

Research Article

Pelvic Exenteration for Centrally Recurrent Gynaecological Malignancy

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Abstract

Background: Pelvic exenteration is an extensive operation, which offers the potential of cure to women with centrally recurrent gynaecological malignancy. The aim of this study was to assess the clinical outcome and factors influencing survival in these patients.

Methods: This was an observational cohort study of all patients who underwent pelvic exenteration for centrally recurrent gynaecological malignancy between March 1999 and October 2015. Data were collected from both the pelvic and gynaecologic oncology prospective databases. Determinants of survival were analysed using Kaplan-Meier survival curves.

Results: This study included 41 women who underwent pelvic exenteration for centrally recurrent gynaecological malignancy. The median patient age was 66 (range 27-79) years with a median follow up of 30 (range 0.4- 178) months. The median survival time was 22.3 (range 0-178.4) months. The 5- year survival rate was 32.4% for the entire cohort. A negative resection margin (R_0) was achieved in 85.4% (35/41). This group had a median survival of 36.2 (range 0.4-178.4) months compared to patients who had a positive resection margin (R_1), who had a median survival of 9.8 (range 1.2-15.1) months (p=0.0053). Postoperative radiotherapy was administered in 24.4% (10/41). Postoperative morbidity and mortality rates were 51% and 2.4% respectively. Major complications were noted in 24.4% of patients.

Conclusion: Pelvic exenteration for recurrent gynaecological malignancy was associated with a reasonably good survival rate, especially if complete resection was achieved. Optimising patient selection and peri-operative care, combined with a high-quality multi-disciplinary surgical approach are key factors in achieving good outcomes.

Keywords: Pelvic exenteration; Cancer recurrence; Pelvic clearance; Gynaecological malignancy; Radiotherapy

Introduction

Pelvic exenteration is an extensive operation, which involves *en bloc* removal of all or some of the pelvic organs. It was first described by Brunschwig in 1948 as a palliative operation for locally advanced cervical cancer [1]. It has now become a recognised form of potentially curative treatment for centrally recurrent gynaecological cancers, especially in institutions where optimal surgical skills and extensive peri-operative support can be provided [2]. In gynaecological oncology it is mainly reserved for centrally recurrent cervical, endometrial, vaginal or vulval cancer. In selected patients with central recurrence of tumour, pelvic exenteration is often the only viable option for cure despite advances in radiotherapy and chemotherapy [3].

Pelvic exenteration can be classified according to anatomical compartments - anterior, posterior and total pelvic exenteration in terms of which organs are removed. It can also be classified in terms of the infra and supra-levator compartments respectively [4]. The 5 year survival rate in the literature is variable with a range from 30-60% [2,5-12]. Furthermore, despite recent advances in surgery, anaesthesia and perioperative care, the procedure still has a high treatment related morbidity (range 50 to 94%) and mortality (range 0 to 5%) [6,12,13].

The Swansea Pelvic Oncology Group was established in 1999 and has developed widespread experience in pelvic exenteration for all pelvic tumour types [14]. More recently we reviewed our clinical outcomes in patients undergoing exenterative surgery for locally advanced primary rectal cancers [15]. The aim of the current study was to analyse clinical outcomes and determinants of survival for patients undergoing pelvic exenteration for centrally recurrent gynaecological malignancy in a single tertiary referral centre.

Methods

All patients undergoing pelvic exenteration for recurrent

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gynaecological malignancy between July 1999 and October 2015 were included in this observational cohort study. Following approval from the Abertawe Bro Morgannwg University (ABMU) Health Board Audit Department, all patients undergoing pelvic exenteration were identified from both the prospectively maintained pelvic and gynaecologic oncology databases respectively, and verified from theatre records, hospital patient management systems and patient records. The study was reported in accordance with STrengthening the Reporting of Observational studies in Epidemiology (STROBE) methodology for observational studies [16] (Figure 1).

