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The effect of preoperative nutritional status on postoperative complications and overall survival in patients undergoing pelvic exenteration: A multi-disciplinary, multi-institutional cohort study

N.J. Lyell [a,*], M. Kitano [b], B. Smith [b], A.L. Gleisner [c], F.J. Backes [b], G. Cheng [d], M.D. McCarter [c], S. Abdel-Misih [b], E.L. Jones [c]

[a] University of Toledo College of Medicine and Life Sciences, Toledo, OH, USA
[b] The Ohio State University, James Cancer Hospital, Columbus, OH, USA
[c] Department of Gastrointestinal, Tumor and Endocrine Surgery, University of Colorado, Aurora, CO, USA
[d] Department of Obstetrics and Gynecology, University of Colorado, Aurora, CO, USA

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ABSTRACT

Introduction: Optimization of preoperative nutritional status has been recommended and associated with improved outcomes for other oncologic procedures, but has not been studied in patients undergoing pelvic exenteration.
Methods: A retrospective chart review of 199 patients was conducted. Overall survival (OS) was calculated using the Kaplan-Meier method and multivariate analysis was performed with Cox proportional hazards.
Results: 199 patients underwent PE with 61 (31%), 78 (40%) and 58 (29%) patients having colorectal, gynecologic and urologic histological diagnoses, respectively. Median OS following PE was 25 months. Preoperative serum albumin <3.5 g/dL was associated with worsened OS (HR 1.661; 95% CI 1.052–2.624) as well as increased incidence of any postoperative complication (85.9% vs 72.3%, $p = 0.034$), but was not associated with 90-day mortality (11.3% vs 7.9%, $p = 0.457$).
Conclusion: Poor preoperative nutritional status is associated with increased complications and decreased OS. Surgeons should maximize preoperative nutritional status to improve perioperative outcomes and long-term survival.

Introduction

Pelvic exenteration (PE) is a radical procedure that involves *en bloc* removal of most or all of the pelvic organs and is a requisite treatment option for patients with locally advanced or recurrent pelvic malignancies treated with curative and sometimes palliative intent. The extensive nature of the procedure and the restrictive anatomic boundaries of the pelvis were associated with increased morbidity and mortality in previous studies,[1–9] but the benefits of PE in select patients for both survival and quality of life reasons warrant its continued pursuit. When PE was originally reported by Dr. Alexander Brunschwig in 1948, the surgical mortality rate was 23% and long-term survival rates were low.[10] Improved criteria for patient selection, implementation of reconstructive measures and advancements in surgical techniques have brought current mortality rates down to 0–8% and significantly increased long-term survival, yet, postoperative complications still occur at rates of up to 86% of patients undergoing PE.[1–9]

Given the high rate of morbidity associated with PE and the relative lack of viable, preoperative indicators associated with successful outcomes, further study into predictive factors is warranted. Some factors such as margin status and lymph node involvement have been thoroughly studied, however, these factors are pathologic and are therefore difficult to predict prior to exenteration.[11–16] Preoperative nutritional status is commonly assessed and has been associated with an increased risk of complication including anastomotic leak.[17] Optimization of nutritional status, if possible, has thus been recommended and has demonstrated improved outcomes following other major abdominal and oncologic procedures.[18–23] Investigation into the

* Corresponding author.
E-mail address: Nathaniel.lyell@rockets.utoledo.edu (N.J. Lyell).

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nutritional impact on outcomes of PE is limited and previous studies have focused mainly on body mass index (BMI) and are limited to a small number of patients.[24] The purpose of this study was to elucidate the effect of preoperative nutritional status on morbidity and survival in patients undergoing PE regardless of the diagnosis. Our hypothesis is that poor preoperative nutritional status is associated with increased incidence of postoperative complications and worsened overall survival (OS).

