Systematic Review of the Clinical Effectiveness of Wound-Edge Protection Devices in Reducing Surgical Site Infection in Patients Undergoing Open Abdominal Surgery.

Gheorghe A, Calvert M, et al:

Ann Surg 2012; 255 (June): 1017-1029

Wound-edge protectors might alter surgical site infection rates among contaminated wounds.

**Background:** Wound-edge protection devices (WEPDs) have theoretical advantages as a device that could reduce surgical site infection (SSI). While these devices have been available a long time their use is not routine.

**Objective:** To review current data evaluating WEPDs as a means to reduce SSI rates.

**Design:** Review of existing publications on the effect of WEPDs using Centre for Reviews and Dissemination and Cochrane Handbook protocols.

**Methods:** 12 studies were identified (1993 patients). Inclusion criteria included adults having open abdominal surgery (elective and emergency), prospective data collection, device description, SSI definition, and SSI as the measured outcome. A standard SSI definition was used in only 2 studies: the definition was the Centers for Disease Control (CDC) definition. Primary outcome was rate of SSI. WEPDs were described in 10 studies by manufacturer. A risk of bias assessment was done using Cochrane methods. A random effects and fixed effects model was used. The goal of this investigation was to develop a meta-analysis of data. Heterogeneity was assessed with the I² statistic. I² values are from 0% to 100% with higher numbers indicating increasing heterogeneity.

**Results:** 10 studies were randomized clinical trials and 2 were controlled trials. All studies were single institution. Bias within studies was found to be high secondary to patient exclusion and SSI definitions. None of the studies were felt to be adequate for meta-analysis inclusion, but data were used to perform an "exploratory" meta-analysis. Pooling all studies showed a risk ratio of 0.60 for a random effects model and a 0.56 for a fixed effects model. I² value was 54%. A sub-group analysis showed that the effect of WEPDs on SSI rates was significant for contaminated and dirty wounds but not for clean and clean-contaminated wounds.

**Conclusions:** A beneficial effect of wound protection devices may be present for abdominal surgical case, but data are poor.

**Reviewer's Comments:** SSI has become a focus as a quality indicator for surgery. Surgical Care Improvement Project defines process measures that should improve outcomes although many reports we have reviewed suggest the correlation may not be as great as we thought. Other methods to reduce SSI rates include manipulations of the wound intra or postoperatively. WEPDs are an intraoperative intervention. They attempt to protect the wound from contamination. Their effect would seem obvious for contaminated and dirty wounds. The authors suggest the effect of WEPDs is a 40% SSI rate reduction. However, they add that the quality of data preclude calculation of this odds ratio. This study only serves to reinforce the idea that we need more data to support or refute WEPDs as a strategy to reduce SSIs. (Reviewer-John A. Weigelt, MD, DVM, FACS).

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Keywords: Wound-Edge Protectors, Surgical Site Infection

Print Tag: Refer to original journal article
High-risk surgical wounds do not benefit from negative pressure wound therapy.

**Background:** Negative pressure wound therapy (NPWT) has become an accepted management approach for open wounds. Benefits include removal of excess fluid, improved vascularity, decreased bacterial colonization and enhanced wound contraction. Whether these benefits could be extended to high-risk closed surgical wounds is an area of interest.

**Objective:** To evaluate NPWT in high-risk closed surgical wounds.

**Design:** Prospective randomized clinical study.

**Participants:** 106 patients agreed to participate, but only 81 completed the study.

**Methods:** There were 37 controls and 44 NPWT patients. Patients were recruited from a wound clinic. All had high-risk wounds with many having chronic wounds that were treated in anticipation of closure. The majority of patients in both groups had lower extremity wounds associated with an amputation. Demographics including comorbidities, glucose control, blood loss during the operation, and use of drains were recorded. Primary outcomes were wound healing assessed by infection and dehiscence. Need for reoperation was also recorded. Controls had their wound dressed with a silver-impregnated dry gauze. NPWT had a vacuum-assisted closure system placed in the wound and pressure adjusted to 125 mm Hg. Dressings were left in place for 3 days and then removed.

**Results:** Patients were well matched by demographics and comorbidities. Of patients in both groups, >50% had a below-knee amputation. Another 13% in both groups had an above-knee operation. Drain use between groups was not different nor was glucose control or blood loss. Wound infection occurred in 5 control (14%) and 3 NPWT (7%) patients. Dehiscence occurred in 11 (30%) control and 16 (36%) NPWT patients. Dehiscence occurred at 60 days for control and 33 days for NPWT patients. Reoperation was needed in 8 control (22%) and 9 NPWT (21%) patients.

**Conclusions:** High-risk wounds had a high rate of infection and dehiscence which was not reduced by the application of NPWT.

**Reviewer’s Comments:** NPWT is common place for open wounds and has been slowly entering the world of closed wounds. Our orthopedic and bariatric surgeons have started placing the device over closed surgical wounds. Data are sparse for this purpose although the industry has already begun to market a NPWT device specific for this purpose. Current data amounts to testimonials and this study, while not perfect, is one of the first to try and study this NPWT use objectively. The results in essence say it does not alter outcomes. Yes, the study should have been larger. Yes, a blinded study might have been designed. However, we must ask ourselves if we should be applying this type of therapy before we know that there is any benefit. NPWT is not inexpensive and if a dry gauze will suffice, why do we need anything else? (Reviewer-John A. Weigelt, MD, DVM, FACS).

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Keywords: Negative Pressure Wound Therapy, Closed Surgical Wounds

Print Tag: Refer to original journal article
Reducing the CT dose of radiation yields acceptable outcomes for diagnosing acute appendicitis.

**Background:** Recently, the amount of medical radiation individuals receive over their lifetime has become a concern as CT scanning is ubiquitous. This concern is for the risk of malignancies occurring as a result of CT scanning. Lowering the dose of CT radiation is one strategy to address this concern.

**Objective:** To assess the ability of low-dose CT scanning to identify patients with acute appendicitis.

**Design:** Noninferiority randomized clinical trial.

**Participants:** 891 patients with suspected appendicitis.

**Methods:** Participants were randomized into a low-dose (438 patients) and standard-dose (441 patients) CT protocol. Adult patients aged 15 to 44 years were included. CT scans were read by a single radiologist during the day, but at night, multiple radiologists read the CT scan and provided a preliminary report which was used to assess CT accuracy. Final diagnosis was confirmed by surgical findings in patients having exploration and by phone call follow-up for nonsurgical patients. Primary end point was rate of negative appendectomy; 172 low- and 186 standard-dose patients were available for analysis. Secondary outcomes included rate of appendiceal perforation. Low-dose CT scanning aimed to achieve a 2 mSv dose and standard dose was 7 to 10 mSv. Noninferiority margin for negative appendectomy rate was 5.5%.

**Results:** Among low-dose patients, 166 had appendicitis (38%). Among standard-dose patients, 180 had appendicitis (41%). In both groups, 6 patients had a negative appendectomy. There were 7 females and 5 males and sex did not appear to affect outcomes between low- and standard-dose scanning. Negative appendectomy rate was 3.5% for low-dose and 3.2% in standard-dose CT scanning. Noninferiority established as this rate is less than the set point for noninferiority. Additional tests were used in 3% of low-dose and 2% of standard-dose patients. Perforation rate was 27% in low- and 23% in standard-dose patients.

**Conclusions:** Low-dose CT scanning for acute appendicitis was noninferior to standard-dose scanning in patients being evaluated for appendicitis.

