase in serum creatinine of 1.15 ±0.80 mg/dl. Mean time to develop an AKI was 2 days, with peak creatinine most commonly occurring on post-operative day 4. Of patients who developed AKI, no patients required dialysis. Average length of stay did not vary significantly between the two populations (p=0.57). BMI >40 kg/m2 was a significant independent predictor of AKI (p=0.01). Other patient co-morbidities, medications, blood pressures, preoperative electrolytes, and postoperative fluid balance were not predictive of AKI.

Conclusion: Acute Kidney Injury appears to be a frequent complication of VHR. Fortunately, the vast majority resulted in minimal short-term patient morbidity. Although severe morbid obesity was predictive of AKI, perioperative fluid management may be a key factor in minimizing kidney injury in patients undergoing ventral herniorrhaphies.

BIODEGRADABLE ESOPHAGEAL STENT PLACEMENT DOES NOT PREVENT STRICTURE FORMATION FOLLOWING CIRCUMFERENTIAL MUCOSECTOMY IN A PORCINE MODEL

Eric M Pauli, Steve J Schomisch, Joseph P Furlan, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Advanced esophageal dysplasia and early cancers have traditionally been treated with esophagectomy. Recently developed tissue ablation techniques are less invasive, but may undertreat and do not permit histological analysis for staging. Endoscopic esophageal mucosectomy (EEM) offers a less-invasive therapy and provides an intact specimen for histo-pathologic assessment. However, high rates and high degrees of stricture formation following EEM limit its applicability. We hypothesized that placement of a self-expanding biodegradable stent (BD-stent; 12 week disintegration time) immediately following circumferential EEM would prevent stricture formation.

Methods: Ten pigs (5 unstented controls, 5 BD-stent) were utilized in the study. Sample size calculations indicated that 5 per group would detect a 25% stricture reduction with a p=0.05 and power of 0.80 using t-test. Following sedation and mechanical ventilation, a flexible endoscope with a band ligator and snare was used to circumferentially incise the mucosal layer approximately 20 cm proximal to the lower esophageal sphincter. A 7-10 cm circumferential segment of tissue was dissected free from the underlying muscle and excised using electrocautery and snare. In the stented group, a 18x120 mm uncovered, self-expanding, woven polydioxanone stent (ELLA-CS, Hradec-Kralove, Czech Republic) was deployed over a 0.035" guidewire. Stents were bridled using a non-absorbable suture passed through the stent interstices and suture to the cheek. Barium sulfate esophagograms were performed weekly to evaluate for percent reduction in diameter, stricture length and proximal dilation. Animals were followed clinically and were euthanized when the stricture exceeded 80% and were unable to gain weight (despite high-calorie liquid diet supplementation) or at 14 weeks.

Results: The control group rapidly developed esophageal strictures; no animal survived beyond the third week of evaluation. At two weeks post-EEM, the BD-stent group had a significant reduction in stricture diameter (77.6% vs 26.6%, p<0.001) and degree of proximal dilation (175% vs 131%, p=0.04) compared to controls. There was no difference in % stricture length between the groups. Survival in the BD-stent group was significantly longer than in the control group (9.2 weeks vs 2.4, p=0.01). However, all BD-stent animals ultimately developed clinically significant strictures (range 4-14 weeks). Comparison between the maximum reduction in diameter and stricture length (immediately prior to euthanasia) demonstrated no differences between the groups. There were no stent related obstructions or migrations.

Conclusions: Circumferential EEM quickly results in a high degree of stricture formation in a porcine model. These strictures result in clinical deterioration (regurgitation, failure to gain weight) within three weeks. The placement of a BD-stent significantly delays the time of clinical deterioration from 2.4 to 9.2 weeks, but does not minimize the maximum degree of luminal narrowing or proximal esophageal dilatation. The timing of stricture formation in the polydioxanone BD-stent group correlated with the known loss of integrity and radial force (6-8 weeks) and the stent disintegration (11-12 weeks). Future areas of investigation will need to focus on the use of fully-covered BD-stents and on the use of BD-stents with a longer in vivo half-life.

BIOLOGIC MESH PLACEMENT DOES NOT ALTER ESOPHAGEAL STRICTURE FORMATION FOLLOWING CIRCUMFERENTIAL ENDOSCOPIC DISSECTION

Eric M Pauli, Yuhsin V Wu, Steve J Schomisch, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Early esophageal cancers have traditionally been treated with esophagectomy. Endoscopic esophageal submucosal dissection (EESD) offers less-invasive therapy but results in prohibitive structuring. We hypothesized that biologic mesh placement after circumferential EESD would prevent stricture formation.

Methods: Fourteen pigs (5 controls, 5 submucosal mesh (SM), 4 dermal mesh (DM)) were utilized. Under anesthesia, an endoscope with band ligator and snare was used to remove a 7-10cm circumferential mucosal segment. In the mesh groups, tubularized SM (Biodesign) or DM (Strattice) mounted on a temporary (3 week) plastic stent (Polyflex) was deployed over the mucosal defect. Weekly barium swallow studies evaluated esophageal dimensions. Euthanasia occured when strictures exceeded 80%.

Results: Control animals developed strictures within three weeks. Two weeks post-EESD, both mesh groups had significant reductions in stricture diameter (77.7% vs. 0.0% SM and DM $p=0.008$) and proximal dilation (175% vs. 114% SM vs. 106% DM $p=0.003$) compared to controls. However, one week after stent removal both mesh groups had a significant reduction in diameter compared to before (0% vs. 86.5% SM $p=0.008$, 94.4% DM $p=0.029$). The mesh groups survived significantly longer than controls (4 weeks (SM/DM) vs. 2.4 $p\leq0.016$). All mesh animals developed significant strictures one week after stent removal. Histology showed no mesh integration.

Conclusions: Biologic mesh placement and temporary esophageal stenting delays the time to stricture formation after EESD, but not the maximum degree of narrowing. No mesh integration was seen and strictures occurred following stent removal, suggesting that the stent alone was responsible for the therapeutic effect.

SEDATION.
IN: MARKS J, DUNIKN B, EDS. PRINCIPLES OF FLEXIBLE ENDOSCOPY. BOOK CHAPTER CURRENTLY IN PRESS.

Phillips M, Stuhldreher J.

The goal of sedation in flexible endoscopy is to facilitate successful performance of the procedure while minimizing patient discomfort. Sedation practices vary widely between surgeons, locations, and hospital practices. Although flexible endoscopy can be performed without sedation, most procedures in the United States use a combination of medications to aid in reducing patient anxiety, diminishing discomfort, and providing amnesia. Surgeons are often familiar with sedation in the operating suite, however, in the endoscopy suite, there are different considerations that must be taken into account. The endoscopist may be solely responsible for the administration of sedation or may have the support of an anesthesiologist for each case. Regardless of the setting and circumstance, it is paramount that the surgical endoscopist be knowledgeable of the options for sedation in flexible endoscopy to ensure patient safety, comfort and effective completion of the procedure.

CAP-ASSISTED ERCP WITH A FORWARD-VIEWING GASTROSCOPE AS A RESCUE ENDOSCOPIC INTERVENTION IN PATIENTS WITH BILLROTH II ANATOMY: A SINGLE NORTH AMERICAN CENTER EXPERIENCE

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Purpose: To describe and report the use and outcomes of a novel, cap-fitted ERCP technique with a forward-viewing gastroscope in patients with Billroth II anatomy.

Methods: Retrospective case series at an academic tertiary center in the United States. Inclusion criteria: a) documented Billroth II anatomy; and b) utilization of cap-assisted ERCP with a forward-viewing gastroscope (Figure 1) as a rescue intervention on the first endoscopic encounter after failed attempts to perform ERCP with a duodenoscope. Demographic, clinical and endoscopic data were collected.

Results: A total of 5 cap-assisted ERCP procedures were performed in 3 patients. A wide variety of diagnostic and therapeutic endoscopic maneuvers were technically feasible and successful in all cases of biliary obstruction (Table 1). Two patients required repeat interventions because of the complexity of the procedure; in the cases that required a repeat ERCP, a cap-assisted, forward-viewing gastroscope was always used as the instrument of choice. In all repeat procedures, cap-assisted ERCP was successfully reproduced. This new technique also enabled the closure of a perforation in the afferent loop caused by a duodenoscope in one patient.

Conclusions: Cap-assisted ERCP is a novel option that adds to the armamentarium of experienced therapeutic endoscopists. This technique may ensure a successful endoscopic outcome and spare patients with Billroth II anatomy a percutaneous or surgical approach when ERCP with a duodenoscope, pediatric colonoscope or non-cap-fitted gastroscope fails.

Table 1: Clinical and endoscopic data on patients who underwent successful cap-assisted ERCP after failure to perform ERCP with a duodenoscope on first endoscopy

Case	Age/ Sex	Indication	Number of endoscopic instruments used before cap-assisted ERCP	ERCP findings	Diagnostic intervention	Therapeutic intervention	Intra-procedural complication	Other endoscopic intervention
1A	71/F	Biliary obstruction	1 (duodenoscope)	Biliary stricture	Cholangiogram	Biliary stent	Afferent limb perforation by duodenoscope	Treatment of perforation with cap-assisted gastroscope
1B	71/F	Biliary obstruction	–	Biliary stricture	Cholangiogram; Bile duct brushings; Pancreatic duct brushings	Pancreatic stent; biliary stent exchange	–	–
2	92/M	Biliary obstruction	2 (duodenoscope; pediatric colonoscope)	Choledocholithiasis	Cholangiogram	Biliary sphincterotomy; balloon dilation of sphincterotomy; partial extraction of large stone; biliary stent	–	–
3A	94/M	Cholangitis	3 (duodenoscope; pediatric colonoscope; non-cap-fitted gastroscope)	Choledocholithiasis	Cholangiogram	Pancreatic stent; biliary sphincterotomy	Hypoxia	–
3B	94/M	Cholangitis	–	Choledocholithiasis	Cholangiogram	Biliary stent	–	–

Figure 1: Cap-fitted, forward-viewing gastroscope

ABDOMINAL WALL RECONSTRUCTION: THE COST OF COMPLEXITY

Will P, Krpata DM, Novitsky YW, Rosen MJ

Background: Recently health care payers have suggested modifying reimbursement of so called "never events", such as surgical site infections (SSI). The incidence of SSI after complex ventral hernia repair (VHR) and the potential cost associated with these events is not well studied. We aimed to identify the morbidity rates of abdominal wall reconstruction (AWR) based on hernia grade and the associated cost.

Methods: Utilizing a prospectively maintained database, all patients undergoing open VHR from 2005-2011 were analyzed for demographic, surgical site infection, and cost data based on hernia grade (VHWG).

Results: 332 patients underwent open AWR during the study period. SSI significantly increased with increasing hernia grade: Grade 1 (5%), Grade 2 (22%), Grade 3 (27%), and Grade 4 (43%) ($p<0.01$). 30-day hospital costs by grade increased by a factor of 1.81±1.95 between grades 1 and 2, 2.72±1.88 between grades 1 and 3, and 3.64±4.45 between grades 1 and 4 ($p<0.01$). Detailed cost analysis identified mesh and pharmacy costs as the most significant contributors to increased costs between hernia grades ($p<0.01$). The cost of SSIs was significantly greater in more complex patients, with mean costs increasing over $30,000 in grade 4 patients, but less than $2,000 in grade 1 patients.

Conclusion: Ventral hernia complexity significantly impacts the occurrence of SSI and the total hospital costs of patients undergoing AWR. Complex AWR performed in contaminated fields have a very high morbidity rate, and high volume centers are at risk for substantial reimbursement losses if these so called "never events" are not appropriately stratified and reimbursed.

DIAGNOSTIC GASTRO-DUODENOSCOPY VIA A GASTRO-GASTRIC FISTULA PRIOR TO OVERSTITCH CLOSURE

Eric M Pauli, Jeffrey M Marks

Video Abstract Summary:

Most surgeons are aware of the challenge posed by Roux-en-Y Gastric Bypass (RYGB) anatomy on the endoscopic evaluation and treatment of foregut pathology. In this video, we describe the successful endoscopic and fluoroscopic evaluation of the bypassed foregut in a RYGB patient using an ultra slim endoscope to traverse a 3mm GG fistula prior to fistula closure with the OverstitchTM endoscopic suturing system.

DISPARITY IN THE MANAGEMENT OF GRAVES' DISEASE OBSERVED AT AN URBAN COUNTY HOSPITAL: A DECADE-LONG EXPERIENCE

Judy Jin, MD, Victor Sandoval, BA, Mary E. Lawless, MA, RN, Ashwini R. Sehgal, MD, Christopher R. McHenry, MD

Background: The objective of this study was to determine whether health care disparities exist in management of Graves' disease.

Methods: Patients treated for Graves' disease from 1999 to 2009 were divided into medical and surgical treatment groups. A comparative analysis of age, sex, race, health insurance, and income was completed. Address and/or zip code were geocoded and median income was determined from census data.

Results: A total of 634 patients were treated for Graves' disease; 535 (84%) medically and 99 (16%) surgically. Mean age (40 ± 15 vs 43 ± 11 y), percentage of women (84% vs 91%), and racial distribution were similar in the 2 groups ($P > .05$). In the surgical group, median income was lower ($31,530 vs $34,404; $P = .07$) and 52% of patients were uninsured compared with 30% of patients treated medically ($P < .0001$).

Conclusions: A disproportionate number of uninsured patients underwent thyroidectomy for Graves' disease. Social and economic factors may have a role in determining definitive therapy for Graves' disease.

DIAPHRAGM PACING FOR ACUTE VENTILATOR WEANING IN THE INTENSIVE CARE UNIT: CHANGING THE PARADIGM

Onders RP.

Oral presentation at the 23rd Conference of the Society for Medical Innovation and Technology, Tel Aviv, Israel, September 14, 2011.

Background: Failure to wean from a ventilator leads to pneumonia, prolonged intensive care unit stay and significant costs. Phrenic nerve injury occurs in up to 20% of patients undergoing high risk cardiac procedures. This leads to diaphragm dysfunction and subsequent respiratory problems of atelectasis, effusions, pneumonia and even need for prolonged mechanical ventilation. Electromyography shows an absence of nerve conduction in these cases, but the nerve is usually not transected, just injured with inflammation causing the inability to transmit impulses to the diaphragm to contract for ventilation. Diaphragm Pacing (DP) has been used in a series of trials to help in respiration ranging from spinal cord injured patients with pure upper motor neuron loss of respiratory control to patients with lower motor neuron loss in amyotrophic lateral sclerosis in over 400 patients worldwide with positive results. This report will describe the use of DP acutely after cardiac procedures to help phrenic nerve recovery and weaning from the ventilator.

Methods: Prospective, nonrandomized, controlled, interventional trials under IRB approval at a single institution. DP involves laparoscopic diaphragm motor point mapping to identify the optimum site where stimulation will cause maximum diaphragm contraction. Two percutaneous intra-muscular electrodes are implanted in each hemi-diaphragm and diaphragm conditioning ensues with a programmed pacing unit to maximize diaphragm movement for respiration.

Results: Two patients were noted to have acute diaphragm dysfunction after difficult cardiac procedures with no radiographic visualized diaphragm movement and electromyographic evidence of phrenic nerve injury. Patients were implanted with DP within 14 days of injury. DP was utilized to not only monitor recovery but help wean the patients from mechanical ventilation.

Conclusion: This is the first report of DP being successfully used to replace mechanical ventilation in patients following cardiac surgery. Functional electrical stimulation has been shown to have trophic effect and implantation through neuroplastisty can help recovery of the damages phrenic nerves. The use of early DP with pressure support also decreased the peak airway pressures by preferentially ventilating the posterior lobes decreasing the likelihood of atelectasis and subsequent pneumonia. These finding support the early use of DP for patients with acute phrenic nerve dysfunction decreasing the significant morbidity of respiratory problems and potentially decreasing the usual year long process of phrenic nerve recovery.

DIAPHRAGM PACING IMPROVES SLEEP IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS

Gonzalez-Bermejo J, Morelot-Panzini C, Salachas, F, Redolfi S, Straus C, Becquemin M, Arnulf I, Pradat P, Bruneteau G, Ignagni A, Diop M, Onders R, Nelson T, Menegaux F, Meininger V, Similowski T.

Amyotrophic Lateral Sclerosis, 2012;13:44-54.

In amyotrophic lateral sclerosis (ALS) patients, respiratory insufficiency is a major burden. Diaphragm conditioning by electrical stimulation could interfere with lung function decline by promoting the development of type 1 muscle fibres. We describe an ancillary study to a prospective, non-randomized trial (NCT00420719) assessing the effects of diaphragm pacing on forced vital capacity (FVC). Sleep-related disturbances being early clues to diaphragmatic dysfunction, we postulated that they would provide a sensitive marker. Stimulators were implanted laparoscopically in the diaphragm close to the phrenic motor point in 18 ALS patients for daily conditioning. ALS functioning score (ALSFRS), FVC, sniff nasal inspiratory pressure (SNIP), and polysomnographic recordings (PSG, performed with the stimulator turned off) were assessed before implantation and after four months of conditioning (n _ 14). Sleep efficiency improved (69 _ 15% to 75 _ 11%, p _ 0.0394) with fewer arousals and micro-arousals. This occurred against a background of deterioration as ALSFRS-R, FVC, and SNIP declined. There was, however, no change in NIV status or the ALSFRS respiratory subscore, and the FVC decline was mostly due to impaired expiration. Supporting a better diaphragm function, apneas and hypopnoeas during REM sleep decreased. In conclusion, in these severe patients not expected to experience spontaneous improvements, diaphragm conditioning improved sleep and there were hints at diaphragm function changes.

CURRENT AND PRACTICAL UTILIZATION OF DIAPHRAGM PACING IN ALS/MND: FROM PILOT TRIAL EXPERIENCE TO FDA HUMANITARIAN DEVICE APPROVAL INDICATION FOR HELPING RESPIRATION

Onders RP, Katirji B, Elmo MJ, Kaplan C, Schilz R.

Platform Oral Presentation at the 22nd International Symposium on ALS/MND, Sydney, Australia, December 2, 2011

Background: Diaphragm pacing (DP) has been proven to be an acceptable alternative therapy to help with respiration in patients with ALS/MND receiving FDA approval in 2011. This report will review the experience of a single institution throughout the trials and highlight the utilization of DP in current clinical practice.

Objective: Review results of DP from trials and describe the 2011 evaluations of patients for suitability and implementation of DP.

Methods: Two sources of patients: 1- Prospective, nonrandomized, controlled, interventional trials under IRB and/or FDA approval for use of DP at a single institution; 2- Clinical use of DP for ALS following humanitarian use designation(HUD) implantation criteria which involves evidence of chronic hypoventilation(MIP less than 60cm H20, FVC less than 50% predicted, PCO2 greater than 45mm Hg or SaO2 less than 88% for 5 consecutive minutes during sleep) with stimulatable diaphragms as shown by radiographic volitional diaphragm contractions or neurophysiologic evaluation with phrenic nerve conduction studies.

Results: From 2005- 2009 during three prospective studies 66 subjects were enrolled with 52 being implanted. The key end result of these trials include: DP can be safely implanted ; survival with DP from onset is 4.7 years using Kaplan-Meir survival analysis with many patients still surviving; in a case match comparison patients who used DP and non-invasive ventilation (NIV) survived 16 months longer than those using NIV alone; and patients undergoing combined DP and PEG had a 0% thirty day mortality and 70% one year survival. From 2010-2011 in clinical practice 23 patients were evaluated with implantation occurring in 15 patients following the HUD criteria. Evaluations included pulmonary functions tests (FVC and MIP), arterial blood gases, fluoroscopic sniff test, phrenic nerve conduction studies and overnight pulse oximetry. Reasons for not implanting included: no evidence of hypoventilation(1), non-stimulatable diaphragms(4), excessive secretions where aspiration would to lead to death or tracheostomy before respiratory failure(2) and one patient declined after discussing end of life issues. Current practice includes discussion of end of life issues and cessation of pacing to allow natural death. 80% (12 out of 15) patients had simultaneous PEG and DP. Post-operative DP use involved 5 initial 30 minute sessions and then increased based on patient presumed benefits. DP is always utilized whenever NIV is used to prevent ensuing atrophy of the diaphragm from NIV suppressing diaphragm function. Ongoing DP adjustments are made according to the patients' need.

Conclusion: DP improves survival and delays tracheostomy ventilation. DP is easily integrated into clinical practice with the primary time of implantation at the time of a PEG. Combining both improves the safety of PEG alone and should decrease total health care cost from separate procedures and hospitalizations.

CURRENT TECHNIQUE OF LAPAROSCOPIC DIAPHRAGM PACEMAKER INSERTION

Eric M Pauli, MaryJo Elmo, Raymond P Onders

Video Abstract Summary:

Mechanical ventilators, while live saving, are associated with significant morbidity and a higy yearly cost. Diaphragm pacing stimulation (DPS) is designed to replace, delay or reduce the need for such mechanical ventilation. DPS provides diaphragm function in ventilator-dependent spinal cord injury (SCI) patients and maintains diaphragm function in respiratory-compromised patients with amyotrophic lateral sclerosis (ALS). This video provides an overview of our current technique of laparoscopic diaphragm pacemaker implantation as modified over the course of more than 500 implantation procedures and highlights differences in technique from previous written descriptions of the method.

DIAPHRAGM PACING: HELPING PATIENTS BREATHE

Mary Jo Elmo BSN, MSN, CNP, Cynthia Kaplan BSN, MSN, Raymond P. Onders MD. FACS

Summer 2012 peer-reviewed excellence in Life Care Planning since 2006 V o l . X I I No. 2

Diaphragm pacing is new technology that can be an alternative or adjunctive therapy to positive pressure ventilation. An electrical stimulus is delivered to surgically implanted electrodes that cause diaphragm contraction. Currently, diaphragm pacing is used in patients who have spinal cord injury or amyotrophic lateral sclerosis. Pacing has both physical and social advantages in both patient populations. Unique to the spinal cord patients, pacing provides a sense of freedom and independence. In the amyotrophic lateral sclerosis population pacing is one of the few therapies shown to prolong survival. The implantation procedure has been shown to be safe. Care and use of the device is easily learned.

INTRAMUSCULAR DIAPHRAGM PACING FOR RESPIRATORY SUPPORT IN TETRAPLEGICS: CURRENT WORLDWIDE STATUS IN 2012. WHY ISN'T AVAILABLE TECHNOLOGY UTILIZED?

Onders RP, Elmo MJ, Kaplan C.

Presented at the Interdependence Global SCI Conference, Vancouver, Canada, May 17th, 2012.

Objective: Direct phrenic nerve pacing to replace ventilators for tetraplegics was initially developed in the 1960's but through the 2000's less than 5% of the estimated annual 300-500 eligible patients utilized the available devices in the United States (US) (HCUPnet database 1997-2004). Intramuscular diaphragm pacing (DP) was first implanted in 2000, European approval in 2007 and US in 2008.

Design: Review DP patients world-wide and published literature in 2010.

Participants/methods: All ventilator dependent spinal cord injured (SCI) patients who were implanted with DP per country and per state in absolute numbers.

Results: A total of 65 DP implants were done in 9 countries: Canada, France, Norway, Spain, Switzerland, Australia, Saudi Arabia, Jordan and the US. The US total was 43 in 13 states with the majority in only 5 states- Ohio, Colorado, Texas, Illinois and Georgia. In Canada in 2010 all DP implants were done in one province, British Columbia. In 2011, another province implanted DP only when the injured patient's First Nation local community guaranteed payment. Nine children were implanted worldwide with the youngest age 2. DP technology is being utilized in other respiratory problems and at the largest US site SCI accounts for less than 30% of DP implants. There were 5 peer-reviewed publications on phrenic or DP in 2010 all with positive results.

Conclusion: Published research continues to show the clinical benefit of removing patients from mechanical ventilation yet there is still an overwhelmingly low adoption of phrenic or diaphragm pacing. A disparity of technology utilization exists between countries, states or provinces. In the US, individual state Medicaid programs are an obstacle. Recent reports of DP utilization by trauma surgeons early after injury will help expand this technology and decrease ventilator associated pneumonias, diaphragm dysfunction and length of stay. There is also growing experience that early DP implantation has neuroplasticity effects and can help recovery of phrenic motor neuron control and volitional breathing. Fortunately, the expanding use of DP in other diseases such as Amyotrophic Lateral Sclerosis (ALS) will maintain this option for SCI patients. In ALS, DP delays the need for a ventilator by 18 months which improves their quality of life.

SUCCESSFULLY TARGETING ALS/MND THERAPIES: THE DIAPHRAGM PACING EXAMPLE OF UTILIZATION OF THE FDA HUMANITARIAN PATHWAY FOR EXPEDIENT AND COST EFFECTIVE ACCESS TO NEW THERAPIES IN AN ORPHAN DISEASE

Onders RP, Ignagi A, Fritz M.

