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Association of obesity with postoperative outcomes after proctectomy

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ABSTRACT

Background: Prior efforts evaluating obesity as a risk factor for postoperative complications following proctectomy have been limited by sample size and uniform outcome classification.
Methods: The ACS NSQIP was queried for patients with non-metastatic rectal adenocarcinoma who underwent elective proctectomy. After stratification by BMI classification, multivariable modeling was used to identify the effect of BMI class on adjusted risk of 30-day outcomes controlling for patient, procedure, and tumor factors.
Results: Of 2241 patients identified, 33.4% had a normal BMI, 33.5% were overweight, 21.1% were obese, and 12.0% were morbidly obese. Increased risk of superficial surgical site infection (SSI) was observed in obese (OR 2.42, 95%CI:[1.36–4.29]) and morbidly obese (OR 3.29, 95%CI:[1.77–6.11]) patients when compared to normal BMI. Morbid obesity was associated with increased risk of any complication (OR 1.44, 95%CI:[1.05–1.96]). BMI class was not associated with risk adjusted odds of anastomotic leak.
Conclusions: Morbid obesity is independently associated with an increased composite odds risk of short-term morbidity following elective proctectomy for cancer primarily due to increased risk of superficial SSI.

Introduction

With its increasing incidence in the United States, obesity is a commonly encountered factor challenging surgeons to provide safe and effective rectal cancer care. Given the anatomic constraints of the bony pelvis, visceral obesity offers unique challenges to successful total mesorectal excision (TME), while increased subcutaneous adiposity complicates stoma creation. However, reported results are mixed with respect to the independent effect of obesity on short- and long-term outcomes following oncologic proctectomy. The increased incidence of surgical site infection (SSI) in this population has been well recognized in retrospective studies,[1–6] and SSI's largely account for the increase in composite morbidity seen in proctectomy patients compared to normal body mass index (BMI).[1,3,4,7,8] However, few evaluate the incidence of anastomotic complications in this population. Some studies report no differences in adjusted risk of complications or short-term mortality in patients with obesity when compared to normal controls,[6,9,10] but many of these previous investigations are single-institutional reviews with limited sample size.[7,9,11–15]

The impact of obesity on surgical outcomes following oncologic proctectomy has been previously (directly or indirectly) evaluated using multi-institutional data from the American College of Surgeons National Quality Improvement Program (ACS NSQIP).[1,2,4,5,8,16] These studies largely associate increasing BMI with increased adjusted risk of wound complications and SSI in particular. However, the investigators were not able to assess or control for important factors such as tumor location within the rectum and pathologic stage, which are known to contribute to disparate outcomes.[9,13] Additionally, these observational studies have not been able to assess for procedure specific outcomes that are important to rectal cancer surgeons, such as anastomotic leak requiring percutaneous or operative intervention and incidence of postoperative ileus.

In this work we utilize the ACS NSQIP database to analyze postoperative outcomes in patients who underwent oncologic proctectomy in 2016–2017, stratified by BMI class. We sought to evaluate the impact of BMI class on 30-day postoperative morbidity profiles following proctectomy, adjusting for patient and tumor factors. We hypothesized that increased BMI class would be associated with increased risk of overall complications – owing primarily to an increased adjusted risk of surgical site infection.

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Materials and methods

Data source

The 2016–2017 ACS NSQIP participant user files (PUFs) were obtained containing Health Insurance Portability and Accountability Act (HIPAA) compliant deidentified patient-level aggregated data with over 150 variables including preoperative, intraoperative, and 30-day postoperative outcomes collected by trained clinical abstractors from 166 sites using validated methods.[17] These PUFs were merged to Procedure Targeted Proctectomy files containing 27 additional rectum-specific variables. The ACS NSQIP and participating hospitals are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors. A Data Use Agreement was obtained, and the Loyola University Chicago Institutional Review Board waived the requirement for informed consent (LU# 211666).

