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Original Research Article

Pelvic exenteration for locally advanced and local recurrent primary rectal cancer: a 5 years Asian retrospective cohort study and lessons to learn

Yeen Chin Leow[1]*, Fitjerald Henry[1], Fei Yee Lee[2]

[1]Department of Surgery, Colorectal unit, Selayang Hospital, Lebuhraya Selayang-Kepong, Batu Caves, Selangor, Malaysia
[2]Clinical Research Centre, Selayang Hospital, Ministry of Health, Malaysia

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***Correspondence:**
Dr. Yeen Chin Leow,
E-mail: y_chin1981@yahoo.com

ABSTRACT

Background: Locally advanced rectal cancer (LARC) and local recurrent rectal cancer (LRRC) were deemed incurable, but with surgical advancement, pelvic exenteration has emerged as a curative option. Although colorectal cancer cases are common, pelvic exenterations are limited to several centres in Malaysia. The study aimed to determine the outcomes of pelvic exenteration from the centre in terms of complete resection, local recurrence rate, mortality rate and complications rate.
Methods: Retrospective data collection was done for pelvic exenteration surgeries of LARC and LRRC from year 2014 till 2018 in a Malaysian tertiary referral centre. Demographic data, types of pelvic exenteration, postoperative complications, postoperative histopathology for complete resection (R0) and local recurrence were collected from the hospital medical records.
Results: From 2014 till 2018, 51 cases of pelvic exenteration were done, with a mean age of 55.8±12.4 years and predominance of male gender (55%). Thirty-four cases (66.7%) completed the exenteration. A mere 24 cases (47.1%) had complete preoperative imaging of computed tomography (CT scan), pelvic magnetic resonance imaging (MRI) and positron emission tomography-computed tomography (PET/CT) scan. R0 resection was achieved in 23 cases (67.6%). Complications were found in 44.8% of patients including anastomotic leak, collection, surgical site infection or cardiac/lung complications. The 30-days postoperative mortality rate is 3.9%. The six-months local recurrence rate was 5.8% and one-year local recurrence rate was 7.8%.
Conclusion: Pelvic MRI and PET-CT scan is suggested to be compulsory for all pelvic exenteration candidates to ensure a good outcome. Multidisciplinary team approach is needed preoperatively to discuss the feasibility of pelvic exenteration to optimise the outcomes of this surgery.

Keywords: Pelvic exenteration, LARC, LRRC

INTRODUCTION

Nearly 30% of rectal cancer patients have LARC, defined as tumour invasion or adherence to local tissue without evidence of distance spread.[1,2] Previous reports indicated that 5-30% of rectal cancer is LRRC, defined as intrapelvic recurrence following a primary rectal cancer resection with or without distant metastasis.[3-5] In the past, LARC and LRRC were rendered incurable and technically inoperable, but the management evolved dramatically over the past few decades with the availability of radical exenterative surgery through multidisciplinary approach in 6 to 10% of LARC patients.[6,7] Without surgery, the median survival of LARC patients were reported to be less than one year, and less than 5% for 5 years overall survival.[8] Palliative

chemotherapy can only extend patients' lifespan by 10 to 15 months.[9] Surgical intervention via pelvic exenteration is the only modality potentially curative for LARC and LRRC.[7,10-12]

Pelvic exenteration is an en bloc operative resection of pelvic tumour, as well as the invaded pelvic viscera involved, which aims to extirpate all pelvic malignant disease to achieve tumour-free margins.[13] Pelvic exenteration is considered when a primary rectal cancer extends through the rectal wall and mesorectal fascia, invading into the prostate, seminal vesicles, bladder, posterior vaginal wall/vault, sacrum or soft tissue and/or the neurovascular contents of the lateral compartments.[13,16] Tumour-free margins are often described as the clear resection margin (R0), which is defined as complete resection margin macroscopically and microscopically, and is the most important predictive factor for survival of patients with LARC or LRRC.[2,15-18]

