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ORIGINAL ARTICLE

Short-term Outcomes of a Dedicated Pelvic Exenteration Unit in a Tertiary Hospital in Malaysia

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ABSTRACT

Background : Pelvic exenteration offers potentially curative resection for locally advanced pelvic malignancy. A dedicated unit performing this complex surgery is recommended to achieve optimal outcomes.
Objectives : The aim of this paper is to show that pelvic exenterations can be performed with acceptable oncological and safe perioperative results in an appropriately resourced specialist centre. **Methods :** Patients undergoing pelvic exenteration in the Colorectal Unit, Hospital Kuala Lumpur between January 2017 and January 2024 were included. Patients operated in the initial setup period of the unit (January 2017 – July 2020) were compared to the second half (August 2020 – January 2024) with univariate analysis. **Results :** A total of 30 patients were included, with a significant increase in the unit caseload over the study period (n = 11 versus n = 19). There was an increased use of neoadjuvant therapy and an increase in stage of disease at presentation (p = 0.014) in the second half of the study period. More complex procedures were performed in the latter period, involving both bony and pelvic side wall resections. There was no difference in complication severity (Clavien Dindo) (p = 0.257) and R0 resection was achieved in 76.7% of operated cases. **Conclusion :** The development of a dedicated pelvic exenteration unit, leads to an increase in patient volume and an increase in the complexity of the procedures performed, without compromising short term outcomes

Keywords: *Pelvic exenteration, Colorectal surgery, pelvic malignancy, Multidisciplinary care*

and safety.

INTRODUCTION

Pelvic exenteration refers to the radical multivisceral resection of tumors of the pelvis, followed by reconstruction or diversion of genitourinary and gastrointestinal function followed by repair of the pelvic defect (Brown et al., 2017, Humphries et al., 2019). Achieving R0 resection is the goal, and it is the most important predictor of survival and quality of life after surgery (Brown et al., 2017). Advances in anaesthesia, blood transfusion, medical imaging, intensive care, patient selection, as well as surgical techniques have allowed increasingly radical, higher and wider resections to be undertaken safely (Harji et al., 2013). As a result, long-term survival has become achievable with an acceptable rate of complications, when performed in dedicated units.

Despite these advances, pelvic exenteration surgery remains a major operation, with R1 resection rates remaining high, and surgery still being associated with significant morbidity and mortality. A systematic review (Platt et al., 2019) reports R0 rates to be 74% (range 41.7% - 90.2%), whilst R1 resection rates were reported to be between 7 and 46.7%, with a median of 17.5%. Globally, significant morbidity (Clavien Dindo (CD) grade 3–4) was seen in 37.8% of patients, with a 30-day mortality rate of 1.5%, and a reported median overall survival of 43 months (PelvEx Collaborative, 2017, Venchiarutti et al., 2017).

Furthermore, there is a high degree of variability in the reporting of outcomes between centres (Platt et al., 2018). Efforts of groups like the Pelvic Exenteration Collaborative (PelvEX Collaborative), which constitutes over 140 units internationally, aim to prospectively analyse and standardise the reporting and outcomes of patients undergoing pelvic exenteration to help define guidelines and optimise treatment strategies. This will lead to further standardisation between groups and drive forward research in this topic.

In this spirit, we have established our dedicated pelvic exenteration unit in January 2017. Hospital Kuala Lumpur is a tertiary hospital in the capital city of Malaysia and is well equipped to handle multidisciplinary complex cases. The aim is to streamline and improve the treatment pathway of patients requiring pelvic exenterations as well as being involved in knowledge and skills transfer through international collaboration. Patients being considered for pelvic exenteration were discussed at the respective oncology mutildisciplinary team (MDT) meeting and a collaborative team plan was made before surgery. Recently, other such centres have shown good oncological and perioperative results in the establishment phase of their dedicated pelvic exenteration unit (Traeger et al., 2019, Dickfos et al., 2018). In this paper we share our experience and compare our outcomes from the year 2017 to present.

