

# First, Do No Harm: Rethinking Routine Diversion in Sphincter-Preserving Rectal Cancer Resection

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- BACKGROUND:** Although diverting stomas have reduced anastomotic leak rates after sphincter-preserving proctectomy in some series, the effectiveness of routine diversion among a broad population of rectal cancer patients remains controversial. We hypothesized that routine temporary diversion is not associated with decreased rates of leak or reintervention in cancer patients at large undergoing sphincter-sparing procedures.
- STUDY DESIGN:** The Florida State Inpatient Database (AHRQ, Healthcare Cost and Utilization Project) was queried for patients undergoing sphincter-preserving proctectomy for cancer (2005 to 2014). Matched cohorts defined by diversion status were created using propensity scores based on patient and hospital characteristics. Incidence of anastomotic leak, nonelective reintervention, and readmission were compared, and cumulative 90-day inpatient costs were calculated.
- RESULTS:** Of 8,620 eligible sphincter-sparing proctectomy patients, 1,992 matched pairs were analyzed. Leak rates did not significantly vary between groups (4.5% vs 4.3%;  $p = 0.76$ ), but diversion was associated with significantly higher odds of nonelective reintervention (2.37; 95% CI 1.90 to 2.96) and readmission (1.55; 95% CI 1.33 to 1.81) compared with undiverted patients. Median costs were higher among those diverted (US\$21,325 vs US\$15,050;  $p < 0.01$ ).
- CONCLUSIONS:** No association between diversion and anastomotic leak was found. However, temporary diversion was associated with increased incidence of nonelective reinterventions, readmissions, and higher costs. We therefore challenge the paradigm of routine diversion in rectal cancer operations. Additional study is needed to identify which patients would benefit most from diversion. (J Am Coll Surg 2019;228:547–559. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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Anastomotic leak after sphincter-sparing proctectomy remains a widely feared and potentially devastating complication. Symptomatic leaks are typically associated with abdominal pain, fevers, peritonitis, and sepsis, often requiring hospitalization and invasive interventions.<sup>1</sup> Such anastomotic failures have also been associated with myriad negative consequences, including increased perioperative mortality and morbidity, poorer functional outcomes, delays in adjuvant treatment, and worse oncologic outcomes.<sup>2-6</sup> To decrease the frequency and severity of these leaks, many surgeons routinely divert patients undergoing sphincter-sparing proctectomy for cancer.<sup>4,7-10</sup>

However, the net benefit of diversion remains unclear. Although diverting stomas—often loop ileostomies—have been correlated with reductions in leak severity,<sup>4,7-10</sup> their role in preventing symptomatic failures remains unclear in others.<sup>11-13</sup> Diversion has also been associated with

significant morbidity, decreased quality of life, and increased healthcare use.<sup>14-18</sup> In addition, temporarily diverted patients seeking reversal require additional admissions and procedures, both carrying extra costs and complication risks.

Few studies have evaluated both the population-wide benefits (reduced leak rate and severity of sequelae) and costs (stoma-related complications, readmissions, and total healthcare costs) associated with routine diversion after sphincter-sparing proctectomy for cancer. Therefore, we performed the following analysis to better understand the complexities of fecal diversion in rectal cancer resection.

## METHODS

A retrospective cohort study was conducted using administrative billing data from the Florida State Inpatient Database (SID) for years 2005 through 2014. This SID, collected at the state level and made available by the AHRQ Healthcare Cost and Utilization Project, included 22 million discrete discharges that occurred from all non-federal inpatient facilities in Florida during the study period.<sup>19</sup> The database contained core clinical and administrative variables, ICD-9-CM diagnosis and procedure codes, patient demographics, payer, total charges, and encrypted dates of admission, discharge, and procedure performance. Hospital characteristics were obtained from the American Hospital Association Annual Survey Database. The SID also included an encrypted patient identifier that facilitated longitudinal patient follow-up. The research protocol was deemed non-human research by the Washington University IRB (#201802006).

### Patient selection and exclusion

Patients undergoing elective sphincter-sparing proctectomy (ICD-9-CM procedure codes 48.61, 48.63, 48.64, 48.65, and 48.69) with or without diverting ostomy (codes 46.01, 46.11, 46.20, and 46.21) were selected. Laparoscopic and robotic modifier codes were used to identify surgical approach. Only patients with an associated diagnosis of distal colorectal malignancy were included. See [eTable 1](#) for a complete list of associated procedure and diagnosis codes used for patient selection and variable definition.

Patients younger than 18 years or older than 90 years of age and those diagnosed with metastatic cancer, inflammatory bowel disease, or intra-abdominal abscess or fistula in the year before the index admission were excluded. Index admissions with associated emergency department charges were deemed nonelective and excluded. To ensure that all patients were at risk for experiencing the outcomes of interest, people who expired during the index admission or resided outside Florida were excluded from the final cohort.

### Independent variables

Demographic, medical comorbidity, and hospital variables were collected for propensity score matching and subsequent analyses. Age, sex, race, and home ZIP code median income quartile were provided by the SID. Medical comorbidities were determined by analyzing the index admission and all inpatient admissions in the 365 days preceding surgical resection with the enhanced Elixhauser algorithm, as described by Quan.<sup>20-22</sup> Six comorbidities were selected for inclusion in propensity score matching based on their clinical relevance to ostomy creation and overall prevalence within the study cohort. The Elixhauser Mortality Index, a continuous weighted sum of all comorbidities defined within the original Elixhauser algorithm, was included in multivariable modeling to adjust for the total burden of underlying comorbidities.<sup>23</sup> Patients with procedure codes for vaginal, uterine, prostate, bladder, or liver procedures at time of proctectomy were considered to have multiorgan resections. Hospital academic affiliation was determined from American Hospital Association data, and each facility's surgical volume was calculated as the sum of proctectomies performed during the study period and then categorized into quartiles.

### Propensity score matching

After selection, patients were divided into treatment cohorts based on ostomy status after the index surgical procedure. To create groups at similar risk of undergoing diversion and to control for significant covariate variation between cohorts in the included population, matching based on propensity scores was performed. A propensity score of diverting stoma creation was calculated for each patient using multivariable logistic regression that included patient-level demographic, socioeconomic, and treatment variables, as well as hospital volume and academic status (see [eTable 2](#)). Using a Greedy algorithm with a caliper distance of 0.2 times the SD of the propensity score logit,<sup>24</sup> undiverted patients were matched 1:1 without replacement to those with diverting stomas. Standardized differences of covariates between cohorts were calculated before and after matching, with values <0.1 signifying balance between groups ([eFig. 1](#)).<sup>25</sup> The distribution of propensity scores before and after matching were compared graphically ([eFig. 2](#)).<sup>25</sup>

### Outcomes

The primary end point was the incidence of anastomotic leak within 90 days of index proctectomy. As no ICD-9-CM code for anastomotic leak exists, we used a composite end point similar to that described by Kang and colleagues,<sup>26</sup> which included diagnoses likely to be associated with an anastomotic leak: postoperative peritonitis, intestinal

perforation, intra-abdominal or pelvic abscess, and abdominal or pelvic fistula. The occurrence of a leak was considered a binary event.

Secondary outcomes included the incidence of nonelective reintervention, nonelective readmission, and elective ostomy reversal, as well as total costs of all inpatient healthcare. Nonelective reinterventions were defined as any invasive abdominal or pelvic procedures other than elective ostomy reversal occurring during an inpatient admission. Procedures performed during the index admission but more than 2 days after the index procedure were considered reinterventions, as were all nonelective procedures from readmissions within the follow-up period. Reintervention was considered a binary variable and reported as the number of patients who underwent any reintervention during the follow-up period.

