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Surgical Site Infection Impact of Pelvic Exenteration Procedure

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Background: We sought to investigate morbidity and infectious complications following pelvic exenteration (PEX) and compare infectious complications of patients undergoing PEX and conventional rectal resections.

Methods: The NSQIP database was utilized to examine the clinical data of patients undergoing elective rectal resections during 2005–2013. Multivariate regression analysis was used to compare postoperative complications of patients who underwent PEX and proctectomy procedure.

Results: We sampled a total of 7,950 patients who underwent rectal resection. Of these, 303 (3.8%) patients underwent pelvic exenteration. Mortality, morbidity, and infectious complications of patients who underwent pelvic exenteration were 1.7%, 65.7%, and 42.6%, respectively. Patients who underwent PEX had a significantly higher rate of morbidity (AOR: 2.01, $P < 0.01$), overall infectious complications (AOR: 1.49, $P < 0.01$), hemorrhagic complications (AOR: 3.36, $P < 0.01$), and surgical site infections (SSI) (AOR: 1.23, $P = 0.04$) compared to patients who underwent proctectomy. Return to operation room (AOR: 4.99, $P < 0.01$), obesity (AOR: 1.43, $P < 0.01$), disseminated cancer (AOR: 1.30, $P = 0.01$) were significantly associated with SSI complications.

Conclusion: Postoperative morbidity and infectious complication are significantly higher after PEX procedure. Return to operation room, obesity, and disseminated cancer are strongly associated with surgical site infections complications in rectal surgery. Specific consideration to infectious complications is recommended for these patients.

Introduction

Colorectal cancer is the third most common cancer and one of the leading causes of death from cancer in western countries [1,2]. Surgery is the only curative treatment and complete tumor resection with negative margins is the most important prognostic factor in colorectal cancer surgery [3]. However, for some patients with locally advanced rectal malignancy, it is difficult to obtain negative margins without resecting adjacent organs/structures. Pelvic exenteration (PEX) procedure has been reported as the only curative option for such patients [4].

Although PEX is associated with a significant survival benefit, overall morbidity rate is reported to be more than fifty percent [5–7]. Moreover, the rates of wound infection and intra-abdominal abscess have been reported to be as high as 40% and 20%, respectively in literature [6]. Identifying risk factors associated with PEX may help curb the significant morbidity related to this procedure. This study aims to investigate risk

factors associated with morbidity and mortality after PEx procedure for rectal cancer and compare infectious complications with proctectomy (e.g., low anterior resection [LAR] and abdominoperineal resection [APR]) in rectal cancer.

Materials and Methods

This study was derived from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database between 2005 and 2013 [8]. ACS NSQIP is a large multiinstitutional database which provides pre-operative to 30-day postoperative clinical information of patients undergoing major surgical procedures in the United States [8]. This study evaluated patients who underwent PEx and proctectomy (APR, LAR) procedures using the appropriate codes as specified by the Current Procedural Terminology (CPT) codes of 45110, 45111, 45112, 45113, 45114, 45119, 45120, 45121, 45126, 45395, and 45397. Patients admitted emergently, moribund patients (American Society of Anesthesiologists score five), patients younger than 18 years old, and patients who underwent rectal resection with minimally invasive approaches were excluded from this study. We only included patients with the diagnosis of rectal cancer according to International Classification of Diseases, 9th Revision, and clinical modifications (ICD-9-CM) diagnosis codes of 154.0–154.8. Pelvic Exenteration is defined as all procedures which include proctectomy with removal of bladder and ureteral transplantation and/ or hysterectomy, or cervicectomy, with or without removal of tubes, with or without removal of ovaries, or any combined thereof.

Variables examined consisted of basic demographic data (age, sex, and race), American Society of Anesthesiologists (ASA) score, preoperative serum albumin level, preoperative sepsis, septic shock, or Systemic Inflammatory Response Syndrome (SIRS), wound classification (clean, clean/contaminated, contaminated, and dirty), operation length, return to operation room in 30 days of surgery, and comorbidity conditions of history of ischemic heart disease (congestive heart failure, myocardial infarction, cardiac surgery, percutaneous coronary intervention, and cardiac angina), obesity, renal failure (acute renal failure or chronic renal failure requiring dialysis), bleeding disorders, hypertension, diabetes mellitus with oral agents or insulin, chronic steroid use (duration more than 10 days in 30 days of surgery), weight loss (more than 10% in the last six months), history of pulmonary disease (chronic obstructive pulmonary disease, current pneumonia, dyspnea, and ventilator dependency), disseminated cancer (rectal cancer that has metastasized or disseminated to a major organ), and current smoker within one year. Outcomes investigated included: mortality, overall morbidity, and postoperative complications (as listed in Table II). The overall rates of each complication were examined. Risk-adjusted analysis was performed to compare the outcomes of patients who underwent PEx with patients underwent proctectomy.