MATERIALS AND METHODS

This study is reported using the Strengthening The Reporting of Observational studies in Epidemiology (STROBE) guidelines (von Elm et al., 2008).

Consecutive patients undergoing pelvic exenteration in Hospital Kuala Lumpur, Malaysia were included between January 2017 and January 2024. The study period is divided into two parts which we term the 'Early' period (January 2017 – July 2020), and 'Later' period (August 2020 – January 2024) for comparison of outcomes. The unit is led by colorectal surgeons and involves gynaeoncology surgeons, orthopedic surgeons, plastic reconstructive surgeons, vascular surgeons, urologist, radiologist and

oncologists. Pelvic exenteration was defined using PelvEx collaboration definitions. Total pelvic exenteration was defined as complete en bloc resection of the rectum, genitourinary viscera, internal reproductive organs, regional lymph nodes and peritoneum. Partial pelvic exenteration included those having an anterior, posterior and/or modified pelvic exenteration. Anterior pelvic exenteration included resection of the bladder with or without the internal reproductive organs (uterus, vagina, cervix, prostate, seminal vesicles). Posterior pelvic exenteration included resection of the rectum with or without the internal reproductive organs, while preserving the bladder. Modified pelvic exenteration was subdivided into those requiring lateral sidewall compartment resection with/without neurovascular resection or those requiring a bony resection (PelvEx Collaborative, 2019).

The patients are identified through the Pelvic Exenteration database, which was set up upon inception of our dedicated PE unit and the data is collected through digital and paper records retrospectively. Demographic, operative, pathological, as well as perioperative outcomes including transfusion requirements, and 30-day complications (CD grades) were recorded (Clavien et al., 2009). We also recorded the patient's length of stay in hospital, readmission rates and 30-day post operative mortality. Patients with incomplete data were excluded from the study. (Figure 1)
Patients were staged preoperatively with a combination of computed tomography, magnetic resonance imaging and positron emission tomography in selected cases. A MDT discussion is then held, and a collective decision is made for treatment with either Ip therapy (TNT), long-course chemoradiotherapy (CRT), short course radiotherapy or no neoadjuvant therapy. Following neoadjuvant therapy and subsequent restaging, the patients were then reassessed at another MDT, with a plan for surgical treatment if indications are fulfilled. Patients deemed suitable for surgery are then planned for operation involving the respective disciplines. Patients were not offered surgery if they had unresectable metastatic disease, were clinically not fit for surgery, had no surgical reconstructive options or in situations where the patients refused surgical treatment. The pathology specimen was examined by a pathologist and was defined as curative with an R0 (microscopic and macroscopic clear margins), R1 (if the margins were <1 mm) or R2 (microscopic or macroscopic evidence of an involved resection margin). Pathological stage was reported based on the American Joint Committee on Cancer, Cancer staging manual.

The analysis was performed using SPSS Statistics for Windows, Version 28.0 (IBM Corp, Armonk, NY, USA). Univariate analysis was performed for continuous variables in the data with the Mann–Whitney U or student-t test, whilst categorical variables were analysed using the $\chi 2$ or Fisher's exact test ($n < 5$). Numerical data are presented as either a mean (standard deviation, SD) or median (range), depending on its parametricity as calculated by the Shapiro–Wilk test. P-values of ≤0.05 were set as the threshold of statistical significance.