Material and methods

An IRB-approved, retrospective chart review was undertaken of 199 patients who underwent PE for locally advanced or recurrent pelvic malignancies at the University of Colorado and the Ohio State University Wexner Medical Center from January 2000 to January 2014 and from January 2002 to January 2015, respectively. Indications for surgery for colorectal, genitourinary, or gynecologic malignancies were included independent of curative or palliative indication and primary or recurrent disease. Patients were excluded if pathologic data was not available. Primary surgical services included gynecologic oncology, surgical oncology and urologic oncology, however, many of the surgical teams were multidisciplinary, including vascular surgery and plastic surgery along with a combination of the aforementioned primary services. For patients undergoing exenteration for recurrent disease, preoperative information including prior surgical history, prior chemotherapy, prior radiation therapy, time to recurrence, location of recurrence, and history of repeat surgery for recurrence was included. Type of exenteration (anterior, posterior or total) was recorded as well as creation of a neovagina, colostomy, urinary reconstruction or usage of intraoperative radiation therapy (IORT) when undertaken. Anterior exenteration included *en bloc* resection of the bladder (and prostate in males), urethra and the female reproductive organs. Posterior exenteration included *en bloc* resection of the rectum, distal sacrum and posterior lobe of the prostate or the posterior wall of the vagina with bladder preservation. Total exenteration included *en bloc* resection of the bladder, rectum, prostate or vagina and internal genitalia and distal sacrum.

Poor nutrition was defined as a preoperative serum albumin level less than 3.5 g/dL.[25] Clinicopathologic data obtained from patient medical records was recorded and included age, race, BMI, comorbid conditions and tobacco usage. Perioperative outcomes were recorded, including operative time, estimated blood loss (EBL), usage of intraoperative blood transfusion, intensive care unit (ICU) length of stay (LOS) and hospital LOS. Major postoperative complications were recorded within 30 days of surgery and included stroke, venous thromboembolism (VTE), cardiac events (myocardial infarction, atrial fibrillation, supraventricular tachycardia, atrial fibrillation or heart failure), respiratory complications (pneumonia, respiratory failure requiring mechanical ventilation >48 h or reintubation), sepsis, acute renal injury, fistula formation, surgical site infection (superficial or deep/organ space) chronic pain (>6 months) and chronic wound (>6 months). Readmission and reoperation rates were also recorded with a median follow-up time of 27 months (1–152 months). Pathologic information included tumor size and margin status. Survival outcomes reported included recurrence rates and OS.

Statistical methods

This study aimed to examine the incidence of perioperative and postoperative morbidity as well as 30-day, 90-day and long-term survival as outcome measures. Disease free survival was defined as the time from PE to the date of first recurrence. Patients who died without evidence of disease recurrence were censored at the time of death. Overall survival was defined as the time from PE until the date of death from disease or complications of surgery. Patients who had not developed recurrent disease or died at the time of analysis were censored at the date of last follow up or known to be alive. Survival estimates were calculated with the Kaplan-Meier method with two-sided, 95% confidence intervals estimated using exact binomial methods for survival proportions based on Greenwood's formula. Comparison between the estimates for patients with adequate versus poor nutritional status was performed with the log rank test. Categorical characteristics were compared using Fisher's exact test of association and chi-square analysis. Continuous characteristics were compared using the Mann-Whitney U test and two-sample unpaired t-tests with Welch's correction. Prior to testing, normality was checked using the D'Agostino-Pearson omnibus normality test. All statistical analyses were run using Stata 12.1, Stata Corporation, College Station, Texas.

Results

There were 199 patients who underwent PE for locally advanced or recurrent pelvic malignancy. Of these, 50 patients (25.1%) underwent anterior PE, 17 patients (8.5%) underwent posterior PE and 132 patients (66.3%) underwent total PE. (Table 1). There were 36 patients (18.1%) that underwent PE for palliative intent while the remaining patients underwent PE for curative intent. Forty-eight patients (24.1%) were male and the median age of all patients was 55 years (range 22–85 years) with a mean BMI of 27.1 (range 14.3–60.1). There were 129 patients (64.8%) who underwent prior surgery related to the recurrent malignancy a mean 35 months earlier (range 1–222 months). Prior to recurrence, 28 patients (14.1%) underwent chemotherapy alone and 20 patients (10.1%) had prior radiation alone. Fifty-one patients (25.6%) received both chemotherapy and radiation prior to recurrence.

