

# Short-term outcomes following development of a dedicated pelvic exenteration service in a tertiary centre

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## Key words

colorectal cancer, gynaecological cancer, multidisciplinary care, pelvic exenteration, sarcomas, urological cancer.

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## Introduction

Pelvic exenteration (PE) involves radical resection of two or more contiguous pelvic organs, followed by reconstruction or diversion of genitourinary and gastrointestinal function and repair of the pelvic defect.<sup>1</sup> This may include resection of bone or neurovascular pelvic structures. The majority of patients are offered this surgery for curative resection of advanced gynaecological, urological or

## Abstract

**Background:** Pelvic exenteration surgery (PE) offers potentially curative resection for locally advanced malignancy but is associated with significant complexity and morbidity. Specialised teams are recommended to achieve optimal patient outcomes. This study aims to analyse short-term outcomes at a tertiary setting before and after creating a dedicated PE service.

**Methods:** Patients undergoing PE between 2008 and October 2021 at the Royal Adelaide Hospital and St. Andrews Hospital in South Australia were included, with prospective data collection since June 2017. Patients operated on prior and post the creation of the PE service were compared via univariate analyses.

**Results:** In total, 113 patients were included, with a significant increase in volume of cases post creation of the PE service, ( $n = 46$  pre versus  $n = 67$  post). There were significant differences in the type of neoadjuvant therapy and patient co-morbidity, with more advanced disease stage and a higher likelihood of bone involvement ( $P < 0.05$ ) in the latter period. An increased proportion of patients had flap reconstruction (40.3 versus 33.9%,  $P = 0.010$ ) as well as lateral lymph node dissection (13.4 versus 2.2%,  $P = 0.046$ ). Despite this, peri-operative outcomes such as urosepsis (11.9 versus 28.3%,  $P = 0.028$ ) and Clavien-Dindo grade of complications grade improved. R0 resections were achieved in 93.9% of curative cases (93.9 versus 84.2%,  $P = 0.171$ ).

**Conclusion:** The development of a PE service significantly improved short term patient outcomes, despite the inclusion of patients with more advanced disease and comorbidity.

colorectal malignancy, however some may be offered PE for palliation or benign symptomatic disease.<sup>2,3</sup> Since the first description of PE in 1948, there has been significant evolution and improvement in technique, leading to better outcomes for patients, some of whom may have been deemed to have incurable disease previously.<sup>4</sup>

In patients treated with curative intent, clear resection margins (R0) and appropriately wider resection, such as sacrectomy, improve long-term survival rates following PE.<sup>3</sup> Whilst often

curative, these patients suffer from significant short-term morbidity and mortality related to the extensive surgery.<sup>5-7</sup> Globally, R0 rates are reported to be 79.9%, with significant morbidity seen in 37.8% of patients (Clavien Dindo (CD) grade 3-4), a 30-day mortality rate of 1.5%, and a median overall survival of 43 months.<sup>5</sup>

Several studies demonstrate that high-volume centres with a multi-disciplinary team (MDT) approach significantly improved R0 resection rates and overall outcomes.<sup>6-9</sup> In Australia, most rectal resections are performed in high-volume metropolitan centres.<sup>10</sup> Although formal centralisation of rectal cancer and PE care has not been achieved in Australia; there is mounting evidence that PE surgery should be performed in higher volume centres by a specialised dedicated MDT.<sup>2,5</sup> This is because the surgery is technically challenging, but also because patient selection, peri-operative decision making, and post-operative rescue for complications are thought to be paramount to improving outcomes.

A dedicated PE service was established at the Royal Adelaide Hospital (RAH), South Australia, in June 2017 to manage an increased volume of patient referrals for consideration of PE. This included identification, engagement, and recruitment (where needed) of dedicated clinicians with PE training and experience in colorectal, urology, gynaecological oncology, sarcoma, orthopaedics and plastic surgery. In addition, a protocol for patients with threatened or involved resection margins was created, and a fortnightly dedicated extended all day operating list was created. Patients being considered for PE were discussed at respective oncology MDTs and a collaborative team plan made before surgery. The lead surgeon was the clinician with expertise in the primary disease process. Patients had informed consent obtained by all relevant consultant surgeons before surgery. The post-operative care was similarly shared. The hospital also joined the PelvEx Collaborative (<https://www.pelvex.org>), an international collaborative group involving over 100 PE units across five continents, who prospectively analyse the results of patients undergoing PE to help optimise patient protocols and treatment strategies.

