



# Perioperative outcomes in male patients undergoing cystectomy, radical colorectal procedure or total pelvic exenteration

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**Background:** Total pelvic exenteration (TPE) in men is a surgical procedure to treat genitourinary and colorectal malignancies. Despite improvement in multimodal strategies and technology, mortality is still high and literature is limited about perioperative outcomes comparison to other radical procedures.

**Methods:** We analyzed National Surgical Quality Improvement Program (NSQIP) baseline database of all male patients undergoing cystectomy, low anterior resection/abdominoperineal resection (LAR/APR) or TPE from January 1, 2005 to December 31, 2016. Postoperative complications within 30 days after surgery were measured including: Wound infection, septic complications, deep vein thrombosis, cardiovascular events, and return to the operating room or mortality, etc. Differences between groups were analyzed using analysis of variance (ANOVA) tests.

**Results:** A total of 7,375 patients underwent radical cystectomy, 49,762 underwent LAR/APR and 792 underwent TPE. Cystectomy patients were on average older compared to TPE or LAR/APR patients ( $P < 0.001$ ). In univariable and multivariable analysis, patients undergoing TPE had greater infectious and septic complications compared to cystectomy (odds ratio = 1.09; 95% confidence interval (CI): 1.06–1.12) and LAR/APR (odds ratio = 1.08; 95% CI: 1.05–1.11). Moreover, TPE had a slightly higher mortality within the 30-day postoperatively than those who underwent LAR/APR (odds ratio = 1.01; 95% CI: 1.00–1.02) and cystectomy (odds ratio = 1.01; 95% CI: 1.00–1.01).

**Conclusions:** Men undergoing TPE had greater rates of infections and postoperative complications compared to those undergoing radical cystectomy and LAR/APR. From a clinical standpoint, TPE has high morbidity that could provide opportunity for quality improvement projects with the goal of mitigating high complication rates.

**Keywords:** Total pelvic exenteration (TPE); cystectomy; low anterior resection (LAR); abdominoperineal resection (APR); perioperative outcomes

Submitted May 07, 2023. Accepted for publication Sep 27, 2023. Published online Nov 23, 2023.

doi: [10.21037/tau-23-266](https://doi.org/10.21037/tau-23-266)

**View this article at:** <https://dx.doi.org/10.21037/tau-23-266>

## Introduction

Total pelvic exenteration (TPE) in men is the surgical removal of the lower colon, rectum, bladder and internal genital organs that is used to treat genitourinary and colorectal malignancies. The limited literature on TPE generally describe single-center small case series with great heterogeneity and little comparative data (1). It was originally described in 1948 by Alexander Brunschwig and mortality rates at that time ranged from 23% to 35%; however, with improvement in multimodal strategies, technology and perioperative care, mortality rates have declined, though continue to vary widely (2).

On the other hand, there is a much stronger body of literature for outcomes in other radical procedures with similar indications, such as cystectomy and low anterior resection/abdominoperineal resection (LAR/APR). A systematic review and cumulative analysis of robot-assisted radical cystectomy found an overall 90-day complication rate of 59%, of which only 15% were high-grade; mortality rates are low with less than 3% reported for all diversion types (3). A meta-analysis of postoperative outcomes in LAR *vs.* APR found that LAR was highly correlated with 5-year survival and significantly lower recurrence rate

compared to APR (4).

TPE is generally performed for locally advanced cancer invading organs outside the primary, which involves similar techniques as done for a radical cystectomy and LAR/APR. Despite overlapping surgical approaches, it remains unclear whether patients undergoing TPE have similar perioperative outcomes compared to those undergoing radical cystectomy or LAR/APR alone. The purpose of the study was to assess and compare patient characteristics, perioperative morbidity and mortality in male patients undergoing radical cystectomy alone, LAR/APR alone and TPE in the National Surgical Quality Improvement Program (NSQIP) database. In addition, we sought to identify the risk factors for complications among patients undergoing radical cystectomy, LAR/APR, and TPE. We hypothesize that patients undergoing TPE will have worse morbidity, including greater rates of complications, compared to LAR/APR and cystectomy patients, given the increased surgical complexity. We decided to compare whether patients undergoing TPE have similar perioperative outcomes compared to those undergoing radical cystectomy or LAR/APR alone. We present this article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-266/rc>).