**Reviewer's Comments:** Reducing the dose of radiation for CT scanning is a valid strategy to reduce radiation exposure. Not getting a scan is another approach. What is not provided is how many patients did not need imaging. While we will never stop CT scanning for patients with abdominal pain including possible appendicitis, it might be worthwhile to assess whether some patients do not need imaging. We have recently tried to establish some scanning guidelines for patients with suspected appendicitis. There are 2 sides to this coin. Will emergency department physicians trust their diagnostic acumen and will surgeons agree to see the patient without a CT scan? Our radiologist will use a low dose of radiation, but no radiation is even lower. (Reviewer- John A. Weigelt, MD, DVM, FACS).

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Keywords: Appendicitis, CT Scan, Low-Dose

Print Tag: Refer to original journal article
Are PD Stents the Answer for Lowering Leak Rates After Distal Pancreatectomy?

The Effect of Prophylactic Transpapillary Pancreatic Stent Insertion on Clinically Significant Leak Rate Following Distal Pancreatectomy. Results of a Prospective Controlled Clinical Trial.

Frozanpor F, Lundell L, et al:
Ann Surg 2012; 255 (June): 1032-1036

Prophylactic pancreatic duct stenting does not reduce pancreatic fistula after distal pancreatectomy.

Background: Pancreatic fistula (PF) is a major cause of morbidity after distal pancreatectomy (DP) and transpapillary stenting has been proposed to reduce the risk.

Objective: To study the effect of pancreatic duct (PD) stenting on PF and complication rates after standardized DP.

Design: Prospective controlled clinical trial.

Participants: 64 patients scheduled for DP between October 2006 and March 2011.

Methods: Participants were recruited and randomized to DP alone versus DP plus pancreatic duct stent. Exclusions were those in whom transpapillary stenting was not possible. All received octreotide every 8 hours and pancreatic transection was via a stapler (TLH 60 Proximate, Ethicon). All pancreatic beds were drained; drains were kept ≥3 days and removed if no amylase was detected and the patient was clinically well. Patients were seen 3 to 4 weeks after discharge and plain films were taken to assess whether the stent remained in the PD. If so, it was endoscopically removed. PFs were graded A to C based on International Study Group on Pancreatic Fistulas definitions. Analysis was by intention to treat.

Results: 64 patients were recruited for DP and 58 included with 29 randomized to each group. Demographics and background data were similar. ERCP-related complications occurred in 3 cases. The main PD could not be cannulated in 2 and both developed grade B PFs. Exclusions were those in whom transpapillary stenting was not possible. All received octreotide every 8 hours and pancreatic transection was via a stapler (TLH 60 Proximate, Ethicon). All pancreatic beds were drained; drains were kept ≥3 days and removed if no amylase was detected and the patient was clinically well. Patients were seen 3 to 4 weeks after discharge and plain films were taken to assess whether the stent remained in the PD. If so, it was endoscopically removed. PFs were graded A to C based on International Study Group on Pancreatic Fistulas definitions. Analysis was by intention to treat.

At follow up, 6 stents passed spontaneously. Of patients, 10 DP (37%) and 13 DP plus stent (50%) developed PF (P=0.052) and there was a trend towards increased length of stay (19.4 ± 14 vs 13.4 ± 6.4 days; P=0.071). At follow up, 6 stents passed spontaneously. Of patients, 10 DP (37%) and 13 DP plus stent (50%) developed PF (P=0.052). Grade B and C PF were observed in 6 DP (22.2%) and 11 (42.3%) DP plus stent patients. Of patients, 10 DP plus stent (38.5%) and 4 DP (14.8%) with clinically significant PF developed intraabdominal abscesses (odds ratio [OR] 3.59; P=0.058); however, 2 in stented patients were unrelated to PFs. There were no mortalities and no overall complication rate differences despite a trend toward more severe grades in the stented group (OR 3.23; P=0.065).

Conclusions: Prophylactic PD stenting does not reduce PF after DP.

Reviewer's Comments: This small randomized study thoughtfully standardizes use of octreotide, pancreatic transection method, and drain use. It included a few pancreatitis patients (firm glands), but numbers were nearly the same in each group. Given length of stay, it would be interesting to know if any PD stents were occluded at the time of extraction thus causing a problem (even beyond risk of initial deployment) rather than helping prevent one. While we still have no panacea to prevent PF, we do need larger randomized controlled trials to draw any firm conclusions from the data. (Reviewer-Kathleen Christians, MD, FACS).

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Keywords: Distal Pancreatectomy, Pancreatic Stent, Pancreatic Leak

Print Tag: Refer to original journal article
Do Somatostatin Analogues Really Help Pancreatic Fistula?

Systematic Review and Meta-Analysis of Somatostatin Analogues for the Treatment of Pancreatic Fistula.

Gans SL, van Westreenen HL, et al:

Br J Surg 2012; 99 (June): 754-760

Somatostatin analogues administration does not cause higher pancreatic fistula closure rates than standard medical management.

**Background:** Somatostatin analogues (SSA) are used for treatment of pancreatic fistula (PF) to reduce output and achieve closure.

**Objective:** To evaluate the effect of somatostatin on closure rate and time to PF closure.

**Methods:** Embase, Cochrane Library, and MEDLINE databases were searched. Inclusion criteria were English- only randomized controlled trials (RCTs) evaluating use of SSAs compared with conservative treatment or placebo in patients with PFs including cohorts mixed with patients with enterocutaneous (EC) fistula. Study quality was assessed using the Jadad score (5 points excellent, 0 points poor). Data analysis was according to PRISMA statement, heterogeneity was tested for by X2 statistic. Pooled analysis of closure rate was conducted with calculation of a Mantel-Haenszel odds ratio and time to closure by inverse variance. Separate analysis was done in the subgroup studies of higher quality (Jadad score 4 or 5).

**Results:** There were 851 possibly relevant articles, and 7 RCTs met inclusion criteria. Examined were 297 patients with gastrointestinal fistula; 102 were pancreatic. Jadad score ranged from 1 to 4 with 3 trials only scoring a 1. In 6 studies, the proportion of EC fistulas was greater than the proportion of PFs. The single study with a majority of PFs (71 of 107 patients) had a Jadad score of 2. Of studies, 3 had no clear definition of fistula, and 3 proved the presence of fistula radiologically. Main end point was fistula closure rate in 6 studies and time to closure in 5. Follow-up ranged from 12 to 60 days from treatment start. There was no significant difference in overall fistula closure rate between intervention and control groups as 65.9% of 135 fistulas closed in the intervention group versus 56.9% of 109 in controls; OR 1.52 (95% CI 0.88 to 2.61). Only 2 of 3 studies with Jadad >3 reported fistula closure for the 2 treatment groups separately, making sub-analysis of the high-quality studies irrelevant.

**Conclusions:** There is no solid evidence that SSAs result in higher closure rates of PFs versus other treatments.

**Reviewer’s Comments:** There was significant diversity in study quality and end points, major differences in definition of a PF (some not defining it at all) and studies lacked distinction between pancreatic and enteric fistulae. The only conclusion one can draw from this review is that there is insufficient data for or against SSAs for the treatment of PF and higher quality studies are needed. (Reviewer-Kathleen Christians, MD, FACS).

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Keywords: Somatostatin, Pancreatic Fistula

Print Tag: Refer to original journal article
Outcomes Not Dependent on Dose Amount of Radioiodine After Total Thyroidectomy

Strategies of Radioiodine Ablation in Patients With Low-Risk Thyroid Cancer.
Schlumberger M, Catargi B, et al:


Low and high doses of radioiodine are equivalent for thyroid ablation after total thyroidectomy for low-risk thyroid cancer.

**Objective:** To report the results of a trial comparing 2 different doses and 2 different methods of administering radioiodine.

