Research article

Urological outcomes following pelvic exenteration for non-urological malignancies

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ABSTRACT

Background: Pelvic exenteration (PE) is a major surgical procedure used as a salvage therapy for patients with locally advanced or recurrent pelvic malignancies. Urinary reconstruction is a major part of PE and is often associated with high rates of post-operative complications. In the current study we evaluate the short and long-term urological outcomes following PE for Colo-Rectal (CR) and gyneco-oncological (GO) malignancies.

Methods: Study included 22 patients who underwent PE for recurrent or locally advanced CR and GO malignancies in our institution between the years 2010–2018. The endpoint was post-operative freedom from urological complications.

Results: Of 22 patients included, 13 (59 %) and 9 (41 %) underwent PE for CR and GO malignancies respectively. The mean age of the patients was 54 years. The median follow-up was 19 months. Seven (78 %) patients with GO malignancy and 11 (85 %) with CR malignancy underwent PE for local recurrence. Hydronephrosis prior to surgery existed in 8 (36.3 %) patients, of which, 5 patients required kidney drainage via nephrostomy tube. Two patients underwent posterior pelvic exenteration (PPE) with bladder preservation whereas the remaining 20 underwent cystectomy with urinary diversion by ileal conduit. Hydronephrosis post PE developed in 13 patients (59 %). eight (36 %) patients needed kidney drainage by nephrostomy tubes post PE, of these, 6 (75 %) had disease recurrence. The 2 years freedom from kidney drainage was 68 %, however the median time for kidney drainage was 0.5 months. The median overall survival was 12.5 months.

Conclusion: The rate of urological complications following PE is relatively high and associated with disease recurrence.

1. Introduction

Pelvic exenteration (PE) stands as a formidable surgical intervention employed for individuals grappling with locally advanced or recurrent pelvic malignancies. This intricate procedure entails the en-bloc resection of the urinary bladder and distal ureters, rectum

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and sigmoid, internal reproductive organs in females, and regional lymph nodes. Notably, colorectal (CR) and gynecologic oncological (GO) malignancies, particularly involving the uterine cervix, frequently precipitate the imperative need for PE. The specter of local recurrence, typically manifesting within three years of the initial surgery, is a formidable challenge, with half of the cases presenting in an isolated manner, unaccompanied by distant metastases. In the palliative realm, adjuvant radiotherapy and chemotherapy emerge as conventional strategies [1].

However, PE exacts a considerable toll, as evidenced by a substantial rate of morbidity and mortality [2]. Prior reports indicate an overall complications rate ranging from 24 % to 97 %, coupled with a median hospitalization period of 19 days, with considerable variation spanning from 7 to 84 days [3].

The post-cystectomy phase during PE necessitates urinary diversion, with the prevailing choice being the ileal conduit [4]. Notwithstanding, investigations reveal a lack of discernible differences in complication rates and quality of life outcomes between continent and incontinent urinary diversion methodologies. Nevertheless, urinary diversion, while commonplace, is intricately associated with a notably elevated incidence of urological morbidity, ranging from 9 % to 24 %. This encompasses an array of complications such as urinary tract infections (UTIs), urinary sepsis, hydronephrosis, urine leak, anastomotic stricture, and the imperative need for kidney drainage, collectively underscoring the heightened risk of urological complications in the context of PE [5, 6].

Despite existing publications delving into the outcomes of such surgeries, certain studies exhibit antiquity, and others fail to comprehensively address both GO and CR malignancies. Furthermore, scant data is available regarding the nuanced urological implications of PE [1,4,7,8]. In light of these considerations, our study endeavors to comprehensively evaluate the spectrum of urological outcomes subsequent to PE.

The primary endpoint of our investigation pivots on discerning the incidence of urological complications following PE, encompassing parameters such as kidney drainage and the necessity for re-operation. A secondary endpoint, equally vital, pertains to the overarching aspect of overall survival.

2. Methods

The research protocol received approval from The Sheba Medical Center Ethics Committee, denoted by the assigned approval number SMC-09-7283.

2.1. Study population

Our study encompassed individuals who underwent elective open approach PE for recurrent or locally advanced colorectal (CR) and gynecologic oncological (GO) malignancies within the confines of a singular medical facility during the period spanning 2010 to 2018. Exclusion criteria encompassed the presence of metastases at the time of PE and a postoperative follow-up duration of less than three months.

Comprehensive clinical assessments were conducted on all patients by a multidisciplinary team, comprising gynecologic oncologic surgeons, surgical oncologists, urologists, and medical oncologists, both pre- and post-surgery. The surgical interventions, inclusive of cystectomy and urinary reconstruction, were executed by a dedicated urologic oncology surgeon boasting over a decade of expertise in the realm of urologic oncology. The evaluation of urological complications involved the utilization of various imaging modalities and pertinent laboratory assays. Notably, a customized imaging regimen was primarily guided by the underlying malignancy, with specific assessments for urological complications performed as necessitated, either within the outpatient setting or during hospitalization.