### Highlight box

#### Key findings

- Patients undergoing total pelvic exenteration (TPE) had greater infectious and septic complications compared to cystectomy.
- Moreover, TPE had a slightly higher mortality within the 30-day postoperatively than those who underwent low anterior resection/abdominoperineal resection (LAR/APR) (odds ratio =1.01) and cystectomy.

#### What is known and what is new?

- LAR is correlated with higher 5-year survival and significantly lower recurrence rate compared to APR.
- The literature is still unclear whether patients undergoing TPE have similar perioperative outcomes compared to those undergoing radical cystectomy or LAR/APR alone.
- This study showed that men undergoing TPE had greater rates of infections and postoperative complications compared to those undergoing radical cystectomy and LAR/APR.

#### What is the implication, and what should change now?

- Despite improvement in multimodal strategies, technology and perioperative care, TPE still has high morbidity compared to other radical procedure. More research and quality improvement projects are required with the goal of mitigating high complication rates.

## Methods

### Data selection

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Institutional review board exemption was obtained from the University of Illinois at Chicago before the NSQIP Participant Use Data Files (PUF) were queried for male patients undergoing TPE, cystectomy and LAR/APR. NSQIP currently includes data from over 700 institutions including that on demographics, preoperative risk factors, intraoperative variables and 30-day postoperative morbidity, mortality and readmission outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting. All male patients undergoing cystectomy, LAR/APR or TPE from January 1, 2005 to December 31, 2016. Patients were identified based on Current Procedural Terminology (CPT) codes for TPE, LAR/APR and cystectomy (Table S1). Cystectomy patients were identified by CPT codes for cystectomy without any major colorectal surgery. LAR/APR patients included CPT codes for low anterior colorectal resection and APR with or without

**Table 1** Baseline characteristics for patients undergoing TPE, cystectomy, and LAR/APR

Baseline characteristics	TPE (n=792)	Cystectomy (n=7,375)	LAR/APR (n=49,762)	Total (n=57,929)	P value
Age (years), mean (SD)	62.968 (12.340)	67.898 (10.526)	59.108 (13.471)	60.280 (13.443)	<0.001*
Body mass index (kg/m <sup>2</sup> ), mean (SD)	27.057 (5.598)	28.565 (5.431)	28.507 (5.768)	28.494 (5.726)	<0.001*
Smoker, n (%)	194 (24.5)	1,743 (23.6)	10,042 (20.2)	11,979 (20.7)	<0.001*
History of hypertension, n (%)	388 (49.0)	4,411 (59.8)	22,291 (44.8)	27,090 (46.8)	<0.001*
History of diabetes, n (%)	140 (17.7)	1,436 (19.5)	6,876 (13.8)	8,452 (14.6)	<0.001*
Operative time (minutes), mean (SD)	435.834 (172.622)	344.476 (124.713)	227.510 (113.812)	245.248 (124.634)	<0.001*
Length of hospital stay (days), mean (SD)	12.338 (9.528)	9.664 (7.736)	7.424 (7.624)	7.777 (7.722)	<0.001*
Morbidity probability, mean (SD)	0.325 (0.092)	0.259 (0.077)	0.163 (0.080)	0.175 (0.087)	<0.001*

Continuous variables by procedure type compared with Kruskal-Wallis rank sum and analysis of variance test; categorical variables by procedure type compared with Chi-squared tests. \*, statistically significant. TPE, total pelvic exenteration; LAR, low anterior resection; APR, abdominoperineal resection; SD, standard deviation.

anastomosis, without any concomitant major urological surgery. CPT codes for TPE as well as patients undergoing both cystectomy (with or without prostatectomy) and LAR/APR surgeries were included for TPE. Observations with missing data in any of the variables analyzed (except for gender and surgery) were included in the study but excluded for the analysis of the variable where the data were missing.

### Variable generation

Patient demographics included age (continuous, in years), body mass index (BMI, continuous, in kg/m<sup>2</sup>), smoking status (smoker or not) and history of diabetes or hypertension. Intraoperative variables included operative time (continuous, in minutes), length of hospital stay (continuous, in days) and morbidity probability. Postoperative complications within 30 days after surgery were considered as binary variables and included: transfusions, wound infection [superficial incision, deep and/or organ-space surgical site infections (SSIs)], septic complications (sepsis and septic shock), wound dehiscence, deep vein thrombosis, cardiac arrest, myocardial infarction, stroke, failure to wean off a ventilator within 48 hours, acute or progressive renal insufficiency, return to the operating room (OR) or mortality.