**Design:** Randomized phase 3 trial.

**Participants:** 752 patients aged ≤18 years with low-risk well-differentiated thyroid cancer.

**Methods:** Participants who had an Eastern Cooperative Oncology Group performance status of 0 or 1 and without major comorbidities were eligible for enrollment. Pathologic stages eligible for enrollment were T1 <2 cm, any nodal status and T2N0 both without metastatic disease. All patients underwent total thyroidectomy, lymph node dissection for obvious lymph node involvement, and prophylactic lymph node dissection if a part of local practice. Patients were randomized 30 to 120 days postoperatively to receive either 1.1 GBq or 3.7 GBq of radioiodine along with either thyroid hormone withdrawal or recombinant human thyrotropin. Those randomized to recombinant human thyrotropin received a dose of 0.9 mg intramuscularly on 2 consecutive days with radioiodine administered the day after the second injection. Those randomized to thyroid hormone withdrawal had 28 days without replacement and administration of radioiodine when the serum thyrotropin level was >30 mIU/L. A total body radioactive iodine scan was done 72 to 120 hours after radioiodine administration. Primary outcome was thyroid ablation. Ablation was considered complete if the neck ultrasound was normal and the level of recombinant human thyrotropin-stimulated thyroglobulin was ≤1 ng/mL or a level >1 ng/mL with a normal total-body 131I scan. Secondary outcomes were hypothyroidism, adverse events, and quality of life as measured by the SF-36.

**Results:** Patients were enrolled from April 2007 through February 2010. Of patients, 92% had papillary thyroid cancer. Complete data were available for 684 patients; ablation was complete in 631. There was no difference in the ablation rate between the 2 doses of radioiodine. Symptomatic hypothyroidism was more common in the group undergoing thyroid hormone withdrawal compared to the group receiving recombinant human thyrotropin, and hypothyroidism was significantly correlated with worse quality of life as measured by the SF-36. There was no difference in SF-36 scores between groups 3 months after ablation. There was no difference in salivary gland dysfunction; lacrimal duct dysfunction was highest in the group receiving thyroid hormone withdrawal and low-dose radioiodine.

**Conclusions:** There is no difference between lower and higher doses of radioiodine used for thyroid ablation after thyroidectomy for well-differentiated low-risk thyroid cancer.

**Reviewer's Comments:** It is intuitive that lower doses of radiiodine would be preferable given the clinical equivalence, although the only clinical difference found was worse lacrimal duct dysfunction in 1 group receiving the lower dose of radioiodine. With respect to the 2 methods of inducing hypothyroidism prior to ablation, short-term quality of life would suggest the use of recombinant human thyrotropin over withdrawal of thyroid replacement. (Reviewer-Karen J. Brasel, MD, FACS).

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Keywords: Radiation, Thyroid Cancer

Print Tag: Refer to original journal article
Splenic Injury More Likely During Open Colectomies for Cancer

Predictive Factors of Splenic Injury in Colorectal Surgery.
Masoomi H, Carmichael JC, et al:
Arch Surg 2012; 147 (April): 324-329

Objective: To use the Nationwide Inpatient Sample (NIS) to provide some epidemiologic information on frequency and predictive risk factors of splenic injury during colorectal surgery.

Design: Retrospective database analysis.

Methods: The NIS is a 20% sample of community hospitals in the United States, using a sampling frame of about 90% of all hospital discharges. It includes information from approximately 1000 hospitals and 8 million annual discharges. This analysis included NIS data from 2006 to 2008 on patients undergoing either laparoscopic or open colectomy. Type of colectomy was identified using ICD-9 codes and principal diagnosis codes; splen injuries were identified using ICD-9 codes specific to the spleen that were not associated with principal diagnosis codes. Data on demographics, comorbidities, pathologic conditions, type of operation, and teaching status of the hospital were abstracted from the database and analyzed as potential risk factors for splenic injury.

Results: 118,877,284 discharges were contained in the database for the 3-year period; 975,825 had a colon or rectal resection. Mean age was 63 years and 53% were female. Hypertension was present in 45%, diabetes in 14%, and chronic lung disease in 16%. Of patients, 58% were admitted electively, and 52% of cases were done in nonteaching hospitals. Of cases, 7.4% were done laparoscopically. Overall rate of splenic injury was 0.96%, but higher in emergent cases (1.28% vs 0.72%, P <0.01). Splenectomy was performed in 85% of these cases, with splenorrhaphy in 14% and partial splenectomy in 1%. The highest rate of splenic injury was seen in transverse colectomies (3.4%). Malignancy was the underlying diagnosis most commonly associated with splenic injury, with a rate of 0.55%. Splenic injury was more likely in patients undergoing open colectomy than laparoscopic colectomy, 1% versus 0.3%, P <0.01, univariate odds ratio 3.41. Using multivariate regression, transverse colectomy (adjusted odds ratio [AOR] 5.30), left colectomy (AOR 5.08), total colectomy (AOR 2.85), open operation (AOR 2.68), malignant tumor (AOR 2.11), diverticulitis (AOR 1.93), teaching hospital (AOR 1.73), male sex (AOR 1.20), peripheral vascular disease (AOR 1.14), and emergent admission (AOR 1.06) were all associated with a higher risk of splenic injury.

Conclusions: Type of resection (transverse, total, or left colectomy), type of pathology (malignancy or diverticulitis), open operation, and teaching hospital are potent independent predictors of splenic injury. Male sex, peripheral vascular disease, and emergent admission are less effective predictors. They further suggest that this information can be used to inform patients about risks and benefits during the informed consent process.

Reviewer's Comments: All general surgeons are trained to be careful around the spleen, particularly during colectomy; this information is unlikely to make anyone "more careful." It does provide solid epidemiologic information, establishing the true incidence of splenic injury during colectomy. (Reviewer-Karen J. Brasel, MD, FACS).

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Keywords: Splenectomy, Nationwide Inpatient Sample, Colorectal Surgery, Prediction

Print Tag: Refer to original journal article
Outpatient arthroscopic and venous surgery is associated with higher risk of venous thromboembolism.

**Objective:** To use American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) data to determine incidence of thromboembolism after outpatient procedures.

**Design:** Prospective observational cohort study.

**Participants:** 259,231 adult surgery patients.

**Methods:** ACS-NSQIP patient file from 2005 to 2009 was queried for all patients who had an outpatient surgery and a length of stay of 0 days. This included all outpatients and those who had a 23-hour observation stay. Demographic information, comorbidities, and current procedural terminology (CPT) codes to identify procedures were abstracted. Primary outcome was a composite thromboembolism measure of deep venous thrombosis (DVT) and pulmonary embolism (PE) that occurred in the 30 days after operation. Secondary outcome was time to thromboembolic events. Patients were randomly allocated to a derivation set or validation set to determine the validity of the risk prediction algorithm, with 67% in the derivation and 33% in the validation set.

**Results:** 173,501 patients were assigned to the derivation cohort. Incidence of DVT in the derivation cohort was 0.12% and incidence of PE was 0.038% for a combined thromboembolic endpoint of 0.15%. On multivariate regression, factors associated with thromboembolism included arthroscopic surgery (adjusted odds ratio [AOR] 5.16), current pregnancy (AOR 7.8), active cancer (AOR 3.66), venous surgery other than that associated with the greater saphenous vein (AOR 15.6), body mass index ≥40 (AOR 1.81), age >40 years (AOR 1.72 for age 41 to 59; AOR 2.48 for age ≥60), and operative time ≥120 minutes (AOR 1.69). Median time to venous thromboembolic event was 8 days. Incidence of DVT in the validation cohort was 0.10% and incidence of PE was 0.043% for a combined incidence of thromboembolism of 0.13%. Weighted risk index showed good discrimination, identifying a high-risk group with a >20-fold higher incidence of VTE than the lowest risk group. Of patients, 11,428 were in the highest risk group, and 97% of these patients had either saphenofemoral venous surgery or other venous surgery. The majority of these patients also had other multiple risk factors. The risk index identified a group with a VTE risk of 1.18%.

