Pelvic Exenteration in Patients with Persistent and Recurrent Cervical Cancer: A Case Series from Belarus

CASE SERIES

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ABSTRACT

INTRODUCTION: The prognosis of patients with persistent or recurrent cervical cancer (CC) is poor, and patient selection for exenterative surgery is challenging. The aim of this study was to determine the outcomes of patients undergoing pelvic exenteration (PE) for persistent or recurrent CC after treatment with radiotherapy in Belarus.

METHODS: A retrospective study was performed of 22 patients with persistent and recurrent CC who underwent supralevator PE from 2006 to 2012 at NN Alexandrov National Cancer Centre. Anterior PE was performed in 16 (72.7%) patients, posterior PE in 2 (9.1%) and total PE in 4 (18.2%) patients.

RESULTS: The mean surgical procedure time was 289.1 minutes. Urinary diversion was performed in 20 patients: 5 (25.0%) underwent ureterostomy and 15 (75.0%) underwent neobladder formation. Fecal diversion with end colostomy (Hartman's procedure) was performed in 5 patients and in one patient a rectosigmoid resection with anastomosis was performed.

The median follow-up time was 87 months (range, 4.4–146.0 months). To date, 16 (72.7%) patients have died of cervical cancer and there were no deaths due to other causes. The median survival was 17 months with a 5-year survival rate of 31.8% (SE 9.9%). Cox regression analysis showed that surgical margin status and pelvic lymph node involvement were independent risk factors for survival.

CONCLUSIONS: PE was found to be a safe and feasible option for patients with persistent or recurrent cervical cancer who do not have other potentially curative treatment options. Careful patient selection is needed to determine which patients will benefit from this treatment.

HIGHLIGHTS:

- Treatment options are limited for patients with persistent or recurrent cervical cancer
- Pelvic exenteration is a safe and feasible option for women in Belarus
- Positive surgical margins and positive lymph node status are risk factors affecting survival

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INTRODUCTION

Since 1999, concurrent chemoradiation therapy is considered to be the standard treatment for locally advanced cervical cancer (CC), with 70% primary CC patients in developed countries undergoing this type therapy [1–3]. Despite modern therapeutic treatments, pelvic recurrence rates range from 10% to 74% at 18 to 24 months following the completion of treatment. Recurrence rates vary by stage of CC: 10% of patients diagnosed with stage IB disease, 17% with stage IIA, 23% with stage IIB, 42% with stage III and 74% with stage IV [4]. Relapses that occur most often involve the surrounding organs and pelvic tissues, which leads to the need to simultaneously remove the bladder and/or rectum along with the recurrent tumor en bloc. This ultraradical operation involving multivisceral resection was first reported by A. Brunschwig, who initially performed pelvic exenteration (PE) with a palliative aim for locally advanced CC in 1946 [5]. Since that time, considerable experience has been gained in performing PE with the continuous improvement of not only surgical techniques, but also in refining the indications and patient selection for the procedure. It is currently recommended in women with recurrent or persistent cervical cancer in the central pelvis following radiation therapy and without evidence of metastatic disease [1].

In our Center in the Republic of Belarus, the PE has been performed in patients with locally advanced persistent and recurrent CC since 2006. The aim of the current study was to summarize a single institution experience with PE over a 7-year period including surgical outcomes, complications, and survival in a cohort of patients with persistent and recurrent CC after radiotherapy.

METHODS

INCLUSION CRITERIA

We performed a retrospective case series study of 22 consecutive CC patients who underwent supralevator PE from January 2006 through December 2012 at the Gynecological Oncology Department of the NN Alexandrov National Cancer Centre. This study was approved by the Ministry of Health of the Republic of Belarus (ID 20071434) and the Ethics Committee of the NN Alexandrov National Cancer Centre (protocol No. 17), Minsk, Belarus on 17 January 2006. This study was registered on *https://www.researchregistry.com*, the registration unique identifying number (UIN) is reserachregistry6506.

Patients were included in the study if they underwent a PE (anterior, posterior or total) for recurrent or persistent CC after treatment with radiotherapy. A persistent lesion, or a new lesion which occurred within 3 months after the completion of radiotherapy was considered persistent disease. Development of a new tumor occurring 3 months or more after complete remission was defined as recurrence of disease. Patients were excluded if they had primary disease or if they had not previously received radiotherapy. After PE there was no adjuvant treatment administered.

