2012-2013 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 2012-2013 research abstracts. The Department of Surgery provides a multi-specialty academic environment where ideas are exchanged and cooperative research programs are planned.

The 2012-13 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
Cardiac Surgery

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2012-2013 Abstracts

CONCURRENT ASYMPTOMATIC CARDIAC MYXOMA AND RENAL CELL CARCINOMA

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Background: Cardiac masses in patients with renal cell carcinoma can occur from direct extension of tumor or metastatic deposits from hematogenous spread. However, simultaneous presence of primary cardiac tumor in patients with renal malignancy has been rarely described.

Case presentation: We present the case of a 66 year old male who was found to have large non-homogenous solid tumor arising from right kidney suspicious for renal cell carcinoma while undergoing workup of asymptomatic microscopic hematuria and palpable abdominal mass. Magnetic resonance imaging showed no renal vein or inferior vena cava tumor extension and no distant metastases. Pre-operative and staging workup revealed a concurrent large well-circumscribed pedunculated left atrial mass attached to inter-atrial septum and base of anterior mitral leaflet most consistent with myxoma on transthoracic echocardiography. Patient described no obstructive, embolic or constitutional symptoms related to this. Coronary angiography revealed high grade lesions of left anterior descending and left circumflex obtuse marginal artery. Patient underwent complete surgical excision of the left atrial mass and coronary artery bypass grafting via median sternotomy. Histology was compatible with left atrial myxoma. After recovery, patient underwent open right radical nephrectomy during same hospitalization. He is doing well post-operatively and preliminary pathology on renal tumor is consistent with renal cell carcinoma.

Conclusion: Cardiac myxomas are usually sporadic but 7% can occur in autosomal dominant syndromes. Association with renal cell carcinomais rarely described in world literature, the two reported cases being of right atrial myxoma. Our case presents first such reported case with left atrial myxoma. In simultaneous presence of cardiac and renal masses, excision of cardiac mass should be undertaken first to reduce risk of embolization as well as identify histology and help with appropriate staging of renal cell carcinoma.

Section 2

Colorectal Surgery

PROCESS IMPROVEMENT IN COLORECTAL SURGERY: MODIFICATIONS TO AN ESTABLISHED ENHANCED RECOVERY PROTOCOL

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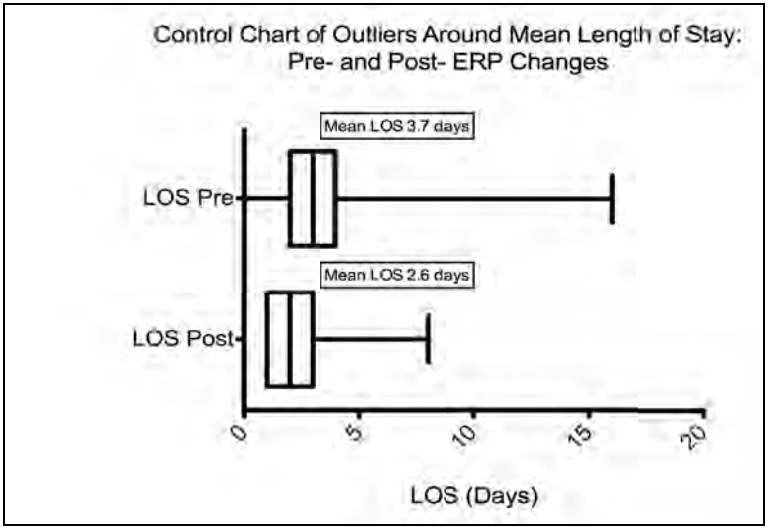
Purpose: To evaluate the impact of modification of an enhanced recovery pathway (ERP) on patient outcomes in colorectal surgery. After more than a decade of improvement, our ERP had laparoscopic colectomy patients going home a mean of 3.7 days after surgery. We hypothesized that the addition of a Transverse Abdominus Plane (TAP) block and IV acetaminophen to this established ERP would improve patient outcomes and reduce resource utilization.

Methods: After adding TAP blocks and IV Tylenol to the ERP 12 months ago, a review of a prospective database of a single surgeon's elective major laparoscopic colorectal cases from 2010-2012 was performed. Patients were matched by procedure type, age and gender. The main outcome measures were hospital length of stay (LOS), readmission rate, post-operative complications, and cost of the hospital episode before and after adding amending our ERP. Paired t-tests, Fisher's exact test, and statistical process control (SPC) were used for analysis.

Results: 208 elective major laparoscopic cases were evaluated. Both groups were similar in age, BMI, and co-morbidities. LOS was significantly shorter once TAP and Tylenol were introduced ($p<0.005$), dropping from 3.7 to 2.6 days. There were significantly more complications in the pre-change group ($p=0.019$), but no significant differences in readmissions or mortality. Direct costs were similar, but there was a $500 increase in total margin per case ($p=0.004$) with the ERP changes. Using SPC to examine the effect on outliers there was noticeably less variation from the mean LOS (2.29 vs. 1.90 days, $p<0.001$) after the addition of TAP blocks and IV Tylenol.

Conclusions: Continuous quality improvement is crucial for ensuring quality outcomes in colorectal surgery. The addition of a TAP block and IV Tylenol significantly reduced LOS over that seen with a previously established ERP. SPC demonstrated our ERP changes significantly reduced the spread of outliers around our mean LOS.

Elective Lap Abdominal Cases	Pre-Change	Post-Change	P-value
Count of Cases	106	102	
Mean Hospital LOS (SD)	3.71 (2.29)	2.58 (1.90)	0.0005
Readmission (30 day)	7	3	0.333
Mean Hospital Costs ($)	$13,799.93	$13,802.78	0.998
Post-operative Complications	22	9	0.019*
Average of Total Margin ($)	$3,452.74	$3,918.91	0.0004*



STATISTICAL PROCESS CONTROL TO ASSESS PROCESS IMPROVEMENT IN COLORECTAL SURGERY: MODIFICATIONS TO AN ESTABLISHED ENHANCED RECOVERY PROTOCOL

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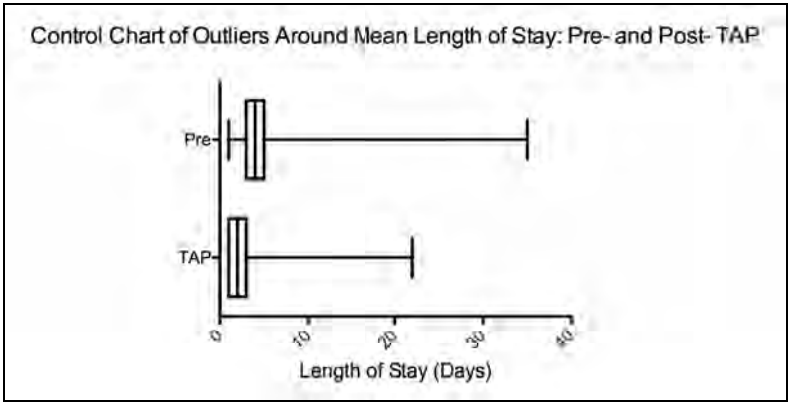
Purpose: To evaluate the impact of modification of an enhanced recovery pathway (ERP) on patient outcomes in colorectal surgery. Our hypothesis was that the addition of Transverse Abdominus Plane (TAP) blocks to an established ERP would improve patient outcomes and reduce resource utilization.

Methods: After adding TAP blocks to the ERP 12 months ago, a review of a prospective departmental database was performed to evaluate elective major laparoscopic colorectal cases from 2010-2012. Patients were matched by surgeon, procedure type, age and gender. The main outcome measures were hospital length of stay (LOS), readmission rate, post-operative complications, and cost of the hospital episode before and after the ERP modification. Paired t-tests, Fisher's exact test, and statistical process control (SPC) were used.

Results: 446 elective major laparoscopic cases were evaluated. Both groups were similar in age and BMI, but TAP patients had significantly more co-morbidities, defined by the ASA score ($p< 0.001$), modified frailty ($p< 0.001$), and Charlson comorbidity indexes ($p< 0.001$). LOS was significantly shorter once TAP was introduced ($p=0.007$), dropping from 4.9 to 2.9 days. There were no significant differences in readmissions, post-operative complications, or mortality. Direct costs were reduced by $2200 per case, with a $1200 increase in total margin per case ($p<0.001$). Using SPC to examine the effect on outliers there was noticeably less variation from the mean LOS (5.55 vs. 3.21 days, $p= .008$) after the addition of TAP blocks.

Conclusions: SPC analysis demonstrated that the addition of a TAP block significantly reduced LOS over that seen with a previously established ERP, even though the TAP group had more co-morbidities. The introduction of TAP blocks significantly reduced the spread of outliers around the mean LOS.

Elective Lap Abdominal Cases	TAP	Pre- TAP	P-value
Count of Cases	104	342	
Mean Hospital LOS (SD)	2.94 (3.21)	4.92 (5.55)	0.0007
Readmission (30 day)	3	21	0.3187
Average of Hospital Costs ($)	$14,373.20	$16,512.21	0.1664
Post-operative Complications	10	51	0.1943
Average of Total Margin ($)	$3,437.30	$2,240.52	0.0003



A PROSPECTIVE MULTICENTER STUDY OF PERFUSION ASSESSMENT IN LAPAROSCOPIC ANTERIOR RESECTION (PILLAR II) UTILIZING THE PINPOINT® ENDOSCOPIC FLUORESCENCE IMAGING SYSTEM

Mehraneh Jafari, MD, Steve Mills, MD, Elisabeth C. McLemore, MD, Steven D. Wexner, MD, Joseph E. Martz, MD, Conor P. Delaney, MD, PhD, David A. Margolin, MD, Michael J. Stamos, MD for the PILLAR Investigators

Background: Anastomotic leak (AL) following colorectal (CR) resection increases morbidity, mortality and, in cancer cases, recurrence rates. Perfusion of CR anastomosis is essential and inadequate perfusion may contribute to AL. The PINPOINT Endoscopic Fluorescence Imaging system (Novadaq Technologies Inc., Ontario, Canada) allows for intra-operative assessment of anastomotic perfusion.

Study Design: This is an on-going prospective, multicenter, open label, clinical study which assessesthe feasibility and utility of PINPOINT for intra-operative perfusion assessment in patients undergoing laparoscopic anterior resection (LAR) in the elective setting at 11 centers in North America.

Results: Forty-five out of a planned 150 Patients are currently enrolled. Colorectal cancer was the most common diagnosis (51%) followed by diverticulitis (33%).Robotic-assisted/ Laparoscopic LAR (75%) requiring splenic mobilization (73%) with high inferior mesenteric artery ligation (67%) was the most common performed procedure. The average level of anastomosis was 9.6cm. Average operative time was 4hours. Evaluation via PINPOINT system resulted in proximal revision of colon transection point in two patients (4.5%). Mean follow up time was 3 months, with ileus (4.5%) and superficial SSI (2.2%) as the only post-operative complications. There were no anastomotic leaks.

Conclusions: The PINPOINT system is a safe and feasible tool for intra-operative assessment of tissue perfusion during colorectal resection and it may lead to a decreased incidence of anastomotic leak.

APPLICATION OF A NOVEL POSTOPERATIVE QUALITY OF LIFE METRIC IN RECTAL CANCER

D. Keller, T. Nobel, B. Ermlich, H. Reynolds, Jr., C. Delaney

Background: The postoperative quality of life instrument (PQL) is a novel simple, point-of-care tool designed for rapid quality of life (QOL) assessment in postoperative abdominal surgery patients. PQL has been validated in both pre and post-operative period, but not previously applied to specific patient populations. Our goal was to use PQL to evaluate quality of in patients undergoing rectal cancer surgery.

Methods: Review of a prospective database was performed to identify patients undergoing a curative rectal cancer surgery between 2006 and 2012. Patients were stratified by operative procedure (low anterior or abdominoperineal resection) and approach (laparoscopic or open). The main outcome measures were the overall PQL and score at each time point by procedure and approach.

Results: 213 patients were evaluated- 76% LAR (95 LAP, 67 OPEN) and 24% APR (28 open 23 laparoscopic). The length of stay ($p< 0.01$, $p< 0.01$) and procedure time ($p=0.04$, $p<0.01$) were significantly shorter LAP for both LAR and APR, respectively. In the APR group, LAP patients had significantly lower readmission and complication rates. The overall PQL was significantly higher for LAP versus OPEN ($p<0.01$) and LAR versus APR ($p<0.01$). When evaluating scores over time by approach and procedure, OPEN and APR patients had lower scores for the initial 60-90 days. After that point, most reported return to normal activities.

Conclusions: QOL is initially better for laparoscopic and low anterior resection patients. By 60-90 days, most patients return to normal function and differences by approach and procedure cease.

PREDICTING PERFORMANCE DURING LAPAROSCOPIC COLECTOMY THROUGH VIRTUAL-REALITY SIMULATION

Purpose: Virtual reality (VR) simulation helps reducing learning curve of laparoscopic colectomy. A tailored training program dedicated to improve the competence of trainee surgeons may be useful. VR simulation may also be utilized to ascertain a surgeon's pre-training skill level. We sought to evaluate whether parameters gathered during VR simulation of sigmoid colectomy correlated with better technical performance during laparoscopic colectomy in the porcine model.

Methods: Seven surgeons novice to laparoscopic colectomy underwent a 2h-duration VR simulation practice. Next, all participants performed a laparoscopic anterior resection in the porcine model. The operations were recorded on DVD. Performance evaluation was conducted by two board-certified colorectal surgeons with experience in over 300 laparoscopic procedures each. Evaluators were blinded to surgeons' identity and used a validated instrument specific for laparoscopic colectomy. For each participant, a specific skills-related score was calculated. Linear regression analysis was used to identify simulator parameters related to the score. The Stepwise method was used to select included parameters. The magnitude of the regression model was measured by the coefficient of determination (R2). For each parameter, a coefficient was calculated. The coefficient value defines the effect in the specific skills score produced by a unitary variation of the parameter value.

Results: Thirty-six parameters results are generated after a sigmoid colectomy module session in the LapMentor VR simulator. The selected parameters were: total path length of the left hand instrument, safety of medial to lateral dissection, total time of energy activation, safety of medial peritoneal incision, risk of injuries to vital structures, incisions performed within 10-mm distance from the line of Toldt, grasping of the tumor, distance of left rectal mobilization from the promontory, and safe use of energy devices. R2 value was 99%. The VR simulator parameters that best correlated with the specific skills score during laparoscopic colectomy in the porcine model were safe use of energy device and safety of medial to lateral dissection (Table).

Conclusions: For trainee surgeons attending a VR simulator practice, the best predictors of a laparoscopic colectomy skills in the porcine model were safe use of energy device and the quality of medial to lateral dissection. This information might facilitate tailoring laparoscopic colectomy training strategies and evaluation of future trainees.

VR simulator parameter	Coefficient	P
Safe use of energy device	25.82199	<0.0001
Safety of medial to lateral dissection	6.804377	0.0012
Incisions performed within 10mm distance from the white line of Toldt	-4.87368	0.0011
Safety of medial peritoneal incisions	2.325099	0.0014
Grasping of the tumor	-0.14614	0.0266
Distance of left rectal mobilization from the promontory	-0.08843	<0.0001
Risk of injury to vital structures	0.028455	0.0282
Total time of energy activation	0.017699	<0.0001
Total path length of the left hand instrument	0.001354	0.0004

SHORT-DURATION VIRTUAL-REALITY SIMULATION TRAINING POSITIVELY IMPACTS PERFORMANCE DURING LAPAROSCOPIC COLECTOMY IN ANIMAL MODEL: RESULTS OF A RANDOMIZED TRIAL

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Purpose: Several studies have demonstrated transferring of skills after virtual reality (VR) simulation training in laparoscopic surgery. However, most studies have demonstrated improved simulation performance only after simulation training. Moreover, the impact of VR simulation training on transfer of skills specific to laparoscopic colectomy remains unknown. The present study aimed at determining the impact of VR simulation warm-up on surgical trainees performance during laparoscopic colectomy in the porcine model.

Methods: Fourteen residents naive to laparoscopic colectomy were randomly assigned to two groups. Seven trainees completed a 2-hour VR simulator training in the laparoscopic sigmoid colectomy module (study group). The remaining seven surgeons (control group) underwent no intervention. On the same day, all participants performed a laparoscopic anterior resection with anastomosis on a pig. All operations were recorded on DVD. Performance evaluation was independently assessed by two board-certified colorectal surgeons blinded to trainee's identity. The two examiners used a previously validated clinical instrument specific to laparoscopic colectomy. General and specific technical skills were analyzed.

Results: Surgeons undergoing short-duration training on the VR simulator performed significantly better during laparoscopic colectomy on the pig based on general and specific technical skills evaluation. The average score of generic skills was 17.2 (16.5 - 18) for the control group and 20.1 (16.5 - 22) for the study group (p=0.002). Regarding specific skills, the average score for the control group was 20.2 (19 - 21.5), and 24.2 (21 - 27.5) for the study group (p = 0.001).

Conclusions: A single short-duration VR simulator practice positively impacted surgeons' generic and specific skills performance required to accomplish laparoscopic colectomy in the porcine model.

C-REACTIVE PROTEIN AS A PREDICTOR OF LENGTH OF STAY AFTER COLORECTAL SURGERY

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Purpose: Despite using laparoscopy and enhanced recovery protocols (ERP), some patients are not ready for early discharge. These patients have unpredictable length of stays (LOS) and readmission rates following colorectal surgery (CRS), increasing healthcare utilization. A safe reduction in length of stay (LOS) has become a major focus to optimize cost and efficiency of care. To date, the variables that predict which patients fail early discharge have not been identified. We evaluated CRP as a predictor for delayed recovery and readmission.

Methods: Review of a prospective departmental database identified patients undergoing elective major colorectal surgery. Patients with POD2 CRP and WBC values were included, and were stratified into early (≤3 days) and late (>4 days) Day of Discharge (DoD) groups. All patients were managed with a standardized ERP and discharge criteria. The main outcome measures were the relationship between CRP value, LOS, and readmission rate. Univariate analysis was used to compare groups, and a stepwise Akaike Information Criterion algorithm was used to develop the best logistic model.

Results: 306 patients were identified for analysis- 99 (32%) in the ≤3 day and 207 (68%) in the >4 day groups. Groups were similar in age and co-morbidities. Pre-operative CRP was significantly lower (p=.0215), and operating time shorter (p=.0005) in the ≤3 day group. POD2 CRP accurately predicted shorter LOS (p< 0.001). Using linear regression, for each g/dL increase in CRP level between the pre-operative and POD2 value, the odds of late DoD increased by 24% (OR 1.24). Only male gender, OR procedure time, and increase in CRP from baseline to POD2 were important in predicting late DoD; the change in CRP was strongly associated with LOS >4 days (p=.0102). The overall readmission rate was 9%. CRP level did not significantly correlate with readmissions. For a CRP increase >5.3g/dL, the readmission rate became > 10%.

Conclusions: Low CRP was highly predictive of shorter LOS. Further, a significant change in CRP from baseline to POD2 was associated with an increased risk of a prolonged hospital stay and readmission. CRP can be used to predict LOS and may be a useful indicator of suitability for early discharge.

Table 1: Demographic Data by Day of Discharge

	≤3 days	>4 days	P-value
Cases	99 (32%)	207 (68%)	
Laparoscopic	87 (88%)	112 (54%)	
Open	12 (12%)	95 (46%)	
Mean Operating Time (min)	176.2	242.5	0.0005*
Mean Pre-op CRP Level	0.63	1.19	0.0215*
Mean POD 2 CRP Level	6.5	11.3	< 0.001*
Mean Pre-op White Blood Cell Count	7.35	7.64	0.4275
Mean POD2 White Blood Cell Count	8.83	9.34	0.2319
Mean Hospital LOS (days, SD)	2.7 (.54)	6.7 (4.3)	< 0.001*
Re-admission Rate (within 30 days)	6%	11%	0.211

LOS- Length of Stay; POD- Post-operative Day

USING THE FRAILTY SCORE TO PREDICT FAILURE OF EARLY DISCHARGE AFTER LAPAROSCOPIC COLORECTAL SURGERY WITH AN ENHANCED RECOVERY PATHWAY

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Purpose: Despite using laparoscopy and enhanced recovery protocols (ERP), some patients are not ready for early discharge. Frailty has been generally accepted as a marker of increased risk, complications and mortality in surgery. Frailty may have the potential to identify patient outcomes. The goal of this study was to evaluate frailty as a predictor of patients who might fail early discharge, so that any defined factors might be addressed and optimized.

Methods: Review of a prospectively maintained database identified all major elective laparoscopic colorectal surgical procedures between 2009-2012. Patients were stratified into the ≤3 and >3 Day of Discharge (DoD) groups, and a modified frailty index (mFI) was calculated. All patients followed a standardized ERP. Student t-tests and Fisher's Exact tests were performed to compare groups, and correlation regression analysis to identify the relationship between LOS and the mFI.

Results: There were 464 ≤3 days patients and 388 > 4 day patients. The groups were similar in age, BMI, Charlson Comorbidity Index, and ASA Class. The mFI ($p<0.001$), operation time ($p<0.001$), post-operative complications ($p< 0.001$), readmission ($p=0.0349$), and re-operation rate ($p=0.0004$) were all significantly lower in the early DoD group. Significantly more patients were discharged directly home in the ≤3 days cohort. Multi-variate analysis demonstrated a higher mFI was indicative of longer LOS; within the >3 day cohort, amFI of 2 was strongly related to LOS 8-14 days.

Conclusions: Elective colorectal surgery patients with a higher mFI are more likely to fail early discharge. Despite similar demographics, the mFI was distinct, and correlated with longer operating times, length of stay, and readmissions. Using a prospective frailty index to preoperatively identify patients at risk of failing early discharge pre-operatively should permit better allocation of resources and post-operative.

Table 1: Demographic Data by Day of Discharge

Elective Laparoscopic Cases	< / = 3d	> 4d	p-value
Cases	464 (54%)	388 (46%)	
Mean Age (SD)	58.87 (15.65)	60.93 (19.56)	0.0878
Mean CCI	0.79	0.90	0.4132
Mean MFI	0.67	0.97	< 0.0001
Mean Operating Time (min)	156.96	189.44	< 0.0001
Readmissions Rate (30 day)	4.7%	8.5%	0.0349
Post-operative Complications	8.5%	37.9%	< 0.0001
Re-Operation Rate (30 day)	<1%	7.8%	< 0.0001
Discharge Disposition-Home	456 (98%)	320 (83%)	< 0.0001
CCI- Charlson Co-morbidity Index; MFI- Modified Frailty Index			

CONSTRUCT VALIDATION AND COMPARISON OF A NOVEL COLORECTAL POSTOPERATIVE QUALITY OF LIFE METRIC AND THE SHORT FORM 36 IN COLORECTAL SURGERY PATIENTS

Purpose: Several questionnaires have been used to measure quality of life (QOL) in colorectal patients. However, existing QoL assessment tools are often complex, require complicated analysis, lack specificity for colorectal surgery, and are not focused on assessment of perioperative care. The postoperative quality of life (PQL) assessment is designed to capture subtle, yet significant QoL factors in an easy tool validated for the colorectal post-operative period. Although internally validated, PQL lacks external validation with a universally accepted QoL metric, such as the Rand Short Form 36 (SF-36). The purpose of this study was to externally validate the PQL metric to the SF-36 for colorectal surgery.

Methods: PQL was designed using 14 questions ranked on a Likert scale (1-10) with surgeon and patient input. After obtaining IRB approval, 100 consecutive colorectal surgery patients at University-Hospitals, Case Medical Center were prospectively administered baseline and post-operative (2, 4, 8, 12, 30, 60, and 90 days) PQL and SF-36 questionnaires between November 2005 and April 2008. Patients were included if over 18 years old, undergoing major colorectal surgery via an abdominal approach (laparoscopic or open) for benign or malignant disease, and complete records of both PQL and SF-36 at baseline and each post-operative time point were available. Factor analysis was performed to confirm the validity of the study group SF-36 scores across all 8 mental and physical health domains. Spearman's rank test determined correlations between each of the 8 SF-36 scales and the 14 PQL questions and summary score. Convergent validity was demonstrated using Spearman's correlation coefficient at domain and scale level. The degree of agreement between PQL and SF-36 was assessed through Bland-Altman plot using standardized scores computed. Pairwise comparisons were made to determine any significant differences between the two scales.

Results: Eighty-eight patients met inclusion criteria, and were included in the analysis. SF-36 factor analysis confirmed comparability between the study group and the general population. All PQL items correlated significantly with all 8 mental and physical health domains in the SF-36(p-value < 0.0001).Bland-Altman plots demonstrated consistently similar measure for level of agreement between PQL and SF-36 as indicated by the 95% limits of agreement.

