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Comparison of Post-Radical Cystectomy Ileus Rates Using GIA-80 versus GIA-60 Intestinal Stapler Device

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Abstract

Objective: To assess the impact on recovery of bowel function using an 80 mm versus 60 mm gastrointestinal anastomosis (GIA) stapler following radical cystectomy and urinary diversion (RC/UD) for bladder cancer.

Methods: We identified 696 patients using a prospectively maintained RC/UD database from January 2006-November 2010. Two nonrandomized consecutive cohorts were compared. Patients between January 2006-December 2007 (n=180) were treated using a 60mm GIA stapler, and 331 patients between January 2008-December 2010 were subject to an 80 mm GIA stapler. All patients were treated on the same standardized postoperative recovery pathway. After accounting for baseline patient and perioperative characteristics, using a multivariable logistic regression model we directly compared rates of postoperative ileus using a standardized definition.

Results: Of 511 evaluable patients, ileus was observed in 32% (57/180) for 60mm GIA versus 33% (110/331) for the 80mm GIA. Preoperative renal function, age, gender, BMI, and type of diversion were comparable between cohorts. On multivariate analysis, stapler size was not significantly associated with the development of ileus (GIA-60 vs. GIA-80: OR 1.11; 95% CI 0.75, 1.66; p=0.6). Positive fluid balance was associated with an increased risk (p=0.019) and female sex a decreased risk (p=0.008) of developing ileus compared to patients with negative fluid balance.

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Conclusions: The size of the intestinal bowel anastomosis (GIA 80 mm vs 60 mm) does not independently impact the time to bowel recovery following RC/UD.

Keywords

cystectomy; ileus; intestinal stapler

Introduction

Postoperative ileus is one of the more common postoperative complications following radical cystectomy with urinary diversion (RC/UD), and is reported to occur in up to 23% of cases [1, 2]. Despite technological advancements, increased surgical experience and improvements in perioperative care, there continues to be a high rate of ileus [1, 3, 4], which in some patients may result in result in an increased length of hospital stay [2, 5–7]. The aim of this study is to assess the impact on recovery of bowel function using an 80 mm versus 60 mm gastrointestinal anastomosis (GIA) stapler following RC/UD for bladder cancer.

The etiology of post-operative ileus is complex and multi-factorial as evidenced by the varied findings for risk factors and hypothesized mechanisms including mechanical manipulation of bowel, impaired neurologic innervation, inflammatory and hormonal responses, systemic cytokine release, intraoperative hypotension/hypoperfusion, bowel edema, increased estimated blood loss (EBL), elevated body mass index (BMI), nutrition/albumin levels, prolonged operative time, gender and age [2, 8–14].

Although randomized clinical trials have previously evaluated different techniques for intestinal anastomosis (hand sewn versus stapled) [15, 16], to our knowledge there is no published literature to date evaluating the size of the stapled intestinal anastomosis and its relationship to ileus. Since the intestinal anastomosis may serve as the point of transition in postoperative ileus or small bowel obstruction, we, hypothesized that the use of a larger intestinal stapler (GIA 80 mm) resulting in a larger intestinal lumen may be less susceptible to edema/obstruction and thereby reduce the risk of postoperative ileus compared to the use of a standard 60mm stapled anastomosis.

Material and Methods

In this retrospective study, after institutional review board approval was obtained (IRB#16–288), we identified 696 consecutive patients who underwent a RC/UD by four high volume surgeons at Memorial Sloan Kettering Cancer Center from January 2006 to November 2010. All patients were treated on the standard postoperative Enhanced Recovery after Surgery (ERAS) pathway initially established at our institution in 1995, and all postoperative complications are prospectively captured in a hospital maintained adverse event database, which is audited quarterly by the institution.