**Conclusions:** Outpatient arthroscopic and venous surgery is associated with a higher risk of venous thromboembolism.

**Reviewer's Comments:** These data highlight that outpatients are not immune from venous thromboembolic events, and define the risk group that is at highest risk and therefore should be considered for perioperative prophylaxis. It remains to be defined what this perioperative prophylaxis would or should look like. (Reviewer-Karen J. Brasel, MD, FACS).

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Keywords: Outpatient, Prophylaxis, Risk, Thromboembolism

Print Tag: Refer to original journal article
Hand-Assisted Laparoscopic Surgery Proficiency Point Defined

Technical Proficiency in Hand-Assisted Laparoscopic Colon and Rectal Surgery: Determining How Many Cases Are Required to Achieve Mastery.

Pendlimari R, Holubar SD, et al:

Arch Surg 2012; 147 (April): 317-322

Background: Hand-assisted laparoscopic surgery (HALS) for colorectal resections combines the most appealing features of open and laparoscopic surgery. Even after competency is established, the learning curve likely continues before technical proficiency is achieved.

Objective: To determine the number of cases necessary to achieve technical proficiency for HALS colorectal resections.

Design: Retrospective review of prospectively collected data.

Methods: HALS colorectal resections by 2 surgeons were reviewed. Operative variables and 30-day outcomes were analyzed. Operative time was used as a proficiency measure. A statistical method called Change-Point Analysis was used to determine the number of cases necessary to achieve a significant change in operative time. Cases performed before the change-point were considered to be during the "learning curve" and subsequent cases were considered to be during the "skilled period" of proficiency. Short-term outcomes were then compared between patient groups.

Results: Surgeon A and surgeon B operated on 397 and 322 patients, respectively. The change point occurred after 105 and 108 cases, respectively. After proficiency was achieved, there was decreased median blood loss (150 mL vs 100 mL; $P < 0.009$) and decreased operative time (263 minutes vs 185 minutes; $P < 0.001$), but no difference in intraoperative complications or conversion rate. Short-term outcomes improved after the change point with a decrease in overall morbidity (33.8% vs 24.9%; $P = 0.02$), infectious complications (12.7% vs 6.9%; $P = 0.02$), readmission rate (10.3% vs 5.5%; $P = 0.03$), and length of hospital stay (7.0 days vs 6.4 days; $P < 0.001$).

Conclusions: Achievement of technical proficiency for a HALS colorectal resection occurred after approximately 100 cases and was associated with improved short-term patient outcomes.

Reviewer's Comments: Surgical residency training programs are tasked with producing technically competent surgeons. Most agree that the learning curve continues after competency is reached, but defining a point when proficiency is achieved is the subject of great debate. Dr. Pendlimari and colleagues demonstrate that mastery of HALS colectomy is achieved at approximately 100 cases, long after completion of residency and fellowship. Some will question the use of operative times as the determining criterion for proficiency. Others will debate the use of a total case number as a marker of mastery given the immense variability of individual aptitude for surgical skills acquisition. Ultimately, if a change in outcomes can be associated with the change point, as the authors have demonstrated in this study, then the criteria are worthy of further investigation. The true value of determining the change point will be in further studies to identify the specific skills and experiences acquired in those first 100 cases that allow a surgeon to achieve proficiency. If we can then find a way to expedite the acquisition of those skills in young surgeons, the learning curve can be reduced. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Colorectal Surgery, Proficiency, Hand-Assisted Laparoscopic Surgery

Print Tag: Refer to original journal article
Laxative-free computed tomographic colonography has comparable adenoma detection compared to colonoscopy for lesions ≥10 mm.

**Background:** Optical colonoscopy (OC) is the gold standard for adenomatous polyp detection in asymptomatic adults; however, the bowel preparation and the procedure itself can be barriers to compliance with screening recommendations. Computed tomographic colonography (CTC) is a less invasive alternative but also requires a bowel preparation. Laxative-free CTC has recently been developed, but its performance has not been fully assessed.

**Objective:** To evaluate patient experience and detection of adenomatous polyps with laxative-free CTC versus OC.

**Design:** Prospective test comparison.

**Participants:** Patients aged 50 to 85 years with average to moderate risk of colon cancer.

**Methods:** Enrolled patients underwent CTC with electronic cleansing and computer-aided detection. A physician blinded to the CTC results then performed an OC examination. An un-blinded second pass OC examination served as the reference standard. Sensitivity and specificity were calculated for detection of adenomas ≥6mm, ≥8mm, and ≥10 mm. Survey data were collected regarding patient experience with each test preparation and procedure.

**Results:** 605 patients qualified for the study and completed protocol. In 74 patients, 95 target lesions were identified (3 cancer, 92 adenomatous polyps). Overall per-patient performance was superior for OC. For lesions ≥10 mm, sensitivity was 0.95 versus 0.91 while specificity was 0.89 versus 0.85 for OC and CTC, respectively. For lesions ≥6 mm sensitivity was 0.76 versus 0.59 while specificity was 0.94 versus 0.88, respectively. No adverse events occurred in either group. Patients reported significantly higher comfort scores, lower preparation difficulty, and lower severity of bowel habit alterations associated with CTC.

**Conclusions:** Adenoma detection using CTC was accurate for lesions ≥10 mm, but less so for smaller lesions. Patient experience was superior in CTC compared to OC.

**Reviewer’s Comments:** Colonoscopy for colorectal cancer screening in average-risk adults has been shown to decrease incidence of colorectal cancer and mortality. Compliance with screening recommendations, however, remains a challenge. Less invasive methods of screening such as fecal immunochemical testing (FIT) and CTC have been proposed as alternatives. Like colonoscopy, CTC has relied on a bowel preparation which has been a barrier to screening participation. It appears that for lesions ≥10 mm, laxative-free CTC may be an alternative to screening colonoscopy. The technique has drawbacks, including radiation exposure, a 2-day small-volume contrast ingestion protocol, and of course, lack of a therapeutic component if a lesion is found. It remains to be seen if laxative-free CTC can produce enough of an increase in screening compliance to justify inferior accuracy. Although the gold-standard recommendation for detection and prevention is colonoscopy, laxative-free CTC may have a role in screening, especially in those who are unable or unwilling to undergo colonoscopy. The technique certainly warrants further investigation. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Adenomatous Polyp, Computed Tomographic Colonography, Colorectal Cancer Screening

Print Tag: Refer to original journal article
Reducing Duration of Ileus After Colorectal Surgery

Expediting Return of Bowel Function After Colorectal Surgery.

Sindell S, Causey MW, et al:


Routine administration of polyethylene glycol is associated with faster recovery of bowel function after colorectal surgery.

Background: Return of bowel function after colon and rectal surgery is viewed as a marker of ileus resolution and is often a criterion for hospital discharge. Delayed return of bowel function can prolong hospitalization and increase health care costs.

Objective: To determine factors associated with early return of bowel function after elective colon surgery.

Design: Retrospective review.

Methods: Patients undergoing partial colectomy during the study period were identified. Exclusion criteria included emergency surgery, a combined gynecologic operation, creation of a stoma, and laparoscopic or laparoscopic-assisted surgery. Recorded variables included patient demographics, type of resection, analgesic requirements, use of nasogastric decompression, polyethylene glycol administration, frequency of ambulation, and time to first oral intake. Measured end points included time to first flatus, time to first bowel movement, and length of hospital stay.

Results: Of 183 patients who met inclusion criteria, 48% received polyethylene glycol postoperatively and 28% had a nasogastric tube (NGT) placed in the operating room. Significant reduction in the time to first bowel movement was seen with polyethylene glycol administration ($P=0.001$), initiation of oral intake within 48 hours of surgery ($P<0.001$), and ambulation more than twice daily ($P=0.012$). Patients leaving the operating room with a NGT had a significantly longer time to first bowel movement ($P=0.002$). Cox regression analysis revealed that only frequent ambulation and polyethylene glycol administration were associated with reduction in time to first flatus and time to first bowel movement while routine NGT placement significantly lengthened time to first bowel movement. No factors were associated with a shorter length of hospital stay.