Conclusions: Our study validates the use of the PQL metric in colorectal surgery. The PQL and SF-36 demonstrated a strong and consistent level of agreement across all 8 domains for pre and post-operative scores in colorectal surgery patients. PQL is also constructually valid in the preoperative period. Based on our analysis, the novel PQL metric represents a simple, point-of-care alternative to SF-36 for rapid QoL assessment.

THE HARM SCORE: A NOVEL, EASY MEASURE TO EVALUATE QUALITY AND OUTCOMES IN COLORECTAL SURGERY

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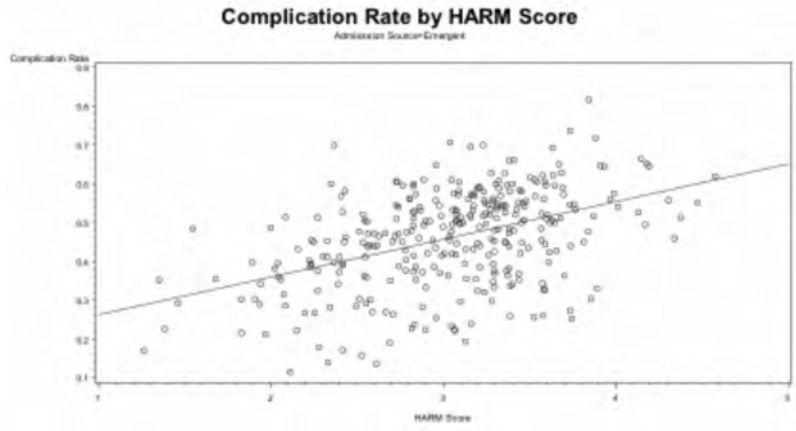
Objective(s): Concerns about patient safety, quality, and healthcare costs have increased demand for outcome measurement. Process and outcome metrics such as SCIP and NSQIP are routinely used, but require significant personnel and financial investment. We present a novel measurement based on Hospital stay, Readmission, and Mortality rates (HARM score), which is easily determined from routine administrative data.

Methods: A national inpatient database was reviewed for colectomy patients from 2010-2011. Cases were stratified as emergent or elective. For each discharge, the HARM score was developed from length of stay (LOS) category, vital status (expired/alive), and 60-day readmissions. HARM was then validated against complication rates.

Results: 81,622 colectomy discharges were evaluated-44% emergent and 56% elective. The provider-level mean HARM was 3.04 (SD=0.57) for emergent and 2.64 (0.65) for elective cases. For hospitals with HARM less than 2, 2-3, 3-4, and 4+, complication rates were 30.3%, 41.9%, 49.3%, and 56.6% (emergent), and 15.2%, 18.2%, 24.0%, and 35.6% (elective), respectively. Pearson correlation coefficients for mean HARM and complication rate were 0.45 ($p<0.01$) for both elective and emergent cases, showing validity. Bootstrapping correlation demonstrated reliability for emergent (0.46) and elective (0.47) cases.

Conclusions: HARM is an easy, reliable and valid score for assessing quality in colorectal surgery. HARM can be calculated using routinely available administrative measures. HARM may decrease the cost and administrative burden of quality measurement, and warrants prospective evaluation.



COMPARATIVE EFFECTIVENESS OF LAPAROSCOPIC VS. ROBOT-ASSISTED COLORECTAL RESECTION

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Objective(s): Over the last 20 years, laparoscopy has revolutionized colorectal surgery. With proven benefits in patient outcomes and healthcare utilization, laparoscopic colorectal surgery has steadily increased in use. Robotic surgery, a new addition to colorectal surgery, has been suggested to facilitate and overcome limitations of laparoscopic surgery. Our objective was to compare outcomes of robot-assisted laparoscopic resection to laparoscopic resections in colorectal surgery.

Methods: A national inpatient database was evaluated for colorectal resections performed over a 30-month period. Cases were divided into traditional laparoscopic resection (LAP) and robot-assisted laparoscopic resection (RALR) groups. Cost of robot acquisition and servicing were not measured. Main outcome measures were hospital length of stay (LOS), surgical time, complications, and costs between groups.

Results: 17,265 LAP and 744 RARL procedures were identified. The RALR cases had significantly higher direct costs ($4,432 increase, $p<.001$), significantly longer operating time (39 minutes, $p<.001$), and were more likely to develop post-operative bleeding (OR 1.5: $p=0.014$) than traditional laparoscopic patients. LOS, complications and discharge disposition were comparable. Similar findings were noted for both laparoscopic colonic and rectal surgery.

Conclusions: Robot-assisted laparoscopic resection had significantly higher costs and operative time than traditional laparoscopic resection without a clear benefit. The results question the need for expanding use of robotics in colorectal surgery.

DISCHARGE WITHIN 24 TO 72 HOURS OF COLORECTAL SURGERY IS ASSOCIATED WITH LOW READMISSION RATES WHEN USING ENHANCED RECOVERY PATHWAYS

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Background: Enhanced Recovery Pathways (ERPs) have demonstrated reduced hospital length of stay and improved outcomes after colorectal surgery. Concerns exist about increases in readmission rates. Laparoscopic colorectal surgery with an ERP can permit earlier discharge without compromising safety or increasing readmission rates.

Study Design: A review of a prospective database was performed for major elective colorectal procedures by a single surgeon. All patients followed a standardized ERP and discharge criteria. Patients were categorized by approach and day of discharge (DoD) of ≤ 1, ≤ 2, ≤ 3, ≤ 7, and >7 days. Main outcomes measures were length of stay and 30-day readmission rates in each group.

Results: Eight hundred and six cases (609 laparoscopic, 197 open) were identified during a 64-month period. Mean age was similar for the laparoscopic (59.1 years) and open (58.3 years) groups. Mean overall DoD was at 5 days (± 4.8 days); by approach, the mean laparoscopic DoD was at 3.9 days and open DoD was at 8.4 days. Twenty-nine percent were discharged within 48 hours (38% laparoscopic and 8% open) and 50% were discharged within 72 hours (62% laparoscopic and 19% open). Only 8.9% of all patients (n = 72) were readmitted (7.2% laparoscopic, 14.2% open). The cumulative readmission rate for laparoscopic patients in early DoD groups postoperative days 1, 2, and 3 were 0.2%, 1.6%, and 3.4%, respectively.

Conclusions: Combining laparoscopy with an ERP optimizes patient care in colorectal surgery. The combination permits early discharge; 38% were discharged within 2 days and 62% within 3 days of surgery, with low readmission rates. These results support that early DoD is possible without compromising patient safety or increasing readmission rates. This might be a marker for low readmission rate, and suggests that readmission rate alone might not be an adequate marker of quality.

TRENDS IN THE COLORECTAL SURGICAL WORKLOAD IN THE UNITED STATES: A POPULATION-BASED ANALYSIS, 1992-2007

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Purpose: Over the last 30 years the workforce of board-certified colorectal surgeons has increased relative to the number of general surgeons. The impact of this increase on the workload and practice patterns of colorectal surgeons is unknown. In this analysis, we use nationally representative data to analyze the colorectal surgical workload within the United States (US).

Methods: We used SEER/Medicare data 1992-2007 to analyze 2 types of procedural claims performed on Medicare patients: 1) colon/rectal/anal surgical (CR) procedures, and 2) operations performed by CRS in the SEER regions. Procedures were categorized as either CR or general surgery (GS) on the basis of CPT codes. The board certification status of each surgeon was determined by linking claims to data from the American Board of Colon and Rectal Surgery. The number of active colorectal surgeons in the US was modeled based on these data; a similar model was used to estimate the number of general surgeons based on data from the American Board of Surgery.

Results: Our analysis included over 314,000 operations in the SEER-Medicare dataset. Between 1992 and 2007, the estimated number of active CRS increased from 784 to 1,249 (60% increase); estimated numbers of active general surgeons increased from 24,758 to 27,649 (12% increase). The overall proportion of CR procedures performed by CRS increased from 14.7% to 25.0% (Fig) ($p < 0.001$). GS procedures (as a proportion of the CRS workload) did not increase significantly during this period. Our dataset included 190,000 colectomies; of these operations, 24% of those performed by CRS were performed laparoscopically, compared with 16% of those performed by general surgeons ($p < 0.001$).

Conclusions: The number of colorectal surgeons practicing in the US increased by 60% between 1992-2007. This rapid growth has resulted in a greater proportion of CR procedures in the US being performed by CRS. The contribution of GS procedures to the CRS workload has remained stable. Given these findings, it appears that the growth in the CRS workforce is supported by the demand for CR surgical procedures and the evolving patterns of treatment of colorectal disease.

APPLICATION OF A NOVEL POSTOPERATIVE QUALITY OF LIFE METRIC IN RECTAL CANCER

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Purpose: The postoperative quality of life (PQL) metric is a novel simple, point-of-care tool for rapid quality of life (QoL) assessment in colorectal surgery patients. PQL has been previously validated both pre and post-operatively, and proven as an alternative to the SF-36, but specifically designed for the postoperative abdominal surgery population. PQL has not yet been evaluated in specific patient populations. Our goal was to use PQL to evaluate QoL in patients undergoing rectal cancer surgery.

Methods: Review of a prospective database identified patients undergoing a low anterior resection (LAR) or abdominoperineal resection (APR) for rectal cancer from 2005-2012. Patients were included if PQL scores at baseline and post-operatively were available, and stratified into laparoscopic (LAP) and open (OPEN) groups. Laparoscopic converted to open procedures were included in LAP for intention to treat analysis. Patients were excluded if undergoing a multi-visceral resection, exenteration, or intra-operative radiation therapy. Main outcome measures were overall PQL and score at each time point by procedure and approach. Univariate analysis examined differences between groups.

Results: 213 patients met inclusion criteria- 76% LAR (84 LAP, 67 OPEN) & 24% APR (28 OPEN, 17 LAP). 17 (11 LAR, 6 APR) were converted to open procedures. 1193 PQL questionnaires were analyzed- 284 APR (161 LAP, 123 OPEN) & 909 LAR (499 LAP, 410 OPEN). There were no significant differences in age or co-morbidities by approach. The LOS (< 0.001, < 0.001) & procedure time (0.0390, 0.0015) were significantly shorter LAP for LAR and APR, respectively. In the APR group, LAP had significantly lower readmissions and post-operative complications. The overall PQL was significantly higher for LAP vs OPEN (p= <.0001) and LAR vs APR (p= <.0001). When evaluating post-operative score by time OPEN patients had lower scores for the initial 3 months. By procedure, LAR scores for higher than APR for the initial 60 days, then most patients reported return to normal activities.

Conclusions: Short-term QoL is better for LAP and LAR patients. However, by 60-90 days, most patients return to normal function and differences by approach and procedure cease.

PQL Results by Surgical Approach and Procedure						
PQL Scores (Mean)		By Approach		By Procedure		
	Lap	Open	P-Value	APR	LAR	P-Value
Pre- Operative	77.92	71.99	0.0005*	66.62	77.36	< 0.0001*
0-30 Day	71.48	61.47	0.0023*	60.58	67.09	0.0707
31-60 Day	73.21	65.93	0.0123*	66.19	71.99	0.0479*
61-90 Day	73.50	63.34	0.0176*	67.00	66.87	0.9799
90-120 Day	74.10	69.35	0.3220	74.40	71.83	0.6570
3 - 6 Months	72.30	72.11	0.9595	72.29	72.04	0.9558
6-12 Months	76.19	74.76	0.5256	75.52	75.41	0.9704
1-2 Years	82.28	78.81	0.0929	76.26	80.58	0.0618
> 2 Years	82.42	81.13	0.6868	75.74	79.24	0.4027

IMPACT OF MODIFICATION OF AN ENHANCED RECOVERY PATHWAY (ERP)

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Purpose: Our goal was to evaluate the impact of modification of an enhanced recovery pathway (ERP) on patient outcomes in colorectal surgery. After more than a decade of improvement, our ERP had laparoscopic colectomy patients going home a mean of 3.7 days after surgery. We hypothesized that the addition of a Transverse Abdominus Plane (TAP) block and IV acetaminophen to this established ERP would improve patient outcomes and reduce resource utilization.

Methods: After adding TAP blocks and IV acetaminophen to the ERP 12 months ago, a review of a prospective database of a single surgeon's elective major laparoscopic colorectal cases from 2010-2012 was performed. Patients were matched by procedure type, age and gender. The main outcome measures were hospital length of stay (LOS), readmission rate, post-operative complications, and cost of the hospital episode before and after adding amending our ERP. Paired t-tests, Fisher's exact test, and statistical process control (SPC) were used for analysis.

Results: 208 elective major laparoscopic cases were evaluated. Both groups were similar in age, BMI, and co-morbidities. LOS was significantly shorter once TAP and acetaminophen were introduced ($p<0.005$), dropping from 3.7 to 2.6 days. There were significantly more complications in the pre-change group ($p=0.019$), but no significant differences in readmissions or mortality. Direct costs were similar, but there was a $500 increase in total margin per case ($p=0.004$) with the ERP changes. Using SPC to examine the effect on outliers there was noticeably less variation from the mean LOS (2.29 vs. 1.90 days, $p<0.001$) after the addition of TAP blocks and IV acetaminophen.

Conclusions: Continuous quality improvement is crucial for ensuring quality outcomes in colorectal surgery. The addition of a TAP block and IV acetaminophen significantly reduced LOS over that seen with a previously established ERP. SPC demonstrated our ERP changes significantly reduced the spread of outliers around our mean LOS.

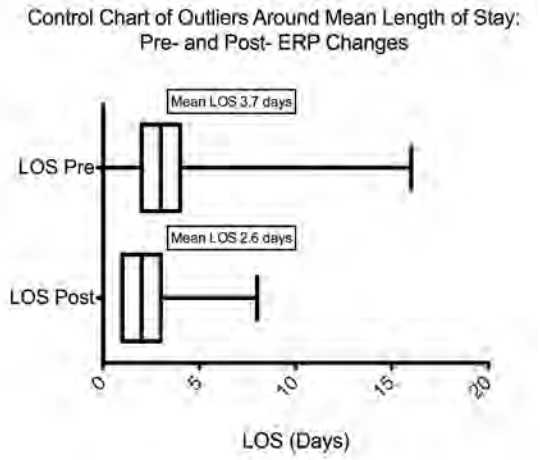

Figure 1: Control Chart of Outliers Around Mean Length of Stay Pre- and Post-ERP Changes.
ERP- Enhanced Recovery Protocol
LOS- Length of Stay

COST-EFFECTIVENESS OF LAPAROSCOPY IN RECTAL CANCER

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Purpose: There is an increasing trend to use of laparoscopy for rectal cancer surgery. While laparoscopic and open rectal resections appear oncologically equivalent, there is little information on the cost of different surgical approaches. With the impending health care crisis and stress on surgeons to optimize healthcare resources and patient outcomes, the cost of care is an important factor. Our goal is to evaluate the cost-effectiveness of laparoscopy in rectal cancer.

Methods: A prospective departmental database was reviewed for elective rectal cancer procedures from 2007-2012. Cases were identified by the ICD-9 code 154.1,and stratified into laparoscopic (LAP) and open (OPEN) groups. Minors, procedures performed through TEM, anorectal, or endoscopic approaches, and open cases not suitable for laparoscopy (super obese, intra-operative radiation therapy, multi-visceral resections, and recurrent cancers) were excluded. Conversions to open remained in the LAP group by intention to treat analysis. The main outcome measures were cost of care, hospital length of stay (LOS), discharge disposition, readmission, post-operative complication, and mortality rates.

Results: 254 cases met inclusion criteria for the analysis- 125 laparoscopic (49%) and 129 open (51%). The groups were similar in age, BMI, and co-morbidities. Operating time ($p< .001$) and cost per OR minute ($p=.0431$) were significantly higher in the OPEN group. The LAP group had significantly lower LOS ($p< .001$) and total hospital cost ($p=.0021$). Post-operative complications, 30-day readmission, re-operation, and mortality rates were similar. However, significantly more OPEN patients required utilization of ICU care ($p=.0303$), SNF ($p=.0318$), and home care services ($p=.0030$) at discharge.

Conclusions: Laparoscopy is cost-effective for rectal cancer surgery, optimizing both healthcare expenditures and patient outcomes. For eligible patients, laparoscopic rectal cancer resection can reduce LOS, operating time, and resource utilization.

Demographic and Outcome Data

Elective Rectal Cancer Procedures	Laparoscopic	Open	P-value
Cases	125	129	
Mean Charlson Score	2.1	2.6	0.0757
Mean Procedure Time (min)	222.1	284.0	< 0.0001
Readmission Rate (30 day)	10%	15%	0.2519
Post-operative Complication Rate	24%	37%	0.3952
Discharge Disposition-Home	97	68	< 0.0001
Mean Total Hospital Costs ($)	$17,214.17	$21,803.65	0.0021
Mean Cost Per OR Minute	$68.36	$103.76	0.0431

THE FRAILTY INDEX: IDENTIFYING THE STANDARD OF CARE FOR OUTCOME PREDICTION IN COLORECTAL SURGERY

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Background: Despite using laparoscopy and enhanced recovery protocols (ERP), some patients are not ready for early discharge. With the current health care crisis, a safe reduction in length of stay (LOS) has become a major focus to optimize costs. Frailty is generally accepted as a marker of increased risk, complications and mortality in surgery. The Modified Frailty Index (MFI) has been introduced as an additional classification to stratify surgical patients and possibly predict patient outcomes. Our goal was to compare the MFI with the CCI as a predictor for patients who might fail early discharge, so that any defined factors might be addressed and optimized. Identifying the best index may facilitate directing care efforts to the patients at highest risk.

Methods: A review of a prospectively maintained database identified all major elective laparoscopic colorectal surgical procedures between 2009-2012. Patients were stratified into the ≤3 and >3 Day of Discharge (DOD) groups, and a MFI and CCI were calculated. All patients followed a standardized ERP. Student t-tests and Fisher's Exact tests were performed to compare groups, and regression analysis to compare the strength of the relationship between the MFI, CCI, and LOS.

Results: There were 464 ≤3 days patients and 388 > 3 day patients. The groups were similar in age, BMI, CCI, and ASA Class, but significantly different in MFI ($p<0.001$). The operation time ($p<0.001$), post-operative complications ($p< 0.001$), 30-day readmissions ($p=0.0349$), and 30-day re-operation rate ($p=0.0004$) were a ????. Significantly more patients were discharged directly home in the ≤3 days cohort. Regression analysis demonstrated a higher MFI/ CCI was a stronger predictor of longer LOS; within the >3 day cohort.

Conclusions: The MFI/ CCI is a stronger predictor of patients who are likely to fail early discharge. Despite similar demographics and CCI, the MFI was distinct, and may be a valuable tool to guide planning and optimize outcomes.

Elective Laparoscopic Cases	</= 3d	> 3d	p-value
Cases	464 (54%)	388 (46%)	
Mean Age (SD)	58.87 (15.65)	60.93 (19.56)	0.0878
Mean BMI (SD)	28.33 (6.19)	28.61 (6.81)	0.5926
Mean ASA Class	2.44	2.48	0.3260
Mean CCI	0.79	0.90	0.4132
Mean MFI	0.67	0.97	< 0.0001
Mean Op. time (min)	156.96	189.44	< 0.0001
Mean EBL (ml)	39.71	57.48	< 0.0001
Mean % by resident	52.14	48.29	0.3320
Intraoperative Complications	13	16	0.3441
Count of ICU Stay (days)	2	16	0.0002
Readmissions (30 day)	22	33	0.0349
Pos-operative Complications	39	147	< 0.0001
Unplanned Re-Op (30 day)	4	30	< 0.0001
Mortality (30 day)	0	1	0.4554
Mean Hospital Costs ($)	$11,344.35	$19,016.79	< 0.0001
Mean Total Margin ($)	$3,056.46	$3,723.17	0.2602
Mean Net Revenue ($)	$14,652.44	$23,354.28	0.0039
Mean Cost Per OR Minute	$72.32	$105.90	< 0.0001
Discharge Disposition			
Home	456	320	< 0.0001
Home with Home Care Services	6	37	< 0.0001
Skilled Nursing Facility	2	29	< 0.0001
Rehabilitation Facility	0	1	0.4554

SYMPTOMATIC RECTOCELE: WHAT ARE THE INDICATIONS FOR REPAIR?

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Introduction: Symptomatic rectocele is a common presentation in the outpatient clinic. However, the indications for repair are nebulous and recurrence rates are high. We developed a novel protocol with dynamic Magnetic Resonance Imaging Defecography (MRID) to evaluate the functional anatomy of the pelvic floor. The objective of this study is to determine if utilizing both clinical presentation and dynamic MRID with selective criteria for repair improves outcomes.

Methods: All patients with constipation and pelvic outlet obstruction symptoms underwent MRID. Imaging was performed while the patient was squeezing, straining, and during evacuation. Surgical repair was offered if defecation required manual assistance and the MRID revealed: a defect greater than 2 cm, incomplete evacuation, and an absence of perineal descent. The primary outcomes were recurrence and quality of life.

Results: From September 2006 to October 2012 118 patients with symptoms of constipation and pelvic outlet obstruction underwent MRID. Of these, 63 (54%) had a rectocele and 37 (31%) patients had evidence of perineal descent. 13 (18%) of the rectocele patients met the above criteria for repair. With a median follow-up of 29 months, Quality of Life (QOL) scores improved from 54.4 to 86.5 ($p = 0.038$). There was 1 recurrence.

Conclusion: The majority of patients with symptoms of pelvic outlet obstruction had a rectocele but only a minority of these patients (18%) met criteria for repair. Utilizing dynamic MRID and a selective treatment approach for rectocele repair results in low recurrence rates and improved QOL.

PILOT STUDY EVALUATING THE EFFICACY OF ALLOMEM™ IN PREVENTION OF INTRAPERITONEAL ADHESIONS AND PERITONEAL REGENERATION AFTER LOOP ILEOSTOMY

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University Hospitals Case Medical Center

Objective: To evaluate the feasibility of AlloMEM™, a novel lyophilized human peritoneal membrane, at peritoneal reconstitution, and decreasing adhesion formation after temporary loop ileostomy.

Methods: In a pilot study, 10 patients had AlloMEM™ used during elective formation of a temporary diverting loop ileostomy for benign or malignant colorectal disease. A blinded investigator and the operating surgeon analyzed the change in adhesion formation and peritoneal remodeling using ileostomy mobilization time and a 5-point adhesion grading scale.

Results: The mean BMI was 31 (SD 5.6), and 40% of patients had previous abdominal surgery. Ileostomies were reversed after a mean 14 weeks (SD 6.0). The mean ileostomy mobilization time was 27.2 minutes (SD 12.0). The adhesion score was a mean 2 (SD 1.01) at the subcutaneous level and 1.7 (SD 1.29) at the fascial level. At the intra-abdominal points, the mean score was .54 (SD .44). The mean adhesive score for the points surrounding the ileostomy were .36 (SD .35). The areas with the most pronounced adhesions were the medial (1.7) and inferior (1.6) subcutaneous locations, and the inferior fascia (1.7). The median hospital length of stay was 2.6 days (range, 2-3). A single adverse event related to product packaging led to re-design of the packaging process.

Conclusions: Use of AlloMEM™ in ileostomy closures suggested improvement in adhesions around the fascia and promotion of peritoneal remodeling. AlloMEM™ was safe and easy to use in this pilot study. Comparative research is needed to assess the outcomes with this novel product.

VIRTUAL REALITY SIMULATION FOR LAPAROSCOPIC COLECTOMY: CAN METRICS HAVE CONSTRUCT VALIDITY?

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Purpose: Virtual reality simulation (VRS) for laparoscopic colectomy has been utilized for training and more recently, the technical skills assessment of board eligible colorectal surgeons. However, construct validity (the ability to distinguish between skill levels) must be confirmed prior to widespread implementation. This study was designed to specifically determine which metrics for laparoscopic sigmoid colectomy have construct validity.

Methods: General surgeons that had performed less than 30 laparoscopic colon resections and laparoscopic colorectal experts (>200 laparoscopic colon resections) performed laparoscopic sigmoid colectomy on the LapMentor VRS model. All participants received a fifteen minute instructional warm up and had never used the simulator prior to the study. Performance was then compared between each group for 21 metrics (Procedural: 14, Intra-Operative Errors: 7) to determine specifically which measurements demonstrate construct validity. Performance was compared with the Mann-Whitney U-test ($P < 0.05$ was significant).