All patients were discussed formally at the Swansea Pelvic Oncology multidisciplinary team (MDT) meeting prior to treatment. Tumours were initially staged at presentation with chest, abdominal and pelvic computerised tomography (CT). After the MDT meeting all patients were assessed clinically in the pelvic-oncology clinic with support from a specialist cancer nurse. At the time of that review, patients are carefully counselled about the potential risks and benefits of operative treatment as well as any alternative treatment options, including neoadjuvant therapy. All patients subsequently underwent examination under anesthesia (EUA) as a part of the standard staging process with complementary cystoscopy and/or endo-anal ultrasound/ sigmoidoscopy as necessary. From 2003 pelvic magnetic resonance

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imaging (MRI) was used for patient selection to determine the extent of contiguous pelvic organ invasion (local staging) and to exclude pelvic side wall involvement, which been shown to be associated with significantly shorter overall survival and disease-free survival [17,18]. Pelvic exenteration was not offered to patients with evidence of distant (extrapelvic) metastatic disease on CT scan. From 2013, Positron Emission Tomography (PET) became routinely available and was added to our staging protocol. If there was no evidence of distant metastatic spread on CT, a PET was performed. Patients were only considered for pelvic exenteration if the PET showed no evidence of distant metastases.

Pre-operative planning in terms of contiguous pelvic organ involvement dictated the surgical expertise represented at each particular case and routinely included colorectal, urological, gynaecological and plastic reconstructive surgeons. Posterior pelvic exenteration (PPE) was defined as en bloc resection of the reproductive organs with the rectum but with bladder preservation. The extent of rectal excision would be determined by the colorectal surgeon present at the time of the operation. Anterior pelvic exenteration (APE) was defined as an block resection of the reproductive organs, including part or the entire vagina with bladder. Rectal sparing was possible in these patients, especially if the posterior vagina remained intact. A Wallace 66-type ureteroileal conduit was used for urinary diversion [19]. Total pelvic exenteration (TPE) was defined as complete resection of the rectum (total or inter-sphincteric), genitourinary viscera and reproductive organs. More recently, we defined pelvic exenteration as supra-levator, when the pelvic organs were removed without disruption of the pelvic floor musculature; or infra-levator, when the pelvic floor muscles were removed with the adjacent organs, leaving the pelvic floor completely disrupted [4]. All patients were considered for pelvic floor reconstruction at the time of surgery, which was performed using a combination of pelvic omentoplasty, collagen implantation (Permacol[™]) although more recently myocutaneous flaps have become the standard.

Data regarding the primary origin of the tumour were collected alongside that regarding tumour type. Complete resection (R₀) was defined pathologically as the absence of tumour cells within 1mm or greater of the resection margin. Microscopic residual pelvic disease (R_1) was defined as a presence of the tumour cells of less than 1 mm from the resection margin. Frozen section analysis was performed at the time of operation if there was suspicion of intraperitoneal or para-aortic node involvement. If this confirmed extra-pelvic metastatic disease, then the procedure was abandoned. Histopathology results were categorised according to whether the patient received neoadjuvant therapy (ypT) or had proceeded straight to surgery (pT). Surgical outcome measures were recorded and included: postoperative length of hospital stay; 30day operative mortality as well as 30- and 90-day morbidity respectively. Surgical complications were classified using the Calvien-Dindo grading system [20]. The need for post-operative perineal reconstruction was recorded. The reconstructive options used included a vertical rectus abdominis myocutaneous (VRAM) flap, gracilis flaps (uni-lateral or bilateral), or inferior gluteal artery myocutaneus (IGAM) flap. Data on the type of reconstruction, post-operative wound complications, or the need for further revision and flap-related morbidity were also recorded.

