There is controversy regarding the potential benefits of diverting ileostomy after low anterior resection (LAR). This study aims to examine the morbidity associated with diverting ileostomy in rectal cancer. A retrospective review of LAR cases was performed using the American College of Surgeons National Surgical Quality Improvement Program (2005 to 2011). Patients who underwent LAR with and without diversion were selected. Demographics, intraoperative events, and postoperative complications were reviewed. Among the 6337 cases sampled, 991 (16%) received a diverting ileostomy. Patients who were diverted were younger (60 vs 63 years), predominantly male (64 vs 53%), and more likely to have received pre-operative radiation (39 vs 12%). There was no significant difference in steroid use, weight loss, or intraoperative transfusion. Postoperatively, there was no significant difference in length of stay, rate of septic complications, wound infections, and mortality. The rate of reoperation was lower in the diverted group (4.5 vs 6.9%). Diversion was associated with a higher risk-adjusted rate of acute renal failure (OR 2.4; 95% CI (1.2, 4.6); P < 0.05). The use of diverting ileostomy reduces the rate of reoperation but is associated with an increased risk of acute renal insufficiency. These findings emphasize the need for refinement of patient selection and close follow-up to limit morbidity.

The surgical approach to rectal cancer has progressed substantially over the past decades. There have been improvements in recurrence, survival rates, postoperative outcomes, and maintenance of intestinal continuity with the evolution of surgical technique and neoadjuvant/adjuvant protocols. Advances in surgical technique have allowed for lower pelvic anastomosis, which are inherently at higher risk for anastomotic leak. Symptomatic anastomotic leak after low anterior resection (LAR) continues to be the most dreaded complication after LAR with a reported incidence of 12 to 39 per cent and an associated risk of mortality of 2 to 24 per cent. Given the high anastomotic leak rates, and its implicated associated morbidity and mortality, many surgeons use a diverting ileostomy to mitigate the clinical significance of an anastomotic leak.

The rationale for creating a diverting ileostomy is to avoid the septic complications associated with high-risk anastomosis. The ultimate goal of a stoma is to
reduce the consequence and complications associated with an anastomotic leak. However, the consideration of the morbidity and mortality of the protective stoma must be weighed against the complication that it is trying to protect. Hence is the premise behind the controversy that exists regarding the role of diverting ileostomies.

A protective ileostomy is thought to decrease the need for reintervention and decrease the clinical anastomotic leak rate.10, 14, 15 However, there is considerable morbidity and a variety of complications related to construction of the stoma, stoma period, and stoma reversal.14 These complications are reported as 19 to 66 per cent.16–20 The presence and need for a second operation can also be psychological and physically demanding for patients.3

To date there are only a few small retrospective studies that examine the specific morbidity related to ileostomy. There is a paucity of literature in regard to the effects of ileostomy on anastomotic leak with no clear conclusion of its benefits. This article therefore aims to analyze the morbidity associated with diverting ileostomies in LARs using a large national database.

Methods

Using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database 2005 to 2011, a retrospective review of LAR cases performed for rectal cancer was conducted. Approval for the use of the NSQIP patient-level data in this study was obtained from the Institutional Review Board of the University of California Irvine and the ACS NSQIP.

Patients with International Classification of Diseases, 9th Revision codes for rectal cancer were included (154.0, 154.1, 154.8, 197.5, 209.17, and 230.4). All patients with rectal cancer who underwent LAR using Current Procedural Terminology codes (44187, 44130, 44145, 44140, 44147, 44204, 44207) were selected. Patients were then stratified into two groups: patients who underwent a diverting ileostomy and those who did not at the index operation. Patients with a history of renal failure or those who were receiving dialysis were excluded. Patient demographics including age, gender, race, body mass index, functional status, comorbidities, and American Society of Anesthesiologists (ASA) class were analyzed. Intraoperative occurrences and postoperative complications were reviewed. All patients with missing data were excluded from analysis. Progressive renal insufficiency was defined in ACS NSQIP as a rise in creatinine of greater than 2 mg/dL from the preoperative value. Acute renal failure was defined as patients who require dialysis postoperatively and did not do so before admission. Readmission rates were available in 2011 data set only and capture readmission to a surgical service within 30 days of the index operation.