Conclusions: Earlier return of bowel function can be achieved with frequent ambulation, early initiation of oral intake, administration of polyethylene glycol, and avoidance of routine nasogastric drainage.

Reviewer’s Comments: Efforts to minimize the duration of ileus have included expensive pharmacologic agents, alternative methods of analgesia, minimizing narcotics, gum chewing, early ambulation, early feeding, and conservative fluid administration just to name a few. Many of these have been included into fast-track protocols which have been effective in reducing the length of hospital stay. Dr. Sindell and colleagues confirm previous findings that show frequent ambulation, early feeding, and avoidance of routine nasogastric drainage significantly reduce postoperative ileus duration. They also demonstrate that polyethylene glycol administration is effective in this regard. I find the prospect of this intriguing given that it is a safe and inexpensive medication. However, hospital length of stay was not significantly changed despite earlier return of bowel function. Independently, any one intervention may not produce a significant change in length of stay, but it is likely that the multiple components of fast-track protocols have an additive effect. Only further prospective studies will determine if these protocols will include the administration of polyethylene glycol. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Ileus, Colorectal Surgery, Polyethylene Glycol, Bowel Function

Print Tag: Refer to original journal article
Fish Oil Supplements May Reduce AVF Complications

Effect of Fish Oil Supplementation on Graft Patency and Cardiovascular Events Among Patients With New Synthetic Arteriovenous Hemodialysis Grafts: A Randomized Controlled Trial.

Lok CE, Moist L, et al:

JAMA 2012; 307 (May 2): 1809-1816

Fish oil supplementation reduces the rate of thrombosis of arteriovenous dialysis fistulas in the first 12 months.

Background: Synthetic grafts are commonly used to construct arteriovenous dialysis fistulas (AVF). Graft thrombosis is high within the first year and occurs secondary to neointimal hyperplasia at the venous anastomosis. The antioxidant, antiproliferative, and vasodilatory effects of omega-3 fatty acids could be helpful in improving AVF patency rates.

Objective: To determine if fish oil supplementation would improve patency of synthetic AVFs.

Design: Multicenter prospective randomized trial.

Participants: 201 patients who had a synthetic AVF placed for dialysis.

Methods: Patients were entered into the study 7 days after the AVF was placed to exclude patients with early technical thrombosis. Baseline patient characteristics were obtained. Local graft surveillance protocols were followed. If flow was reduced an angiogram was obtained and if a lesion was >50% stenosis intervention was done. Primary outcome was loss of native patency in 12 months, which was defined as thrombosis or a radiologic intervention to maintain patency. Secondary outcomes included thrombosis and intervention rate, time to these events, and cumulative graft loss. Graft loss was defined as a non-salvageable graft. Fish oil or placebo was given as 4 one-gram capsules daily. Final analysis included 99 receiving fish oil and 97 a placebo.

Results: Native patency was similar between groups: fish oil 48% and placebo 62% ($P =0.06$). Thrombotic or intervention rates were significantly lower in the fish oil patients at 3 per 1000 access days compared to 6 per 1000 access days. Thrombosis was actually reduced by 50% in fish oil patients. Cumulative graft patency was no different between groups: 28% for fish oil and 35% for placebo patients.

Conclusions: 12-month patency rate for AVFs was not improved by fish oil supplementation although rate of thrombosis was lowered by fish oil.

Reviewer’s Comments: While the current emphasis on native fistulas has reduced the use of synthetic AVFs, some patients still require the use of a synthetic AVF for many reasons. The neointimal hyperplasia problem has not been solved although secondary patency rates have improved as a result of radiologic interventions. Antiplatelet drugs have been evaluated and found to have a small beneficial effect on native patency but no long-term graft patency effect. Fish oil has properties that might help improve patency although this study did not show a statistical increase in primary patency. Fish oil patients did have a lower rate of thrombosis, but again cumulative patency rate was similar to the placebo group. The downside to fish oil supplementation is low and while further study is appropriate this intervention may just “catch” on. Pun is suggested. (Reviewer: John A. Weigelt, MD, DVM, FACS).

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Keywords: Arteriovenous Dialysis Fistulas, Synthetic Grafts, Fish Oil

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Safety Compliance Associated With Higher Complications, Lower Mortality

Variations in Surgical Outcomes Associated With Hospital Compliance With Safety Practices.
Brooke BS, Dominici F, et al:

Surgery 2012; 151 (May): 651-659

Full hospital compliance with safe practices is associated with higher complication rates but better mortality for high-risk surgical procedures.

**Background**: Measuring hospital quality is not an easy task. Leapfrog Group and National Quality Forum (NQF) have combined their efforts attempting to provide a meaningful metric for hospital quality. NQF endorses a set of safe practices and Leapfrog has a survey that attempts to measure compliance with these measures as well as some outcomes in high-risk surgical patients.

**Objective**: To determine if compliance with safe practices is associated with better outcomes.

**Design**: Survey tool that self-reports hospital data and compliance with NQF safe practices.

**Participants**: 658 hospitals with adequate safe practice and enough high-risk patients.

**Methods**: Hospitals were rated on their compliance with the 27 NQF safe practices into fully compliant and partially compliant. Of procedures, 6 high-risk were identified and their outcomes assessed. These were: esophagectomy, pancreatectomy, hepatectomy, colectomy, gastrectomy, and open abdominal aneurysm repair. Only elective procedures were considered. Main outcome measures were mortality, failure to rescue, pressure ulcers, deep venous thrombosis (DVT), pulmonary embolism, aspiration, central line infection, malnutrition, surgical site infection (SSI), and postoperative cardiac complications. Failure to rescue is defined as death associated with ≥1 of these complications.

**Results**: Most hospitals were urban and part of a health system. High-risk operations ranged from a low mean of 1 for hepatectomy to a high mean of 32 for colectomy. There were 273 (41%) fully and 385 (59%) partially compliant hospitals. Full compliance hospitals had higher complication rates (12%) compared to partial compliance (11%) hospitals ($P < 0.05$). This association was found for all procedures except gastrectomy although the differences were not significant. DVT, SSI, and postoperative cardiac event were significantly higher in full compliance hospitals. Full compliance hospitals had a lower mortality associated with any complication (2.5% versus 3.0%) and better failure to rescue rate (8% versus 9%).

**Conclusions**: Despite higher complication rates with high-risk surgical procedures, hospitals that were fully compliant with NQF safe practices had lower mortality and less failure to rescue patients who developed complications.

**Reviewer’s Comments**: Is the glass half full or half empty is a great question to ask about this report. Are fully compliant hospitals just better at capturing and managing complications in high-risk surgical patients because they do more of them or have better reporting systems or what? Hard to tell! Safe-practice compliance is self-reported. Outcome data is administrative. Combining the two creates a lot of questions that may or may not be solved by statistical manipulation. Suffice it to say, this report will be used to support NQF and Leapfrog activities and to refute them. Once again we all will have to make our own minds up. (Reviewer- John A. Weigelt, MD, DVM, FACS).

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Keywords: Quality Metrics, Compliance

Print Tag: Refer to original journal article
Patients with first-degree relatives with any size adenoma have an absolute risk for colorectal cancer of 2.31%.

**Background:** Colorectal cancer (CRC) risk for patients with first-degree relatives who have adenomas is unclear.

**Objective:** To define risk for CRC in patients with first-degree relatives with adenomas.

**Design:** Published systematic review.

**Methods:** A systematic review using the search terms colorectal cancer, colorectal adenoma, and family history was conducted and subsequently, MEDLINE and Cochrane databases were searched. Cross-sectional, case-control, and cohort study designs were included and information about each study's objective, design, and population was extracted. Odds ratios (OR) and relative risks (RR) were retrieved.