### Statistical analysis

Univariable analyses of patient demographics, preoperative comorbidities, and postoperative outcomes were performed by procedure type (TPE, cystectomy and LAR/APR). Chi-

squared test were used for categorical variables. Normally distributed continuous variables were measured using analysis of variance (ANOVA) tests; otherwise, continuous variables were measured with Kruskal-Wallis rank sum tests. Primary outcomes included the incidence of wound or infectious complications, any complications, complications requiring return to the OR, and mortality, all within 30 days postoperatively. Univariable and multivariable logistic regression models were used to determine factors associated with complications and 30-day mortality. Covariates were chosen a priori based on factors identified in prior studies as relevant to the primary outcomes (5-11). Covariates in the regression model included age, BMI, smoking status, and history of diabetes or hypertension. All statistical analyses were two-tailed and performed using R statistical programming version 4.0.0 (R foundation for Statistical Computing, Vienna, Austria) using 95% confidence intervals (CIs) with two-sided P values <0.05 considered significant.

### Results

A total of 57,929 male patients were identified from the NSQIP database from 2005 to 2016. Of these, 7,375 patients underwent radical cystectomy, 49,762 underwent LAR/APR and 792 under TPE. *Table 1* describes the preoperative characteristics and perioperative factors by the type of procedure.

Cystectomy patients were on average older compared to TPE or LAR/APR patients (67.9, 63.0 and 59.1 years, respectively; P<0.001). In addition, patients undergoing

**Table 2** Complications for patients undergoing TPE, cystectomy and LAR/APR

Postoperative complications	TPE (n=792)	Cystectomy (n=7,375)	LAR/APR (n=49,762)	Total (n=57,929)	P value
Transfusions, n (%)	356 (44.9)	2,427 (32.9)	2,978 (6.0)	5,761 (9.9)	<0.001*
Wound dehiscence, n (%)	39 (4.9)	217 (2.9)	746 (1.5)	1,002 (1.7)	<0.001*
Superficial incisional SSI, n (%)	72 (9.1)	395 (5.4)	3,353 (6.7)	3,820 (6.6)	<0.001*
Deep incisional SSI, n (%)	23 (2.9)	114 (1.5)	786 (1.6)	923 (1.6)	0.012*
Organ/space SSI, n (%)	92 (11.6)	438 (5.9)	2,804 (5.6)	3,334 (5.8)	<0.001*
On ventilator >48 hours, n (%)	28 (3.5)	132 (1.8)	661 (1.3)	821 (1.4)	<0.001*
Acute renal failure, n (%)	783 (98.9)	7,265 (98.5)	49,498 (99.5)	57,546 (99.3)	<0.001*
Progressive renal insufficiency, n (%)	21 (2.7)	158 (2.1)	542 (1.1)	721 (1.2)	<0.001*
Deep vein thrombosis, n (%)	29 (3.7)	200 (2.7)	500 (1.0)	729 (1.3)	<0.001*
Stroke, n (%)	4 (0.5)	38 (0.5)	82 (0.2)	124 (0.2)	<0.001*
Cardiac arrest, n (%)	8 (1.0)	70 (0.9)	204 (0.4)	282 (0.5)	<0.001*
Myocardial infarction, n (%)	8 (1.0)	103 (1.4)	302 (0.6)	413 (0.7)	<0.001*
Sepsis, n (%)	88 (11.1)	645 (8.7)	2,061 (4.1)	2,794 (4.8)	<0.001*
Septic shock, n (%)	25 (3.2)	203 (2.8)	741 (1.5)	969 (1.7)	<0.001*
Return to the OR, n (%)	73 (9.2)	427 (5.8)	3,064 (6.2)	3,564 (6.2)	<0.001*
Death within 30 days, n (%)	14 (1.8)	116 (1.6)	397 (0.8)	527 (0.9)	<0.001*

Categorical variables by procedure type compared with Chi-squared tests. \*, statistically significant. TPE, total pelvic exenteration; LAR, low anterior resection; APR, abdominoperineal resection; SSI, surgical site infection; OR, operating room.

cystectomy more often had a history of hypertension (59.8%) compared to those undergoing TPE (49.0%) and LAR/APR (44.8%;  $P<0.001$ ).