Poster presentation at the 22nd International Symposium on ALS/MND, Sydney, Australia, November 30th to December 2nd, 2011

BACKGROUND: Diaphragm Pacing (DP) has been developed as a treatment for respiratory insufficiency in persons with ALS based on the successful use in high level spinal cord injury. The U.S. FDA Humanitarian Use Device (HUD) designation provides a regulatory pathway to bring devices to market in orphan diseases. Once designated as a HUD, evidence may be presented, to FDA, of safety and "probable benefit" for Humanitarian Device Exemption (HDE) market approval. DP has successfully navigated these pathways for ALS.

OBJECTIVES: Review the entire regulatory pathway to bring a novel new therapy for ALS/MND.

METHODS: Retrospective analysis of all of the regulatory pathways to commercialize DP.

RESULTS: DP initial success in pure upper motor neuron (UMN) of SCI led to the initial FDA investigator initiated investigational device exemption (IDE) and IRB applications which began in 2003 with approval in 2004 for the pilot trial with first surgical implantation in 2005. Success of the pilot trial led to the FDA approved multi-center pivotal trial with first implantations in 2007. Prior to start of the trial the IDE was transferred to a commercial entity (Synapse Biomedical) and funding for the trial was raised through venture capital. The final one year patient follow-up occurred at the end of 2009 which allowed statistical analysis. There was a delay in obtaining HUD designation which needed a medically plausible subset of less than 4,000 US patients a year until an agreement was reached in 2010. HDE application was approved for probable benefit in ALS patients in 2011.

DISCUSSION: The HDE pathway is rarely used in the U.S. compared to other means. In 2009 there were approximately 3,000 510(k) approvals, 15 original Pre-Market Approvals (PMA)'s and only 1 HDE approved. With the average total cost, from concept to approval, of a higher-risk PMA device of US$94 million; the return on investment for a company to develop devices in orphan diseases is severely limited.

CONCLUSIONS: DP is the first humanitarian device to be approved for ALS; it may also be the first device with an explicit indication for ALS. DP has been shown, using the HDE pathway, to be safe and of benefit in the treatment of respiratory insufficiency in ALS. The HDE pathway is a cost effective means to bring therapies to market for ALS patients. The success of DP will allow more commercial entities to invest in developing new therapies to improve the quality of life in patients with ALS/MND.

SURGICAL THERAPIES IN ALS/MND: OPTIMIZING TECHNIQUES TO IMPROVE PATIENT CARE

Elmo MJ, Kaplan C, Onders R, Katirji B.

Allied Health Care Presentation at the 22nd International Symposium on ALS/MND, Sydney, Australia, November 29th, 2011

Background: There are two surgical therapies that have been shown to either improve quality of or prolong life in ALSMND: percutaneous endoscopic gastrostomy (PEG) and diaphragm pacing (DP). Twenty five percent of patients present with bulbar symptoms with approximately 80% developing bulbar dysfunction. Malnutrition is associated with poor survival. Guidelines suggest PEG placement with a 10% weight loss or, because of associated increase mortality, before FVC falls below 50%. Less than 50% of patients, recommended to have PEG, receive it. Alteration of body image is a major factor in PEG refusal. Respiratory failure is the leading cause of death in ALSMND. Guidelines recommend tracheostomy mechanical ventilation (TMV) when non-invasive ventilation (NIV) fails yet this therapy is deemed unacceptable by most patients with less than 5% of US and European patients choosing TMV. DP is a new FDA approved therapy in ALS that aids respiration.

Objective: Describe how early discussion of surgical therapies allows improved planning and decision making for patients with ALS/MND and their families. DP prolongs life, improves survival during PEG placement, delays the need for TMV and can help acceptance of PEG by offering simultaneous insertion of a low profile feeding tube.

Programme Description: Using case studies, illustrate our short and long term management of patients undergoing DP and low profile feeding tube surgical therapies.

Clinical Outcomes: Data from DP clinical trials has been previously reported. In summary, patients who used DP and NIV survived 16 months longer than those using NIV alone; and patients undergoing combined DP and PEG had a 0% thirty day mortality and 70% one year survival. Knowledge gained from the clinical trial has been implemented into our standard practice. Only those patients showing stimulatability of the diaphragm by fluoroscopy or phrenic nerve testing were offered DP. All patients receiving PEG requested buttons prompting a change from standard PEG to direct placement of low profile feeding gastrostomy. Pacer usage was individualized based on pre-implantation status. As their disease progressed, pacing time and power were adjusted. To date, there is a 100% 6-month survival. DP has delayed death or need for TMV in this group.

Recommendations to the Field: DP prolongs life, delays need for TMV and makes PEG placement safer. DP should be offered and the use of an immediate low profile button for increased patient satisfaction and acceptance of enteral feeding in ALS.

OUTCOMES OF SIMULTANEOUS ABDOMINAL WALL RECONSTRUCTION AND ENTEROCUTANEOUS FISTULA TAKEDOWNS

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Objective: The surgical management of enterocutaneous fistulas(ECF) in the setting of large abdominal wall defects can be challenging. We aimed to review our experience with simultaneous single-stage ECF takedown and abdominal wall reconstruction(AWR).

Methods: Using a prospectively collected database, patients requiring surgical management of an ECF and AWR over a five-year period were reviewed. Outcome measures included hernia recurrence and surgical site infection(SSI).

Results: Thirty-seven patients(mean age 58.6 years, median ASA 3, mean BMI 31.3 kg/m2) underwent ECF repair/AWR. Ten(27%) had concomitant synthetic mesh infection. Mean defect size was 426±192 cm2. Thirty-three(89%) patients required components separation to achieve fascial closure. Thirty-six(97%) patients had biologic mesh to reinforce the repair, while one patient had primary repair alone. Post-operatively, 24(65%) patients developed a SSI(8-superficial; 8-deep; 8-organ space). Seven(19%) patients required surgical debridement and 7(19%) IR drain placement for intra-abdominal abscesses. Three patients developed an early anastomotic leak. One patient died from an anastomotic leak. A patient developed and anastomotic stricture and recurrent ECF requiring re-operation 4-months after initial repair. With mean follow-up of 20-months, hernia recurrence rate was 32%(n=12). Two patients had recurrent hernias repaired while remaining recurrences were small and asymptomatic, not requiring repair.

Conclusions: The simultaneous reconstruction of ECF and complex abdominal wall defects resulted in the successful single-staged management of these challenging cases in nearly 70% of patients in this series. Despite the high rate of SSI, the single-staged reconstruction of the abdominal wall during ECF takedowns can result in a durable repair in this morbid group of patients.

ESOPHAGEAL STENTS DELAY, BUT DO NOT PREVENT, STRICTURE FORMATION FOLLOWING CIRCUMFERENTIAL ENDOSCOPIC SUBMUCOSAL DISSECTION IN A PORCINE MODEL

Eric M Pauli, Yuhsin V Wu, Steve J Schomisch, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Circumferential endoscopic esophageal submucosal dissection (EESD) for high grade dysplasia or early carcinoma is less-invasive than esophagectomy and potentially curative. However, aggressive stricture formation has limited its clinical application. We hypothesized that placing a self-expanding plastic stent (SEPS) after EESD would prevent stricturing.

Methods: Ten pigs (5 control, 5 SEPS) were utilized. Under anesthesia, an endoscopic band ligator and snare was used to incise the mucosa. An 8-10cm circumferential mucosal segment was excised from the muscularis. In the SEPS group, a 18x120mm fully-covered silicone stent (Polyflex, Boston Scientific) was deployed for 3 weeks. Esophageal dimensions were measured via weekly barium swallow. Animals were followed clinically and euthanized when the stricture exceeded 80%. A blinded pathologist evaluated histology.

Results: The control group rapidly developed strictures; no animal survived beyond week 3. At 2 weeks post EESD, the control group had a statistically significant decrease in esophageal diameter compared to the SEPS group (77.7 vs. 0.0%, $p<0.008$). However, 1 week after stent removal, the SEPS group had a significant reduction in esophageal diameter (80.5% vs. 0.0%, $p<0.008$) compared to before removal. Survival in the SEPS group was significantly longer than in control animals (4.8 vs. 2.4 weeks, $p<0.001$). All SEPS animals developed clinically significant strictures after stent removal. The SEPS group demonstrated significantly fewer PMNs ($p=0.026$) in the stricture zone.

Conclusions: Placement of a SEPS significantly delays stricture formation following circumferential EESD, but does not alter maximal luminal narrowing or proximal dilation after stent removal.

4:1 FASCIAL CLOSURE: UNDERSTANDING OPTIMAL LAPAROTOMY CLOSURE TECHNIQUE

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Development of incisional hernias following primary celiotomy occurs in as many as 25% of patients. Factors that contribute to the formation of these hernias include patient characteristics and surgical technique. Given most patient characteristics are not modifiable by the surgeon, maximizing surgical technique may be the most important factor that surgeons can modify to reduce incisional hernia formation. Although not frequently recognized, available literature supports a method of wound closure that utilizes a suture length to wound length ratio of at least 4:1. In this video, we outline this technique of 4:1 fascial closure while providing a stepwise approach to the elements involved allowing easy reproducible results. Included in these elements are the choice of suture and needle, mastering the self-locking anchor knots and maximizing the suturing technique.

A FEASIBILITY AND DOSIMETRIC EVALUATION OF ENDOSCOPIC RADIOFREQUENCY ABLATION FOR HUMAN COLONIC AND RECTAL EPITHELIUM IN A TREAT AND RESECT TRIAL

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

Surgical Endoscopy. 25(2):491-6, 2011 Feb.

Background: Endoscopic radiofrequency ablation (RFA) has been used effectively for ablation of foregut disorders and also may have a role in treating colonic pathology. This study aimed to assess the feasibility of delivering RFA to locations within the colon and to determine a range of safe treatment parameters.

Methods: Patients undergoing left hemicolectomy or proctocolectomy were evaluated. Focal RFA using a colonoscope-mounted device was delivered to normal segments of the colon and rectum within the planned surgical resection specimen. Endocopic accessibility and feasibility of delivering heat energy to the colon and rectum were assessed as well as the maximum incurred histologic depth of ablation in relation to the number of applications (2 or 4) and the energy density (12, 15, or 20 J/cm2).

Results: A total of 51 ablation zones in 16 patients had available histopathology. None of the sites receiving two applications demonstrated serosal layer alteration compared with 15% of the sites receiving four applications ($p = 0.11$). Muscularis propria alterations were seen in 25% of the two-application sites and 63% of the four-application sites ($p < 0.05$). Increasing energy density from 12 to 20 J/cm2 did not correlate with a deeper ablation effect.

Conclusions: Endoscopic RFA is capable of delivering therapy to the distal colon. Injury is limited to the muscularis propria or less depth when no more than two ablations are applied regardless of the energy density used. Based on these feasibility and dosimetry results, the authors will continue investigation using these and smaller energy doses to initiate trials ultimately with patients who have suitable mucosal and submucosal disorders of the lower gastrointestinal tract including chronic, nonulcerated hemorrhagic radiation proctitis and angiodyplasia.

DO FEWER PORTS REDUCE PAIN OR IMPROVE COSMETIC OUTCOME AFTER LAPAROSCOPIC CHOLECYSTECTOMY?

Eric M Pauli, David M Krpata, Jeffrey M Marks, Raymond P Onders

Objective: Recent advancements in single-port laparoscopy offer theoretical advantages of reduced pain and improved cosmesis. We hypothesized that reducing the number of ports for laparoscopic cholecystectomy to three (3PLC) would result in reduced pain and improved cosmesis while avoiding the technical challenges posed by single-port surgery.

Methods: Data were culled from the standard cholecystectomy arm of a prospective, multicenter trial of single-incision versus standard 4-port laparoscopic cholecystectomy (4PLC). 3PLC or 4PLC was determined by surgeon practice patterns. Data included patient demographics and operative information. Pain (worst and average) was assessed at intervals over the first post-operative month. Cosmetic scoring was performed at intervals over 12 months.

Results: Eighty patients (63 4PLC, 17 3PLC) were included. Patient characteristics and pre-operative pain scores were similar between groups. 3PLC had a significantly shorter operative time than 4PLC (34.3 vs. 48.1 min, p=0.003) and a lower average pain scores on post-operative day one (3.47 vs. 4.66, p=0.014). At all other times (Day 0, 3, 5, 14, 30), worst and average pain scores were similar. The cosmetic scores demonstrated no significant differences between the groups at 3 and 12 months (p=0.21 and p=0.69 respectively).

Conclusions: In this non-randomized trial, 3PLC appears to offers a safe alternative to 4PLC and may reduce pain on the first post-operative day. Pain scores were identical at all other times. Shorter operative times in the 3PLC group can be explained by reduced numbers of ports to place and to close. Cosmesis scoring did not favor 3PLC over 4PLC.

DESIGN AND INITIAL IMPLEMENTATION OF HERQLES: A HERNIA RELATED QUALITY OF LIFE SURVEY TO ASSESS ABDOMINAL WALL FUNCTION

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Introduction: Success of a surgical intervention is often measured by hard clinical outcomes. In ventral hernia repair (VHR) these include wound morbidity and hernia recurrence. These outcomes fail to account for a surgical interventions' effect on a patient's quality of life (QofL) which is an equally important outcome measure following surgery. Our objective was to create a disease-specific QofL instrument to assess the impact of VHR on abdominal wall function.

Methods: A panel of four general surgeons constructed a 16 question QofL survey tool. Patients presenting for elective VHR completed the survey. Rasch modeling was used to evaluate the items; fit statistics, person-item mapping, separation index and reliability were examined. Associations between baseline characteristics and QofL were assessed.

Results: Eighty-eight patients completed the survey prior to assessment for VHR. Mean age was 57.2 years(± 12.4), mean ASA was 2.8(±0.5), and mean BMI was 34.9 kg/m2(±9.3). Comorbidities included: 43% diabetics, 19% smokers, 18% COPD, and 11% immunosuppressed patients. Based on Rasch modeling, 14 of 16 items showed ordinal response patterns. The 2 items showing non-ordinal response patterns were eliminated from further analysis. The 14 items retained have good internal consistency reliability (0.86) and separation index (2.52). On a 0-100 point scale, mean QofL score was 47.2 ±15.6. Patients with higher grade hernias had a lower HerQLes scores (p=0.06). Patients with an active smoking history had lower baseline QofL on average (p=0.03). Other patient characteristics did not appear to be associated with baseline QofL (p>0.2).

Conclusions: Quality of life is an important component of surgical management of ventral hernias. We have created a 14 question QofL survey, HerQLes, which is reliable and valid. At baseline, patients with more complex hernias tended to have a lower QofL. HerQLes is a valuable tool to assess abdominal wall functional improvements after VHR.

LEVOTHYROXINE REPLACEMENT DOSAGE DETERMINATION FOLLOWING THYROIDECTOMY

Judy Jin, M.D., Matthew Allemang, M.D., Christopher R. McHenry, M.D.

Background: The goal of this study was to identify a simple and effective way of calculating levothyroxine doses for postsurgical hypothyroidism.

Methods: Levothyroxine dosage was calculated using a weight (μg/kg) based formula for patients who underwent thyroidectomy for benign disease from 2001-2011. Other formulas utilizing age gender, ideal body weight, body mass index and body surface area were also evaluated .

Results: 404 patients were included: 85% were women. The mean initial levothyroxine dosage was 1.4 μg/kg, which resulted in TSH normalization in 59%, suppression in 23% and elevation in 18% of patients. After dose adjustments, the mean therapeutic levothyroxine dosage following total thyroidectomy and lobectomy were 1.5 μg/kg and 1.3 μg/kg. A regression model incorporating other patient factors did not produce a more reliable dosing regimen.

Conclusion: A 1.5 and 1.3 mcg/kg dosage calculation based on actual weight is currently the best estimation for levothyroxine replacement therapy following thyroidectomy.

DOES NEGATIVE PRESSURE THERAPY REDUCE WOUND INFECTIONS FOLLOWING CONTAMINATED VENTRAL HERNIA REPAIR?

David M Krpata, Eric M Pauli, Arielle E Kanters, Yuri W Novitsky, Michael J Rosen

Background: Repair of large ventral hernias in the presence of bacterial contamination has a high rate of surgical site infections (SSI). Recent clinical and laboratory studies suggest that negative pressure therapy (NPT) on closed surgical incisions may reduce the risk of SSI in high risk populations. We hypothesized that NPT would reduce the risk of SSI in patients undergoing contaminated ventral hernia repair.

Hypothesis: We hypothesized that NPT would reduce the risk of SSI in patients undergoing contaminated ventral hernia repair.

Methods: We retrospectively reviewed our prospectively collected database for patients undergoing Grade 3 (potentially contaminated) and Grade 4 (infected) large ventral hernia repairs with or without NPT. Patients with fistulae or undergoing anterior component separation were excluded. All patients underwent primary wound closure. In the NPT group, a vacuum dressing (VAC, KCI, San Antonio, TX) was placed over the closed midline wound. Primary outcome measure was SSIs at 30 days post-op.

Results: There were 119 patients identified for evaluation (70 standard wound dressing (SWD), 49 NPT). The groups were similar in age, sex, body mass index, comorbid conditions (chronic obstructive pulmonary disease, diabetes mellitus, immunosuppressive medications, steroid use or smoking) or number of prior abdominal surgeries or herniorrhaphies. The SWD group had a higher American Society of Anesthesiologists (ASA) Score than the NPT group (3.0 vs 2.8 $p=0.01$). Groups were similar in hernia defect size and operative time. There was no difference in the 30 day SSI rate between the two groups (25.8% SWD vs 20.4% NPT $p=0.50$) or in the distribution of major and minor SSIs (SWD: 6 major, 12 minor vs NPT: 2 major/8 minor; $p=0.56$). Factors associated with an increased risk of SSI included ASA ($p=0.02$), BMI ($p=0.05$), Defect Area ($p<0.01$), diabetes mellitus ($p=0.01$), and OR time ($p<0.01$).

Conclusions: In this retrospective, non-randomized study, the use of NPT in the setting of closed surgical incisions after potentially contaminated or infected large ventral hernia repair did not reduce 30 day SSIs. Although prophylactic NPT has reduced wound morbidity in some surgical populations, it does not appear to offer the same improvement in wound morbidity for high risk contaminated and potentially contaminated cases of open ventral hernia repair.

WHAT'S IN YOUR OPERATIVE NOTE? A REPORT ON THE INACCURACIES OF OPERATIVE DICTATIONS IN PATIENTS UNDERGOING VENTRAL HERNIA REPAIRS WITH MESH

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Introduction: Given the high rate of failures of ventral hernia repairs (VHR), the re-operative surgeon can obtain critical information as to what has been previously preformed through review of the operative report. Accurately documenting hernia characteristics, intra-operative findings, mesh selection and location are important points to consider. . We aimed evaluate the rate and extent of inaccuracies in VHR operative reports in patients undergoing recurrent VHR.

Methods: All patients undergoing recurrent VHR at a tertiary care Hernia Center were identified. Those patients with an operative report from an OSH on file were included and retrospectively reviewed. OSH operative notes were reviewed for various integral operative documentation details. Intra-operative findings were then compared to the data from OSH notes, particularly with respect to mesh and technical nuances.

Results: Forty-eight patients had OSH operative notes from a previous VHR with mesh. Forty-eight(100%) operative reports included patient tracking information, pre- and post-operative diagnosis, list of procedure(s) and surgeons/assistants. Conversely, only 15(31.25%) included estimated blood loss, urine output and fluid input. Ventral hernia repair specific content was as follows: 38%(n=18) included the size of the hernia defect, 96%(n=46) included mesh type, 56%(n=27) included the size of the mesh, 81%(n=39) included the location of mesh placement and 98%(n=48) included the method of mesh fixation. When compared with our intra-operative findings, 8(17%) OSH reported incorrect mesh.

Conclusions: Incorrect and/or incomplete data in VHR operative reports may negatively impact subsequent repairs. We found over half of VHR operative notes were missing important herniorrhaphy-specific content. Although the exact clinical impact of operative report omissions/inaccuracies is difficult to establish, such errors clearly compromise subsequent pre-operative strategies in cases of failed repairs. Given an unacceptably high rate of deficiencies found in this study, we call for a consensus report to mandate specific content in the operative notes in patients undergoing VHR.

PERIOPERATIVE CONSIDERATIONS IN PATIENTS WITH ADRENAL TUMORS

Roy Phitayakorn, MD MHPE ,Christopher R. McHenry, MD

ABSTRACT: In this chapter the pre-operative, intraoperative, and postoperative management of patients with pheochromocytoma, aldosterone-producing adenoma, cortisol-producing tumors, and adrenal cortical carcinoma are reviewed. A detailed plan for preoperative assessment and medical optimization is discussed. The potential intraoperative and postoperative complications that occur in patients with an adrenal tumor are reviewed with emphasis on recognition, treatment and prevention. Recommendations for anesthetic management, intraoperative and postoperative monitoring, blood pressure management, laboratory analysis and medication adjustments are presented.

PER-ORAL ENDOSCOPIC MYOTOMY (POEM): TECHNIQUES FOR SUCCESSFUL SUBMUCOSAL DISSECTION

Eric M Pauli, Jeffrey M Marks, Jeffrey L Ponsky

Recently, a new endoscopic method for reducing lower esophageal sphincter pressure in achalasia patients, per-oral endoscopic myotomy (POEM), has been developed. The most difficult part of POEM is the submucosal dissection, which spatially separates the mucosa and the musculature and provides an intact tissue plane for secure esophageal closure. The purpose of this video is to review six technical pearls identified over our series of POEM patients that permit successful, reproducible creation of the submucosal tunnel.

PRE-PERITONEAL RETRO-MUSCULAR FLANK HERNIA REPAIR IN A CHILD

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Multiple approaches to flank hernias have been described including primary repair or mesh repair with either an on-lay or underlay. Here we present our approach to a large, symptomatic flank hernia in a 3 year old child with cystic fibrosis using a pre-peritoneal, retro-muscular sublay technique. The child's past surgical history was significant for a repair of 6 cm congenital umbilical hernia requiring biologic mesh reinforcement. Given the child's medical and surgical history we choose to perform an open pre-peritoneal retro-muscular flank hernia repair with wide mesh overlap using an ultra-lite macroporous synthetic mesh to maximize reinforcement of the weakened abdominal wall. In this video we highlight key aspects of our pre-peritoneal retro-muscular approach including the pre-peritoneal dissection which extends from the psoas muscle to linea alba, and placement of the mesh with wide overlap of the defect.

PROSPECTIVE, MULTICENTER TRIAL COMPARING PAIN AND COSMETIC OUTCOMES IN THREE PORT AND FOUR PORT LAPAROSCOPIC CHOLECYSTECTOMY

Eric M Pauli, David M Krpata, Melissa S Phillips, Jeffrey M Marks, Raymond P Onders

Introduction: Four port laparoscopic cholecystectomy (4PLC), first introduced in 1985, is now considered standard of care. Recent advancements in minimally invasive techniques (single port laparoscopy and natural orifice surgery) offer theoretical advantages of reduced pain and improved cosmesis. We hypothesized that reducing the number of laparoscopic ports for cholecystectomy to three (3PLC) would result in reduced pain and improved cosmesis while at the same time avoiding the technical challenges posed by more novel minimally invasive methods.

Methods: Data were culled from the standard cholecystectomy arm of a multicenter, prospective single blinded, randomized trial of single incision versus standard laparoscopic cholecystectomy sponsored by Covidien. 3PLC or 4PLC was determined by surgeon practice patterns. Data measures included patient demographics, operative time, estimated blood loss and procedure conversion (3PLC to 4PLC or 3PCL/4PLC to open). Pain (worst and average) was assessed at intervals over the first post-operative month and cosmetic scoring was performed by the patient at intervals over 12 months.

Results: Eighty patients (63 4PLC and 17 3PLC) were included in the study. Patient characteristics, including age, sex, body mass index (BMI) and pre-operative pain scores were similar between the two groups. No patients required conversion of technique and blood loss was similar between the two groups (p=0.32). There were no common bile duct injuries. 3PLC had a statistically shorter operative time than 4PLC (34.3 vs. 48.1 min, p=0.003). The 3PLC group had significantly lower average pain scores on post-operative day one (3.47 vs. 4.66, p=0.014), but on all other days (pre-discharge and Day 3, 5, 14, 30) worst and average pain scores were similar. The self-reported cosmetic scale demonstrated no significant differences between the 4PLC and 3PLC groups at 3 months and 12 months (p=0.21 and p=0.69 respectively).

Conclusions: In this non-randomized, blinded, prospective, multicenter trial of 3PLC vs. 4PLC, 3PLC appears to be safe with a similar blood loss and procedural conversion rate. Reduced operative times in the 3PLC group can be explained by surgeon proficiency and reduced numbers of ports to place and to close. 3PLC had significantly reduced average pain on the first post-operative day. Pain scores were identical at all other times assessed during the first month. Cosmesis scoring did not favor 3PLC over 4PLC. 3PLC offers a safe alternative to 4PLC and may reduce early post-operative pain. 3PLC can be safely utilized as a training bridge for the techniques involved in single incision or reduced-port cholecystectomy.