Nonelective readmissions were defined as inpatient readmissions with a primary discharge diagnosis other than adjuvant therapy or elective stoma reversal and were categorized based on the primary discharge diagnosis (eTable 1). Due to variability in length of readmissions, counts of readmissions were not analyzed; rather, this end point was also considered a binary variable and was reported as the number of patients experiencing at least 1 readmission within 90 days of operation.

Total inpatient costs accrued during the 90-day study period were calculated using the following methodology. The SID included a total charge for all care provided per discharge record. Because charges vary widely between institutions and do not adequately reflect the cost of providing a particular service, the total charges per patient were converted to estimated costs using hospital and year-specific charge-to-cost ratios provided by the Healthcare Cost and Utilization Project.<sup>27</sup> These ratios, developed from hospital accounting reports from the Centers for Medicare and Medicaid Services, are specific to individual hospitals and represent estimations of expenses incurred by hospitals in treating individual patients.<sup>27,28</sup> Therefore, reported costs estimate the total resources expended by inpatient facilities during the study period per patient. Physician and outpatient costs are not included.

The incidence of ostomy reversal was also compared between groups. Elective ostomy reversal was considered to occur at a readmission associated with the appropriate ICD-9-CM procedure code (eTable 1), a primary discharge diagnosis related to the stoma, and no emergency department charges. A 2-year follow-up period from index procedure was used for this end point. To ensure equal follow-up time, proctectomies that occurred after 2012 were excluded from this analysis.

### Statistical analysis

All analyses were performed with SAS, version 9.3 (SAS Institute). Univariate chi-square, Kruskal-Wallis, and Student's *t*-tests were used to calculate descriptive statistics. The incidence of leak, readmission, and reintervention were compared between groups with chi-square tests, and Kruskal-Wallis test was used to compare differences in median cost.

The McNemar test of difference of proportions was used to compare leak, reintervention, and readmission with calculation of odds ratios (ORs) for matched pairs. For each end point, the odds of the event occurring in diverted patients were compared with the odds in the undiverted cohort. Additional analysis of leak and reintervention were performed with hierarchical logistic regression models in the unmatched population with random intercept fixed effects. Patients were clustered by the facility performing index proctectomy. Variables were selected manually for model inclusion based on clinical relevance to each modeled end point.

Cost differences within each matched pair were calculated by subtracting the total costs of the undiverted patient from the total costs of his diverted match. The median cost difference was reported as the median difference in cost attributable to diversion within the matched pairs. Statistical significance was determined a priori to be  $p \leq 0.05$  for all statistical testing, and all tests were 2-sided. The 95% CIs for regression ORs were calculated by the Wald method, and CIs for matched-pair ORs were approximated as described by Selvin.<sup>29</sup>

## RESULTS

There were 8,620 patients who underwent sphincter-sparing proctectomy and met study inclusion criteria (Fig. 1). Of these, 2,142 were diverted at index operation, and the remaining 6,478 were not. Diverted patients tended to be younger (mean age 61.4 years vs 65.0 years;  $p < 0.01$ ), male (63.7% vs 54.4%;  $p < 0.01$ ), and more often treated with preoperative radiation (18.5% vs 3.4%;  $p < 0.01$ ) compared with those without stomas (Table 1). They were also more likely treated at the highest-volume centers (40.0% vs 18.1%;  $p < 0.01$ ) and those affiliated with medical schools (61.8% vs 41.6%;  $p < 0.01$ ).

After matching, the final sample included 3,984 patients divided evenly between diverted and undiverted patients. Adequate balance was achieved across all demographic, clinical, and hospital variables included in the match, with standardized mean differences  $< 0.1$  (eFig. 1 and eTable 3).

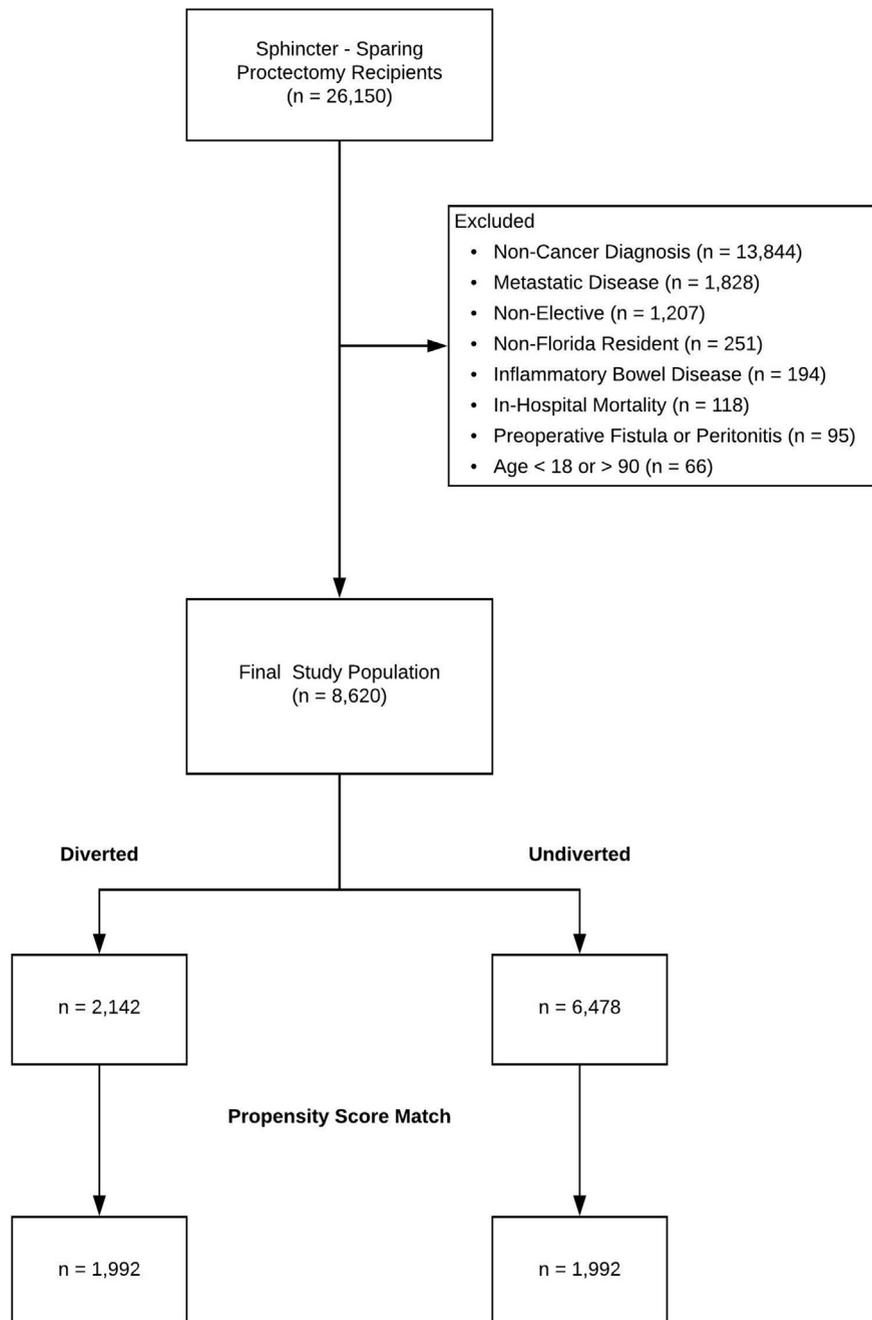
### Outcomes

The incidence of anastomotic leak did not differ significantly by diversion status; 89 diverted patients experienced

a leak compared with 85 undiverted patients (4.5% vs 4.3%, respectively;  $p = 0.76$ ) (Table 2). Approximately half of all leaks were diagnosed during the index admission. Significantly more diverted patients underwent nonelective reintervention (14.1% vs 6.4%;  $p < 0.01$ ) and readmission (25.7% vs 18.3%;  $p < 0.01$ ) within 90 days of proctectomy compared with those without stomas. In addition, the median total costs among the diverted cohort were

significantly higher than the median costs of undiverted patients (US\$21,325 vs US\$15,050;  $p < 0.01$ ). Finally, electively diverted patients were reversed at a higher rate than undiverted patients who required subsequent stomas (88% vs 74%;  $p = 0.01$ ) (eFig. 3).