Perioperative complications occurred in 177 patients (88.9%) within 30 days of surgery (Table 2). Ninety-three patients (46.7%) died of recurrent disease or surgical complication during follow-up. The most common complication was a deep space/organ infection in 67 patients (33.7%) followed by chronic pain (>6 months) (63 patients, 31.7%) and chronic wound(s) (>6 months) (55 patients, 27.6%). Superficial wound infections occurred in 46 patients (23.1%). A total of one hundred nineteen patients (59.8%) required postoperative blood transfusion and twenty-two patients (11.1%) required re-intervention for a complication; most commonly, radiographic drainage for deep space/organ infections (61 patients, 30.7%) or surgical fistula takedown (26 patients, 13.1%). The mean LOS was 16 days (4–68 days) and the 90-day readmission rate was 53%. In this cohort, only one patient died within 30 days of exenteration (0.5%). Median survival after PE was 25 months. Overall 1-year, 3-year and 5-year survival was 66.7%, 51.4% and 33.5%, respectively.

In specifically examining nutritional parameters related to patient outcomes, the median preoperative serum albumin level of patients in this cohort was 3.6 g/dL. There were 71 patients (35.7%) who presented with preoperative serum albumin level of <3.5 g/dL. Poor preoperative nutritional status was associated with increased incidence of postoperative complications (87.1% vs. 72.4% $p = 0.02$), however, the risk of readmission and reoperation was not increased with poor nutritional status. Preoperative albumin level was not associated with 90-day mortality (11.3% vs 7.9%, $p = 0.457$). Poor nutritional status with serum albumin level of <3.5 g/dL was associated with worsened long-term survival (HR 1.661; 95% CI

Table 1
Patient clinicopathologic characteristics.

Characteristic	Cohort (n = 199)	Albumin ≥ 3.5 g/dL (n = 101)	Albumin < 3.5 g/dL (n = 71)	*p*-value
Median age at diagnosis (range)	55 (22–85)	56 (25–80)	57 (23–85)	0.774
Gender				0.723
Male	48 (24.1%)	26 (25.7%)	20 (%)	
Female	151 (75.9%)	75 (74.3%)	51 (%)	
Race/Ethnicity				
Caucasian	156 (78.4%)	81 (80.2%)	51 (71.8%)	0.201
African American	8 (4.0%)	4 (4.0%)	3 (4.2%)	0.760
Hispanic/Latino	6 (3.0%)	2 (2.0%)	3 (4.2%)	0.688
Other	4 (2.0%)	1 (1.0%)	2 (2.8%)	0.757
Not reported	25 (12.6%)	13 (12.9%)	12 (16.9%)	0.460
BMI				
>30	52 (26.1%)	25 (24.7%)	15 (21.1%)	0.217
18.5–30	127 (63.8%)	70 (69.3%)	44 (62.0%)	0.316
<18.5	15 (7.5%)	4 (4.0%)	9 (12.7%)	0.033
Not reported	5 (2.5%)	2 (2.0%)	3 (4.2%)	0.688
Comorbidity				
Diabetes mellitus	9 (4.5%)	5 (4.9%)	3 (4.2%)	0.824
Hypertension	34 (17.1%)	22 (21.8%)	11 (15.5%)	0.302
Hyperlipidemia	3 (1.5%)	2 (2.0%)	2 (2.8%)	0.720
Obesity	7 (3.5%)	3 (3.0%)	2 (2.8%)	0.953
Primary service				
Surgical oncology	58 (31.9%)	37 (36.6%)	29 (40.8%)	0.576
Gynecologic oncology	85 (46.7%)	38 (37.6%)	31 (43.7%)	0.426
Urologic oncology	39 (21.4%)	26 (25.7%)	11 (15.5%)	0.107
Histologic diagnosis				0.688
Uterine/Endometrial	13 (7.1%)	5 (4.9%)	4 (5.6%)	0.843
Cervical	34 (18.7%)	18 (17.8%)	12 16.9 (%)	0.876
Vulvar/Vaginal	12 (6.6%)	5 (4.9%)	3 (4.2%)	0.824
Ovarian	11 (6.0%)	4 (4.0%)	5 (7.0%)	0.372
Bladder/Urothelial	37 (20.3%)	24 (23.8%)	9 (12.7%)	0.069
Anal SCC	6 (3.0%)	3 (3.0%)	3 (4.2%)	0.659
Rectal	42 (23.1%)	27 (26.7%)	21 (29.6%)	0.682
Colon	5 (2.7%)	4 (4.0%)	1 (1.4%)	0.327
Prostate	2 (1.1%)	2 (2.0%)	3 (4.2%)	0.388
Other	20 (10.6%)	9 (8.9%)	10 (14.1%)	0.287
Surgical intent				0.115
Curative	163 (81.9%)	84 (83,2%)	52 (73.2%)	
Palliative	36 (18.1%)	17 (16.8%)	19 (26.8%)	
Disease status				0.380
Primary	78 (39.2%)	36 (35.6%)	30 (42.3%)	
Recurrent	118 (59.3%)	65 (64.4%)	41 (57.7%)	
Exenteration type				0.0414
Anterior	50 (25.1%)	31 (30.7%)	11 (15.5%)	0.022
Posterior	17 (8.5%)	10 (9.9%)	5 (7.0%)	0.513
Total	132 (66.3%)	60 (59.4%)	55 (77.5%)	0.013
Median time from diagnosis to exenteration in months (range)	19 (0–458)	23 (0–458)	18 (0–281)	0322