Study design

Adults undergoing elective proctectomy from January 1, 2016–December 31, 2017 were retrospectively identified using primary Current Procedural Technology (CPT) codes previously defined by NSQIP to be included in the proctectomy participant user file (44155–44158, 44211, 44212, 45110–45114, 45116, 45119–45121, 45123, 45126, 45130, 45135, 45160, 45395, 45397, 45402, 45550). Only those with pathologic confirmation of malignant neoplasm of the colon, rectosigmoid junction, or rectum were included. Excluded patients had evidence of disseminated/metastatic disease, underwent proctectomy for prolapse, had an underweight BMI <18.5 kg/m^2, or had missing pathologic data. Patients were stratified by BMI into normal weight (BMI 18.5–24.9 kg/m2), overweight (BMI 25–29.9), obese (BMI 30.0–34.9), and morbidly obese (BMI $\geq$ 35.0) groups based on World Health Organization definitions.[18] Multivariable logistic regression (MVR) models were built to compare outcomes for each cohort to those of patients with normal BMI adjusting for potentially confounding variables. Candidate independent covariates included age, race, comorbid conditions (dyspnea, smoking, weight loss, chronic steroid use, hypertension (HTN), diabetes (DM), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), preoperative serum creatinine > 1.2 mg/dL), proctectomy type (low anterior resection [LAR], abdominoperineal resection [APR], or other), initial operative approach (open, laparoscopic, or robotic-assisted), primary tumor location within the rectum (high, middle, or low), American Society of Anesthesiologists (ASA) class, prolonged (4th quartile) operative time, wound class $\geq$ 3, pathologic stage, preoperative chemotherapy or radiation, and proximal enteric diversion.

Outcomes

Outcomes evaluated included new onset complications that occurred within 30 days of surgery: surgical site infection (SSI: including superficial, deep, or organ space types), wound dehiscence, sepsis, *Clostridium difficile* infection (C. diff), urinary tract infection (UTI), pneumonia, reintubation, deep vein thrombosis (DVT), pulmonary embolism (PE), stroke, myocardial infarction (MI), renal failure or injury, bleeding requiring >4 unit transfusion, return to the operating room, prolonged length of stay (LOS) defined by patients in 4th quartile for LOS ($\geq$8 days), readmission, anastomotic leak (AL), anastomotic leak requiring percutaneous or operative intervention (Major Leak), prolonged NPO/nasogastric tube >48h (ileus), or all-cause mortality. Incidence of any one of the above complications (not including prolonged LOS) was described in a composite outcome: any complication.

Statistical analysis

To account for confounding relationships between BMI and outcomes, unique MVR models were constructed for each outcome and independent covariates were considered possible confounders and included in MVR models if a univariate relationship revealed an association at $p < 0.2$. Relationships were assessed between cohorts with the normal BMI patients set as reference. Unadjusted comparisons of continuous variables were performed using independent two-sample student's t-tests, Wilcoxon rank-sum (Mann-Whitney) tests and Kruskal-Wallis tests, as appropriate, and comparisons of proportions between cohorts were performed using Pearson's χ^2. Data are presented as means $\pm$ standard deviation, median with interquartile range (IQR), or counts with percentages as appropriate. Adjusted odds ratios (OR) are represented with the 95% confidence interval (CI). Statistical tests were two-sided and a $p < 0.05$ was considered statistically significant. Observations with missing values were censored from analysis. All statistical analyses were performed using Stata software (Version 14.2; StataCorp LLC; College Station, TX).

Results

Cohort patient and operative characteristics

A total of 2241 patients underwent proctectomy with histologically confirmed malignancy and met inclusion criteria. 748 (33.4%) had a normal BMI, 751 were overweight (33.5%), 472 were obese (21.1%), and 270 were morbidly obese (12.0%) at the time of surgery. As summarized in Table 1, factors associated with increased BMI class included hypertension, diabetes and white race, while clinical and pathologic stage were similar among cohorts.