Statistical Analysis

We performed our statistical analyses using the SPSS[®] software, Version 22 (SPSS Inc., Chicago, IL). Multivariate analysis using logistic regression analysis was utilized to estimate the impact of PEx on postoperative complications. The postoperative complications were measured as the dependent variable and all perioperative factors were

entered into the risk adjustment analysis as covariates. P-values less than 0.05 were considered statistically significant. For each outcome, the adjusted odds ratio (AOR) with a 95% confidence interval was calculated and reported to estimate the relative risk associated with PEx. Adjustment was made for all variables of the study.

Results

The study population consisted of 7,950 patients who underwent proctectomy or PEx between 2005 and 2013, of these, 303 (3.8%) patients underwent PEx. The median age of patients was 62 years old, 60.7% were male, and the majority of the patients were Caucasian (85.2%). The most common comorbidities included hypertension (47.2%), obesity (30.4%), and diabetes (15.4%). Patients who underwent PEx and proctectomy were compared for factors such as demographic data, comorbidities, and preoperative laboratory values. Patients who underwent PEx had a significant longer operation length compared to proctectomy procedure (mean difference 129 min, CI: 117–141, $P < 0.01$). Also, total hospital stay for patients who underwent PEx was significantly longer than those who underwent proctectomy (mean difference 3 days, CI: 2–4, $P < 0.01$). Summary of demographic data of patients are shown in Table I.

Mortality rate of patients who underwent PEx and proctectomy were 1.7% and 1.1%, respectively. Multivariate analysis did not show significant differences in mortality (AOR: 1.33, $P = 0.65$). However, patients who underwent PEx had significantly higher morbidity (AOR: 2.01, $P < 0.01$) (Table II).

Overall infectious complications after PEx and proctectomy were 42.6% and 26.6%, respectively. Patients who underwent PEx had a significant higher rate of infectious complications (AOR: 1.49, $P < 0.01$). The risk-adjusted analysis for postsurgical complications after PEx and proctectomy is reported in Table II. Postoperative hemorrhagic complications (AOR: 3.36, $P < 0.01$), ventilator dependency (AOR: 2.26, $P < 0.01$), and septic shock (AOR: 2.35, $P = 0.03$) were significantly higher in patients who underwent PEx.

Finally, the risk-adjusted analyses for factors associated with surgical site infection complications are reported in Table III. Factors such as return to operation room (AOR: 4.99, $P < 0.01$), obesity (AOR: 1.43, $P < 0.01$), and disseminated cancer (AOR: 1.30, $P = 0.01$), were associated with higher rates of surgical site infections. Also, serum albumin level was reversely associated with surgical site infections.