The end points of primary interest were chosen a priori and included 30-day mortality, sepsis, hospital length of stay, overall postoperative complications, and acute/progressive renal failure. All statistical analyses were conducted using SAS, Version 9.3, and the R Statistical Environment. χ² with Yates’ correction and t test with unequal variance were used. Multivariate linear and logistic regression were used to compare selected end points between the diverted and nondiverted groups. Estimates of adjusted mean differences and adjusted odds ratios were obtained with
95 per cent confidence intervals. Statistical significance was declared if \( P < 0.05 \). Robust standard error was used to guard against model misspecification. Holm’s method was used to account for multiplicity in \( P \) values.\(^{21–23}\)

Results

During the 5-year study period, 6337 patients who underwent LAR for rectal cancer were identified. Diversion was used in 991 patients during the index operation (15%). Patients who were not diverted were older (63 vs 60 years). Males consisted of the majority of patients in both groups. Patients with ASA Class II were more likely to have received a stoma (\( P < 0.05 \)) (Table 1). Patients who had received preoperative radiation were more likely to have received a diverting ileostomy (39 vs 12%; \( P < 0.05 \)). Patient comorbidities are listed in Table 2.

TABLE 1. Demographics of Patients with Rectal Cancer Undergoing Low Anterior Resection with Diverting Ileostomy Compared with Those without Diversion

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>No Diversion (( n = 5346 ))</th>
<th>Diverting Ileostomy (( n = 991 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>46.6*</td>
<td>35.9</td>
</tr>
<tr>
<td>Male</td>
<td>53.1*</td>
<td>63.5</td>
</tr>
<tr>
<td>BMI (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \leq 18 \text{ kg/m}^2 )</td>
<td>2.0*</td>
<td>1.0</td>
</tr>
<tr>
<td>19–25 \text{ kg/m}^2</td>
<td>32.7</td>
<td>31.6</td>
</tr>
<tr>
<td>26–30 \text{ kg/m}^2</td>
<td>33.9</td>
<td>32.8</td>
</tr>
<tr>
<td>&gt; 30 \text{ kg/m}^2</td>
<td>30.6*</td>
<td>34.1</td>
</tr>
<tr>
<td>ASA class (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. no disturbance</td>
<td>3.2</td>
<td>3.4</td>
</tr>
<tr>
<td>2. mild disturbance</td>
<td>48.9*</td>
<td>53.2</td>
</tr>
<tr>
<td>3. severe disturbance</td>
<td>44.3</td>
<td>41.1</td>
</tr>
<tr>
<td>4. life-threatening</td>
<td>3.5*</td>
<td>2.0</td>
</tr>
<tr>
<td>Functional health status (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent</td>
<td>59.5*</td>
<td>46.3</td>
</tr>
<tr>
<td>Partially dependent</td>
<td>1.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Totally dependent</td>
<td>0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Missing</td>
<td>38.9*</td>
<td>53.0</td>
</tr>
<tr>
<td>Emergency case</td>
<td>1.3</td>
<td>0.61</td>
</tr>
</tbody>
</table>

\* \( P \) value < 0.05 compared with diverting ileostomy.
BMI, body mass index; ASA, American Society of Anesthesiologists.

TABLE 2. Comorbidities of Patients with Rectal Cancer Undergoing Low Anterior Resection with Diverting Ileostomy Compared with Those without Diversion
Outcomes

On univariate analysis, patients who had undergone diversion had significantly higher rates of organ space infections (7.5 vs 5.3%) and progressive renal insufficiency (2.1 vs 0.8%). The rate of return to operating room was significantly lower in the diverted group (4.2 vs 7.6%). Readmission rates were higher in the diverted group (20 vs 11%). Table 3 lists postoperative outcomes. On multivariate regression analysis, no difference was detected in terms of 30-day mortality, overall complications, septic complications, or hospital length of stay (Table 4). Diversion is associated with 2.5-fold increase in the odd ratio of acute renal failure (95% confidence interval, 1.21 to 4.6; P < 0.05).