The operative time for TPE had a longer average length of 435.8 minutes compared to a mean time of 344.5 and 227.5 minutes for cystectomy and LAR/APR patients, respectively ( $P<0.001$ ). Furthermore, the length of stay (LOS) for patients undergoing TPE was the longest at 12.3 days compared to the other two procedures with a LOS mean range of 7.4–9.7 days ( $P<0.001$ ).

Table 2 describes the postoperative outcomes by the type of procedure. Patients undergoing TPE had greater rates of superficial incisional SSIs (9.1%) compared to the other two procedure types with a range of 5.4–6.7% ( $P<0.001$ ). This was also true for deep incisional SSI, with a rate of 2.9% compared to cystectomy (1.5%) and LAR/APR (1.6%;  $P=0.012$ ).

The most common SSI for TPE patients was in the organ/space at 11.6%, which was a higher rate than those for cystectomy or LAR/APR patients (5.9% and 5.6%, respectively;  $P<0.001$ ).

In univariable and multivariable analyses, patients undergoing TPE had greater infectious and septic complications compared to cystectomy (odds ratio =1.09; 95% CI: 1.06–1.12) and LAR/APR (odds ratio =1.08; 95% CI: 1.05–1.11). A similar pattern was seen for total complications where TPE patients had highest rates of the three procedure types (Table 3). In addition, TPE patients were associated with a slightly increased risk of returning to the OR in the 30-day postoperative period than cystectomy (patients OR =1.03; 95% CI: 1.01–1.04) but similar to the risk of return to OR among patients undergoing LAR/APR (OR =1.01; 95% CI: 0.99–1.02). Patients that underwent TPE had a slightly higher mortality within the 30-day postoperatively than those who underwent LAR/APR (odds ratio =1.01; 95% CI: 1.00–1.02) and cystectomy (odds ratio =1.01; 95% CI: 1.00–1.01).

## Discussion

In this study, we compared patient characteristics, perioperative factors and postoperative outcomes among male

**Table 3** Multivariable analysis of complications by procedure type

Postoperative complications	TPE vs. cystectomy, odds ratio (95% CI)	TPE vs. LAR/APR, odds ratio (95% CI)
Infections and sepsis	1.09 (1.06–1.12)	1.08 (1.05–1.11)
Return to the OR	1.03 (1.01–1.04)	1.01 (0.99–1.02)
Death within 30 days	1.01 (1.00–1.01)	1.01 (1.00–1.02)
Total complications	1.09 (1.06–1.12)	1.09 (1.06–1.12)

TPE, total pelvic exenteration; CI, confidence interval; LAR, low anterior resection; APR, abdominoperineal resection; OR, operating room.

patients who underwent TPE, LAR/APR and cystectomy between 2005 to 2016 in the NSQIP database (12). We found that patients undergoing TPE were older with more comorbidities and their surgeries had higher operative times resulting in longer LOS. In addition, TPE patients suffered higher rates of complications compared to cystectomy and LAR/APR patients, including wound infections, sepsis, total complications, return to the OR and mortality within the 30-day postoperative period.

Factors associated with complications in urologic and colorectal procedures have been evaluated in multiple previous studies (7,11). For example, a retrospective analysis using the NSQIP database identified factors such as age, American Society of Anesthesiologists (ASA) Class and operative time longer than 6 hours associated with any post-operative complications in radical cystectomy patients (7). Specifically, following cystectomy, longer operative times, smoking, BMI >30 and chronic obstructive pulmonary disease were associated with increased risk of return to the OR (11). Another NSQIP study found that operative time was independently associated with risk of reoperation after LAR, while smoking, chronic obstructive pulmonary disease and operative time were independent risk factors for reoperation after APR (13). Relevant patient factors including age, history of hypertension and diabetes, operative time and smoking status were controlled for in the multivariable analysis in order to better compare outcomes across procedure types.