This study aimed to measure and characterise the effect of developing a dedicated PE service on short-term patient outcomes.

## Methods

This study is reported using the Strengthening The Reporting of Observational studies in Epidemiology (STROBE) guidelines.<sup>11</sup> Ethics approval was obtained through the Central Adelaide Local Health Network Human Research Ethics Committee (HREC/17/RAH/470). Informed consent was obtained from all patients.

### Patient selection and definitions

Consecutive patients undergoing PE at the RAH and the affiliated St. Andrews Private Hospital, South Australia, were included between 2008 and October 2021. The service involved specialist colorectal, gynae-oncology, urology, sarcoma, plastic, vascular, medical and radiation oncologists working between both sites. Surgery was performed for colorectal cancer, gynaecological malignancy, sarcoma or benign disease (pelvic sepsis and fistula).

Patients over the age of 18 years old were included. PE was defined using PelvEx collaboration definitions.<sup>3,5,12</sup> Total PE was defined as complete en bloc resection of rectum, genitourinary, reproductive, regional LN, and peritoneum. Anterior PE included resection of bladder and reproductive organs but preserving the rectum. Posterior PE included resection of rectum and reproductive organs, with preservation of the bladder.<sup>5</sup> This was further categorised as modified (posterior exenteration with colonic anastomoses), or infralevator, with wider extended dissection below the level of the levator muscles.<sup>5</sup>

### Data collection

The PelvEx database was established, and data collected prospectively from June 2017. From 2008 to June 2017, historical data were collected retrospectively from the Binational Colorectal Cancer Audit (BCCA), RAH Colorectal Cancer and Gynaecological Oncology databases, as previously reported.<sup>1</sup> Demographic, operative, pathological and postoperative data were collected from electronic and paper medical records. Perioperative outcomes including transfusion requirements, and 30-day complications (CD grade and comprehensive complication index (CCI)) were recorded.<sup>13,14</sup> Specific complications of interest, such as flap breakdown requiring intervention were recorded. Length of stay, readmission rates and 30-day mortality were also recorded.

### Staging and surgery

Preoperative staging, neoadjuvant therapy type, time from radiotherapy to surgery, and adjuvant therapy rates, were recorded. Patients were preoperatively staged with computed tomography, magnetic resonance imaging and positron emission tomography in selected cases. After the MDT discussion, patients were treated depending on the pathology with either long-course chemoradiotherapy (CRT), total neoadjuvant therapy (TNT), short course radiotherapy or no neoadjuvant therapy. Following neoadjuvant therapy and restaging, patients were rediscussed at the MDT, with a plan for surgery if indicated. Patients were excluded from surgery if they had high volume metastatic disease, were unfit for surgery, had no surgical reconstructive options or declined operative intervention. A small proportion of patients were referred to a quaternary care unit due to significant iliac and bone involvement, requiring specialist services.

### Pathology

Postoperative pathology reports were generated by a consultant pathologist and confirmed with discussion at MDT. Pathology was defined as curative with an R0 (microscopic and macroscopic clear margins), R1 (<1 mm margin) and R2 (microscopically or macroscopically involved resection margin). Pathological stage was reported based on the American Joint Committee on Cancer, Cancer staging manual.<sup>15</sup>

## Statistical analysis

The analysis was performed using SPSS Statistics for Windows, Version 28.0 (IBM Corp, Armonk, NY, USA). Univariate analysis was performed using for continuous variables the Mann–Whitney *U* or student-*t* test, and for categorical variables the  $\chi^2$  or Fisher's exact test ( $n < 5$ ). Numerical data are presented as median (range) or mean (standard deviation) depending on parametricity determined with Shapiro–Wilk test. *P*-values of  $\leq 0.05$  were considered statistically significant.