n: sample size; SCC: squamous cell carcinoma.

1.052–2.624) (Fig. 1).

Discussion

When Brunschwig first described PE in 1948, he did so as a palliative treatment option for patients who, prior to his report, presented with all the traditional criteria of inoperability.[10] Today, due to advancements in surgical techniques, improved perioperative management and refinements of the procedure itself,[26,27] PE has a low perioperative mortality rate (0–8%) and is one of the only curative treatments for what was previously a terminal diagnosis. However, given the nearly universal morbidity associated with the procedure, further investigation is warranted. In this study, we aimed to elucidate the effect of preoperative nutritional status on morbidity and survival in patients undergoing PE. Seventy-one patients (35.7%) presented with a serum albumin level of <3.5 g/dL and experienced a higher rate of postoperative complications than those with normal serum albumin levels (85.9% vs. 72.3%, $p = 0.034$). The reoperation rate of this cohort was 30%, which may simply be due to the drastic nature of PE and thus may be useful during preoperative counseling. The thirty-day mortality was 0.5% and overall 1-year, 3-year and 5-year survival of 66.7%, 51.4% and 33.5%, respectively, are consistent with recent studies.[1–9,14,16,26,28,29] Postoperative transfusions occurred in 119 (59.8%) patients and may be considered an expected outcome in this patient population. In comparison to other studies, it is possible that selection bias and single institution and specialty reporting resulted in a lower than expected complication rate.

Although the procedure is radical and prone to nearly universal morbidity, the continued practice of PE is necessitated due to its life-altering ramifications for patients with locally advanced or recurrent malignancies, for which there are currently few treatment options.[30,31] In order to reduce the high rate of morbidity associated with PE, it is essential to identify preoperative risk factors and refine patient selection criteria.[32] Unfortunately, due to the small amount of pelvic cancer recurrences that lend themselves to surgery, it is difficult to identify risk factors predictive of postoperative complications. Furthermore, a review of the literature demonstrates that the majority of currently acknowledged contraindications for PE are either difficult to measure prior to surgery – such as positive margins and lymph node metastases[13,16,28,33] – or are subject to controversy – such as age.[1,12,29,33,34] Nevertheless,

Table 2
—Perioperative outcomes.