2.2. Data collection

Patient demographics and operative details were collected retrospectively. Clinicopathologic variables recorded included: age, gender, primary disease histology, oncological treatment (including local and systemic) pre and post-operative renal function, need for kidney drainage (Yes/No) and time to drainage. Operative variables included type of operation (anterior/posterior). Lastly, we reviewed survival outcome including disease progression and overall survival.

2.3. Statistical analysis

Statistical analysis was performed using SPSS version 21. Descriptive analysis was used to report variable frequencies. Differences between patient groups were evaluated using the x2 test, Student *t*-test, and the Mann–Whitney *U* test as appropriate. Reported intergroup comparisons were significant at the 5 % level ($P < 0.05$). Survival was estimated by the Kaplan–Meier method, and group differences were assessed with the log-rank test for statistical significance.

3. Results

Among the 22 participants, 13 (59 %) presented with colorectal (CR) malignancy, while 9 (41 %) exhibited gynecologic oncological (GO) malignancies. Within the CR subgroup, 10 (77 %) patients were male, with a mean age of 58 (SD = 10.5). Comparatively, the GO subgroup demonstrated a mean age of 48.2 (SD = 8.9), representing a statistically significant difference (p = 0.043). Predominant malignancies in the CR and GO groups were rectal adenocarcinoma (85 %) and uterine cervix squamous cell carcinoma (78 %),

respectively. Notably, local recurrence prompted PE in 85 % and 78 % of the CR and GO cases, respectively (Table 1).

Within the CR cohort, 10 (76.9 %) patients underwent total PE (TPE), 1 (7.7 %) anterior PE (APE), and 2 (15.4 %) posterior PE (PPE). In the GO group, 5 (55.6 %) underwent TPE, 4 (44.4 %) APE, and none had PPE. Renal drainage was required in 8 renal units (18 %) among 5 patients prior to PE (Table 1).

The mean surgical duration was 399 min (SD = 172.3), with complete macroscopic resection achieved in all cases. Urinary diversion by ileal-conduit was performed in 20 patients, with 84.6 % in the CR group and all in the GO group. Two (15.4 %) CR patients underwent PPE with bladder preservation. Median hospitalization was 15 days (range 6–90), significantly longer for the CR group (28 days vs. 11, $p < 0.037$) (Table 2).

Re-hospitalization within 30 days occurred in 6 patients (27 %). Median follow-up was 12 months (range 3–36) for the CR group and 19 (range 4–86) for the GO group. Complications, classified by Clavien-Dindo, revealed a higher rate of urinary tract infections ($p < 0.001$) and urinary sepsis ($p < 0.001$) in the CR group compared to the GO group. Reoperation within 30 days was required in 5 patients (23 %), with two patients (9 %) necessitating additional late urological surgery (Table 3). One patient in the CR group succumbed to acute bleeding 9 days post-PE.

A total of 16 urological complications in 14 patients (63 %) manifested postoperatively. Early complications included hydronephrosis necessitating kidney drainage in 3 patients, pelvic urinoma requiring urinary diversion, and enteral leak. Overall, 13 patients (59 %) in the cohort (21 renal units) developed hydronephrosis, with kidney drainage by nephrostomy tubes in 8 patients (36.4 %) at a median of 1-month post-surgery (Table 3). Unilateral and bilateral drainage was done in 3 (14 %) and 5 (23 %) patients, respectively. The probability of kidney drainage was 50 % for those with disease recurrence following PE compared to 25 % without recurrence ($p = 0.37$), showing no difference between CR and GO groups ($p = 0.086$). At 2 years, 68 % were free from kidney drainage, with a median time to drainage of 0.5 months. Median overall survival was 12.5 months, and 5-year overall survival was 39 % (KM = 0.079, $p = 0.779$).

4. Discussion

To our knowledge, this study represents one of the few comprehensive investigations into urological complications following pelvic exenteration (PE). The observed early complication rate, occurring within 30 days of PE, was noteworthy, with 68 % of patients (15/22) affected. A predominant majority (63 %) exhibited Clavien-Dindo 1–2 complications, while 8 patients (36 %) faced Clavien-Dindo 3 or higher complications. This heightened incidence aligns with findings in other PE series, underscoring the intricate and challenging nature of the surgery [7,9].