Results: Fifty three (29 general surgeons (GS), and 24 laparoscopic colorectal experts (LC)) enrolled in the study. The VRS for laparoscopic sigmoid colectomy demonstrated construct validity for eight of fourteen procedural metrics by distinguishing levels of surgical experience ($p < 0.05$) (Table1). The most discriminatory procedural metrics ($p < 0.01$) favoring experts were reduced instrument path length, accuracy of the peritoneal/medial mobilization, and dissection of the inferior mesenteric artery. Intra-operative errors were not discriminatory for most metrics and favored general surgeons for colonic wall injury (GS: 0.7, LC: 3.5, $P = 0.045$).

Conclusions: The VRS for laparoscopic sigmoid colectomy demonstrated construct validity for eight procedure specific metrics. However, using VRS metrics to detect intra-operative errors did not discriminate between groups. If the VRS continues to be utilized for the technical assessment of trainees and board eligible surgeons, evaluation of performance should be limited to procedural metrics.

PREDICTING WHO WILL FAIL EARLY DISCHARGE AFTER LAPAROSCOPIC COLORECTAL SURGERY WITH AN ESTABLISHED RECOVERY PATHWAY

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Purpose: Despite using laparoscopy and enhanced recovery protocols (ERP), some patients are not ready for early discharge. The goal of this study was to identify predictors for patients who might fail early discharge, so that any defined factors might be addressed and optimized.

Methods: A review of a prospectively maintained database identified all major elective laparoscopic colorectal surgical procedures between 2009-2012. Patients were divided into Day of Discharge groups: ≤3 days and > 3 days. All followed a standardized ERP. Demographic and clinical data was compared using students paired t-tests or Fisher's Exact test, with p-value < 0.05 statistically significant. Regression analysis was performed to identify significant variables.

Results: There were 275 ≤3 days patients and 273 > 3 day patients. There were significant differences between groups in BMI (p=0.0123), co-morbidities (p=0.0062) ASA Class (p=0.0014), operation time (p<0.001), post-operative complications (p< 0.001), and 30-day re-operation rate (p=0.0004). There were no significant differences in intra-operative complications (p=0.724), readmissions (p=0.187), or mortality rate (p = 1.00). Significantly more patients were discharged directly home in the ≤3 days cohort. Using logistic regression, every hour of operating time increased the risk of length of stay >3 days by 2.35%.

Conclusions: Elective colorectal surgery patients with longer operation times and more co-morbidities are more likely to fail early discharge. These patients should have different expectations of the ERP, as an expected 2-3 day stay may not be achievable. By identifying patients at risk for failing early discharge, resources and post-operative support can be better allocated.

Values	<3 days	>3 days	p-value
Cases	275	273	
Segmental Colectomy	157 (57%)	179 (66%)	
Low Anterior Resection	48 (17.5%)	44 (16%)	
Proctectomy, Colo-anal anastomosis w/ pouch	15 (5.5%)	11 (4%)	
Total Abdominal Colectomy w/o Proctectomy	13 (5%)	10 (3.5%)	
Total Abdominal Colectomy w/ Proctectomy	16 (6%)	7 (2.5%)	
Abdominoperineal Resection	13 (5%)	4 (1.5%)	
Other	11 (4%)	20 (7%)	
Mean BMI (SD)	27.3 (5.6)	28.5 (6.8)	0.0123
Mean Age (SD)	59.9 (15.4)	61.3 (18.5)	0.3421
Mean LOS (SD)	2.4 (.8)	7.1 (7.1)	< 0.0001
Mean Charlson Comorbidity Index	0.5	0.8	0.0062
Mean ASA	2.3	2.4	0.0014
Previous Abdominal Operations	21	38	0.0192
Mean Operating Time (SD, min)	156.7 (60.2)	189.1 (75)	< 0.0001
Mean Blood Loss (SD, mL)	37.2 (54.5)	56.9 (69.1)	0.0002
Intraoperative Complications	3 (1.1%)	4 (1.5%)	0.7241
ICU Stay in Days	1 (<1%)	1 (<1%)	1
30d Readmissions	11 (4.0%)	18 (6.6%)	0.1872
30d Mortality	0	0	1
30d Re-Operations	1 (<1%)	14 (5.1%)	0.0004
Postoperative Complications	15 (5.4%)	66 (24.2%)	< 0.0001
Discharge Disposition			
Home	275 (100%)	259 (94.9%)	< 0.0001
Skilled Nursing /Rehabilitation Facility	0	14 (5.1%)	< 0.0001
Mean Total Margin ($)	$4,236.08	$3,232.97	0.4685
Mean Net Revenue ($)	$15,558.99	$22,225.88	0.0007
Mean Total Direct Hospital Costs ($)	$11,367.86	$18,246.06	< 0.0001

THE HARM SCORE: A NOVEL, EASY MEASURE TO EVALUATE QUALITY AND OUTCOMES IN COLORECTAL SURGERY

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Objectives: Concerns about patient safety, quality, and healthcare costs have increased demand for outcome measurement. Process and outcome metrics such as SCIP and NSQIP are routinely used, but require significant personnel and financial investment. We present a novel measurement based on Hospital stay, Readmission, and Mortality rates (HARM score), which is easily determined from routine administrative data.

Methods: A national inpatient database was reviewed for colectomy patients from 2010-2011. Cases were stratified as emergent or elective. For each discharge, the HARM score was developed from length of stay (LOS) category, vital status (expired/alive), and 60-day readmissions. HARM was then validated against complication rates.

Results: 81,622 colectomy discharges were evaluated-44% emergent and 56% elective. The provider-level mean HARM was 3.04 (SD=0.57) for emergent and 2.64 (0.65) for elective cases. For hospitals with HARM less than 2, 2-3, 3-4, and 4+, complication rates were 30.3%, 41.9%, 49.3%, and 56.6% (emergent), and 15.2%, 18.2%, 24.0%, and 35.6% (elective), respectively. Pearson correlation coefficients for mean HARM and complication rate were 0.45 ($p<0.01$) for both elective and emergent cases, showing validity. Bootstrapping correlation demonstrated reliability for emergent (0.46) and elective (0.47) cases.

Conclusions: HARM is an easy, reliable and valid score for assessing quality in colorectal surgery. HARM can be calculated using routinely available administrative measures. HARM may decrease the cost and administrative burden of quality measurement, and warrants prospective evaluation.

Figure 1: HARM score vs. complication rate

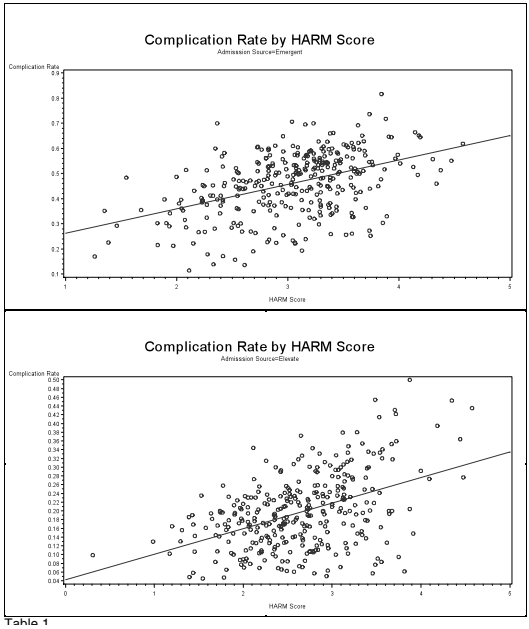


Table 1

	Average Complication Rate	
HARM Score	Emergent	Elevate
Less than2	30.3%	15.2%
Between 2 and 3	41.9%	18.2%
Between 3 and 4	49.3%	24.0%
Greater than 4	56.6%	35.6%

Figure 2 Bootstrap Results for Correlation Coefficients

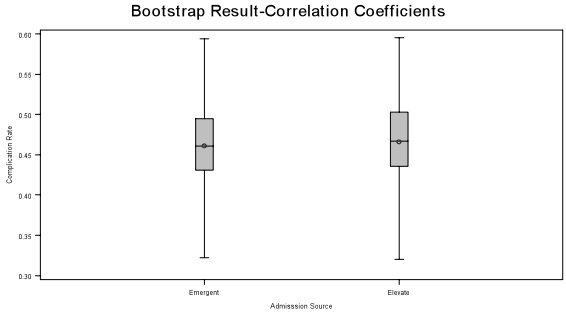
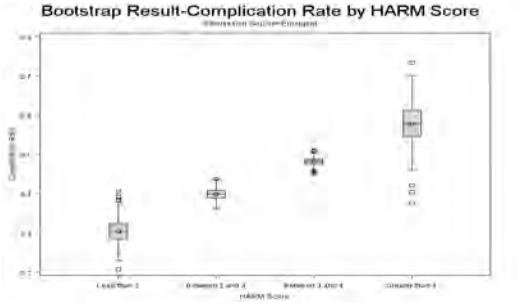
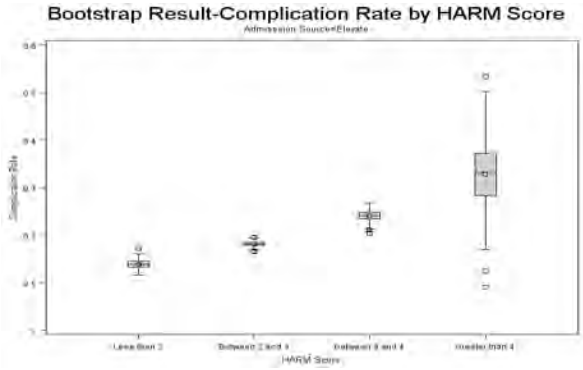


Figure 2 Bootstrap Results for Complication rate by HARM Score



	Less than 2	Between 2 and 3	Between 3 and 4	Greater than 4
N	500	500	500	500
Mean	30.4%	39.9%	48.1%	57.7%
Medium	30.1%	39.8%	48.1%	57.7%
Min	20.8%	36.1%	45.1%	37.6%
Max	40.7%	43.7%	50.9%	73.3%



	Less than 2	Between 2 and 3	Between 3 and 4	Greater than 4
N	500	500	500	500
Mean	13.9%	18.1%	24.1%	32.9%
Medium	14.0%	18.1%	24.1%	33.3%
Min	11.6%	16.6%	20.5%	9.1%
Max	17.3%	19.6%	26.8%	53.3%

LAPAROSCOPIC RECTOPEXY WITHOUT RESECTION: MESH OR NO MESH?

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Purpose: Although the efficacy of laparoscopic nonresectional rectopexy for full thickness rectal prolapse has been well established, the advantages and disadvantages of routine mesh use during this procedure compared to suture rectopexy alone are unstudied. The goal of this study was to compare both recurrence rates and complications between patients undergoing laparoscopic nonresectional rectopexy with or without mesh.

Methods: All patients (2006-2012) undergoing nonresectional laparoscopic rectopexy with (WM) or without (WOM) mesh were included. Cases performed for recurrent prolapse were excluded. In all cases, complete posterior and lateral mobilization to the pelvic floor was performed to fully reduce the prolapse. WOM patients underwent suture rectopexy to the sacral promontory while patients in the WM group all had mesh placed posteriorly behind the mesorectum in the Well's fashion. The mesh was anchored to the sacral promontory and then sutured to the redundant lateral mesorectum. Our primary endpoint was recurrence. Secondary endpoints included operative, post-operative and mesh-related complications. Patient demographics, operative time, and length of stay were also collected.

Results: 97 consecutive patients undergoing nonresectional laparoscopic rectopexy were included. The mean age was 67 (WM, n = 43) and 71 (WOM, n= 54). Median follow-up was similar between groups (WM = 38 months; WOM 35 = months; P=0.73). The recurrence rate for WOM was significantly higher than WM patients (17% vs. 2%; P=0.009). Operative times, length of stay, and overall complications were similar between groups. There were no mesh-related complications.

Conclusions: Laparoscopic nonresectional rectopexy with posterior mesh is safe and may yield lower recurrence rates when compared to suture rectopexy alone. Prospective evaluation is warranted.

Section 3

General and Gastrointestinal Surgery

OPEN PRE-PERITONEAL REPAIR OF INCARCERATED FLANK HERNIA UTILIZING POSTERIOR COMPONENT SEPARATION

Jeffrey A. Blatnik MD, Yuri W. Novitsky, MD

Case Comprehensive Hernia Center, Department of Surgery, University Hospitals Case Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH

Introduction: The repair of flank hernias can be technically challenging due to proximity to major neurovascular and boney structures. Achieving adequate mesh overlap and fixation can be limited with standard repair techniques. This video presents a repair of a large flank hernia utilizing posterior component separation with wide pre-peritoneal sublay mesh reinforcement.

History: This patient is a 52 year-old female who presented 2 years after an open appendectomy with an enlarging and painful flank bulge. She was found to have a large chronically incarcerated flank hernia.

Surgical Details: The patient was positioned in the left lateral decubitus position with the table flexed. Landmarks for surgery including the costal margin, iliac crest and midline were marked and the incision was carried down through the lateral abdominal wall muscles to the large hernia sac. Following opening of the hernia sac, and reduction of its contents, a preperitoneal plane was created and extended superiorly towards the root of the diaphragm, inferiorly into the pelvis exposing the entire myopectineal orifice. Posterior component separation was performed by incising the lateral aspect of the posterior rectus sheath and advancing it laterally. Once a large extraperitoneal pocket was created a 30x30cm piece of midweight polypropylene mesh was positioned with a wide reinforcement of the inferior-lateral aspect of the visceral sac and secured into place utilizing transfascial sutures.

Results: The patient had uncomplicated post-operative course and was discharged on post-operative day 3. At a 1-year follow-up, the patient had no signs of recurrence on physical exam or imaging.

Teaching Points: Traditional approach to flank hernias are challenging secondary to their proximity to major structures that limit appropriate mesh overlap, resulting in a high risk for recurrence. In this video we demonstrate how utilizing aextraperitoneal plane in combination with a posterior component separation we can achieve primary defect closure with appropriate mesh overlap in an effort to reinforce the visceral sac. This plane also facilitates the use of inexpensive unprotected synthetic mesh and minimize the need for fixation.

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

Rosen, Michael J. MD; Krpata, David M. MD; Ermlich, Bridget RN; Blatnik, Jeffrey A. MD

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 multistaged reconstructive approach with delayed definitive repair, whereas others perform definitive repair at the initial operation.

Methods: Patients undergoing single-staged VHR in a contaminated field with biologic mesh over a 5-year period were retrospectively reviewed from a prospectively maintained database. Outcome measures included wound complication and hernia recurrence.

Results: A total of 128 patients (76 F, 52 M) were identified, with a mean age of 58.2 years, mean American Society of Anesthesiologist (ASA) score 3.1, and mean body mass index (BMI) 34.1 ± 9.7 kg/m2. Comorbidities included COPD (n = 29), diabetes (n = 65), smoking (n = 29), and immunosuppression (n = 8). Mean hernia defect size was 431 cm2 (range 40–2450 cm2). Reasons for contamination included the presence of infected mesh (n = 45), stoma (n = 24), concomitant gastrointestinal (GI) surgery (n = 17), enterocutaneous fistula (n = 25), open nonhealing wound(s) (n = 6), enterotomy/colotomy (n = 5), and chronic draining sinus (n = 6). Postoperative wound complications were identified in 61 (47.7%) patients. Predictors of wound complications included ASA score, 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 7 patients underwent repair.

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

CERVICOFACIAL NECROTIZING FASCIITIS: A RARE DISEASE WITH A HIGH MORTALITY REQUIRING EARLY DEBRIDEMENT FOR SURVIVAL: A REPORT OF 5 CASES. JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY

Alan Y. Martinez, DDS, Christopher R. McHenry, MD, Leopoldo V. Meneses, DDS.MS

Purpose: To review the clinical experience, management and outcome of cervicofacial necrotizing fasciitis (CFN) in patients from two large health care institutions.

Methods: A retrospective review of patients with CFN from two different institutions was completed over a 10-year period.

Results: Five patients with complete data were identified. CNF was polymicrobial in 4 and monomicrobial in 1 patient and occurred as consequence of odontogenic infection in 3 trauma in 1 and idiopathic in 1 patient. All patients were treated with extensive debridement, broad spectrum antibiotics and soft tissue coverage. There was 1 mortality.

Conclusions: Early diagnosis and rapid and aggressive debridement are key elements for reducing mortality and optimizing the cosmetic and functional outcome in patients with CFN.

IMAGE OF THE MONTH

Jane H Kim, Ph.D., Stephen Somach, M.D. and Christopher R. McHenry, M.D

A 52 year old man with type II diabetes mellitus and end-stage renal disease presented with painful and progressive, cutaneous necrosis of his fingers, toes and calves and generalized muscle weakness with difficulty getting out of bed and walking. He was on hemodialysis for the past year and had a brachiocephalic fistula in his left arm. His medical history was also significant for peripheral vascular disease, hypertension and antiphospholipid antibody syndrome for which he was on warfarin since 2010. In addition to warfarin, his other medications were epoetin alpha, ferrous gluconate, cinacalcet, paricalcitol, sevelamer carbonate, amlodipine, labetalol, lisinopril, simvastatin, pentoxifylline, and humalog and lantus insulin. He was a non-smoker.

On physical examination, the patient had a temperature of 37.6oC and a grade II/VI systolic ejection murmur. He had necrosis and eschar formation involving his fingers (Figure 1A), toes (Figure 1B, C) and left posterior medial calf (Figure 1D). He had early violaceous skin with central eschar on the posterior medial aspect of his right leg (Figure 1E) that was exquisitely tender with early gangrenous change. He had normal femoral pulses bilaterally with no distal pulses palpable. Both feet were warm with good Doppler signals in the dorsalis pedis and posterior tibial arteries. He had a palpable pulse and thrill in the brachiocephalic fistula in his left upper arm. There was also a weak distal radial pulse. He had good Doppler signals over the radial, ulnar and palmar arch arteries bilaterally.

Laboratory studies revealed: a white blood cell count 13.9 K/ul, hemoglobin 7.7 g/dl, hematocrit 23.4%, platelet count 309 K/ul, INR 2.4, BUN 88 mg/dl, creatinine 9.9 mg/dl, calcium 7.5 mg/dl, albumin 2.4 g/dl, and an intact PTH level of 349.7 pg/ml. The patient had a plain radiograph of his right foot which demonstrated diffuse soft tissue swelling and extensive vascular calcifications. There was no periosteal reaction or osseous destruction. A skin biopsy specimen of the calf showed epidermal necrosis, dermal hemorrhage, focal dermal intravascular thrombi, subcutaneous intravascular (arrowhead) and extravascular (arrow) calcifications, and no features of vasculitis (Figure 2).

What is the diagnosis?

INVASIVE TALL CELL VARIANT OF PAPILLARY CANCER ORIGINATING FROM THE PYRAMIDAL LOBE OF THE THYROID GLAND WITH EXTENSION TO THE BASE OF THE TONGUE: A CASE REPORT

Elena Wagner, M.D., Santhi Ganesan, M.D., and Christopher R. McHenry M.D.

Background: A pyramidal lobe of the thyroid gland is a common anatomic variant. However, primary malignancy of the pyramidal lobe is rare with the exception of cancer in a thyroglossal duct cyst.

Patient Findings: A 61 year old morbidly obese woman presented with a 30 lb. weight loss and a large asymptomatic submental neck mass that extended to the base of her tongue. The mass was invading the hyoid bone and the sternohyoid muscles. The patient had a short thick neck and "double chin", which lead to delay in recognition of the neck mass. Further workup and final pathology revealed a locally invasive, tall cell variant of papillary cancer arising from the pyramidal lobe of the thyroid gland with regional and systemic metastases.

Summary: To our knowledge this is only the second case of a thyroid cancer arising from a pyramidal lobe reported in the literature.

Conclusions: Primary thyroid cancer arising from the pyramidal lobe should be considered in the differential diagnosis of a midline neck mass.

ADVANCES IN MANAGEMENT OF THYROID CANCER

Judy Jin, M. D., Roy Phitayakorn, M.D.,MHPE and Scott M. Wilhelm, M.D. Christopher R. McHenry, M.D

In this monograph, a comprehensive review of thyroid cancer is presented. This represents the work of four endocrine surgeons all of whom have been or are currently affiliated with Case Western Reserve University School of Medicine and have important roots in Cleveland, Ohio. The monograph is a case-based review of primary malignancies of the thyroid gland, in which the clinical presentation, diagnosis, treatment, follow-up, outcome and new advancements are emphasized.

AN UPDATE ON PEDIATRIC DIAPHRAGM PACING: WHAT WE LEARNED AND HOW DIAPHRAGM PACING IS AN EXCELLENT OPTION IN PEDIATRIC SPINAL CORD INJURED PATIENTS

Elmo MJ, Kaplan C, Onders R

Presentation at Howard H. Steel Conference on Pediatric Spinal Cord Injuries and Dysfunction, Orlando, November 30th 2012

Background: Diaphragm Pacing (DP) has successfully replaced or decreased tracheostomy mechanical ventilation in adult SCI. The incidence of cervical cord injuries is disproportionately high in young children. The success of diaphragm pacing in the pediatric patient has been previously described. This report will summarize all pediatric patients implanted at one institution highlighting the differences in surgical implantation and diaphragm condition among the age groups.

Methods: Retrospective review of all implanted pediatric DP patients.

Results: A total of 11 patients between ages of 27 months and 17 years were implanted between January 2009 and May 2012. Additionally at operative exploration, two patients unexpectedly had denervated diaphragms and were not implanted. Four patients were between 2-3 years old, two 5-year olds, 4 patients were between 9-10 years and 1 seventeen year old. The average time spent on TMV was 31.65 months with a range of 11 days to 91 months. Over 50 % (six) patients achieved full time pacing. Three patients are off the ventilator 12-16 hours daily while the others are still in the conditioning phase. One patient, from the possible neurplasticy effects of functional electrical stimulation regained full volitional breathing with easy removal of the wires. No patients had peri-operative or post-operative complications. To date, there are no long term complications. The two patients implanted early post injury went directly to full time pacing. Scoliosis and use of a hard shell back brace can affect pacing. Children ages 4-5 and those on TMV greater than 5 years have the most anxiety with pacing. Utilizing the pacer simultaneously with TMV can lead to severe hypocapnia. As little as 15-20 minutes of pacing time daily can significantly improve lung compliance affecting tidal volumes when using pressure control mode. Parents report improvement in freedom, independence, mobility, and activity with pacing.

Conclusions: Early diaphragm pacing is the optimal utilization and may help with functional recovery. In the 2-3 year olds, the major obstacle to pacing is habituating to the change in sensation. In the 5-10 year olds, the major obstacle to pacing is fear. Early implantation decreases conditioning times. Pacing improves quality of life.

PRELIMINARY DATA ON ANTI-SCARRING AGENTS IN THE PREVENTION OF POST ESOPHAGEAL ENDOSCOPIC SUBMUCOSAL DISSECTION (EESD) STRICTURES

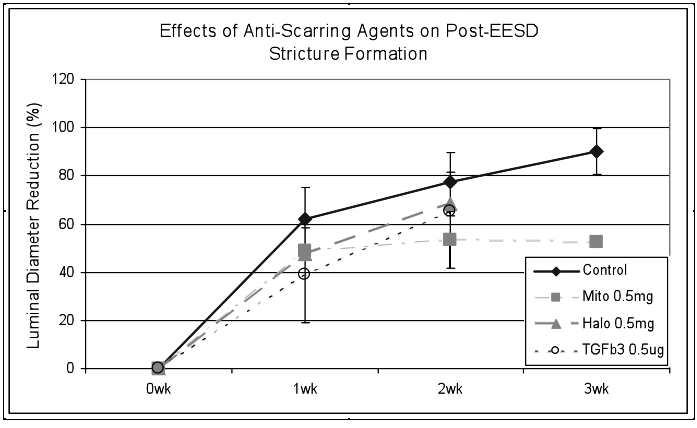
Yuhsin V Wu, Eric M Pauli, Steve J Schomisch, Cassandra N Cipriano, Amitabh Chak, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: Esophageal endoscopic submucosal dissection (EESD) is an effective minimally invasive therapy for early esophageal cancer and high grade Barrett's dysplasia. However, severe esophageal stricture formation following circumferential or large EESDs has limited its wide adoption. Mitomycin C (DNA crosslinker), Halofuginone (an inhibitor of type I collagen synthesis), and Transforming Growth Factor 3 (TGF3) (naturally found in healing wounds) exhibit anti-scarring effects which may be of benefit in preventing stricture formation after EESD.