On the other hand, the literature regarding outcomes following TPE is very limited (13,14). A retrospective analysis of the NSQIP database from 2005–2010 revealed 377 TPE patients with a similar mortality rate of 1.3% (14). Preoperative variables such as ASA class 3 or more and preoperative transfusion were found to be at increased risk of major postoperative complications. Kuhrt *et al.* investigated a small cohort of 53 patients (15). The cohort had a mean LOS of 17 days and no 30-day mortality. The current study demonstrated a shorter LOS average of 12 days,

and a 1.8% mortality rate which is consistent with other contemporary studies that have had rates range from 0% to 10% (16-19). The majority of these small series have focused on TPE for colorectal carcinomas, while we have included TPE surgeries for any cancer indication. A recent NSQIP study described perioperative outcomes after TPE; the study only included 2,305 male and female patients who underwent TPE for malignant indications and focused on differences in outcomes based on cancer origin. The authors found a transfusion rate of 50% and wound infectious rate of 23%, which coincide with our findings (20). However, only 7.6% of patients required return to the OR; the current study's higher rate can be explained by the inclusion of only male patients, who are associated with worse outcomes. Brown *et al.* compared urological complications among 231 patients who underwent radical cystectomy versus TPE (21). Patients undergoing cystectomy alone had a higher median age (72 *vs.* 61 years, respectively) and significantly lower rates of postoperative complications rates compared to those who underwent urinary diversion after TPE, coinciding with our findings. However, this analysis limited its scope to mostly urologic complications such as urinary tract infections, urine leaks and ureteric strictures.

From a clinical perspective, our study suggests that while TPE had an overall low mortality rate, the morbidity was quite high even when compared to cystectomy and LAR/APR alone. These findings can aid in patient counseling and expectations before radical concomitant procedures as well as provide insights into potential areas for improvements in patients undergoing TPE. As advancements in surgical techniques such as the use of minimally invasive approaches allow for extensive and radical resections with smaller incisions, less pain and fast overall recovery times, simultaneous improvements in perioperative care are also needed to mitigate such high morbidity. Perioperative care models such as an Enhanced Recovery After Surgery (ERAS) protocol could be useful. ERAS protocol has shown promising results when used in radical cystectomy, including

significantly lower rates of wound healing disorders, fever, thrombosis, as well as less time spent in the intermediate care unit and less demand for analgesics (22). However, currently only the 2019 update to ERAS guidelines for gynecologic oncology offers weak recommendations related to TPE, in which they recognize the paucity of available data (23). TPE is a complex, multidisciplinary procedure that often involves multiple surgical and medical care teams, so any potential protocols must appreciate the added complexities to care for this patient population.

This is the first study to utilize a national database to compare outcomes between patients undergoing TPE and other radical procedures, including LAR/APR and cystectomy. It has several strengths, including its large sample size and contemporary data. However, like any retrospective database study, there are limitations. Minimal invasive surgery (MIS) is not reliably coded in NSQIP and thus was not analyzed, NSQIP also does not have a sampling strategy that adequately represents all factions of patients in the United States, which may affect the generalizability of our results. Furthermore, it only includes postoperative outcomes up until 30 days, so longer-term complications were not evaluated in the study. Given the low-quality data available for race or ethnicity, we were unable to determine the impact of such variable in perioperative outcomes of patients undergoing TPE. Possible confounding factors such as performance status, body composition, detailed staging and surgical margin outcomes, and the use of ERAS protocols could not be incorporated into the analysis as they are not included in NSQIP. While comparisons are drawn across the three types of operations with overlap in indication, the procedures have distinct techniques and indication. This has been partially mitigated by incorporating factors that have been previously suggested as contributing to complications in the multivariable analysis. However, it is plausible that the indication for the procedure and associated factors could, in part, be responsible for some of the differences in perioperative outcomes observed across the three groups instead of the actual surgical procedure.

## Conclusions

In conclusion, men undergoing TPE had greater rates of infections and postoperative complications compared to those undergoing radical cystectomy and LAR/APR. From a clinical standpoint, TPE has high morbidity that could

provide opportunity for quality improvement projects with the goal of mitigating high complication rates.

## Acknowledgments

*Funding:* None.

## Footnote

*Reporting Checklist:* The authors have completed the STROBE reporting checklist. Available at <https://tau.amegroups.com/article/view/10.21037/tau-23-266/rc>

*Peer Review File:* Available at <https://tau.amegroups.com/article/view/10.21037/tau-23-266/prf>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-266/coif>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Institutional review board exemption was obtained from the University of Illinois at Chicago before the NSQIP Participant Use Data Files (PUF) were queried for male patients undergoing TPE, cystectomy and LAR/APR.

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**Cite this article as:** Naha U, Khurshudyan A, Vigneswaran HT, Mima M, Abern MR, Moreira DM. Perioperative outcomes in male patients undergoing cystectomy, radical colorectal procedure or total pelvic exenteration. *Transl Androl Urol* 2023;12(11):1631-1637. doi: 10.21037/tau-23-266