Pre-operatively all patients received a mechanical bowel prep, which included two bottles of magnesium citrate and a clear liquid diet starting the day before surgery. Postoperatively, patients were managed by a standardized pathway including guidance for managing perioperative fluids, removal of nasogastric tubes with extubation, early ambulation,

chewing gum/lemon candy, opioid receptor inhibitors, minimization of narcotics with non-steroidal anti-inflammatory drugs (NSAIDs) and epidural pain control, bowel stimulants, as well as early initiation of diet. Deviation from the pathway is allowed for medical issues requiring it. Replacement of nasogastric tubes secondary to ileus was at the discretion of the attending physician. Following the radical cystectomy, re-anastomosis of the bowel was performed using either the standard GIA-60 (60 mm) or the GIA-80 (80 mm) stapler device (Covidien, Mansfield, MA, USA). The technique of the bowel re-anastomosis consisted of side to side anastomosis using the GIA stapler, and the top portion was closed utilizing a TA stapler along with interrupted silk sutures to reinforce the closure.

Prior to January 2006, all bowel anastomoses for RC at our institution were performed using a standard 60mm GIA stapler, with the exception of patients undergoing a continent stomal diversion where an 80–100mm GIA stapler was used to anastomose the small bowel to the transverse colon. For the purpose of the ileus study, in January 2008 the bladder group (4 surgeons) at our institution came to a consensus to trial the use of an 80mm stapler in an effort to reduce the risk of ileus. All surgeons except one consistently switched from the GIA-60 to the GIA-80 in January 2008 for the study. To eliminate the risk of surgeon selection bias influencing the outcomes, that surgeon's patients (185) were excluded from the study. In addition, we excluded any patients with prolonged intubation, as this may have also impacted return of bowel function. Our final cohort consisted of 511 patients, of whom 180 underwent a bowel anastomosis with the 60 mm stapler, and 331 with whom the 80 mm stapler was utilized. Compliance to the study was good with 88% of patients undergoing a bowel anastomosis with the standard GIA-60 stapler prior to the switch point, and following the switch point in January 2008, only 4% of patients were reanastomosed with a GIA-60 stapler (96% with the GIA-80).

Baseline data on a variety of clinical and patient characteristics were collected prospectively. These included age, sex, BMI, stage, American Society of Anesthesiologists (ASA) score, use of neoadjuvant chemotherapy, previous pelvic surgery, abdominal or pelvic radiotherapy prior to surgery, preoperative creatinine, pre-operative and post-operative albumin, comorbidities including diabetes and inflammatory bowel disease, surgeon of record, fluid balance, type of postoperative pain control (epidural anesthesia or intravenous patient controlled anesthesia), EBL, blood transfusions, operative time, type of urinary diversion, post-operative abdominal x-ray findings, and all post-operative 90-day complications.

We utilized the same standard definition for ileus described in a previous publication from our institution characterizing complications after RC/UD [7]. Accordingly, ileus included patients with nausea or vomiting associated with abdominal distension requiring cessation of oral intake and intravenous fluid support, and/or nasogastric tube placement with or without abdominal imaging diagnostic of ileus, or intolerance of oral intake by postoperative day five resulting in fasting with or without nasogastric tube placement or antiemetic medication.

We initially analyzed the entire data set of 696 patients and found gender and glomerular filtration rate (GFR) to be significant factors in univariate analyses affecting ileus; thus, we included these factors in a multivariable logistic regression along with stapler size to predict the development of ileus. We also included fluid balance in our model based on prior outside

studies, including a prospective randomized clinical trial indicating there may be some association with ileus [8, 9]. Because we found several baseline differences between patients with anastomoses using the GIA-60 and GIA-80, we adjusted for patient characteristics that were found to be significantly different between the two in a sensitivity analysis. We additionally adjusted for preoperative albumin level, neoadjuvant chemotherapy, ASA score, operating time, use of postoperative epidural anesthesia, type of UD, and amount of colloid versus crystalloid infused, and blood transfused. We did not include year of surgery because of the temporal shift from the use of 60 mm staplers to 80 mm staplers. All statistical analyses were performed using Stata 12.0 (StataCorp, College Station, TX, USA).