Methods: An endoscopic band ligator and snare were used for the initial mucosa incision in a porcine model. An 8-10 cm circumferential mucosal segment was then excised using standard ESD techniques. The exposed muscularis was either left without intervention (Control n=5) or received 4 quadrant, 1 cm interval injections of anti-scarring drug immediately and followed by weekly injections for up to three weeks. Three drugs were used in both high and low doses: Mitomycin C 5mg (n= 2), 0.5mg (n=2); Halofuginone 1.5mg (n=2), 0.5mg (n=2); TGF3 2ug (n=2), 0.5ug (n=2). The degree of esophageal stricture formation was assessed endoscopically and with a barium swallow on a weekly basis. Animals were followed clinically and euthanized when stricture formation prevented further therapy.

Results: The control group had a mean luminal diameter reduction of 77.7 +/- 12.1% by two weeks and was euthanized by 3 weeks. Compared at two weeks, the halofuginone group showed decreased stricture formation with a luminal diameter reduction of 68.4 +/-13.3% (low dose) and 57.7+/-38.3% (high dose). The TGF3-low dose group luminal diameter reduction was 65.3 +/- 2.0% compared to TGF3-high dose group of 76.2%. The second animal in the TGF3-high dose group was euthanized after one week with a stricture of 64.1%, preventing further therapy. Mitomycin C was the most effective in stricture prevention with luminal diameter reduction of 53.6+/-11.8% (low dose) and 35+/-10.2% (high dose). Of concern, gross inspection of the mitomycin C treated esophageal wall appeared to be necrotic and lead to perforation after three weeks in one animal. In contrast, the resected area of TGF-3 and halofuginone animals appeared re-epithelialized and healthy. Final histology of the tissues is pending.

Conclusion: From our primary data with a small number of animals, anti-scarring drugs such as mitomycin C, halofuginone, and TGF3 show promise in reducing post-EESD stricture formation. Repeat experiments and further investigations on optimal dose and delivery systems need to be studied to prevent complications and determine overall efficacy of anti-scarring therapy.



ASSOCIATION OF THYROID, BREAST AND RENAL CELL CANCER: A POPULATION-BASED STUDY OF THE PREVALENCE OF SECOND MALIGNANCIES

Van Fossen VL, Wilhelm SM, Eaton JL, McHenry CR

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Background: Analysis of the National Cancer Institute's Surveillance, Epidemiology, and End Results data has shown that the incidence of thyroid cancer is higher in patients with a preexisting malignancy and that the incidence of other malignancies is higher in patients with thyroid cancer. The purpose of this study was to evaluate the prevalence of a second malignancy in patients treated for thyroid, breast or renal cell cancer and determine what associations, if any, exist between these cancers.

Methods: This study utilized the novel data system, Explorys, as its population base. Patient cohorts were constructed using ICD-9 codes, and prevalence rates were obtained for each cancer. Rates of second malignancy were obtained and compared to the baseline prevalence for a particular malignancy.

Results: Female thyroid cancer patients had a 0.67- and twofold increase in prevalence of a subsequent breast and renal cell cancer. Female breast and renal cell cancer patients had a twofold and 1.5-fold increase in the prevalence of thyroid cancer, respectively. Male patients with thyroid cancer had a 29- and 4.5-fold increase in prevalence of subsequent breast and renal cell cancer. Male patients with breast and renal cell cancer had an increased prevalence of subsequent thyroid cancer, 19- and threefold, respectively.

Conclusions: Our study demonstrated a bidirectional association between thyroid, breast and renal cancer in both male and female patients. This may have important implications for patient follow-up and screening after treatment of a primary cancer.

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

David M. Krpata, MD[a], Brian J. Schmotzer, MS[b], Susan Flocke, PhD[c], Judy Jin, MD[a], Jeffrey A. Blatnik, MD[a], Bridget Ermlich, RN[a], Yuri W. Novitsky, MD[a], Michael J. Rosen, MD, FACS[a]

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Background: 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 intervention's effect on a patient's quality of life (QofL). Our objective was to design a hernia-specific QofL instrument with a focus on abdominal wall function, evaluate its measurement properties, and assess the impact of VHR on QofL using this new instrument.

Study Design: A 16-question QofL survey tool, HerQLes, was constructed. 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 before assessment for VHR. Mean age was 57.2 years (±12.4 years), mean American Society of Anesthesiologists score was 2.8 (±0.5), and mean body mass index was 34.9 kg/m2 (±9.3 kg/m2). Based on Rasch modeling, 12 of 16 items met model fit criteria. The 4 poorly fitting items were eliminated from further analysis. The 12 items retained have good internal consistency reliability (0.86). On a 0- to 100-point scale, mean QofL score was 47.2 (±15.6). Patients with higher grade hernias had lower HerQLes scores ($p = 0.06$). Patients showed significant improvement in abdominal wall function and QofL 6 months after VHR ($p < 0.01$).

Conclusions: Quality-of-life is an important component of surgical management of ventral hernias. The 12-question QofL survey, HerQLes, is reliable and valid. At baseline, patients with more complex hernias tended to have a decreased abdominal wall function and QofL. Six months after surgical repair, HerQLes scores change in the predicted direction. We believe HerQLes is potentially a valuable tool to assess patient-centered abdominal wall functional improvements after VHR.

DIAPHRAGM PACING IS STIMULATING BREATHING

Elmo M, Kaplan C, Onders R

Poster Presentation at the 28th National Conference of the American Association of Nurse Practitioners, Las Vegas, June 19-23, 2013

Purpose: The goal of diaphragm pacing (DP) is to decrease, delay or replace mechanical ventilation. It has improved the quality of life of its users. This presentation will introduce diaphragm pacing technology. It will identify patient populations and describe the benefits of pacing.

Review of Literature: DP involves laparoscopically placed intramuscular electrodes into the diaphragm. An electrical charge is delivered stimulating the diaphragm muscle. It provides negative pressure ventilation, increases lung compliance and decreases peak airway pressure. DP can be utilized in ventilator dependant spinal cord injured (SCI) persons and in Amyotrophic Lateral Sclerosis (ALS) patients who have chronic hypoventilation. High cervical spinal injuries, a rare occurrence, often result in the need for tracheostomy mechanical ventilation. The first DP implant occurred in a SCI patient in March 2000 with DP becoming his only modality for breathing. Since then a clinical trial was completed, FDA approval secured and over 200 SCI patients have been implanted with no operative or post operative complications reported. Fifty percent of clinical trial participants were able to replace mechanical ventilation full time with 100% replacing MV at least part time. Benefits of breathing with DP include silence of the machine, compactness of box, elimination of ventilator tubing, decreased secretions and suctioning needs, increased freedom and independence and potential for decannulation. ALS is a progressive degenerative fatal motor neuron disease with devastating affects on respiratory muscles. Average onset of symptoms to death is 3-5 years. There is no cure and very limited effective therapies. DP has been shown to improve survival in this group. 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. DP has been utilized under IRB approved protocols in central hypoventilation syndromes, diaphragm dysfunction and failure to wean post open heart surgery. Children as young as 2 years old and adults into their 70's have all been successfully implanted.

Summary: DP is FDA approved therapy in SCI and ALS and has been successfully utilized in other patient populations to help breathing. DP can decrease, eliminate or delay the need the MV while improving quality of life. It requires surgical implantation of electrodes and conditioning of the diaphragm muscle.

Implications for NPs: Nurse practitioners are increasingly working with niche populations that could benefit from DP and they need to be aware of newer technology available to treat their patients.

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

Jin J, Sandoval V, Lawless ME, Sehgal AR, McHenry CR

Department of Surgery, Division of General Surgery, Case Western Reserve University School of Medicine, 2500 Metrohealth Dr., Cleveland, OH 44109, USA.

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: A BRIDGE TO FUNCTIONAL RECOVERY

Onders R, Elmo M, Kaplan C, Katirji B

Award presentation at the American Spinal Injury Association(ASIA) 40th Annual Anniversary Annual Meeting, Chicago May 6th, 2013

Objective: Neuroplastic effects from diaphragm pacing can lead to return of volitional breathing in high cervical tetraplegics.

Design: Prospective trial data base under FDA and/or IRB approval.

Participant/Methods: Patients underwent laparoscopic placement of electrodes. Assessment of volitional breathing and EMG activity of the diaphragm was obtained pre diaphragm conditioning and after conditioning.

Results: A total of 95 spinal cord injured patients have had diaphragm pacing from 2000 to 2012 (subset of 250 total implanted patients). Ages ranged from 27 months to 74 years old. EMG data was obtained on 28 patients pre diaphragm conditioning. Of those patients 15 had positive EMG activity of the diaphragm muscle. Their level of injuries at the time of implantation were as follows: 3 brain stem injuries, 1 transverse myelitis, 1 encephalitis, 1 post polio, 1 C2-3, 3 C3, 1 C4 and 4 C4-5. Time on invasive mechanical ventilation ranged from 10 days to 10 years with an average of 2.7 years. We were able to obtain post conditioning EMG data on 16 patients. Three patients with no EMG activity at the time of implantation developed good EMG activity and 8 patients with some burst activity showed significant improvement after conditioning. Six patients regained some volitional breathing with an additional five patients regaining complete volitional control of their diaphragm and the electrodes can be removed.

Conclusions: Diaphragm Pacing can be an effective therapy in regaining diaphragm muscle control. Regaining this level of function can have positive implications for survival with early implantation after injury having a greater likelihood of complete recovery of volitional breathing. The ability to wean off a life support device significantly improves quality of life.

A COST-EFFECTIVE, EASILY REPRODUCIBLE ENDOSCOPIC TRAINING MODEL

Yuhsin V Wu, Steve J Schomisch, Cassandra N Cipriano, Jeffrey L Ponsky, Jeffrey M Marks

Introduction: The future of surgery is constantly evolving. With advancements in endoscopic techniques and equipment, more surgical procedures are becoming purely endoscopic or hybrid. In addition, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) will soon launch Fundamentals of Endoscopic Surgery (FES) for surgery residents. In order to keep up with this trend, surgeons need an effective training model to learn and practice therapeutic endoscopic procedures. We have devised a simple, reproducible, and cost-effective endoscopic model that can train future surgical endoscopists in band ligation, saline lift polypectomy, lesion tattooing, thermal and non-thermal methods of hemostasis, endoscopic mucosal resection, percutaneous gastrostomy tube placement (PEG), foreign body removal, esophageal and pyloric dilations.

Methods: To start, an explanted porcine esophagus and stomach is stabilized on a modified peg board. The esophageal orifice is cannulated with a custom over-tube and the duodenal segment ligated. Using an upper endoscope, an endoscopic band ligator is used to practice endoscopic band ligation. As a result, multiple gastric pseudopolyps are created. Once the "polyps" are created, the participant will now practice saline lift polypectomy techniques and tattooing of the "lesion" site. The resected pseudopolyp site now resembles a gastric ulcer. The participant will then practice obtaining hemostasis utilizing thermal (cautery, APC) and non-thermal techniques (epinephrine injections, clipping). Additionally, marbles, coins, paper clips, safety pins, and jacks may be placed into the explant to practice foreign body removal. A stricture can be simulated at the explant lower esophageal sphincter and pylorus. This allows the participant to practice balloon dilations. A PEG tube may also be placed using pull, push, or introducer technique.

Results: This model is capable of teaching 9 therapeutic endoscopic procedures without the need for special laboratory space, live animals, or human cadavers. Techniques learned also carry over for lower gastrointestinal procedures. Our training supplies were generously supported through an educational grant. However, if calculated at standard purchasing costs, each module would cost approximately $1410 excluding the cost of the endoscopic tower and scope (Table 1 lists the cost of supplies). Of note, many pieces of equipment are reusable (indicated by *). To date, this model has successfully trained 1200 surgical residents, 640 MIS fellows, and 240 attending surgeons.

Conclusion: Explanted gastroesophageal endoscopic model is an easily reproducible and cost effective model suitable for training all levels of trainees in therapeutic endoscopic techniques.

Table 1:

Supplies (quantity)	**Cost**
Explanted Esophagus & Stomach (1)	$25
Basic Surgical Supplies	$50
*Overtube (1)	$150
Multi-band ligator (6 bands)	$236
*Injection Needle (1)	$20
*Polyp Snare (1)	$34
*EMR Cap (1)	$24
*Thermal Hemostasis Catheter w/inj needle (1)	$240
Endoscopic clips (5)	$341
Roth Net (1)	$75
*Esophageal Balloon Dilator (1)	$116
Initial PEG KIT (1)	$99
Total	**$1410**
* reusable	

FINAL ANALYSIS OF THE PILOT TRIAL OF DIAPHRAGM PACING IN AMYOTROPHIC LATERAL SCLEROSIS WITH LONG TERM FOLLOW-UP: DIAPHRAGM PACING POSITIVELY AFFECTS DIAPHRAGM RESPIRATION

Onders R, Elmo M, Kaplan C, Katirji B, Schilz R

An oral presentation at the 56th Annual Meeting of the Midwestern Surgical Association, 2013

Background: Respiratory insufficiency is the major cause of mortality in patients with amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). This is the final report of the diaphragm pacing (DP) pilot trial since the final patient expired 6 years post implant.

Methods: Patients underwent laparoscopic diaphragm electrode implantations and subsequent conditioning of diaphragms. Serial respiratory function tests were performed for initial year and followed until death.

Results: 16 patients were implanted with no peri-operative or unanticipated device related adverse events. There were 452 implant-months of follow-up. DP allowed greater movement of the diaphragm under fluoroscopy, increased muscle thickness, and decreased the decline in forced vital capacity. Median survival from implant was 19.7 months with the cause of death respiratory in only 31%.

Conclusion: Long term analysis of DP in ALS showed no safety issues and can positively influence diaphragm physiology and survival. This formed the initial basis for subsequent FDA approval.

HYPERCARBIA IN ALS/MND PATIENTS: UNDER-RECOGNIZED AND UNDER DIAGNOSED - YET ASSESSING CAN CHANGE TREATMENT ALGORITHMS AND IMPROVE QUALITY OF LIFE

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

Poster Presentation at the 23rd International Symposium on ALS/MD, Chicago, December 5th to 7th, 2012

Background: Patients with ALS/MND suffer from hypoventilation and can suffer from the effects of hypercarbia which can lead to headaches, cognitive impairments and decreased survival. In many patients hypercarbia will precede any evidence of hypoxia. Increasing knowledge of developing hypoventilation and hypercarbia will help identify patients before acute respiratory failure.

Objective: Identify the incidence of hypercarbia in ALS/MND patients during presentation with routine utilization of arterial blood gases for analysis of carbon dioxide levels (CO2).

Methods: All arterial blood gas results were prospectively obtained at one institution during respiratory evaluation in an ALS/MND clinic under local IRB protocols and a retrospective analysis of prospective data in the pivotal FDA trial of diaphragm pacing for ALS at multiple sites.

Results: An analysis of the database of 148 ALS patients arterial blood gases obtained on initial evaluation were analyzed and 44% of patients presenting had an elevated CO2 level. 25% of subjects had a severely elevated pCO2 and none of them had a previous evaluation for hypercarbia. In the diaphragm pacing multi-centre pivotal trial paired sample analysis (74 subjects) there was a decrease of 2.0 mmHg of CO2 with utilization of diaphragm pacing ($p<0.001$). In patients with severely elevated pCO2in the diaphragm pacing study (18 subjects) there was a decrease of 2.6mmHg of CO2 ($p< 0.03$) with use of diaphragm pacing. In clinical practice the largest change of pC02 was from 54 to 40 with diaphragm pacing alone and in this patient there was no utilization of non-invasive ventilation (NIV).

Conclusion and Discussion: This evaluation is limited since the ALS subjects evaluated were being assessed at research centres involved in therapies for diaphragm dysfunction so the results may not reflect the global ALS/MND population but the incidence of hypercarbia is still significant and represents a large subset. Hypercarbia can be unrecognized and is an ominous predictor of acute respiratory failure and death. Assessment should become a standard in ALS/MND management. Future assessment with short term awake supine capnography or transcutaneous CO2 techniques may alleviate arterial blood gases but these techniques need further evaluation before they can replace arterial blood gases. Once identified, hypoventilation and hypercarbia can be treated with either increasing use of NIV or diaphragm pacing if the patient has a stimulatable diaphragm. Early detection and knowledge can allow utilization of available therapies to slow the progression of hypoventilation and improve the patients' quality of life by decreasing the adverse effect of an elevated CO2 and its systemic effects which includes cognitive dysfunction.

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, an 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.

LEVOTHYROXINE REPLACEMENT DOSAGE DETERMINATION AFTER THYROIDECTOMY

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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 to 2011. Other formulas using age, sex, ideal body weight, body mass index, and body surface area were also evaluated.

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

Conclusions: A 1.5- and 1.3-μg/kg dosage calculation based on actual weight is currently the best estimation for levothyroxine replacement therapy after thyroidectomy.

OUTCOMES OF SIMULTANEOUS LARGE COMPLEX ABDOMINAL WALL RECONSTRUCTION AND ENTEROCUTANEOUS FISTULA TAKEDOWN

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

Methods: Using a prospectively collected database, patients requiring surgical management of an ECF and AWR over a 5-year period were reviewed.

Results: Thirty-seven patients (mean age = 58.6 years) underwent ECF repair/AWR. The mean hernia defect size was 426 ± 192 cm(2). Thirty-five (95%) patients required fascial releases to achieve abdominal wall closure. Thirty-six (97%) patients had sublay biologic mesh placed to reinforce the repair. Twenty-four (65%) patients developed a surgical site infection (8 superficial, 8 deep, and 8 organ space). Four patients developed an early anastomotic leak/refistulization. With a mean follow-up of 20 months, the hernia recurrence rate was 32% (n = 12).

Conclusions: The simultaneous reconstruction of ECF and complex abdominal wall defects resulted in successful single-stage management of these challenging cases in nearly 70% of patients in this series.

SELECTIVE LATERAL COMPARTMENT NECK DISSECTION FOR THYROID CANCER

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Background: Compartment-oriented lymph node dissection in patients with thyroid cancer and macroscopic lymph node metastases reduces recurrence and improves survival. However, the extent of lymph node dissection remains controversial. The purpose of this study was to examine the results of selective lateral compartment neck dissection (LCND) for thyroid cancer.

Methods: We completed a retrospective review of patients with thyroid cancer who underwent selective LCND from 1992-2012 to determine the extent of lymph node resection, morbidity, recurrence, subsequent operations, mortality, and duration of follow-up.

Results: A total of 45 LCNDs (five bilateral) were performed in 40 patients, 35 with differentiated thyroid cancer (DTC) and five with medullary carcinoma. Nineteen LCNDs (42%) were completed at the time of thyroidectomy. Levels IIA, III, IV, and VB were included in 43 LCNDs (96%) and levels IIA, III, and IV in two LCNDs (4%). Morbidity included neck or ear numbness in 19 patients (48%), neuropathic symptoms in 14 (35%), Horner syndrome in two (5%), marginal mandibular nerve paresis in two (5%), and wound infection in one (3%). Recurrence rate was 25% (10 patients) and one or more reoperations were performed in seven patients (18%) with a mean follow-up of 58 ± 60 mo (range, 1-244 mo). There were 3 ipsilateral recurrences (8%) after 40 LCNDs for DTC. Four patients died from systemic disease: three with medullary carcinoma and one with PTC.

Conclusions: Selective LCND is an effective therapeutic strategy for macroscopic lymph node metastases, with an 8% recurrence rate in the ipsilateral neck in patients with DTC. Neuropathic symptoms, however, remain an important source of morbidity.

SHOULD RADIOLOGIC EVALUATION OF THE CHEST AND DIAPHRAGM BE ROUTINE PRACTICE IN ALS/MND PATIENTS?

Onders R, Katirji B, Elmo M, Kaplan C, Schilz R

Platform Presentation at the 23rd International Symposium on ALS/MND December, 2012

Background: Patients with ALS/MND suffer from significant diaphragm dysfunction that leads to hypoventilation with subsequent respiratory failure. Standard assessment of respiratory function involves functional pulmonary function tests but these tests may underestimate unilateral diaphragm dysfunction. There is little literature on radiographic analysis of diaphragm function in ALS/MND patients.

Objective: Review chest radiologic evaluations of patients to assess diaphragm abnormalities in patients with ALS/MND.

Methods: All patients with ALS/MND who had chest radiographic examinations were reviewed at a single site. All of the patients were under IRB approved protocols to assess for suitability of diaphragm pacing. All data was obtained prospectively although it was re-analyzed retrospectively with specific attention to diaphragm abnormalities. Chest x-rays were evaluated and assess for right compared to left diaphragm differences using the standard values that the left diaphragm should be 1.5 to 2cm lower than the right diaphragm. Digital fluoroscopy was performed with a grid measuring system. Normal excursions would be expected to be 4-5 cm of movement. In this ALS population it was considered abnormal if less than 3cm of movement. There were two sources of patients: prospective, nonrandomized, controlled, interventional trials under IRB and/or FDA approval for use of diaphragm pacing and standard of care use of diaphragm pacing following FDA approved criteria.

Results: 111 ALS subjects had prospective radiographic evaluations available for review. On plain chest radiograph 65% of the subjects had an abnormality of the diaphragm noted. In 86% of these patients the initial report was noted as normal because radiologic interpretation focused on lung parenchyma but not diaphragm abnormalities. When films were re-assessed to evaluate the diaphragm, the report changed. On these radiographs a unilateral diaphragm abnormality was noted in 70% of the patients. Under digital real time fluoroscopy, 89% of the subjects had abnormal diaphragm movement during volitional inspiration.

Conclusion: Chest radiography can help diagnosis diaphragm abnormalities in ALS/MND patients which can change therapy for patients. Significant diaphragm elevations independent of forced vital capacity demands therapeutic manoeuvres that include: changes in sleep position to maximize ventilation, use of non-invasive ventilation to prevent recumbent pulmonary atelectasis, and diaphragm pacing if the involved diaphragm is stimulatable. In a severely elevated diaphragm with paradoxical movement, although not studied yet in ALS, minimally invasive hemi-diaphragm plication could improve dyspnea scores as it does in idiopathic unilateral diaphragm paralysis. Future studies with spiral CT scans or dynamic MRIs can assess which part of the diaphragm that is involved. If the crucial posterior diaphragm is specifically involved then diaphragm pacing which can focus on this posterior diaphragm can help improve posterior lobe ventilation decreasing the risk of pneumonia. Presently a routine chest radiograph requesting diaphragm analysis can help identify abnormalities and allow early recommendations for therapeutic interventions.

BOWEL OBSTRUCTION SECONDARY TO AN UNUSUAL INTERNAL HERNIA

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Description: 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 acongenital "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.

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.

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.

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 to 2010 was completed to determine indications for thymectomy, the yield of parathyroid tissue, and outcome of therapy.

Results: Seventy of 379 patients with hyperparathyroidism underwent parathyroidectomy and transcervical thymectomy. Intrathymic parathyroid tissue was present in 23 (33%) patients, including supernumerary glands in 8 patients (11%). Indications for thymectomy were renal hyperparathyroidism in 35 patients (50%) and primary hyperparathyroidism with a missing inferior gland in 20 patients (29%), an ectopic adenoma in 9 patients (13%), hyperplasia in 5 patients (7%), and carcinoma in 1 patient (1%). Cure rates were similar (96% and 98%; P = not significant) and only transient hypocalcemia was higher (51% vs 24%, P < .05) after parathyroidectomy with thymectomy versus parathyroidectomy alone.

Conclusions: 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.

WORLDWIDE STATUS OF INTRAMUSCULAR DIAPHRAGM PACING FOR RESPIRATORY SUPPORT IN TETRAPLEGICS IN 2012: CONTINUED LOW UTILIZATION OF TECHNOLOGY

Onders R, Elmo M, Kaplan C

Presentation at the 51st Annual Scientific Meeting of the International Spinal Cord Society. London, September 3-5, 2012

Objective: Tetraplegics with chronic respiratory insufficiency needing tracheostomies and mechanical ventilation have a much higher cost of care, increased pneumonia rates and higher mortality rates than non ventilated patients. Direct phrenic nerve pacing to replace ventilators for tetraplegics was initially developed in the 1960's and intramuscular diaphragm pacing (DP) was first implanted in 2000 with full FDA approval in 2008.

Methods: Review all ventilator dependent spinal cord injured (SCI) patients who were implanted with DP per country.

Results: In the United States from 2010 to 2011 there was a 15% annual increase in DP for SCI (43 to 50 implants a year). Even with this increase and accounting for the phrenic nerve pacing patients implanted only a maximal 20% of all eligible SCI patients were implanted. For the rest of the world only 68 patients have been implanted over the last 4 years and include the following countries: Canada, France, Iceland, Germany, Spain, Switzerland, Israel, Netherlands, Australia, Belgium, Norway, Italy, Brazil, Jordon, Turkey, and Saudi Arabia. There was a significant difference in utilization rate between countries from 100% of eligible patients in Iceland to a small percentage in most countries.