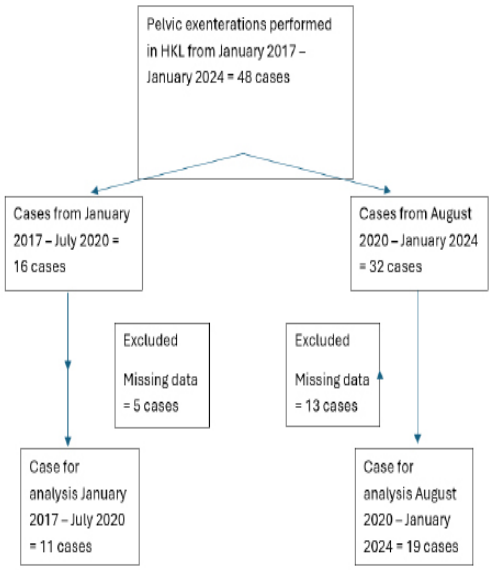

Figure 1: Flow diagram of patient selection

RESULTS

Throughout the study period (January 2017 – January 2024), a total of 48 pelvic exenterations were performed. The medical records were screened through retrospectively and were assessed for completeness of data. Any cases which had incomplete data were then excluded, leaving 30 cases for analysis (Figure 1). When looking at the number of pelvic exenterations performed year to year, it shows an increasing trend with a total of 13 cases performed in 2023 (Figure 2). The eligible cases were then divided to two separate phases, the 'early' (January 2017 – July 2020) and the 'later' (August 2020 – January 2024) whilst there were 3 cases (15.8%) performed for recurrent disease from August 2020 – January 2024 which suggests the increased complexity of the surgery performed.

There were more cases performed for Stage II and III disease in the latter period (Stage II 27.3% versus 63.2%, Stage III 27.3% versus 36.8%, P = 0.014). Looking at the utilisation of neoadjuvant therapy in the patient groups, reveals more patient undergoing neoadjuvant therapy in the later group (54.6% versus 73.7%, P = 0.237) which was not statistically significant. There appears to be an increase in the use of TNT in the later group which

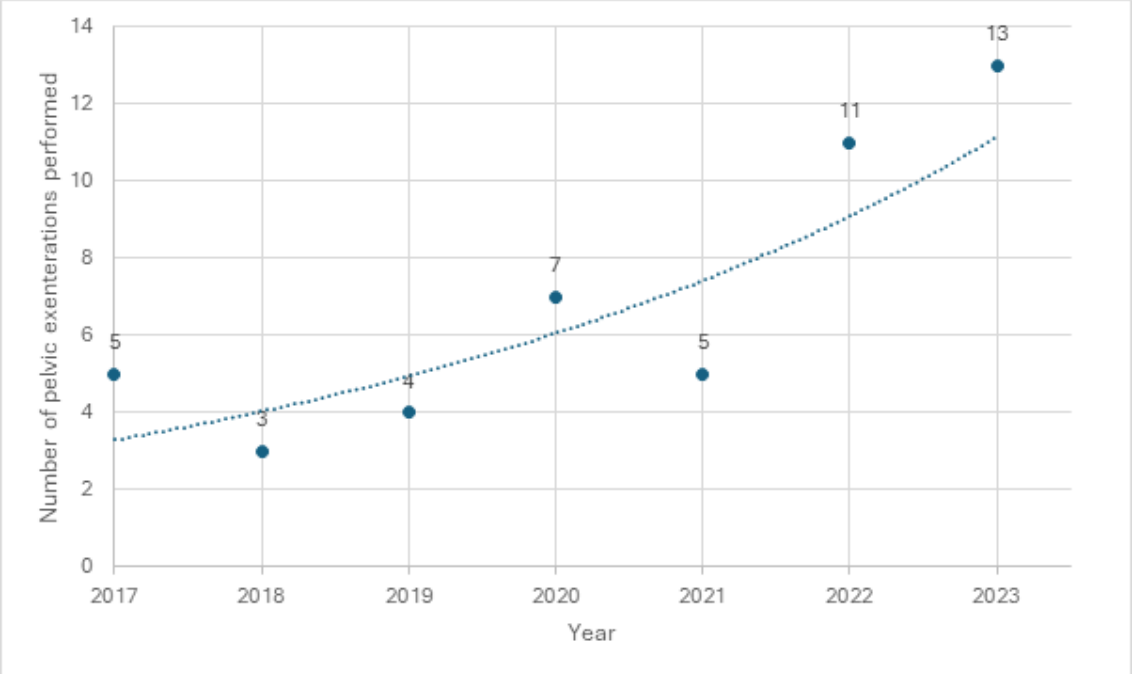

Figure 2: Number of pelvic exenterations performed in Hospital Kuala Lumpur by year 2017 - 2023

which constitutes 11 cases (36.7%) and 19 cases (63.3%).