TABLE 3. Outcomes of Patients with Rectal Cancer Undergoing Low Anterior Resection with Diverting Ileostomy Compared with Those without Diversion
TABLE 4. Risk-adjusted Postoperative Outcomes of Patients with Rectal Cancer Undergoing Low Anterior Resection with Diverting Ileostomy Compared with Those without Diversion*

<table>
<thead>
<tr>
<th>Event</th>
<th>No Diversion (n = 5346)</th>
<th>Diverting Ileostomy (n = 991)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative red blood cells transfused</td>
<td>4</td>
<td>3.8</td>
</tr>
<tr>
<td>1</td>
<td>1.4</td>
<td>1.11</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1.92</td>
</tr>
<tr>
<td>&gt; 3</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Deep incisional SSI</td>
<td>1.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Organ/pace SSI</td>
<td>5.3*</td>
<td>7.5</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Progressive renal insufficiency</td>
<td>0.8*</td>
<td>2.1</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>0.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>4.1</td>
<td>4.8</td>
</tr>
<tr>
<td>Stroke/cerebrovascular accident with neurologic deficit</td>
<td>0.3</td>
<td>0.1</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Bleeding transfusion</td>
<td>3.7</td>
<td>4.6</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>1.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Sepsis/septic shock</td>
<td>6.3</td>
<td>6.7</td>
</tr>
<tr>
<td>Return to operating room in 30 days</td>
<td>6.9*</td>
<td>4.5</td>
</tr>
<tr>
<td>30-day readmission rates</td>
<td>11*</td>
<td>20.3</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>1.6</td>
<td>1.3</td>
</tr>
<tr>
<td>Hospital length of stay (days)</td>
<td>8 ± 3</td>
<td>8 ± 2</td>
</tr>
</tbody>
</table>

* P value < 0.05 compared with diverting ileostomy. SSI, surgical site infection.

Discussion

Although improved surgical techniques have allowed for lower anastomoses with equivalent oncological resection for rectal cancer, the frequency of anastomotic dehiscence continues to be a concern.\textsuperscript{1, 2, 24} Diversion is often used to reduce the impact
of pelvic sepsis secondary to anastomotic leaks. The resulting morbidity and mortality of
anastomotic leaks is substantial and the use of diversion has been shown to decrease
these effects.\textsuperscript{1, 10–12, 24} However, the morbidity associated with diverting ileostomy cannot
be disregarded. Despite the evidence that diverting ileostomies may decrease possible
catastrophic septic complications, the consequences of the morbidity associated with
diversion must also be considered. Our study demonstrates a higher rate of acute renal
failure, readmission rates, organ space infections, and a lower rate of reinterventions.
This in turn emphasizes the need for improvement of patient selection to limit morbidity
and ultimately preserve quality of life for these patients.

There are a number of complications associated with ileostomies, including
dehydration, renal failure, electrolyte imbalances, parastomal hernias, obstruction,
bleeding, prolapse, necrosis, stenosis, parastomal abscesses, and skin problems/leakage.\textsuperscript{14, 24, 25}
There is a reported morbidity rate of 19 to 66 per cent associated with diverting
ileostomies with dehydration as the most common complication.\textsuperscript{14, 16, 25–34} As described
by our results, after controlling for confounding variables, diverting ileostomy is
associated with a 2.4 increase in odd ratio of acute/progressive renal failure which is
likely due to fluid losses from high stoma output. There is a 1 to 29 per cent reported
dehydration and electrolyte imbalance secondary to high stoma output, which is
responsible for up to 43 per cent of readmissions and is more common in patients
receiving adjuvant chemotherapy and the elderly.\textsuperscript{14, 16, 33} We report a readmission rate of
20 per cent, which is twice that of the nondverted group. Beck-Kaltenbach et al.,
in a prospective study of 107 patients undergoing temporary loop ileostomy,
demonstrated that all patients with an ileostomy are at risk of renal impairment secondary
to a decrease in glomerular filtration rate (GFR), which can lead to severe renal failure.
This decrease in GFR (less than 30 mL/min/1.73 m\textsuperscript{2}) was observed in 30 per cent of
patients.\textsuperscript{32} Our study demonstrated that patients who were diverted presented 6 days later
with acute or progressive renal than those who were not diverted. This could be
secondary to early discharge and possible readmission.