Conclusion: Published research of over 10 articles in the last 2 years continues to show the clinical benefit of removing patients from mechanical ventilation with phrenic or diaphragm pacing yet there is still an overwhelmingly low adoption of phrenic or diaphragm pacing. The low utilization of available technology may lead to less corporate research to help SCI patients in other areas. Fortunately this same technology is utilized for amyotrophic lateral sclerosis (ALS) or motor neuron disease (MND) accounting for 90% of DP implants at the largest US site which will help to maintain the DP technology for SCI patients even with low utilization.

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

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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: FNAB 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 = .001) but no difference in the rate of malignancy (6.5% vs 6.4%, P = 1.0). Fewer operations (29% vs 21%, P = .02) and more repeat FNABs (3.9% vs 11%, P < .001) were performed in the BSRTC group. Sixty-one (16%) patients had A/FLUS, 56 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-two (57%) patients underwent thyroidectomy, and 6 patients (19%) were diagnosed with cancer.

Conclusion: 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% with a rate of malignancy of 19%.

Section 4

Oral and Maxillofacial Surgery

ANALYSIS OF MODERATE AND DEEP SEDATION IN GRADUATE PROGRAMS: A RETROSPECTIVE OBSERVATIONAL STUDY

Setty M, Montagnese, T, Mickel A, Baur DA

IRB Approved

A review of sedation techniques were evaluated among the graduate programs at the School of Dental Medicine.

ANTIBIOTIC USAGE AMONG OHIO ORAL AND MAXILLOFACIAL SURGEONS

Schneider KM, Atencio I, Kronenwetter N, Baur DA

Current controversies in the literature regarding antibiotic prophylaxis and usage have left practitioners without clearly defined guidelines. This study surveys the antibiotic prescription patterns of 155 practicing and retired Oral and Maxillofacial Surgeons in the State of Ohio.

IRB approval #EM-13-29

CORRELATION OF BLOOD LOSS AND OPERATING TIME DURING ORTHOGNATHIC SURGERY

Schneider KM, Manlove AE, Demko C, Quereshy FA, Baur DA

Today, orthognathic surgery is being performed less in private practice and more commonly in teaching institutions. There is inadequate data showing outcome assessment from these procedures in this setting. This study evaluates the correlation between blood loss, operating time, and specific orthognathic surgical procedures performed at UH/CWRU from 2002-2007.

DISTANCE BETWEEN ARTICULAR EMINENCE AND FORAMEN SPINOSUM, FORAMEN SPINOSUM AND PETROTYMPANIC FISSURE: AN ANATOMIC LANDMARK STUDY ON DRY SKULLS

Baur DA, Beushausen M, Leech B, Quereshy, FA, Fitzgerald, N

A review of bony landmarks to help avoid the middle meningeal artery during TMJ surgery.

EVALUATION OF IMMEDIATE FUNCTIONAL LOADING ON EARLY RESTORATION OF MAXILLARY DENTAL IMPLANTS

Schneider, KM

IRB Pending

This study will evaluate the outcome of immediate functional loading on single tooth replacement with the OsseoSpeedTx Profile implant restored at 4 weeks. The study design includes different loading protocols in order to test the marginal bone quality and retention as well as long term stability of the implant. We suspect that immediate functional loading of these implants will aid in marginal bone retention as previously described for other OsseoSpeed dental implants.

ORTHOGNATHIC SURGERY FOR CORRECTION OF PATIENTS WITH MANDIBULAR EXCESS: DON'T FORGET TO ASSESS THE GONIAL ANGLE

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Purpose: To evaluate the gonial angle (GA) and associated factors that can contribute to stability after bilateral sagittal split ramus osteotomy setback and Le Fort I advancement osteotomy for the treatment of patients with mandibular excess.

Materials and Methods: This retrospective study included 42 randomly selected, adult patients. Lateral cephalometric radiographs were obtained before and 1 week and 1 year after surgery. Patients in group 1 (n = 18) had a GA smaller than 125° and those in group 2 (n = 24) had a GA larger than 125°. Data were analyzed by analysis of variance and Pearson correlations. Multivariate linear regression analysis was used to identify factors that influenced postsurgical stability.

Results: Mean surgical changes were similar in the 2 groups. The mandible was set back an average of 5.4 mm in group 1 and 6.4 mm in group 2, whereas the maxilla was advanced 2.5 mm in group 1 and 1.7 mm in group 2. Statistically significant postoperative changes were noted for group 1 only. Relapse was found at the innermost point of the contour of the mandible between the incisor tooth and bony chin and the pogonion for the horizontal landmarks; the innermost point of the contour of the maxilla between the anterior nasal spine and incisor tooth and the menton for the vertical landmarks; and the GA, the angle between the sella-nasion line and the innermost point of the contour of the mandible between the incisor tooth and bony chin, and the esthetic plane to the upper lip for the dimensional landmarks. No statistically significant changes were noted for group 2 (GA >125°).

Conclusion: Patients with a preoperative GA smaller than 125° have a greater risk of relapse after receiving bilateral sagittal split ramus osteotomy setback and Le Fort I advancement for the treatment of mandibular excess. Patients with a preoperative GA larger than 125° appear to have a more predictable procedure.

OUTCOME ASSESSMENT AFTER FACIAL COMPUTER TOMOGRAPHY: A 10 YEAR REVIEW

Schneider, KM

IRB Pending

CT has become a regularly used diagnostic tool to assess facial structures over the past 10 years. Due to this limited time, evaluation of clinical outcomes after performing these studies has not been well documented. The aim of this study is to review the accuracy of patient diagnosis before and after CT examination, and how this effected clinical decisions.

SCLEROTHERAPY OF LOW FLOW VASCULAR MALFORMATIONS BY THE USE OF 3% SODIUM TETRADECYLSULPHATE AND 50% TETRACYCLINE

Alakailly X, Kummona R, Baur DA, Quereshy FA

A case series reviewing outcomes in the management of vascular malformations.

THE ASSOCIATION OF ENDODONTIC CONDITIONS WITH SYSTEMIC MEDICAL DISEASE

Safadi S, Baur DA, Mickel A

IRB Approved

Relationships between medical conditions and endodontic diagnosis were evaluated.

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

Baur DA, Kaiser AC, Leech BN, et al

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 (Potgieter et al., 2005). Thorough knowledge and understanding of the pathway and innervations of the MMN is important in order to avoid nerve injury.

Purpose: The aim 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 the 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 1.38mm below the angle of the mandible, 3.1mm inferior to the posterior border of the antegonial notch, 2.66 mm inferior to the anterior border of the antegonial notch , 1.33mm superior to the point at which facial artery reaches the inferior border of the mandible, and 12.4 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. Further study is warranted in order to accurately predict the path of the MMN in patients prior to surgical procedures.

Section 5

Pediatric Cardiothoracic Surgery

EFFECT OF CARDIOPULMONARY BYPASS ON NITRIC OXIDE BIOACTIVITY

Matto F, Smith R, Cina AJ, Ostrowsky J, Kouretas PC, Reynolds JD, Stamler JS

Introduction: S-nitrosylated hemoglobin (SNO-Hb) has been shown to carry vasodilatory nitric oxide (NO) bioactivity in the blood and deploy it upon de-oxygenation, thereby matching blood flow and O2 delivery to local tissue metabolic demand. Corrective cardiac surgery for congenital heart defects requires patients to be on cardiopulmonary bypass (CPB), which has been shown to increase the incidence of end-organ dysfunction and post-operative morbidity. Organ dysfunction has been linked to the duration that the patient is on CPB and may reflect decreased tissue oxygenation. The effects on SNO-Hb during CPB of going on-pump, cross-clamping (which effectively isolates the heart and the lung from the circulation) and blood transfusion are unknown. Studying effects of CPB in neonates as compared to adults offers a biological model which may not be confounded with diseases like diabetes that have been known to affect NO homeostasis.

Objective: To determine the effects of CPB on SNO-Hb levels, end-organ perfusion and kidney function.

Methods: Neonates and infants < 3 years old (n=10) undergoing open-heart surgery for repair of congenital heart disease were enrolled. For assessment of SNO-Hb levels, arterial blood samples were obtained from patients at eight time points: 1) baseline (pre- op); 2) 5 min after going on CPB; 3) 5 min after cross-clamping; 4) 30 min after cross clamping; 5) upon removal of the cross clamp; 6) 30 min after clamp removal (still on CPB); 7) 5 min after patient was put on ventilator support; 8) postop day one. Brain and kidney tissue O2 saturations were measured using near-infrared spectroscopy. Kidney function was assessed and acute kidney injury was defined as a decrease in post-op glomerular filtration rate and/or rise in creatinine levels greater than 50% over baseline values.

Results: SNO-Hb levels are reduced at baseline in patients with heart defect-associated hypoxemia (cyanotic heart disease). Correction of the hypoxemic state at the start of CPB acutely enhances SNO-Hb. Further, surgical correction of the heart defect results in enhanced SNO-Hb levels assessed post- operatively. During CBP, a positive correlation was found between SNO-Hb levels and tissue oxygenation, confirming the role of SNO-Hb in maintenance of tissue perfusion. Intra-operative transfusion results in a decrease in SNO-Hb levels that is associated with decreased tissue oxygenation, and with end-organ dysfunction as demonstrated by decreased glomerular filtration rate and increased creatinine levels assessed post-operatively.

Conclusions: Surgical correction that alleviates hypoxemia increases SNO- Hb levels. SNO-Hb levels of patients on CPB are positively correlated with tissue perfusion. Decreases in SNO-Hb levels induced by intra-operative transfusion are associated with end-organ dysfunction assessed post-operatively. Thus, enhancement of SNO-Hb levels in transfused blood prior to transfusion may confer therapeutic benefit and lead to improved clinical outcomes.

This study was funded by the NHBLI grant 7R01HL095463

FETAL DIAGNOSIS OF SUPERIOR VENA CAVA ANEURYSM

Flores S, Dangol A, Strainic, JP, Holt BD, Kouretas, PC, Ashwath RC

Superior vena cava aneurysm is a rare intrathoracic vascular lesion with only 27 cases reported in the literature. The majority are fusiform and can be associated with cystic hygroma due to the close embryonic relationship between lymphatic vessels and systemic veins. This is the first report of superior vena cava aneurysm diagnosed with fetal echocardiography in a fetus with a cystic hygroma. There is a need of a prospective registry to further delineate all aspects of this condition and establish the most appropriate therapeutic approach.

Section 6
Pediatric Surgery

LAPAROSCOPIC CHOLECYSTECTOMY WITH PRESERVATION OF ANTERIOR ABERRANT HEPATIC ARTERY

Jeffrey A. Blatnik MD, Edward M. Barksdale MD

Department of Pediatric Surgery, Rainbow Babies & Children's Hospital, University Hospitals Case Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH

Introduction: Laparoscopic cholecystectomy is a commonly performed procedure for general surgeons. The operative steps and anatomy are often predictable, however aberrant anatomy can be seen up to 15% of the time. This case demonstrates a laparoscopic cholecystectomy with an aberrant hepatic artery coursing anterior to the gallbladder.

History: This patient is a 17 year old female who presented with right upper quadrant abdominal pain, and was found to have choledocholethiasis and cholelethiasis. ERCP with sphincterotomywas performed with removal of common bile duct stones. This was followed 2 days later by laparoscopic cholecystectomy.

Surgical Details: A standard 4 port cholecystectomy was performed, with initial dissection within Calot's triangle to identify a critical view of safety. While attempting to identify the cystic duct, a large, pulsatile vessel was noted to be coursing initially lateral to the cystic duct, then anterior to the gallbladder. Careful dissection of this artery identified it entering the liver. Slowly the gallbladder was freed from the aberrant artery, and ultimately a presumed cystic artery was identified and clipped. The gallbladder was removed from the liver bed in a lateral to medial approach until the only remaining structure was the cystic duct and the aberrant artery, which was preserved. The cystic duct was secured with an endoloop, and the gallbladder was removed from the abdomen in the standard fashion.

Results: The patient had an uncomplicated post-operative course and was discharged on post-operative day 2. At 3 week follow-up the patient was doing well, and back to her baseline.

Teaching Points: Aberrant anatomy can be found in up to 15% of patients undergoing cholecystectomy. This can be in either the biliary or arterial system, however both scenarios require caution on the part of the surgeon to avoid potentially devastating complications. This video demonstrates an unusual course of an aberrant hepatic artery coursing anterior to the gallbladder before entering the liver.

A RARE COMPLICATION AFTER ESOPHAGEAL DUPLICATION CYST EXCISION IN A PEDIATRIC PATIENT

Bobanga ID, Robke JM, DeRoss AL

A four-year old girl presented with abdominal pain, constipation and chest pain. Computed tomography of the abdomen revealed a 2cm cystic structure in the right posterior mediastinum. The cyst was dissected thoracoscopically from the muscle layer of the esophagus while no compromise of the mucosa was noted endoscopically. Pathology revealed esophageal duplication cyst. Two months postoperatively, the patient presented with chest pain while eating solids. Upper GI revealed an epiphrenic esophageal diverticulum at the site of cyst excision. This was resected transabdominally, along with esophageal myotomy and partial fundoplication. The diverticulum partially recurred and ultimately required resection via thoracotomy.

Section 7

Surgical Oncology

THE UTILITY OF FROZEN SECTION EXAMINATION FOR PATIENTS WITH A THYROID NODULE AND "ATYPIA/FOLLICULAR LESION OF UNDETERMINED SIGNIFICANCE"

S Posilico, SM Wilhelm, CR McHenry

University Hospitals Case Medical Center and MetroHealth Medical Center. Cleveland, OH.

Introduction: The National Cancer Institute introduced the Bethesda system for reporting thyroid cytopathology (BSRTC) to help promote more consistent management of patients with nodular thyroid disease. However, the creation of a new diagnostic category "atypia/ follicular lesion of undetermined significance (A/FLUS)" has raised questions about the operative management of patients with a thyroid nodule and a fine needle aspiration biopsy (FNAB) diagnosis of A/FLUS. The purpose of this study was to evaluate the role of frozen section exam (FSE) for determining extent of thyroidectomy in patients with A/FLUS.

Methods: Using a prospectively-maintained data base, a retrospective review of all patients operated on for a thyroid nodule with a FNAB diagnosis of A/FLUS after initiation of the BSRTC in 2010 was completed to determine if FSE affected intraoperative decision making. Demographic data, clinical and sonographic findings, cytologic and pathologic results and extent of thyroidectomy were obtained for all patients.

Results: 86 patients(70 female, mean age=51yrs, range 18-84 yrs) with nodular thyroid disease and a FNAB interpreted as A/FLUS underwent thyroidectomy; 15(17%) had carcinoma. Indication for operation was: an abnormal or inconclusive repeat FNAB, prior neck irradiation, family history of thyroid cancer, sonographic features raising suspicion for malignancy, compressive symptoms, concominant parathyroidectomy or patient preference. FSE was obtained in 45 (52%) patients and was interpreted as follicular or Hurthle cell neoplasm (15), benign colloid or adenomatous nodule (23), Hashimoto's thyroiditis (3) and papillary cancer (4). FSE was not performed in 41 (48%) patients who underwent total thyroidectomy for treatment of bilateral nodular thyroid disease. FSE altered intraoperative management in 30(66%) patients, limiting the extent of surgery to lobectomy in 26 patients diagnosed with benign disease and resulting in definitive total thyroidectomy in 4 patients diagnosed with cancer.

Conclusion: While previous studies have shown FSE to be of limited or no value for follicular neoplasms, our results show that FSE can be of value in helping determine extent of thyroidectomy for patients with A/FLUS.

BOWEL OBSTRUCTION SECONDARY TO AN UNUSUAL INTERNAL HERNIA

Jeffrey A. Blatnik, MD, and Scott M. Wilhelm, MD

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.

ALGENPANTUCEL-L IMMUNOTHERAPY FOR PANCREATIC CANCER INDUCES ANTI-MESOTHELIN ANTIBODY (AB) TITERS THAT POSITIVELY CORRELATE WITH IMPROVED OVERALL SURVIVAL

Gabriela R. Rossi, Jeffrey M Hardacre, Mary Frances Mulcahy, Mark S. Talamonti, Jennifer Carrie Obel, Caio Max S. Rocha Lima, Howard Safran, Heinz-Josef Lenz, E. Gabriela Chiorean, Nicholas N. Vahanian, Charles J. Link, NLG0205; NewLink Genetics, Ames, IA; University Hospitals Case Medical Center, Cleveland, OH; Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL; Kellogg Cancer Center NorthShore University Health System, Evanston, IL; NorthShore University HealthSystem, Evanston, IL; Sylvester Comprehensive Cancer Center, University of Miami, Miami, FL; Brown University Oncology Research Group, Providence, RI; University of Southern California Norris Comprehensive Cancer Center, Los Angeles, CA; Indiana University Melvin and Bren Simon Cancer Center, Indianapolis, IN

Background: Hyperacute rejection of tissues expressing the carbohydrate (1,3) Gal xenoantigen is a potent innate immune defense mechanism that was leveraged to treat resected pancreatic cancer patients by immunization with genetically modified allogeneic tumor cells expressing Gal moieties (algenpantucel-L). We propose that adding algenpantucel-L to SOC adjuvant therapy may improve survival and induce immunological biomarkers that positively correlate with improved median overall survival (OS).

Methods: Open-label, multicenter phase II study evaluating algenpantucel-L+SOC (RTOG-9704: gemcitabine + 5-FU-XRT) for resected pancreatic cancer patients. Endpoints: 1°) disease-free survival (DFS) at 1 year; 2°) OS, toxicity and immunologic analysis. Biomarkers were evaluated including total IgG, complement, CA19-9 levels, anti-Gal Ab, anti-CEA Ab, and anti-membrane-bound recombinant mesothelin (MSLN) Ab.

Results: Patients received gemcitabine with 5-FU modulated radiation therapy plus algenpantucel-L. The primary endpoint, 12-month DFS, was 62% and 12-month OS was 86%. All evaluable patients have been in follow-up for ≥ 3 years. We now report OS rates at 3 years of 39% and DFS of 26% at 3 years. Evaluable patients (n=64) were tested for the induction of anti-MSLN Ab where ≥ 25% increase in the anti-MSLN Ab compared to baseline was considered significant ($p<0.001$). Twenty of 64 patients (31%) had increased anti-MSLN Ab. Patients responding with anti-MSLN Ab had a median OS of 42 months compared to 20 months for patients without sero-conversion. The positive correlation between increased anti-MSLN Ab and improved median OS was statistically significant ($p=0.027$).

Conclusions: The addition of algenpantucel-L to SOC for resected pancreatic cancer may improve survival. In 20/64 patients, algenpantucel-L-induced anti-MSLN Ab responses that correlates with improved survival (median OS 42 vs 20 months). Immunological monitoring of algenpantucel-L immunotherapy with this biomarker is feasible and might predict patient response to therapy. A multi-institutional, phase III study is currently underway (ClinicalTrials.gov NCT01072981).

Clinical trial information: **NCT00569387**

CHEMOKINES AS CANCER VACCINE ADJUVANTS

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We are witnessing a new era of immune-mediated cancer therapies and vaccine development. As the field of cancer vaccines advances into clinical trials, overcoming low immunogenicity is a limiting step in achieving full success of this therapeutic approach. Recent discoveries in the many biological roles of chemokines in tumor immunology allow their exploitation in enhancing recruitment of antigen presenting cells (APCs) and effector cells to appropriate anatomical sites. This knowledge combined with advances in gene therapy and virology allows researchers now to employ chemokines as potential vaccine adjuvants. This review will focus on recent murine and human studies that use chemokines as therapeutic anti-cancer vaccine adjuvants.

A DUAL-INSTITUTION RANDOMIZED CONTROLLED TRIAL OF REMNANT CLOSURE AFTER DISTAL PANCREATECTOMY: DOES THE ADDITION OF A FALCIFORM PATCH AND FIBRIN GLUE IMPROVE OUTCOMES?

Carter TI, Fong ZV, Hyslop T, Lavu H, Tan WP, Hardacre J, Sauter PK, Kennedy EP, Yeo CJ, Rosato EL

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Objective: The objective of the study was to assess the efficacy of two pancreatic remnant closure techniques following distal pancreatectomy: (1) stapled or sutured closure versus (2) stapled or sutured closure plus falciform patch and fibrin glue reinforcement in the setting of a prospective randomized trial, with the primary endpoint being pancreatic fistula. Pancreatic stump leak following left-sided pancreatic resection (distal pancreatectomy) remains common. Despite multiple and varied techniques for closure, the reported leak rate varies up to 30 %. A retrospective analysis by Iannitti et al. (J Am Coll Surg 203(6):857-864, 2006) detected a decreased leak rate in patients receiving a traditional closure buttressed with an autologous falciform ligament patch and fibrin glue.

Methods: Between April 2008 and October 2011, all willing patients scheduled to undergo distal pancreatectomy at the authors' institutions were consented and enrolled at the preoperative office visit. Patients were intraoperatively stratified as having hard or soft glands and randomized to one of two groups: (1) closure utilizing stapling or suturing (SS) versus (2) stapled or sutured plus falciform ligament patch and fibrin glue (FF). The trial design and power analysis (=0.05, =0.2, power 80 %, chi-square test) hypothesized that the FF intervention would reduce the primary endpoint (pancreatic fistula) from 30 % to 15 % and targeted an accrual goal of 190 patients. Secondary endpoints included length of postoperative hospital stay, 30-day mortality, hospital readmission, and ISGPF fistula grade (A, B, and C).

Results: The trial accrued 109 patients, 55 in the SS group and 54 in the FF group. Enrollment was closed prior to the target accrual, following an interim analysis and futility calculation. Due to insufficient enrollment, patients stratified as having a hard gland were excluded (n=8) from analysis, leaving 101 patients in the soft stratum. The overall pancreatic leak rate was 19.8 % (20 patients) for patients with soft glands. Patients randomized to the FF group had a leak rate of 20 %, as compared with 19.6 % in the SS group (p=1.000). Fistula grades in both groups were identical: 1A, 8B, and 1C in the FF group as compared to 1A, 8B, and 1C in the SS group. Complication rates were comparable between the two groups. The median length of postoperative hospital stay was 5 days in both groups. There was a trend towards a higher 30-day readmission rate in the FF group (28 % vs. 17.6 %, p=0.243).

Conclusion: The addition of a falciform ligament patch and fibrin glue to standard stapled or sutured remnant closure did not reduce the rate or severity of pancreatic fistula in patients undergoing distal pancreatectomy (ClinicalTrials.gov NCT00889213).

TRENDS IN THE SURGICAL TREATMENT OF GASTRIC ADENOCARCINOMA

Siavash Raigani, Jeffrey M. Hardacre, Julian Kim, John Ammori

Introduction: Over the past decade, the treatment of gastric adenocarcinoma has evolved due to the publication of two seminal randomized controlled trials. The National Cancer Data Base (NCDB) is a national oncology outcomes database for over 1,500 Commission on Cancer-accredited cancer programs. We aimed to examine treatment trends for surgically resectable gastric cancer (stage I-III). Our hypothesis was that the use of chemotherapy and chemoradiation in addition to surgery for the treatment of gastric adenocarcinoma has increased from 2000-2009.

Methods: Patients diagnosed with Stage I-III gastric adenocarcinoma between 2000-2009 were selected from the NCDB Hospital Comparison Benchmark Reports. Attention was paid to the initial treatment regimen, such as surgery alone, surgery plus chemotherapy, or surgery plus chemoradiation. In addition, data on hospital setting were collected and analyzed. The Cochran-Armitage test for trend was used to assess changes in treatment over time.

Results: 50,778 patients with Stage I-III gastric adenocarcinoma were included in the analysis. Between 2000-2009, the use of surgery alone for first course treatment across all three stages decreased significantly at both teaching hospitals and community hospitals ($P<0.0001$ for both cases). In the same period, the use of chemotherapy in addition to surgery as treatment increased significantly across all three stages and at both types of hospitals ($P<0.0001$ for all cases). Treatment with surgery plus chemoradiation increased for Stage I-III disease at community hospitals ($P<0.05$ for all), but only increased significantly for Stage II disease at teaching hospitals ($P<0.01$). Incidentally, it wsa noted that non-surgical treatment increased across all three stages at both hospital settings ($p<0.001$ for all cases).

Conclusion: Data from the NCDB from 2000-2009 demonstrate that there has been an increasing use of chemotherapy in addition to surgery for resectable gastric cancer.