TABLE I. Demographics of Patients Who Underwent Rectal Resection

Variables	Patients underwent pelvic exenteration(303)	Patients underwent proctectomy (7647)	P-value
Age			
Mean ± SD (year)	58 ± 11	61 ± 13	<0.01
Median (year)	57	62	—
Sex			
Male	163 (53.8%)	4660 (61%)	<0.01
Race			
White	235 (86.7%)	5836 (85.2%)	0.29
Black or African American	18 (6.6%)	637 (9.3%)	<0.01
Asian	13 (4.8%)	258 (3.8%)	<0.01
Others	5 (1.8%)	121 (1.8%)	0.33
Comorbidity			
Hypertension	112 (37%)	3639 (47.6%)	0.01
Disseminated cancer	100 (33%)	660 (8.6%)	<0.01
Obesity	63 (21.1%)	2323 (30.8%)	<0.01
Weight loss	53 (17.5%)	530 (6.9%)	0.13
Diabetes mellitus	33 (10.9%)	1192 (15.6%)	<0.01
Anemia	33 (11.2%)	326 (4.4%)	<0.01
Pulmonary disease ^a	22 (7.3%)	770 (10.1%)	<0.01
Ischemic heart disease ^b	8 (2.6%)	497 (6.5%)	0.03
Steroid use	9 (3%)	169 (2.2%)	0.22
Bleeding disorder	5 (1.7%)	212 (2.8%)	0.35
Renal failure ^c	2 (0.7%)	36 (0.5%)	0.93
Ascites	2 (0.7%)	19 (0.2%)	0.20
White blood cell count			
Mean ± SD (cell/mm ³)	7.7 ± 2.7	6.3 ± 2.5	<0.01
Median	6.6	5.9	—
ASA score ^d			
I	1 (0.3%)	148 (1.9%)	<0.01
II	95 (31.4%)	3264 (42.7%)	<0.01
III	191 (63%)	3979 (52%)	<0.01
IV	16 (5.3%)	256 (3.3%)	0.15
Intraoperative transfusion ^e			
No transfusion	191 (71.3%)	4461 (89.1%)	<0.01
One or two units	23 (8.6%)	371 (7.4%)	0.02
More than two units	54 (20.1%)	173 (3.5%)	<0.01
Serum albumin level			
Mean ± SD (g/dL)	3.6 ± 0.6	3.8 ± 0.5	<0.01
Median	3.8	3.9	—
Other factors			
Operation length > 4 hours	288 (95%)	3565 (46.6%)	<0.01
Smoking	85 (28.1%)	1581 (20.7%)	<0.01
Return to operation room	28 (9.2%)	553 (7.2%)	<0.01
Preoperative sepsis ^f	9 (3%)	89 (1.2%)	0.01

^aPreoperative pneumonia, chronic obstructive pulmonary disease, ventilator dependency before surgery, and preoperative dyspnea.

^bCongestive heart failure, cardiac angina, history of cardiac surgery, history percutaneous coronary intervention, history of myocardial infarction.

^cAcute renal failure or chronic renal failure need for dialysis.

^dAmerican Society of Anesthesiologists score.

^eIntraoperative transfusion of packed cell or whole blood.

^fPreoperative sepsis, septic shock, Systemic Inflammatory Response Syndrome.

TABLE II. Risk Adjusted Analysis of Outcomes of the Pelvic Exenteration Procedure Compared to the Proctectomy Procedure

Complication	Pelvic exenteration (303)	Proctectomy (7647)	Adjusted odds ratio	95% confidence interval	P-value
Mortality	5 (1.7%)	84 (1.1%)	1.33	0.37–4.68	0.65
Overall morbidity	199 (65.7%)	2834 (37.1%)	2.01	1.48–2.74	<0.01
Infectious complications ^a	129 (42.6%)	2031 (26.6%)	1.49	1.11–2.01	<0.01
Overall SSI ^b	87 (28.7%)	1527 (20%)	1.23	1.03–1.71	0.04
Hemorrhagic complications	117 (38.6%)	904 (11.8%)	3.36	2.32–4.87	<0.01
Septic shock	12 (4%)	111 (1.5%)	2.35	1.08–5.10	0.03
Ventilator dependency	18 (5.9%)	146 (1.9%)	2.26	1.14–4.49	0.01
Unplanned intubation	13 (4.3%)	160 (2.1%)	2.18	1.04–4.55	0.03
Pneumonia	17 (5.6%)	177 (2.3%)	2.08	1.11–3.90	0.02
Hospitalization > 30 days	13 (4.3%)	154 (2%)	1.95	1.01–3.84	0.04
Organ space SSI ^a	33 (10.9%)	437 (5.7%)	1.85	1.16–2.793	<0.01
Sepsis	36 (11.9%)	420 (5.5%)	1.48	0.92–2.37	0.10
Cardiac arrest	2 (0.7%)	32 (0.4%)	3.05	0.57–16.22	0.18
Urinary tract infection	31 (10.2%)	433 (5.7%)	1.31	0.81–2.12	0.25
Superficial SSI ^c	46 (15.2%)	916 (12%)	1.16	0.78–1.72	0.46
Deep vein thrombosis	9 (3%)	117 (1.5%)	1.20	0.54–2.70	0.64
Pulmonary embolism	4 (1.3%)	54 (0.7%)	1.18	0.32–4.29	0.79
Acute renal failure	2 (0.7%)	49 (0.6%)	0.85	0.18–3.93	0.84
Progressive renal insufficiency	4 (1.3%)	98 (1.3%)	0.54	0.12–2.36	0.42
Wound disruption	9 (3%)	202 (2.6%)	0.60	0.25–1.41	0.24
Myocardial infarction	1 (0.3%)	58 (0.8%)	0.58	0.07–4.48	0.60
Deep incisional SSI ^c	12 (4%)	366 (3.5%)	0.80	0.43–1.49	0.49

^aPneumonia, Sepsis, Septic Shock, Superficial SSI, Organ Space SSI, Urinary Tract Infection, and Deep Incisional SSI.