This case series has been reported in line with the PROCESS 2020 (*www.processguideline.com*) criteria [6].

EXAMINATION

Patients with biopsy-proven persistent or recurrent CC underwent a thorough preoperative assessment to evaluate their and indication for surgery. The primary indication for PE was persistent or recurrent CC without distant metastases after radiotherapy. Computerized tomography (CT) of the chest, abdomen and pelvis was performed in all patients (Positron Emission Tomography – Computed Tomography (PET–CT) was not available in Belarus during the study period). To assess the involvement of urinary bladder, all the patients underwent cystoscopy and intravenous urography. To assess the involvement of rectum, rectosigmoidoscopy was performed. Locoregional CC spread was evaluated by clinical gynecological examination and pelvic Magnetic Resonance Imaging (MRI).

All patients being considered for PE were reviewed at the tumor board – a multidisciplinary team meeting including gynecologic oncologists, radiation oncologists, diagnostic radiologists, and pathologists. Once PE was recommended, the procedure was discussed at length with the patient and family members. The patient was counseled regarding the risks, benefits and alternatives of the procedure as well as the possible complications and need for post-operative care and rehabilitation. Preoperative counseling also included discussion that metastatic disease may be discovered at the time of surgery and the PE abandoned. All surgical procedures were performed by experienced gynecological oncologists, who collaborated with urologists and general surgeons with the ultimate goal of curing cervical cancer in each patient. Postoperative complications were defined as early if they occurred within the first 30 days after surgery and late if they occurred more than 30 days after surgery. Complications were graded according to the Clavien–Dindo classification [7].

STATISTICAL ANALYSIS

Data were summarized using basic descriptive statistics. Survival times were estimated from the date of the PE surgery. Survival measures were calculated using the Kaplan-Meier method. Comparison of survival in two groups was performed according to the Log rank test, and in groups of three or more using the χ^2 criterion. To calculate the risk ratio (RR) and the 95% confidence interval (CI) of the RR, a Cox proportional risk analysis was used. Differences were considered statistically significant at $p < 0.05$. All p values were two-sided. The calculations were performed using the STATISTICA 10.0 application

software package (TIBCO Software Inc, Palo Alto, CA, USA) and Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows version 23.0, Armonk, NY, USA).

RESULTS

SURGICAL PROCEDURE

Age at surgery ranged from 28.0 to 62.0 years, with a median age of 46.4 years. Nineteen (86.4%) patients had a pathological diagnosis of squamous cell carcinoma and three (13.6%) patients had adenocarcinoma. Of the 22 patients enrolled, 12 patients had persistent (residual) stage IIIB CC with a mean time from chemoradiotherapy of 90.4 days (range, 45.0–181.0 days). Ten patients (stage IIB-IIIB) had recurrent disease with a mean time from primary treatment of 6.9 years (range, 7 months–12 years). Of the 22 patients enrolled, anterior PE was performed in 16 (72.7%) patients, posterior PE in two (9.1%), and total PE in four (18.2%). In two cases, an intermediate surgical step preceded PE: percutaneous nephrostomy tubes were placed due to anuria and renal insufficiency. Following stabilization of general health and bloodwork profiles, PE was performed.

The median duration of the surgical intervention was 289.1 minutes (range, 170.0 to 460.0) and it depended on the extent of the reconstructive procedures performed. The median estimated blood loss (EBL) was 1,089 ml (range, 700 to 2,200). Transfusion of blood components was required in all cases; in two patients, the erythrocyte reinfusion apparatus was used. The mean hospital stay was 40.1 days (range, 21.0 to 72.0). No intraoperative or perioperative deaths occurred.

Thirteen patients (59.1%) had negative margins and nine patients (40.9%) had positive margins (microscopically positive in 6 and macroscopically positive in 3). Pathological examination detected tumor metastases in pelvic lymph nodes (N1) in 8 (36.4%) patients despite negative preoperative imaging. Seven of eight patients (87.5%) with tumor metastases in pelvic lymph nodes had persistent CC.