Surgical management of LARC and LRRC is challenging, especially when patients present with obstruction, fistulation and/or bleeding.[10] LRRC cases are complicated by patients' past surgical histories and the use of adjuvant treatments. Pelvic exenteration is linked with high rate of morbidity and mortality in the past, due to its extensiveness.[19,20] However, the advancement in surgical techniques over time, optimised preparation from multidisciplinary team approach, advances in imaging, and perioperative care have improved the morbidity and mortality of pelvic exenteration.[13,21] The 5-year overall survival after pelvic exenteration for LARC varied in different practice, ranging from 22-66%.[15-17]

Despite the fact that colorectal cancer is the second most common cancer in Malaysia, there are limited availability of centres for LARC and LRRC care.[22] The review and optimisation of pelvic exenteration in Malaysian centres are therefore important to facilitate the delivery of better care to LARC and LRRC patients. The primary aim of this study is to describe pelvic exenteration cases in an Asian tertiary centre over five years in term of R0 rate, complications, 30-days mortality rate, as well as six-months and one-year local recurrence rate.

METHODS

This retrospective cohort study reviewed all LARC and LRRC patients who were decided to undergo pelvic exenteration over five-years from 1 January 2014 to 31 December 2018 in Selayang hospital, a public tertiary care colorectal centre in the central region of Malaysia. This 960-bed hospital is governed by the ministry of health, Malaysia and is one of the tertiary referral centres that provide pelvic exenteration for LARC and LRRC patients, as well as colorectal surgery training for over ten years.

Inclusive criteria included patients who diagnosed with LARC or LRRC and had their preoperative imaging work up (either only thorax, abdomen and pelvic CT or with pelvic MRI and PET/CT and were deemed eligible or suitable for pelvic exenteration after multidisciplinary team meeting (colorectal surgeon, radiologist, oncologist, urologist, onco-gynaecologist) were included in analyses.

Surgical procedures and associated care: the decision for pelvic exenteration for each patient was made upon multidisciplinary discussion involving radiologists, urologists, oncologists, colorectal surgeons and if implicated, onco-gynaecologists. All pelvic exenterations were aimed for curative intention after the imaging discussion. Some of the patients were referred from other hospital with at least preoperative CT scan and colonoscopy findings available during referral. Some of the patients were worked up completely in Selayang Hospital, including the MRI and PET-CT scans. Total pelvic exenteration was defined as en bloc resection of rectum, genitourinary viscera and reproductive internal organs.[23] Anterior pelvic exenteration included resection of the bladder with or without 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.[23]

Patients subjected to pelvic exenteration were also reviewed by anaesthetists pre-operatively with optimisation of comorbidities. Blood transfusion was done if haemoglobin level was less than 10 g/dL. In addition, pre-operative antibiotic prophylaxis, venous thromboembolism prophylaxis, bowel preparation and antiemetics were prepared for patients prior to the pelvic exenteration. Patients and their family members were counselled thoroughly on the risks and benefits of the surgery. Specialised nurses provided additional counselling to patients who require stoma post-surgery.

Surgeries were leaded by two senior consultant colorectal surgeon assisting by two colorectal trainees in main operative theatres in the centre. Two consultant urologists and one consultant onco-gynaecologist were involved if needed for radical cyst prostatectomy and total hysterectomy. All consultants with at least 5 years' experience in their subspecialty. All pelvic exenterations were performed in open laparotomy method. The anaesthetists administered general anaesthesia and epidural analgesics for post-surgery pain control. Patients underwent the surgeries in supine lithotomy position for six to eight hours. Patients were observed in intensive care unit post-surgery. The resected specimens were sent to our hospital's pathology department for histopathological analysis.

Subjects were discharged when they were clinically stable, indicated by ambulating, tolerating orally, well-functioning stoma or normal bowel function, and satisfactory wound condition. Patients were followed up at outpatient clinics two weeks, one month then two monthly post-discharge. Short term complications which

occur 30 days post-operation, including anastomotic leak (bowel or ileal conduit), surgical site infection, intraabdominal/pelvic collections, cardiac/lung complications (post-operative myocardial infarction, nosocomial pneumonia) were recorded. Patients were also followed up for at least one-year post-surgery via routine clinic visits to detect local recurrence through proper work up including imaging.

Data collection: the subjects' demographic data (age, gender), types of pre-operative workout imaging, intra-operative procedures, immediate postoperative complications (within 30 days from surgery), 30-days mortality, histopathological reports from resected specimens and recurrence in one-year post surgery were collected from the hospital electronic medical records (Cerner Millenium®, Missouri, United States of America).