**Results:** Of 273 candidate articles, 12 studies were potentially relevant. Of these, 9 were included in 2 systematic reviews on the risk for CRC based on family history and 1 is cited directly to support recommendations from 3 guideline organizations. However, 10 did not answer the study question of "do persons who have a first-degree relative with an adenoma have a higher risk for CRC?" (not vice versa). Of studies, 2 did address the question and were cross-sectional designs. In study A, CRC was present in 15 of 648 (2.31% [95% CI, 1.3% to 3.8%]) who had relatives with adenomas compared to 29 of 5491 (0.53% [CI, 0.35% to 0.96%]) who did not. RR was 4.36% (CI, 1.60 to 10.21). The study did not verify survey answers (validity) and only included 1 nationality (generalizability). Study B reported large adenomas or CRC was present in 14 of 168 (8.3% [CI, 4.6% to 13.6%]) in patients with first-degree relatives with large adenomas compared to 13 to 307 (4.2% [CI, 2.3% to 7.1%]) of those who did not. Adjusted OR was 2.27 (CI, 1.01 to 5.09). RR for advanced neoplasia was higher if the first-degree relative with an adenoma was aged <60 years, male, or had a distal adenoma. The study's limits were difference in risk was not statistically significant, it inadvertently included CRC in the risk factor group, and only 55% of relatives had a colonoscopy. In summary, persons who have first-degree relatives with any adenoma have an absolute risk of CRC of 2.31% (CI, 1.3% to 3.8%). In persons who have first-degree relatives with large adenomas, absolute risk for CRC is 3.00% (CI, 0.98% to 6.80%) and risk for either large adenomas or CRC is 8.3% (CI, 4.6% to 13.6%), mostly due to large adenomas.

**Conclusions:** Most studies cited for the risk of CRC when relatives have adenomas do not address the question. The two that do show an increased risk but have methodological limitations. Properly designed studies are needed to measure the risk and identify modifiable risk factors.

**Reviewer's Comments:** The review delineates significant design flaws in the studies that are the basis for screening guidelines for CRC based on family history of adenoma. It clearly discusses methodological limitations of the two "better" studies and cautiously summarizes these results, offering a prescription of how to design a better trial to truly answer the question. (Reviewer-Kathleen Christians, MD, FACS).

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Keywords: Adenomas, Colorectal Cancer, Colorectal Cancer Screening

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Probiotics Associated With Reduction in Antibiotic-Associated Diarrhea

Hempel S, Newberry SJ, et al:

JAMA 2012; 307 (May 9): 1959-1969

Pooled evidence suggests probiotics are associated with a reduction in antibiotic-associated diarrhea.

**Background:** Probiotics are microorganisms used to help prevent or treat antibiotic-associated diarrhea (AAD).

**Objective:** To evaluate evidence for probiotic use to prevent and treat AAD.

**Design:** Systematic review and meta-analysis.

**Methods:** 12 electronic databases were searched. Two independent reviewers identified parallel randomized controlled trials (RCTs) using the probiotics *Lactobacillus*, *Bifidobacterium*, *Saccharomyces*, *Streptococcus*, *Enterococcus* and/or *Bacillus* to treat or prevent AAD. Primary outcome was number of participants with diarrhea in each treatment group. Secondary outcomes included severity of diarrhea, measures of stool consistency, and probiotic-related adverse effects. The Cochrane Risk of Bias tool was used to assess sources of bias.

**Results:** 82 RCTs met inclusion criteria. Most used *Lactobacillus*-based probiotics alone or in combination with other genera but strains were not well documented. Pooled relative risk (RR) random-effects meta-analysis of 63 RCTs (n=11,181 patients) revealed a significant association between probiotic use and reduction in AAD (RR 0.58; 95% CI, 0.50 to 0.68; *P* <0.001; I² 54%). The result was insensitive to multiple subgroup analyses. Significant heterogeneity existed in pooled results and evidence was insufficient to determine whether an association varies systematically by population, antibiotics, or probiotic utilized.

**Conclusions:** Pooled evidence suggests probiotics are associated with reduction in AAD. However, further study is needed to determine which probiotics have greatest efficacy in which patients on what particular antibiotic.

**Reviewer’s Comments:** The studies’ limitations are unexplained heterogeneity, insufficient documentation of probiotic strains, and lack of assessment of probiotic specific adverse events. Only 10% of these trials were adequately powered. What clinicians also may not realize is that there are rare case reports of probiotic-associated fungemia and bacterial sepsis. In addition, AAD does not occur in the majority of patients on antibiotics and when it does, it is usually self-limited. What is good for one may not be good for the masses, especially without better data and understanding of the mechanism and anticipated result. (Reviewer-Kathleen Christians, MD, FACS).

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Keywords: Probiotics, Antibiotic-Associated Diarrhea, Lactobacillus

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Does rhAPC in Adult Severe Sepsis Help or Hurt?

Evaluating the Use of Recombinant Human Activated Protein C in Adult Severe Sepsis: Results of the Surviving Sepsis Campaign.
Casserly B, Gerlach H, et al:

Crit Care Med 2012; 40 (May): 1417-1426

Recombinant human activated protein C is associated with significant improvement in hospital mortality in those participating in the Surviving Sepsis Campaign.

Background: Activated protein C acts as an anticoagulant by cleaving and inhibiting factors Va and VIIIa and also has an indirect anti-inflammatory action by inhibiting thrombin and interacting with cell surface receptors. The Surviving Sepsis Campaign (SSC) developed guidelines for the use of recombinant human activated protein C (rhAPC) in adult severe sepsis but results were unclear.

Objective: To analyze the association between treatment with rhAPC and outcomes among patients with severe sepsis.

Methods: Data submitted to the SSC database from January 2005 through March 2008 were evaluated regarding the administration of rhAPC in adult severe sepsis.

Results: 15,022 patients at 165 hospitals were evaluated. Over 2 years, 6.7% (n=1009) of patients received rhAPC. It is unknown how many patients had contraindications to rhAPC and were ineligible. Patients were 7 times more likely to receive steroids than rhAPC. Unadjusted hospital mortality was 37.5% and 34.6% in those who did and did not receive rhAPC and was not significant (P=0.065). Patients receiving rhAPC were less likely to have single organ dysfunction (29.4% vs 42.8%, P<0.001) but more likely to have multi-organ failure (P<0.001). In patients, 76% (n=771) of rhAPC was administered within 24 hours of sepsis onset and they were more likely to receive rhAPC if sepsis was identified in the ICU (7.1%) or ward (7.7%) as opposed to the emergency department (5.9%). Those in North America (7.1%) and Europe (6.8%) were more likely to receive rhAPC than in South America (4.2%, P<0.001). After adjusting for confounding variables, patients who received rhAPC had a significantly reduced hospital mortality (odds ratio [OR] 0.76; CI, 0.66 to 0.86, P<0.001), but this was restricted to those who received it within 24 hours (OR 0.71; 95% CI, 0.60 to 0.84, P<0.001) as opposed to those >24 hours (OR 0.95, P=0.737). Patients with coagulopathy who received rhAPC had a reduction in adjusted risk of hospital mortality (OR 0.68; 95% CI, 0.50 to 0.94, P=0.017) and was also true if they received rhAPC within 24 hours (OR 0.61; 95% CI, 0.42 to 0.88, P=0.009). There was a significant increase in compliance over time from 47.4% to 60.7% in the final quarter (P<0.001).

Conclusions: rhAPC was associated with significant improvement in hospital mortality in patients who participated in the SSC.