Patients were followed up routinely at regular intervals for an indefinite length of time in a dedicated pelvic-oncology clinic. A CT was performed at the end of any adjuvant treatment and also after one year. The primary outcome measure was overall survival, which was defined as the time from the date of exenteration to the date of death or date of last follow up. Secondary outcome measures included time to

recurrence, which was defined as the time from the date of exenteration to date of radiological or histological detection of recurrent disease. Factors influencing survival and recurrence were also analyzed.

The level of socio-economic status was measured by the Welsh Deprivation Index. The "Indices of multiple deprivation" (IMD) is a validated tool that has been used by the UK government to audit and analyse deprivation since 2007. The devolved Welsh government uses its own version (WIMD) for analysis in Wales due to its rural population and high levels of deprivation.

Statistical Analyses

Statistical analyses were performed using the StatsDirect version 3.0 for Windows (StatsDirect Ltd. UK). Survival curves were calculated by the Kaplan–Meier method and differences between curves compared using the Wilcoxon log rank test. The results were presented as a Hazard Ratio and 95% Confidence Interval. Other comparisons between treatments were done with the Mann–Whitney test for continuous or ordered categorical data or the Chi² test, if appropriate. P=0.05 (two-sided) was considered the limit of significance.

Results

From July 1999 to October 2015, 41 women underwent pelvic exenteration for centrally recurrent gynaecological malignancy. The median age was 66 (range 27-79) years. The median ASA score was 2. The median survival time was 22.3 (range 0.4 - 178.4) months. The overall three and five year survival rates were 47.9% and 32.4% respectively. There was no difference in survival rate between patients above (22/41) and below (19/41) sixty five years of age (p=0.34) [HR 0.67 95% CI 0.30 - 1.52]. The level of socioeconomic status did not appear to influence survival time (p=0.1) (Table 1).

Complete excision (R_0) was achieved in 35/41 (85.4%) patients. This was associated with a median survival of 36.16 (range 0.4-178.4) months. Conversely, incomplete excision was associated with a poor median survival of 9.97 (range 1.17-15.07) months. The difference in survival between R_0 and R_1 resection was found to be statistically significant (p=0.0053) [HR 0.28 95% CI 0.06 - 1.35] (Figure 2). Of the six patients who had R_1 resection (6/41, 14.6%), none received post operative radiotherapy due to previous radiation treatment for their primary tumour. Five of these patients received chemotherapy and one refused it.

Histopathological examination revealed that there was one complete pathological response to chemoradiotherapy. Pelvic lymph node dissection was not routinely performed in any of the patients. Involvement of mesenteric or mesorectal nodes did have a trend towards shorter survival, but this did not reach statistically significant. (p=0.07) [HR 0.44 95% CI 0.14-1.47] (Figure 3).

There were 13 anterior (APE), five posterior (PPE) and 23 total pelvic exenterations (TPE). The median operative time was 333 minutes (range 88-574). There was no difference in survival rate in relation to the type of exenteration performed (p=0.70). The most commonly treated cancer was endometrial (53.7%) 22/41, followed by cervical (29.7%) 12/41, Vulvar (7.3%) 3/41, vaginal (7.3%) 3/41 and one ovarian cancer (2.4%) 1/41. There was no difference in survival time in terms of primary site (p=0.27).

The most common histological type of cancer was adenocarcinoma 20/41 (48.8%), followed by squamous cell carcinoma (SCC) 15/41 (36.6%). There were also six other tumours (14.6%) - four low grade sarcomas arising from endometrium (Mullerian type sarcoma) one

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adenosquamous carcinoma and one complete pathological response to neoadjuvant chemo radiotherapy. There was no statistical difference in survival rate in relation to tumour histological type (p=0.60), even after removing sarcomas from the analysis (p=0.43) Fifteen patients had lymphovascular invasion (LVI) and ten had perineural invasion (PNI) in their tumour. There was no statistical difference in survival in relation to LVI (p=0.41) [HR 1.44 95% CI 0.62-3.34] and PNI (p=0.75) [HR 1.17 95% CI 0.45-3.03].