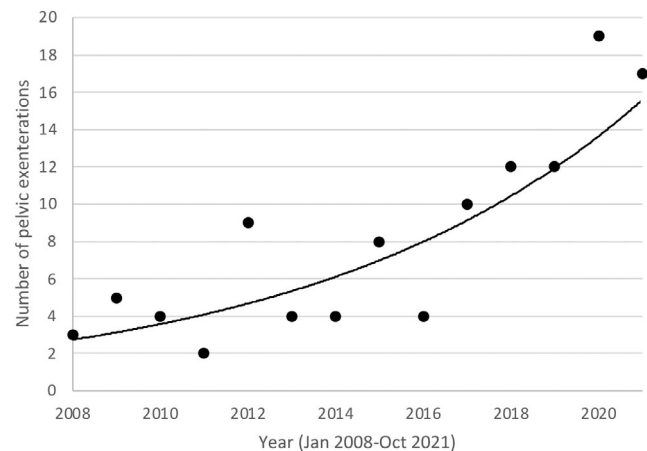
## Results

In total, 113 consecutive patients underwent exenteration during the study period. Before establishing the PE service, 46 (40.7%) patients underwent PE between January 2008 and June 2017 with retrospective data ( $\sim 5$  patients/year). Between June 2017 and October 2021, 67 (50.9%) cases were performed with prospective data ( $\sim 15$  patients/year) (Fig. 1), and numbers increased every year during that time (Fig. 2).

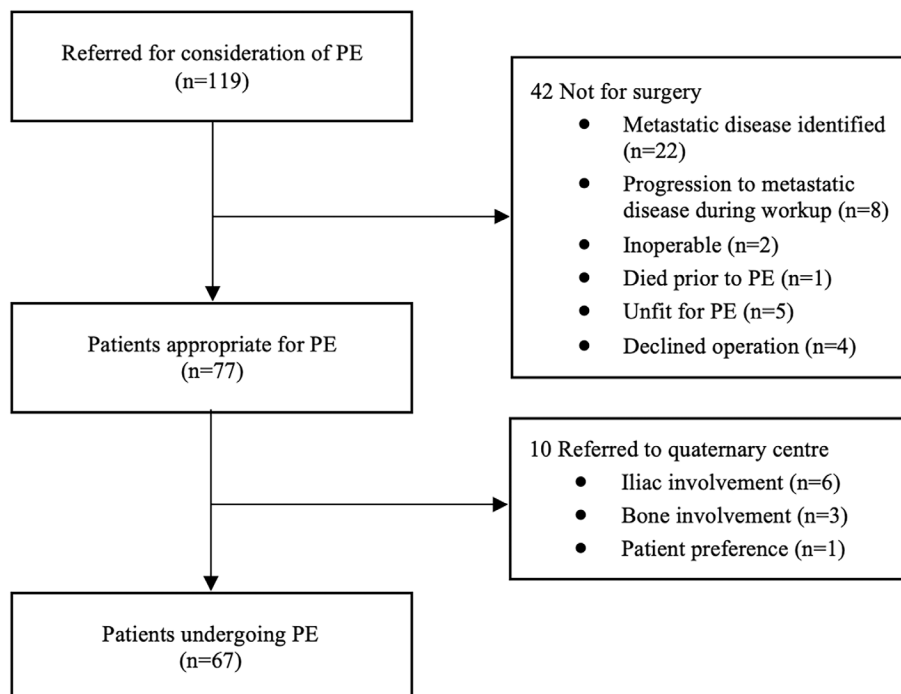
Table 1 summarises the differences in baseline characteristics. No differences were observed in age, gender and BMI. Following June 2017, a greater proportion of higher-grade, American Society of Anaesthesiologists (ASA) 3 and 4 patients underwent surgery (30.4 versus 54.6%,  $P = 0.036$ ). Disease type also changed with a greater incidence of gynaecological cases (34.3 versus 19.6%) and benign disease (10.4 versus 2.2%,  $P = 0.034$ ). Patients had more advanced cancer, with a greater proportion of T4b cases (48.1 versus 6.7%,  $p < 0.001$ ). There was also a shift in the type of neoadjuvant therapy administered, with greater utilization of TNT in patients with rectal cancer. Subsequently, less adjuvant therapy was given post resection (46.6 versus 71.1%,  $P = 0.012$ ), and there was

an increase in the length of time from radiotherapy to surgical resection (14.5(8–300) versus 10 (1–17) weeks,  $P = 0.002$ ).