Specific reintervention procedure and readmission indication also varied based on stoma status. Excluding elective stoma reversal, percutaneous drain placement (19.7%),



**Figure 1.** Flow diagram of study population selection.

**Table 1.** Study Cohort Characteristics, Before Matching

Variable	Diverted (n = 2,142)	Undiverted (n = 6,478)	p Value	Standardized mean difference
Age, y, mean (SD)	61.4 (12.0)	65.0 (12.3)	<0.01	0.30
Sex, male, n (%)	1,365 (63.7)	3,521 (54.4)	<0.01	0.19
Race, n (%)			<0.01	
White	1,542 (72.5)	4,906 (76.4)		0.09
Black	135 (6.3)	416 (6.5)		<0.01
Hispanic	360 (16.9)	839 (13.1)		0.11
Other	91 (4.3)	260 (4.1)		0.01
Home ZIP code median income quartile, n (%) <sup>*</sup>			0.22	
1: US\$1–40,999	539 (27.7)	1,555 (27.8)		0.03
2: US\$41,000–50,999	601 (30.9)	1,856 (33.2)		0.01
3: US\$51,000–66,999	537 (27.6)	1,484 (26.5)		0.05
4: >US\$67,000	266 (13.7)	704 (12.6)		0.04
Comorbidity, n (%)				
Obesity	219 (10.2)	645 (10.0)	0.72	0.01
Diabetes mellitus	394 (18.4)	1,288 (19.9)	0.13	0.04
COPD	259 (12.1)	1,027 (15.9)	<0.01	0.11
Electrolyte abnormality	558 (26.1)	1,303 (20.1)	<0.01	0.14
Congestive heart failure	76 (3.4)	333 (5.1)	<0.01	0.08
Renal failure	78 (3.6)	270 (4.2)	0.28	0.03
Elixhauser Mortality Index score, median (IQR)	7 (6 – 15)	7 (6 – 12)	<0.01	0.06
Admitting hospital type, n (%)			<0.01	0.41
Teaching	1,322 (61.8)	2,691 (41.6)		
Nonteaching	819 (38.2)	3,780 (58.4)		
Admitting hospital volume quartile, n (%)			<0.01	
1: <60	361 (16.9)	2,299 (35.5)		0.43
2: 60–120	384 (17.9)	1,723 (26.6)		0.21
3: 121–240	541 (25.3)	1,283 (19.8)		0.13
4: >240	856 (40.0)	1,173 (18.1)		0.50
History of radiation, yes, n (%)	397 (18.5)	221 (3.4)	<0.01	0.50
Surgical approach, n (%)			<0.01	
Open	1,687 (78.8)	5,316 (82.1)		0.08
Laparoscopic	281 (13.1)	878 (13.6)		0.01
Robotic	174 (8.1)	284 (4.4)		0.15
Multi-organ resection, yes, n (%)	79 (3.7)	182 (2.8)	0.04	0.05

<sup>\*</sup>The median income quartile limits change year-to-year; for general reference, the values for the middle year of this study, 2010, are listed. IQR, interquartile range.

small bowel resection (19.7%), and lysis of adhesions (8.9%) were the most common reinterventions performed among patients with diverting stomas; percutaneous drain placement (11.5%) and ileostomy creation (5.9%) were the most frequent procedures performed in the undiverted group (Fig. 2). Conditions associated with unregulated ileostomy output, such as kidney injury (16.4%) and dehydration (9.8%), were the most frequent reasons for readmission in ostomates, and infections (7.1%) and leaks (6.1%) were the most common among undiverted patients (Fig. 3).

Within matched pairs, temporary diversion was not significantly associated with risk of leak (OR 0.95; 95% CI 0.70 to 1.29) (eTable 4). However, risks of reintervention and readmission were 2.37-fold (95% CI 1.90 to 2.96) and 1.55-fold (95% CI 1.33 to 1.81) higher, respectively, among diverted patients compared with matched controls. Additionally, the median cost difference between diverted and undiverted patients was US\$5,574 (interquartile range US\$ –2,071 to US\$14,197) (Fig. 4). Among all patients with anastomotic leak, median costs were higher but did not differ significantly by diversion status (eTable 5).

**Table 2.** Primary and Secondary Outcomes, Unadjusted

Outcome	Diverted (n = 1,992)	Undiverted (n = 1,992)	p Value
Anastomotic leak, n (%)			0.76
Total	89 (4.5)	85 (4.3)	
Index admission	42 (2.1)	43 (2.2)	
Readmission	47 (2.4)	42 (2.1)	
Reintervention, n (%)			<0.01*
Total	280 (14.1)	127 (6.4)	
Index admission	66 (3.3)	54 (2.7)	
Readmission	214 (11.1)	73 (3.8)	
Readmission, n (%)			<0.01*
Nonelective	511 (25.7)	364 (18.3)	
Elective <sup>†</sup>	603 (30.3)	55 (2.8)	
Total cost, US\$, median (IQR)	21,325 (15,650–28,986)	15,050 (11,134–21,103)	<0.01*

\*Significant.

<sup>†</sup>Elective readmissions are defined as any 90-day readmission for adjuvant treatment or ostomy reversal without associated emergency department charges. IQR, interquartile range.

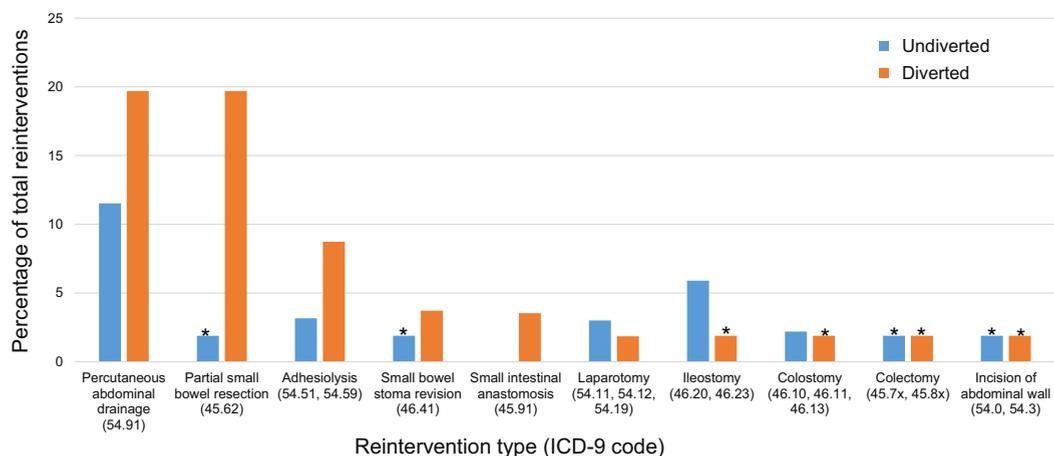
In hierarchical multivariable regression analysis, the presence of diverting ostomy remained unassociated with leaks (OR 0.99; 95% CI 0.71 to 1.37;  $p = 0.93$ ), despite the association of radiation, age, and overall mortality index with anastomotic failures (eTable 6). Similar analysis of reintervention, however, revealed a 2.76-fold increased risk among ostomates (OR 2.76; 95% CI 2.14 to 3.58;  $p < 0.01$ ) (eTable 7).