Table 1 summarises the differences in baseline characteristics of our patients. No differences were seen in patient age, and gender. Both patient groups also showed no difference in the grade of the American Society of Anaesthesiology (ASA) grading (ASA 2 54.5% versus 78.9%, ASA 3 27.3% versus 15.8%, P = 0.33). Before August 2020 all of the cases performed were for primary malignant disease depicts the change in the worldwide trend of patient treatment throughout the 2019 COVID pandemic period. All cases were discussed in the MDT before planning for surgery.

Table 2 depicts the perioperative outcomes of the patients in our study. There were more modified pelvic exenterations after August 2020 as compared to the first half of our study period although this did not achieve statistical significance (P=0.516). From January

Table 1: Patient Demographics (presented as mean (+/-standard deviation), median (range) or number (proportion)diagram of patient selection

	January 2017 - July 2020 n = 11	August 2020 - January 2024 n = 19	p-value
Age, years	56.3 (+/-13.25)	52.3 (+/-17.74)	0.189
Gender			0.592
Male	3 (27.3)	7 (36.8)	
Female	8 (72.7)	12 (63.2)	
ASA			0.33
1	2 (18.2)	1 (5.3)	
2	6 (54.5)	15 (78.9)	
3	3 (27.3)	3 (15.8)	
4	0 (0.0)	0 (0.0)	
Primary or recurrence			0.2973
Primary	11 (100)	16 (84.2)	
Recurrence	0 (0.0)	3 (15.8)	
Palliative resection	3 (27.3)	0 (0.0)	
TNM staging			
T			
0	1 (9.1)	0 (0.0)	
1	0 (0.0)	0 (0.0)	
2	1 (9.1)	0 (0.0)	
3	2 (18.2)	4 (21.1)	
4a	0 (0.0)	2 (10.5)	
4b	7 (63.6)	13 (68.4)	
N			0.893
0	6 (54.5)	12 (63.1)	
1	3 (27.3)	4 (21.1)	
2	2 (18.2)	3 (15.8)	
AJCC staging			0.014
I	2 (18.1)	0 (0.0)	
II	3 (27.3)	12 (63.2)	
III	3 (27.3)	7 (36.8)	
IV	3 (27.3)	0 (0.0)	
Neoadjuvant Therapy			0.237
CCRT	2 (18.1)	4 (21.1)	
SCRT	0 (0.0)	1 (5.3)	
TNT	1 (9.1)	7 (36.8)	
Chemotherapy only	4 (36.4)	2 (10.5)	
No Neoadjuvant	5 (45.4)	5 (26.3)	
Discussed at MDT	11 (100)	19 (100)	

Abbreviations : ASA, American Society of Anaesthesiologists; CCRT, concurrent chemoradiation therapy; SCRT, short course radiation therapy; TNT, Total neoadjuvant therapy; MDT, multidisciplinary team

2017 – July 2020 all cases were performed as open surgery as opposed to after, where the laparascopic approach was attempted in a total of 8 cases (42%). Of this number 2 were performed via laparascopic surgery successfully while the remaining 6 cases required conversion to open surgery. There were no cases performed laparascopically prior to August 2020 and this was statistically significant (P value = 0.043).

Bone resections were performed in 2 cases (1 case S3 sacrectomy, 1 case S4 sacrectomy). Operative time was longer in

the second group (420 minutes versus 540 minutes, P value = 0.02). All of these findings is in relation to the likely increased complexity of cases performed within the unit over the years. Despite this the intraoperative blood loss remained similar (1000ml versus 1500ml, P value = 0.5) and the total ICU stay, and hospital stay were also similar between the two groups (14 days versus 15 days). There was no difference in the highest Clavien Dindo complication rates (P = 0.257).