^bSuperficial SSI, Organ Space SSI, and Deep Incisional SSI

^cSurgical Site Infection.

Discussion

Compared to proctectomy, pelvic exenteration is associated with significantly higher rate of infectious complications. We found almost half (42.6%) of patients who underwent PEx had an infection complication. Also, we found that surgical site infections rate is significantly higher in PEx compared to proctectomy. According to the literature, infectious complications are the most common complication after PEx [3], which may be justified by the characteristic patient population who generally tend to undergo PEx (i.e. more advanced disease) compared to those who undergo proctectomy alone. For example, we found that patients who underwent PEx had a significantly higher rate of disseminated cancer compared to those who underwent proctectomy. Also, serum albumin level in surgical patients was inversely associated with mortality, and albumin was significantly lower in patients who underwent PEx [9–11]. Patients who undergo PEx procedure also appear to be more ill with greater risk factors for postoperative infectious complications than patients undergoing proctectomy. Minimizing risk factors for postoperative infection prior to operation may be the best way to reduce postoperative infectious complications in patients undergoing PEx.

Pelvic exenteration is associated with a high complication rate. We found most of patients who underwent PEx had a postoperative complication (65.7%). When comparing our results with previous published studies, although the mortality rate after PE has significantly diminished during the last few decades, the morbidity rate remains high. In the 19 the operative mortality rate of patients who underwent PEx was more than 20%; however, the mortality rate has decreased to 5% over the past decade and to less than 2% in our study and other more recent studies [6,7,12–14]. Refinements in surgical technique, improved anesthesia care, and improvement in perioperative care are factors likely responsible for improved operative mortality [6]. However, high morbidity rate of PEx is still a challenge as our results did not show significant decreases in morbidity of PEx during the 9 years of our study. Recent published studies reported morbidity rate greater than 60% for PEx which is in line with our result [3,4,7,14]. The considerable morbidity rate associated with PEx can be explained by more advanced disease in

patients who generally undergo PEx, factor that naturally make them more prone to develop postoperative complications. Intensive perioperative care for patients who underwent PEx is needed. Due to the considerable morbidity associated with PEx candidates for PEx should be referred to tertiary centers where adequate staffing and surgical experience may be more readily available [15].

Perioperative factors can predict the risk of postoperative surgical site infections in patients who underwent rectal resection. We found the return to the operation room is the strongest predictor of surgical site infections in rectal resection which increases the risk of surgical site infection complications by more than four times. Return to operation rooms has been introduced as a factor which increases mortality, morbidity, and infectious complications following different operations [16,17]. Also, we found operation length is associated with postoperative infectious complications in rectal cancer surgery. We found a 34% increase in risk of infectious complications in operations longer than four hours. Associations between operative time and infectious complications have been cited multiple times [20,21]. Not surprisingly, we observed that 95% of PEx procedures lasted more than four hours. Patients undergoing PEx may benefit from a decrease of the operation length.

Our study results show that disseminated cancer strongly associated with postoperative surgical site infections. Our results confirm prior studies that report advanced tumor stage as an independent risk factor for postoperative infectious complications following colorectal surgery [18]. However, with the possible exception of serum albumin level, other risk factors elucidated in this study are nonreducible in a given patient. Although malnutrition is independently associated with infectious complications after colorectal surgery [18], a decrease in serum albumin level does not necessarily correlate with malnutrition in surgical patients and serum albumin level can reflect the overall clinical status of patients rather than nutritional status in surgical patients [9,10]. Further clinical trials are needed to confirm whether correcting serum albumin levels in patients with advance malignancy can decrease complications.

Hemorrhagic complications are one of the most common complications in patients who underwent rectal cancer surgery, and were significantly higher after PEx compared to proctectomy procedure. Our study shows rates of 38.6% for hemorrhagic complications after PEx which is in line with prior reports of 32% [7]. Also, we have found that patients who underwent PEx required significantly more blood products compared to proctectomy. Although previous studies report higher rates of infectious complications with increasing use of intraoperative packed cell transfusion, our multivariate analysis did not show intraoperative transfusion as a predictor of surgical site infections [19].