PROSPECTIVE RANDOMIZED CONTROLLED TRIAL OF FOUR PORT LAPAROSCOPIC CHOLECYSTECTOMY VERSUS SINGLE INCISION LAPAROSCOPIC CHOLECYSTECTOMY: FINAL ONE YEAR ANALYSIS

Eric Pauli, Melissa Phillips, Jeffrey Marks, Roberto Tacchino, Kurt Roberts, Raymond Onders, George DeNoto, Paraskevas Paraskeva, Homero Rivas, Arsalla Islam, Nathaniel Soper, Alexander Rosemurgy, Sajani Shah

Introduction: First reported in 1985, four port laparoscopic cholecystectomy (4PLC) is now considered standard of care. Single incision laparoscopic cholecystectomy (SILC), has favorable outcomes in small, non-randomized reports. We have previously presented the interim analysis of a prospective randomized multi-center, single blinded trial comparing SILC to 4PLC for feasibility and safety. This report describes the final analysis of these data with 12 month follow up.

Methods: Patients with biliary colic and documented gallstones or polyps, or with biliary dyskinesia (documented EF <30%) were randomized to SILC or 4PLC in a 1.5-to-1 ratio. Patients were blinded to the procedure for the first post-operative week. Data measures were operative time, estimated blood loss, adverse events and conversion to 4PLC or laparotomy. Pain, satisfaction and cosmetic scoring were performed by the patient at intervals over the 12 month follow-up.

Results: 200 patients were randomized to SILC (n=119) or 4PLC (n=81). Patient characteristics were similar, except for a significantly lower mean BMI in the SILC group (29 vs. 30.9, p=0.03). SILC had a statistically longer operative time than 4PLC (56.8 vs. 45.3 min, p<0.0001), but no difference in operative blood loss (p=0.75). One SILC patient required conversion to 4PLC for bleeding. There were no common bile duct (CBD) injuries. Each arm had one episode of retained CBD stone. There were no delayed CBD injuries or strictures noted. Nine SILC and one 4PLC patients developed port site hernias (p=0.052). Hernia formation in SILC patients was independent of BMI, incision length, wound infection and center procedure volume. Nine SILC and 2 4PLC experienced incision related complications (p=0.13). The SILC group had a statistically significant higher pain score (0.7 point difference) on days 3 and 5, but at one month they had significantly less pain (p=0.024). There was no difference, however, in the analgesic use between the two groups during all assessment days. The patient-evaluated scar rating photo questionnaire and the self-reported cosmetic scale significantly favored SILC. Satisfaction scores, however, were in favor of 4PLC at 3 and 7 days and 4 weeks for the SF-8 and SF-12 respectively, but all other time points did not reach statistical difference.

Conclusions: In this randomized, multicenter, blinded trial of SILC vs. 4PLC, SILC appears to be safe with a similar complication profile at 12 months. There was a trend toward more port site hernias in the SILC group, but this did not reach significance. BMI, incision length, infection and surgeon experience were not identified as risk factors for formation of hernias in SILC patients. Although analgesic use was comparable, pain scores were higher for SILC in the early post-op period but lower at one month. Lower early satisfaction scores for SILC may relate to these pain scores. SILC showed higher self-reported cosmetic results up to 12 months when compared to 4PLC. In addition, patient preference and cosmesis scoring strongly favored SILC. For patients preferring a more cosmetic outcome and accepting of higher incision related morbidity and increased early post-operative pain, SILC offers a safe alternative to the standard 4PLC.

REACHING THE UNREACHABLE: A NOVEL OVER THE SCOPE DEPLOYMENT METHOD FOR ENTERAL STENTS

Eric M Pauli, Steve J Schomisch, Jeffrey A Blatnik, David M Krpata, Juan S Sanabria, Jeffrey M Marks

Video Abstract Summary:

Over the last 2 decades, self-expanding enteral stents have gained popularity and shown therapeutic potential for strictures, obstructions, fistulae and perforations of the GI tract. Currently available stent delivery systems make deployment in many locations in the GI tract difficult, due to inability to traverse curves, or impossible due to deployment system limitations. In this video, we describe a novel over the scope deployment method for self-expanding enteral stents that permits delivery of a wide variety of stent to locations unreachable by currently available delivery methods.

DEVELOPMENT OF A ROBUST STRICTURE MODEL TO ASSESS THERAPEUTIC INTERVENTIONS FOLLOWING CIRCUMFERENTIAL ENDOSCOPIC ESOPHAGEAL SUBMUCOSAL DISSECTION

Eric M Pauli, Steve J Schomisch, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Circumferential endoscopic esophageal submucosal dissection (EESD) for high grade dysplasia or early cancer provides an intact specimen for histology, offers less-invasive therapy than esophagectomy and potentially allows one-step en bloc eradication of Barrett's esophagus. As such, the technique holds potential for staging, treating and preventing esophageal cancer. However, aggressive stricture formation after EESD has limited its clinical use. We hypothesized that an in vivo esophageal stricture model could be developed to assess endoscopic interventions designed to prevent stricture formation following EESD.

Methods: Five swine were utilized in this study. Under anesthesia, a flexible endoscope with a band ligator and snare was used to circumferentially incise the mucosal layer 20 cm proximal to the lower esophageal sphincter. An approximately 10 cm circumferential segment of tissue was dissected free from the underlying muscle and excised using electrocautery and snare. Weekly barium esophagograms evaluated for reduction in esophageal diameter and assessed stricture length and proximal dilation. Animals were followed clinically and were euthanized when the stricture exceeded 80% and they were unable to gain weight (despite high-calorie liquid diet). A blinded pathologist evaluated EESD and necropsy specimens.

Results: Resected specimens ranged from 90-110 mm in length. Histology confirmed uniform en bloc mucosal resection down to the superficial submucosa. All five animals rapidly developed strictures following EESD. At one week, animals demonstrated a 62.2±12.9% reduction in luminal diameter, longitudinal shortening to 77.6±12.4% of the original resected length with dilation in the proximal esophagus to 128±6.2% baseline diameter. By two weeks, animals demonstrated a 77.7±12.1% reduction in luminal diameter, longitudinal shortening to 62.7±12.3% of the original resected length with dilation in the proximal esophagus to 174.8±27.3%. Based on criteria, no animal survived beyond the third week of study. There was no correlation between resected specimen length and the degree of luminal narrowing or survival. Stricture zone histology showed unepitheliazed submucosa with abundant PMNs, fibrosis and neovascularization.

Conclusions: We describe the successful development of an esophageal stricture model. EESD in the porcine esophagus removes specimens of uniform length and depth without damaging the underlying muscule. Circumferential EESD results in clinically significant stricture formation within weeks. Esophagograms demonstrated uniform reduction in luminal diameter in the area of resection with concomitant proximal esophageal dilation. Histology confirmed the presence of inflammation and fibrosis. Future areas of investigation will focus on endoscopic methods to alleviate or prevent stricture formation following EESD.

DOES PRE-SOAKING SYNTHETIC MESH IN ANTIBIOTIC SOLUTION REDUCE MESH INFECTIONS? AN EXPERIMENTAL STUDY

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Background: Prosthetic mesh infection is one of the most challenging complications after hernia repair. One proposed method of reducing infection rates is to preemptively soak meshes in antibiotic solution prior to implantation; however, little data is available to support this practice. In this study, we evaluate the efficacy of soaking mesh in antibiotics to prevent prosthetic infection in an animal model of clean-contaminated ventral hernia repair (VHR).

Study Design: Rats underwent an acute VHR with one of four synthetic meshes (monofilament polypropylene (SoftMesh), composite monofilament polypropylene (Ventralight), multifilament polyester (Parietex TET), or composite multifilament polyester (Parietex PCO)). Prior to implantation, mesh was soaked in saline or 10 mg/ml of Vancomycin for 15 minutes. Following implantation, meshes were contaminated with 104 CFU of MRSA bacteria. Thirty-days after implantation, mesh samples were cultured and evaluated under scanning electron microscope for biofilm formation.

Results: Pre-soaking meshes significantly improves bacterial clearance in composite meshes and multifilament polyester mesh. Bacterial clearance was as follows for all meshes (saline-soaked v vanco-soaked): Parietex PCO (0% v 56%, p= 0.006), Parietex TET (0% v 50%, p= 0.01), Ventralight (20% v 78%, p=0.012) and SoftMesh (70% v 80%, p= 0.6). MRSA biofilm formation was consistent with bacterial growth.

Conclusion: Soaking multifilament and composite mesh in Vancomycin solution prior to implantation reduces MRSA bacterial growth. These findings suggest that the clinical implementation of soaking these meshes in antibiotic solution prior to implantation may reduce the risk of mesh infections in clean-contaminated cases and further investigation with human trials should be performed.

STENT MOUNTED BIOLOGIC MESH DOES NOT PREVENT STRICTURE FORMATION FOLLOWING CIRCUMFERENTIAL ENDOSCOPIC ESOPHAGEAL SUBMUCOSAL DISSECTION IN A PORCINE MODEL

Eric M Pauli, Steve J Schomisch, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Advanced esophageal dysplasia and early cancers have traditionally been treated with esophagectomy. Unfortunately, modern tissue ablation technique may undertreat and do not permit histological analysis. Endoscopic esophageal submucosal dissection (EESD) offers a less-invasive therapy and provides an intact specimen for assessment, but aggressive stricture formation after EESD has limited its application. We hypothesized that placement of a stent mounted biologic mesh immediately after circumferential EESD would prevent stricture formation.

Methods: Fourteen pigs (5 controls, 5 porcine submucosal mesh (PSM), 4 porcine dermal mesh (PDM) were utilized. Sample size calculations indicated that 5/group would detect a 25% stricture reduction ($p=0.05$ power of 0.80). Under anesthesia, an endoscope with band ligator and snare was used to incise the mucosa 20 cm proximal to the lower esophageal sphincter. A 7-10 cm circumferential segment of tissue was dissected free from the muscle and excised. In the mesh groups, tubularized PSM (Biodesign, Cook Medical) or PDM (Strattice, Lifecell) mounted on a 18/21 x 120 mm silicone stent (Polyflex, Boston Scientific) was deployed. Weekly barium esophagograms evaluated for percent reduction in diameter and proximal dilation. Stents were removed at 3 weeks. Animals were followed clinically and euthanized when the stricture exceeded 80% and were unable to gain weight on a high-calorie liquid diet. A blinded pathologist evaluated histology.

Results: The control group rapidly developed esophageal strictures; no animal survived beyond the third week of study. At two weeks post-EESD, both mesh groups had significant reductions in stricture diameter (77.7 vs 0.0% (PSM and PDM $p=0.008$) and degree of proximal dilation (175 vs 114 PSM vs 106% PDM $p\leq0.003$) compared to controls. However, one week post stent removal both mesh groups had a significant reduction in lumen diameter compared to before removal (PSM 86.5% $p=0.008$, PDM 94.4% $p=0.029$ vs 0.0%). Survival in the mesh groups was significantly longer than in the controls (4 weeks (PSM and PDM) vs 2.4 $p\leq0.016$). However, all mesh animals ultimately developed clinically significant strictures one week after stent removal. Histology demonstrated no differences between the resected specimens and failed to identify mesh integration.

Conclusions: Circumferential EESD quickly results in clinically significant strictures within three weeks. The placement of stent mounted biologic mesh significantly delays the time of clinical deterioration from 2.4 to 4 weeks, but does not minimize the maximum degree of luminal narrowing or proximal esophageal dilation after stent removal. No mesh integration was seen on pathology, suggesting that the stent, not the mesh, was responsible for delayed stricture formation. Future areas of investigation will focus on improving mesh integration.

SURGICAL ANATOMY AND MORPHOLOGIC VARIATIONS OF UMBILICAL STRUCTURES

Amir H Fathi MD, Hooman Soltanian MD, Alan A Saber Alan MD

The umbilicus is the main access route to the abdominal cavity in laparoscopic surgeries. However, its anatomical configuration is rarely studied in the surgical and anatomical literature. With introduction of laparoendoscopic single-site surgery and considering the significant number of primary and postoperative umbilical hernias, we felt the necessity to comprehensively study the umbilical structures and analyze their protective function against hernias. Twenty-four embalmed cadavers were studied in the anatomy laboratory of Case Western Reserve University. Round hepatic, median and medial ligaments, umbilical ring, umbilical and umbilicovesicular fasciae, and pattern of attachment to the ring were dissected and measured. Mean age was 82.1 years, ranging between 56 and 96 years, with a male-to-female ratio of 1.4:1. Ninety-two per cent was white and 8 per cent black adults. According to shape and attachment pattern of ligaments, umbilical ring is classified into five types. Hernia incidence was 25 per cent. All hernia cases lacked the umbilical fascia and the round hepatic ligament was not attached to the inferior border of the ring. The umbilical ring and its morphologic relation with adjacent ligaments are described and classified into five types. In contrary to sparse existing literature, we propose that umbilical fascia is continuation and condensation of umbilicovesicular rather than transversalis fascia. It was absent in cadavers forming conjoined median and medial ligaments with a single insertion site to the ring. Round ligament insertion to the inferior border of the ring provides another protective factor. These two protective measures were absent in all the observed umbilical hernias.

TECHNETIUM-99M SESTAMIBI IMAGING: ARE THE RESULTS DEPENDENT ON THE REVIEWER?

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Background: Minimally invasive parathyroidectomy (MIP) is dependent upon accurate preoperative parathyroid localization. We hypothesized that surgeon recognition of subtle differences in radiotracer accumulation would increase the sensitivity of technetium-99m sestamibi imaging and result in more frequent use of MIP.

Methods: Technetium-99m sestamibi scans completed at our institution for patients who underwent resection of a solitary parathyroid adenoma were reviewed by a surgeon and a radiologist who were blinded to patient identifying information, prior scan interpretation, and results of the operation. For each scan, the reviewer determined whether there was abnormal radiotracer accumulation and documented its location. Results were correlated with outcome of operation and final pathology. Blinded interpretations of the surgeon and radiologist were compared to each other and to the original radiologic interpretation.

Results: From 1994 to 2009, 274 patients with primary hyperparathyroidism (HPT) had sestamibi imaging prior to parathyroidectomy; 149 patients with a single adenoma underwent curative parathyroidectomy and had scans available for review. Seventeen radiologists who reviewed an average of 11 ± 14 scans (range = 1–61) completed the original interpretations of the sestamibi imaging. Sensitivity of sestamibi imaging was 86% for the blinded surgeon compared to 75% for the blinded radiologist and 69% for the original radiologists ($P < 0.05$). There was no difference in the false positive rates (blinded surgeon = 5%, blinded radiologist = 5%, original radiologists = 5%, $P > 0.05$).

Conclusion: Radiologists were less likely to call a scan positive. Surgeon recognition of subtle anatomic asymmetry increases the sensitivity of sestamibi imaging and successful completion of MIP.

TECHNIQUE OF PER-ORAL ENDOSCOPIC MYOTOMY (POEM) FOR ACHALASIA

Eric M Pauli, Jeffrey M Marks, Jeffrey L Ponsky

Therapy for achalasia traditionally includes pneumatic balloon dilation, injection of botulinum toxin or surgical division of the muscles of the lower esophageal sphincter (Heller myotomy). Recently, a new endoscopic method for reducing lower esophageal sphincter pressure in achalasia patients, per-oral endoscopic myotomy (POEM), has been developed and is being performed clinically throughout the world and by surgeons in a number of centers in the United States. The technique utilizes a flexible endoscope to tunnel beneath the esophageal mucosa and divide the circular muscle fibers of the lower esophagus and upper stomach. The purpose of this video is to provide a technical overview of the POEM procedure, including pre-operative and post-operative management strategy.

THE ROLE OF TRANSCERVICAL THYMECTOMY IN PATIENTS WITH HYPERPARATHYROIDISM

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Background: The most common location for supernumerary or ectopic parathyroid glands is the thymus.

Methods: A review of patients who underwent parathyroidectomy for hyperparathyroidism from 1990-2010 was completed to determine: indications for thymectomy, the yield of parathyroid tissue and outcome of therapy.

Results: 70 of 379 patients with hyperparathyroidism underwent parathyroidectomy and transcervical thymectomy. Intrathymic parathyroid tissue was present in 23 (33%) patients, including supernumerary glands in 8 (11%). Indications for thymectomy were: renal hyperparathyroidism 35 (50%) and primary hyperparathyroidism with: a missing inferior gland 20 (29%), an ectopic adenoma 9 (13%), hyperplasia 5 (7%) and carcinoma 1 (1%). Cure rates were similar (96% and 98 %, p=NS) and only transient hypocalcemia was higher (51% vs. 24%, $p<0.05$) following parathyroidectomy with thymectomy versus parathyroidectomy alone.

Conclusion: Transcervical thymectomy results in a high yield of parathyroid tissue and is essential for cure of selected patients with hyperparathyroidism.

THYROID INCIDENTALOMA

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Thyroid incidentaloma is defined as an unsuspected, asymptomatic thyroid lesion that is discovered on an imaging study or during an operation unrelated to the thyroid gland. Thyroid incidentalomas are most commonly detected on ultrasound, followed in frequency by computed tomography (CT) and magnetic resonance imaging (MRI), carotid duplex scanning and 2-18[F] fluoro-2-deoxy-D-glucose (FDG) positron emission tomography (PET). The incidence of carcinoma in incidentally discovered thyroid disease is not insignificant. There are significant shortcomings of CT, MRI and PET imaging of the thyroid gland. As result, a thorough sonographic evaluation of the thyroid gland should be performed in all patients with a thyroid incidentaloma, regardless of the radiographic features identified on the "non thyroid "imaging modality. A sonographically confirmed thyroid nodule should be managed in an identical fashion to a clinically apparent thyroid nodule.

UNIVARIATE ANALYSIS OF PAIN, QUALITY OF LIFE, AND COSMESIS SCORES FOR SINGLE INCISION AND STANDARD LAPAROSCOPIC CHOLECYSTECTOMY IN A MULTICENTER PROSPECTIVE RANDOMIZED TRIAL

Melissa Phillips, Jeffrey Marks, Roberto Tacchino, Kurt Roberts, Raymond Onders, George DeNoto, Paraskevas Paraskeva, Homero Rivas, Arsalla Islam, Nathaniel Soper, Alexander Rosemurgy, Sajani Shah

Introduction: Single incision laparoscopic cholecystectomy (SILC) was first described in 1997. Since its introduction, there is a paucity of data to show which patient population(s) will benefit most from this approach. The purpose of this study was to identify factors associated with positive outcomes including pain, self-evaluated cosmesis, and quality of life after SILC as part of a prospective, randomized, multicenter trial.

Methods: Inclusion criteria included biliary colic and documented gallstones or polyps, or those with biliary dyskinesia (documented EF < 30%). Patients were randomized to SILS versus 4PLC in a 1.5-to-1 ratio in a single blinded manner. Average and worst pain evaluation scores were collected on days 0, 1, 3, 5, 7, and 30. Satisfaction scores (Mental and Physical quality of life) were evaluated on days 1, 3, 5, 7, 14, and 30. Cosmesis scores were evaluated at weeks 1, 2, 4, 12, and 52.

Results: 197 patients were randomized to SILC (n=117) or 4PLC (n=80). We analyzed 5 factors, including gender, age, BMI, accrual from centers with >10 patients, and SILC approach. Univariate analysis showed female gender, younger age, and SILC to be significant predictors of increased overall worst postoperative pain scores within the first week, but none were significant by one month postoperatively (p=0.006-0.03). Patient-evaluated scar ratings up to 3 months post-op showed SILC to be a significant predictor of satisfaction (p=<0.0001), where gender, age, and BMI had no influence. Accrual of > 10 patients was associated with an improved one year scar self-evaluation score (p=0.05). When assessing quality of life (QOL), there is a trend to decreased physical QOL by SF-8 in the SILC group over the first week postoperatively. This becomes statistically significant (p=0.01) at two weeks with the SF-12, but this difference was lost by 1 month. Higher BMI improved the mental QOL at days 1 and 3 (p=0.03) but the effect was lost at later time points. Older age correlates with decreased mental QOL at 1 week (p=0.05), but at no other time points.

Conclusions: This prospective randomized trial shows that female gender, younger age, and single incision approach are correlated with increased pain. Also identified is an increased cosmesis scores with single incision cholecystectomy. Physical QOL scores are lower in the first two weeks after SILC, likely related to increased postoperative pain, but improve by one month. Patients who have a preference for a more cosmetic outcome and are willing to accept a potential increase in initial postoperative pain may find a benefit from single incision laparoscopic cholecystectomy.

MODIFIED HERNIA GRADING SCALE TO STRATIFY SURGICAL SITE OCCURRENCE AFTER OPEN VENTRAL HERNIA REPAIRS

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Introduction: The lack of a universally accepted classification system for incisional hernia repair has led to inconsistent reporting of ventral hernias repairs, the inability to compare various series, and the lack of appropriate risk adjusted stratification systems to evaluate surgical outcomes. This study evaluates the ventral hernia working group's grading scale to accurately predict SSO after open ventral hernia repair.

Methods: All open ventral hernia repairs performed at Case Medical Center were evaluated from a prospectively maintained database. Hernias were graded according to the VHWG grading scale, and patients were evaluated for the incidence of a SSO. The relationship between comorbidities, hernia defect characteristics, CDC wound classification and SSOs was also evaluated.

Results: 299 patients met inclusion criteria and were available for follow up. SSO was identified in 14% grade 1, 29% grade 2, 38% grade 3, and 49% grade 4 patients (p=0.003). However, Grade 3 patients with only a prior wound infection had a significantly different incidence of SSO than those with a violation of the GI tract and were actually more similar to Grade 2 patients. Likewise violation of the GI tract had a similar rate of SSO to Grade 4 patients. Finally, CDC wound classification also accurately predicted SSO across all levels of contamination.

Conclusion: Modification of the VHWG grading scale into a 3 level grading system would significantly improve the accuracy of predicting SSO after open ventral hernia repairs. Grade 2 patients should include those with comorbidities and prior wound infections. Grade 3 patients should be stratified based on CDC definitions of wound contamination. This modified grading scale would significantly improve outcomes reporting after open ventral hernia repair.

YIELD OF REPEAT FINE NEEDLE ASPIRATION BIOPSY AND RATE OF MALIGNANCY IN PATIENTS WITH ATYPIA OR FOLLICULAR LESION OF UNDETERMINED SIGNIFICANCE: THE IMPACT OF THE BETHESDA SYSTEM FOR REPORTING THYROID CYTOPATHOLOGY

Joy C. Chen, M.S., S. Carter Pace, M.D.**, Boris A. Chen, B.S.*, Amer Khiyami, M.D.**, Christopher R. McHenry, M.D.**

BACKGROUND: Atypia/follicular lesion of undetermined significance (A/FLUS) is a new category in the Bethesda System for Reporting Thyroid Cytopathology (BSRTC) for which repeat fine-needle aspiration biopsy (FNAB) is recommended.

METHODS: A retrospective review was completed to evaluate the impact of the BSRTC on management of nodular thyroid disease. Patients were divided into pre-BSRTC and BSRTC groups. A comparative analysis of cytopathologic diagnoses and rates of repeat FNAB and malignancy was completed.

RESULTS: aFNAB was performed in 730 patients, 337 pre-BSRTC and 393 BSRTC. There was a decrease in follicular/Hürthle cell neoplasm (FN/HCN) (9.5% vs. 3.6%, p=0.001) and no difference in malignancy rate (6.5% vs. 6.4%, p=1.0). Fewer operations (29% vs. 22%, p=0.02) and more repeat FNABs (3.9% vs. 11%, p<0.001) were performed in the BSRTC group. Sixty-one (16%) patients had A/FLUS, 57 with complete follow-up. Repeat FNAB in 26 patients was benign (11), A/FLUS (6), suspicious for malignancy (4), FN/HCN (2) and nondiagnostic (3). Thirty-three (58%) patients underwent thyroidectomy and 6 (18%) were diagnosed with cancer.

CONCLUSIONS: The BSRTC resulted in more frequent repeat FNAB, fewer thyroidectomies and no change in malignancy rate. In patients with A/FLUS, repeat FNAB was definitive in 65% and the rate of malignancy was 18%.