A R0 resection from histopathological evaluation is defined as all margin are adequately clear including proximal and distal margin and a circumferential resection margin (CRM) of >2 mm. R1 resection was the presence of microscopic residual disease defined, whereas R2 resection was the presence of macroscopic residual disease.

Sample size calculation estimation was calculated using the population proportion formulae.[24] Prior data indicate that the proportion of R0 rate among pelvic exenteration cases is 0.799 and population size is 51. If the type I error probability and precision are 0.05 and 0.05, will need to study 43 samples. With an additional of 10% dropout rate, the sample size is 48 samples.[25]

Statistical analysis: the data obtained were entered in a database using excel 2013. The data analysis was performed by using the IBM SPSS statistics for windows version 23.0 (IBM Corp., New York). The categorical variables are summarized as frequencies and percentages, and the numerical variables as means and standard deviations (SDs). Fisher's exact test was used to study association between categorical data and local recurrence at six months and one year respectively. All probability values are two-sided and a level of significance of less than 0.05 (p value <0.05) is considered as statistically significant.[26]

RESULTS

Patient demographics: a total of 51 patients were decided for pelvic exenteration during the study period. The number of pelvic exenteration increased from 7 cases in year 2014 to 15 cases in year 2018. The mean age of patients was 55.8±12.4 years old. Male gender was predominant in this cohort (28 cases, 54.9%). The ethnicity distribution corresponded with the demographics of Malaysian population, with the most recorded cases among Malay ethnicity (27 cases, 52.9%), followed by Chinese ethnicity (19 cases, 37.3%) and Indian ethnicity (5 cases, 9.8%) (Table 1). Pre-operation workup and types of exenteration surgery performed: There was no pre-operative MRI or PET-CT scan performed in more than half of the patients with 27 cases (52.9%) (Table 1). Out of the 51 cases, 17 cases (33.3%) have failed to proceed with pelvic exenteration mainly due to discovery of peritoneal metastases or irresectable disease intraoperatively. Therefore, 34 cases (66.7%) completed pelvic exenteration. Posterior exenterations recorded the highest number at 15 cases (29.4%), followed by total exenteration with 10 cases (19.6%) and anterior exenteration with 9 cases (17.6%) (Table 1).

Table 1: Characteristics of patients who were scheduled pelvic exenteration in the centre.

Characteristics	Results (n=51) (%)
Number of cases per year	
2018	15 (29.4)
2017	8 (15.7)
2016	8 (15.7)
2015	13 (25.4)
2014	7 (13.7)
Age (years) (mean ± SD)	55.8±12.4
Gender	
Male	28 (54.9)
Female	23 (45.1)
Race	
Malay	27 (52.9)
Chinese	19 (37.3)
Indian	5 (9.8)
Preoperative MRI/PET-CT	
Yes	24 (47.1)
No	27 (52.9)
Procedures	
Total exenteration	10 (19.6)
Anterior exenteration	9 (17.6)
Posterior exenteration	15 (29.4)
Failed exenteration	17 (33.3)

MRI, magnetic resonance imaging, PET-CT, Positron emission tomography-computed tomography

Pathology: From the 34 cases with completed pelvic exenteration, the post-operative histopathological results showed that 67.6% (23 cases) achieved complete clear margin resection (R0). R1 and R2 were reported as 29.4% (10 cases) and 2.9% (1 case) respectively. In term of number of total lymph nodes harvested, 67.6% (23 cases) harvested more than 10 lymph nodes (Table 2).

Patient outcomes: Short-term outcomes, out of the 51 cases, 28 cases (54.9%) were discharged home without any complications. Surgical site infection is the most common type of post-operative complication reported with 8 cases (15.6%), followed by anastomotic leak (bowel or ileal conduit), as well as cardiac/lung complications with 6 cases (11.7%) respectively.

Table 2: Outcomes of pelvic exenteration and mortality.