TABLE III. Risk Adjusted Analysis of Factors Associated With Surgical Site Infection Complications

Variables	Adjusted odds ratio	95% confidence interval	P-value
Age			
Age	0.99	0.98–0.99	<0.01
Sex			
Female	References	References	References
Male	1.22	1.06–1.42	<0.01
Comorbidity			
Obesity	1.43	1.23–1.67	<0.01
Disseminated cancer	1.30	1.05–1.61	0.01
Pulmonary disease ^a	1.33	1.07–1.66	<0.01
Ischemic heart disease ^b	1.09	0.82–1.47	0.53
Weight loss	0.90	0.70–1.16	0.45
Steroid use	0.82	0.52–1.29	0.40
Diabetes mellitus	1.24	1.02–1.51	0.02
Anemia	1.02	0.74–1.40	0.89
Hypertension	1.02	0.87–1.20	0.72
Ascites	0.65	0.17–2.43	0.52
Renal failure ^c	0.96	0.39–2.36	0.93
Bleeding disorder	0.59	0.37–1.07	0.11
Procedure			
Proctectomy	References	References	References
Pelvic exenteration	1.23	1.03–1.71	0.04
Intraoperative transfusion ^d			
No transfusion	References	References	References
One or two units	1.14	0.84–1.55	0.37
More than two units	1.17	0.79–1.72	0.42
Other factors			
Return to operation room	4.99	4.02–6.19	<0.01
Operation length > 4 hours	1.34	1.15–1.55	<0.01
Serum albumin level	0.85	0.74–0.97	0.01
Smoking	1.12	0.95–1.33	0.16
Serum white blood cell count	1.01	0.98–1.04	0.28
Preoperative sepsis ^e	1.13	0.65–1.97	0.64

^aPreoperative pneumonia, chronic obstructive pulmonary disease, ventilator dependency before surgery, and preoperative dyspnea.

^bCongestive heart failure, cardiac angina, history of cardiac surgery, history percutaneous coronary intervention, history of myocardial infarction.

^cAcute renal failure or chronic renal failure need for dialysis.

^dIntraoperative transfusion of packed cell or whole blood.

^ePreoperative sepsis, septic shock, Systemic Inflammatory Response Syndrome.

Study Limitations

The main limitation of this study was its retrospective nature, which make it difficult to draw any conclusion difficult. We compared postoperative complications of patients undergoing PEx and proctectomy. However, the patient populations undergoing PEx and proctectomy were understandably heterogeneous groups, including factors such as more patients in the PEx group with advanced disease. NSQIP database does not include some tumor-specific details, such as tumor pathology, prior history of rectal operations, perioperative antibiotic use, degree of complete tumor resection, assessment of quality of life following PEx, and long term oncological outcomes. Also, the reasons of offering PEx for patients who underwent PEx were not collected by NSQIP. Despite these limitations, this study is one of the largest reports on postoperative complications of patients who underwent PEx.

Conclusion

Postoperative morbidity and infectious complication are significantly higher after PEx procedure. Most of the patients who underwent PEx develop a postoperative complication (66%) and almost half (42.6%) of patients who underwent PEx had an infectious complication. Hemorrhagic complications are the second most common complication (39%) in patients who underwent PEx. Due to the considerable morbidity associated with PEx, candidates for PEx should be referred to tertiary centers where adequate staffing and surgical experience may be more readily available. Return to the operating room, obesity, disseminated cancer, and prolonged operation length are strongly associated with surgical site infection complications. Minimizing operative time may decrease morbidity and postoperative infectious complications in patients with advanced rectal cancer undergoing PEx.

Disclosures

Dr. Stamos has received educational grants and speaker fees paid to the Department of Surgery, University of California, Irvine, from Ethicon, Gore, Covidien, and Olympus. Dr. Mills and Dr. Carmichael received Ethicon educational grants paid to the Department of Surgery, University of California, Irvine. Dr. Pigazzi is a consultant for Intuitive Surgical and has also received consultancy fees and educational grants paid to the Department of Surgery, University of California, Irvine. Dr. Moghadamyeghaneh, Dr. Hwang, and Dr. Hanna have no disclosures. Dr. Moghadamyeghaneh had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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