## DISCUSSION

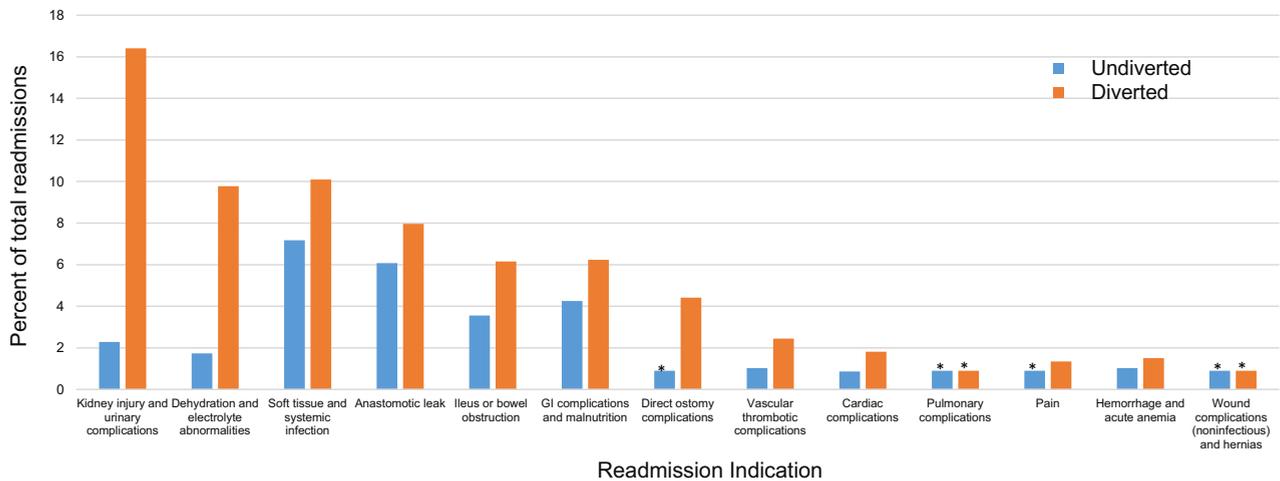
In this population study of patients undergoing proctectomy for cancer, temporary diversion was not associated with lower incidence of anastomotic leak. Instead,

diverting stomas were associated with significantly higher risk of nonelective readmissions and reinterventions, as well as higher total costs after controlling for patient demographics and burden of disease, variations in surgical approach and extent, and hospital-level factors.

These findings add to the controversy about routine temporary diversion in patients undergoing rectal cancer resection. Several randomized studies have argued that fecal diversion reduces the prevalence of leak or the severity of its sequelae. The largest, performed by Chude and colleagues,<sup>30</sup> found anastomotic leaks in 2% of diverted patients compared with 10% in those without stomas among rectal cancer patients with tumors <6 cm from the anal verge. Matthiessen and colleagues<sup>7</sup> also reported higher



**Figure 2.** Reinterventions performed based on diversion status. Distribution of the 10 most common reinterventions performed within 90 days of index proctectomy among the diverted (orange) and undiverted (blue) populations. Percentages were calculated from a total of all reinterventions performed across both groups. \*Each of these categories account for <1.9% of total reinterventions. Due to the small number, the data use agreement prohibited reporting of these exact percentages.

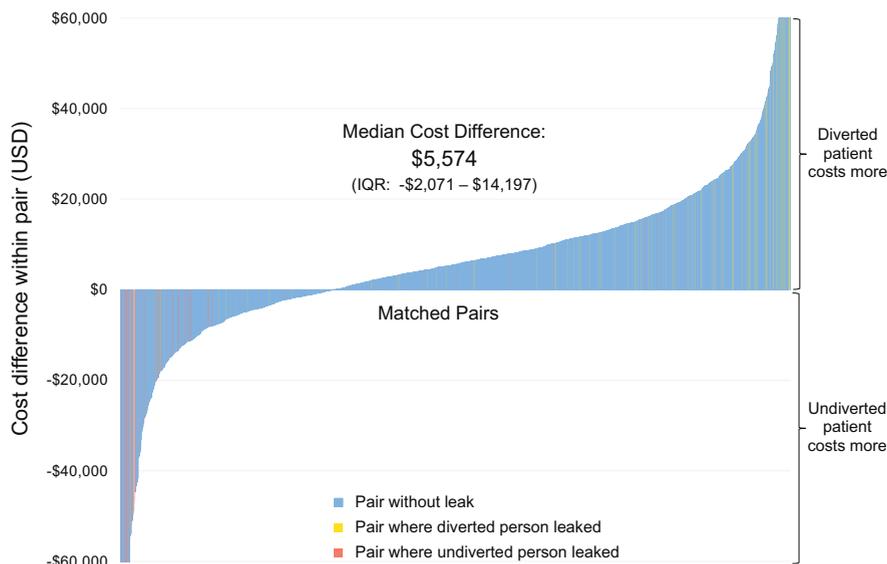


**Figure 3.** Indications for readmission based on diversion status. Distribution of principal diagnoses associated with readmissions in the diverted (orange) and undiverted (blue) cohorts after proctectomy for cancer. Percents were calculated from a total of all readmissions that occurred across both cohorts. \*Each of these categories account for <0.9% of total readmissions. Due to the small number of readmissions, the data use agreement prohibited reporting of these exact percentages.

leak rates among undiverted patients—28% vs 10%—in their randomized analysis of more than 200 Swedish participants with tumor heights of  $\leq 7$  cm. Of the 33 patients with leaks in their undiverted cohort, 28 required reoperation and diversion. Another randomized study by Ulrich and colleagues<sup>8</sup> was halted prematurely when a 37% leak rate among 16 undiverted patients was found on interim analysis. Several nonrandomized and post-hoc analyses

have identified increased incidence of either symptomatic leak or reoperation among patients who were not diverted or drained after initial operation.<sup>10,31-34</sup> Based on these data, many in the surgical community routinely divert rectal cancer patients undergoing sphincter-sparing resections.

Other studies, however, raise questions about this practice. Shiomi and colleagues<sup>35</sup> reported no difference in leak rates between diverted and undiverted cohorts in



**Figure 4.** Cost differences within matched pairs. Cost difference within matched pairs is calculated by subtracting the total cost of the undiverted patient from the total cost of their matched counterpart. Negative values denote pairs where the undiverted patient generated higher costs than the diverted patient. Pairs where no leak occurred are depicted in blue. Pairs in which the diverted member suffered a leak are denoted in yellow, and pairs in which the undiverted member leaked are pictured in red. USD, US dollars; IQR, interquartile range.

their prospective multicenter study of 1,000 patients with tumors  $\leq 10$  cm from the anus. Kang and colleagues<sup>26</sup> found a higher incidence of leak among diverted patients in their nationwide retrospective series, mirroring results from several earlier studies.<sup>4,11,36</sup> Other groups have focused on the sequelae of diversion, noting a higher rate of postoperative complications<sup>18</sup> or overall healthcare use<sup>14</sup> among ostomates compared with undiverted patients. Most interestingly, long-term follow-up from Matthiessen and colleagues<sup>7</sup> prospective trial—a study widely cited in support of routine diversion—found more readmissions and increased overall costs (€21,663 vs €15,922;  $p < 0.01$ ) in patients randomized to diversion, despite the significantly lower leak rate in that group.<sup>37</sup> The authors concluded that although diversion did reduce the clinical leak rate, it was not a cost-effective intervention.

Within this context, we draw several conclusions from our study. First, diversion is not a benign procedure. Although easily performed and perioperatively tolerated, ileostomies are difficult to manage and are associated with repeated procedures and readmissions, higher costs, and lower quality of life. Second, diversion does not appear effective across a population of sphincter-sparing proctectomy patients. Although randomized trials have shown stomas efficacious in select patients at high risk of leak, these same outcomes are not achieved among all patients. This lack of effectiveness on the population level is likely explained by the greater variability in risk factors among our study cohort. For example, low tumors—the only type included in the study by Matthiessen and colleagues<sup>7</sup> and Chude and colleagues<sup>30</sup>—are likely less prevalent among our cohort. The cohort, therefore, has an overall lower cumulative risk of leak compared with the randomized samples, which in turn weakens the effect of diversion applied at large. Therefore, although diversion can benefit specific patients, it does not appear effective in our population. Third, anastomotic leaks are associated with poor outcomes and high costs regardless of diversion status. Undiverted patients who leak and undergo subsequent diversion are still able to undergo stoma reversal in the majority cases.