There was no difference in survival rate for patients receiving preoperative radiotherapy (p=0.66) [HR 0.82 95% CI 0.36-1.91], preoperative chemotherapy (p=0.17) [HR 1.89 95% CI 0.82-4.36], or post operative chemotherapy (p=0.78) [HR 1.12 95% CI 0.48-2.63].

Pelvic reconstruction was performed in fourteen (34.1%) patients. The most common type of flap used for reconstruction was the VRAM flap (Table 2). Flap reconstruction did not influence survival time (p=0.26) [HR 0.57 95% CI 0.24-1.36]. Of those having a flap reconstruction 85.7% (12/14) had R₀ resection compared to 85.2% (23/27) without flap (p=0.68).



Figure 1: Flow diagram showing patients included in the cohort. Only patients undergoing pelvic exenteration for centrally recurrent gynaecological malignancy were included in the study.



Six patients developed recurrence during the follow up period. Five recurrences were diagnosed on CT scan as a mass in the pelvis and one was diagnosed by ascitic fluid biopsy. The median time from operation to recurrence was 13.5 months (range 4.1-80.3). Median survival time from the time recurrence was diagnosed was 4.6 months (2.3-37.3). There was no correlation between local recurrence and the presence of complications (P=0.25)[HR 0.59 95% CI 0.2-1.75], flap reconstructions (P=0.12) [HR 0.54 95% CI 0.17 - 1.64],LVSI (P=0.15) [HR 0.52 95% CI 0.17 - 1.63]age above or below 65 (P=0.38) [HR 0.67 95% CI 0.24 - 1.9] and tumour location (P=0.13) [HR 0.51 95% CI 0.16 - 1.58].

Fifty one percent of patients experienced post operative

Features	Values		
Age	Median 66 (range 27-79) years		
Previous radiotherapy	24		
Previous chemotherapy	15		
	Complete pathological response - 1		
	Adenocarcinoma - 19		
Histology	Squamous cell carcinoma (SCC) - 15		
	Adenosquamous - 1		
	Sarcoma (mullerian type) - 4		
Tumour location	Endometrium - 22		
	Cervix - 13		
	Vagina - 2		
	Vulva - 3		
	Ovary - 1		
Median operative time	322 min (range 88-574)		
Type of exenterations	APE - 13		
	PPE - 5		
	TPE - 13		
Boringol reconstruction	Yes - 14		
Perineal reconstruction	No - 27		
Type of reconstruction	VRAM - 7		
	Gracilis flap - 4		
	IGAP - 3		
Reoperation due to complications	8		
Completeness of resection	R0 - 35		
	R1 - 6		
Mean LOS	22 (range 7-46)		

Table 1: Patient demographics and surgical details.



Figure 3: Differences in overall survival depending on original primary site of tumour (p=0.27). Vulval, vaginal and ovarian tumour are displayed together as other pelvic tumour.

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complications of which 24.4% had major complications (Table 3). The 30 day post operative mortality rate was 2.4% (1/41). This patient died as a result of cardiac arrest due to myocardial infarction. The ninety day mortality was 5%. The most common complications were wound related (infection or dehiscence, 40.7%), followed by pelvic collection (18.5%) and fistula formation (7.4%). Three patients (11.1%) developed flap relation complications (ischaemia, wound complications). There was no difference in survival rate between patients with complications

Type of flap	No of patients	
VRAM	7	
GRACILUS	4	
IGAP	3	

 Table 2: Types of flaps used for pelvic reconstruction - VRAM, vertical rectus abdominis myocutaneous, IGAP inferior gluteal artery perforator.

Complications	No of patients	Calvien -Dindo Classifications	
Wound infections	8	1	
Wound dehiscence	3	3	
Flap ischaemia	2	3	
Pelvic collection	5	3	
Small Bowel Obstruction	2	3	
Fistula (recto-vaginal or vesico-vaginal)	2	3	
Stoma retraction	1	3	
Myocardial infarction	1	5	
Urinary incontinence	1	2	
Bladder leakage	1	3	
Injury to the iliac vessels	1	3	

Table 3: Post-operative complications using Calvien-Dindo classification.