Reviewer's Comments: The study is an observational design limited to variables contained in the SSC database making calculations such as APACHE II scores impossible. It also means that physicians may have withheld therapy if the patient was believed to be less likely to benefit (confounding by indication). In addition, the SSC database did not contain data about bleeding complications. Based on results of the PROWESS-SHOCK trials, the drug was withdrawn from the market thus further speculation about efficacy will remain just that. (Reviewer-Kathleen Christians, MD, FACS).

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Keywords: Sepsis, Recombinant Human Activated Protein C, Surviving Sepsis Campaign

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Audit Filters Associated With Outcomes for Trauma Patients

Association Between Trauma Quality Indicators and Outcomes for Injured Patients.

Glance L, Dick AW, et al:

Arch Surg 2012; 147 (April): 308-315

Several current American College of Surgeons Committee on Trauma audit filters have strong associations with outcome.

Objective: To investigate the association between process and outcome in injured patients.

Design: Cross-sectional study.

Participants: 210,942 patients admitted to 35 trauma centers during the 10-year study period.

Methods: Data were obtained from the Pennsylvania Trauma Outcome Study from 2000 to 2009. This database includes all patients admitted to accredited trauma centers and contains information on patient demographics, Abbreviated Injury Score and ICD-9 codes, mechanisms of injury, comorbidities, physiology, mortality, complications, processes of care, and American College of Surgeons Committee on Trauma (ACSCOT) audit filters. Complex statistical analysis was used to determine the association between processes of care, including audit filters, and both in-hospital mortality and death and major complications. Analyses adjusted for the potential confounders of age, sex, injury severity, mechanism of injury, motor component of the Glasgow Coma Scale (GCS) score, and year of admission.

Results: Median patient age was 47 years and 63% were male. Overall mortality was 6.3%, and major complications occurred in 7.2%. Median length of stay was 4 days. The highest rates of mortality and major complications occurred in patients suffering gunshot wounds (GSW), those with a motor component score of 1 to 4, and those with a systolic blood pressure <90 mm Hg. Processes of care/audit filters associated with increased mortality included admission GCS <13 without a head CT, abdominal GSW managed nonoperatively, and non-fixation of a femoral fracture. Processes of care/audit filters associated with decreased mortality included absence of an ambulance report, absence of documentation of hourly vital signs in the emergency department (ED), laparotomy performed >4 hours after arrival, and craniotomy for epidural or subdural >4 hours after arrival. Processes of care/audit filters associated with decreased mortality included absence of an ambulance report, absence of documentation of hourly vital signs in the emergency department (ED), laparotomy performed >4 hours after arrival, and craniotomy for epidural or subdural >4 hours after arrival. Processes of care/audit filters associated with increased death and major complications included scene time >20 minutes, admission GCS <13 without head CT, laparotomy performed >2 hours after arrival, non-fixation of a femoral fracture, reintubation within 24 hours of extubation, and a cervical spine injury not addressed on admission. Processes of care/audit filters associated with a decreased rate of death and major complications included absence of documentation of hourly vital signs in the ED, lack of a definitive airway in patients with a GCS <8, craniotomy for an epidural or subdural >4 hours after arrival, ≥8 hours to treatment of an open tibia fracture, and an admitting physician who was not a surgeon.

Conclusions: Several current ACSCOT audit filters have strong associations with outcome in injured patients.

Reviewer's Comments: It is interesting that some of the strong associations are in the opposite direction than would be anticipated, and are thus not the reason the audit filters were established; for instance, craniotomy >4 hours after admission. The anticipation is that early craniotomy is necessary to improve survival. This highlights the need for further drill-down analyses in individual cases using current filters, and the true need to establish filters based on outcome rather than process. (Reviewer-Karen J. Brasel, MD, FACS).

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Keywords: Quality, Process, Audit Filters, Injured Patients

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Brachytherapy Inferior to Whole-Breast Irradiation After Lumpectomy

Association Between Treatment With Brachytherapy vs Whole-Breast Irradiation and Subsequent Mastectomy, Complications, and Survival Among Older Women With Invasive Breast Cancer.

Smith GL, Xu Y, et al:

JAMA 2012; 307 (17): 1827-1837

Brachytherapy has more complications but equivalent survival to whole-breast irradiation in elderly breast cancer patients.

**Objective:** To compare brachytherapy to whole-breast irradiation in elderly patients with invasive breast cancer.

**Design:** Retrospective population-based study.

**Methods:** Data from the national Medicare dataset from 2003 to 2007 for patients with the diagnosis of invasive breast cancer treated with lumpectomy followed by radiation were used. Those with metastatic disease or a prior history of breast cancer were excluded, as were patients treated with both whole-breast irradiation and brachytherapy. Outcomes of interest were subsequent mastectomy, taken as failure of radiation to control local disease, infectious and other postoperative complications, and mortality. Cause of death is not available in this dataset, so overall survival was used rather than disease-specific survival.

**Results:** 92,735 women were included in the dataset with a median follow-up of 3.03 years. Mean age was 74.8 years and 92% were white. Use of brachytherapy increased from 3.47% in 2003 to 12.52% in 2007. Patients with brachytherapy were less likely to have received chemotherapy, were less likely to have axillary lymph node involvement, but were more likely to have undergone axillary dissection. Patients receiving brachytherapy were more likely to undergo subsequent mastectomy, with a hazard ratio of 2.19 (95% CI, 1.84 to 2.61) on multivariate analysis. Using propensity analysis, brachytherapy remained associated with an increased risk of mastectomy even after adjusting for imbalanced covariates. Brachytherapy was also associated with an increased risk of infectious complications, adjusted odds ratio 1.76 (95% CI, 1.64 to 1.88) and noninfectious complications, adjusted odds ratio 2.03 (95% CI, 1.89 to 2.17). There was no difference in overall 5-year survival.

**Conclusions:** Brachytherapy is associated with decreased success of breast conservation therapy and a greater risk of complications, but similar overall survival to treatment with whole-breast irradiation after lumpectomy in patients with invasive breast cancer.

**Reviewer's Comments:** The analyses performed do take into account all of the baseline differences that exist in the groups of patients, in terms of patient factors, tumor factors, and sociodemographic factors. These are considerable, as the only factor that was not significantly different between groups was the level of poverty. Dramatic differences in the groups, and lack of difference in overall survival suggests that we still need a randomized clinical trial to evaluate whether these are equivalent methods of delivering radiation in terms of outcomes of importance to both patient and clinician. (Reviewer-Karen J. Brasel, MD, FACS).

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Keywords: Elderly, Brachytherapy, Whole-Breast Irradiation, Invasive Breast Cancer

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Can We Predict Early Postop Bowel Obstruction After Colorectal Surgery?

Masoodi H, Kang CY, et al:


Relevant predictors of early bowel obstruction after colorectal surgery include Crohn disease, malignancy, diverticulitis, and need for emergent surgery.

Background: Early postoperative small bowel obstruction (EBO) after colorectal surgery can cause significant morbidity and mortality; however, its incidence and relevant risk factors associated with this diagnosis have not been evaluated in a large patient population.

Objective: To determine incidence of in-hospital EBO after colon and rectal surgery and to identify relevant predictors of EBO.

Design: Retrospective review of a large nationwide inpatient care database.

Methods: The Nationwide Inpatient Sample (NIS) database was queried for patients who underwent colon or rectal resection during the study period. Patients who had EBO were identified by searching for ICD-9 diagnosis codes associated with intestinal obstruction. Patients were excluded if intestinal obstruction was part of the principal admission diagnosis. For patients who met criteria for EBO after colon or rectal surgery, preoperative and operative factors were analyzed. Risk-adjusted analysis and both univariate and multivariate logistic regression analyses were performed to determine characteristics associated with EBO.