IMMUNE ASPECTS OF THE BREAST TUMOR MICROENVIRONMENT

Akhil Chawla, Gheath Alatrash, Yun Wu & Elizabeth A Mittendorf

The immune response in the tumor microenvironment is complex, consisting of cells from both the adaptive and innate immune systems. The phenotype and function of these cells are dictated by cytokines present in the microenvironment, as well as by the interactions of these cells with the tumor cells and each other. Technological advances have allowed investigators to better identify the specific immune cells present and immune-related gene signatures overexpressed in the tumor microenvironment. Increased knowledge of tumor immunology has allowed us to better understand how these cells and the developing tumor interact. Together, these advances have prompted the conduct of numerous studies investigating the prognostic and predictive significance of immune infiltrates.

IMPAIRED T-CELL RESPONSES TO SPHINGOSINE-1-PHOSPHATE IN HIV-1 INFECTED LYMPH NODES

Mudd JC, Murphy P, Manion M, Debernardo R, Hardacre J, Ammori J, Hardy GA, Harding CV, Mahabaleshwar GH, Jain MK, Jacobson JM, Brooks AD, Lewis S, Schacker TW, Anderson J, Haddad EK, Cubas RA, Rodriguez B, Sieg SF, Lederman MM

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The determinants of HIV-1-associated lymphadenopathy are poorly understood. We hypothesized that lymphocytes could be sequestered in the HIV-1+ lymph node (LN) through impairments in sphingosine-1-phosphate (S1P) responsiveness. To test this hypothesis, we developed novel assays for S1P-induced Akt phosphorylation and actin polymerization. In the HIV-1+ LN, naïve CD4 T cells and central memory CD4 and CD8 T cells had impaired Akt phosphorylation in response to S1P, whereas actin polymerization responses to S1P were impaired dramatically in all LN maturation subsets. These defects were improved with antiretroviral therapy. LN T cells expressing CD69 were unable to respond to S1P in either assay, yet impaired S1P responses were also seen in HIV-1+ LN T cells lacking CD69 expression. Microbial elements, HIV-1, and interferon - putative drivers of HIV-1 associated immune activation all tended to increase CD69 expression and reduce T-cell responses to S1P in vitro. Impairment in T-cell egress from lymph nodes through decreased S1P responsiveness may contribute to HIV-1-associated LN enlargement and to immune dysregulation in a key organ of immune homeostasis.

INFLAMMATORY CHEMOKINE MIP-1A ENHANCES IMMUNITY AGAINST A MURINE COLORECTAL CANCER MODEL

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Purpose: Inflammatory chemokines Macrophage Inflammatory Protein-1 alpha and beta (MIP-1 and MIP-1) are crucial in generating memory CD8 T cells via interaction with the receptor CCR5 on T cells during vaccinations. The current study seeks to determine the effect of tumor-secreting MIP-1 and MIP-1 on the generation of anti-tumor adaptive immunity in a murine colon tumor model, CT26.

Methods: Prior to tumor inoculation, age-matched recipient female BALB/c mice were depleted of T cell subsets with intraperitoneal injections of the following neutralizing antibodies on days -3, -1, and then weekly following tumor inoculation: 1) Phosphate Buffered Saline control; 2) anti-CD4 neutralizing antibody; 3) anti-CD8 neutralizing antibody; and 4) anti-CD4 and CD8 neutralizing antibodies. The treated groups were then injected subcutaneously on Day 0 with one million live cells as follows: A) CT26 wildtype (WT); B) CT26 secreting MIP-1 and MIP-1; C) CT26 secreting MIP-1 only; D) CT26 secreting MIP-1 only; E) equal mixture of C and D. The mice were then monitored for tumor growth by palpation twice weekly for four weeks. Tumors were measured using a micro-caliper. The mice were sacrificed when tumors reached a diameter of 15 millimeters or larger, and the tumor nodules were removed for further analysis including histology, flow cytometry and ELISA assays. Additionally, the interactions between fluorescent-labeled T cells and tumor cells in the metastatic lymph node are visualized by performing 2-photon laser-scanning microscopy.

Results: Tumors that were engineered to secrete MIP-1 (subgroups B and C) displayed slowest growth kinetics, particularly in the absence of CD4 T cells. In contrast, MIP-1 secreting tumors (subgroups D and E) grew as aggressively as CT26WT, particularly in the absence of CD8 T cells (groups 3 and 4) (see Figure). Intriguingly, some mice either never developed tumors (in group B) or experienced dramatic tumor regression (groups B and C).

Conclusions: CT26 cells engineered to secrete MIP-1 or both MIP-1 and MIP-1 exhibited slow growth kinetics in vivo in a CD8-dependent manner, suggesting a protective role of MIP-1 in anti-CT26 CD8 T cell generation.

INFLAMMATORY CHEMOKINES ALTER IMMUNOGENICITY OF COLORECTAL CANCER IN A MOUSE MODEL

Iuliana D. Bobanga, Jay T. Myers, Alex Y. Huang

Inflammatory chemokines Macrophage Inflammatory Protein-1 alpha and beta (MIP-1A and MIP-1B) are crucial in generating memory CD8 T cells via interaction with the receptor CCR5 on T cells during vaccinations. They are also important chemoattractants of various immune cells to the tumor microenvironment. Our experiments seek to determine the effect of MIP-1A and MIP-1B on the generation of anti-tumor adaptive immunity in a murine colon tumor model, CT26. When tumor cells of CT26 cell lines engineered to secrete MIP-1A and/or MIP-1B were inoculated in the thigh of age-matched recipient female BALB/c mice, different tumor growth kinetics were observed that suggested a protective role for tumors that secrete chemokines when compared to wildtype tumors. The growth kinetics between the different cell lines were very similar when inoculated in immunocompromised nude mice. In subsequent experiments, mice were depleted of T cell subsets with intraperitoneal injections of neutralizing antibodies prior to tumor inoculation to determine the contribution of CD4 and/or CD8 T cells on the generation of anti-tumor immunity. Our data suggests a protective role of CD8 T cells against tumor cells. Additionally, we performed vaccination experiments with irradiated tumor cells that secrete these chemokines, and again observed a stronger protective effect in mice injected with chemokine-secreting tumors compared to wildtype tumors when re-challenged with wildtype tumors. Subsequently, we are injecting MIP-1A and/or MIP-1B chemokines directly into small wildtype tumors and evaluating the effects on tumor size and microenvironment chemotaxis of various immune cell subsets via flow cytometry, histology, and ELISA. This will allow us to elucidate the mechanism by which these chemokines stimulate the anti-tumor adaptive immune response and bring us closer to a translational model for intratumoral inflammatory chemokine injection.

TRENDS IN THE TREATMENT OF RESECTABLE PANCREATIC ADENOCARCINOMA

*Siavash Raigani, John Ammori, Julian Kim, Jeffrey M. Hardacre**

Background: Multiple prospective, randomized trials have demonstrated that the addition of adjuvant therapy after surgical resection of pancreatic cancer improves survival compared to surgery alone. However, the optimal type of adjuvant therapy, chemotherapy alone or chemotherapy combined with chemoradiation therapy, remains controversial. Our aim was to examine the treatment trends for surgically resectable (stages I and II) pancreatic cancer in the United States using the National Cancer Data Base.

Methods: the National Cancer Data Base (NCDB) is a national oncology outcomes database for over 1,500 Commission on Cancer-accredited cancer programs. Patients diagnosed with Stage I-II pancreatic adenocarcinoma between 2003-2010 were selected from the NCDB Hospital Comparison Benchmark Reports. Attention was paid to the initial treatment regimen, such as surgery alone, surgery plus chemotherapy, or surgery plus chemoradiation. In addition, data on hospital setting (teaching hospitals vs. community hospitals) were collected and analyzed. The Cochran-Armitage test for trend was used to assess changes in treatment over time.

Results: 59,094 patients with Stage I-II pancreatic adenocarcinoma were included in the analysis. Between 2003-2010, the use of surgery alone as first course treatment of Stage II disease decreased significantly at both teaching hospitals and community hospitals among patients who underwent surgery ($P<0.0001$ for both cases). In the same period, the use of chemotherapy in addition to surgery as treatment of Stage I and II disease increased at least two-fold at both hospital settings ($P<0.0001$ for all cases). Treatment with surgery plus chemoradiation decreased significantly for both stages in both hospital settings ($P<0.0001$ for all cases). Non-surgical treatment for Stage II disease was surprisingly high and significantly increased over time ($P<0.0001$ for both hospital types), ranging from approximately 30-37% at teaching hospitals and 39-47% at community hospitals.

Conclusion: Data from the NCDB from 2003-2010 illustrate changes in the adjuvant treatment of pancreatic cancer. The use of chemotherapy alone as adjuvant therapy increased whereas the use of multimodality therapy decreased. In addition, there remains an alarmingly high rate of non-surgical therapy for Stage I and II disease.

STEREOTACTIC BODY RADIATION THERAPY FOR NONRESECTABLE TUMORS OF THE PANCREAS

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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.

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

Section 8
Transplant Surgery

A COMPARISON OF PATENCY BETWEEN ONE AND TWO STAGE ARTERIOVENOUS FISTULA TRANSPOSITIONS

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Objectives: Renewed interest in arteriovenous fistula(AVF) transposition has arisen as emphasis is being placed on autologous hemodialysis access construction. We report our experience with one and two stage techniques for AVF transposition.

Methods: A database of all patients who had AVF placed between January 2008 and June 2011 was retrospectively reviewed. Patients were stratified into those whose AVF was transposed using a one stage technique (AVFT-1) and those done with a two stage technique (AVFT-2). Outcomes measured were assisted primary and secondary patency. Marginal survival models utilizing Cox proportional hazards regression were used for statistical comparison. Results are reported as hazard ratio (HR) and 95% confidence intervals (CI).

Results: A total of 125 AVF were created using a transposition technique. AVFT-1 (n .38) and AVFT-2 (n .87) were analyzed. After accounting for multivariate association with age, diabetes, PAD, tobacco use, previous number of accesses, and presence of tunneled catheter at AVF creation, AVFT-2 was associated with both better assisted primary (HR, 0.47; CI, 0.25-0.90) and secondary patency (HR,0.44; CI, 0.23-0.87) when compared to AVFT-1.

Conclusions: In our experience two stage operations demonstrated improved assisted primary and secondary patency and as a corollary could extend the duration of autologous access in challenging hemodialysis patients.

Author Disclosures: M. T. Allemang: Nothing to disclose; S. Brian: Nothing to disclose; A. Chang: Nothing to disclose; W. John: Nothing to disclose

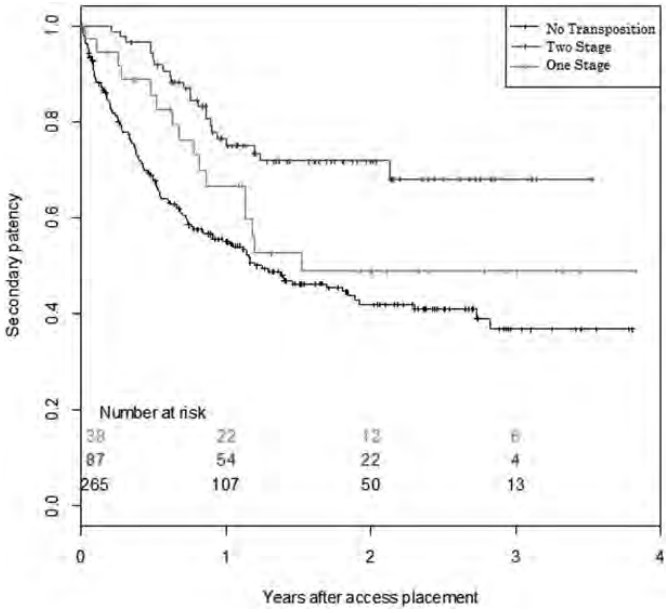

Fig. Kaplan-Meier survival curves of secondary patency for one stage and two-stage AVF transposition.

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

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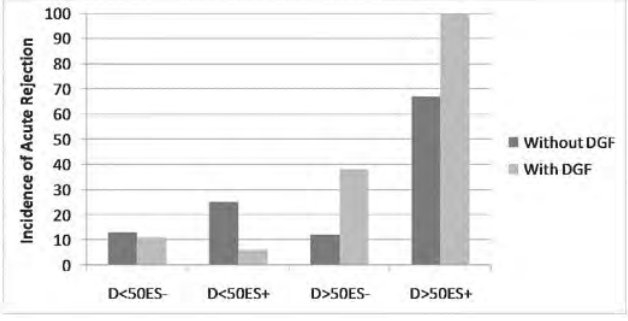
Advanced donor age and pretransplant humoral sensitization adversely affect kidney transplant outcomes. We have described the ELISPOT assay for interferon gamma as a measure of cellular alloimmunity. To determine the interplay between cellular presensitization and donor age, we studied 118 recipients 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.



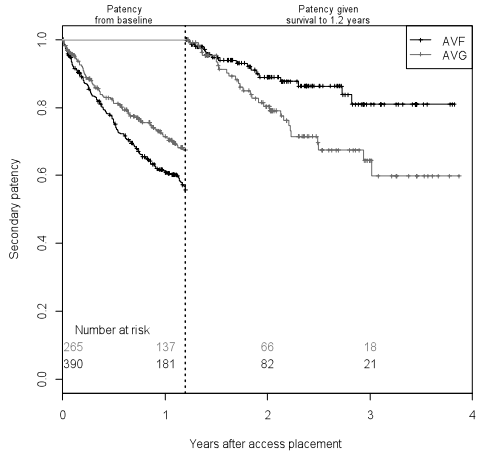
ARTERIOVENOUS GRAFTS ARE ACCEPTABLE FOR DIALYSIS PATIENTS WITH LIMITED LIFE EXPECTANCY

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

Objectives: To estimate the patency of arteriovenous fistulas (AVF) and grafts (AVG) for dialysis access in a tertiary care setting and understand clinical variables that affect outcomes.

Methods: Records of patients who had a dialysis access placed from January 2008 until June 2011 were retrospectively reviewed. Outcomes were assisted primary patency and secondary patency. Marginal survival models (to account for correlation of accesses within subjects) utilizing Cox proportional hazard regression were used for statistical comparisons. The proportional hazards assumption was found to be met if the time course was bisected, resulting in separate hazard ratio (HR) estimates before and after 1.2 years.

Results: A total of 494 patients with 655 accesses (390 AVF, 265 AVG) were examined. 271 patients had only AVFs, 153 had only AVGs, and 70 had sequential AVF/AVG. The average age was 58.3 ± 16.4 for AVF and 60.8 ± 16.6 for AVG with 46% male, 72% African-American, 52% diabetic, and 66% with a tunneled catheter at the time of access placement. Seventy-seven percent of primary accesses (N=305) were "fistula-first". We found AVG were worse for both assisted primary patency and secondary patency (median 1 intervention) after 1.2 years (HR: 4.8 CI: (2.8, 8.3) and HR: 2.1 CI: (1.2, 3.9), respectively). However, from time of placement until 1.2 years, secondary patency for AVGs was better (HR: 0.7 CI: (0.5 to 0.9)) while assisted primary patency was worse (HR: 1.4 CI: (1.1, 1.8)). Kaplan-Meier estimates for secondary patency before and after the 1.2 year cutoff were constructed (Figure). In a multivariable model including age, diabetes, PVD, ever used tobacco, previous access placement, and tunneled catheter, the HR for AVG was 0.6 (CI: 0.4, 0.8) before 1.2 years. Other results were also similar in the multivariable model.



Conclusions: AV grafts can be maintained with high rates of secondary patency in the short-term, but are not as durable in the long-term. Patients with limited life expectancy can effectively be offered an AV graft when native veins are of limited quality for fistula construction.

Alternatives?!?: An AVG may be more appropriate for patients who require hemodialysis but have limited life expectancy due to its better patency and lower intervention rate, in short term outcomes. AV grafts can also be maintained with high rates of secondary patency in the short-term, but are not as durable in the long-term and thus may be more appropriate in patients with limited life expectancy.

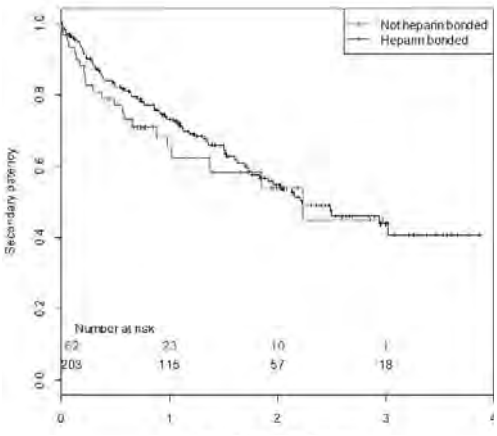
HEPARIN BONDING DOES NOT IMPROVE PATENCY OF PTFE ARTERIOVENOUS GRAFTS

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

Objectives: To compare the patency of arteriovenous grafts (AVG) for dialysis access with and without heparin bonding in a tertiary care setting.

Methods: Records of patients who had a AVGs placed from January 2008 until June 2011 were retrospectively reviewed. Outcomes were assisted primary patency and secondary patency. Marginal survival models (to account for correlation of accesses within subjects) utilizing Cox proportional hazard regression were used for statistical comparisons.

Results: A total of 223 patients with 265 Grafts. Of these 62 (23%) were heparin bonded. The average age was 65.9 ± 15.3 for heparin and 59.2 ± 16.7 for control ($p<0.01$). Of the heparin group, 39% were male, 81% were black, 63% were diabetic, and 81% had a tunneled catheter at the time of access placement. Of the control group, 35% were male, 85% were black, 56% were diabetic, and 83% had a tunneled catheter. Heparin bonded grafts were no different in either assisted primary or secondary patency (HR: 1.39 CI: (0.98, 1.96) and HR: 1.20 CI: (0.73, 1.96) respectively). Kaplan-Meier estimates for secondary patency are shown in the Figure. There was no significant difference in the number of interventions ($P>0.30$). To correct for inequalities, a multivariable model including age, diabetes, PVD, ever used tobacco, previous access placement, and tunneled catheter found HR for heparin bonded grafts was again not significantly different than standard grafts in either assisted primary patency or secondary patency (HR: 1.35 CI: (0.91, 1.99) and HR: 1.15 CI: (0.62, 2.16) respectively).



Conclusions: In this retrospective review, heparin bonded grafts did no better in long-term patency or number of interventions. Prospective studies are needed to confirm these results.

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.

MANY DCD KIDNEYS REACH PUMP RESISTANCE TARGETS BY 4 HOURS

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Many organ procurement organizations routinely pump and biopsy higher risk kidneys, such as those from donors-after-cardiac-death (DCD) or expanded criteria donors (ECD). We sought to determine the minimal time to adequately pump a DCD kidney as part of an initiative to determine the optimal time to expect organ acceptances and refusals from transplant centers.

Methods: Pump parameter data was collected from 41 DCD donors who underwent organ procurement. Kidneys from 2 donors were discarded intraoperatively, and not pumped and another donor provided a single kidney, while the remaining 77 kidneys were placed on Waters RM3 pumps. Pump data was collected at 2 hour intervals. Resistance ratio targets of < 0.35 and < 0.30 were utilized for analysis.

Results: Donor age ranged from 6 to 61 (median 48). Due to local constraints, premortem heparin was utilized in only 3 of the donors. By 4 hours, 71.4% and 61.0% of DCD donors had reached the resistance targets of < 0.35 and 0.30, respectively (table). Two kidneys were taken off pump before the 6 hour timepoint before reaching either target, with another 4 and 5 organs removed from the pump before reaching the < 0.35 and < 0.30 targets, respectively, before the 8 hour timepoint.

Number of Kidneys Reaching Resistance Targets

Time (hours)	Resistance <0.35 (%)	Cumulative %	Resistance <0.30 (%)	Cumulative %
0	13 (17%)	17%	6 (8%)	8%
2	34 (44%)	61%	25 (33%)	40%
4	8 (10%)	71%	16 (21%)	61%
6	5 (7%)	78%	3 (4%)	65%
8	3 (4%)	82%	5 (7%)	71%
Never	14 (18%)	100.0%	22 (29%)	100.0

Conclusion: Many DCD kidneys reach target resistance ratios by 4 hours, with some improvement afterwards.

DISCLOSURE: The authors of this abstract have nothing to disclose.

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

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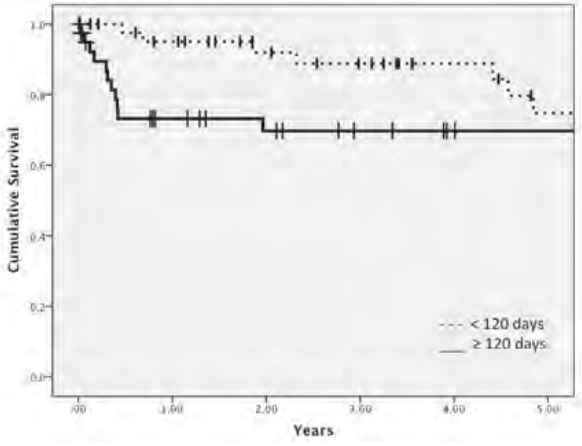
Management of the failed renal transplant is controversial. Transplant nephrectomy often occurs after immunosuppression has been withdrawn, which can lead to sensitization. We sought to determine the impact of nephrectomy timing on perioperative outcomes to better define the risk-benefit ratio of allograft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

SURVIVAL ADVANTAGE OF ALLOGRAFT NEPHRECTOMY EARLY AFTER TRANSPLANT FAILURE

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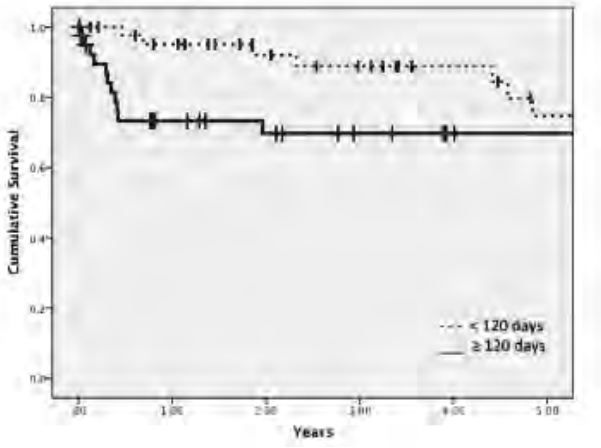
Management of the failed renal transplant is controversial. We sought to determine the impact of nephrectomy timing on perioperative complications and survival. Methods: After IRB approval, we retrospectively analyzed outcomes from 86 patients who underwent transplant nephrectomy for cause between 2000 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.

Section 9

Trauma, Critical Care, Burns, & Acute Care Surgery

A NOVEL PROSPECTIVE APPROACH TO EVALUATE TRAUMA RECIDIVISM: THE CONCEPT OF THE PAST TRAUMA HISTORY

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Background: The purpose of this study was to determine the incidence and burden of trauma recidivism at a regional Level 1 trauma center by incorporating the concept of the past trauma history (PTHx) into the general trauma history.

Methods: All trauma patients who met prehospital trauma criteria and activated the trauma team during a 13-month period were asked about their PTHx, that is, their history of injury in the previous 5 years. A recidivist presented more than once for separate severe injuries. Recurrent recidivists presented multiple times during the study period.

Results: Of the 4,971 trauma activations during the study period, 1,246 (25.2%) were identified as recidivists. Recidivists were 75% male, 62% white, 36% unemployed, 26% uninsured, and 90% unmarried. The recidivism rate among admitted patients was 23.4% compared with 29.3% in those discharged from the emergency department. The highest recidivism rates were noted in patients who reported alcohol or illegal drug use on the day of injury and in victims of interpersonal violence (IPV), defined as those who sustained gunshot wounds, stab wounds, or assaults, Those involved in IPV were more likely to have been involved in IPV at the previous trauma than those with other trauma mechanisms. Key risk factors for recidivism among all patients were male sex and single marital status. Seventy-three patients (1.5%) were recurrent recidivists, representing 157 unique encounters.

Conclusion: This is the highest trauma recidivism rate reported on a large population of all consecutive trauma activations at a regional Level 1 trauma center. These data illustrate the tremendous burden of recidivism in the modern era, more than previously recognized. Efforts specifically targeting those involved in IPV may reduce recidivism rates. Incorporating the concept of the PTHx into the general history of the trauma patient is feasible and provides valuable information to the provider.

Level of Evidence: Prognostic study, level II.

ANTERIOR ABDOMINAL STAB INJURY: A COMPARISON OF SELF-INFLICTED AND INTENTIONAL THIRD-PARTY STABBINGS

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Background: There is minimal literature comparing self-inflicted (SI) with non–self-inflicted (NSI) anterior abdominal stab wounds (AASW).

Methods: Adult patients treated at a level 1 trauma center from 2006 through 2011 with an AASW were reviewed.