Section 5

Oral and Maxillofacial Surgery

ASSESSING THE BONE QUALITY OF GRAFTED VS. NON-GRAFTED EXTRACTION SITES WITH CONE BEAM COMPUTER TOMOGRAPHY IMAGING

PI: Faisal A. Quereshy, MD, DDS, FACS Co-Investigator: Tyman Loveless

Specific aims: Tooth extraction leads to a significant amount of resorption of the alveolar ridge. The bone resorption process begins immediately following extraction, leading to an average 40-60% decrease in the horizontal and vertical dimensions of the alveolar ridge, during the first 2 years. The majority of postextraction bone loss is more significant on the buccal aspect of the alveolar ridge and occurs mainly within the first 3 months.1 In a recent study Scrop et., al. assessed bone formation following extraction of single tooth using study casts and standardized periapical radiographs. The authors reported a 5-7 mm reduction in the width of the alveolar ridge that generally occurred during the first three postextraction months.2

It is essential that ideal bone quality should be provided prior to implant placement to maximize the benefit of prosthetic treatment. The preservation of sites by means of socket grafting is a predictable procedure for improving the surgical site prior to implant fixture placement and it has been supported by various researches.3-5

In order to maintain the original natural ridge contours following extraction, various bone grafts and substitutes have been employed for grafting of the postextraction socket including autogenous bone, demineralized freezed dried bone allograft, mineralized freezed dried bone allograft, deproteinized bovine bone, alloplastic polymers and bioactive glasses.1Socket preservation techniques may limit bone remodelling, thereby preventing tissue collapsing following extractions. Several studies have evaluated different ridge preservation techniques following tooth extraction including placement of various graft materials in the socket.6 Many of these graft materials used in human extraction socket sites, such as demineralized freeze-dried bone allograft, bioactive glass and deproteinized natural bovine bone do not reabsorb and remain for a long time after healing. Biopsies from the grafted extraction sites before implant placement have shown the presence of graft material particles 6-9 months after their insertion. Moreover the quantity and the quality of the bone tissue formed in the socket have been variable and their presence often interfere with the normal healing process. As the primary implant stability, which is a function of local bone quality and quantity, has a significant importance to achieve successful osseointegration, it's essential to radiographically assess the bone quality of grafted socket sites prior to dental implant surgery.1,6,7

CBCT is an imaging technology based on the axial cross-sectional reconstruction of radiographic images of cylindirical or spherical volumes.8 CBCT is mainly used to ensure planar cross-sections and three dimensional reconstructions of bone with a lower radiation dose. As an alternative option to conventional CT, it is appropriate for a broad range of craniomaxillofacial indications for cross sectional imaging and three dimensional reconstruction.9 It has also been employed for the objective quantification of direct density measurements of bone, expressed in hounsfield unit (HU),10which has been used as a measurement tool for the evaluation of many different bone augmentation and preservation techniques performed to either increase or preserve viable bone in sites in which the implants are placed. As an established method for determining bone density, it ensures quantitative data regarding trabecular and cortical bone. It provides both three-dimensional anatomic localizations and direct density measurements in terms of HUs. The units are based on density values for air (−1,000 HU) and pure water (0 HU), and cortical bone may range from +1,000 to+1,600 HU values.7

The purpose of this study is to evaluate the definability and usability of CBCT imaging for the identification of bone quality of grafted and non-grafted socket sites prior to dental implant placement. We hypothesize that CBCT is a valuable tool for predicting the bone density of grafted and non-grafted socket sites prior to dental implant placement.

The specific aims of this study are:

1. Assessment of the bone quality of grafted and non-grafted socket sites by the identification of HU values obtained from the CBCT scanner.

2. Comparison of the HU values of the grafted and non-grafted socket sites.

Experimental design: This study will evaluate the definability and usability of CBCT imaging for the identification of bone quality of grafted and non-grafted socket sites in patients undergoing dental implant therapy. In this retrospective study design CBCT scan data obtained from 40 healed extraction socket sites which have been either grafted or non-grafted will be evaluated. The patient data for the experimental and control groups will be reviewed from the data base of patient charts at Case Western Reserve University, School of Dental Medicine, Department of Oral and Maxillofacial Surgery. The patients will be selected based on the following inclusion criteria: age between 18-70 years, good general health, previous extraction site or sites in the mandibular or the maxillary area which have been either grafted or non-grafted. The exclusion criteria will be: chronic treatment with a certain medication affecting oral health and bone turn over, heavy smoking (>10 cigarettes per day) and uncontrolled diabetes mellitus. The CBCT data which have been acquired with the CB Mercuray (CB Mercuray; Hitachi Medical Corporation, Tokyo, Japan) CBCT scanner prior to dental implant placement will be used in this study. Experimental group will consist of CBCT images of 20 selected extraction sites which have been grafted using Straumann Bone Ceramic (InstitutStraumann AG, Basel, Switzerland). Control group will consist of CBCT images of 20 selected extraction socket sites which has been non-grafted. HU values will be determined for both groups on the CBCT scan. The patient data will be individually de-identifiable and it will be coded to mask the participant identity. The numbers will be randomly assigned to each patient as a code and a key will be fabricated. The data will be entered into an Excel spreadsheet and will be stored on a secure encrypted USB drive that will remain in a locked cabinet in the department. Only Dr. Loveless and Dr.Quereshy will have access to that drive.

Statistics: The data will be analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0. The results will be collected and descriptive statistics including range, mean, median and mode evaluated. Intragroup variability will be assessed utilizing standard deviation and standard error of the mean. For the current study, probabilities of <0.05 will be considered significant. Intergroup differences will also be evaluated by t-test.

References:

1. Mardas N, Chadha V, Donos N. Alveolar ridge preservation with guided bone regenerationand a synthetic bone substitute or a bovine-derived xenograft: a randomized controlled clinical trial. Clin Oral Implants Res 2010; 21: 688-98

2. Schropp L, Wenzel A, Kostopoulos L, Karring T. Bone healing an soft tissue contour changes following single-tooth extraction: a clinical and radiographic 12-month prospective study. Int J Periodontics Restorative Dent 2003; 23: 313-23

THE MARGINAL MANDIBULAR NERVE IN RELATION TO THE INFERIOR BORDER OF THE MANDIBLE

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Background: Injury to the marginal mandibular nerve (MMN) can occur in numerous surgeries that involve incisions near the inferior border of the mandible. Injury to this nerve can cause significant cosmetic deformity, and is one of the more common sources of litigation against oral surgeons (4). Thorough knowledge and understanding of the pathway of the MMN is important in order to avoid nerve injury.

Purpose: The purpose of this study was to ascertain the relative position of the marginal mandibular nerve to several key mandibular anatomical landmarks, as well as identifying variations of the nerve as it approaches the inferior border of the mandible.

Materials and Methods: Human cadavers were dissected superficially to expose the marginal mandibular nerve (MMN) from the parotid gland to mental protuberance. Upon complete exposure of the nerve, five anatomical landmarks on the inferior border of the mandible were identified and labeled. The distance between the MMN and these landmarks was recorded and averaged to deduce a common path of the MMN.

Results: It was found that the MMN runs .75mm below the gonion, .085mm superior to the posterior border of the antegonial notch, .063mm superior to the arc of the antegonial notch, 1.29 mm superior to the anterior border of the antegonial notch, 3.6mm superior to the point at which facial artery reaches the inferior border of the mandible, and 10.9 mm superior to a vertical line that extends from the commissure of lip to the inferior border of the mandible.

Conclusion: Our data suggest three general paths of the MMN in relation to the inferior portion of the mandible.

SEPTOPLASTY: CONSIDERATIONS AND OPERATIVE TECHNIQUES

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Pearls:

- The term septoplasty encompasses a small procedure, like scoring the nasal septum, to a larger operation, like removing large portions of the septum.
- One needs to consider a variety of etiologies for nasal obstruction, including, but not limited to allergic rhinitis, pregnancy, hypothyroidism, nasal valve collapse, nasal tumors, menstruation, and encephaloceles3.
- The inferior turbinate has thegreatest impact on airway resistance. The internal nasal valve, which is the angle formed by the junction of the nasal septum and the margin of the upper lateral cartilage, can be responsiblefor 50% of the total airway resistance and is the narrowest segment of the nasal airway7.
- Anatomically, the bony septum includes the vomer inferiorly and the ethmoid bones superiorly. The shape of the cartilaginous septum anterior to the bony portion is referred to as Quadrangular septum.
- A major support mechanism of the nasal tip is formed by the septal ligaments, which run in anterior-posterior fashion within the membranous septum1.
- Septoplasty may need to be performed in conjunction with rhinoplasty if the entire nasal complex is involved, giving an appearance of a "twisted nose."

Pitfalls:

- Saddling of the nose can occur if a 1-1.5 cm dorsal hump is not left behind. Hence, hump reduction is performed prior to resection in this area to ensure 1-1.5 cm will remain behind dorsally1.
- If design of transcolumellar incision is not considered, a scar may develop5.
- Nasal tip debulking must be avoided to avoid risking injury to the subdermal plexus, which may lead to skin necrosis7.
- If septal hematoma forms, it must be evacuated promptly to avoid septal necrosis.
- Patient with short caudal septal lengths are not appropriate for medialcrura setback on the caudal septum. The use of the "tongue in groove" technique, in which the medialcrura is setback and sutured on the caudal septal, may result in a foreshortened nose or long upper lip5.
- If a caudal extension graft is used, it must be sutured at midline, or the nasal tip may deviate5.

Introduction:

The nose, which can be divided into the external skin, soft tissue, and underlying framework, forms a central point of focus for the face. It is important not only for airway management, but it is a pivotal esthetic zone. Hence, thorough understanding of anatomical relationships is essential. The upper 2/3 of the nose is thinner and more mobile and less sebaceous than the lower third8. Additionally, differences in skin character also exist between ethnic subpopulations, and this should be considered in preoperative planning. Thicker skin requires greater manipulation to achieve desired results7.

THE USE OF CONE BEAM COMPUTER TOMOGRAPHY TO VOLUMETRICALLY ASSESS BUCCAL BONE DEFECTS

PI: Faisal A. Quereshy, MD, DDS, FACS; Co-Investigator: Yeliz Kilinc

Specific aims: Dental implant therapy is increasingly being used for replacing lost teeth. It has been widely accepted to be a predictable procedure with good long-term results. However some clinical parameters should be considered prior to surgery. One of these is that the implant should be placed in a certain way that the bottom and sides are covered with bone.1

Implant success rates are strongly correlated with the adequate bone volume, which ensures the installation of dental implants at the correct position and maintains osseointegration.2 The sufficient buccal bone volume around implants is essential, especially for achieving esthetic results in the anterior region and its importance has been shown by various authors.3,4 Following extraction there is a resorption process leading to apicocoronal and buccolingual attenuation of the affected buccal segment of the alveolar ridge. The presence of buccal bone defects increase the risk of mechanical failure due to the lack of sufficient bone support for the implant.1,5 Therefore various reconstruction techniques are used to re-establish the anatomic morphology before or at the time of implant placement. Autogenous bone grafting is stated as the current gold standard and accepted as the most predictable and best documented method.6 As a method , first proposed by Breine and Branemark7, alveolar ridge augmentation with onlayautogenous grafts has been demonstrated to have predictable increases in bone volume for maxillary and mandibular alveolar augmentation.8,9

Extensive evaluation and proper planning are the key factors for the bony reconstruction procedures prior to dental implant surgery. The surgeon needs to know the morphology and volume of the bone defects to harvest the required amount of bone graft. In reconstructive surgery the use of cone beam tomography has provided the necessary information for preoperative planning. Compared to panoramic radiography CBCT provides a better evaluation of the bone defects in the jaw and volumetric analyses may be performed. It is also possible to generate high resolution isotropic volumetric data with high geometric accuracy at a low effective radiation dose by using its volumetric imaging.10

There have been a number of studies performed on the use of CBCT systems for volumeric analysis. Agbaje et., al. performed a volumetric analysis of extraction sockets using CBCT and concluded that CBCT allows for reliable volume estimates.11 Quereshy et., al. used CBCT to volumetrically assess the alveolar cleft defects and showed the accuracy of CBCT for calculating the estimated volume of the cleft.12 Leung et., al. also demonstrated the accuracy and reliability of CBCT for the measurement of bone height and detection of bony dehiscences and fenestrations.13

The use of CBCT for volumetrically assess the buccal bone defects prior to dental implant surgery would be very useful for determining the sufficient volume of the graft to be harvested as well as the selection of the appropriate donor site. Digital planning by means of CBCT would aid in performing a minimally invasive surgery with a lower complication rate and predictible postoperative results.

The aim of this study is to evaluate the usability of CBCT for measuring the volume of buccal bone defects prior to dental implant placement. We hyphothesize that CBCT is a valuable tool to volumetrically assess the buccal bone defects and to aid in digital planning preoperatively.

The specific aims of this study are:

1. Assessment of the morphology of the buccal bone defects
2. Identification of the possible anatomic landmarks which is used as a reference point for the volume measurements
3. Measurement of the volume of buccal bone defects

Experimental design: This study will evaluate the usability of CBCT for measuring the volume of buccal bone defects prior to dental implant surgery. In this retrospective study design CBCT data obtained from 60 patients with mandibular or maxillary buccal bone

defects who underwent preoperative CBCT imaging prior to dental implant surgery will be evaluated. The patient data for the experimental group will be reviewed from the data base of patient charts at Case Western Reserve University, School of Dental Medicine, Department of Oral and Maxillofacial Surgery. The CBCT data which have been acquired with the CB Mercuray (CB Mercuray; Hitachi Medical Corporation, Tokyo, Japan) CBCT scanner prior to dental implant placement will be used in this study. The measurements will be performed by using CBCT data for each patient. Three anatomic landmarks will be used for themeasurements: buccolingual diameter, superior-inferior width and mesio-distal width. The estimated volume (EV) of the defect will be calculated by means of in vivo dental image software (AnatomageInc, Sab Jose, CA). Measurements will be taken by a single rater at 3 different times approximately 2 weeks apart. The patient data will be individually de-identifiable and it will be coded to mask the participant identity. The numbers will be randomly assigned to each patient as a code and a key will be fabricated. The data will be entered into an Excel spreadsheet and will be stored on a secure encrypted USB drive that will remain in a locked cabinet in the department. Only Dr. Nijhawan will have access to that drive.

Statistics: The data will be analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0 The results will be collected and descriptive statistics including range, mean, median and mode will be evaluated. Intrarater reliability will be estimated using the interclass correlation coefficient (ICC) computed from a 2-way mixed model of reliability specifying absolute agreement. Ratings based on single measurement reliability will be examined.

References:

1. Shiratori LN, Marotti J, Yamanouchi J, Chilvarquer I, Contin I, Tortamano-Neto P. Measurement of buccal bone volume of dental implants by means of cone-beam computed tomography. Clin Oral Implants Res doi:10.1111/j.1600-0501.2011.02207.x.
2. Spin-Neto R, Stavropoulos A, Pereira LA, Marcantonio E Jr, Wenzel A. Fate of autologous and fresh-frozen allogenic block bone grafts used for ridge augmentation. A CBCT-based analysis.Clin Oral Implants Res. doi:10.1111/j.1600-0501.2011.02324.x.

Section 6

Research Management

COMMUNICATION TOOL FOR PERIOPERATIVE RESEARCH STUDY PATIENTS

University Hospitals Case Medical Center

Purpose: To improve communication between perioperative and research staff involving patients enrolled in clinical research studies in a busy, academic medical center. This collaborative effort was initiated to develop a tool that is used to notify and communicate essential information and details of clinical research protocols to OR staff.

Preparation and Planning: The tool was developed by a task force of registered nurses from the Department of Surgery and Perioperative Services.

Implementation: After several revisions of the tool, the document was piloted, revised, and ultimately introduced to operating room (OR) staff. After a patient's surgery was scheduled that had been identified to be included in a study, the research staff member sent the completed form with details, including date of surgery, purpose of the study, verification of signed informed consent, and other pertinent details regarding the research to the appropriate staff members in the OR.

Outcome: The OR staff reported an increase in knowledge of the care of patients enrolled in research studies. The tool increased safety measures through a more effective method of checks and balances, compliance with protocol, and identified the need for appropriate training with clinical protocols and devices. The research staff reported a more effective process for accurate data collection, better overall communication with OR staff, and improved billing of study devices.

Implications for Perioperative Nursing: This new tool assists the perioperative nurse to plan the research patient's care effectively, increases patient safety, and provides a collaborative effort to assure compliance within the study protocol

SELF MONITORING PROGRAM TO PROMOTE QUALITY ASSURANCE

Bridget O'Brien-Ermlich, RN, MSN, Cristina Ferrazzano Yaussy, MPH, CCRP

Purpose: The purpose of self-monitoring is not only to ensure that subjects are safe and their welfare and rights are upheld, but also to establish that the quality of the research is up to the highest standards. Quality Assurance (QA) through self-monitoring is critical in maintaining good clinical practice while conducting research and should be ongoing. In addition to ongoing QA, there are particular circumstances for which an internal review of a protocol should be implemented. These triggers include, but are not limited to, the start of a new employee, investigator-initiated research, and research that may not have any additional oversight. Self-monitoring, both as ongoing QA and event specific is a way to ensure that checks and balances are being completed. This poster will discuss the process by which the Department of Surgery at University Hospitals Case Medical Center (UHCMC) has implemented a self-monitoring program.

Methods: The principal investigator, co-investigators, research coordinators, and the UHCMC Office of Research Compliance and Education (ORC) all collaborate during the self-monitoring of a study. The ORC is available as a resource to ensure that the monitoring is conducted appropriately and according to federal and state law and institutional policies. The investigators are consulted for protocol related questions. The research coordinator is responsible for completing the monitoring within the department. To avoid overlooking potential omissions, the protocols reviewed by the research coordinator are not the protocols she/he is managing.

A systematic review of the following research related documents are some of the items reviewed during a typical audit: executed consent documents, the regulatory binder, delegation logs, training logs, device accountability, and event reporting including adherence to reporting requirement.

All types of studies are monitored; however, a priority is placed in the following order: investigator initiated studies; sponsored studies for which on-site monitoring is not being conducted by the sponsor or designee; sponsored studies that are monitored; and chart reviews.

The frequency of the monitoring is influenced by many factors including: enrollment, involvement of new employees, complexity of the protocol, and level of oversight from external monitors.

Results: Self-monitoring of studies within the Department of Surgery greatly reduces the chances for error. Self-monitoring gives the research team an opportunity to have their work reviewed by their colleagues and promotes quality assurance, cohesiveness, and collaboration within the clinical trials and department. This method also provides opportunities to educate members of the research team and promotes training. Self-monitoring within the department has also proven effective in identifying areas of risk for which targeted education and retraining is provided.

Conclusions: Quality assurance contributes to patient safety and human subjects' protections. In addition, self-monitoring takes the QA process one step further and holds the research professional accountable for his/her work by colleagues. By promoting self-monitoring within the department, the opportunity to educate new staff and to promote ongoing education to senior staff is enhanced. The systematic implementation of self-monitoring will lead to fewer errors, promoted collaboration, and increased knowledge.

Section 7
Surgical Oncology

DEMOGRAPHIC TRENDS IN THE RISING INCIDENCE OF THYROID CANCER (1973-2006)

*John D. Cramer, BS, Pingfu Fu, PhD, Seunghee Margevicius, MA, Karem C. Harth, MD, MHS, Scott M. Wilhelm, MD, FACS**

University Hospitals-Case Western Reserve University School of Medicine Cleveland, OH

Background: Thyroid cancer is currently the fastest increasing cancer among all cancer types. We sought to examine the demographic factors associated with this rise in thyroid cancer.

Methods: We conducted a retrospective cohort analysis of 50,212 cases of thyroid cancer using the Surveillance Epidemiology and End Results (SEER) database (1973-2006). We evaluated trends in the incidence of thyroid cancer and the staging of thyroid cancer with respect to demographics including: age (15 year intervals), race, gender, county income level, and county population size.

Results: All age groups, except the <15 year (yr) old group, had a significant increase in thyroid cancer incidence. The 46-60yr age group had the largest increase at 353% over the 33yr period, or 10.7%/yr. When examined by stage, cancers in the age group >60yr were associated with more advanced disease, with distant metastases in 12.8% compared with 3.5% in 30-60yr and 4.1% in <30yr ($p<0.0001$). Both genders saw a significant increase in thyroid cancer rates. Incidence for women and men rose at 7.8%/yr and 6.5%/yr, respectively ($p<0.0001$); women accounted for 74.3% of total cases of thyroid malignancy. Advanced stage disease was more common in men than in women, with 9.1% and 4.5% with distant metastases, respectively ($p<0.0001$). All races saw a significant increase in cancer rates, however, Caucasians had the greatest increase at 8.4%/yr compared with 5.7%/yr in African-Americans and 3.5%/yr in other races including Asian/Pacific Islander and American Indian/Alaska Native ($p<0.0001$). Advanced stage disease was more common in African-Americans than in Caucasians and other races, with 7.8%, 5.6%, and 6.4% at distant stage, respectively ($p<0.0001$). Rates of thyroid cancer increased at 7.2%/yr in urban counties and 8.9%/yr in rural counties, although rural counties started from a lower baseline incidence. Thyroid cancer increased across counties of all average yearly income levels, increasing 8.4%/yr in counties with <$25,000 , 7.7%/yr in counties with $25-35,000, 7.3%/yr in counties with $35-45,000 and 6.2%/yr in counties with >$45,000 ($p<0.0001$).

Conclusions: The incidence of thyroid cancer increased most rapidly in the 46-60yr age group, women, and Caucasians. There was an association with more advanced stage of disease in the age group >60yr, African-American race, and male gender. County features including income and rural versus urban setting had similar rates of increase in thyroid cancer.

BOWEL OBSTRUCTION SECONDARY TO AN UNUSUAL INTERNAL HERNIA

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A 45 year old female with no prior medical or surgical history presented to our Emergency Department (ED) with a chief complaint of crampy left lower quadrant abdominal pain associated with nausea. Initial evaluation by ED staff including laboratories and CT scan of the abdomen was unremarkable for any acute process, and she was discharged home. She returned to the ED 15 hours later with worsening abdominal pain, and bilious emesis. Laboratory evaluation at this time demonstrated a leukocytosis of 20.4, which had been previously normal. On physical exam the patient had diffuse abdominal pain, with focal guarding in the left lower quadrant. Repeat CT scan revealed findings concerning for partial or early complete small bowel obstruction, with a transition point in the left lower quadrant, along with signs of "ectasia of the left-sided uterine vasculature". Based on the patient's worsening clinical exam and imaging, the decision was made to take her to the operating room for diagnostic laparoscopy, possible laparotomy.

Upon initial laparoscopic evaluation, multiple dilated loops of small bowel, some appearing ischemic, were identified. After attempts to mobilize the dilated loops were unsuccessful, we converted to a lower midline laparotomy. An internal hernia was identified, with over 2 feet of small bowel passing under the left fallopian tube, through a defect in the middle of her broad ligament. This represented a congenital "fenestra" type defect of the broad ligament. Due to the small size of the defect, we were unable to safely reduce the herniated bowel. Therefore we performed a left salpingectomy to release the strangulated bowel. The bowel was viable, and no resection was required. The remainder of the patient's post-operative course was uneventful.

CAN COMPLETION THYROIDECTOMY BE PERFORMED AS OUTPATIENT SURGERY?

T Shah, SM Wilhelm.

University Hospitals/Case Medical Center. Cleveland, OH

Purpose: The main complications following thyroidectomy are: recurrent laryngeal nerve (RLN) injury, hypocalcemia, and postoperative neck hematoma. Patients undergoing hemithyroidectomy (HT) have a low risk of hypocalcemia and hematomas usually occur within 4 hours of surgery. Thus, HT patients are generally discharged the same day. Patients undergoing total thyroidectomy (TT) are usually admitted for observation and calcium monitoring. Guidelines for completion thyroidectomy (CT) are less clear and at our institution are treated as a TT. Our hypothesis challenges that complication rates for CT may mirror those of HT rather than TT. If so, we may consider same day discharge for these patients.

Methods: From 5/2004- 1/2010, 385 patients underwent thyroid surgery at our institution. 219 (57%) had TT and 26 (6.7%) had CT. Because we do not admit and measure postoperative calcium levels in HT, this group was excluded. 208/237 (88%) of TT and all CT had calcium data available for analysis; 205/232 (94 %) of TT patients and 25 (96%) of CT patients had follow-up/complication status available. Hospital length of stay (LOS) and postoperative complications were analyzed including hypocalcemia, neck hematoma, RLN injury, and readmission rates.

Results: Average LOS was significantly higher in the TT group (29.9 hours) vs. the CT group (29.9 hours vs. 23.0 hours respectively, p = 0.000018). 14% of patients undergoing TT stayed longer than the typical 23 hour observation. In regard to complications: 52% of CT and 39% of TT had no recorded complications. 28% of CT patients compared to 41% of TT had temporary asymptomatic hypocalcemia that resolved by 2 or 6 week follow-up. Only 3.8% of CT patients had symptomatic hypocalcemia (parasthesias, carpal/pedal spasm) compared with 7.3% of TT patients. No CT patients had permanent hypocalcemia, whereas 5.8% of TT had unresolved hypocalcemia with further follow-up still pending. Average calcium value for patients undergoing TT was 8.39 on POD #1 and 9.16 at follow-up, an 11.2% change. For patients undergoing CT average calcium was 8.51 at POD#1, 9.25 at follow-up, a 9.8% change. Calcium at POD #1 (p= .17) and at follow-up (p=0.267) was not significantly different between groups. RLN palsy affected 8% (n=2) of CT patients and 6.4% (n=14) of TT patients. Of those affected, all VC paresis resolved in CT patients, whereas 9/14 (64 %) resolved in TT patients. Hematoma affected 4% (n=1) of CT patients and 2.4% (n=5) of TT patients. Readmission was necessary in 11.5% (n=3) of the CT patients,: 1 for bleeding, 1 for shortness of breath, and 1 for hypocalcemia. Of the TT patients, 2% (n=4) were readmitted: 2 for bleeding, 1 for hypocalcemia, and 1 for infection.