Results: 975,825 patients were identified who underwent colon or rectal resection. Most operations were done electively (58.0%) and were for colorectal malignancy (34.7%). Overall rate of EBO was 8.65%. EBO was significantly higher after emergent surgery compared to elective surgery (13.26% vs 5.32%; \( P < 0.01 \)), and after open surgery compared to laparoscopic surgery (8.81% vs 6.61%; \( P < 0.01 \)). Patients with EBO had a higher in-hospital mortality rate (6.24% vs 4.34%; \( P < 0.01 \)) and a longer mean length of hospital stay (14.78 days vs 10.29 days; \( P < 0.01 \)). Major risk factors associated with EBO included Crohn disease, malignancy, diverticulitis, and emergency surgery. There was no association with EBO and hypertension, diabetes, congestive heart failure, chronic renal failure, liver disease, obesity, or smoking.

Conclusions: EBO after colon and rectal surgery is fairly common and results in higher mortality as well as longer hospital stays. Relevant predictors of EBO include Crohn disease, malignancy, diverticulitis, and the need for emergent surgery.

Reviewer’s Comments: The authors rightfully point out that data collection from large national databases can be flawed. In this study, patient selection is based entirely on ICD-9 codes and there is no way to examine clinical criteria used for the diagnosis of bowel obstruction. That being said, Dr. Masoodi and colleagues remind us that EBO after colorectal surgery is a significant source of morbidity and mortality. Although an incidence of 8.65% is on par with prior published rates (4.5% to 10.3%), surgeons likely underestimate this risk in clinical practice. EBO can be a difficult diagnosis in the postoperative setting given the fact that prolonged postoperative ileus present with similar signs and symptoms. The presence of risk factors for EBO identified by this study can trigger a heightened suspicion in patients who fall off the expected recovery course after colorectal surgery. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Bowel Obstruction, Colorectal Surgery

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Minimally invasive component separation results in fewer wound complications than open component separation for complex abdominal wall hernias.

**Background:** Complex abdominal wall hernias pose a unique reconstructive challenge. The open component separation (CS) technique has allowed more consistent primary fascial closure of these difficult hernias. The technique, however, is associated with significant wound morbidity which can compromise the success of the hernia repair. Minimally invasive component separation techniques have been developed in an effort to reduce the wound morbidity. The impact of a minimally invasive component separation on wound morbidity and hernia recurrence is uncertain.

**Objective:** To compare wound complication rates and recurrence rates after ventral hernia repair using minimally invasive component separation with inlay bioprosthetic mesh (MICSIB) versus CS.

**Design:** Retrospective analysis of prospectively collected data.

**Methods:** Patients with complex abdominal wall hernias underwent repair using MICSIB or CS at the discretion of the operating surgeon. Compered end points included total complications, reoperation, abscess, hematoma, seroma, wound-healing complications, hernia recurrence, and abdominal wall laxity/bulge.

**Results:** 107 patients underwent ventral hernia repair. MICSIB was performed on 57, while 50 had CS. MICSIB had a lower incidence of wound-healing complications (14% vs 32%; \(P = 0.026\)) and abdominal wall laxity/bulge (4% vs 14%; \(P = 0.056\)). Hernia recurrence rate was also slightly lower in the MICSIB group (4% vs 8%; \(P = 0.3\)). Rates of abscess, seroma, and hematoma were not significantly different. Mean follow-up was 15.2 months versus 20.7 months, and mean fascial defect size was 405.4 cm\(^2\) versus 273.8 cm\(^2\) for the MICSIB and CS groups, respectively.

**Conclusions:** MICSIB for ventral hernia repair produced fewer wound healing complications than CS and should be considered for the repair of complex ventral hernias especially in patients who have increased risk of wound morbidity.

**Reviewer's Comments:** Wound morbidity is the Achilles heel of the open component separation technique used for repair of complex abdominal wall hernias. Dr. Ghali and colleagues have demonstrated a reduction in wound complications by avoiding the creation of lipocutaneous flaps. This benefit was noted despite a significantly larger fascial defect size in the MICSIB group. Creation of large lipocutaneous flaps sacrifices perforating vessels and can devascularize overlying skin. Additionally, these flaps create an enormous amount of dead space where fluid collections can develop and surgical site infections take hold. Resulting wound complications require significant health care resources and ultimately are one of the biggest risk factors for hernia recurrence. Hernia recurrence is difficult to interpret in this study since follow-up time was short and recurrence numbers small. I generally use a posterior component separation technique in my practice to avoid creating flaps. MICSIB, endoscopic component separation, and posterior component separation all avoid flap creation, but none of them have been well-studied or compared. I anticipate seeing further evidence that these techniques have a true clinical impact on wound complications. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Minimally Invasive Component Separation, Ventral Hernia, Incisional Hernia, Complex Abdominal Wall Hernia

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Determining Who Needs Calcium Supplementation After Thyroidectomy

Predictable Criteria for Selective, Rather Than Routine, Calcium Supplementation Following Thyroidectomy.

Landry CS, Grubbs EG, et al:

Arch Surg 2012; 147 (April): 338-344

Measurements of parathyroid hormone and calcium level on postoperative day 1 can identify patients at highest risk of hypocalcemia after thyroidectomy.

Background: Predicting hypocalcemia after thyroidectomy has proven difficult. Physicians have adopted a variety of algorithms for selective calcium supplementation. Alternatively, many administer routine calcium supplementation. Widely accepted criteria for calcium supplementation do not exist.

Objective: To determine criteria for selective calcium supplementation after thyroidectomy.

Design: Retrospective review of 156 consecutive patients undergoing thyroidectomy.

Methods: After thyroidectomy, serum calcium levels and parathyroid hormone (PTH) levels were assessed 2 hours postoperatively, at 5 PM on the day of surgery, at 5 AM the day after surgery, and at the follow-up clinic visit. Patients were divided into 2 groups and compared. Group 1 consisted of patients with ≥1 of the following criteria: symptoms of hypocalcemia at any time during the postoperative course, a PTH level <3 pg/mL on postoperative day 1, and/or a serum calcium level <7 mg/dL on postoperative day 1. Group 2 included all remaining patients.

Results: Group 1 consisted of 34 patients (22%). Patients in this grouping were significantly more likely to have malignant disease, have a central node dissection, and to have ≥1 parathyroid gland removed. Not all symptomatic patients had a low PTH or calcium level on postoperative day 1. Changing the criteria to a PTH level <6 pg/mL or a serum calcium <8 mg/dL on postoperative day 1 captured all symptomatic patients. Changing the criteria to capture all symptomatic patients resulted in capturing 26% of asymptomatic patients in group 2. By using these criteria, 42% of patients would require calcium supplementation after thyroidectomy.

Conclusions: Limiting calcium or calcitriol administration to patients with a PTH level <6 pg/mL or a calcium level <8 mg/dL on postoperative day 1, will potentially spare 58% of patients from unnecessary medication supplementation, phlebotomy, and follow-up assessments while still treating individuals at highest risk of hypocalcemia.

Reviewer’s Comments: Avoiding initial biochemical assessment and providing calcium or calcitriol supplementation for all patients after thyroidectomy would certainly seem like the safest and easiest solution; however, there are drawbacks. First, some hypocalcemic patients fail basic calcium supplementation. These “high-risk” patients determined by biochemical testing are ideally identified early so that closer follow-up assessment can be performed. Second, many patients who will never require supplementation are relegated to taking unnecessary medications. The authors offer simple criteria to identify patients at high risk for hypocalcemia. These patients can then be given prophylactic supplementation and placed into a close follow-up assessment protocol. The criteria presented potentially spare more than half of the thyroidectomy patients from unnecessary medication administration, phlebotomy, and follow-up visits. All patients, however, still require education and counseling on the symptoms of hypocalcemia. Decreasing unnecessary treatment is certainly something that physicians, patients and administrators can rally around. (Reviewer-Andrew S. Kastenmeier, MD).

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Keywords: Thyroidectomy, Hypocalcemia, Calcium Supplementation

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