Table 2 demonstrates the surgical characteristics. Post-PE service development, there were more modified and infralevator cases (31.3 versus 4.3%,  $P < 0.001$ ). No bone resection was performed prior to 2017, but 8 resections were performed after (five sacrum, two coccyx and one pubic bone) (11.9 versus 0.0%,  $P = 0.013$ ). More lateral pelvic lymph node dissections (LPLND) were also performed (13.4 versus 2.2%,  $P = 0.046$ ). Since the commencement of the PE service, there has also been a change in the stoma types, with increased double barrel uro-colostomies (8.8 versus 0.0%) and primary ileal conduits without colostomy (6.0 versus 0.0%). Also noted was an increased proportion of cases using myocutaneous



**Fig. 2.** Pelvic exenterations performed at Royal Adelaide Hospital and St Andrews hospital.



**Fig. 1.** Patient selection for patients undergoing pelvic exenteration (PE) post creation of PE service.

**Table 1** Baseline characteristics. Presented as mean ( $\pm$ standard deviation), median (range) or number (proportion)

	Pre-exenteration service (2008–May 2017) ( <i>n</i> = 46)	Post-exenteration service (June 2017–October 2021) ( <i>n</i> = 67)	<i>P</i> -value
Age, years	63.7 ( $\pm$ 14.8)	62.7 ( $\pm$ 12.6)	0.690
Gender			0.337
Female	36 (78.3)	47 (70.1)	
Male	10 (21.7)	20 (29.9)	
BMI, kg/m <sup>2</sup>	26.0 (17.0–67.0)	26.0 (14.0–51.0)	0.546
ASA			0.036
1	2 (4.3)	2 (3.0)	
2	30 (65.2)	28 (41.8)	
3	14 (30.4)	36 (53.7)	
4	0 (0.0)	1 (0.9)	
Tumour type			0.034
Colorectal	36 (78.3)	37 (55.2)	
Rectal	34	31	
Colon	2	5	
Anal	0	1	
Gynaecological	9 (19.6)	23 (34.3)	
Ovarian	2	12	
Vulval	4	5	
Endometrial	2	4	
Cervical	1	2	
Other	1 (2.2)	7 (10.4)	
Benign	1	3	
Anastomotic leak	0	2	
Bladder cancer	0	1	
Myosarcoma	0	1	
Primary or recurrence			0.257
Primary	38 (84.4)	46 (75.4)	
Recurrence	7 (15.6)	15 (24.6)	
Palliative resection	7 (15.6)	10 (16.7)	0.878
Clinical staging			<0.001
T			
0	1 (2.2)	1 (1.9)	
1	3 (6.7)	0 (0.0)	
2	2 (4.4)	0 (0.0)	
3	10 (22.2)	4 (7.7)	
4a	26 (57.8)	22 (42.3)	
4b	3 (6.7)	25 (48.1)	
N			0.815
0	23 (51.1)	29 (56.9)	
1	10 (22.2)	11 (21.6)	
2	12 (26.7)	11 (21.6)	
Neoadjuvant therapy	17 (37.8)	32 (52.5)	0.134
Neoadjuvant therapy type			0.005
Chemoradiotherapy	16 (94.1)	15 (46.9)	
Total neoadjuvant therapy	0 (0.0)	11 (34.4)	
Short course radiotherapy	1 (5.9)	3 (9.4)	
Chemotherapy only	0 (0.0)	2 (6.3)	
Brachytherapy	0 (0.0)	1 (3.1)	
Time from radiotherapy to resection, weeks	10 (1–17)	14.5 (8–300)	0.002
Adjuvant therapy	32 (71.1)	27 (46.6)	0.012
Discussed at MDT	46 (100.0)	64 (95.5)	0.269

Abbreviations: ASA, American Society of Anaesthesiologists physical status; BMI, body mass index; MDT, multidisciplinary team.

flaps (40.3 versus 33.9%,  $P = 0.010$ ). Despite increased surgical and patient complexity, theatre operating time remained unchanged (300 (150–660) versus 323 (125–743) min,  $P = 0.952$ ), and blood loss was significantly reduced in the latter period (500 (100–3000) versus 700 (50–4500) ml,  $P = 0.032$ ).