Results

Patient characteristics for the study cohort are described in Table 1. Notably, patients receiving 80mm GIA received significantly more neoadjuvant chemotherapy (40% vs 29%, p=0.026), reflecting a change in practice consistent with standard of care in that time period. They also more often received epidural pain control (24% vs 5.0%, p<0.0001), and had a lower volume of intraoperative colloid and blood transfusions (median 0.5 L vs 0.8 L, p=0.010). Although the difference in operative time between the two cohorts was statistically significant (Table 1, p=0.042) a median time difference of 15 minutes would not seem clinically relevant.

There were similar rates of postoperative ileus between the two cohorts: 33% (110/331 patients) of the GIA-80 cohort vs. 32% (57/180 patients) of the GIA-60 cohort. There was no significant difference in the severity of the ileus between the two groups as measured by the need for a nasogastric tube (NGT) to resolve (16% vs 23% for patients with 60mm vs 80 mm stapler, respectively, Fisher's exact p-value = 0.3), or the length of time the NGT remained (Wilcoxon rank-sum p-value 0.9).

In a multivariable analysis, stapler size was not independently associated with the development of ileus (OR 1.11; 95% CI 0.75, 1.66; p=0.2; Table 2). The relationship between GFR and ileus development was not significant (p=0.10). Positive fluid balance was found to be associated with an increased risk of developing postoperative ileus compared to patients with negative fluid balance (p=0.019), whereas female gender was found to demonstrate a significant protective association (p=0.008). As a sensitivity analysis, we again adjusted for gender, GFR, fluid balance and other factors that were found to be significantly different at baseline. Adjustment for the additional variables did not change our conclusion (GIA-60 vs. GIA-80: OR 1.01; 95% CI 0.65, 1.55; p=0.9).

Discussion

Post-operative ileus continues to represent the most commonly reported post-operative complication following RC/UD [17–19]. Using a standardized definition for ileus and prospective data collection, roughly one-third of all patients in our series developed post-operative ileus reaffirming the clinical significance of this complication after RC/UD and need for continued prospective studies. In addition, the burden of this complication may translate into an increased length of hospital stay, increasing the cost of care [20].

Despite the implementation of enhanced recovery pathways in 1995 at our institution, the rates of post-operative ileus have been largely unchanged. In addition, we did not see a decline of ileus, in our recent RCT comparing robotic RC to open RC [21], indicating less bowel manipulation in of itself does not significantly impact ileus. In an attempt to explore other alterable factors for ileus, we hypothesized that the bowel anastomosis may serve as a transition point for ileus/obstruction, and therefore sought to determine if by increasing the size of the bowel anastomosis using a larger GIA stapler we might see a decrease in the rate of ileus after RC/UD.

Two recent publications aimed to examine the role of surgical technique in effecting ileus, including a randomized controlled trial (RCT) comparing hand-sewn to stapled anastomosis and a retrospective study comparing laparoscopic versus extraperitoneal radical cystectomy [15, 22]. Both studies also failed to show a significant difference, although outcomes in the latter study may have been affected by the lack of standardized postop recovery pathways.

Researchers have also attempted to decrease post-operative ileus by investigating nonsurgical risk factors. Raynor et al. determined that there is no significant advantage in the use of preoperative mechanical bowel preparation in patients undergoing RC/UD, and a RCT showed that parenteral nutrition did not improve postoperative recovery, including ileus [23]. It has also been shown that postoperative use of NGT does not decrease length of stay or decrease incidence of ileus [24], in fact, Donat et al. demonstrated early removal may reduce postoperative atelectasis and expedite return of bowel function [25]. Other studies have reported improved postoperative outcomes with the use of preoperative immuno nutrition [26], post-operative use of opioid receptor inhibitors [27] and post-operative enhanced recovery programs [28, 29].

We did find that a positive fluid balance is associated with an increased risk of developing ileus. This finding is consistent with those of a randomized clinical trial conducted by Studer et al, who reported that a restrictive-deferred hydration combined with preemptive norepinephrine infusion during RC/UD significantly reduced the postoperative complication rate including ileus, and hospitalization time [8]. To further examine this theory, we are currently performing a randomized clinical trial at our institution evaluating perioperative fluid management in RC/UD patients.