Conclusion: Our study shows that although CT patients have a shorter average LOS than TT patients, they both had similar complication rates. Higher percentages of TT patients had both symptomatic and asymptomatic hypocalcemia, and only TT patients had unresolved hypocalcemia at follow-up. Yet immediate postoperative calcium values appear to be comparable for both CT and TT patients. RLN injury similarly affected both groups, but unresolved vocal cord paresis occurred only in TT patients. Contrary to our hypothesis, CT and TT patients had similar postoperative calcium values and complication rates. Thus, we would recommend that postoperative admission for observation be the standard of care in CT patients.

CAN COMPLETION THYROIDECTOMY BE PERFORMED AS OUTPATIENT SURGERY?

T Shah, SM Wilhelm.

University Hospitals Case Medical Center. Cleveland, OH

Objective: Patients undergoing total thyroidectomy (TT) or completion thyroidectomy (CT) are usually observed overnight to assess for complications whereas hemithyroidectomy (HT) patients are discharged home. This study was designed to determine if CT patients could be treated as outpatients.

Methods: A retrospective review of a prospectively maintained database was performed of thyroidectomies, 5/2004-1/2010. HT were excluded. TT and CT were compared for length of stay (LOS), complications (hypocalcemia, recurrent laryngeal nerve (RLN) injury, neck hematoma), and readmission rates. Student's t-tests were performed, $p< 0.05$ significant.

Results: 385 patients underwent thyroidectomy: TT (n=219), CT (n=26). 140 HT were excluded. LOS was significantly higher after TT (29.9) vs. CT (23 hours, $p<0.00001$). Hypocalcemia was similar between groups (calcium 8.39 vs. 8.51 ($p=0.17$) on postoperative day #1 (TT vs. CT). Temporary asymptomatic hypocalcemia occurred in 44% of TT vs. 28% of CT patients. Symptomatic hypocalcemia was rare, 7.3% TT vs. 3.8% CT. Permanent hypoparathyroidism was only seen in TT (n=1). RLN palsy affected 6.4% (n=14) of TT vs. 8% (n=2) of CT patients (NS). Palsy resolved in CT (100%) and TT (64%). Hematoma occurred in 2.4% (n=5) of TT patients and 4% (n=1) of CT (NS). Readmission was seen in 2% of TT (n=4) and 11.5% (n=3) of CT patients.

Conclusions: Our study shows that although CT patients had a shorter average LOS than TT patients, they had similar complication rates in all measured parameters. Thus, we would recommend that postoperative admission for observation be the standard of care in CT patients.

AN UNUSUAL ADRENAL CYST

Stuhldreher, J and Wilhelm S.

Presented at: Midwest Surgical Society Meeting, August 2011 and Cleveland Surgical Society, Fantastic and Unusual Cases, May 2011

A 25 year-old woman presented with nonspecific nausea and vague abdominal pain. Computed tomography of the abdomen revealed a 9 cm cystic lesion in the left upper quadrant, arising from the left adrenal gland. Evaluation for functional adrenal neoplasm was negative. Laparoscopic adrenalectomy was recommended. At the time of the operation, the left adrenal gland was found to be normal. There was, however, a cystic lesion arising from the greater curvature of the stomach. Intraoperative endoscopy revealed a corresponding submucosal gastric mass. Laparoscopic sleeve gastrectomy was performed. Final pathology of the lesion revealed a benign gastric duplication cyst. Gastric duplication cyst is a rare finding, especially in adults. Due to a low, but undefined, risk for malignancy, resection is recommended.

TRENDS IN THE USE OF BREAST CONSERVING SURGERY AND ADJUVANT RADIATION THERAPY IN PATIENTS WITH DCIS- A U.S. POPULATION BASED ANALYSIS FROM 1996-2007

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Background: The treatment for patients with DCIS remains controversial. Current guidelines based upon best available evidence suggest that breast conserving surgery (BCS) followed by adjuvant radiation therapy (RT) result in acceptable local control and breast cancer specific survival. The purpose of this study was to analyze trends in patterns of care as well as identify factors associated with surgery type and use of adjuvant radiation therapy in a select cohort of patients enrolled into the SEER database.

Methods: The study included females 18 years and older with focal DCIS and known tumor size of 5 cm or less diagnosed between 1996 and 2007. The Cochran-Armitage trend test was applied to identify trends in the use of BCS and RT over time. Multivariate logistic regression analyses were used to determine factors associated with receiving BCS vs. mastectomy and BCS plus RT vs. BCS alone. Cox proportional hazard model was used to determine associations with breast cancer-specific mortality.

Results: Of the 34,233 women with DCIS, 76.59% were treated with BCS. 66.36% of BCS patients received adjuvant RT over the study period. The proportion of women receiving BCS increased from 71.5% in 1996 to 76.9% in 2007 ($p<0.0001$). Additionally, the proportion of women who underwent BCS and received adjuvant radiation therapy over the same time period increased from 55.3% to 69.7% ($p<0.0001$). Multivariate analysis demonstrated that year of diagnosis, race, marital status, geographic region, tumor size, tumor grade and comedo necrosis all were significantly associated with the use of adjuvant radiation therapy, but age was not. Cox proportional hazards models did not associate either surgery type or use of adjuvant radiation in patients undergoing BCS with breast cancer-specific mortality.

Conclusions: Based upon reporting within the SEER database, the proportion of DCIS patients undergoing BCS and the BCS patients receiving adjuvant radiation increased over the study time period. Surgery type and use of adjuvant radiation therapy in patients with BCS was not associated with decreased risk of breast-cancer specific death in this cohort.

ADDITION OF ALGENPANTUCEL-L IMMUNOTHERAPY TO STANDARD ADJUVANT THERAPY FOR PANCREATIC CANCER: A PHASE 2 STUDY

Jeffrey M. Hardacre[1], Mary Mulcahy[2], William Small[2], Mark Talamonti[3], Jennifer Obel[3], Smitha Krishnamurthi[1], Caio S. Rocha-Lima[4], Howard Safran[5], Heinz-Joseph Lenz[6], E. Gabriela Chiorean[7]*

Background: Despite continued investigation, limited progress has been made in the adjuvant treatment of resected pancreatic cancer. Novel or targeted therapies are needed. Immunosuppressive mechanisms have been involved in the pathogenesis and progression of pancreatic cancer.

Methods: Multi-institutional, open-label, dose-finding, phase 2 trial evaluating the use of Algenpantucel-L (NewLink Genetics Corporation, Ames, IA) immunotherapy in addition to chemotherapy and chemoradiotherapy in the adjuvant setting for resected pancreatic cancer (ClinicalTrials.gov identifier: NCT00569387). The primary outcome was 12-month disease-free survival. Secondary outcomes included overall survival and toxicity.

Results: Seventy patients were treated with gemcitabine and 5-fluorouracil based chemoradiotherapy as well as Algenpantucel-L (mean 12 doses, range 1-14). After a median follow-up of 21 months, the 12-month disease-free survival was 62%, and the 12-month overall survival was 86%. The most common adverse events were injection site pain and induration.

Conclusions: The addition of Algenpantucel-L to standard adjuvant therapy for resected pancreatic cancer may improve survival. A multi-institutional, phase 3 study is ongoing (ClinicalTrials.gov identifier: NCT01072981).

EXPANSION OF MELANOMA-SPECIFIC T CELLS FROM LYMPH NODES OF STAGE III PATIENTS: IMPLICATIONS FOR ADOPTIVE IMMUNOTHERAPY OF CANCER

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INTRODUCTION: Adoptive immunotherapy for patients with metastatic melanoma has yielded encouraging results. However, methods to expand melanoma-specific T-cells from Stage III are limited. The objective of this study is to determine whether melanoma-specific T-cells could be generated from the melanoma-draining lymph nodes (MDLN) of Stage III patients.

METHODS: Stage III patients undergoing completion lymphadenectomy were enrolled onto an IRB-approved protocol. MDLN cells were tested for ability to undergo cryopreservation, expand ex vivo in IL-2 or IL-2 and IL-7 and mediate melanoma-specific antitumor responses in vitro.

RESULTS: Cryopreservation produced no significant differences from fresh cultures in terms of cell growth and cellular phenotype. IL-2 and IL-2/IL-7 cultures resulted in similar growth rates, and functional studies revealed the presence of T cells which secreted interferon gamma in response to melanoma antigen peptides. Both IL-2 and IL-2/IL-7 cultured MDLN cells mediated significant apoptosis of human melanoma cell lines as compared to breast and brain tumor lines in vitro. Overall there did not seem to be a benefit of adding IL-7. Both CD4+ and CD8+ T-cells appear to mediate tumor cell apoptosis.

CONCLUSION: This study demonstrates that melanoma antigen-specific T-cells can be generated from regional melanoma-draining lymph nodes and expanded ex vivo from patients with Stage III disease.

CYBERKNIFE ABSTRACT

Goyal K., Einstein D., Ibarra RA., Yao M., Kunos Co., Ellis R., Brindle J., Singh D., Hardacre J., Zhang Y., Fabians J., Funkhouser G., Machtay M., Sanabria JR.

Background: Stereotactic body radiation therapy (SBRT) has emerged as a potential treatment option for local tumor control of primary malignancies of the pancreas. We report on our experience with SBRT in patients with pancreatic adenocarcinoma who were found not to be candidates for surgical resection.

Methods: The prospective database of the first 20 consecutive patients receiving SBRT for unresectable pancreatic adenocarcinomas and a neuroendocrine tumor under an IRB approved protocol was reviewed. Prior to SBRT, cylindrical solid gold fiducial markers were placed within or around the tumor endoscopically (n = 13), surgically (n = 4), or percutaneously under computerized tomography (CT)-guidance (n = 3) to allow for tracking of tumor during therapy. Mean radiation dose was 25 Gray (Gy) (range 22-30 Gy) delivered over 1-3 fractions. Chemotherapy was given to 68% of patients in various schedules/timing.

Results: Patients had a mean gross tumor volume of 57.2 cm(3) (range 10.1-118 cm(3)) before SBRT. The mean total gross tumor volume reduction at 3 and 6 mo after SBRT were 21% and 38%, respectively ($P < 0.05$). Median follow-up was 14.57 mo (range 5-23 mo). The overall rate of freedom from local progression at 6 and 12 mo were 88% and 65%. The probability of overall survival at 6 and 12 mo were 89% and 56%. No patient had a complication related to fiducial markers placement regardless of modality. The rate of radiation-induced adverse events was: grade 1-2 (11%) and grade 3 (16%). There were no grade 4/5 adverse events seen.

Conclusions: Our preliminary results showed SBRT as a safe and likely effective locate treatment modality for pancreatic primary malignancy with acceptable rate of adverse events.

ETHICS ABSTRACT

Minter RM., Angelos P., Coimbra R., Dale P., de Vera ME., Hardacre J., Hawkins W., Kirkwood K., Matthews JB., McLoughlin J., Peralta E., Schmidt M., Zhou W., Schwarze ML.

Background: A significant increase in industry support of professional medical associations coupled with data suggesting that gifts from industry have significant clinical influence have prompted calls from the Institute of Medicine and physician leaders to identify and manage conflicts of interest that stem from financial support of professional medical associations by industry.

Methods: A joint task force of members appointed by the Association for Academic Surgery and the Society of University Surgeons was convened in July 2009. Recommendations were developed regarding management of all potential conflicts of interest that can arise within the context of an academic surgical society, with specific focus on relationships with industry. Task force members reached consensus around each recommendation and the guidelines were subsequently adopted by the Executive Councils of both societies.

Results: The committee identified 4 primary areas of need for transparent and definitive management of conflict of interest: 1) individual society activities, including general budget support, society endorsements, and journal affiliation; 2) individual personnel conflicts such as society leadership and standards for disclosure of conflict; 3) meeting activities including budgetary support, program committee associations, and abstract review process; and 4) foundation support and research and travel awards. The resulting guidelines aim to protect the societies and their membership from undue bias that may undermine the credibility and mission of these associations.

Conclusions: Policy guidelines to mitigate conflict of interest are necessary to protect the integrity of the work of academic surgical societies and their fiduciary duty to members and patients. Guidelines created and adopted by the Association for Academic Surgery and Society of University Surgeons form an effective model for academic surgical societies and their members.

ORGAN SPARING PANCREATECTOMY FOR SYNCHRONOUS PANCREATIC INTRADUCTAL PAPILLARY MUCINOUS NEOPLASMS

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Introduction: IPMN is characterized by papillary proliferation of mucin-producing epithelial cells. They arise from the main pancreatic duct, its branch ducts or both. 39-64% of IPMNs are commonly multifocal. Standard of care for treating multifocal disease has been total pancreatectomy. Recently, there has been increased attention to limited resection procedures. To date, only 10 cases of middle segment preserving pancreatectomy have been reported.

Method: 47 year old female was seen for evaluation of a pancreatic cystic neoplasm. Her work-up included CT scan of abdomen/pelvis and EUS evaluation of the pancreas with FNA of the neoplasm. These studies revealed a cystic lesion in the tail with another cyst comprising a solid component in the head. Thick viscous fluid was aspirated from head mass with high CEA levels. The patient subsequently underwent middle preserving pancreatectomy to address both lesions. We also performed a comprehensive literature search to summarize all data on middle segment preserving pancreatectomy.

Results: Multifocal IPMN was found in pathological examination. Her postoperative course was complicated with hospital acquired pneumonia, grade B delayed gastric emptying and grade B pancreatic fistula. Short term follow up revealed no complications. However, her blood glucose levels remained higher than normal, which were successfully controlled by Januvia without any insulin requirement.

Conclusion: Although middle-preserving pancreatectomy is a relatively new technique in organ sparing pancreatectomies, the short term follow-up of the few case reports demonstrates it is a promising and safe procedure. This procedure minimizes the consequences of a total pancreatectomy and improves patients' overall quality of life.

PATTERNS OF CARE IN ADJUVANT SYSTEMIC THERAPY OF PATIENTS WITH STAGE III MELANOMA: A U.S. POPULATION-BASED STUDY

Boyu Hu, Henry B. Koon, Julian Kim

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Background: Use of adjuvant systemic therapy in patients with stage III melanoma is widely known to be variable based upon multiple factors such as patient age and comorbidities as well as the preference and even geographic location of the oncologist and patient. The purpose of this study was to compare the use of adjuvant therapy among patients treated in teaching hospitals and community hospitals.

Methods: The study population consisted of patients with stage III melanoma enrolled into the National Cancer Database (NCDB) between 2000-2008. Patients were selected based upon surgery as the first course of therapy which resulted in a total of 27,353 eligible for analysis. The study population was then categorized into those who were treated at Teaching Hospitals (TH) including National Cancer Institute-designated cancer centers or Community Hospitals (CH). Multiple variables including age, median household income, insurance status, race and overall survival were compared between patients in the two hospital groups.

Results: The overall proportion of stage III patients who received adjuvant systemic therapy was approximately 30%. There was no difference in the proportion of patients receiving adjuvant systemic therapy between patients treated in TH as compared to CH, and there was no obvious trend towards increased use over time. Of interest was that the cohort of patients designated as being treated at TH had a higher proportion of patients less than 70 years old as compared to CH. Median household income was found to be higher in patients treated at TH. Finally, despite the observation that the proportion of patients who received adjuvant therapy was not different, there a significantly higher 5-year overall survival in patients treated at TH as compared to CH.

Conclusions: Although the proportion of patients who received adjuvant systemic therapy was comparable in TH and CH, there was a significant increase in 5-year overall survival within TH. Additional factors such as age, lesser comorbidities, more favorable socioeconomic factors or other unmeasured factors such as type of adjuvant therapy or whether adjuvant therapy was completed may have contributed to the improved survival in patients treated at TH.

GIANT RECURRENT PHYLLODES TUMORS OF THE BREAST: TREATMENT DILEMMAS AND LITERATURE REVIEW

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Objective: This study describes two cases of recurrent malignant phyllodes tumors, and comprehensively reviews the literature published to date.

Background: Since its original introduction in 1838 by Johannes Miller, Cystosarcoma Phyllodes has presented diagnostic and treatment dilemmas for physicians. These tumors are almost exclusively found in female breast tissue, and predominantly exhibit benign behavior. The median size of a phyllodes tumor is approximately 4 cm, but 20% achieve diameters of 10-40 cm, and are thus designated giant tumors. Histologically, these tumors have a tendency to contain microcysts. Phyllodes tumor is the currently accepted nomenclature according to the World Health Organization (WHO). The diagnosis and management of phyllodes tumors is comprehensively explained in the literature. However, few studies address the management of giant malignant phyllodes tumors, a challenging entity for physicians.

Methods: We conducted a Medline search for articles in the English language to include the most current data. The key words phyllodes tumor, malignant giant breast tumors and cystosarcoma phyllodes were used for literature review. Additionally, we report two patients with recurrent giant phyllodes tumors of the breast and delineate the preoperative work up, diagnosis, tumor excision and postoperative course.

Conclusion: Recurrent malignant phyllodes tumors of the breast impose a challenging treatment dilemma for surgeons. Sonographic evidence can delineate important differentiating clues for malignant processes. Core tissue sampling provides more conclusive diagnostic results than FNA due to the necrotic and hemorrhagic nature of these tumors. The pathological subtype of the phyllodes tumor and the extent of local invasion should dictate the extent of surgical resection.

FANTASTIC AND UNUSUAL CASES

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A 25 year old woman presented with nonspecific nausea and vague abdominal pain. Computed tomography of the abdomen revealed a 9 cm cystic lesion in the left upper quadrant, arising from the left adrenal gland. Evaluation for functional adrenal neoplasm was negative. Laparoscopic adrenalectomy was recommended. At the time of the operation, the left adrenal gland was found to be normal. There was, however, a cystic lesion arising from the greater curvature of the stomach. Intraoperative endoscopy revealed a corresponding submucosal gastric mass. Laparoscopic sleeve gastrectomy was performed. Final pathology of the lesion revealed a benign gastric duplication cyst.

"Clinical Pearl": Gastric duplication cyst is a rare finding, especially in adults. Due to a low, but undefined, risk for malignancy, resection is recommended.

SURGICAL CONSIDERATIONS IN PATIENTS RECEIVING NEOADJUVANT SYSTEMIC THERAPY

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Neoadjuvant chemotherapy is being increasingly used in the treatment of patients presenting with early-stage, operable breast cancer. Neoadjuvant chemotherapy downsizes most tumors, allowing appropriately selected patients to undergo breast conserving therapy. Management of the axilla in patients receiving neoadjuvant chemotherapy is dictated by whether patients present with clinically node-negative or node-positive disease. Patients with clinically node-negative disease can undergo sentinel lymph node dissection after neoadjuvant chemotherapy, with axillary lymph node dissection reserved for patients with a positive sentinel lymph node. For patients with clinically node-positive disease at presentation, the current standard of care is axillary lymph node dissection. An ongoing cooperative group trial is investigating the utility of sentinel lymph node surgery in the clinically node-positive population.

Section 8
Surgical Quality

DEVELOPMENT OF A SAFETY CHECKLIST FOR BOWEL RESECTION: AN EXPERT PANEL APPROACH

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Introduction: Many potentially preventable complications may occur with bowel resection surgery (BR). Use of the World Health Organization Safe Surgery Checklist increases adherence with best practices and reduces preventable complications and deaths. Despite the utility of this checklist, it is very general, and experts recommend checklists optimized for procedure-specific tasks. Our objective was to develop an evidence-based checklist for BR to improve perioperative safety and clinical outcomes.

Methods: A RAND/UCLA Delphi process was used to develop a bowel surgery specific checklist. A nationally representative, multidisciplinary group of experts (colorectal and general surgery, anesthesiology, perioperative nursing) reviewed 149 surgical safety measures ("checkpoints"). Checkpoints were grouped into 6 pause points [pre-op, preinduction, time out, intra-op, debriefing, post-anesthesia care unit (PACU) hand-off]. The panelists completed a pre-meeting rating of the individual checkpoints. At a 2 day meeting, they discussed areas of disagreement and re-rated the checkpoints. Checkpoints for which there was a high or moderate level of agreement were included in the final checklist.

Results: In the final round of ratings there was high agreement to include 23 (22.1%) of the checkpoints and moderate agreement to include 13 (12.5%). Of these 36 checkpoints, 14 were at pre-op, 6 at preinduction, 10 at time out, 2 at intra-op, 3 at debriefing, and 1 at PACU hand-off. Checkpoints were formatted into a checklist. Panelists reviewed the checklist and their comments were incorporated into the final version. The panel enumerated additional items considered "best practices" but not needed as part of a checklist.

Conclusion: The Delphi process was used to derive a 36 item checklist specific to bowel surgery. The checklist was organized around natural breaks in workflow, and was designed to improve communication and detect errors at a time when they can still be corrected. The panel refrained from assigning responsibility to a team member for each checkpoint or from providing detailed implementation advice since institutional practices vary. The panel recommended pilot testing before final implementation. An expert panel and Delphi process is highly recommended when developing procedure specific surgical checklists.

Section 9

Thoracic and Esophageal Surgery

DONOR PRETREATMENT WITH MONTELUKAST AND ATORVASTATIN IMPROVE PHYSIOLOGY AND HISTOLOGY IN XENO MOUSE LUNG PERFUSION

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Background: Lung injury after xeno-transplantation occurs despite control of _-galactosyl (Gal) natural antibodies. The lung xeno-transplant model provides insides in analyzing the apleiotropic effects of the statin atorvastatin (AT) and leukotriene inhibitor montelukast (LTI) regarding inflammation and organ injury. Combination of AT and LTI have potential to attenuate the inflammatory response and improve graft survival.

Materials and Methods: Using an established xenogenic mouse lung perfusion model, fresh human blood was perfused through mouse lungs pretreated for >14 days with atorvastatin (AT, n=6), montelukast (LTI, n=7), combined AT+LTI (n=5), vehicle control (DMSO, n=6) and untreated control (n=7) at unchanged flow conditions.Lung survival, PVR, complement and platelet activation, BTG, CBC, mouse and human plasma (Luminex) and tissue (qRT-PCR) cytokine levels are routinely tested.

Results: All lungs survived until elective termination at 240min. Lung pulmonary vascular resistance was significantly decreased in all treated groups within 30min. ($p=0.006$, Fig.1). This effect blunted after 90min. of perfusion. Histologic grading revealed a highly significant difference in thrombosis between treated groups and controls ($p=0.006$). Furthermore AT treated lungs demonstrated significantly diminished thrombosis ($p=0.015$) and hemorrhage ($p=0.016$) than controls (Fig.2). Platelet activation was significantly reduced in combination of AT+LTI at 240min. ($p<0.05$ vs contols, Fig.3). Neutrophil sequestration at 30min. of perfusion was strongest in AT and LTI single treatment experiments. All groups sequestrated at 120min. significantly into perfused lungs accept AT+LTI group (Fig.4). Complement, BTG and cytokine analysis data were not available at time of abstract submission.

Conclusions: The physiological and histological phenotype of xenogenic lung injury appears to be blunted by AT and LTI donor pretreatment. Statins as single treatment seem to have ambivalent effects. The combination of statins and leukotrien inhibition seemed to be synergistic. There might even be a clinical implication in current human lung transplantation for donor and/or recipient AT+LTI treatment.

FIDUCIAL MARKER PLACEMENT AND TISSUE SAMPLING IN ADVANCED LUNG DISEASE UNDER ELECTROMAGNETIC NAVIGATION GUIDANCE AND MODERATE SEDATION

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Background: Lung cancer is the leading cause of cancer-deaths in the United States. Surgical resection offers the best survival benefit for Stage I disease. For medically inoperable patients with Stage I lung cancer, CyberKnife stereotactic radiosurgery offers a curative alternative option. To perform it, Electromagnetic navigational bronchoscopy (ENB) is often used to guide placement of fiducial markers in, or in the vicinity of, the tumor. Several studies have shown this technique to be safe and effective. However, very few combine diagnostic maneuvers with fiducial marker placement in one setting in patients with severe chronic obstructive lung disease (COPD)

Purpose: The purpose of this study is to look at safety and efficacy of ENB guided lung tissue sampling, followed by fiducial marker placement in patients with advanced lung disease.

Patients and Methods: Our local lung cancer multidisciplinary tumor board refers medically inoperable patients to bronchoscopy for placement of fiducial markers. Patients without tissue diagnosis have additional maneuvers including transbronchial nodule biopsy or fine needle aspiration to the fiducial placement. On average 4 fiducial markers are placed per lesion. All procedures are conducted in an out-patient bronchoscopy suite. Local anesthesia is achieved with 2% lidocaine. Moderate sedation is reached using combination of 2 mg of midazolam and 50 mcg of fentanyl as an initial bolus, followed by smaller boluses every 5 to 10 minutes throughout the procedure as needed.

Retrospective review of our bronchoscopy database revealed a total of 165 patients referredfor placement of fiducial markers. We selected the ones with severe COPD defined by FEV1 ≤ 50%, DLCO ≤ 50% or were on home O2 for more than one year. We describe our experience with this population in the following.

Results: A total of 126 patients with COPD were identified, 75 of whom met inclusion for severe disease. The average age was 73 ± 9. Women made up 56% of this cohort. Thirty eight patients (50%) required tissue sampling in addition to the fiducial marker placement. Complications included one small pneumothorax requiring chest tube drainage and 2 self-limiting, short lived oxygen desaturations to 85%; thus, a complication rate of 4%. This population utilized 304 ± 50 mg of lidocaine, 3.7 ±1.8 mg of midazolam as well as 79± 39 mcg of fentanyl. The duration of each procedure was 35 ± 13 minutes. When compared to patients with less severe COPD there was no difference in the amount of lidocaine, midazolam, or fentanyl used; nor any difference in the procedure duration.