In summary, this study suggests that diversion should be used selectively among patients undergoing sphincter-preserving proctectomy for cancer. Although appropriate in certain cases, the significant morbidity and costs of routine diversion outweigh the clinical benefit among the rectal cancer population at large.

### Limitations

Several limitations to this study must be considered. First, the retrospective design potentially introduces confounding

by indication and selection bias. To reduce the impact of this bias, we performed propensity score-matched pair analysis and hierarchical regression modeling of the complete cohort to assess the association of diversion with the outcomes of interest. But, because neither method can completely negate such bias, we can only conclude that associations exist between diversion and the observed outcomes. The causal nature of these relationships cannot be assessed here. Second, the analysis is inherently limited to data included in the discharge billing summary. These records are prepared by coding personnel for reimbursement purposes. Therefore, some clinical details relevant to rectal cancer treatment, such as tumor height or history of pelvic radiotherapy, are either unavailable or undercoded. For example, neoadjuvant radiation—recommended for most patients with nonmetastatic rectal cancer—was documented for  $<15\%$  of this cohort. Due to the limitations associated with these 2 variables in particular, we were unable to fully evaluate the specific impact of diversion in irradiated patients with low tumors. Future evaluation of these factors in a population-level analysis is needed. Third, no specific ICD-9-CM diagnosis code exists for anastomotic leak, and clinical definitions vary substantially.<sup>1</sup> A composite variable that included various diagnoses likely to represent leaks in patients who have had rectal operations—postoperative fistulas, intra-abdominal abscesses, and peritonitis—was therefore used. Previous investigators have taken similar approaches,<sup>26</sup> but variation in code selection can contribute to significant differences in outcomes between studies of administrative data. However, this method should facilitate relative comparisons within a single-study population as long as a consistent definition is used throughout.

### CONCLUSIONS

Using a longitudinal administrative database, we found that temporary diversion in patients undergoing sphincter-sparing proctectomy for cancer was not associated with decreased anastomotic leaks. However, diverting ostomy was associated with higher incidence of nonelective readmission and reintervention within 90 days, as well as greater total costs during the study period. We conclude that diversion should be used thoughtfully in this patient population in light of the costs and complications associated with temporary stomas. Additional study is needed to identify patients undergoing proctectomy who are most likely to benefit from diversion.

### Author Contributions

Study conception and design: Chapman, Subramanian, Mutch, Hunt, Silveira, Olsen, Wise

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Interpretation of data: Chapman, Subramanian, Makhdoom, Mutch, Hunt, Glasgow, Olsen, Wise

Drafting of manuscript: Chapman, Makhdoom, Hunt, Wise

Critical revision: Chapman, Subramanian, Jayarajan, Mutch, Silviera, Glasgow, Olsen

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## Discussion



**DR JONATHAN EFRON** (Baltimore, MD): To divert or not divert, that is the question Dr Wise and colleagues have posed to us while performing their extensive review of the Florida State Inpatient Database. This timeless question has vexed pelvic surgeons for decades.

The presenters have examined the outcomes of patients who underwent proctectomies comparing those who received stomas with those who did not. Their propensity-score matched comparison of retrospectively acquired claims data demonstrated a significantly higher cost and complication rate for those patients who were diverted with a stoma as opposed to those who were not, and these findings cause us to question the common practice of fecal diversion for patients with low rectal anastomoses.

Would the presenters please rationalize why they excluded in-hospital mortality from their study cohort? Mortality resulting from sepsis as a result of an anastomotic leak is indeed the main risk factor that leads surgeons to create fecal diversion. Do you feel that you may have eliminated some patients who suffered this significant complication from the analysis and may that have influenced your findings?

Based on the complications incurred from stoma creation, I am assuming the majority of these patients had ileostomies. Did the database differentiate between colostomies and ileostomies? And if so, would it be possible to assess if the type of stoma influenced the complication rate? Should we be performing colostomies as opposed to ileostomies for fecal diversion on those patients who are still thought to require diversion to reduce complications such as bowel obstruction and dehydration? Based on the significant rate of dehydration in the diverted group of patients, should we consider discharging all diverted patients home on intravenous fluids to reduce this risk of readmission and acute kidney injury?

Finally, has this study influenced the presenter's current practice at Washington University? What is the group's current practice with respect to fecal diversion after proctectomy?

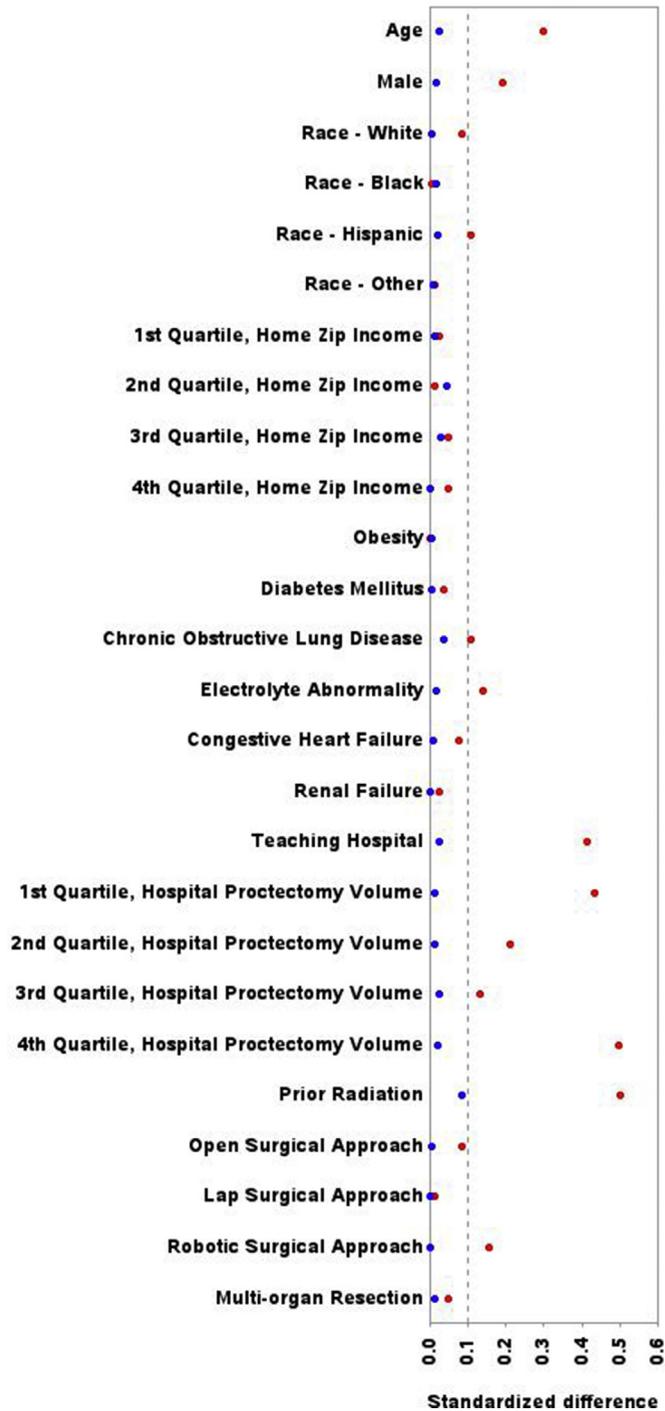
**DR EUGENE F FOLEY** (Madison, WI): I commend the authors on this attempt to add meaningful data to help us objectively answer an important question that persists in colorectal surgery: What is the value or not of routine proximal diversion to protect a colorectal anastomosis after partial proctectomy for cancer?