Table 3 demonstrates the pathological and postoperative outcomes. R0 resection was achieved in 84.2% of attempted curative cases pre-PE service, and this increased to 93.9% with PE service development, albeit not significantly different ( $P = 0.171$ ). There was a significant reduction in total and positive nodes in the

colorectal surgical cases ( $P < 0.05$ ), likely owing to increased rates of neoadjuvant treatment.

There was no change in overall complications (68.7 versus 69.6%,  $P = 0.918$ ), however there was a significant reduction in the high CD grade 4 complications (8.5 versus 31.3%,  $P = 0.001$ ), and a reduction in the median length of ICU stay (2 (1–8) versus 3 (2–9) days,  $P = 0.052$ ). CCI demonstrated no difference between the two cohorts (22.70 versus 26.95,  $P = 0.488$ ). 30-day mortality rate reduced with PE service creation; however this was not significantly different (1.5 versus 4.3%,  $P = 0.566$ ). Post commencement

**Table 2** Operative characteristics. Presented as median (range), or number (proportion)

	Pre-exenteration service (2008–May 2017) ( <i>n</i> = 46)	Post-exenteration service (June 2017–October 2021) ( <i>n</i> = 67)	<i>P</i> -value
Exenteration type			<0.001
Total	18 (39.1)	16 (23.9)	
Posterior	22 (47.8)	18 (26.9)	
Anterior	3 (6.5)	4 (6.0)	
Modified	2 (4.3)	13 (19.4)	
Infralevator	0 (0.0)	8 (11.9)	
Other	1 (2.2)	8 (11.9)	
Surgical approach			0.223
Open	44 (95.7)	65 (97.0)	
Laparoscopic assisted	0 (0.0)	2 (3.0)	
Laparoscopic converted to open	1 (2.2)	0 (0.0)	
Robotic	1 (2.2)	0 (0.0)	
Side wall extension	9 (19.6)	20 (29.9)	0.219
Side wall reconstruction	0 (0.0)	0 (0.0)	
Bone involvement	0 (0.0)	8 (11.9)	0.013
Bone operation type			0.068
No	46 (100.0)	59 (88.1)	
Sacrectomy	0 (0.0)	5 (7.5)	
S2	–	1	
S3	–	1	
S4	–	3	
Coccyx	0 (0.0)	2 (3.0)	
Pubic bone debridement	0 (0.0)	1 (1.5)	
Lateral pelvic lymph node dissection	1 (2.2)	9 (13.4)	0.046
Stoma type			0.016
None	9 (19.6)	11 (16.4)	
Ileostomy	12 (26.1)	10 (14.9)	
Colostomy	22 (47.8)	30 (44.8)	
Colostomy + ileal conduit	3 (6.5)	2 (3.0)	
Ileal conduit	0 (0.0)	4 (6.0)	
Double barrel uro-colostomy	0 (0.0)	10 (8.8)	
Flap used			0.010
None	35 (76.1)	34 (50.7)	
VRAM	7 (15.2)	8 (11.9)	
Omental	2 (4.3)	12 (17.9)	
VRAM & Omental	0 (0.0)	5 (7.5)	
Gracilis	2 (4.3)	3 (4.5)	
Other–gluteal, cecal, bladder, lotus	0 (0.0)	5 (7.5)	
Theatre operating time, minutes	323 (125–743)	300 (150–660)	0.952
Blood loss, ml	700 (50–4500)	500 (100–3000)	0.032
Drain	38 (82.6)	65 (97.0)	0.015

Abbreviation: VRAM, vertical rectus abdominis musculocutaneous flap.

of the PE service, the frequency of urosepsis reduced (11.9 versus 28.3%,  $P = 0.028$ ). Furthermore, complications such as flap breakdown (9.1 versus 18.2%,  $P = 0.0586$ ), pelvic collection (1.5 versus 8.7%,  $P = 0.156$ ), and anastomotic leak (4.0 versus 4.8%,  $P = 1.0$ ) exhibited no statistically significant reduction. Length of stay was 3.5 days shorter though not statistically significant, and 30-day readmissions remained unchanged (13.6 versus 13.0%,  $P = 0.928$ ).