As expected, procedures with diagnostics were longer by 11 minutes, 30 second additional fluoroscopy time and almost 20 mcg of extra Fentanyl were needed ($p < 0.05$; details in table)

	Diagnostics + Fiducial	Fiducial	p-value
Number of patients	38	37	
Lidocaine (mg)	309 ± 45	299 ±53	0.360
Midazolam (mg)	4.0 ± 1.6	3.4 ± 1.9	0.134
Fentanyl (mcg)	88 ± 34	70 ± 41	0.037
Procedure Duration (min)	40 ±11	29 ± 14	0.000
Fluoroscopy Time (sec)	94 ± 46	64 ± 32	0.001

Conclusions: In conclusion, one setting ENB for diagnosis and placement of fiducial markers is safe. Its longer duration and higher sedative use are clinically insignificant. One speculates that for this critically compromised population, this approach offers less risk than a 2 setting approach, for the same benefit at an obviously lower cost.

FIVE-YEAR SURVIVAL DOES NOT EQUAL CURE IN NON-SMALL CELL LUNG CANCER: A SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS-BASED ANALYSIS OF VARIABLES AFFECTING 10- TO 18-YEAR SURVIVAL

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OBJECTIVE: Five-year survival after the diagnosis of non-small cell lung cancer is the most common benchmark used to evaluate long-term survival. Data on survival beyond 5 years are sparse. We sought to elucidate variables affecting 10- to 18-year survival.

METHODS: A total of 31,206 patients alive at least 5 years after diagnosis of non-small cell lung cancer who were registered in the Surveillance, Epidemiology, and End Results database from 1988 to 2001 were examined. Primary end points were disease-specific survival and overall survival. Survival analysis was performed with Kaplan-Meier estimates, multivariable Cox proportional hazards regression, and competing risk models.

RESULTS: Overall survival at 10, 15, and 18 years was 55.4%, 33.1%, and 24.3%, respectively. Disease-specific survival at 10, 15, and 18 years was 76.6%, 65.4%, and 59.4%, respectively. In multivariable regression analysis, squamous cell cancers had a disease-specific survival advantage (hazard ratio, 0.88; $P < .0001$) but an overall survival disadvantage (hazard ratio, 1.082; $P = .0002$) compared with adenocarcinoma. Pneumonectomy (hazard ratio, 0.44) and lobectomy (hazard ratio, 0.474) had improved disease-specific survival compared with no surgery ($P < .0001$). Left-sided tumors (hazard ratio, 0.723; $P = .036$) and node-negative cancers (hazard ratio, 0.562; $P < .001$) also had a better disease-specific survival and, to a lesser extent, overall survival advantage.

CONCLUSIONS: Five-year survivors of non-small cell lung cancer have a persistent risk of death from lung cancer up to 18 years from diagnosis. More than one half of all deaths in 5-year survivors are related to lung cancer. In multivariable regression analysis, age, node-negative disease, and lobar or greater resection were strong predictors of long-term survival (i.e., 10-18 years).

SEVEN YEAR DISEASE FREE SURVIVAL FOLLOWING RADICAL RESECTION OF PULMONARY ARTERY SARCOMA

Philip A. Linden MD, Jeffrey Morgan MD, Gregory Couper MD

A 50 year old female without significant medical history presented with fatigue, fever and shortness of breath. She underwent a PE protocol CCT in January of 2004 which showed filling defects of the right main pulmonary artery and an 11 cm right hilar mass. An EBUS guided biopsy revealed the diagnosis of mixed spindle cell and epithelioid cell neoplasm. She received six cycles of ifosfamide, mesna, and adriamycin. A repeat CT scan performed 4/04 showed a decrease in the size of the mass to 7cm. A repeat CT scan at the conclusion of the six cycles of chemotherapy in 6/04 showed continued shrinkage of the mass. She underwent exploratory thoracotomy at an outside hospital where invasion of the atrium was noted, and the patient was closed without resection. On arrival at our institution in 9/04 she had a CCT (figures 1 and 2) and PET scan which only showed activity in the right hilum. A cardiac MRI showed thickening of the left atrial wall, but did not suggest involvement of the interatrial septum. In 10/04 she underwent median sternotomy with right hilar dissection. The right pulmonary artery was divided with a stapler just lateral to the SVC. On bypass, the left atrium was opened, and a cuff of left atrium was resected en bloc with primary closure of the left atrium. The bronchus was stapled and divided at its takeoff from the carina. Intraoperative frozen section returned positive on the pulmonary artery, and negative on the bronchus and atrium. The right pulmonary artery was dissected behind the SVC and aorta to its origin off the main pulmonary artery. A portion of attached SVC and right atrium were resected and reconstructed with bovine pericardium. Sessile lesions were noted in the lumen of the right pulmonary artery. Frozen section at the junction of the right and main pulmonary artery returned positive. The main pulmonary artery was opened and smooth sessile lesions were noted along the wall of the artery which appeared to extend to the base of the pulmonic valve leaflets. These returned positive for neoplasia. The origin of the left main pulmonary artery appeared free of disease, and the right ventricular outflow tract, as visualized through the pulmonic valve, appeared free of disease. The pulmonic valve and root were excised and replaced with a pulmonic homograft. The homograft main pulmonary artery was anastomosed end to end to the proximal portion of the left main pulmonary artery.

The final pathology was read as malignant pleomorphic spindle cell neoplasm consistent with leiomyosarcoma, with extensive fibrosis and necrosis consistent with treatment. The tumor stained positive for smooth muscle actin, and CD34, and negative for CK7, CK20, desmin and s100. Final microscopic margins showed that all margins were negative except for the proximal left main pulmonary artery. Post treatment pathologic staging was T4N1 (2/7 hilar nodes positive).

Postoperative radiation to the pulmonary anastomosis was administered six weeks after the operation. She has been followed with periodic chest MRI and PET/CT and remains alive without evidence of recurrent disease seven years and eight months following resection.

COMMENT: The largest review of mediastinal sarcomas consists of 47 patients from Memorial Sloan Kettering treated between 1940 and 1991. No mention was made as to how many were pulmonary artery sarcomas. Twelve were malignant peripheral nerve tumors, and only 5 were leiomyosarcomas. Malignant peripheral nerve tumor patients had a 36% five year survival, while none of the other sarcoma patients survived more than 2 years.1

Primary pulmonary artery sarcomas are rare, with fewer than 250 patients described in the literature. 2 In 1995, the largest series until that time, involving six cases, was published from the University of California at San Diego. No patient survived more than 19 months, even with adjuvant chemotherapy and radiation. The invited commentary for this report suggested that "pulmonary artery sarcomas are almost invariably incurable."3

More recently, a series and review of the literature from MD Anderson Cancer Center showed encouraging results in eight pulmonary artery sarcoma patients with bi and trimodality therapy and aggressive surgical resection.2 All were resected via median sternotomy on bypass and all received pre or postoperative chemotherapy. Five had replacment of the main PA, 3 had pulmonic valve replacement and five underwent pneumonectomy. They reported a median survival of 71 months and five year survival of 72.9%, though no patient was alive and disease free beyond 30 months.

Ninety two months represents one of the longest disease free survival intervals in a patient with a pulmonary artery sarcoma, and supports aggressive surgical resection along with multimodality treatment in fit patients. The use of postoperative, high dose, focused radiation to the proximal left main pulmonary artery margin appears to have eradicated residual microscopic disease. The vast majority of long term survivors in the literature have been treated with either pre or postoperaive chemotherapy, and radical resection via median sternotomy on cardiopulmonary bypasss, with resection of the main pulmonary artery and/or valve with homograft replacement. This strategy should be explored in all fit patients with such disease.

SARCOIDOSIS PRESENTING AS ACUTE BACTERIAL PNEUMONIA

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A 65 year old male with no significant medical history presented with one week of cough, dyspnea and fever. Chest X-ray showed left mid-lung infiltrate suggestive of pneumonia. He was treated with antibiotics without improvement. Two months later, he developed worsening of his symptoms and a new hypoxemia. Chest computed tomography showed a left lower lobe (LLL) alveolar infiltrate, extensive mediastinal and hilar adenopathy and a new left-sided pleural effusion. Pleural fluid sampling showed a lymphocytic exudate. Bronchoscopic sampling was non-diagnostic. Positron emission tomography scan showed increased uptake in the region of the LLL infiltrate and the mediastinal lymph nodes. Surgical biopsy of the mediastinal lymph node, the LLL infiltrate and the pleura showed non-necrotizing granuloma. Acid-fast bacilli and fungal stain and cultures on all the samples were negative. The diagnosis of sarocidosis was made and the patient was treated with systemic steroids, resulting in clinical and radiographic improvement.

TRANSAORTIC VIDEO-ASSISTED RESECTION OF A RECURRENT LEFT VENTRICULAR MYXOMA

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An asymptomatic 57-year-old woman presented for resection of a fifth cardiac myxoma. To avoid complete redissection of the heart, we proposed a video-assisted transaortic approach for a recurrent left ventricle (LV) myxoma resection. In a hybrid approach, sternotomy and open aortotomy provided the minimally invasive transaortic access to the myxoma. The myxoma was discovered during a routine echocardiographic screening. A 30° 5-mm scope, video-assisted thoracic surgery graspers, and endoshears were used for resection. The video-assisted technique significantly enhanced the intracardiac visualization, and a smaller, second myxoma was discovered after resection of the primary lesion. Both myxoma beds were additionally ablated to prevent recurrence. The total video-assisted operating time was 58 minutes. The transaortic valve approach avoided an atriotomy or ventriculotomy in a fifth redo operation. A transaortic valve approach to LV intracardiac lesions is safe and feasible, and it provides excellent visibility for complex cardiac cases.

SLEEP APNEA PATIENTS DO NOT HAVE ELEVATED RISK OF COMPLICATIONS OR LENGTH OF STAY POST-LOBECTOMY

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Background: Obstructive sleep apnea (OSA) has been associated with an increased risk of postoperative complications. The complication rate and length of hospital stay in patients with OSA undergoing lung resection has not specifically been evaluated. We postulate that OSA may be associated with an increased length of stay and risk of complications post-lobectomy.

Methods: Three hundred and twenty patients who underwent lobectomy between January 2009 and December 2011were reviewed. Those with either an OSA ICD-code, or documented history of OSA, were deemed as having OSA. Age, gender, a variety of preoperative co-morbidities, and lung function were used as covariates. Data analysis was performed using independent t-test/Kruskal-Wallis test for continuous variables, and Chi square/ Fisher exact test was used for categorical variables. Multiple logistic regression method was used to control for potential confounders.

Results: Out of 320 patients, 25 carried the diagnostic code of OSA. The two groups were equivalent in regards to age, FEV1, DLCO and smoking status., but differed in body mass index (BMI). Four out of the 25 patients with OSA developed post-lobectomy complications compared to 55 in the OSA negative group (16.0% vs. 18.6%, p value> 0.999). Length of stay in the OSA group was 4.16 ± 3.68 days compared to 4.32±3.14 days in OSA negative group (p value=0.639). After adjusting for comorbidities, the relationship remained insignificant.

Conclusion: OSA is not associated with an increase in complications or length of hospital stay following major lung resection.

TEE GUIDED OPTIMAL EPICARDIAL LEFT VENTRICULAR LEAD PLACEMENT BY VIDEO-ASSISTED THORACOSCOPIC SURGERY (VATS) IN NON RESPONDERS TO BIVENTRICULAR PACING AND PRIOR CHEST SURGERY

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OBJECTIVE: To study the feasibility, safety and efficacy of TEE guided intraoperative left ventricular (LV) lead placement via a video-assisted thoracoscopic surgery (VATS) approach in patients who are non-responders to conventional biventricular pacing (BIVP).

METHODS: Eight patients underwent epicardial LV lead placement by VATS. 5/8 patients had prior chest surgery. For safety reasons the positioning was a modified far lateral supine exposure with 30° bed tilt, allowing for groin and sternal access if needed. To determine the optimal LV location for lead placement, the whole LV surface was divided arbitrarily into 9 segments. These segments were transpericardially paced using a hand held malleable pacing probe to identify the optimal site verified by TEE functional assessment. The pacing lead was screwed into position via a limited pericardiotomy. The leads were then tunneled subcutaneously to the device.

RESULTS: The VATS approach was successful in all patients. BIVP was achieved in all patients and all reported symptomatic benefit with reduction in New York Heart Association class from III to I-II ($p<0.03$). Baseline mean QRS interval was 168ms (range 148-182). At 3 months follow up the mean QRS was 160ms (range 132-196). Satisfactory pacing thresholds and impedances were achieved intraoperatively and at subsequent follow-up. The mean follow-up was 338 days. The median length of hospital stay was 7 days (range 3-16) with chest tube removal between post-op days 2-5.

CONCLUSIONS: In patients who are non responders to conventional BIV pacing, intraoperative LV lead placement using anatomical and functional characteristics via a VATS approach is effective in improving heart failure symptoms. This optimized LV lead placement is feasible and safe. Prior chest surgery is no longer an exclusion criterion for a VATS approach.

THORACOSCOPIC RESECTION OF A GIANT TERATOMA COMPRESSING THE RIGHT HEART

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A 26 year old female had an incidental finding of a large mediastinal mass. On further radiographic workup a cystic mass (10.8 x 9.4 x 10.0 cm) was identified in the inferio-anterior mediastinum. It had a mass-effect on the superior vena cava, right atrium and right ventricle. Advanced imaging studies could not exclude right heart involvement. She underwent resection via right thoracoscopy (VATS). The right groin vessels were accessible for bypass, if needed. Intraoperatively the mass was found to be extrapericardial and originating from the thymus. Complete resection was achieved using a minimally invasive technique. The largest incision was 2.5cm in a three port approach. She was discharged on post -op day one. The interdisciplinary planning and cooperation on this case avoided thoracotomy or sternotomy and allowed for a safe and complete minimally invasive resection.

Section 10

Transplant and Hepatobiliary Surgery

ADVANCED DONOR AGE CONVERGES WITH PRETRANSPLANT CELLULAR SENSITIZATION TO INCREASE THE RISK OF ACUTE REJECTION AFTER KIDNEY TRANSPLANTATION

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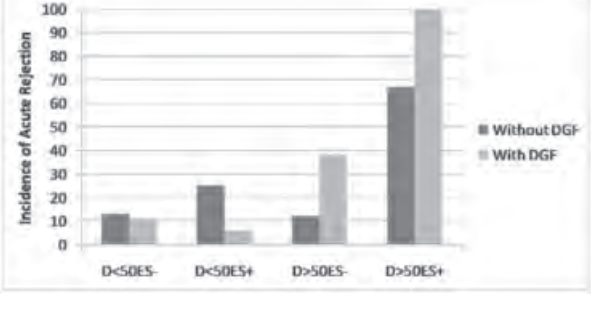
Advanced donor age and pretransplant humoral sensitization adversely affect kidney transplant outcomes. We have described the ELISPOT assay for interferon gamma as a measure of cellular alloimmunity. To determine the interplay between cellular presensitization and donor age, we studied 118 recipients of deceased donor kidneys in whom pretransplant donor specific ELISPOTs were available. Patient characteristics: age 47.5±12 yrs, 63% male, 52% African American, HLA mismatches 3.9±1.9, time on dialysis 48.6±31 mos. 33% had a positive ELISPOT (≥25/300K cells), 13% had peak PRA≥60%. 23% had DGF (dialysis in first week). Donor age was ≥50 yrs in 35%. 21% experienced acute rejection (AR) in the first year. The incidence of AR was 36% versus 14% in patients with and without a positive pretransplant ELISPOT. There was a trend for higher rates of AR when donors ≥50 yrs were compared to younger donors (27% versus 10%, p=NS). In logistic regression, the combination of donor age ≥50 yrs and a positive ELISPOT correlated with AR in the first year after transplantation (OR 12.1,95% CI 1.1-133, p=0.041), independent of recipient age, PRA, ethnicity, gender, HLA mismatch, and time on dialysis. The interaction between pretransplant cellular presensitization, donor age, and DGF was further examined by categorizing patients into 4 groups based on donor age <or≥50 years of age, and either a negative or positive pretransplant ELISPOT (i.e., D<50ES- (n=57), D<50ES+ (n=31), D≥50ES- (n=25), or D≥50ES+(n=5)) as shown below.



Our results indicate a very high incidence of AR when patients with pretransplant cellular sensitization receive kidneys from older donors, especially in the presence of DGF. The donor-specific ELISPOT assay for interferon gamma may prove to be useful in selecting optimal recipients for transplantation of kidneys from older donors.

EXTENDED AND STANDARD CRITERIA KIDNEYS WITH SIMILAR KDRI SCORES HAVE SIMILAR OUTCOMES

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ECD kidneys are less frequently transplanted than SCD. We investigated whether the ECD label discourages organ acceptance compared to SCD kidneys with similar Kidney Donor Risk Index (KDRI) values.

METHODS: KDRI scores, recovery and transplant rates were determined for all non-DCD adult kidneys between 11/1/2002- 5/31/2010 using OPTN/SRTR data. Kidneys whose KDRI values fell into an overlap range (1.4-2.1), which included both SCD and ECD kidneys, comprised the study cohort. Kidneys were further divided into KDRI intervals (1.4-1.6, 1.6-1.8, 1.8-2.1), and recovery and transplant rates calculated. Patients receiving first kidney transplants were divided by these KDRI intervals, and death-censored graft survival determined, adjusting for recipient age, gender, race, and diabetes.

RESULTS: Within the overlap region, a significantly higher percentage of ECD kidneys than SCD kidneys were recovered, as well as at each KDRI interval. Transplant rates decreased with increasing DRI intervals, and the overall transplant rate was lower for ECD kidneys than for SCD kidneys (66% vs. 72%). However, transplant rates were similar for the lower and higher KDRI intervals, but significantly higher for ECD kidneys in the 1.6-1.8 interval (72% vs. 64% for SCD). Among transplanted kidneys, adjusted graft survival was not different for ECD vs. SCD in any of the KDRI intervals.

CONCLUSIONS: The ECD designation does not adversely affect utilization beyond that predicted by KDRI. At a given KDRI, the ECD designation does not confer an increased risk for graft failure compared with SCD kidneys.

INTERACTIVE EFFECTS OF PRETRANSPLANT CELLULAR SENSITIZATION AND DELAYED GRAFT FUNCTION ON ACUTE REJECTION AFTER DECEASED DONOR KIDNEY TRANSPLANTATION

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Pretransplant sensitization and delayed graft function (DGF) adversely affect the outcomes of kidney transplantation. Innate immune mechanisms triggered by ischemia-reperfusion injury may interact with adaptive immune mechanisms to promote acute allograft rejection (AR). Humoral sensitization, conventionally assessed by detecting preformed anti-HLA antibodies (i.e. panel reactive antibodies or PRA), is associated with higher rates of DGF and AR. We have previously described the ELISPOT assay for interferon gamma as a measure of cellular alloimmunity. To determine the interplay between cellular presensitization and DGF, we studied 118 recipients of deceased donor kidney transplants in whom both pretransplant donor specific ELISPOT and PRA were available at two centers. Characteristics of the patients: age 47.5±12 yrs, 63% male, 52% African American, HLA mismatches 3.9±1.9, time on dialysis 48.6±31 mos. 33% had positive pretransplant ELISPOT (≥25/300K cells); 5% had peak PRA≥80%; 13% had PRA≥60%. 23% had DGF (need for dialysis in first week); 21% experienced acute rejection (AR) in the first year. The incidence of AR was 40% versus 16% in patients with and without DGF (p=0.014), and 36% versus 14% in patients with and without a positive pretransplant ELISPOT. The incidence of AR was 77% for patients with a combination of DGF and a positive pretransplant ELISPOT versus 17% in those without DGF and with a negative ELISPOT (p=0.005). Logistic regression showed that the combination of DGF and a positive pretransplant ELISPOT was a significant correlate of AR (odd ratio 14.4, 95% CI 2.6-79, p=0.002), independent of PRA, age, ethnicity, gender, HLA mismatch, time on dialysis, or either DGF or a positive ELISPOT alone. Our results suggest that heightened pretransplant cellular alloimmune responses measured by the ELISPOT assay for interferon gamma increase the risk of AR in patients with DGF, independent of humoral sensitization. The donor-specific ELISPOT assay for interferon gamma may play an important role in pretransplant immune risk assessment, especially in patients at risk for ischemia-reperfusion injury and DGF.

OUTCOME OF LOCOREGIONAL THERAPY FOR HEPATOCELLULAR CARCINOMA (HCC) BEFORE LIVER TRANSPLANTATION

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Introduction: Liver transplantation (LT) is considered the best treatment option for HCC patients within Milan criteria (MC). The effectiveness of locoregional therapies (LRT) to maintain tumor characteristics within these criteria or to downstage more advanced tumors is not well understood. The aim of this study was to examine the impact of pre-LT LRT on post-transplant patient survival, and tumor pathological response to the treatment.

Methods: A two-center prospectively maintained IRB approved liver transplant database was queried for treated HCC patients undergoing LT. Among patients within MC pre-LT LRT was provided (group A) or no pre-LT LRT was attempted (group B). Similarly, beyond MC patients received pre-LT LRT (group C) or no treatment (group D). Demographics, tumor characteristics, etiology of liver disease, time on waitlist to transplant and oncological outcomes were analyzed among groups. Chi-square, Fisher exact test, Wilcoxon rank sum test, and Kaplan Meier estimates were used for statistical analysis. $P<0.05$ was considered significant.

Results: Between 2002-2009, 286 patients with HCC were transplanted in our institutions. 145 (50.7%) patients received LRT in the form of standard transarterial chemoembolization (n=91), chemoembolization via drug eluting beads (n=10), radiofrequency ablation (n=37), transarterial radioembolization (n=5), bland embolization (n=5) or a combination of these (n=9). The mean age was 57.7±8.3 years. 80% were males. Mean follow-up was of 43.3±45.6 months. Median waitlist time was 48 days. 227 patients (95 group A, 132 group B) were within MC on initial HCC diagnosis and 57 patients (48 group C, 11 group D) beyond MC. There was no significant difference in age (p=0.2), gender (p=0.1), etiology of liver disease (p=0.4) and waitlist time (p=0.5) among groups. The mean overall survival (OS) and disease free survival (DFS) for patients within and beyond MC were 121, 93 vs. 84, 50 months respectively (p=0.001). The 1-, and 3-years OS were 94%, 95%, 85%, 82% and 87%, 85%, 64%, 61% and DFS were 91%, 88%, 81%, 72% and 85%, 83%, 61%, 52% for groups A, B,C and D respectively. There was no significant difference in OS between group A vs. group B (p=0.3) and group C vs. D (p=0.7). Also there was no difference in DFS between group A vs. group B (p=0.5), however there was a significant difference in DFS between group C vs. D (p=0.01). Complete pathological response was in 10/95 patients (10.5%) in Group A and 5/48 in Group C (10.4%). Patients with complete pathological response did not experience tumor recurrence.

Conclusions: With short waitlist time patient survival appears not to be affected by pre-LT LRT for within MC HCC. On the other hand for beyond MC patients pre-LT LRT may have a more significant role. The ideal consequence of LRT which is complete tumor necrosis is still an occasional phenomenon in the current era.

OUTCOMES OF PLANNED MULTIMODALITY THERAPY FOR UNRESECTABLE, UNTRANSPLANTABLE HEPATOCELLULAR CARCINOMA

HEPATOLOGY, VOLUME 54, NUMBER 4 (SUPPL) AASLD ABSTRACTS 1403A

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The majority of patients with hepatocellular carcinoma (HCC) are not candidates for curative resection or liver transplantation (LT). The past two decades have witnessed the development of a number of systemic and locoregional therapies for HCC. We examined eligibility for and outcomes of these therapies in patients managed at our multidisciplinary hepatobiliary tumor clinic between January 2009 and December 2010.

Methods: Patients with unresectable HCC were excluded if they had Barcelona Clinic Liver Cancer (BCLC) classes A and D, any therapy with curative intent, ECOG Performance Status >1 and follow up < 6 months. Planned Multimodality therapy (PMT) was defined as a combination of two or more therapies initiated within 60 days of the first therapeutic intervention after HCC diagnosis. Initial Monotherapy (IM) was defined as monotherapy with any modality and subsequent therapy if any, triggered by disease progression. Results: 121 patients met study criteria and were included in the analysis. Patients were mostly male (76%) and Caucasian (66%). Mean baseline bilirubin was 1.7 and MELD 12. 33% had BCLC class B and 67% had BCLC class C. Mean imaging follow up interval was 3.2 months. None of these parameters were statistically significantly different between the PMT and IM groups. Overall, 49% received sorafenib, 15% conventional Transarterial Chemoembolization (TACE), 17% doxorubicin eluting bead-TACE, 9% Y90 radioembolization, 26% Radiofrequency Ablation or Cryoablation, 14% stereotactic body radiation therapy and 6% palliative surgery. 81% received at least one therapy while 44% received PMT. Among sorafenib-treated patients, 71% in the IM group versus 55% in the PMT group received therapy >3 months (p=0.03). Mean overall survival at data censorship was 14.6 months in the PMT group and 8.1 months in the IM group (Odds Ratio (OR) 1.80, 95% Confidence Intervals (CI) 1.36-3.46; p=0.02). Mean time to radiological progression (TTP) was 6.1 months for the PMT group and 3.7 months for the IM group (OR 1.62, 95% CI 1.2-3.8; P=0.008). In binary logistic regression, sorafenib therapy >3 months (OR 1.4, 95% CI 1.1-3.8; p<0.001), PMT (OR=1.9, 95% CI 1.6-4.7; p<0.0001) and solitary lesion of any size (OR 2.3, 95% CI 1.7-4.3; p<0.0001) were associated with survival >12 months.