As the authors point out, although in many centers proximal diversion in these patients is routine practice, the data supporting it are at best inconsistent and have, in fact, been increasingly called into question as the costs and morbidity of a temporary ostomy and its closure have been increasingly recognized. There are no specific diagnosis codes for anastomotic leak in your data set. How comfortable are you with the surrogate measures you have used for a leak, such as rates of peritonitis and pelvic abscess? How comfortable are you that they are detecting your primary outcome with a high degree of sensitivity and specificity?

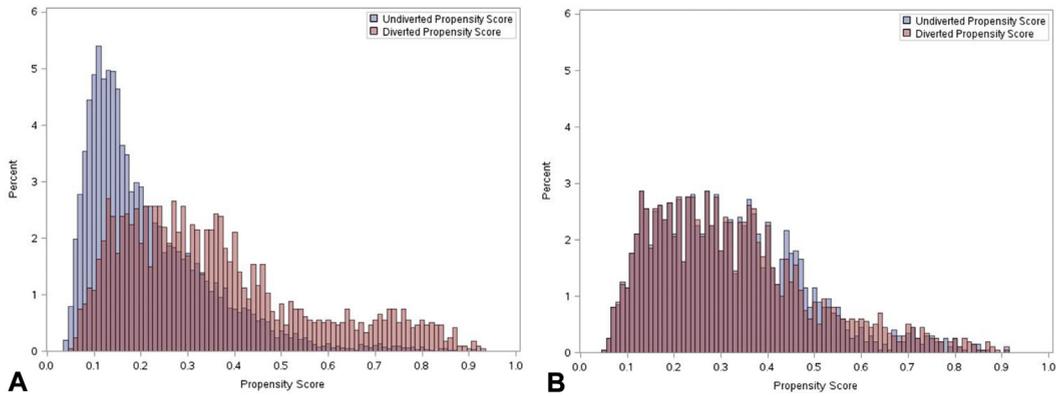
My own experience with looking into such large inpatient sample data sets is that the accuracy and completeness of their coding can be frustratingly a bit suspect. I am curious about your selection of the Florida State Inpatient Sample. Is there something about this data set that makes it a better tool for this analysis than others that might exist and should help me feel more comfortable or secure in its accuracy?

I worry that this administrative data set does not contain the important clinical variables required to assure that the diverted and nondiverted groups were at equivalent risk for developing anastomotic leak or other surgery-specific complications—variables such as the specific distance of the cancer from the pelvic floor, the cancer stage, and the specific rates and nature of the neoadjuvant treatment that the patients received. It is hard to be certain that the 2 groups are the same. In fact, it would seem intuitive that the nondiverted patients were deemed by the operating surgeon to be less complex, less difficult, and less at risk of leak, biasing their outcomes favorably when compared with the diverted patients. Another way of putting it, were all the nondiverted patients having straightforward anterior resections for early stage rectosigmoid and proximal rectal cancers, and the diverted patients all had difficult resections deep in the pelvis with a tough anastomosis at the pelvic floor? Given that significant limitation, to what degree have your observations in this study led you and your group to treat individual patients differently than in the past and to decrease your rates of performing proximal protecting ostomies in this group of patients?

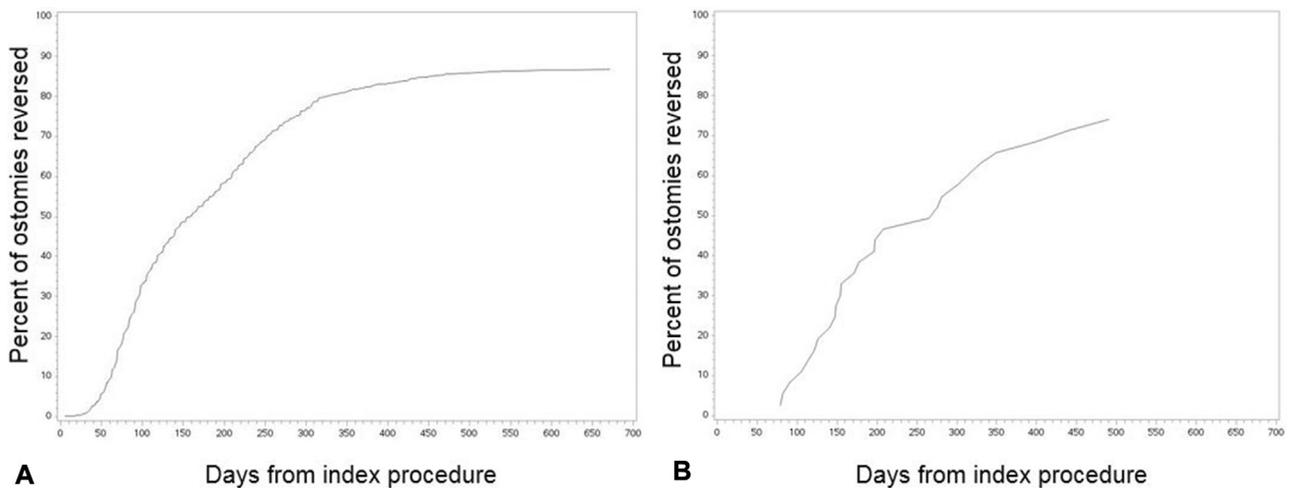
**DR JOHN DANIEL STANLEY** (Chattanooga, TN): Can you explain why, in your graph, it appeared as if the people who were diverted had a higher incidence of percutaneous drainage? I would think maybe that is related to some of these other variables, such as the distance from the anal verge. After doing the study, what is your thought about the early closure of a stoma such as within 9 days in order to diminish these readmissions and renal failure sort of things?



**eFigure 1.** Matched pair standardized mean differences before and after matching. The standardized mean difference between diverted and undiverted cohorts of patient demographic-, comorbidity-, and treatment-related variables. Differences both before (red dots) and after (blue dots) matching are displayed. Sufficient balance between cohorts is assumed wherever the standardized difference is <.1 (dashed line) after matching. Lap, laparoscopic.



**eFigure 2.** Propensity score distributions. Distribution of propensity scores among cohorts (A) before and (B) after matching. Propensity scores of undiverted patients represented in blue, diverted scores in red.



**eFigure 3.** Time to ostomy reversal. Cumulative frequency of ostomy reversal during 2-year follow-up in the (A) electively diverted and (B) initially undiverted populations; patients represented in (B) underwent subsequent diversion after leaking. Overall reversal rates within the follow-up period were 88% and 74%, respectively.