## Discussion

Since the development of a PE service in June 2017, there has been a significant increase in the overall volume of surgery, and surgery was performed for patients with increased comorbidity and advanced cancer stage. Patients also underwent more complex surgery, with a higher rate of bone resections, LPLND and myocutaneous flap reconstruction. Despite this, there was an improvement seen in short-term surgical and clinical outcomes,

with reduced blood loss, major complications (CD grade 4), and length of ICU stay.

Our findings are well supported in the literature, showing that PE surgery by higher volume dedicated teams lead to more complex resections, higher R0 resection rates and lower mortality.<sup>7</sup> As in our cohort, advanced tumours were managed by more complex surgery with an increased number of flaps, bone resections, and LPLND performed.<sup>7</sup> Despite increasing surgical complexity there was no difference in theatre operating times, flap complications and pelvic collection/bleeding. CCI, encompassing all complications, also remained unchanged despite increased surgical complexity. Other short-term outcomes improved, with a significant reduction in intraoperative blood loss, ICU stay, and higher-grade complications. Additionally, we saw a clinically relevant (but not statistically significant) improvement in the 30-day mortality rate, now matching the reported global rate of 1.5%.<sup>5–7</sup> R0 resection rates improved to 93.9%, but this did not reach statistical significance as the study was underpowered for this outcome. Worldwide R0 rates

**Table 3** Pathological and perioperative outcomes. Presented as median (range), or number (proportion)

	Pre-exenteration service (2008–May 2017) (n = 46)	Post-exenteration service (June 2017–October 2021) (n = 67)	P-value
Pathological outcomes			
Pathological staging			
T			0.167
0/Tis	2 (4.4)	4 (7.8)	
1	0 (0.0)	4 (7.8)	
2	6 (13.3)	4 (7.8)	
3	11 (24.4)	10 (19.6)	
4a	16 (35.6)	11 (21.6)	
4b	10 (22.2)	18 (35.3)	
N			0.162
0	26 (57.8)	38 (76.0)	
1	12 (26.7)	7 (14.0)	
2	7 (15.6)	5 (10.0)	
M			0.474
0	37 (82.2)	42 (76.4)	
1	8 (17.8)	13 (23.6)	
R0 achieved	32 (84.2)	46 (93.9)	0.171
Lymph nodes <sup>†</sup>			
Total	19 (7–45)	14 (2–38)	0.005
Positive	0 (0–8)	0 (0–11)	0.043
Perioperative outcomes			
ICU length of stay, days	3 (2–9)	2 (1–8)	0.052
Complication	32 (69.6)	46 (68.7)	0.918
Transfusion required	21 (45.7)	25 (37.3)	0.375
pRBCs units given to patient	2 (1–23)	2 (1–20)	0.344
Major Flap breakdown/necrosis	2 (18.2)	3 (9.1)	0.586
Pelvic collection	4 (8.7)	1 (1.5)	0.156
Anastomotic leak	1 (4.8)	1 (4.0)	1.000
Urosepsis	13 (28.3)	8 (11.9)	0.028
Urinary leak	1 (4.3)	5 (12.5)	0.402
Pelvic bleeding	2 (4.3)	3 (4.5)	1.000
Total stay, days	14.5 (4–66)	11 (5–93)	0.754
Readmission within 30 days	6 (13.0)	9 (13.6)	0.928
30-day mortality	2 (4.3)	1 (1.5)	0.566
Highest CD grade			0.001
1	1 (3.1)	0 (0.0)	
2	19 (59.4)	33 (70.2)	
3	0 (0.0)	9 (19.1)	
4	10 (31.3)	4 (8.5)	
5	2 (6.3)	1 (2.1)	
CCI	26.95 (0–100)	22.70 (0–100)	0.488
CCI excluding patients with no complications	29.6 (21–100)	29.6 (9–100)	0.897

Abbreviations: CCI, comprehensive complication index; CD, Clavien–Dindo grade; ICU, intensive care unit; pRBCs, packed red blood cells.