Surprisingly we also found female gender to be protective against ileus, the etiology and significance of which remains uncertain and will require further investigation.

Although our reported ileus incidence rate is consistent with recent reports, a potential explanation for the high variability of ileus in the literature may be due to inherent differences in the definition utilized for ileus, variations in perioperative care, retrospective data collection, and also patient population characteristics. The standardization of ileus definition would allow for more accurate comparisons of this widely prevalent and significant complication among institutions. In a review by Donat evaluating standards for reporting complications after major urologic surgeries, 6 different definitions were used to define the term “ileus” out of 11 published reports [19]. This problem does not seem to have improved, as a more recent review by Ramirez et al. specifically looking at ileus after RC,

identified 21 definitions of ileus [30]. In fact some studies did not provide a definition at all, which is a major limitation in determining the importance of outcomes for those studies. The higher rate of ileus in our study is most likely related to the fact that we strictly defined ileus prior to the start of the study and obtained the data prospectively. Moreover, we included in our definition of ileus patients that required a cessation of their diet or were not tolerating regular diet by 5 days despite the lack of a nasogastric tube. These two criteria are not routinely included in other studies.

In addition, ERAS pathways are ideal strategies to investigate new treatment ideas, especially in the postoperative setting. The rationale is that these programs allow specific interventions to be changed or added while maintaining a standardized protocol. We have a well-established ERAS and perioperative care pathway for RC, and feel that the differences in postoperative care between patients may have less impact on ileus than differences seen in an institution where perioperative care is not standardized.

There are several limitations to our study worth discussing. Although, our investigation was non-randomized in design, the date upon which the primary surgeon agreed to use the 80 mm stapler instead of the 60 mm device was agreed upon and largely adhered to by all participating surgeons in the study. In addition, the adverse event database is maintained prospectively and audited quarterly by the institution. We acknowledge that in most cases a randomized trial would be better, however we first wanted to see if the change in staple size made any impact in ileus rate, and to make sure that there were not obvious increase in complications related to the larger stapler before implementing a randomized trial. If there appeared to be a trend in either arm, then we would pursue a randomized trial to confirm our observation.

In analyzing the two cohorts, we did however identify some statistically significant differences in baseline patient characteristics between the two cohorts including ASA level, preoperative albumin level, rate of neoadjuvant chemotherapy, operative time, and use of epidural pain control. That said, when we adjusted for all patient characteristics differences between the two groups in our sensitivity analyses and the results with respect to ileus were unchanged (Table 3). In addition, although the differences in these 5 characteristics between the two groups were statistically significant, other than ASA, they would not seem clinically relevant. For example, neoadjuvant chemotherapy has been previously demonstrated not to be a significant contributing factor to complications in the post-cystectomy setting [1], and was not a significant factor for ileus in this study. Epidural use should in theory have provided an advantage to the 80mm GIA group, due to the more frequent use in that group, but the ileus rate was the same. Furthermore, a 15 minute difference in operative time and a 100cc difference in blood loss also would not seem to be sufficient to be clinically relevant. Finally, only one type of stapler device and two sizes were compared. Given the array of devices currently on the market, the size of intestinal stapler device may have an impact on the development of postoperative ileus, but the difference between a 60 mm and 80 mm stapler may not be great enough to be detected in this study.

Conclusions

Postoperative ileus remains a common complication following RC with potential impact on length of stay. Studies to date have found a variety of possible risk factors, indicating the etiology is multifactorial. We did not find evidence of an advantage for use of a larger (80mm) GIA stapler for reducing ileus in prospective consecutive group of 511 RC patients. Positive fluid balance negatively impacted ileus, which is consistent with recent RCT looking at perioperative fluid balance and ileus and deserves further study. In addition, female gender was associated with a decreased incidence of ileus in this study, the mechanism of which is unknown. This data is valuable in expanding our knowledge as to what factors may be important in contributing to ileus.