Outcome	n = 199
Average OR time (min, SD)	613 (137.7)
Average EBL (mL, SD)	2007 (1569.8)
Mean units of intraoperative blood transfusion (SD)	4 (3.9)
Postoperative complication (%)	
Blood transfusion	119 (59.8%)
MI/Arrhythmia	16 (8.0%)
VTE/PE	28 (14.1%)
Deep wound/organ space infection	67 (33.7%)
Superficial wound infection	46 (23.1%)
Incisional dehiscence	50 (25.1%)
Pneumonia	17 (8.5%)
Respiratory failure	24 (12.1%)
Sepsis	41 (20.6%)
Acute renal insufficiency	41 (20.6%)
Urinary	46 (23.1%)
Fistula	40 (20.1%)
Chronic pain	63 (31.7%)
Chronic wound	55 (27.6%)
Average LOS (days, SD)	
ICU	4 (5.6)
Hospital	17 (10.4)
90-day Readmission (%)	106 (53.3%)
Reoperation (%)	61 (30.7%)

n: sample size; OR: operating room; SD: standard deviation; EBL: estimated blood loss; MI: myocardial infarction; VTE: venous thromboembolism; Chronic: lasting for more than six months; LOS: length of stay; ICU: intensive care unit.

recent studies have shown that smaller tumor size and increased time since previous radiation therapy are criteria of optimal candidates for cure by PE.[13,14,16]

Despite the abundance of medical literature regarding clinical nutrition,[35] many areas of nutritional support remain controversial. Other studies have used BMI and prealbumin levels as surrogates of nutrition status rather than serum albumin.[24] Although it remains unclear as to which of these is the best measurement for nutritional assessment (prealbumin has a shorter half-life than albumin and is therefore more sensitive to short-term changes in nutritional status, but albumin is more commonly used by physicians to measure a patient's nutritional status), these differences as well as differences in threshold values of serum protein and varying primary diagnoses of cohort patients make comparison difficult. Still, most studies have concluded that preoperative malnutrition is a universal predictor of poor surgical outcomes in patients undergoing major abdominal and oncologic procedures.[18–20,22,35] Furthermore, nutritional supplementation has been shown to significantly improve surgical outcomes in cases of severe malnourishment but confers virtually no benefit otherwise.[36] While it remains unclear which mode of administration (e.g. total parenteral nutrition, tube feeding, oral supplementation, etc.) is most efficacious,[37,38] nutritional consult followed by nutritional supplementation administered 2–3 weeks preoperatively and continued postoperatively appears to yield the best results.[39] For those able to tolerate it, oral supplementation products such as Boost or Ensure are highly effective. Total parenteral nutrition (TPN) should be reserved for patients with non-functional GI tract or failure to thrive. These methods and their success in improving surgical outcomes may likely translate to patients undergoing radical pelvic surgery, but no studies analyzing these factors specifically in patients undergoing PE could be found.

This study's finding that poor preoperative nutrition is associated with increased morbidity and worsened OS is notable, as it adds to the short list of measurable, preoperative characteristics associated with outcomes of PE. While the extent to which nutritional optimization may benefit patients undergoing PE remains unclear, overall survival is improved in patients with better nutrition (Fig. 1) and thus an effort should be made by surgeons to optimize nutritional status prior to surgery. This study's data defines a risk factor predictive of poor outcomes, which may enable patients and surgeons to make more informed decisions regarding the risks and benefits of this ultra-radical procedure.

Limitations of this study include its retrospective nature as well as the wide variety of malignancies, procedures, surgical teams, previous treatments and disease history of the cohort, which are all potential confounding factors to consider when reviewing these results. This study included patients with various indications for

Table 3
Univariable analysis of preoperative albumin level and postoperative complications.