The median overall survival in our cohort was recorded at 12.5 months, with a 5-year survival rate of 39 %. A publication by the PelvEx collaboration group reported 5-year overall survival ranging from 17 % to 28 % [1]. Within our cohort, twenty patients underwent radical cystectomy as part of pelvic exenteration, all of whom received ileal conduit diversion. The impact of pelvic irradiation before pelvic exenteration on surgery duration, urinary reconstruction, and urological complications following PE remains a subject of debate [9,10]. Ileal conduit emerged as the preferred choice for prolonged surgeries [11].

Despite all patients undergoing pelvic exenteration with curative intent, it is crucial to acknowledge that, despite successful surgery, the life expectancy of these patients may be limited. The consideration of cutaneous ureterostomy arises as a potentially simpler procedure, holding the promise of reduced operating time, fewer additional bowel manipulations, and a lower likelihood of urological complications. However, a retrospective cohort study reported a 13.2 % ureteral obstruction rate necessitating stent placement [12]. Contemplating cutaneous ureterostomies as an alternative urinary reconstruction method in selected patients seems reasonable.

Table 1
Patient's characteristics and preoperative data.

	Parameters	All patients	GO malignancies (n = 9)	CR malignancies (n = 13)	P value
Gender					
	Male (%)	10 (45.4)	0	10 (76.9)	
	Female (%)	12 (54.6)	9 (100)	3 (23.1)	
Age (y)	Mean (SD)	54 (10.8)	48.2 (8.9)	58 (10.5)	0.043
Disease primary					
	Uterine cervix (%)		7 (78)		
	Uterine sarcoma (%)		1 (11)		
	Endometrial carcinoma (%)		1 (11)		
	Rectal Adenocarcinoma (%)			11 (84.6)	
	Sigmoid colon Adenocarcinoma (%)			1 (7.7)	
	Anal SCC (%)			1 (7.7)	
Indication for PE					
	Recurrence (%)	18 (81.8)	7 (77.8)	11 (84.6)	
	Primary tumor (%)	3 (13.6)	2 (22.2)	1 (7.7)	
	Functional (%)	1 (4.6)	0	1 (7.7)	
Neo-Adjuvant therapy					
	Chemotherapy (%)	21 (95.4)	8 (89)	13 (100)	
	Radiotherapy (%)	17 (77.2)	8 (89)	9 (69.2)	
Pre-PE kidney drainage		5 (22.7)	4 (44.4)	1 (7.7)	0.11

GO = Gyneco-oncological; CR= Colorectal; PE= Pelvic exenteration; SD= Standard deviation.

Table 2
Operative and perioperative data.

	Parameters	All patients	GO malignancies (n = 9)	CR malignancies (n = 13)	P value
Type of PE					
	Total (%)	15 (68.2)	5 (55.6)	10 (76.9)	
	Anterior (%)	5 (22.7)	4 (44.4)	1 (7.7)	
	Posterior (%)	2 (9.1)	0	2 (15.4)	
Lymph nodes involvement	Yes (%)	3 (13.6)	0	3 (23.1)	0.164
Surgical margins	Involved (%)	6 (27.2)	1 (11.1)	5 (38.5)	0.21
Duration of hospitalization (days)	Median (range)	15 (6–90)	11 (6–19)	28 (8–90)	0.037

GO = Gyneco-oncological; CR= Colorectal; PE= Pelvic exenteration.

Table 3
Follow-up and urological complications.

	Parameters	All patients	GO malignancies (n = 9)	CR malignancies (n = 13)	P value
Follow-up (months)	Median (range)	13 (3–86)	19 (4–86)	12 (3–36)	0.27
UTI post PE, CD1 (%)		7 (31.8)	1 (11)	6 (46.2)	0.001
Urinary Sepsis post PE, CD2 (%)		5 (22.7)	1 (11)	4 (30.8)	0.001
Hydronephrosis (%)		13 (59)	5 (55.5)	8 (61.5)	1
	With disease recurrence (%)	10 (45.5)	3 (33.3)	7 (53.8)	
	Without disease recurrence (%)	3 (13.6)	2 (22.2)	1 (7.7)	
Kidney drainage, CD3a (%)		8 (36.4)	3 (33.3)	5 (38.5)	1
Additional urological surgery, CD3b (%)		2 (9)	1 (11)	1 (7.7)	0.154

GO = Gyneco-oncological; CR= Colorectal; PE= Pelvic exenteration; UTI= Urinary tract infection; CD= Clavien-Dindo.

The rate of urinary tract infection (UTI) and urinary sepsis was significantly higher in the colorectal (CR) group. The older age and higher rate of comorbidities in the CR group may explain these elevated rates. Koh et al. recommend routine intravenous antibiotics for five days following PE as infection prophylaxis [13].