Results: There were 215 patients with an AASW; 20% were SI. NSI patients had more nonabdominal injuries (47% vs 16%, P , .01) and disposition directly to the operating room (45% vs 26%, P 5 .02). Intra-abdominal injury rates were similar. One hundred twenty-eight patients had isolated AASWs; 28% were SI. SI patients had higher admission rates (86% vs 63%, P 5 .01). One hundred three patients had isolated stable/asymptomatic AASWs; 31% were SI. SI patients had more admissions (84% vs 52%, P ,.01), had higher intensive care unit admission rates (23% vs 5%, P 5.01), longer LOS (3.2 vs 1.4, P ,.01), and higher hospital charges ($18,000 vs $11,000, P ,.01). The rates of intra-abdominal injury were again similar.

Conclusions: Controlling for extra-abdominal injuries, SI AASW patients have similar rates of intra-abdominal injury but use more resources.

EFFECTS OF ELECTRICAL STIMULATION ON WOUND HEALING AND MACROPHAGE MOTILITY IN AN ACUTE WOUND MOUSE MODEL

Iuliana D. Bobanga, Deborah S. Barkauskas*, Francesca Scrimeri, Alex Y. Huang*

Introduction: Electrical stimulation (ES) has been proposed as a method to accelerate wound healing. To date, research mostly focused on the effects of ES on keratinocyte migration and extracellular matrix formation, and less on immune cells critical to wound healing. We hypothesize that ES exerts direct cellular effect on the motility, recruitment and function of macrophages to accelerate wound healing.

Methods: Two acute wound models were used: a 0.5mm punch biopsy on the ear and a 1-2mm full-thickness punch biopsy on the scalp of C57/B6 and CX3CR1GFP/+ mice expressing GFP in skin macrophages. After 100mV, 100Hz stimulation was applied for 1 hour with an electrode across the wound, daily photos and wound measurements were taken. After one week, wounds were excised to measure tensile strength, perform immunohistochemistry (IHC) for cell infiltrate quantification, or perform RT-PCR to determine levels of cytokines and growth factors in stimulated wounds compared to controls. Two-photon laser-scanning microscopy (2P-LSM) was used to dynamically visualize macrophage motility within the wound in live anesthetized mice during ES.

Results: ES enhanced wound healing and increased tensile strength in stimulated wounds at seven days. The presence of M2-phenotype specific macrophage markers (Arginase, CD206) increased in stimulated wounds, along with IL-6 and VCAM-1. IHC demonstrated increased macrophage migration in the wound, while 2P-LSM showed an acute increase in macrophage accumulation and motility around wound edges after ES.

Conclusion: ES accelerates wound healing, improves wound tensile strength, causes an increase in accumulation and velocity of macrophages around the wound, and improves the function of macrophages critical to the inflammatory phase of wound healing.

IMPLEMENTATION OF CLOUD-BASED IMAGE SHARING TECHNOLOGY SIGNIFICANTLY REDUCED REPEAT CT IMAGING IN A REGIONAL TRAUMA SYSTEM

Banerjee A, Bronson D, Allen D, Wilczewski PA, Ferguson R, Claridge JA

Introduction: The practice of repeating computed tomography (re-CT) is common among trauma patients transferred between hospitals incurring additional cost and radiation exposure. This study sought to evaluate the effectiveness of implementing modern cloud-based technology (lifeIMAGE) across a regional trauma system to reduce the incidence of re-CT imaging.

Methods: This is a prospective interventional study to evaluate outcomes after implementation of lifeIMAGE in January 2012. Key outcomes were rates of CT imaging, including the rates and costs of re-CT from January 2009 through December 2012.

Results: There were 1082 trauma patients transferred from participating hospitals during the study period (657 patients before and 425 patients after implementation) with the overall re-CT rate of 20.5%. Rates of any CT imaging at referring hospitals decreased (62% vs. 55%, $p < 0.05$) and also decreased at the accepting regional level 1 center (58% vs. 52%, $p < 0.05$) following system implementation. There were 639 (59%) patients who had CT imaging performed prior to transfer (404 patients before and 235 patients after implementation). Of these patient the overall re-CT rate decreased from 38.4% to 28.1% ($p = 0.01$). Rates of re-CT head (21% vs. 11%, $p < 0.001$), chest (7% vs. 3%, $p = 0.05$), and abdomen and pelvis (12% vs. 5%, $p < 0.001$) were significantly reduced following system implementation. The cost of repeat imaging per patient was significantly lower following system implementation (mean charges of $1,046 vs. $589, $p < 0.001$). These results were more pronounced in a subgroup of patients with an ISS > 14 with a reduction in overall re-CT from 51% to 30% ($p = 0.03$).

Conclusion: The implementation of modern cloud-based technology across the regional trauma system resulted in significant reductions in re-CT imaging and cost.

TRAUMA CENTER VARIATION IN SPLENIC ARTERY EMBOLIZATION AND SPLEEN SALVAGE: A MULTICENTER ANALYSIS

Banerjee A, Duane TM, Wilson SP, Haney S, O'Neil P, Evans H, Como J, Claridge JA

Objective: This study aimed to evaluate if variation in management of blunt splenic injury (BSI) among level 1 trauma centers is associated with different outcomes related to the use of splenic artery embolization (SAE).

Methods: All adult patients admitted for BSI from 2008 to 2010 at 4 level 1 trauma centers were reviewed. Use of SAE was determined and outcomes of spleen salvage and non-operative management (NOM) failure were evaluated. A priori, a 10% SAE rate was used to group centers into high or low use groups.

Results: There were 1,275 BSI patients. There were inter-center differences in age, injury severity, and grade of spleen injury (SIS). Mortality was similar by center; however BSI treatment varied significantly by center. Initial SAE was highest at Center A compared to center B, C, and D (14% vs 7%, 1% and 4%,$p<0.01$). Overall SAE use was highest at center A compared to B, C, and D (19%, 11%, 1% and 4%,$p<0.01$). There were significant differences in initial splenectomy rates by center, ranging from 10% to 22% ($p<0.01$), with Center A having the lowest initial splenectomy rate and highest spleen salvage rate (range 73% - 86%,$p<0.05$). Outcomes (Table 1) were evaluated by high vs low SAE use. High SAE use centers had significantly higher spleen salvage rates and fewer NOM failures. Differences in use of SAE and salvage rate were dramatic between high and low use SAE centers for grade 3 and 4 injured spleens. In patients who received initial NOM, multivariate logistic regression analysis showed SAE was an independent predictor of spleen salvage (OR = 5; 95% CI = 1.8 – 13.5,$p<0.01$) as were lower age, lower SIS, and ISS. Patients treated at high SAE use centers were more likely to leave the hospital with their spleen in situ (OR = 3; 95% CI = 1.7 – 6.3,$p<0.01$).

Conclusion: Significant practice variation exists in the use of SAE in treating BSI at level 1 trauma centers. Centers with higher rates of SAE use have higher spleen salvage and less NOM failure. SAE was shown to be an independent predictor of spleen salvage.

PRESUMPTIVE ANTIBIOTIC USE IN TUBE THORACOSTOMY FOR TRAUMATIC HEMOPNEUMOTHORAX: AN EASTERN ASSOCIATION FOR THE SURGERY OF TRAUMA PRACTICE MANAGEMENT GUIDELINE

Moore FO, Duane TM, Hu CK, Fox AD, McQuay N Jr, Lieber ML, Como JJ, Haut ER, Kerwin AJ, Guillamondegui OD, Burns JB

Background: Antibiotic use in injured patients requiring tube thoracostomy (TT) to reduce the incidence of empyema and pneumonia remains a controversial practice. In 1998, the Eastern Association for the Surgery of Trauma (EAST) developed and published practice management guidelines for the use of presumptive antibiotics in TT for patients who sustained a traumatic hemopneumothorax. The Practice Management Guidelines Committee of EAST has updated the 1998 guidelines to reflect current literature and practice.

Methods: A systematic literature review was performed to include prospective and retrospective studies from 1997 to 2011, excluding those studies published in the previous guideline. Case reports, letters to the editor, and review articles were excluded. Ten acute care surgeons and one statistician/epidemiologist reviewed the articles under consideration, and the EAST primer was used to grade the evidence.

Results: Of the 98 articles identified, seven were selected as meeting criteria for review. Two questions regarding presumptive antibiotic use in TT for traumatic hemopneumothorax were addressed: (1) Do presumptive antibiotics reduce the incidence of empyema or pneumonia? And if true, (2) What is the optimal duration of antibiotic prophylaxis?

Conclusion: Routine presumptive antibiotic use to reduce the incidence of empyema and pneumonia in TT for traumatic hemopneumothorax is controversial; however, there is insufficient published evidence to support any recommendation either for or against this practice.

PROPHYLACTIC ANTIBIOTIC USE IN PENETRATING ABDOMINAL TRAUMA: AN EASTERN ASSOCIATION FOR THE SURGERY OF TRAUMA PRACTICE MANAGEMENT GUIDELINE

Goldberg SR, Anand RJ, Como JJ, Dechert T, Dente C, Luchette FA, Ivatury RR, Duane TM

Background: The use of prophylactic antibiotics in penetrating abdominal trauma has resulted in decreased infection rates. The Eastern Association for the Surgery of Trauma (EAST) first published its practice management guidelines (PMGs) for the use of prophylactic antibiotics in penetrating abdominal trauma in 1998. During the next decade, several new prospective studies were published on this topic. In addition, the practice of damage control laparotomy became widely used, and additional questions arose as to the role of prophylactic antibiotics in this setting. Thus, the EAST Practice Management Guidelines Committee set out to update the original PMG.

Methods: A search of the National Library of Medicine and the National Institutes of Health MEDLINE databases was performed using PubMed (www.pubmed.gov) and specific key words. The search retrieved English language articles regarding the use of antibiotics in penetrating abdominal trauma published from 1973 to 2011. The topics investigated were the need for perioperative antibiotics, the duration of antibiotic therapy, the dose of antibiotics in patients presenting in hemorrhagic shock, and the appropriate duration of antibiotic therapy in the setting of damage control laparotomy.

Results: Forty-four articles were identified for inclusion in this review.

Conclusion: There is evidence to support a Level I recommendation that prophylactic antibiotics should only be administered for 24 hours in the presence of a hollow viscus injury. In addition, there are no data to support continuing prophylactic antibiotics longer than 24 hours in damage control laparotomy.

EVALUATING THE IMPACT OF A TARGETED INPATIENT ANTIBIOTIC STEWARDSHIP PROGRAM

Aman Banerjee MD, Andrea Son PharmD, Nina Naeger Murphy PharmD, Peter Wiest MD, Jeffrey Claridge MD, MS, FACS, Michelle Hecker MD

Background: To address our hospital-wide concerns regarding antibiotic stewardship and gain buy-in across all specialties, especially surgery, we formed a multidisciplinary antibiotic stewardship team (MAST). The purpose of this study was to evaluate the MAST program over time and to analyze compliance with MAST recommendations between surgical and non-surgical services.

Hypothesis: There are differences in MAST intervention and compliance rates between surgical and non-surgical services.

Methods: Patients prescribed any of the following antibiotics for a suspected infection: a carbapenem, daptomycin, linezolid, advanced-generation cephalosporins, or tigecycline were prospectively reviewed by MAST from January through June 2012. MAST interventions and acceptance rates of according inpatient service were recorded. Infectious disease (ID) consult rates were also evaluated.

Results: There were 316 patients identified during the study period. Of these 258 (82%) were on a medical service and 57 (18%) were on a surgical service. Indication for antimicrobial use varied by specialty (Table 1). MAST intervention rates did not significantly vary between surgical or medical services (32% vs. 44%, p=0.1). MAST compliance rates did not vary by surgical or medical specialty (87% vs. 83%, p = 1). ID consult rates were similar between surgical and non-surgical groups, (49% vs. 50%, p =1).

Table 1: Indication for Antimicrobial Use By Inpatient Specialty			
	Non-Surgical Service	Surgical Service	p-value
n	258	57	
Intra-Abdominal Infection	28 (11 %)	17 (30 %)	< 0.01
Bone or Joint Infection	36 (14 %)	16 (28 %)	0.02
Healthcare-Associated Pneumonia	104 (40 %)	12 (21 %)	0.01
Community-Acquired Pneumonia	28 (11 %)	0 (-)	< 0.01
Fever	16 (6 %)	8 (14 %)	0.05

Conclusion: Differences in indications for antimicrobial use between surgical and non-surgical services exist. The need for MAST intervention was similar for both surgical and medical services. High compliance rates were observed for both surgical and non-surgical services services.

AN ANALYSIS OF PAST SURGICAL INFECTION SOCIETY AWARD RECIPIENTS

J.A. Claridge, A. Banerjee, P.S. Barie, R.W. Sawyer, P.A. Lipsett

Background: The Surgical Infection Society (SIS) organized its first meeting in 1981. Since that time it has conferred numerous awards through its Foundation (FDTN) to individuals who have demonstrated interest in researching infection in the surgical setting. We sought to characterize the research output from prior award recipients and determine the impact of these awards on the individual and the SIS.

Hypothesis: Providing scholarship awards are beneficial to both the society and the recipients.

Methods: The SIS website and leadership were queried for the names of all past award recipients. A MEDLINE search of the recipients was performed. Total number of publications, publications in the society's journal, Surgical Infections (SI) was identified. Gender and leadership positions within SIS were determined. Meeting attendance and participation were evaluated. Donations by scholarship recipient to the FDTN were also evaluated.

Results: Between 1984 and 2012, there were 116 individuals who received an SIS award or scholarship. Of these 28% were female and 72% were male. There were 101 scholarships awarded, totaling nearly $3 million. Of these 19 new Junior Faculty scholarships awarded, 4 were to consecutive recipients (competitive renewal). There were 11 clinical evaluative award scholarships awarded, 3 to consecutive recipients. There were 100 Resident/Fellow scholarships awarded, of these 22 were awarded to consecutive recipients. Past recipients had multiple publications (median total publications = 27; interquartile range (IQR): 9–62) and published multiple papers on the topic for which they received an award (median 2; IQR: 0–4). The majority of recipients did not publish in SI (median SI publications = 0; IQR: 0–1). There was no significant difference in the number of publications by gender. Multiple awards were conferred to 26 (22%) individuals. Six (5.1%) assumed an executive position within SIS, 2 (1.7%) became SIS president. Those who received multiple awards were more likely to serve as an officer than those who only received one award (15% vs. 2%, $p = 0.02$).

Conclusions: SIS award recipients publish multiple articles in peer-reviewed journals. However, very few of these publications are in the society's journal. The majority of award recipients do not serve as officers within SIS. Those conferred multiple awards were more likely to later assume an officer position within SIS. These scholarships have large benefit for the individual recipients, however the benefit to the society remains harder to quantify.

THE EASTERN ASSOCIATION OF THE SURGERY OF TRAUMA APPROACH TO PRACTICE MANAGEMENT GUIDELINE DEVELOPMENT USING GRADING OF RECOMMENDATIONS, ASSESSMENT, DEVELOPMENT, AND EVALUATION (GRADE) METHODOLOGY

Andrew J. Kerwin, MD, Elliott R. Haut, MD, J. Bracken Burns, DO, John J. Como, MD, Adil Haider, MD, Nicole Stassen, MD, Philipp Dahm, MD

The Eastern Association for the Surgery of Trauma (EAST) is a leader in evidence-based medicine and the development of practice management guidelines (PMGs) in trauma and acute care surgery. The previous primer describing EAST's approach for assessing the quality of available evidence and making recommendations for developing PMGs was published in 2000. Since that time, many new systems have been developed in an attempt to overcome previous shortcomings and to devise a methodologically rigorous and transparent approach to the assessment of quality of evidence and development of guidelines. One of these is the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. The membership of EAST has determined that the GRADE methodology will be the system used in all future EAST PMGs. The purpose of this article was thus to describe the GRADE methodology.

THE IMPACT OF MAJOR OPERATIVE FRACTURES IN BLUNT ABDOMINAL INJURY

Nickolas J. Nahm, MD, John J. Como, MD, MPH, Heather A. Vallier, MD, Cleveland, Ohio

Background: Abdominal injury has been shown to be an independent risk factor for pulmonary complications in patients with extremity injuries. We propose to characterize orthopedic patients with severe abdominal trauma. We hypothesize that operative fractures of the thoracolumbar spine, pelvis, acetabulum, or femur increase systemic complications in patients with blunt abdominal injury.

Methods: A retrospective review of patients presenting to a Level I trauma center with abdominal injury between 2000 and 2006 was performed. Adult patients between the ages of 18 years and 65 years with high-energy, blunt trauma resulting in severe abdominal injury (abdomen Abbreviated Injury Scale [AIS] score Q 3) and Injury Severity Score (ISS) of 18 or greater were included. Patients were divided into two comparison groups as follows: the fracture group had operative fractures of the pelvis, acetabulum,thoracolumbar spine, and/or femur, and the control group did not sustain these fractures of interest. Systemic complications were documented. Unadjusted and multivariable logistic regression analyses were performed.

Results: The control group included 91 patients, and the fracture group included 106 patients with 136 fractures of interest. With unadjusted analysis, the fracture group had more complications (34% [36 of 106] vs. 18% [16 of 91], p = 0.010), including adult respiratory distress syndrome (8% [8 of 106] vs. 1% [1 of 91], p = 0.040), and sepsis (11% [12 of 106] vs. 3% [3 of 91], p = 0.056). Logistic regression modeling demonstrates that the presence of an operative fracture increased the odds of developing at least one complication approximately three times (odds ratio, 2.88, p = 0.006), after controlling for presence of chest injury and type of injured abdominal organ.

Conclusion: Operative fractures of the thoracolumbar spine, pelvis, acetabulum and femur increase the risk of developing systemic complications in patients with blunt abdominal injury. Further study is necessary to optimize treatment protocols for these high-risk patients.

Level of Evidence: Prognostic study, level III.

THE MISAPPLICATION OF THE TERM SPINAL CORD INJURY WITHOUT RADIOGRAPHIC ABNORMALITY (SCIWORA) IN ADULTS

John J. Como, MD, MPH, Hoda Samia, MD, Gregory A. Nemunaitis, MD, Vikas Jain, MD, James S. Anderson, MD, Mark A. Malangoni, MD, Jeffrey A. Claridge, MD, MS, Cleveland, Ohio

Background: Spinal cord injury without radiographic abnormality (SCIWORA) is generally considered a disease of children; however, it is commonly used when referring to adults who have spinal cord injury without computed tomography evidence of trauma (SCIWOCTET). The purpose of this study was to describe characteristics of patients with both adult and pediatric cervical SCIWOCTET admitted to hospitals in our region.

Methods: A retrospective review of all patients admitted to our two ACS-verified trauma centers with cervical spinal cord injury from January 2005 to December 2009 was performed. All patients with vertebral or ligamentous injury identified on computed tomographic (CT) scan of the cervical spine were excluded. Data gathered on the remaining patients included demographics, injury mechanism, Injury Severity Score, neurologic level and severity of spinal cord injury, magnetic resonance imaging results, and mortality rates.

Results: During the 5-year period of this study, 11,644 adult patients and 3,458 pediatric trauma patients were admitted. Of these, 313 patients were thought to have cervical spinal cord injury based on International Classification of Diseases, Ninth Revision (ICD-9) codes, 279 (89.1%) were excluded due to injury noted on CT cervical spine, and 9 were excluded as they were found to not truly have cervical spinal cord injury after review of the medical record. The remaining 25 patients were identified as having cervical SCIWOCTET. Twenty-three patients (92%) were male. The patient ages ranged from 10 to 83 years with a median age of 56 years. The mean Injury Severity Score was 22.6. Sixty-eight percent had a mechanism of fall. Degenerative changes were found on the CT scan of the cervical spine in 96% of all patients and in all 24 adult patients. There was only one pediatric patient with SCIWORA, a 10-year-old boy who had a normal CT scan of the cervical spine but had a persistent neurologic deficit.

Conclusion: SCIWOCTET is mainly a disease of adults, and its subset SCIWORA, a disease of children, is much less common. Adults with this disease have CT scans showing canal stenosis and significant degenerative changes in the cervical spine; thus, it is not accurate to state that they have SCIWORA. The characteristics of this patient population are important as SCIWOCTET is the concern when clearing the cervical spines of trauma patients with a CT scan of the cervical spine negative for injury.

Level of Evidence: Epidemiologic study, level III.

TIMING OF ORTHOPAEDIC SURGERY IN MULTIPLE TRAUMA PATIENTS: DEVELOPMENT OF A PROTOCOL FOR EARLY APPROPRIATE CARE

Heather A. Vallier, MD, Xiaofeng Wang, PhD, Timothy A. Moore, MD, John H. Wilber, MD, John J. Como, MD

Objectives: The purpose was to define which clinical conditions warrant delay of 3 definitive fixation for pelvis, femur, acetabulum, and spine fractures. A model was developed to predict complications.

Design: Statistical modeling based on retrospective database.

Setting: Level 1 trauma center

Patients/participants: 1443 adults with pelvis (n=291), acetabulum (n=399), spine (n=102), and/or proximal or diaphyseal femur (n=851) fractures

Intervention: All fractures were treated surgically.

Main Outcome Measurements: Univariate and multivariate analysis of variance assessed associations of parameters with complications. Logistic predictive models were developed with the incorporation of multiple fixed and random-effect covariates. Odds ratios, F-tests, and receiver operating characteristic (ROC) curves were calculated.

Results: 12% had pulmonary complications, with 8.2% overall developing pneumonia. pH and base excess values were lower ($p<0.0001$), and the rate of improvement was also slower (all $p<0.007$), with pneumonia or any pulmonary complication. Similarly, lactate values were greater with pulmonary complications (all $p<0.02$), and lactate was the most specific predictor of complications. Chest injury was the strongest independent predictor of pulmonary complication. Initial lactate was a stronger predictor of pneumonia ($p=0.0006$) than initial pH ($p=0.047$) or the rate of improvement of pH over the first 8 hours ($p=0.0007$). An uncomplicated course was associated with absence of chest injury ($p<0.0001$) EAC protocol development and definitive fixation within 24 ($p=0.007$) or 48 hours ($p=24$ 0.005). Models were developed to predict probability of complications with various injury combinations using specific laboratory parameters measuring residual acidosis.

Conclusions: Acidosis on presentation is associated with complications. Correction of pH within 8 hours to >7.25 was associated with fewer pulmonary complications. Presence and severity of chest injury, number of fractures, and timing of fixation are other significant variables to include in a predictive model and algorithm development for Early Appropriate Care. The goal is to minimize complications by definitive management of major skeletal injury once the patient has been adequately resuscitated.

Section 10

Vascular Surgery & Endovascular Therapy

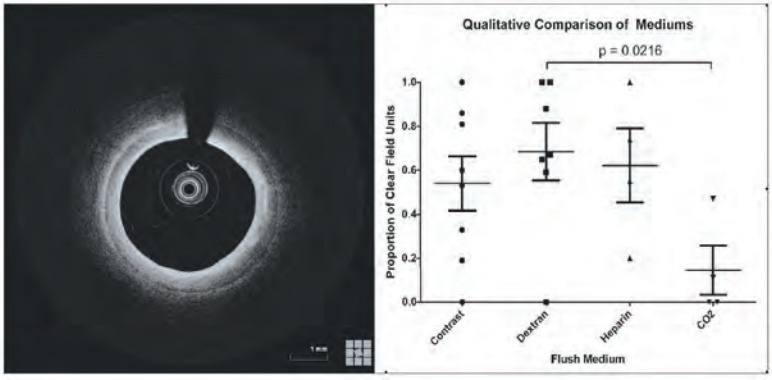
INITIAL EXPERIENCE WITH INTRAVASCULAR OPTICAL COHERENCE TOMOGRAPHY IN LOWER EXTREMITY ARTERIES

Matthew T. Allemang MD, Benjamin A. Eslahpazir BS, Ryan O. Lakin MD, Henry Baele MD, Nathaniel Liu MD, Kentaro Tanaka MD, Hiram G. Bezerra MD, Vikram S. Kashyap MD

Objectives: Intravascular optical coherence tomography (OCT) uses near infrared light to provide rapid,high-resolution intraluminal axial images of vessel wall architecture. This technology requires the region-of-interest be clear of blood for satisfactory acquisition and has been used mostly in coronary vessels. The purpose of this study is to report our initial experience with OCT in lower extremity peripheral arteries. We compared the clearance quality between four different infusion media for optimizing imaging: (1)iodinated contrast, (2) dextran, (3) heparinized saline, and (4) carbon dioxide gas.