Outcome	Albumin ≥ 3.5 g/dL (n = 101)	Albumin < 3.5 g/dL (n = 71)	*p*-value
Average OR time (min, SD)	592 (135.8)	614 (123.2)	0.199
Average EBL (mL, SD)	1859 (1516)	1921 (995.8)	0.134
Mean units of intraoperative blood transfusion (SD)	4 (3.6)	4 (3.3)	0.505
Any complication	73 (72.3%)	61 (85.9%)	0.034
Blood transfusion	55 (54.5%)	44 (62.0%)	0.326
MI/Arrhythmia	9 (8.9%)	6 (8.4%)	0.916
VTE/PE	14 (13.9%)	11 (15.5%)	0.765
Deep wound/organ space infection	35 (34.7%)	27 (38.1%)	0.649
Superficial wound infection	18 (17.8%)	18 (25.3%)	0.232
Incisional dehiscence	20 (19.8%)	19 (26.8%)	0.283
Pneumonia	7 (6.9%)	8 (11.3%)	0.321
Respiratory failure	11 (10.9%)	6 (8.4%)	0.597
Sepsis	18 (17.8%)	18 (25.3%)	0.232
Acute renal insufficiency	19 (18.8%)	17 (23.9%)	0.415
Urinary	18 (17.8%)	23 (32.4%)	0.027
Fistula	17 (16.8%)	19 (26.8%)	0.115
Chronic wound	22 (25.0%)	25 (40.3%)	0.046
Average LOS (days, SD)			
ICU	4 (6)	4 (6)	0.138
Hospital	15 (9.1)	20 (12.1)	0.041
Readmission (%)	51 (50.5%)	42 (59.1%)	0.262
Reoperation (%)	28 (27.7%)	24 (33.8%)	0.393

n: sample size; OR: operating room; SD: standard deviation; EBL: estimated blood loss; MI: myocardial infarction; VTE: venous thromboembolism; Chronic: lasting for more than six months; LOS: length of stay; ICU: intensive care unit.

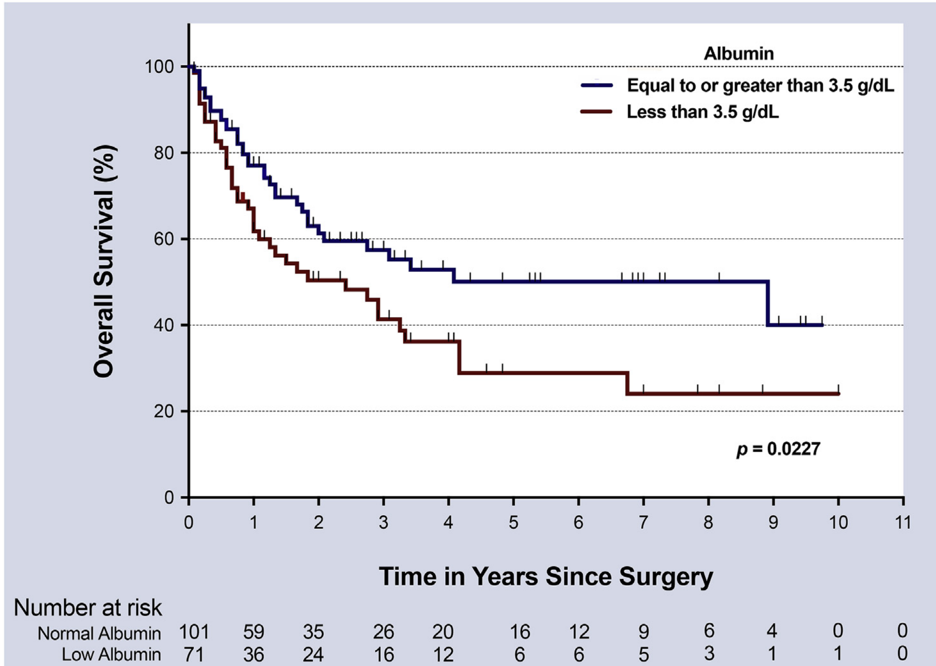

Fig. 1. Kaplan-Meier survival curve.
Albumin ≥3.5 g/dL was associated with improved OS (HR 1.661; 95% CI 1.052–2.624).

surgery and each patient's postoperative outcome was considered independent of curative or palliative intent and primary or recurrent disease status. This could be considered a limitation as patients undergoing PE for palliation, for example, are more likely to have extensive disease and worse OS, however, this group was small and consisted of only 36 (18.1%) patients.

Conclusions

Poor preoperative nutritional status is associated with increased complications and decreased OS in patients undergoing PE. The preoperative nutritional status of patients undergoing PE, particularly those presenting with malnutrition, should be assessed and closely monitored. Based on our findings we suggest including preoperative albumin testing and nutritional consultation followed by appropriate nutritional supplementation with a goal of achieving an albumin level >3.5 g/dL prior to surgery when possible.

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Appendix A. Supplementary data

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