Variables	OS (overall survival) months	DFS (disease free survival) months	5 years survival	p-value
Cervix	14.4 (range 3-158.1)	14.3 (range 3-158.1)	30.8%	
Endometrium	30.4 (range 0.4-178.4)	30.4 (range 0.4- 178.4)	45%	0.27
Vulva	20.1 (range 3.2-37.1)	16.8 (range 3.2- 26.2)	0	
Vagina	19.5 (range 1.2 - 19.5)	19.5 (range 1.2- 19.5)	0	
R ₀	32.9 (range 0.37-158.1)	31.3 (range 0.37- 158.1)	40.74%	0.0053
R ₁	9.97 (range 1.17-15.1)	9.4 (range 1.17- 15.1)	0%	
Adenocarcinoma	14.3 (range 1.2-158.1)	14.3 (range 1.2- 158.1)	23.1%	
SCC	30.4 (range 0.4 - 178.4)	30.4 (range 0.4- 178.4)	28.6%	0.60
Others	96.8 (range 7.2-155.4)	79.28 (range 7.2- 155.4)	66.7%	
Lymph node negative	31.3 (range 1.2-178.4)	28.8 (range 1.2- 178.4)	33.4%	0.07
Lymph node positive	12.6 (range 3.03-37.1)	11.3 (range 3.03- 37.1)	0%	0.07
T0-T2	95.3 (range 3.2-178.4)	95.3 (range 3.2- 178.4)	66.7%	
T3-T4	15.1 (range 1.2-158.1)	14.9 (range 1.2- 158.1)	20%	0.34
APE	52.2 (range 0.4-155.4)	52.18 (range 0.4- 155.4)	46.2%	
PPE	31.3 (range 6.3-119.7)	31.3 (range 6.3- 80)	40%	0.7
TPE	14.9 (range 1.2-178.4)	14.4 (range 1.2- 178.4)	13%	

Table 4: Univariable analysis for factors associated with overall survival.

and those without it (p=0.29) [HR 1.57 95% CI 0.69-3.57]. The median length of stay (LOS) was 22 days (range 7-46). Patients who experienced complications had a longer median length of stay than patients who didn't- 25 (range 11 -56) days vs. 16.5(range 7 - 30) days, but this was not statistically significant (p=0.70) (Table 4).

Discussion

Overall 5 year survival in our study was 32.4% after curative pelvic exenteration for gynaecological malignancy and with an acceptable morbidity and mortality rate, similar to that reported in the literature [12,21].

Longer survival was strongly dependent on clear resection margins, as no patients with an R₁ resection survived more than 16 months. This is consistent with published data, where margin involvement is one of the strongest negative predictors of survival [12,13,21,22]. This emphasises the importance of careful patient selection, planning and a highly developed multidisciplinary surgical approach. Recent studies suggest that MRI can accurately predict pelvic organ involvement and with CT scan allows selection of patients in whom it may be possible to achieve clear margins [17,23]. In our institution examination under anaesthetic (EUA), MRI pelvis and CT of the thorax, abdomen and pelvis are a part of standard pre-operative assessment. Despite this, 14% of patients still had microscopic margin involvement. This is consistent with other studies which have highlighted the difficulty in predicting a negative resection margin [13,18,23]. Furthermore, clear resection margins do not necessarily result in a survival benefit if the tumour has already metastasised. Thus PET has recently become our standard practice to identify patients with distant metastatic disease prior to consideration of exenterative surgery. In fact, recent data suggest that fusion of PET and MRI has higher sensitivity with detecting peritoneal spread as well as lateral pelvic wall extension, enhancing the staging process and thereby potentially contributing to better survival outcomes by virtue of better patient selection [17,23,24]. A large number of patients in our study were diagnosed and treated before the routine introduction of PET. We have found that frozen section analysis can be helpful at the time of surgery when there is suspicious intraperitoneal disease or enlarged para-aortic nodes. It can also help to discriminate whether there is true invasion of the pelvic side wall as opposed to extensive radiation fibrosis, thus guiding laterally extended pelvic resection [25].