Operative characteristics are shown in Table 2. Procedure type was well matched between cohorts, with the most common procedure type being APR (49.9–54.6%, $p = 0.34$). On unadjusted analysis, increasing BMI class was associated with increased risk of conversion to open approach when compared to normal BMI patients (9.9%, 15.0%, 22.2% vs 7.6%; $p < 0.001$). No difference was noted with respect to tumor location within the rectum ($p > 0.31$) between groups. Operative time was noted to increase with BMI class from a median of 258 min (95% CI: 199–341) in the normal BMI patients to 324 min (95% CI: 246–409) in the morbidly obese patients, $p < 0.001$. There was no noted difference in median nodal harvest between cohorts (median 16 for all, $p = 0.85$), however, a decreased rate of circumferential resection margin (CRM) positivity was observed in the obese (6.0%) and morbidly obese (4.1%) groups when compared to normal (8.8%, $p < 0.05$).

30-Day postoperative outcomes

On unadjusted analysis (Table 3), patients with morbid obesity demonstrated increased incidence of overall complications (53.0% vs 39.2%, $p = 0.001$). Increased superficial surgical site infection was observed in overweight (5.2%), obese (7.2%), and morbidly obese patients (10.7%) compared to normal BMI patients (2.9%; $p < 0.001$). No difference was observed in anastomotic leak (5.9%, 6.9%, 4.7%, vs 6.9%; $p = 0.85$) or major anastomotic leak requiring intervention (2.4%, 2.9%, 0.9%, vs 4.0%; $p = 0.41$) in patients who underwent proctectomy with entero-enteric anastomosis.

Risk adjusted odds of complications compared to normal BMI controls are displayed in Fig. 1, accounting for patient, procedure, and tumor characteristics. No adjusted differences in postoperative

Table 1
Patient characteristics.

Characteristic	BMI Class				*P*
	Normal	Overweight	Obese	Morbidly Obese	
	n = 748	n = 751	n = 472	n = 270	
Age, median (IQR)	63 (53–73)	62 (53–71)	63 (54–71)	60* (52–66)	0.004
Female, %	42.4%	32.0%*	35.6%*	45.9%	<0.001
Race/Ethnicity, %					
White	62.0%	65.3%	71.6%*	77.0%	<0.001
Black	5.4%	5.1%	4.7%	5.2%	0.96
Hispanic	4.7%	5.1%	3.6%	0.7%*	0.02
Asian	9.2%	4.7%*	2.1%*	0.7%*	<0.001
Other	18.7%	20.0%	18.0%	16.3%	0.58
Medical History, %					
Dyspnea	4.7%	3.2%	6.6%	10.4%*	<0.001
Smoking	22.1%	15.9%*	14.6%*	11.9%*	<0.001
Steroids	4.1%	3.9%	3.8%	3.0%	0.86
Preoperative Chemotherapy	53.7%	52.6%	50.8%	50.0%	0.65
Preoperative Radiotherapy	53.2%	51.1%	49.5%	48.7%	0.55
Weight Loss	9.5%	4.1%*	2.8%*	1.1%*	<0.001
Hypertension	30.2%	42.2%*	54.9%*	59.6%*	<0.001
Diabetes Mellitus	9.4%	15.3%*	21.8%*	30.4%*	<0.001
COPD	2.5%	2.4%	4.7%*	3.3%	0.11
CHF	0.3%	0.7%	0.2%	1.1%	0.25
Preoperative Cr > 1.2 mg/dL	8.8%	10.0%	10.6%	13.0%	0.27
Hypoalbuminemia	4.3%	2.0%*	1.7%*	2.2%	0.06
ASA, %					
1	2.7%	1.3%	0.4%*	1.5%	0.02
2	41.4%	42.9%	33.3%*	17.4%*	<0.001
3	52.8%	52.3%	62.5%*	75.6%*	<0.001
4	3.1%	3.5%	3.8%	5.6%	0.31
Clinical Stage, %					
0	0.1%	0.4%	0.0%	0.0%	0.33
1	9.6%	10.1%	9.5%	13.0%	0.43
2	19.1%	18.4%	15.5%	17.8%	0.43
3	34.1%	32.5%	34.3%	32.6%	0.87
Missing data	37.0%	38.6%	40.7%	36.7%	0.58
Pathologic Stage, %					
1	30.1%	36.1%*	33.5%	40.0%*	0.01
2	33.0%	31.3%	30.9%	26.3%*	0.24
3	36.9%	32.6%	35.6%	33.7%	0.35