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Table 1.

Patient characteristics.

Data presented as medians with interquartile ranges in parentheses or frequency with percentages in parentheses. P-values are calculated using Wilcoxon rank sum test and Fisher's exact test, respectively.

Pre-operative Clinical Characteristics			
	60 mm (n=180)	80 mm (n=331)	p-value
Age at surgery	69 (61, 75)	67 (59, 76)	0.3
Female gender	52 (29%)	84 (25%)	0.4
Body mass index (kg/m^2) (n=510)	27 (24, 31)	28 (25, 32)	0.14
CKD-Epi GFR (mL/min/1.73m^2) (n=504)	58 (46, 67)	56 (46, 67)	>0.9
Diabetes	26 (14%)	49 (15%)	>0.9
Irritable bowel syndrome	5 (2.8%)	3 (0.9%)	0.14
Albumin level (g/dL) (n=507)	4.4 (4.2, 4.6)	4.3 (4.1, 4.5)	0.015
Neoadjuvant chemotherapy	53 (29%)	131 (40%)	0.026
ASA score			0.001
1 or 2	70 (39%)	80 (24%)	
3 or 4	110 (61%)	251 (76%)	
Post-operative Clinical Characteristics			
Operating time (min) (n=510)	315 (272, 368)	330 (276, 400)	0.042
Estimated blood loss (mL) (n=510)	800 (500, 1200)	700 (500, 1000)	0.067
Toradol use	43 (24%)	56 (17%)	0.061
Epidural use (n=510)	9 (5.0%)	80 (24%)	<0.0001
Type of urinary diversion			0.15
Ileal conduit	124 (69%)	199 (60%)	
Neobladder	47 (26%)	109 (33%)	
Continent cutaneous diversion	9 (5.0%)	23 (6.9%)	
Fluid Balance			0.7
Negative	125 (69%)	230 (69%)	
Neutral	12 (6.7%)	28 (8.5%)	
Positive	43 (24%)	73 (22%)	
Crystalloid transfusion (L) (n=508)	4.8 (3.9, 6.0)	4.6 (3.8, 5.5)	0.3
Colloid transfusion (L)	0.5 (0.0, 1.0)	0.5 (0.0, 0.8)	0.2
Colloid and blood transfusion (L)	0.8 (0.5, 1.2)	0.5 (0.3, 1.0)	0.010

Table 2.

Multivariable logistic regression analysis of ileus development. (N=504)

	Odds Ratio	95% Confidence Interval	p-value
Stapler size (60 vs. 80 mm)	1.11	0.75, 1.66	0.6
Female gender	0.53	0.33, 0.85	0.008
GFR (per 5 mL/min/1.73m^2)	0.95	0.89, 1.01	0.10
Fluid Balance			
Negative	Ref.	Ref.	
Neutral	0.62	0.28, 1.36	0.2
Positive	1.70	1.09, 2.65	0.019

Table 3.

Multivariable logistic regression analysis of ileus development adjusted for statistically significant differences in baseline characteristics between 60mm cohort and 80mm cohort. (N=498)

	Odds Ratio	95% Confidence Interval	p-value
Stapler size (60 vs. 80 mm)	1.01	0.65, 1.55	>0.9
Female gender	0.51	0.31, 0.82	0.006
GFR (per 5 mL/min/1.73m^2)	0.94	0.88, 1.01	0.074
Fluid Balance			
Negative	Ref.	Ref.	
Neutral	0.64	0.29, 1.43	0.3
Positive	1.63	1.03, 2.60	0.038
Albumin (g/dL)	0.65	0.36, 1.18	0.2
Neoadjuvant chemotherapy receipt	0.97	0.64, 1.47	0.9
ASA score			
1 or 2	Ref.	Ref.	
3 or 4	0.70	0.45, 1.08	0.11
Operating time (per 15min)	1.00	0.97, 1.03	0.9
Epidural use	1.49	0.88, 2.50	0.13
Colloid and blood transfusion (L)	0.71	0.50, 1.01	0.056