**eTable 1.** Variable Definitions using ICD-9-CM Diagnosis and Procedure Codes

Category, clinical variable	Associated ICD-9-CM codes
Inclusion criteria	
Sphincter-sparing proctectomy	48.61, 48.63, 48.64, 48.65, 48.69
Diverting ostomy	46.01, 46.11, 46.20, 46.21
Malignancy	153.1, 153.2, 153.3, 153.7, 153.8, 153.9, 154.0, 154.1, 154.2, 154.3, 154.8
Descriptive variables	
Laparoscopic approach	17.31, 17.32, 17.33, 17.34, 17.35, 17.36, 17.39, 54.51
Robotic approach	17.41, 17.42, 17.49
Comorbidity	See Elixhauser and colleagues and Quan and colleagues <sup>20-22</sup>
History of radiation	V15.3, 558.1
Multi-organ resection (procedure)*	50.21, 50.22, 50.23, 50.24, 50.25, 50.26, 50.29, 50.3, 57.6, 57.71, 57.79, 60.0, 60.11, 60.12, 60.13, 60.14, 60.15, 60.18, 60.19, 60.21, 60.29, 60.3, 60.4, 60.5, 60.61, 60.62, 60.69, 60.71, 60.72, 60.73, 60.79, 60.81, 60.82, 60.91, 60.92, 60.93, 60.94, 60.95, 60.96, 60.97, 60.99, 68.0, 68.11, 68.12, 68.13, 68.14, 68.15, 68.16, 68.19, 68.21, 68.22, 68.23, 68.24, 68.25, 68.29, 68.31, 68.39, 68.41, 68.49, 68.51, 68.59, 68.61, 68.69, 68.71, 68.79, 68.8, 68.9, 69.19, 70.31, 70.32, 70.33, 70.4, 70.61, 70.62, 70.63, 70.64
Elective ostomy reversal	46.50, 46.51, 46.52
Outcome	
Anastomotic leak	567.21, 567.22, 567.23, 567.29, 569.5, 569.81, 569.83, 619.1, 998.6
Readmission indication	
Soft tissue and systemic infection	003.1, 038.0, 038.10, 038.11, 038.12, 038.19, 038.2, 038.3, 038.40, 038.41, 038.42, 038.43, 038.44, 038.49, 038.8, 038.9, 112.5, 112.85, 536.41, 558.2, 566, 567.1, 567.31, 567.38, 567.89, 572.0, 616.4, 682.2, 682.5, 682.6, 686.1, 728.86, 780.60, 780.62, 790.7, 995.91, 995.92, 998.51, 998.59, 999.31, 999.32
Ostomy complication	V55.2 <sup>†</sup> , V55.3 <sup>†</sup> , V55.4 <sup>†</sup> , 569.60, 569.61, 569.62, 569.69
Acute kidney injury and other genitourinary complication	584.5, 584.6, 584.7, 584.8, 584.9, 591, 585.6, 585.9, 593.3, 593.4, 593.5, 593.8, 593.9, 595.0, 595.82, 595.89, 596.0, 596.2, 596.54, 596.6, 598.2, 599.0, 599.1, 599.60, 599.7, 599.84, 600.21, 600.91, 608.83, 608.86, 614.9, 619.0, 788.1, 788.20, 788.30, 788.99, 867.0, 867.1, 867.2, 867.3, 996.64, 996.65, 996.76
Cardiac complication	410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.71, 410.81, 410.91, 411.81, 414.8, 427.0, 427.1, 427.3, 427.4, 427.5, 427.61, 427.69, 427.81, 427.89, 427.9, 428.21, 429.83, 786.50, 786.51, 786.52, 786.59, 794.31
Pulmonary complication	480.0, 480.1, 480.2, 480.3, 480.8, 480.9, 481, 482.0, 482.1, 482.2, 482.30, 482.31, 482.32, 482.39, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, 482.89, 482.9, 485, 486, 512.1, 512.8, 514, 515, 516.8, 518.0, 518.81, 519.19, 786.05, 786.06, 786.09, 799.02
Vascular thrombotic complication	452, 415.11, 415.12, 415.13, 415.19, 451.11, 451.19, 451.2, 451.81, 453.2, 453.40, 453.41, 453.42
Hemorrhage and acute anemia	280.0, 285.1, 459.0, 562.02, 562.12, 568.81, 569.3, 578.1, 578.9, 596.7, 998.11, 998.12
Gastrointestinal complications and malnutrition	008.41, 008.42, 008.43, 008.44, 008.45, 008.46, 008.47, 008.49, 008.5, 009.0, 009.1, 009.3, 261, 262, 263.0, 263.1, 263.2, 263.3, 263.9, 568.0, 569.1, 569.2, 569.7, 569.49, 570, 572.0, 572.1, 573.4, 577.0, 577.1, 577.2, 577.8, 577.9, 579.3, 579.9, 783.0, 783.2, 783.3, 783.7, 783.9, 787.0, 787.3, 787.6, 787.91, 997.4, 936, V55.1

(Continued)

**eTable 1.** Continued

Category, clinical variable	Associated ICD-9-CM codes
Anastomotic leak	Same as above
Dehydration and electrolyte abnormality	250.0, 275.2, 275.3, 275.4, 276.0, 276.1, 276.2, 276.3, 276.4, 276.5, 276.7, 276.8, 276.9, 458.0, 458.29, 458.8, 458.9, 785.59
Pain	569.41, 569.42, 569.43, 789.00, 789.01, 789.03, 789.04, 789.05, 789.06, 789.07, 789.09, 789.3, 789.6, 338.18, 338.19, 338.28, 338.29, 338.3
Ileus or bowel obstruction	560.0, 560.1, 560.2, 560.30, 560.31, 560.32, 560.39, 560.81, 560.89, 560.9, 564.00, 564.09, 564.1, 564.2, 564.3, 564.4, 564.5, 564.6, 564.7, 564.89, 564.9, 568.0, 568.81, 568.82, 568.89
Wound complication including hernia	551.00, 551.01, 551.02, 551.03, 551.1, 551.20, 551.21, 551.29, 551.3, 551.8, 551.9, 552.00, 552.01, 552.02, 552.03, 552.1, 552.20, 552.21, 552.29, 552.3, 552.8, 552.9, 553.0, 553.1, 553.2, 553.3, 553.8, 553.9, 707.00, 707.01, 707.02, 707.03, 707.04, 707.05, 707.06, 707.07, 707.09, 707.10, 707.12, 707.13, 707.14, 707.15, 707.19, 707.20, 707.21, 707.22, 707.23, 707.24, 707.25, 707.8, 707.9, 998.13, 998.30, 998.31, 998.32, 998.33
Elective readmission for adjuvant therapy	V58.11, V58.12
Elective readmission for ostomy reversal	V55.2 <sup>†</sup> , V55.3 <sup>†</sup> , V55.4 <sup>†</sup> , V58.41, V58.42
Reintervention	See <a href="#">Figure 2</a>
Elective stoma reversal <sup>‡</sup>	46.50, 46.51, 46.52

\*These codes are used to designate a multi-organ resection if used simultaneously with a partial proctectomy code and diagnosis of malignancy.

<sup>†</sup>These codes are considered ostomy complications if associated with an admission that includes emergency department (ED) charges. If associated with procedure codes for ostomy reversal but no ED charges, then these codes are considered to represent an admission for elective ostomy reversal.

<sup>‡</sup>If not associated with ED charges during the admission where these procedure codes were used, then these procedures are assumed to represent an elective stoma closure.

**eTable 2.** Variables Included in Propensity Score Calculation

Variable	Type
Age	Continuous
Sex	Binary
Comorbidities	
Obesity	Binary
Diabetes mellitus	Binary
Chronic obstructive lung disease	Binary
Electrolyte abnormality	Binary
Congestive heart failure	Binary
Renal failure	Binary
Race	Categorical
Quartile of home ZIP code median income	Categorical
History of radiation therapy	Binary
Surgical approach	Categorical
Multi-organ resection	Binary
Admitting hospital proctectomy volume	Categorical
Hospital academic affiliation	Binary