Characteristics	Results (n=51) (%)
Completeness of resection [a]	
R0	23 (67.6)
R1	10 (29.4)
R2	1 (2.9)
Number of lymph nodes harvested [a]	
< 5	5 (14.7)
1-0	6 (17.6)
11-15	6 (17.6)
>15	17 (50.0)
Post-operative complications	
None	28 (54.9)
Surgical site infection	8 (15.7)
Leak	6 (11.8)
Lung/cardiac complications	6 (11.8)
Intraabdominal/pelvic collections	3 (5.9)
Six-months local recurrence	
Yes	2 (5.8)
No	32 (94.2)
Not applicable (failed exenteration)	17 (33.3)
One-year local recurrence	
Yes	4 (7.8)
No	28 (54.9)
Not applicable (failed exenteration and had local recurrence at six months)	19 (37.2)
30 days mortality	
Exenteration performed	2 (3.9)
Failed exenteration	-
One-year mortality	
Exenteration performed	5 (9.8)
Failed exenteration	8 (15.7)

[a] Not including cases with failed exenteration.

Table 3: Comparison between the characteristics of local recurrence in six months and one year.

Variables	Local recurrence in six months (N=34)		P value	Local recurrence in one year (N=32)		P value
	Yes N=2 (5.8%)	No N=32 (94.2%)		Yes N=4 (11.7%)	No N=28 (89.3%)	
Age (years) (mean ± SD)	66.0±2.8	53.5±12.5	0.176	46.3±1.5	54.1±12.7	0.306
Ethnicity						
Malay	0 (0)	20 (62.5)	0.082	3 (100)	17 (58.6)	0.655
Chinese	1 (50)	9 (28.1)		0 (0)	9 (31)	
Indian	1 (50)	3 (9.4)		0 (0)	3 (10.3)	
Gender						
Male	2 (100)	12 (37.5)	0.162	2 (66.7)	10 (34.5)	0.299
Female	0 (0)	20 (62.5)		1 (33.3)	19 (65.5)	
Preoperative MRI/PET-CT						
Yes	1 (50)	14 (43.8)	1.000	0 (0)	14 (48.3)	0.238
No	1 (50)	18 (56.3)		3 (100)	15 (51.7)	
Type of Procedures						
Total Exenteration	2 (100)	8 (25)	0.144	1 (33.3)	7 (24.1)	0.929
Anterior Exenteration	0 (0)	9 (28.1)		1 (33.3)	8 (27.6)	
Posterior exenteration	0 (0)	15 (46.9)		1 (33.3)	14 (48.3)	

Continued.

Failed Exenteration	-	-		-	-	
Post-Operative Complications						
None	1 (50)	13 (40.6)	0.663	2 (66.7)	11 (37.9)	0.363
Leak	0 (0)	5 (15.6)		0 (0)	5 (17.2)	
Surgical site infection	0 (0)	7 (21.9)		0 (0)	7 (24.1)	
Intraabdominal/pelvic	0 (0)	3 (9.4)		1 (33.3)	2 (6.9)	
Collection Lung/ cardiac complications	1 (50)	4 (12.5)		0 (0)	4 (13.8)	
Completeness of resection						
R0	2 (100)	21 (65.6)	1.000	2 (66.7)	19 (65.5)	1.000
R1	0 (0)	10 (31.3)		1 (33.3)	9 (31)	
R2	0 (0)	1 (3.1)		0 (0)	1 (3.4)	

MRI=Magnetic resonance imaging, PET-CT=Positron emission tomography-computed tomography.

Intra-abdominal/pelvic collections were reported in 3 cases (5.8%) (Table 2). The 30-days mortality rate was 3.9% (Table 2).

Long-term outcome: from the 34 pelvic exenterations performed, recurrence of disease was seen among 6 cases (17.6%) within a year from the surgery. From the 6 recurrent cases, local recurrence rate was reported in six months from the surgery with 2 cases, which corresponds to 5.8% of the cohort (Table 2). The remaining 4 cases (7.8% of the cohort) had local recurrence after six months. The one-year mortality rate of patients with pelvic exenterations completed was 9.8% (Table 2). The comparison between local recurrent cases and non-recurrent cases of the 34 pelvic exenterations performed in six months and one-year post-surgery respectively did not display significant difference in age, ethnicity, gender, pre-operative imaging, types of exenteration, post-operative complications, and completeness of resection (Table 3).