* $p < 0.05$ in reference to Normal BMI cohort; IQR: Interquartile range, Preoperative = within 90 days, COPD: Chronic Obstructive Pulmonary Disease, CHF: Congestive Heart Failure, Cr: Serum Creatinine, ASA: American Society of Anesthesiologists score.

Table 2
Operative characteristics.

Characteristic	BMI Class				*P*
	Normal	Overweight	Obese	Morbidly Obese	
	n = 748	n = 751	n = 472	n = 270	
Proctectomy Type, %					
LAR	28.9%	32.9%	30.7%	33.7%	0.29
APR	54.6%	49.9%	53.2%	52.6%	0.34
Other Proctectomy	16.6%	17.2%	16.1%	13.7%	0.61
Entero-Enteric Anastomosis, %	36.8%	38.5%	36.9%	39.3%	0.83
Initial Approach, %					
Open	38.6%	37.8%	36.2%	41.5%	0.55
Laparoscopic	40.4%	38.2%	41.1%	36.7%	0.54
Robot	21.0%	24.0%	22.7%	21.9%	0.58
MIS Converted to Open	7.6%	9.9%	15.0%*	22.2%*	<0.001
Tumor Location, %					
Upper 1/3	12.4%	12.4%	12.3%	16.3%	0.35
Middle 1/3	26.6%	25.4%	29.7%	29.6%	0.31
Lower 1/3	46.1%	47.0%	45.3%	41.1%	0.41
Unknown	14.8%	15.2%	12.7%	13.0%	0.57
Operative time, median (IQR)	258 (199–341)	286* (227–381)	302* (229–387)	324* (246–409)	<0.001
Wound Class 3+, %	17.7%	16.5%	14.2%	18.5%	0.35
Positive DRM, %	1.9%	2.5%	1.5%	1.5%	0.54
Positive CRM, %	8.8%	6.8%	6.0%*	4.1%*	0.03
Any Positive Margin, %	9.2%	8.0%	6.4%	4.8%*	0.08
Nodes Evaluated, median (IQR)	16 (12–22)	16 (12–21)	16 (12–22)	16 (12–23)	0.85

* $p < 0.05$ in reference to Normal BMI cohort; LAR: Low anterior resection, APR: Abdominoperineal resection, MIS: laparoscopic or robot assisted, IQR: Interquartile range, DRM: Distal resection margin, CRM: Circumferential resection margin.

Table 3
Unadjusted outcomes.

Outcome, %	BMI Class				*P*
	Normal	Overweight	Obese	Morbidly Obese	
	n = 748	n = 751	n = 472	n = 270	
SSI	8.8%	12.0%*	14.4%*	18.5%*	<0.001
Superficial	2.9%	5.2%*	7.2%*	10.7%*	<0.001
Deep	0.8%	1.5%	1.5%	3.3%*	0.03
Organ space	5.8%	6.0%	7.2%	5.9%	0.76
Wound Dehiscence	1.5%	2.1%	1.5%	4.4%*	0.02
Sepsis	3.9%	4.1%	3.6%	5.9%	0.45
C. diff	0.7%	0.4%	1.1%	0.7%	0.59
UTI	1.7%	3.5%*	2.8%	4.8%*	0.05
Pneumonia	1.6%	1.1%	1.5%	1.5%	0.83
Reintubation	0.7%	0.3%	0.9%	0.7%	0.55
DVT	0.8%	1.5%	0.6%	0.7%	0.43
PE	0.3%	0.9%	0.6%	0.0%	0.19
Stroke	0.5%	0.4%	0.4%	0.0%	0.70
MI	0.8%	0.5%	0.6%	0.4%	0.86
Cardiac arrest	0.3%	0.1%	0.2%	0.0%	0.82
Renal Failure/Injury	0.9%	0.9%	1.5%	2.6%*	0.15
Bleeding	10.7%	11.2%	9.8%	15.9%*	0.07
Return to OR	5.9%	5.1%	4.2%	8.5%	0.09
Prolonged LOS	30.2%	28.8%	28.2%	37.4%*	0.04
Readmission	13.6%	16.9%	14.6%	19.6%*	0.08
Anastomotic Leak**	6.9%	5.9%	6.9%	4.7%	0.85
Major Leak	4.0%	2.4%	2.9%	0.9%	0.41
Ileus	18.9%	19.2%	17.4%	21.1%	0.66
Mortality	0.3%	0.1%	0.2%	0.4%	0.90
Any Complication	39.2%	42.9%	39.6%	53.0%*	0.001