R0 resection was achieved in 9 cases (81%) and 14 cases (74%), before and after August 2020 respectively. The difference between the two groups did not achieve statistical significance (P = 0.612).

DISCUSSION

Since the establishment of our pelvic exenteration service in January 2017, there has been a significant increase in the overall volume of surgery. This increase in volume is also matched with an increase in surgery performed for patients with increased comorbidity and more advanced stages of cancer. In addition to that, patients also underwent more technically complex surgery, with a higher rate of bone resections. There has also been an introduction of the utilisation of minimally invasive surgery in our pelvic exenterations. Despite a longer operative time, there appears to be no compromise in the outcomes of the surgery with similar R0 rates as well as no increase in the overall rates of perioperative complications. Our findings are well supported in the literature, showing that pelvic exenteration surgery which were performed by higher volume dedicated teams, leads to more complex resections, higher R0 rates and at the same time lower overall mortality rates (Venchiarutti et al., 2019).

Overall R0 resection rates in our study was 76.7% (23/30 cases). This is comparable to the worldwide R0 rates of 74% (Platt et al., 2018). Although these rates appeared to decline when comparing the earlier study period versus the latter (81% versus 74%), the decline was not statistically significant and is likely explained by the increase in case complexity and higher staging of the cases being treated.

The pattern of neoadjuvant therapy utilisation showed a trend favouring the use of TNT in the second period. Before the year 2019, our patients were offered the option of standard short course radiotherapy or long course CCRT preoperatively with the addition of adjuvant chemotherapy if clinically indicated and the patients were fit enough. Throughout the COVID pandemic, as a response to further understanding of neoadjuvant therapy options and as an adaptation to the changing patient treatment environment, patients are offered a TNT approach. This regimen involves the use of short course radiotherapy followed by a period of consolidation chemotherapy (RAPIDO regime) (Bahadoer et al 2021). At 3 years after randomisation, the cumulative probability of disease-related treatment failure was 23·7% (95% CI 19·8–27·6) in the experimental group versus 30·4% (26·1–34·6) in the standard of care group (hazard ratio 0·75, 95% CI 0·60–0·95; p=0·019) (Bahadoer et al., 2021). However, the long term follow up of the same cohort has raised questions on it effectiveness in controlling locoregional recurrences (LRR). At the 5 year follow up, LRR was detected more often [44/431 (10%) vs. 26/428 (6%); P =0.027], with more often a breached mesorectum (9/44 (21%) vs. 1/26 (4); P =0.048) possibly due to the longer waiting interval post radiation leading to more difficult surgery (Djikstra et al. 2023). The balance between improving local control and managing systemic disease will require further refinement in the treatment of rectal cancer. Although the principles of TNT appear practical and sound, further evidence are needed to prove whether this approach will contribute to long-term disease-free survival by increasing overall compliance with chemotherapy.

Table 2: Perioperative outcomes, presented as median (range), number (proportion)