Notably, none of the patients in our cohort developed parastomal hernia (PH) during the follow-up period. Stomal stenosis, a late and rare complication, developed in one patient (4.5 %) and was managed by stomal dilatations. One patient (4.5 %) developed a pelvic urinoma due to bilateral ureteral leak and was treated with bilateral percutaneous nephrostomy tube insertion without the need for surgical revision. A delay in the diagnosis of urine leak may contribute to high morbidity rate and extended length of hospitalization. Particular attention should be given to high drain output, low urine volume, wound discharge, and persistent sepsis.

The most significant urological complication following urinary reconstruction is upper urinary tract dilation and obstruction, occurring in up to 30 % of cases [2]. The rate of hydronephrosis in our cohort was 59 %. In the gynecologic oncological (GO) group, 5 patients (8 renal units) developed hydronephrosis, with 3 experiencing disease recurrence. In the CR group, 8 patients (13 renal units) developed hydronephrosis, with 7 demonstrating disease recurrence. A study by Pan G et al. [14] reviewed computerized tomography scans of 33 patients following PE following a median interval of 8 months from PE and found the presence of hydronephrosis in 55 %. Disease recurrence was detected in 51 % in a median interval of 9 months after PE. The rates of hydronephrosis in our cohort is similar to other cohorts and is associated with disease recurrence (45.45 %).

All PE within our cohort were conducted through an open approach utilizing midline laparotomy. In the current landscape characterized by the ascendancy of minimally invasive and robotic surgical modalities, thoughtful consideration should be given to the viability of robotic-assisted PE. While existing literature encompasses relatively diminutive case series [15], isolated case reports [16, 17], and a paucity of review articles [18], the potential advantages of a robotic approach merit examination. This modality may confer diminished morbidity, inclusive of truncated hospitalization periods, reduced intraoperative blood loss, and expedited recuperation. However, it is imperative to acknowledge that robotic-assisted PE may necessitate prolonged operating room durations and should ideally be performed in high-volume centers, where all members of the surgical team exhibit advanced proficiency in robotic procedures [15–17]. The incorporation of enhanced recovery protocols holds promise in further mitigating hospital stays and augmenting overall recovery. Despite the potential benefits associated with the robotic approach, it is crucial to note that the complication rate may remain substantial, reaching up to 50 %, owing to the intrinsic complexity of the procedure [18].

Our investigation accentuates the intricate nature of PE in the context of non-urological malignancies. The interdisciplinary cohort overseeing patients confronted with these conditions should anticipate an elevated incidence of hydronephrosis subsequent to PE in non-urological malignancies, contrasting notably with rates observed in radical cystectomy and urinary reconstruction for bladder cancer. Consequently, there exists a pronounced imperative for vigilant post-procedural surveillance encompassing both imaging assessments and serum creatinine monitoring, complemented by a judicious schedule of oncological monitoring to facilitate timely intervention in cases of urinary obstruction and forestall any ensuing compromise in renal function.

Furthermore, our findings reveal a notable recurrence rate of the underlying disease, necessitating the consideration of supplementary systemic therapeutic modalities. This observation underscores the criticality of preserving optimal renal function in this population. The heightened incidence of post-surgical complications within the first 30 days post-PE should enhance the situational awareness of the healthcare team, prompting heightened sensitivity to symptomatic manifestations indicative of potential

complications. Notably, attention to abdominal symptoms and vigilant monitoring of renal function are paramount, as these may signify complications such as urine leakage or urinary tract obstruction.

Additionally, the elevated frequency of UTIs observed warrants consideration for the incorporation of a routine post-surgical antibiotic regimen. This proactive measure is essential to preclude the onset of infections and mitigate the risk of progression to sepsis.

The strengths of this study include a uniform multidisciplinary team and the comparison between two groups of patients who underwent PE. The main limitations of the study are its retrospective nature and a relatively small size of study population and short follow-up time.

In conclusion, the incidence of urological complications following PE is substantial, significantly impacting morbidity and the quality of life of patients. Our study did not identify differences in the rate of urological complications between GO and CR malignancies, except for the rate of urinary infections in the first 30 days post-PE. The high prevalence of hydronephrosis appears to be associated with disease recurrence. This study underscores the intricate nature of PE in the context of non-urological malignancies, emphasizing the need for heightened post-procedural surveillance, multidisciplinary management, and consideration of alternative urinary reconstruction methods in selected cases.

Data availability statement

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy policy.

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A. Lazarovich: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **T. Drori:** Data curation, Writing – original draft. **Y. Guttman:** Data curation. **B. Rosenzweig:** Validation, Visualization, Writing – review & editing. **A. Ben-Ya'aqov:** Validation, Visualization. **J. Korach:** Validation, Visualization. **A. Nissan:** Supervision, Validation, Visualization. **Z.A. Dotan:** Conceptualization, Supervision, Validation, Visualization, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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