* $p < 0.05$ in reference to Normal BMI cohort; **Only includes procedures with an enteroenteric anastomosis, SSI: Surgical Site Infection, UTI: Urinary Tract Infection, DVT: Deep Vein Thrombosis, PE: Pulmonary Embolism, MI: Myocardial infarction, OR: Operating Room, Prolonged LOS: Length of Stay in 75th percentile, Major Leak: requiring percutaneous or operative intervention.

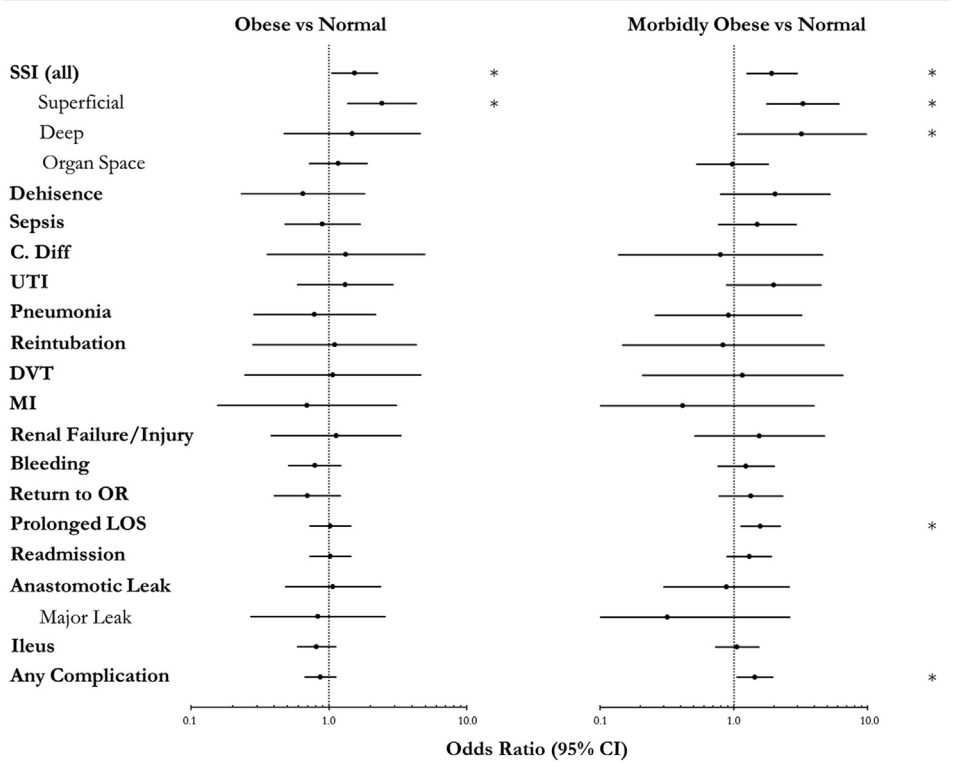

Fig. 1. Effect of BMI class on adjusted risk of outcomes compared to normal BMI.
* $P < 0.05$; SSI: surgical site infection, UTI: urinary tract infection, DVT: deep vein thrombosis, MI: myocardial infarction, OR: operating room, Prolonged LOS: Length of Stay in 75th percentile, Major Leak: requiring percutaneous or operative intervention.