	January 2017 - July 2020	August 2020 - January 2024	p - value
Exenteration Type			0.516
Total	4 (0.36)	5 (0.26)	
Anterior	2 (0.18)	2 (0.11)	
Posterior	5 (0.46)	9 (0.47)	
Modified	0	3 (0.16)	
Surgical Approach			0.043
Open	11 (1.0)	11 (0.58)	
Laparascopic	0 (0.0)	2 (0.11)	
Laparascopic convert to open	0 (0.0)	6 (0.31)	
Side wall extension	2 (0.18)	2 (0.11)	
Bony involvement	0 (0.0)	2 (0.11)	0.265
Lateral Pelvic Lymph node dissection	0 (0.0)	1 (0.05)	0.439
Type of bone resection			0.265
No	11 (1.0)	17 (0.89)	
Sacrectomy	0 (0.0)	2 (0.11)	
Extent of resection			0.612
R0 resection	9 (0.81)	14 (0.74)	
R1 resection	2 (0.19)	5 (0.26)	
Operating time, minutes	420 (208-660)	540 (330-1140)	0.02
Blood Loss	1000 (500-4000)	1500 (200-5000)	0.5
Packed cells transfused	2 (0-4)	2 (0-4)	
Anastomotic leak	0 (0.0)	0 (0.0)	
Surgical site infection	2 (0.18)	4 (0.21)	
Urinary leak	1 (0.09)	1 (0.05)	
Total ICU Stay, days	1 (0-4)	1 (0-2)	
Total Hospital Stay, days	14 (7-30)	15 (5-150)	
Readmision within 30 days	1	1	
30-day mortality	0 (0.0)	0 (0.0)	
Highest CD grade			0.257
1	7 (0.64)	7 (0.37)	
2	2 (0.18)	9 (0.47)	
3	2 (0.18)	3 (0.16)	
4	0 (0.0)	0 (0.0)	
5	0 (0.0)	0 (0.0)	

Abbreviations : CD, Clavien - Dindo

The complexity and potentially high associated morbidity of these extended surgeries necessitate meticulous planning and a MDT approach. Since the year 2022, our unit has been involved in a dedicated pelvic exenteration MDT initiated by our colleagues from Hospital Pulau Pinang. This MDT is focused on pelvic exenterations and receives interstate referrals from within Malaysia as well as the occasional international cases for discussion. The MDT process allows for a thorough review of the resectability of a tumor and discusses the possibility of other treatment adjuncts i.e radiotherapy, chemotherapy. Offering patients with advanced pelvic malignancy the reasonable chance of cure is the fundamental basis on which these radical and potentially morbid procedures are performed, and therefore ensuring appropriate patient selection processes are critical (O'Shannassy et al. 2020).

In achieving the goal of optimizing

patient outcomes, there has been a trend towards centralisation of pelvic exenteration surgery in dedicated units in tertiary hospitals. Looking at the PelvEx Collaborative data (PelvEx Collaborative, 2019). (the trend analysis from 2004 – 2015 reveals improvements in blood transfusion and resection margins status over time in high-volume centres (>20 pelvic exenterations per year) (PelvEx Collaborative, 2019). These findings reflect improvements in patient selection, better multidisciplinary input, and improvements in overall perioperative care. Several authors have also shown a reduction in 5-year overall mortality in high-volume referral centres (Aquina et al., 2016, Liu et al., 2015). Our centre currently performs 7-10 pelvic exenterations per year, and with hopes of further centralisation as well as a strengthening referral network, these numbers are likely to rise.

There are several limitations to this study. The use of retrospective data exposes the study to recall and reporting bias. The use of the retrospective database has also led to incomplete data retrieved, as seen in our study where 18 cases were excluded from the initial 48 cases. Long term outcomes were also not discussed as the analysis would be difficult given the mix of different procedures as well as different oncological approach and follow up duration between groups. A larger population and prospectively collected data would be more valuable in a future study to look at the outcomes post pelvic exenteration in our centre. Moving forward, our goal is to further improve our pelvic exenteration services and this can be achieved with the inclusion of other perioperative care processes such as psychological, the involvement of pre-rehabilitation, as well as palliative care services as part of the MDT workflow.

CONCLUSION

The development of a dedicated pelvic exenteration unit significantly improved short term patient outcomes despite more complex surgical resections and the inclusion of patients with more advanced disease. It also allows for the development of high-volume centres focused on performing pelvic exenteration surgery, which will improve the overall provision and training of locally advanced pelvic malignancy care. This supports a dedicated specialised multidisciplinary approach to locally advanced pelvic malignancy.

CONFLICT INTEREST

There is no conflict of interest declared by the authors.

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