There are suggestions by some authors, that selective use of chemotherapy may prolong disease free and overall survival after exenteration [26]. In our series postoperative use of adjuvant chemotherapy did not appear to influence overall survival. Unfortunately none of the patients who had positive resection margins were suitable for post-operative radiotherapy. This was due to previous radiation treatment for their primary cancer. Eighty three percent of patients with R_1 resection received adjuvant chemotherapy instead and one patient refused. There was no difference in survival rate between patients who received or did not receive adjuvant chemotherapy.

Lymphovascular invasion (LVSI) is a well documented risk factor in colonic, breast, urothelial and endometrial cancer [27]. Some authors also suggest that presence of LVSI in recurrent gynaecological cancer is associated with an adverse prognosis [12]. We found no difference in overall survival in patients with LVSI. Similarly the presence of lymph node (mesenteric or mesorectal) involvement was not associated with adverse survival, which may be explained by the heterogeneous nature of the cancer types. In a study undertaken by Westin and colleagues, both LVSI and lymph node involvement were associated with poor prognosis only in recurrent cervical tumour [12]. We did not observe shorter survival when there was regional lymph node involvement, as has been reported in other series [13], although we do not routinely perform pelvic lymphadenectomy at the time of exenteration. In terms of primary site, some authors have suggested that shorter survival is observed after exenterative treatment for recurrent vulvar cancer, with the longest survival observed after treatment for recurrent uterine cancer [28]. In our series however, there was no survival difference depending on primary site, although our numbers are small. This is consistent with findings reported in other series [13,29].

The postoperative complication rate after exenteration in the literature varies between 51 to 100% [12,13,21] and in our series was 51%, and most commonly wound related (infection and dehiscence), which is similar to other reports [7,12,13]. Our 30 day and 90 day mortality was 2.4% and 5% respectively, which again is similar to other reports [6,7,12,13,21,22]. We believe that our relatively low complication rate is directly attributable to our multidisciplinary pelvic surgical approach and the patient selection process, which is managed by the Pelvic Oncology MDT. This is supported by a robust preoperative workup, peri-operative care and support from the cancer specialist nurses in coordinating patient care and subsequent rehabilitation.

The obvious limitation of this study is its retrospective nature, although all cases were from a consecutive patient cohort and details were recorded using a prospectively maintained surgical database. Despite this, data capture was incomplete in some circumstances and case notes were needed to independently verify the dataset. In some cases, there were pre and perioperative risk factors, which we could not determine that may have influenced postoperative morbidity rates as well as overall survival. In addition, this is a single institution series and there have been changes in practice over the study period such as new staging modalities (PET). Quality of life (QOL) outcomes were not routinely collected until recently, and these outcomes are vital when considering the extensive nature of the surgery being performed. We have introduced a regular QOL assessment for our patients at the time of surgery and during their follow-up in the pelvic-oncology clinic.

Conclusion

Pelvic exenteration is an ablative surgical procedure that should be reserved for highly selected patients with centrally recurrent gynaecological cancer. Good outcomes can be achieved with careful preoperative selection. Our multidisciplinary surgical approach is an essential feature given that margin involvement (R_1) was the strongest predictor of poor prognosis. Furthermore when these procedures are undertaken by an experienced, dedicated multidisciplinary surgical team in a high-volume tertiary referral centre, relatively low mortality and morbidity rates can be achieved. Improvement is needed in terms of patient selection to determine predictors of survival and R_0 resectability, as well as other outcomes that are relevant to the patient and her quality of life following surgery.

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