complications were observed in overweight patients in comparison to normal BMI patients. On multivariable analysis, obese patients demonstrated no difference in adjusted risk of any complications (OR 0.87, 95% CI: [0.67–1.12]). However, increased risk of superficial SSI was observed in obese patients when compared to normal BMI (OR 2.42, 95% CI: [1.36–4.29]). Morbid obesity was associated with increased risk of any complication (OR 1.44, 95% CI: [1.05–1.96]), superficial SSI (OR 3.29, 95% CI: [1.77–6.11]), deep SSI (OR 3.22, 95% CI: [1.07–9.75]), and risk of prolonged LOS (OR 1.58, 95% CI: [1.13–2.22]). Obesity class was not associated with risk adjusted odds of anastomotic leak: overweight OR 0.93 [95% CI: 0.45–1.91], obese OR 1.07 [95% CI: 0.48–2.36], morbidly obese OR 0.88 [95% CI: 0.30–2.5]. BMI class was similarly not associated with organ space SSI, wound dehiscence, sepsis, C. diff infection, pneumonia, reintubation, DVT, MI, renal failure/injury, bleeding requiring transfusion, return to the OR, 30-day readmission, or postoperative ileus. PE, stroke, cardiac arrest, and 30-day mortality were not examined in adjusted analysis due to event rates less than 0.1% in one or more BMI classes.

Discussion

In this retrospective review of 2241 patients undergoing elective proctectomy for cancer, BMI class was a significant risk factor for 30-day postoperative complications, primarily owing to increased incidence of deep and superficial SSI. With increasing BMI class, we observed increasing adjusted risk of SSI, most commonly superficial SSI. However, our data do not suggest that obesity independently increases risk for anastomotic leak in patients undergoing proctectomy for cancer. Our analysis supports previous studies which have demonstrated an association between increased BMI and increased risk of SSI.[1–6] For example, using NSQIP data from 2005 to 2011, Smith et al. found that patients with BMI $\geq$35 kg/m^2 demonstrated a more than 3-fold increased risk of SSI following proctectomy for rectal cancer (OR 3.42, 95% CI: [2.81–4.15]).[4] In addition, a 2016 meta-analysis of 290 articles found that obesity is associated with an increased risk of wound infections (OR 2.22, 95% CI: [1.47–3.36]) in rectal cancer patients.[3] We recognize this risk factor has been previously described, however, our analysis is strengthened by the availability of procedure-targeted variables to improve risk adjustment in a large contemporary population during an era of increased utilization of minimally invasive techniques and enhanced-recovery protocols.

We found no difference however, in risk of anastomotic leak in our obese and morbidly obese cohorts. While our retrospective analysis is underpowered to definitively deny this association, it provides multi-institutional evidence from trained clinical abstracters at hundreds of centers nationally in a contemporary sample that is lacking from prior studies. In a single-institution review of 471 patients treated between 1976 and 2011, Aytac and colleagues observed that obese patients with a BMI $\geq$30 kg/m^2 demonstrated an increased risk of anastomotic leak (12.2% vs 2.3%, $p < 0.001$) on matched analysis.[12] However, this study was limited by inclusion of patients prior to the advent of minimally invasive approaches, and included a lesser percentage of sphincter-sacrificing procedures (20.8%). A single-center French study, also found that a BMI >27 was associated with increased risk of anastomotic leak (16% vs 7%, $p < 0.05$), however this was an unadjusted comparison and cohorts had significantly different anastomotic and tumor characteristics.[11] Again understanding the limitations of our analysis, when rectal surgeons are considering an anastomosis versus end stoma, our findings suggest that increased BMI does not independently confer increased risk of anastomotic leak.