The role of a diverting ileostomy has been questioned and this controversy is
more relevant given the increased use of ultra-low anastomosis. On multivariate
analysis, we did not demonstrate a difference in overall postoperative complications,
septic complications, length of stay, or mortality. Studies have shown longer lengths of
stay for patients receiving diverting ileostomy as well as increase rates of morbidity.\textsuperscript{14, 24, 35}
In our study, there was an increase in the rate of organ space infections in the stoma
group (8 vs 5\%). This may reflect the number of high-risk anastomosis with clinical leaks
in the diverted group. In the Swedish trial, Mathiessen et al. randomized 234 patients to
diversion versus no diversion and concluded that defunctioning loop ileostomy decreases
the rate of symptomatic anastomotic leakage and therefore recommended it after LAR.
This group had a 25.4 per cent rate of reoperation in patients who did not receive stomas.\textsuperscript{7}
Our rate of reoperation in patients who were not diverted was 6.9 per cent compared with
4.5 per cent in the diverted group. Ulrich et al.\textsuperscript{36} in a prospective study of 34 patients
undergoing LAR for rectal cancer concluded that their leak rate of 37.5 per cent in the
nondverted patients clearly demonstrated that all patients should receive a diverting
ileostomy. By contrast, Machado et al.\textsuperscript{37} in a retrospective study observed no significant
difference in anastomotic leakage between two groups and concluded that a protective
ileostomy is not required after LAR. Platelle et al. in a prospective observational study of 233 patients recommended diversion in patients undergoing LAR. However, they concluded that ileostomy did not have any benefit in 90 per cent of the patients.33

Despite the continued controversy regarding the role of a diverting ileostomy in rectal cancer, the psychological ramifications for patients with a new ileostomy continue to exist. The complexity of living with a new stoma and understanding and adapting to a new physiological state can be a difficult process for patients. Tsunoda et al. conducted a prospective study to examine the change in quality of life of patients with rectal cancer who had an ileostomy for at least 2 months. They concluded that ileostomies impose restrictions on patient activities. They proposed that given the functional and quality-of-life issues, these patients required increased resources compared with those who did not receive an ostomy.3 There also exists the knowledge of a second procedure with an associated 4 to 63.5 per cent morbidity rate and mortality rate of 0.5 to 1.4 per cent.1, 2, 10, 14, 25, 31, 34, 38–42 There is a 10 to 25 per cent likelihood that most patients who receive temporary ileostomy will not be reversed10, 14, 34, 35 and longer duration of ileostomy is associated with higher rates of morbidity.29, 31, 43 These considerations have a great impact on a patient’s psychological and physical well-being. Given the unpredictability of anastomotic leakage after LAR, the literature appears to be divided on whether to use a diverting stoma as routine in patients with rectal cancer. The benefits of a stoma are to mitigate the consequences of a clinical leak; however, the fear of this complication must be balanced with the morbidity associated with the stoma as well as the morbidity and mortality associated with its closure. The purpose of this study is not to examine the effects of ileostomy on leak rates or prevention of anastomotic leaks, but rather to report the inherent morbidity that is associated with diversion using a large national administrative database.

This study has certain limitations. ACS NSQIP data are a retrospective review of patient data, which is limited by its inherent biases and may be prone to coding errors. ACS NSQIP does not give information regarding level of anastomosis. The NSQIP database restricts information to 30-day postoperative morbidity and mortality; thus, complications and readmission beyond 30 days are unknown. Furthermore, long-term outcomes of each procedure are not available. Patients undergoing diversion did so at the discretion of the surgeon and factors favoring one approach versus the other are unavailable. There is no information as to the nature of reoperation. There is no data point for anastomotic leak. As best as we could, factors believed to be confounding and were available in the data set were adjusted for in the main analysis; however, there is always a possibility that some unmeasured confounding factors explain the differences we observed. Nevertheless, this study is one of the largest to date analyzing the 30-day morbidity of ileostomy in patients with rectal cancer undergoing LAR.

Conclusion

There is significant morbidity associated with diverting ileostomy. These morbidities can lead to decreased tolerance to chemotherapy and potential delay in treatment. Therefore, the decision for diversion should not be taken lightly and the need for better tools for patient selection and evaluation of high-risk anastomosis are obvious. It is difficult to estimate the incidence of asymptomatic anastomotic leaks in
patients with protective ileostomy and therefore difficult to assess the true benefit from creation of an ileostomy. However, a careful decision should be made at the time of primary surgery with respect to possible associated complications. This decision, which is usually left to the surgeon’s discretion and experience, is highly variable and therefore a need for new and more objective modalities for the assessment of the anastomosis needs to be explored. Better patient education and stringent postoperative follow-up in regard to the care of ileostomy may also improve overall morbidity. Therefore, a combined approach to refine the use of protective ileostomy is desirable to decrease the morbidity associated with this particular intervention.

Disclosures

American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used here; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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