<sup>†</sup>Colorectal cases only; Pre-exenteration service n = 36, Post-exenteration service n = 37.

are reported to be 79.9%.<sup>5</sup> We speculate our higher result is due to patient selection, a high proportion of primary (rather than recurrent cancers) and the comprehensive MDT approach.

We also noted a reduction in the total number of nodes harvested during surgery, representing the paradigm shift towards personalised TNT at our institution. Prior to 2019, patients were offered standard short course radiotherapy or long course CRT pre-operatively with the addition of adjuvant chemotherapy if patients were fit enough for this. Post-2019, rectal cancer patients were offered personalised TNT (pTNT). This regimen consisted of induction chemotherapy, followed by long course CRT for patients with a need for systemic control (distant failure) or, long-course CRT followed by consolidation chemotherapy for patients at risk of loco-regional failure (more common in this cohort).<sup>16</sup> In the present study 57.4% of rectal cancer patients requiring PE before 2019 underwent neoadjuvant therapy, and 70.4% received adjuvant

therapy. Post-2019, all rectal cancers undergoing PE had either neoadjuvant therapy (94.1%) and/or adjuvant therapy (20%). It remains hopeful that pTNT will contribute to long-term disease-free survival by increasing overall compliance with chemotherapy.<sup>17,18</sup>

Since June 2017, there has also been increased adoption of double barrel uro-colostomies in selected patients.<sup>19</sup> This method of diversion benefits patients by having a single stoma appliance, and avoiding an additional small bowel anastomosis, as would be required for separate ileal conduit urinary diversion.<sup>19,20</sup> This technique is becoming increasingly popular for these reasons, and may have contributed to the reduction in major complications seen in our study. Notably, there was a significantly lower rate of urinary sepsis recorded after 2017.

This study has several limitations. First, comparing a retrospective and prospective cohort is subject to recall bias. However, prospective data collection typically records higher rates for variables



like complications compared to retrospective data collection. Therefore, we are relatively confident that outcomes were better in the latter phase of the study, and if anything, the effect is under-estimated. Pre-PE service, cases were not correctly identified as modified or infralevator PE in operative records. We also do not report long term outcomes, despite having follow up ranging from 3 to 158 months. A long-term comparison between the two cohorts would be underpowered and difficult to interpret due to the mix of gynaecological and colorectal cases and different follow-up duration between groups. This will be subject to further study once longer follow-up is achieved and there are a larger number of comparable groups with minimum follow-up greater than 2 years. We look to further improve the PE service, through the involvement of pre-rehabilitation, psychological and palliative care services as part of the MDT process.

## Conclusion

The development of a dedicated PE service significantly improved short term patient outcomes, despite the inclusion of patients with more advanced disease and comorbidity. This supports a dedicated specialised multidisciplinary approach to locally advanced pelvic malignancy.

## Author Contributions

**Luke Traeger:** Conceptualisation; formal analysis; investigation; writing – original draft; writing – review and editing. **Sergei Bedrikovetski:** Formal analysis; investigation; writing – original draft; writing – review and editing. **Martin Oehler:** Investigation; writing – review and editing. **Jonathan Cho:** Investigation; writing – review and editing. **Marcus Wagstaff:** Investigation; writing – review and editing. **Jack Harbison:** Investigation; writing – review and editing. **Mark Lewis:** Investigation; writing – review and editing. **Ryash Vather:** Investigation; writing – review and editing. **Tarik Sammour:** Conceptualisation; investigation; methodology; supervision; writing – review and editing.

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## Conflicts of interest

None declared.

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## Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

**Data S1.** STROBE Statement—checklist of items that should be included in reports of observational studies.