Of utmost importance in proctectomy for malignancy is the oncologic efficacy of the procedure. Similar to prior findings,[9,14] we observed on unadjusted analysis that increasing BMI class was associated with increased operative time in a dose-dependent pattern. This observation, along with the increased minimally invasive to open conversion rate seen in our obese and morbidly obese cohorts, provide evidence to support surgeon anecdotal claims that obesity increases technical difficulty of proctectomy. An increased conversion rate in obese populations has been previously described.[3] Our study supports that although operative time and conversion rates are increased, the oncological efficacy of the procedure is not sacrificed as evidenced by equal nodal harvests and reduced rates of overall specimen margin positivity in morbidly obese patients when compared to normal (4.8% vs 9.2%, $p = 0.08$). The reduced rate of margin positivity seen in obese patients requires further adjusted investigation, however, others have shown that visceral obesity (as measured via computed tomography) can be used as a predictor of survival following TME for rectal adenocarcinoma.[19] Perhaps increased adiposity in the mesorectum provides a protective mechanism against circumferential resection margin positivity during TME. Of course in the absence of long term follow-up we are not able to extrapolate these outcomes to determine important long-term oncologic outcomes such as disease free survival (DFS), however, in a single institutional review of 596 patients with locally advanced rectal cancer, researchers from the Memorial Sloan-Kettering Cancer Center found no difference in DFS ($p = 0.75$) or overall survival ($p = 0.92$) between patients with obesity vs those with a normal BMI at a median follow-up of 39 months.[14] These data emphasize the preserved oncologic efficacy of proctectomy in patients with increased BMI.

There are several limitations to this analysis. We utilize a large patient-based retrospective data source which allows for potential sampling bias limiting the external generalizability of our conclusions. In addition, inherent to the selection of certain CPT codes to be included in the “Procedure-Targeted Proctectomy” file, our analysis does not include rectal cancer patients who may have undergone a distal colectomy with low-pelvic coloproctostomy (CPT 44145, 44146, 44207, and 44,208) which is classified by NSQIP in the “Colectomy” file. This exclusion explains the selection of our population with almost half of patients having tumors in the lower 1/3 of the rectum and more than half of patients undergoing APR – proportions that may not be nationally representative for all rectal cancer patients. In addition, our findings describe outcomes from participating NSQIP institutions and external generalizability should be cautioned.

In a large review of greater than two thousand proctectomies for cancer, we found that increasing BMI class is associated with increased adjusted risk of SSI. These data have important clinical implications supporting the use of more consistent perioperative measures for SSI prevention. Perhaps more aggressive use of SSI reduction bundles (preoperative hair removal, skin cleansing, antibiotic prophylaxis, intraoperative wound protectors, antibiotic wound irrigation, normothermia, antibiotic impregnated sutures, postoperative chlorhexidine washes, or advanced wound dressings) may be employed to reduce SSI incidence in these high-risk populations. Also, as BMI is a known modifiable risk factor for several adverse outcomes, these data support aggressive preoperative counseling on risk optimization via weight loss strategies in the elective setting. Collectively, our study provides surgeons, patients, and stakeholders with an enhanced contemporary analysis of the increased SSI risk observed in obese populations and may inform future discussions and interventions.

Conclusion

Morbid obesity is independently associated with an increased composite odds risk of short-term morbidity following elective

proctectomy for cancer. This increased odds risk is driven primarily by increased risk of superficial surgical site infection. After controlling for patient, procedure, and tumor characteristics, BMI class does not demonstrate an association with anastomotic leak indicating BMI class alone should not significantly deter surgical decision-making to perform anastomoses in this population. Future quality efforts may be directed at more aggressive SSI prevention techniques for obese and morbidly obese patients undergoing oncologic proctectomy.

Declaration of competing interests

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article. Author MAS discloses consulting interests with Ethicon, Olympus, and Applied. Institutional resources provided financial support for this study and no external funding was received.

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