DISCUSSION

Pelvic exenteration is a curative surgical approach for LARC and LRRC without distance metastasis. R0 resection and negative nodal status are fundamental to favourable survival outcomes.[10,17,23,27] To the best of our knowledge, this is the first retrospective cohort study describing the outcome of pelvic exenteration practice in Malaysia. Centre caters most of the LARC and LRRC mainly from centre and northern regions of the country and is one of the highest referral cases for pelvic exenteration in Malaysia.

To achieve a good outcome, proper patient selection, pre-operative work up and post-operative care are essential.[11,12] From study, more than half of the patients who subjected to pelvic exenteration had only with preoperative imaging of CT TAP (thorax, abdomen and pelvic) done and no preoperative MRI pelvis and PET-CT, which may contributed partially to the failed exenterations (open and close or palliative diversion stoma due to intraoperative findings of inoperable peritoneal carcinomatosis or infiltration to major vessel and bony structures). Pre-operative MRI or PET-CT imaging are suggested to be included in part of the preoperative work up apart from CT TAP before a patient is subjected to major pelvic exenteration considering that the surgery carries high morbidity.[6,7,10-12] Pre-operative MRI or PET-CT imaging could improve the judgment on the suitability of patient as a good pelvic exenteration candidate by detecting unresectable disease, such as distant metastasis, bilateral sciatic nerve involvement and circumferential bone involvement.[13]

From the study, about one-third of pelvic exenterations failed to proceed intra-operatively as due to disease progression to peritoneal region or to other compartments. Involvement of lateral compartment and neurovascular bundle is a major challenge in our setting given our limited experiences and absence of back up team to deal with that. Other countries with advanced vascular and reconstructive surgical techniques have high radical resection rate to achieve clear resection margins.[15,28,29] However, resection of pelvic sidewall is still challenging.[30,31] Hence, we need to enhance our multidisciplinary back up system for pelvic exenterations, and we need to be given more training opportunities on such surgical techniques, especially pelvic side walls resection to improve the success rate of pelvic exenterations.

Approximately one-third of our pelvic exenterations did not have R0 resection, which is not the best outcome that we want to achieve. Incomplete resection margin (R1 or R2) increases the probability of local recurrence.[13] One year local recurrent rate was about 17.6% (6 cases) among the successful pelvic exenterations. Enhanced multidisciplinary management can improve the R0 outcome. Vigilant patient selection for neoadjuvant therapy may render an unresectable LARC and LRRC to a resect able condition with higher chances of R0. Besides, by involving more sub-specialists intraoperatively if needed, especially experience vascular surgeons and spinal orthopaedic surgeons can contributes to more R0. In addition, surgeons' techniques and skills might have room for improvement.

The rate of our post-operative complications concurs with the previously reported rates ranging from 37-100%.[13] The presence of various complications post-operatively

suggest that the patient management of pelvic exenterations could be improved. This is important to minimise the duration of hospital stay and subsequently healthcare costs associated with such post-operative complication care.

Although nearly half of the pelvic exenterations had post-operative complications, the 30-days mortality reported was only 3.9% (2 cases) from post-operative myocardial infarction and nosocomial pneumonia. The findings were similar with previous studies which suggest that the survival benefits from pelvic exenteration overweigh the post-operative complications of pelvic exenteration.[13]

The study is limited by its retrospective nature with small sample size in single centre setting, which is unsurprising as pelvic exenteration is highly subspecialized and only performed in limited number of institutions among selected patients, resulting in a small number of patients over a long period of time.[13] Further evaluation with prospective cohort study, or study with longer follow up period could be carried out to study the long-term survival rate in our setting.

CONCLUSION

In conclusion, optimisation of pelvic exenteration is important as it is the only curative treatment option for LARC and LRRC in this era. A multidisciplinary approach encompassing sub-specialists would be helpful in optimising the outcomes of pelvic exenteration. Pre-operative planning and workout, especially preoperative MRI and PET-CT scans, should be made mandatory for pelvic exenteration candidates. Long-term survival in LARC and LRRC is possible with pelvic exenteration if local recurrence is truly isolated, diagnosed early and treated aggressively with resected clear margin.

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