Conclusions: The majority of HCC patients with unresectable, untransplantable BCLC class B/C are eligible for at least one therapy and 44% for PMT. In this retrospective analysis, PMT appears associated with increased survival and TTP in these patients. Prospective trials examining survival and societal costs are needed to confirm and refine these findings.

OUTCOMES OF TRANSPLANT NEPHRECTOMY: A POSSIBLE BENEFIT OF TRANSPLANT NEPHRECTOMY EARLY AFTER ALLOGRAFT FAILURE

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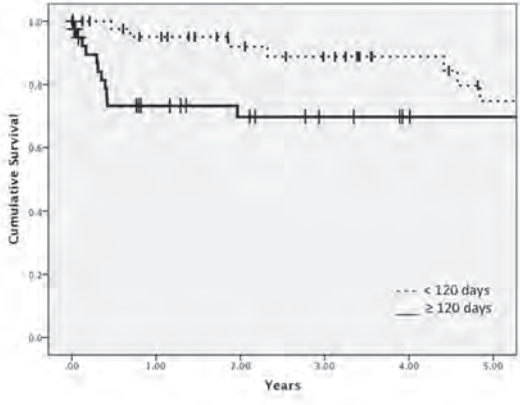
Management of the failed renal transplant is controversial. Transplant nephrectomy often occurs after immunosuppression has been withdrawn, which can lead to sensitization. We sought to determine the impact of nephrectomy timing on perioperative outcomes to better define the risk-benefit ratio of allograft nephrectomy.

Methods: After IRB approval, we retrospectively analyzed outcomes from 86 patients who underwent transplant nephrectomy for cause between 2000 and 2011. Group 1 underwent nephrectomy < 120 days after allograft failure (n=45) and group 2 underwent nephrectomy > 120 days after allograft failure (n=41).

Results: There were no significant differences between the two groups in age, gender, race, BMI, or diabetes. Group 1 included 3 patients who also had a pancreas transplant, while group 2 included 8 such patients. Patients in group 2 had a longer time from transplant to allograft failure (2986 ± 1782 d vs 1760 ± 1863 d for group 1, p=0.003). Complications were not significantly different, except for superficial surgical site infection (15% in group 1 vs 0% in group 2, p=0.02). Deep surgical site infections and organ space infections were similar (2.5 vs 3.0%, respectively). Hernia rates were 1.4% overall (0% for group 1 vs 3% for group 2, p=NS). DVT rate was 7.5% in group 1, and 0% in group 2 (p=NS). There were no myocardial infarctions in either group, but a patient in group 2 suffered flash pulmonary edema and atrial fibrillation. Kaplan-Meyer analysis demonstrated an early significant difference in patient survival favoring early transplant nephrectomy (Breslow's generalized Wilcoxon test, p=0.02). Late survival was not significantly different (Logrank test, p=0.25). Thirty day and 1 year survival were 100% and 95% for group 1, and 95% and 73% for group 2.



Conclusions: Complications are similar for those undergoing early versus late transplant nephrectomy. There may be an early survival advantage associated with transplant nephrectomy soon after allograft failure.

PERSISTENT STEROID AVOIDANCE PREDICTS LESS BK VIREMIA AFTER KIDNEY TRANSPLANTATION

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Background: The incidence of BK viral infection is thought to correlate with overall immunosuppressive exposure after kidney transplantation. We sought to determine the rate of BK viremia in the first year after transplantation in relation to steroid therapy.

Methods: Since 8/2007 we incorporated screening for BK using plasma quantitative PCR testing at 3, 6, and 12 months post-transplantation. We analyzed the incidence of BK viremia related to both early steroid withdrawal and steroid resumption within the first year. Steroids were withdrawn after four days except in patients who had high sensitization, prior failed transplants, delayed graft function (DGF), or preexisting steroid therapy. All patients received tacrolimus/MMF after induction with basiliximab or anti-thymocyte globulin (ATG).

Results: We analyzed 233 consecutive solitary kidney recipients from a three year time period after excluding 6 with early death/graft loss. BK viremia was detected within the first year in 14% (median peak viral load 59,200 copies). The incidence of BK was 12% in patients with early steroid withdrawal (n=170) vs. 21% in patients with maintenance steroid therapy (n=63), (p=0.09). Patients on maintenance steroids had a higher rate of ATG induction therapy (78% vs. 62%, p=0.03), while patients with steroid withdrawal had a higher rate of expanded criteria (ECD) transplants (19% vs. 8%, p=0.04). In patients with early steroid withdrawal, 24% resumed steroids within the first year, primarily for acute rejection or allograft dysfunction. Patients who resumed steroids had a 20% incidence of BK, and 3/4 of these patients developed BK after restarting steroids. Alternatively, BK occurred in just 9% of patients with persistent steroid withdrawal (p=0.07 vs. patients with steroid resumption). A logistic regression model was used to analyze the risk of BK in patients with persistent steroid withdrawal (n=130) vs. those who either maintained or resumed steroids (n=103) after controlling for donor source (living vs. deceased), ECD donor, ATG induction, and DGF. In this model, ECD transplant predicted more BK (Odds ratio 2.54, p=0.05), while persistent steroid avoidance predicted less BK viremia (Odds ratio 0.37, p=0.02).

Conclusion: Early steroid withdrawal after kidney transplantation appears protective against BK viremia. This protective benefit was lost in the minority of patients who resumed steroid therapy after withdrawal.

MULTICENTER RESULTS OF STEREOTACTIC BODY RADIOTHERAPY (SBRT) FOR NON-RESECTABLE & NON-TRANSPLANTABLE PRIMARY TUMORS OF THE LIVER

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Departments of Surgery[1], Medicine[2] and Radiation Oncology[3], University Hospitals-Case Medical Center[1], Cleveland Clinic[2], Memorial Sloan-Kettering Cancer Center[3] and University of Rochester Medical Center[4]

Background: 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. Non-surgical therapies, i.e. TACE, RFA have limited response and no significant impact on patient survival. SBRT has emerged as an alternative therapy. The aim of this study was to determine tumor response to SBRT treatment and if SBRT may confer survival benefit to patients with non-resectable and non-transplantable primary liver tumors.

Methods: patients with Barcelona Class (BCL) C/D Hepatocellular carcinoma (HCC) and patients with stage IV intrahepatic cholangiocarcinoma (ICC) treated with SBRT from four Academic Medical Centers were entered into a common database. Descriptive statistics and survival curves were performed using SPSS.

Results: 38 patients underwent SBRT for BCL C/D HCC (n=24) or Stage IIIa ICC (n=14) at a dose of 30 Gy (mean) in 3 consecutive fractions (median) at an average Isodense line of 70%. 96% of the patients with HCC experienced a Grade III/IV local response with a mean decrease in maximum diameter from 7.9±4.9 cm to 5.5±2.3 cm and a calculated mean total tumor volume reduction of 44%. 84% of the patients with ICC had an objective response to SBRT but local recurrence was common in areas out of the radiated field. SBRT conferred a survival advantage in patients with HCC in whom both PV thrombosis and extrahepatic disease were absent when compared with matched controls at a mean of 12 months follow-up ($p<0.05$).

Conclusion: SBRT is a safe and effective treatment modality for the local control of primary liver neoplasms. SBRT appears to confer survival benefit in patients with ESLD and advanced HCC confined to the liver without PV thrombosis. Further follow-up is ongoing to assess the role of SBRT in the downstage management for HCC.

MULTICENTER RESULTS OF STEREOTACTIC BODY RADIOTHERAPY (SBRT) FOR SECONDARY TUMORS OF THE LIVER

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Departments of Surgery[1], Medicine[2], and Radiation Oncology[3], University Hospitals-Case Medical Center[1], Cleveland Clinic[2], Memorial Sloan-Kettering Cancer Center[3] and University of Rochester Medical Center[4]

Background: More than 250,000 patients are diagnosed with liver metastases 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. Non-surgical therapies, i.e. TACE, RFA have limited response and no significant impact on patient survival. SBRT has emerged as an alternative therapy.

Objective: to determine the response of liver metastases to SBRT and if SBRT treatment may confer survival benefit to patients with non-resectable liver metastases.

Methods: patients with secondary liver tumors treated with SBRT from four Academic Medical Centers were entered into a common database. Descriptive statistics and survival curves were performed using SPSS.

Results: 155 patients underwent SBRT for liver metastases. 52% of tumors originated in the GI tract while 35% were from the thorax including breast. 89% of treated neoplasms responded to SBRT at a median dose of 32 Gy in 3 consecutive fractions (median). A Grade III/IV local response was observed with a mean decrease in maximum diameter from 4.3 ± 1.9 cm to 2.5 ± 1.3cm and a calculated mean total tumor volume reduction of 39%. Recurrences in the radiated field were observed in 2% of treated cases. SBRT did not conferred a survival advantage in patients with secondary liver tumors when compared with matched controls ($p>0.05$). Systemic recurrences were common. 42% of patients were readmitted to the hospital for medical complications. No complications attributable to fiducial placement or SBRT treatment were observed.

Conclusion: SBRT is a safe and effective treatment modality for the local control of secondary liver neoplasms. Further analyses are undergoing to determine grade of response to SBRT according to tumor type.

SURVIVAL ADVANTAGE OF ALLOGRAFT NEPHRECTOMY EARLY AFTER TRANSPLANT FAILURE

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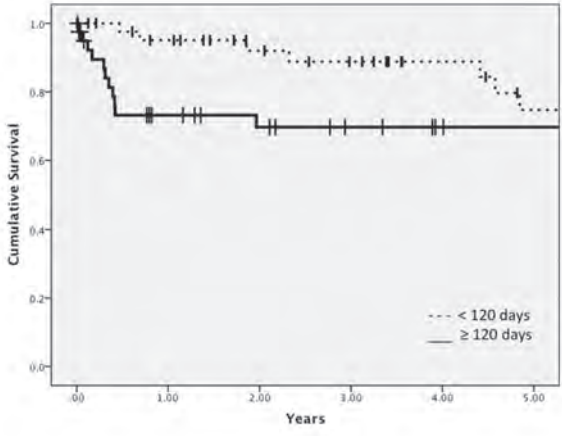
Management of the failed renal transplant is controversial. We sought to determine the impact of nephrectomy timing on perioperative complications and survival.

Methods: After IRB approval, we retrospectively analyzed outcomes from 86 patients who underwent transplant nephrectomy for cause between 2000 and 2011. Group 1 underwent transplant nephrectomy < 120 days after allograft failure (n=45) and group 2 underwent transplant nephrectomy 120 days after allograft failure (n=41).

Results: There were no significant differences between the two groups in age, gender, race, BMI, or diabetes. Group 1 included 3 patients who also had a pancreas transplant, while group 2 included 8 such patients. Patients in group 2 had a longer time from transplant to allograft failure (2986 ± 1782 d, vs 1760 ± 1863 d for group 1, p=0.003). Complications were not significantly different, except for superficial surgical site infection (15% in group 1 vs 0% in group 2, p=0.02). Deep surgical site infection and organ space infection rates were similar. Kaplan-Meyer analysis demonstrated an early significant difference in survival favoring early transplant nephrectomy (Breslow's generalized Wilcoxon test, p=0.02). Late survival was not significantly different (Logrank test, p=0.25). Thirty day and 1 year survival were 100% and 95% for group 1, and 95% and 73% for group 2.



Conclusion: There may be an early survival advantage associated with transplant nephrectomy soon after allograft failure.

THE PERILS OF WEANING: FEBRILE REJECTION AND ALLOANTIBODY SENSITIZATION AFTER KIDNEY TRANSPLANT FAILURE

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Patients returning to dialysis after kidney transplant failure have high rates of morbidity and mortality and a low rate of retransplantation. We noticed episodes of hospitalization with fever and alloantibody sensitization in patients after weaning immunosuppression, and analyzed rates of hospitalization and sensitization in 266 patients with failed kidney transplants. Sensitization was defined as a panel reactive antibody (PRA) ≥60% for HLA class I or II by flow cytometry, and PRA data after transplant failure was available in 178 patients. Weaning was defined as discontinuation of all immunosuppression with the possible exception of prednisone ≤10 mg/day, and the majority (77%) of patients weaned immunosuppression. Reasons for not weaning included a functioning pancreas transplant (n=24), early living donor retransplantation within six months of failure (n=17), or physician preference (n=20). Hospitalization for fever within six months of failure was common and occurred in 42% of patients, and rates were similar in patients who weaned or maintained immunosuppression. However, 88% of patients who maintained immunosuppression had actual infection, while only 38% of patients who weaned immunosuppression had infection documented clinically or with positive cultures ($p<0.001$). The remaining 62% had symptomatic rejection and most underwent subsequent allograft nephrectomy. Regardless of hospitalization history, weaning immunosuppression correlated highly with sensitization after failure ($r=0.667$, $p<0.001$), and rates of sensitization were similar in patients who required nephrectomy (88%) or did not (80%) (p=ns). Weaning remained a significant correlate with sensitization after controlling for allograft nephrectomy, early retransplantation, and other variables (Odds ratio: 7.39, $p=0.025$). Rates of sensitization rose from 27% of patients at the time of failure to 79% of patients within one year of weaning ($p<0.001$). Alternatively, patients maintained on immunosuppression after allograft failure had low rates of sensitization and rarely required nephrectomy. In conclusion, weaning immunosuppression after kidney allograft failure was a triggering event leading to hospitalization for febrile rejection, allograft nephrectomy, and alloantibody sensitization.

GLUTATHIONE SPECIES DISTURBANCES AS AN EARLY MAKER OF HCC IN THE CIRRHOTIC WOODCHUCK AND THE HUMAN

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Introduction: The incidence of liver neoplasms is rising in USA and the sensitivity and specificity of available tumor markers for their early detection are low. We have shown disturbances in the glutathione redox couple (GSH:GSSG) and its analog ophthalmate (OA) in a rabbit model of secondary liver tumors. The aim of this study was to evaluate the oxido-reductive status of the liver as a marker for hepatocellular carcinoma (HCC).

Material and Methods: Glutathione species and OA concentrations were measured by LC-MS/MS techniques in processed plasma from animals infected with the Woodchuck hepatitis virus (WHV) and from humans with end stage liver disease (ESLD). The presence of HCC in animals and humans was determined by imaging modalities (CT/MRI and/or PET scans) and confirmed by pathology. Blood from woodchucks were obtained from three groups: i) WHV+/HCC+ animals (n=3) prior to tumor ablation and 8 hours after tumor ablation, ii) WHV+/HCC- animals (n=4) and iii) WHC-/HCC- healthy animals (n=4). Patients with ESLD+/HCC+ (n=12) were compared to patients with ESLD+/HCC- (n=41) and to healthy controls ESLD-/HCC- (n=19). Statistical analyses were performed using paired t-tests and independent t-tests.

Results: Plasma concentration of GSH and GSH/GSSG ratio were lower in the WHV+/HCC+ animals when compared to the other groups (Mean±SD in μM; see Table). In addition, the concentrations of GSSG and OA were significantly higher in the WHV+/HCC+ animals. The concentration of GSH increased in all WHV+/HCC+ animals after tumor ablation when compared to pre-ablation levels (7.2±0.9 10.3±2.5 μM, $p<0.05$). The concentrations of GSH:GSSG in humans were similar among groups. In contrast, the concentration of OA was significantly higher in the ESLD+/HCC+ patients.

GROUP	GSH	GSSG	GSH/GSSG ratio	OA
WHV-/HCC-	14.4±1.2	0.8±0.2	36.3±7.5	0.04±0.01
WHV+/HCC-	20.5±1.9**	1.2±0.1*	33.0±1.7	0.2±0.1*
WHV+/HCC+	7.2±0.9**	4.4±0.1**	2.7±0.6**	0.9±0.2**
ESLD-/HCC-	38±15	3.6±2.3	21.1±4	4.0±2.1
ESLD+/HCC-	31±19	2.4±2.0	25.8±5	6.2±4.0
ESLD+/HCC+	31±20	2.1±2.1	29.5±24	13.0±4.1*

*$p<0.05$ and **$p<0.01$ versus controls (WHV-/HCC- or ESLD-/HCC-)

Conclusion: Woodchucks and humans with HCC presented disturbances in the GSH/GSSG redox buffer system and OA. This compound may be a more sensitive index of oxidative stress than GSH and it may prove to be useful in the early detection of HCC.

Section 11

Trauma, Critical Care, Burns

PLANNED VENTRAL HERNIA FOLLOWING DAMAGE CONTROL LAPAROTOMY IN TRAUMA: AN ADDED YEAR OF RECOVERY BUT EQUAL LONG-TERM OUTCOME

*KB Kelly, BM Zosa, JJ Como, JA Claridge**

Purpose: We evaluated hospital and long-term outcomes of damage control laparotomy (DCL) for trauma managed with either primary fascial closure during the index hospitalization or discharge with a planned ventral hernia.

Methods: DCLs for trauma from 2005-2010 at a regional Level 1 trauma center were identified and compared based upon whether they had primary fascial closure or a planned ventral hernia.

Results: 121 patients had a DCL and 47% were following penetrating injuries. The mean age and injury severity score (ISS) were 40 and 25, respectively. Hospital mortality was 21%. 91 (75%) DCLs had primary fascial closure during the index hospitalization. Of these, 8 (9%) had their fascia re-opened which was associated with a mortality rate of 25%. 14 (12%) never had primary fascial closure and were discharged with a planned ventral hernia. Primary fascial closure and planned ventral hernia patients were similar in age, gender, ISS, and injury mechanism. Planned ventral hernias had more subsequent laparotomies (3.3 vs 1.5, $p<0.001$), hospital days (43 vs 27, $p<0.05$), need for tracheostomy (57% vs 31%, $p=0.039$), and intra-abdominal infections (57% vs 17%, $p=0.003$). Enteric fistulas during the index hospitalization were seen in 21% of planned ventral hernias and 6 % of primary fascial closure patients (p=NS). Planned ventral hernias were discharged to home less often (14% vs 42%, $p=0.045$). 11 (76%) patients with a planned ventral hernia had definitive reconstruction (mean days = 330). Once definitive abdominal wall closure was achieved, the two groups achieved similar rates of work clearance (71% vs 70%). The days to work clearance were also similar (190 vs 181). Primary fascial closures and planned ventral hernias had similar rates of hernia recurrence (15% vs 18%), intra-abdominal infection (10% vs 0%) and enteric fistulas (2% vs 0%) long term. Study follow-up has been 21 months with an overall mortality rate of 25%.

Conclusions: Following a DCL for trauma, patients with a planned ventral hernia are set back approximately 1 year in their recovery as compared to patients with primary fascial closure. However, once definitive abdominal wall closure is achieved, patients with primary fascial closure or planned ventral hernia do equally well.

A REVISED PRE-HOSPITAL TRAUMA TRIAGE PROTOCOL: SAVING PATIENTS AND RESOURCES

Katherine B Kelly MD, Michael Nowak PhD, Patricia A Wilczewski RN, Deborah Allen BSN, RN, Aman Banerjee MD, Jeffrey A Claridge MD, MS, FACS

MetroHealth Medical Center

Purpose: As the regional Northern Ohio Trauma System (NOTS) develops, a key goal is to establish an efficient and effective trauma triage protocol that reliably identifies the severity of a patient's injury and safely delivers that patient to the appropriate level of care. Current state law requires all trauma victims to be transported to the nearest trauma center. This policy results in a large number of mildly injured and/or uninjured patients taking up resources at the trauma centers. We hypothesized that a revised pre-hospital trauma triage protocol would identify a subset of trauma victims who could be safely treated at their local ED. In the midst of this study, it was announced that one of the NOTS Level II centers might relinquish its trauma center status. We therefore secondarily set out to determine the impact of this closure on the system.

Methods: A revised EMS trauma triage protocol checklist was drafted and divides patients into Red, Yellow, or Green. Red patients are most likely to be severely injured while Green patients are unlikely to be seriously injured. Green patients, according to the revised trauma protocol, would be transported to the nearest ED. From 3/11-6/11, the city EMTs were instructed to triage, care, and transport trauma patients according to the current trauma protocol. The EMTs were also asked to complete the revised triage checklist for each trauma run. Hospital volumes, average transport times, patient checklist categorizations, and patient outcomes were determined. The revised checklist's over/under triage rates were calculated. Any Green patient requiring admission to the ICU/OR had their chart reviewed in depth to determine whether the protocol had failed to identify their injuries or if a coding error had been made.

Results: "City EMS" transported 614 patients to 3 trauma centers. EMS designated 143(23%) Reds, 299 (49%)Yellows, and 172 (28%) Greens. 510 (83%) of the patients were transported to the Level I center. Level II West received 37 (6%) patients and Level II East received 67 (11%) patients. 28% of all "City EMS" transports were Green and could be taken to the nearest ED if the protocol went into effect. Zero Green patients died from traumatic injury. 7 Green patients required admission to the ICU or OR. The chart review for these patients revealed that coding errors occurred in 4/7 of the cases. If these patients had been correctly categorized the under-triage rate was 1%. In the event of Level II East's closure, 67 patients would be redirected to the Level I center under the current protocol. This would increase the patient transport seen by the Level I center by 13%. The average hospital transport time for these patients would increase from 9 minutes to 18 minutes (100% increase). With the revised triage protocol, 17 Green patients would be taken to a local ED and patient volume at the Level I center would increase by only 10%.

Discussion: According to this pilot study, a revised triage protocol could identify the patients most likely to be severely injured and direct their immediate transport to the highest level of care. 28% of patients could be transported to the nearest ED and would decrease the trauma burden to the designated trauma centers throughout NOTS. The 1% under-triage rate found here is well below the target rates described in the ACS. Additionally, 2/7 under-triaged patients were victims of falls >10 ft but <20 ft. Based on this finding, we will change to protocol to categorize falls ≥ 10 feet (or one story) as Yellow.

A STAB TO THE ABDOMEN IS A STAB TO THE ABDOMEN, REGARDLESS OF WHO DID IT

Aman Banerjee, Hannah Y. Zhou, Bianca D. Downs, Katherine B. Kelly, Linda M. Quinn, John J. Como, Jeffrey A. Claridge

Objective: There is minimal literature comparing self-inflicted (SI) to non self-inflicted (NSI) anterior abdominal stab wounds (AASW). We hypothesized that there would be significant differences between these groups.

Methods: Adult patients treated at a level 1 regional trauma center from 2006 through 2011 with an AASW were included. Demographics, procedures, length of stay (LOS), and hospital charge information were compared between SI and NSI AASW.

Results: Initially 215 patients were identified with AASW; 43(20%) were SI. These patients had other injuries in addition to AASW. NSI patients had significantly more non-abdominal (47% vs. 16%, $p<0.01$), intra-abdominal injuries (40% vs. 16%, $p<0.01$), and disposition directly to OR(45% vs. 26%, $p=0.02$). Otherwise, the groups were similar. 128 patients had isolated AASW; 36(28%) were SI. Age, ISS, initial vitals, gender, and percent of patients with multiple AASW were similar. SI patients were more likely to be admitted (86% vs. 63%, $p=0.01$) with similar LOS. There were no significant differences in percent hemodynamically unstable/symptomatic patients, operative rates, or intra-abdominal injuries between the two groups. There were 103 stable/asymptomatic patients with isolated AASW; 32(31%) were SI. SI patients were more likely admitted (84% vs. 52%, $p<0.01$), had higher ICU admission rates (23% vs. 5%, $p=0.01$), longer LOS (3.2 vs. 1.4, $p<0.01$), and had higher hospital charges ($18,000 vs. $11,000, $p<0.01$). Rates of intra-abdominal injury were similar between these two groups at 21%.

Conclusion: After controlling for extra-abdominal injuries, SI and NSI patients with AASW have similar risks of intra-abdominal injuries. SI patients utilize more resources.

DIAGNOSIS OF INFECTION AFTER TRAUMA SPLENECTOMY: IT'S ABOUT THE LACK OF PLATELETS AND NOT THE WHITE BLOOD CELL COUNT

Aman Banerjee, Katherine Kelly, Hannah Zhou, Shanteria Dixon, and Jeffrey Claridge

Background: There is a lack of evidence-based criteria to assist with diagnosing infection in patients s/p trauma splenectomy (TS). The literature suggests that white blood cell count (WBC) is associated with infection in TS patients.