**eTable 3.** Matched Population Characteristics

Variable	Diverted (n = 1,992)	Undiverted (n = 1,992)	p Value	Standardized mean difference
Age, y, mean (SD)	61.9 (11.8)	61.6 (12.4)	0.42	0.03
Sex, male, n (%)	1,254 (63.0)	1,270 (63.8)	0.60	0.02
Race, n (%)				
White	1,429 (71.7)	1,425 (71.5)	—	<0.01
Black	124 (6.2)	115 (5.8)	0.89	0.02
Hispanic	338 (17.0)	353 (17.7)	—	0.02
Other	88 (4.4)	84 (4.2)	—	0.01
Home ZIP code median income quartile, n (%) <sup>*</sup>				
1: US\$1–40,999	487 (24.5)	476 (23.9)	—	0.01
2: US\$41,000–50,999	561 (28.2)	604 (30.3)	0.76	0.05
3: US\$51,000–66,999	501 (25.2)	476 (23.9)	—	0.03
4: ≥US\$67,000	249 (12.5)	248 (12.5)	—	<0.01
Comorbidities, n (%)				
Obesity	205 (10.3)	202 (10.1)	0.88	<0.01
Diabetes mellitus	366 (18.4)	370 (18.6)	0.87	0.01
Chronic obstructive lung disease	252 (12.7)	228 (11.5)	0.24	0.04
Electrolyte abnormality	509 (25.6)	493 (24.8)	0.56	0.02
Congestive heart failure	72 (3.6)	69 (3.5)	0.80	0.01
Renal failure	76 (3.8)	77 (3.9)	0.93	<0.01
Elixhauser Mortality Index Score, median (IQR)	7 (6–15)	7 (6–13)	0.06	—
Admitting hospital type, n (%)				
Teaching	1,184 (59.4)	1,160 (58.2)	0.44	0.02
Nonteaching	808 (40.6)	832 (41.8)	—	—
Admitting hospital volume quartile, n (%) <sup>†</sup>				
1: <60	358 (18.0)	348 (17.8)	—	0.01
2: 60–120	379 (19.0)	390 (19.6)	0.62	0.01
3: 121–240	512 (25.7)	489 (24.6)	—	0.03
4: >240	743 (37.3)	765 (38.4)	—	0.02
History of radiation, yes, n (%)	257 (12.9)	202 (10.1)	0.01	0.09
Surgical approach, n (%)				
Open	1,581 (79.4)	1,584 (79.5)	—	<0.01
Laparoscopic	259 (13.0)	257 (12.9)	0.91	<0.01
Robotic	152 (7.6)	151 (7.6)	—	<0.01
Multi-organ resection, yes, n (%) <sup>‡</sup>	72 (3.6)	77 (3.9)	0.68	0.01

<sup>\*</sup>Median income per ZIP code changes during the study period. For general reference, the median incomes for the middle year of this study, 2010, are listed in the table.

<sup>†</sup>Defined as the sum of sphincter-sparing proctectomies performed during the study period.

<sup>‡</sup>Includes resection codes for bladder, prostate, vaginal, uterine, or liver resection performed at time of index proctectomy. IQR, interquartile range.

**eTable 4.** Outcomes Attributable to Diverting Ostomy, Matched Pair Analysis

Outcome	Odds ratio (95% CI)*	p Value
Anastomotic leak	0.95 (0.70–1.29)	0.76
Reintervention within 90 d	2.37 (1.90–2.96)	<0.01
Readmission within 90 d	1.55 (1.33–1.81)	<0.01

\*Displayed odds ratios compare the odds of diverted patients experiencing the specified outcomes compared with the odds of undiverted patients experiencing the same event within matched pairs. Confidence intervals for matched pair odds ratios were approximated as described by Selvin,<sup>29</sup> and significance testing was performed with McNemar's test of difference in proportions.

**eTable 5.** Median Costs among Patients with Leak, by Diversion Status

Diversion status	Median total cost, US\$	Interquartile range, US\$	p Value
Diverted (n = 89)	37,608	25,043–53,171	0.31
Undiverted (n = 85)	41,363	26,682–71,957	—

**eTable 6.** Multivariable Logistic Regression of Anastomotic Leak

Variable	Model of anastomotic leak		p Value
	Odds ratio	95% CI	
Diverting ostomy			
Yes	0.91	0.69–1.20	0.51
No	Reference	—	—
Age	0.98*	0.97–0.99	<0.01
Sex			
Male	Reference	—	—
Female	0.84	0.67–1.07	0.15
Elixhauser Mortality Index <sup>†</sup>	1.06*	1.05–1.08	<0.01
Race			
White	Reference	—	—
Black	0.88	0.56–1.38	
Hispanic	0.83	0.58–1.19	
Other	0.76	0.41–1.34	0.60
Home ZIP code median income quartile <sup>‡</sup>			
1: US\$1–40,999	Reference	—	—
2: US\$41,000–50,999	1.07	0.81–1.43	—
3: US\$51,000–66,999	0.91	0.66–1.24	—
4: >US\$67,000	1.02	0.70–1.49	0.73
Admitting hospital affiliation			
Teaching	1.03	0.80–1.34	0.80
Nonteaching	Reference	—	—
Admitting hospital volume quartile <sup>§</sup>			
1: <60	Reference	—	—
2: 60–120	1.18	0.88–1.58	—
3: 121–240	0.95	0.68–1.32	—
4: >240	0.74	0.51–1.07	—
History of radiation, yes	1.60*	1.09–2.34	0.02
Surgical approach			
Open	Reference	—	—
Laparoscopic	1.30	0.96–1.77	0.21
Robotic	1.20	0.76–1.89	—
Multi-organ resection, yes <sup>  </sup>	1.55	0.86–2.79	0.14

\*Odds ratios denote statistically significant associations.

<sup>†</sup>The Elixhauser mortality index is a weighted sum of 29 independent comorbidities used to incorporate the influence of comorbid conditions on inpatient mortality. For this model, the index is used as a surrogate for overall comorbidity burden as relates to a patient's risk of anastomotic leak.

<sup>‡</sup>Median income per ZIP code changes during the study period. For general reference, the median incomes for the middle year of this study, 2010, are listed in the table.

<sup>§</sup>Defined as the sum of sphincter-sparing proctectomies performed during the study period.

<sup>||</sup>Includes resection codes for bladder, prostate, vaginal, uterine, or liver resection performed at time of index proctectomy.

**eTable 7.** Multivariable Logistic Regression of Nonelective Reintervention

Variable	Model of reintervention		p Value
	Odds ratio	95% CI	
Anastomotic leak			
Yes	30.22*	23.38–39.06	<0.01
No	Reference	—	—
Diverting ostomy			
Yes	2.90*	2.37–3.55	<0.01
No	Reference	—	—
Age	0.99	0.98–1.00	0.08
Sex			
Male	Reference	—	—
Female	0.98	0.81–1.19	0.0
Elixhauser Mortality Index <sup>†</sup>	1.03*	1.02–1.04	<0.01
Race			
White	Reference	—	—
Black	0.99	0.68–1.47	0.55
Hispanic	1.19	0.92–1.54	—
Other	0.90	0.56–1.44	—
Home ZIP code median income quartile <sup>‡</sup>			
1: US\$1–40,999	Reference	—	—
2: US\$41,000–50,999	0.97	0.76–1.25	<0.01
3: US\$51,000–66,999	1.42*	1.11–1.82	—
4: >US\$67,000	1.32	0.97–1.79	—
Admitting hospital affiliation			
Teaching	1.00	0.81–1.24	0.99
Nonteaching	Reference	—	—
Admitting hospital volume quartile <sup>§</sup>			
1: <60	Reference	—	—
2: 60–120	1.01	0.79–1.30	—
3: 121–240	0.96	0.73–1.25	—
4: >240	0.83	0.63–1.09	0.49
History of radiation, yes	0.67*	0.47–0.95	0.02
Surgical approach			
Open	Reference	—	—
Laparoscopic	1.65*	1.30–2.10	<0.01
Robotic	1.25	0.87–1.80	—
Multi-organ resection, yes <sup>  </sup>	0.76	0.42–1.37	0.36

\*Odds ratios denote statistically significant associations.

<sup>†</sup>The Elixhauser mortality index is a weighted sum of 29 independent comorbidities used to incorporate the influence of comorbid conditions on inpatient mortality. For this model, the index is used as a surrogate for overall comorbidity burden as it relates to a patient's risk of anastomotic leak.

<sup>‡</sup>Median income per ZIP code changes during the study period. For general reference, the median incomes for the middle year of this study, 2010, are listed in the table.

<sup>§</sup>Defined as the sum of sphincter-sparing proctectomies performed during the study period.

<sup>||</sup>Includes resection codes for bladder, prostate, vaginal, uterine, or liver resection performed at time of index proctectomy.