Methods: Patients undergoing elective lower extremity diagnostic angiography with possible endovascular intervention were enrolled in this study. All OCT images were acquired using an automated pullback for a 54mm length of artery in approximately 2 seconds. Analysis for each pull-back included blood clearance grading by two independent reviewers with a third arbiter for disagreements. Adequate clearance was defined as a lack of signal attenuation for 270 degrees of each transverse slice throughout an axial sweep and categorically recorded as yes or no. Unpaired t-tests were used to compare image quality between each medium type.

Results: Ten patients underwent OCT imaging after initial contrast arteriography was obtained in either the external iliac, common femoral or superficial femoral arteries (n=8) depending on lesion distribution. The average age was 65 and 60% were female. OCT imaging allows 10-15μmresolution of the luminal border (Figure 1). The proportion of high fidelity images in each pullback for contrast, dextran, heparinized saline, and CO2 were 54±35%, 68±35%, 63±33%, and 15±22% respectively (Figure 2). Dextran was significantly better in clearance quality than CO2 (p=0.02).There were 3 catheter failures, but no procedural related complications occurred.



Conclusions: In this initial experience, OCT is feasible in large caliber peripheral vessels. Carbon dioxide does not provide adequate clearance for OCT imaging. Contrast, dextran, and heparinized saline are promising but need further investigation as clearance mediums for OCT.

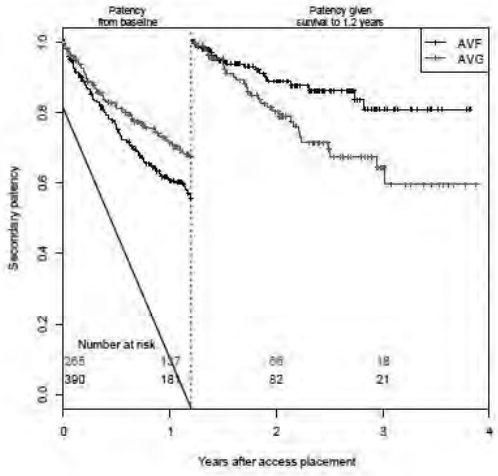
ARTERIOVENOUS GRAFTS ARE ACCEPTABLE FOR DIALYSIS PATIENTS WITH LIMITED LIFE EXPECTANCY

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

Objectives: To estimate the patency of arteriovenous fistulas (AVF) and grafts (AVG) for dialysis access in a tertiary care setting and understand clinical variables that affect outcomes.

Methods: Records of patients who had a dialysis access placed from January 2008 until June 2011 were retrospectively reviewed. Outcomes were assisted primary patency and secondary patency. Marginal survival models (to account for correlation of accesses within subjects) utilizing Cox proportional hazard regression were used for statistical comparisons. The proportional hazards assumption was found to be met if the time course was bisected, resulting in separate hazard ratio (HR) estimates before and after 1.2 years.

Results: A total of 494 patients with 655 accesses (390 AVF, 265 AVG) were examined. 271 patients had only AVFs, 153 had only AVGs, and 70 had sequential AVF/AVG. The average age was 58.3 ± 16.4 for AVF and 60.8 ± 16.6 for AVG with 46% male, 72% African-American, 52% diabetic, and 66% with a tunneled catheter at the time of access placement. Seventy-seven percent of primary accesses (N=305) were "fistula-first". We found AVG were worse for both assisted primary patency and secondary patency (median 1 intervention) after 1.2 years (HR: 4.8 CI: (2.8, 8.3) and HR: 2.1 CI: (1.2, 3.9), respectively). However, from time of placement until 1.2 years, secondary patency for AVGs was better (HR: 0.7 CI: (0.5 to 0.9)) while assisted primary patency was worse (HR: 1.4 CI: (1.1, 1.8)). Kaplan-Meier estimates for secondary patency before and after the 1.2 year cutoff were constructed (Figure). In a multivariable model including age, diabetes, PVD, ever used tobacco, previous access placement, and tunneled catheter, the HR for AVG was 0.6 (CI: 0.4, 0.8) before 1.2 years. Other results were also similar in the multivariable model.



Conclusions: AV grafts can be maintained with high rates of secondary patency in the short-term, but are not as durable in the long-term. Patients with limited life expectancy can effectively be offered an AV graft when native veins are of limited quality for fistula construction.

Alternatives?!?: An AVG may be more appropriate for patients who require hemodialysis but have limited life expectancy due to its better patency and lower intervention rate, in short term outcomes. AV grafts can also be maintained with high rates of secondary patency in the short-term, but are not as durable in the long-term and thus may be more appropriate in patients with limited life expectancy.

Case Surgery

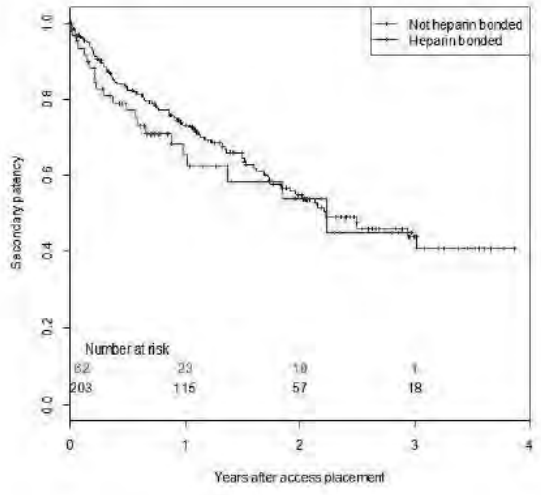
HEPARIN BONDING DOES NOT IMPROVE PATENCY OF PTFE ARTERIOVENOUS GRAFTS

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

Objectives: To compare the patency of arteriovenous grafts (AVG) for dialysis access with and without heparin bonding in a tertiary care setting.

Methods: Records of patients who had a AVGs placed from January 2008 until June 2011 were retrospectively reviewed. Outcomes were assisted primary patency and secondary patency. Marginal survival models (to account for correlation of accesses within subjects) utilizing Cox proportional hazard regression were used for statistical comparisons.

Results: A total of 223 patients with 265 Grafts. Of these 62 (23%) were heparin bonded. The average age was 65.9 ± 15.3 for heparin and 59.2 ± 16.7 for control ($p<0.01$). Of the heparin group, 39% were male, 81% were black, 63% were diabetic, and 81% had a tunneled catheter at the time of access placement. Of the control group, 35% were male, 85% were black, 56% were diabetic, and 83% had a tunneled catheter. Heparin bonded grafts were no different in either assisted primary or secondary patency (HR: 1.39 CI: (0.98, 1.96) and HR: 1.20 CI: (0.73, 1.96) respectively). Kaplan-Meier estimates for secondary patency are shown in the Figure. There was no significant difference in the number of interventions ($P>0.30$). To correct for inequalities, a multivariable model including age, diabetes, PVD, ever used tobacco, previous access placement, and tunneled catheter found HR for heparin bonded grafts was again not significantly different than standard grafts in either assisted primary patency or secondary patency (HR: 1.35 CI: (0.91, 1.99) and HR: 1.15 CI: (0.62, 2.16) respectively).



Conclusions: In this retrospective review, heparin bonded grafts did no better in long-term patency or number of interventions. Prospective studies are needed to confirm these results.

A COMPARISON OF PATENCY BETWEEN ONE AND TWO STAGE ARTERIOVENOUS FISTULA TRANSPOSITIONS

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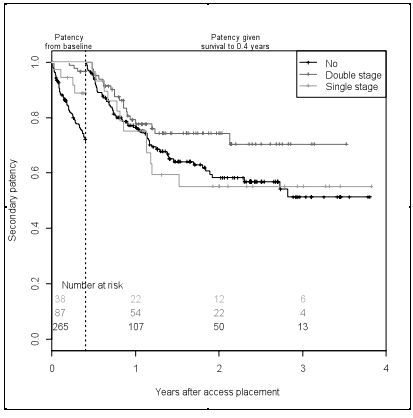
Background: Renewed interest in basilic vein transposition has arisen as more emphasis is being placed on autologous hemodialysis access. We report our experience with one and two stage techniques in the creation of native vein fistulas.

Methods: A database of all patients who had a dialysis access placed from January 2008 through June 2011 was retrospectively reviewed. Over that period of time 265 patients underwent fistula creation and of that group 125 had upper extremity vein transpositions. The patients were stratified into those accesses created using a single stage technique and those with a two-stage technique. Outcomes measured were assisted primary patency and secondary patency. Marginal survival models utilizing Cox Proportional Hazards regression were used for statistical comparisons.

Results: A total of 125 arteriovenous fistulas were created that required transposition in order to be accessible. 38 were created using a one stage technique and 87 using a two stage technique. In the single stage group 40.2% were male, 72.4% were African American, for 55.2% it was the first attempted surgical access and 59.7% had a tunneled catheter at the time of access formation. For the two stage group 42.1% were male, 81.6% were African American, for 50% it was the first attempted surgical access and 63.2% had a tunneled catheter at the time of access formation. We found that fistulas created using a two stage surgical technique achieved both better assisted primary patency (HR: 0.47 CI:(0.25, 0.90) and secondary patency (HR: 0.44 CI:(0.23, 0.87) when compared to one stage operations. The Kaplan-Meier estimate for secondary patency is shown below in figure 1.

Figure 1: Univariate association between transposition and secondary patency



Conclusions: In our experience two stage operations demonstrated improved assisted primary and secondary patency and as a corollary could extend the duration of autologous access in challenging hemodialysis patients.

Case Surgery

IMMEDIATE- AND LONG-TERM RESULTS AFTER ENDOVASCULAR MANAGEMENT FOR CHRONIC AORTOILIAC OCCLUSIVE DISEASE IN A VETERAN POPULATION

Zachary Love, MD, Stephanie Soriano, MD, Jessie M. Jean-Claude, MD, Gilles Pinault, MD, Preet Kang, MD

Objectives: There is a national trend towards endovascular interventions for treatment of aortoiliac occlusive disease (AIOD). We investigated the long-term effectiveness of endovascular treatment at a Veteran Affairs hospital in order to evaluate variables associated with therapeutic efficacy and clinical outcome in this unique population.

Methods: A retrospective chart review was performed on patients who underwent primary stenting for their AIOD in the Interventional Radiology department at the Louis Stokes VA Medical Center in Cleveland, Ohio from 2002-2010. Patient review included co-morbidities, prior endovascular procedures, Trans-Atlantic Intersociety Consensus (TASC) II classification, presence of infrainguinal disease, and Rutherford classification. Evaluation of variables in relation to patient outcomes was done using Student t test and ANOVA. Time to loss of patency was analyzed with Kaplan-Meier curves and compared with log-rank test.

Results: Primary stenting was performed in 184 arterial lesions in 111 patients, with mean follow up of 1131 days (± 603 days). A majority of patients had TASC-II A and B disease, 65% and 24%, respectively. Ankle brachial indices improved from 0.64 ± 0.23 to 0.88 ± 0.22 ($p < .001$). Five years after stent placement, primary patency was 65%; primary assisted patency, 99%; and secondary patency, 98%. Thirteen (12%) of 111 patients underwent bypass surgery or amputation during this time. Patency was associated with lesion location, favoring common versus external iliac lesions ($p = .03$). No significant association was found between primary patency and co-morbid disease (hypertension, coronary artery disease, chronic renal disease, dyslipidemia), number of co-morbidities, history of smoking, stent size or length, or presence of infrainguinal disease. Kaplan-Meier analysis showed that TASC-II A classification accorded longer primary patency ($p = .02$).

Conclusions: Rate of stent primary patency at 5 years was lower than previously published values. This may be due to multiple factors such as ipsilateral common femoral artery disease or post stent medical optimization. The high primary assisted and secondary patency rates may be associated with frequent and long-term follow up, intensive surveillance, and a multidisciplinary management approach.

PRINCIPLE CONSIDERATIONS FOR THE CONTEMPORARY HIGH-FIDELITY ENDOVASCULAR SIMULATOR DESIGN USED IN TRAINING AND EVALUATION

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Introduction: The simulation and rehearsal of virtual endovascular procedures is anticipated to improve the outcomes of actual procedures. Contemporary, high-fidelity simulation is based on mechatronic feedback systems that lead to a virtual reality endovascular case. These devices depend on a sophisticated combination of mechanical, electrical and control systems theory to recreate the endovascular experience with added psychometric instruments for objective surgical skill assessment. This report identifies the design characteristics of commercially-available simulators for endovascular procedures and provides a cross-section comparison across all devices.

Methods: Data were obtained via (1) a standard questionnaire issued to four simulator companies prompting for design details of each model with the expressed purpose of publication, (2) data procured from each manufacturer's respective website including appended sales brochures and specification sheets and (3) an evaluation of peer-reviewed literature. Focus topics emphasized haptic technology, vessel segmentation, physiologic feedback, performance feedback and physical logistics (i.e. weight, dimensions and portability). All data sources were surveyed between January 1, 2012 and June 30, 2013.

Results: All of the commercially-available, high-fidelity endovascular simulators use interactive virtual environments with pre-programmed physics and physiology models for accurate reproduction of surgical reality. The systems differ in the number of access sites and haptic devices, the ability to reconstruct patient-specific anatomy for pre-procedural rehearsal, and the available peripheral training modalities. Also, hardware and software options can vary within the same device when comparing patient-specific to generic cases.

Conclusion: From our review, we believe simulation and rehearsal will occupy an increasing role in both training and practice of endovascular therapy. Despite our limited knowledge about the potential of high-fidelity simulation within the endovascular world, today's currently available simulators successfully provide high-fidelity reproductions of the endovascular environment. We have found that all of the commercially available devices incorporate the necessary features for a high-fidelity experience but variations in design do exist and may influence differences in skill development, evaluation or cost. Further validation of these differences would benefit program directors interested in expanding these platforms for vascular training and certification.

PULSE VOLUME RECORDING DOES NOT ENHANCE SEGMENTAL PRESSURE READINGS FOR PERIPHERAL ARTERIAL DISEASE STRATIFICATION

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Background: Non-invasive vascular laboratory determinations for peripheral arterial disease (PAD) often combine pulse volume recordings (PVR), segmental pressure readings (SP) and Doppler waveform traces (DW) into a single diagnostic report. Our objective was to assess the corresponding diagnostic values for each test when subjected to interpretation by four vascular specialists.

Methods: 2,226 non-invasive diagnostic reports were reviewed through our institutional database between January 2009 and December 2011. Data from non-invasive records with corresponding angiograms performed within 3 months led to a cohort of 76 patients (89 limbs) for analysis. Four vascular specialists, blinded to the angiographic results, stratified the noninvasive studies as representative of normal, <50% "sub-critical" or ≥50% "critical" stenosis at the upper thigh, lower thigh, popliteal and calf segments using four randomized non-invasive modalities: (1) PVR alone; (2) SP alone; (3) SP+DW; and (4) SP+DW+PVR. The angiographic records were independently graded by another three evaluators and used as a standard to determine the non-invasive diagnostic values and interobserver agreements for each modality. Statistical tests used include the Fleiss-modified Kappa analysis, Kruskall-Wallis ANOVA with Dunn's multiple comparison test, the Kolvogorov-Smirnov test and the unpaired t-test with Welch's correction.

Results: Interobserver variance for all modalities except SP was high. When surveying for any stenosis (<50% and ≥50%), sensitivity (range 25-75%) was lower than specificity (range 50-84%) for all modalities. When surveying for critical stenosis only (≥50%), sensitivity (range 27-54%) was also lower than specificity (range 68-92%). Accuracy for detecting any stenosis with SP+DW was significantly higher than PVR alone (66±7% vs. 56±12%, p = 0.017). There was a significant reduction in accuracy when including incompressible readings within the SP-only analysis compared to exclusion of incompressible vessels (p = 0.0006). However, the effect of vessel incompressibility on accuracy was removed with the addition of DW (p = 0.17) to the protocol.

Conclusion: SP has the greatest interobserver agreement in evaluation of PAD and can be used preferentially for PAD stratification. Given the lower accuracy of PVR for detecting either sub-critical or critical disease, PVR tests can be omitted from the non-invasive vascular exam without significant reductions in overall diagnostic value and reserved for patients only with incompressible vessels.

DOES PULSE VOLUME RECORDING AID IN PERIPHERAL ARTERIAL DISEASE STRATIFICATION?

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Objective: Noninvasive vascular laboratory determinations of peripheral arterial disease (PAD) often combines pulse volume recordings (PVR), segmental pressure readings (SP) and Doppler waveform traces (DW). Our objective was to assess the diagnostic value of each test and compare their corresponding accuracies.

Methods: Over 2000 non-invasive diagnostic reports were reviewed through our institutional database. Data from non-invasive records with corresponding angiograms performed within 3 months led to a cohort of 76 patients (89 limbs) for analysis. Four vascular specialists, blinded to the angiographic results, stratified the noninvasive studies as representative of normal, <50% "sub-critical" or >50% "critical" stenosis at the upper thigh, lower thigh, popliteal and calf segments using four randomized non-invasive reports: (1) PVR alone; (2) SP alone; (3) SP+DW; and (4) SP+DW+PVR. The cohort was randomized between each modality during interpretation. The angiographic records were independently graded by three different evaluators. Angiographic results were compared to the non-invasive interpretations from each modality to determine the corresponding diagnostic value and interobserver agreement.

Results: Interobserver variance for all modalities except SP was high (Figure 1). Sensitivity (range 25-75%) was lower than specificity (range 50-84%) for all modalities when averaged between interpreters. Accuracy for detecting a critical or sub-critical stenosis of SP+DW or SP+DW+PVR was significantly higher than PVR alone (Figure 2). However, when assessing > 50% stenoses, no statistically significant relationships were found between any modalities of the same segment for sensitivity, specificity or diagnostic accuracy.

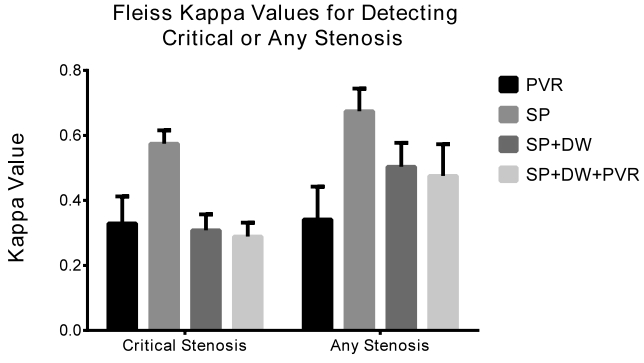

Figure 1: Fleiss Kappa agreement values for 4 interpreters (Mean between segments with SD).

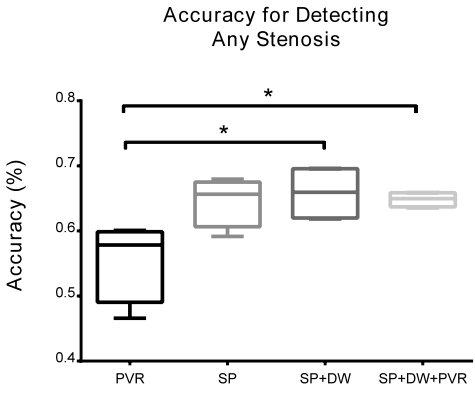

Figure 2: Diagnostic accuracy values of each modality for detecting critical or sub-critical stenosis. (Box margins indicating interquartile range, whiskers indicating minimum and maximum, and bar indicating median of segments determined by 4 interpreters, *p < 0.05)

Conclusions: SP has the greatest interobserver agreement in evaluation of PAD. Given the lower accuracy of PVR for moderate and severe disease, PVR tests could be omitted from the non-invasive vascular exam without significant reductions in overall diagnostic value.

IN VIVO EVALUATION OF AN ENDOTHELIAL CELL-SPECIFIC BIOMIMETIC PEPTIDE FLUOROSURFACTANT POLYMER COATING FOR EXPANDED POLY(TETRAFLUOROETHYLENE) VASCULAR GRAFTS

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Statement of Purpose: Our goal is to improve the patency of expanded poly(tetrafluoroethylene) (ePTFE) vascular grafts by promoting endothelialization and reducing thrombosis via biomimetic peptide fluorosurfactant polymer (FSP) coating. The use of ePTFE vascular grafts is limited in small diameter applications due to the increased prevalence of thrombosis. ePTFE could be engineered to promote endothelialization and resist thrombosis by modifying the luminal surface to attach endothelial cells (EC) and limit platelet adhesion and activation. The RGD peptide has been widely used to facilitate cell attachment, but it is not endothelial cell specific. In contrast, the CRRETAWAC (cRRE) peptide has been shown to have high affinity for the 51 integrin which is present in a high density on ECs and to a much lesser extent on platelets1. Our group has developed a cRRE FSP that adheres to ePTFE through hydrophobic interactions. We have previously demonstrated that this polymer has low affinity for platelet integrins and promotes EC attachment, growth, and shear stability, making it endothelial cell selective2. In this study, we evaluate the ability of the cRRE-FSP to improve ePTFE graft patency in an in vivo porcine model, and compare its effectiveness to uncoated, RGD-coated, and heptamaltose (M7) coated grafts.

Methods: Peptides and FSPs were synthesized as previously described2. Peptide-FSPs were dissolved in water and pumped through a flow system containing two ePTFE grafts (4 mm internal diameter) for 24 hr to coat the luminal surface. FSP coated grafts were ethylene oxide gas sterilized and cRRE- and RGD-FSP grafts were sodded with porcine pulmonary artery endothelial cells (PPAECs) using a pressure-sodding technique. A 4 cm graft was evaluated for cell adhesion via fluorescent labeling with DAPI and FITC-conjugated phalloidin to visualize cell nuclei and -actin cytoskeleton, respectively. Five cm long grafts were implanted into porcine carotid arteries using a modified interposition model. At 1 month, grafts were visualized via contrast angiography then explanted and processed for histological evaluation. The fraction of the luminal area occluded by thrombus and intimal hyperplasia (IH) was quantified along 5 regions of the implant: proximal native vessel, proximal anastomosis, mid graft, distal anastomosis, and distal native vessel. In cases where a thrombus visible in histology appeared very acute, and occlusion of the sample contradicted angiography results, the thrombus was deemed to have occurred as a consequence of post-mortem processing and was removed from the quantified occlusion results.

Results: Immunofluorescent staining of RGD- and cRRE-coated grafts showed a complete layer of adherent and spread PPAECs after sodding. Angiography of the grafts after 1 month implant showed all grafts were at least partially patent. The lumen became more occluded along the graft from proximal to distal end in one uncoated and both RGD-coated grafts. Thrombus formation was present in one uncoated graft but not in coated grafts. IH developed to some extent in all grafts, and developed to the highest extent in RGD-coated grafts. Total graft occlusion was similar for uncoated and RGD-coated grafts, and lower for M7 and cRRE-coated grafts.

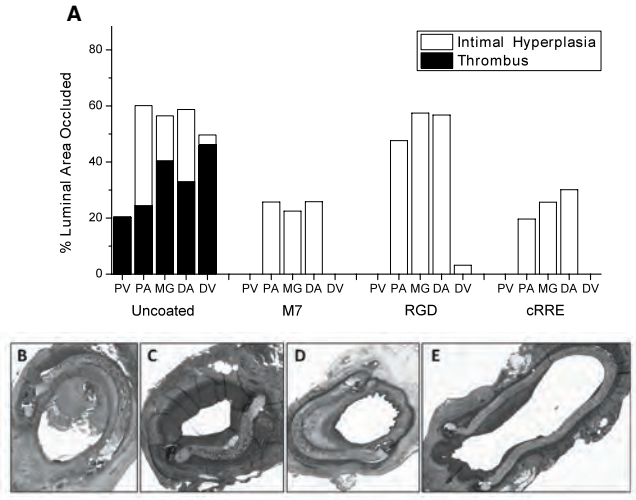

Figure 1. Percent of graft/vessel luminal area occluded at the proximal vessel (PV), proximal anastomosis (PA), mid graft (MG), distal anastomosis (DA), and distal vessel (DV) due to IH and thrombosis in uncoated, M7-coated, RGD-coated, and cRRE-coated ePTFE grafts (A, n=2). Movat pentachrome stains of the proximal anastomosis of uncoated (B), M7-coated (C), RGD-coated (D), and cRRE-coated (E) ePTFE grafts after 1 month of implantation.

Conclusions: The reduced thrombosis in M7-coated and PPAEC-sodded RGD and cRRE-coated grafts suggests that the presence of a coating reduced the thrombo-genicity of these grafts compared to the uncoated grafts. Increased IH in RGD grafts suggests that RGD, a prominent cell adhesion peptide, may facilitate ingrowth of IH-causing cells compared to the other grafts. The cRRE-FSP has shown promise in improving patency of ePTFE grafts. Future work includes the analysis of endothelialization of these grafts.

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