Hypothesis: There exist key differences in laboratory and clinical parameters that can help diagnose infection s/p TS.

Methods: All consecutive trauma patients s/p TS at a Level 1 trauma center from 2005 to 2011 were evaluated for the development of infection. Demographic, laboratory, and clinical parameters on odd postoperative days (POD) 1 through 15 were compared between infected and non-infected patients. Backward stepwise logistic regression was used to identify significant independent predictors of infection.

Results: 127 patients had a TS, 25 patients died within 48 hours leaving 102 cases for analysis. The mean day for the first infectious episode in the 41 patients that developed an infection was POD 7 (range 4 – 14). In the 41 patients who developed infection, the three most common infections were pneumonia (51%), urinary tract infection (24%) and bacteremia (20%). An evaluation of laboratory and clinical parameters demonstrated no differences in WBC between groups at any time. The table below summarizes some key significant differences. Over the 15 days analyzed, POD 5 was most strongly associated with different laboratory and clinical differences between and non-infected patients. Independent predictors of infection were platelet count on POD5 (OR = 0.99; 95% CI = 0.989 - 0.999, p = 0.029) and maximal temperature on POD 5 (OR = 4.1; 95% CI = 1.44 - 11.85, p = 0.008). The C statistic was 0.83.

	Non-infected (n = 61)	**Infected** (n = 41)	**p-value**
Injury Severity Score (ISS)	23	33	0.000
Platelet Count POD3	245	154	0.000
Platelet Count POD5	349	224	0.003
Platelet Count POD7	607	317	0.000
Platelet:WBC Ratio POD5	22.0	14.9	0.005
Maximum Temperature (Tmax) POD5	37.5	38.3	0.000
Peak Heart Rate POD5	103	116	0.001
Maximum Systolic POD5	139	154	0.007

Conclusion: The most significant parameters for prediction of infection after TS are Tmax POD5 and a platelet count that rises at approximately half the rate of non-infected patients. WBC and ISS were not key predictors. The use of serial clinical and laboratory data over time may allow for improved diagnosis of infection.

Section 12

Vascular Surgery and Endovascular Therapy

VASCULAR INJURIES DURING ANTERIOR EXPOSURE OF THE THORACOLUMBAR SPINE

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Objective: The aim of this study is to evaluate the vascular injuries, repairs and complications encountered during the anterior exposures of the thoracolumbar spine and their relationship to the pre- and intra-operative variables.

Methods: From January 2004 to July 2010, patients undergoing anterior exposures to the lower thoracolumbar spine were identified via examination of institutional databases. The electronic medical records of these patients were reviewed and demographics, preoperative variables, vascular complications, types of repair and outcome were recorded. The presence or absence of an access vascular surgeon was noted as well.

Results: A total of 269 anterior exposures to the lower thoracolumbar spine were performed in 260 patients. The average age at operation was 50.1 years. Of these cases, 146 were in females (54.3%), the average BMI was 29.01, previous spinal surgery was noted in 145 (53.9%) exposures and 19 (7.1%) had previous anterior exposure. The median estimated blood loss was 300 cc and there were no postoperative mortalities. A vascular injury occurred in 37 exposures (13.8%); significantly higher in redo anterior exposure (n= 19, 52 vs. 11%; P<.001), prior spinal surgery (n = 145, 19 vs 7%; P=.007), and in the setting of tumor (n= 14, 36 vs 12.5%; P=.03). A vascular injury resulted in greater EBL (median 800 vs. 300 ml, P<0.001) and longer length of stay (median 7 vs. 5 days, P=0.035). Most frequently injured was the left common iliac vein in 21 (52.5%) cases. A vascular surgery team performed the anterior exposures in 159 (59.1%) cases. Cases with vascular surgery participation had increased incidence of any vascular injury, but lower estimated blood loss (250cc vs 500cc;P<.001), total incision time (290 vs 404 min; P=.002), and length of stay (5 vs 6.5 days;P<.001). There was no difference demonstrated between the vascular injury, repair type and the incidence of deep venous thrombosis.

Conclusion: Anterior exposure of the spine can be done safely with experienced surgeons. Collaboration between spine and vascular teams may result in lessening blood loss and consequently morbidity and length of stay. These results need to be confirmed with prospective analysis.

TECHNIQUES TO HARVEST DISEASED HUMAN PERIPHERAL ARTERIES AND MEASURE ENDOTHELIAL FUNCTION IN AN EX-VIVO MODEL

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Objectives: Endothelial dysfunction has been studied in animal models. However, direct evidence of endothelial function from human vessels is limited. Our objectives were to optimize methods in harvesting human arteries from amputation specimens, determine endothelial function, and measure responsiveness to the nitric oxide precursor, L-arginine (L-arg).

Methods: Fresh amputation specimens were transferred expeditiously from the operating room to the bench laboratory for dissection and arterial harvest in an IRB-approved protocol. Popliteal and tibial vessels were examined in pilot experiments leading to the use of the anterior tibial artery in consecutive experiments. Human lower extremity anterior tibial artery segments were harvested from amputation specimens (N=14). Specimens were rapidly collected and divided for endothelial dependent relaxation (EDR) studies in a tissue bath apparatus, immunohistochemistry, and intravascular ultrasound derived virtual histology (IVUS-VH). A total of 47 ring segments were studied. The data were compared with two-way ANOVA.

Results: Human lower extremity arteries exhibited low EDR (24.9%, Ach 10-4). L-arg supplementation enhanced EDR by 38.5% ($P<0.0001$). L-NAME (N-nitro-L-arginine methyl ester) abrogated EDR ($P<0.0001$) in vessels exposed to L-arg. Arterial responsiveness was intact in all vessels (endothelial independent relaxation to sodium nitroprusside, 104 ± 58%). Histology and immunohistochemistry confirmed intact endothelium by morphometric analysis, CD31, eNOS, and arginase II staining. IVUS-VH indicated atheroma burden was 11.9 ± 4.7 mm3/cm, and plaque stratification indicating fibrous morphology predominant (59.9%; necrotic core, 16.9%; calcium, 11.2%). Variations in plaque morphology did not correlate with endothelial function nor responsiveness to L-arg.

Discussion: Human lower extremity arteries demonstrate low baseline endothelial function in patients requiring amputation. Endothelial dysfunction is improved by L-arginine supplementation in an ex vivo model. These results support strategies to increase local levels of nitric oxide in human vessels.

ACUTE KIDNEY INJURY FOLLOWING VENOUS PHARMACOMECHANICAL THROMBOLYSIS

Jacquelenn Stuhldreher MD, Constantinos Constantinou MD, Henry Baele MD, Jerry Goldstone MD, and Vikram S. Kashyap MD

Background: Endovascular techniques including thrombolysis and percutaneous mechanical thrombectomy (PMT) are being used with increased frequency to treat severely symptomatic venous thrombosis. Acute kidney injury following pharmacomechanical thrombolysis has been reported, however the true incidence is unknown.

Case Presentations: An 18 year-old male athlete with Paget von Schroetter disease underwent PMT using the Angiojet device and thrombolysis with tissue plasminogen activator (tPA). Total PMT volume was 200 mL. Postoperatively, the patient developed hematuria, and elevated serum creatinine. e wHUrine output was normal, and his creatinine slowly normalized without intervention. He successfully underwent first rib resection.

A 42 year-old male with factor V Leiden and Protein C and S deficiency but normal preoperative serum creatinine, developed recurrent bilateral ileofemoral deep venous thromboses. He underwent "power pulse thrombolysis" using the Angiojet device, and subsequent catheter directed thrombolysis. Total PMT volume was 300 ml with additional infusion of tPA. Intraoperative hematuria was noted, and postoperatively, the patient developed an acute increase in serum creatinine. Urine output was normal, and investigations regarding the etiology of the acute kidney injury were inconclusive. There were no laboratory signs of hemolysis, interstitial nephritis, or hemodynamically mediated kidney injury.

Conclusions: These cases illustrate acute kidney injury after PMT and thrombolysis for venous thrombosis. PMT can lead to hemolysis in cases of high volume injection and aspiration. In both cases, hematuria was present either during or immediately following pharmacomechanical thrombolysis. Limiting PMT volume appears to ameliorate the risk of hemolysis, but in the cases presented, PMT using the Angiojet device was performed with < 500mL. As the use of endovascular techniques for thrombosis increases, further studies are needed to assess the relationship of PMT, postoperative hemolysis and its' impact on renal function. Vigilance of PMT volume and renal status in these patients appears warranted.

THE LARGPAD TRIAL: PHASE IIA EVALUATION OF L-ARGININE SUPPLEMENTATION IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

Vikram S. Kashyap, Ryan O. Lakin, Timur P. Sarac, Lindsay E. Feiten, James F. Bena and Sandra Harris

Objective: Endothelial function is improved by L-Arginine supplementation (L-arg) in preclinical studies. We hypothesize that endothelial function improves with catheter-directed L-Arg delivery in arteries of patients with peripheral arterial disease (PAD).

Methods: Patients with PAD (n=25, mean age 62, 48% male) requiring lower extremity angiography were enrolled. Endothelial dependent relaxation (EDR) was measured using intravascular ultrasound and a Doppler Flow wire after the infusion of acetylcholine (Ach, FDA IND). Patients received either 50 (n=5), 100 (n=10) or 500mg (n=10) L-Arg intra-arterial supplementation followed by repeat EDR measurement. IVUS derived virtual histology (IVUS-VH) of the same vessel was calculated. Endothelial independent relaxation (EIR) was measured with infusion of nitroglycerin (NTG). Levels of NOx and serum arginine were determined by laboratory analysis.

Results: Patients tolerated L-Arg infusion with no side effects or adverse events. Limb blood flow increased for all patients with Ach infusion 10-6-10-4 with greater increases after L-arg (68% vs. 91%, p=.085, Figure). Griess reaction analysis showed a mean NOx increase of 85% (p=.046) post L-Arg infusion. Serum arginine levels increased by 54.3% (p<.005) after limb L-arg infusion using mass spectrometry. Arterial responsiveness was intact in all vessels (EIR, 137 +/- 28% volume flow increase). IVUS-VH indicated plaque volume was 14.89 ± 5.5 mm3/cm, and plaque stratification indicated predominantly fibrous morphology (45.5%; necrotic core, 28.9%; calcium, 18.2%).

Discussion: We conclude that despite extensive atherosclerosis, endothelial function is intact in diseased lower extremity human arteries. Endothelial function can be improved by L-Arg infusion secondary to increased nitric oxide bioactivity. Further studies of L-Arg as a therapeutic modality in patients with endothelial dysfunction (i.e. acute limb ischemia) are warranted.

PRESSURIZED VASCULAR ANASTOMOSIS SIMULATION WITH CRYOPRESERVED VESSELS

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Introduction: Residency duty hour restrictions and advances in endovascular surgery have diminished open vascular surgery training experience. Simulation has become widespread among general surgery curricula. Purpose of this study was to provide general surgery residents a low stress forum to practice open vascular anastomotic techniques and determine its impact on attitudes toward vascular surgery skills and career choice.

Methods: Cryopreserved cadaveric aortoiliac arterial, femoropopliteal and great saphenous venous segments were donated for use in a liquid-pressurized model of vascular anastomosis complete with vascular clamp training. Working in pairs over 2 hours, each resident took turns as primary operator and first assistant. Juniors undertook a femoropopliteal bypass model, and seniors completed the aortobifemoral bypass model. A multifaceted survey was distributed upon completion.

Results: Forty-three of 45 General Surgery PGY 1-5 residents participated. Eighty-six percent had no previous formal training in vascular surgery skills. Seventy-two percent of residents had at least a good understanding of "vascular technical skills, flow of operation, and hemodynamic considerations" after the modules, compared to 21% prior. Sixty-nine percent were "able to perform, confident, or very confident" in their ability to perform a vascular anastomosis after the lab, compared to 34% prior. Ninety-three percent felt the simulation was realistic compared to live surgery. Sixty-eight percent of residents preferred multiple sessions throughout the academic year. Consideration for vascular surgery as a career did not change.

Conclusions: A pressurized vascular anastomotic simulation with cryopreserved tissue is both feasible and effective in a general surgery curriculum.

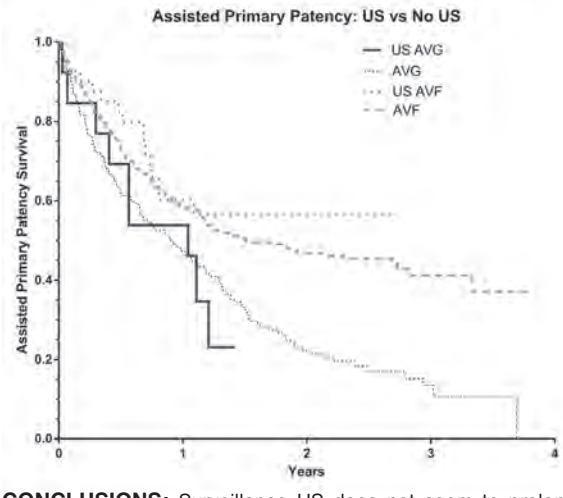
ULTRASOUND SURVEILLANCE MAY NOT PROLONG PATENCY OF ARTERIOVENOUS ACCESS

Matthew T. Allemang MD, Virginia L. Wong MD, Alexander Chang MD, Ryan O. Lakin MD, Kenneth J. Woodside MD, John Wang MD, Vikram S. Kashyap MD

OBJECTIVES: To determine if surveillance ultrasound improves the patency of arteriovenous dialysis access grafts and fistulas.

METHODS: Records of patients who had an arteriovenous (AV) access placed from January 2008 until June 2011 were retrospectively reviewed. The outcomes were assisted primary patency and secondary patency of the AV fistula (AVF) or AV graft (AVG). Kaplan-Meier survival curves were constructed and log rank tests were used for statistical comparisons.

RESULTS: There were a total of 500 patients with 664 accesses (396 AVF, 268 AVG). The patients had a mean age of 59.4 ± 17.2 and mean BMI of 30.0 ± 8.7. Fifty-four percent of the patients were female, 73% were African American, 52% had some form of diabetes, 95% had hypertension, and 26% congestive heart failure. Of the 664 accesses placed, 54 had ultrasound (US) surveillance based on surgeon preference (41AVF, 13 AVG). These underwent an average of 2.0 ± 1.3 surveillance scans. For autologous fistulas, the median assisted primary patency was 20.3 months, and for prosthetic grafts, the median primary assisted patency was 11.0 months ($p<0.0001$). For autologous fistulas, the median secondary patency was 25.5 months, and for prosthetic grafts, the median secondary patency was 26.6 months ($p = 0.21$). Surveillance US did not improve assisted primary patency of AVF ($p= 0.48$) or AVG ($p= 0.69$) nor secondary patency ($p= 0.43$ and $p= 0.26$, respectively) (See Figure)



CONCLUSIONS: Surveillance US does not seem to prolong either assisted primary patency or secondary patency of AV access. These results need to be corroborated by larger prospective studies.

PRESCRIBING PATTERNS OF ANTITHROMBOTICS ARE HIGHLY VARIABLE AFTER LOWER EXTREMITY ENDOVASCULAR PROCEDURES

Matthew T. Allemang MD, Ravi R. Rajani, MD, Peter R. Nelson MD, MS, Anil Hingorani MD, and Vikram S. Kashyap MD

OBJECTIVE: The use of antiplatelet and antithrombotic agents following peripheral vascular interventions is a common clinical practice despite lack of clear convincing evidence or accepted practice guidelines. Our goal was to assess surgeon prescribing practices after endovascular procedures for lower extremity occlusive disease.

METHODS: Attendees of the 2011 Peripheral Vascular Surgery Society Winter Meeting were asked to complete a voluntary survey indicating their prescription practices of antiplatelet/antithrombotic agents for the following procedures: iliac bare metal stent, iliac covered stent, infrainguinal angioplasty alone, infrainguinal bare metal stent, infrainguinal covered stent, lower extremity atherectomy, lower extremity cryoplasty. The surveyors were given choices of aspirin (ASA) alone, clopidogrel alone, ASA/clopidogrel combined, warfarin alone, or ASA/clopidogrel/warfarin combined. They were also asked to indicate preferred length of treatment for each medication or combination for each procedure: 1, 3, 6, or 12 months.

RESULTS: There were 51 respondents (48 Vascular Surgeons and 3 Vascular Fellows) with an average of 11.02 years in practice. Their practice settings were mainly university hospital (48%), community hospital (44%) and university/VA hospitals (6%). The ASA/ Clopidogrel combinations were spread over many of the time periods with a 1-3 month course being the most common. ASA was indicated for at least 12 months in 96% of all ASA only responses.

	Procedures Per Year Ave ± StdDev	ASA Only	Clopidogrel Only	Warfarin Only	ASA/ Clopidogrel Combinations	ASA/ Clopidogrel / Warfarin Combinations
Iliac Bare Metal Stent	22.1 ± 13.6	18 (36.7)	5 (10.2)	0	26 (53.1)	0
Iliac Covered Stent	7.6 ± 7.6	15 (31.9)	4 (8.5)	0	28 (59.6)	0
Infrainguinal Angioplasty Alone	32.7 ± 37.1	10 (20.8)	8 (16.7)	0	30 (62.5)	0
Infrainguinal Bare Metal Stent	29.8 ± 27.5	3 (6.5)	7 (15.2)	0	36 (78.3)	0
Infrainguinal Covered Stent	8.5 ± 12.5	4 (8.7)	4 (8.7)	1 (2.2)	35 (76.1)	2 (4.3)
Lower Extremity Atherectomy	17.6 ± 40.9	3 (8.6)	6 (17.1)	0	24 (68.6)	2 (5.7)
Lower Extremity Cryoplasty	1.2 ± 2.5	3 (15.8)	2 (10.5)	0	14 (73.7)	0
		KEY: Frequency (Percentage)				

CONCLUSIONS: The antiplatelet/antithrombotic prescribing practices of vascular surgeons after a range of lower extremity endovascular procedures is highly variable. Multicenter randomized controlled trials are needed to define optimal treatment efficacy.

TREATMENT AND OUTCOME ANALYSES OF SPLENIC ARTERY ANEURYSMS IN A 5-YEAR POPULATION BASED SAMPLE

Matthew T. Allemang MD, Jesse Schold PhD, MStat, Ryan O. Lakin MD, and Vikram S. Kashyap MD

Objective: Endovascular treatment of splenic artery aneurysms (SAA) is increasingly common in clinical practice. The objective was to analyze the treatment and compare outcomes between endovascular and open surgery of this relatively rare diagnosis using national administrative data.

Methods: We identified patients from the Nationwide Inpatient Sample (2003-2007) using ICD-9 codes for SAA as the primary or secondary diagnosis. These patient encounters were subdivided into endovascular treatment, open surgical treatment, or observation. Where appropriate, multivariable logistic and linear regression modeling were used to compare elective admission, type of payer, length of stay, total charges, and mortality.

Results: In this representative sampling of non-federated hospital admissions, 684 patient encounters were identified resulting in a weighted estimate of 3,347 SAAs in the United States for the 5 year interval. Sixty-three percent were female, and the average age was 56.9 years. The overall mean length of stay was 5.99 days. The majority of patients were treated via open surgery (54%) when compared to endovascular means (26%). The remaining (20%) underwent in-hospital observation. In-hospital mortality after endovascular therapy was 4.2% and 6.0% after surgery ($p=0.49$). Non-elective admission was associated with higher mortality (adjusted odds ratio [AOR] 10.7, 95% confidence interval [CI] 3.3-34.6, $p<0.001$). Female gender (AOR 2.26, CI 1.56-3.27) and open surgery (AOR 0.62, CI 0.42-0.92) were independently associated with elective admission. Although elective treatment was more likely an open repair, a significantly shorter length of stay was associated with both elective admission (-3.6 days, $p<0.001$) and endovascular procedures independently (-3.7 days, $p<0.001$). Finally, when analyzed for total charges, elective and endovascular procedures were significantly less costly ($p \leq 0.001$).

Conclusions: Elective treatment and endovascular repair of SAA result in a shorter length of stay and lower total charges. Given the comparable mortality outcomes for open and endovascular treatment, endovascular therapy may be preferable. As with all retrospective reviews, this issue deserves additional prospective study.

THE LONG-TERM OUTCOMES AFTER LOWER EXTREMITY AMPUTATION FOR PERIPHERAL ARTERIAL DISEASE: A CONTEMPORARY SERIES

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BACKGROUND: The management of lower extremity peripheral arterial disease (PAD) may require amputation in cases where limb salvage is not achievable. Previous studies have demonstrated elevated mortality rates after major transtibial and transfemoral amputation. The aim of this study was to clarify patient- and amputation-related factors associated with higher mortality following lower extremity amputation.

STUDY DESIGN: We retrospectively identified patients who underwent transfemoral or transtibial amputation for PAD from 2004 to 2009. A total of 454 consecutive amputations were performed on 391 patients: 391 index amputations, 63 subsequent contralateral amputations. Demographic information, data regarding comorbidities and prior ipsilateral lower extremity vascular intervention, and relevant procedural information were extracted from patient records. Kaplan-Meier estimates of survival were calculated. Cox proportional hazard models were used to estimate the risk of death. A multivariable Cox proportional hazards model was fit for all variables shown to be marginally associated with mortality via univariate analyses ($p<0.10$).

RESULTS: In 391 amputees, the mean age was 67.3 years, 63% were male, and 62% were white. Patients had high rates of diabetes (63%), hypertension (83%), renal insufficiency (35%), hyperlipidemia (51%) and prior ipsilateral vascular intervention (75%). 70% of patients had below-knee amputations. Perioperative mortality was 9.2% (n=36). Long-term survival at 1, 2, and 5 years was 70% (95% CI 65-74%), 60% (95% CI 55-65%), and 44% (95% CI 38-50%), respectively. Multivariate analysis demonstrated that factors associated with elevated post-amputation mortality included increasing age at amputation (HR 1.03 per year increase), non insulin-dependent diabetes (HR 1.42), chronic obstructive pulmonary disease (COPD, HR 2.0), dialysis-dependence (2.86), and hospital transfer prior to amputation (HR 1.52).

CONCLUSIONS: Major lower extremity amputation has an extraordinary mortality rate. Elderly patients with diabetes, COPD, and dialysis-dependence transferred from outside hospitals have worse outcomes. Strategies to enhance limb salvage and decrease mortality after amputation warrant further investigation.

IN VIVO ASSESSMENT OF ENDOTHELIAL FUNCTION IN HUMAN LOWER EXTREMITY ARTERIES

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OBJECTIVES: Endothelial function has been measured in human brachial and coronary arteries, but not in lower extremity arteries affected by atherosclerosis. We describe a novel, first-in-man, evaluation of endothelial function in patients with peripheral arterial disease (PAD) of the superficial femoral arteries (SFA).

METHODS: Patients with PAD (n=25) requiring lower extremity angiography were enrolled. Endothelial dependent relaxation (EDR) was measured using intravascular ultrasound and a Doppler Flow wire after acetylcholine infusion (Ach). IVUS derived virtual histology (IVUS-VH) of the same vessel was calculated. Endothelial independent relaxation (EIR) was measured with infusion of nitroglycerin (NTG, 200 ug).

RESULTS: Patients (mean age 62, 48% male) had a history of hypertension (80%), coronary disease (32%), and diabetes (56%). The mean SFA diameter was 5.2±0.99 mm (range 3.2-6.9 mm). EDR increased over baseline for all patients with Ach infusion 10-6-10-4. Diameter (0.5% at Ach10-4) and area (1.83% at Ach10-4) changes in the diseased SFA were modest. But, average velocity of blood flow (APV) significantly increased 26.2, 46 and 63% with Ach infusion 10-6-10-4. Calculations of blood flow (mm2/sec, 67% change, Ach10-4) and limb volume flow (mm3/sec, 68.1%, Ach10-4) were performed. Lower extremity NOx levels approximated systemic venous levels (P=0.6). NTG infusion indicated normal smooth muscle responsiveness (3.3% diameter, 8.9% area, and 116% velocity change over baseline). IVUS-VH plaque stratification indicated predominantly fibrous morphology (45.5%; necrotic core, 28.9%; calcium, 18.2%). Atheroma burden was 14.89 ± 5.5 mm3/cm and did not correlate with endothelial responsiveness.

CONCLUSIONS: Endothelial function can be measured directly in human lower extremity arteries. Despite extensive atherosclerosis, endothelial function is still intact. These data support the application of regional endothelial-specific biological therapies in patients with PAD.

Section 13
Surgical Research

2011-2012 DEPARTMENT OF SURGERY RESEARCH UNIVERSITY HOSPITALS CASE MEDICAL CENTER

Protocol for Off Label Use of the Diaphragm Pacing System in ALS patients undergoing Gastrostomy Tube Placement
Principal Investigator –Raymond Onders, MD

Protocol for Off Label Use of the Diaphragm Pacing System for Ventilatory Assist in Central Hypoventilation Syndrome
Principal Investigator –Raymond Onders, MD

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Protocol for Off Label Use of the Diaphragm Pacing System in Pediatric Diaphragm Dysfunction
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Electrical Activation of the Diaphragm for Ventilatory Assist
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