Urinary diversion was performed in 20 patients (2 patients underwent posterior PE only): 5 (25.0%) patients underwent ureterostomy, 15 (75.0%) had plastic interventions for neocyst formation: W-like Hautmann ileocystoplasty in 6, continent heterotopic reservoir in 4, Bricker's operation in 5 patients. Reconstructive procedures were performed in the majority of patients: in 72.7% (8/11) of patients with persistent tumor and in 77.8% (7/9) of patients with recurrent disease.

Fecal diversion with colostomy was performed in six patients: five had end colostomy (Hartmann's procedure) and one had a complete rectal resection with anastomosis.

MORBIDITY

Early postoperative complications are described in ***Table 1***.

Early complications were observed in 14 (63.6%) patients, two of the patients had two complications – a postoperative wound infection in combination with pyelonephritis and an abscess in the pelvis in combination with venous thromboembolism. Five (22.78%) patients had severe early complications (grade III–IV) and required additional surgical intervention under general anesthesia. One of these patients had a postoperative wound dehiscence and infection and required a complex anterior abdominal wall closure by plastic surgery with mercilene mesh. Two patients developed a pelvic abscess requiring drainage. One patient developed a rectovaginal fistula and underwent diverting colostomy. Another patient developed a failure of the intestinal anastomosis of the urinary reservoir and required removal of the neocyst.

There were two cases of postoperative wound infection, one case of vaginal necrosis, and three cases of urinary incontinence; all classified as grade I complications. Grade II complications included exacerbations of chronic pyelonephritis, which were successfully controlled with antibiotics.

COMPLICATIONS		GRADE	
CHARACTERISTIC	NUMBER OF PATIENTS	GRADE	NUMBER OF PATIENTS (%)
Wound infection	2	I	6 (27.3)
Urinary incontinence	3		
Vaginal necrosis	1		
Pyelonephritis	4	II	4 (18.2)
Wound dehiscence and infection	1	IIIb	5 (22.7)
Pelvic abscess	2		
Recto-vaginal fistula	1		
Failure of the intestinal anastomosis of the urinary reservoir	1		
Venous thromboembolism	1	IV	1 (4.5)

Table 1 Early postoperative complications (within 30 days of surgery) according to the classification of Clavien-Dindo [7].

Late postoperative complications are summarized in ***Table 2*** and occurred in 8 (36.4%) patients. Two patients had two complications each: vesicovaginal fistula in combination with a lymphocyst (drainage was performed) and pyelonephritis in combination with partial urinary incontinence. Grade I-II late complications were noted in 6 patients: two patients had partial urinary incontinence, and five patients had recurrent pyelonephritis.

SURVIVAL

The median follow-up for all 22 patients was 87 months (range, 4.4–146.0 months). During the follow-up period, 16 (72.7%) patients died from cervical cancer, there were no deaths from other causes, therefore, for this group of patients, the overall and adjusted survival rates coincide. The median survival was 17 months, one-year survival was 63.6% (SE 10.3%), three-year survival rates was 40.9% (SE 10.5%), and 5-year survival rate was 31.8% (SE 9.9%).

To identify factors that may have affected the survival rate, a univariant analysis was performed using the Cox regression model. It should be noted that in accordance with the Harrell rules [8], Cox regression analysis can be carried out in the presence of at least 10 completed observations, and the number of predictors included in the analysis should be at least 10 times less than the number of completed observations. Since the number of completed observations in the studied cohort of patients is 16, it is correct to include in the Cox regression analysis no more than one predictor, that is, a univariate analysis. The results of a univariate analysis are presented in ***Table 3***.

Regression analysis showed that factors that can be reliably argued that they have a clinically and statistically significant effect on the risk of death from the underlying disease (and from any other causes) in the studied category of patients after PE are two: the margin status and pelvic lymph nodes involvement (N1). The risk after surgery with positive margin status is 4.36 (95% CI 1.51–12.563, p = 0.006) times higher than the risk after surgery with negative postoperative margins. The presence of metastases in the pelvic lymph nodes has a 3.33-fold (95% CI 1.18–9.42, p = 0.024) greater risk of death than in patients with N0 and confirms the negative effect of the presence of metastases in the lymph nodes on the survival of patients after PE [10].

The survival of patients based on margin status is presented in ***Figure 1***.

The median survival after surgery in patients with negative surgical margins was 57 months in comparison with 6 months in patients with positive surgical margins. The difference in the survival of patients of these two subgroups were clinically and statistically significant (p = 0.003). When resection margins were negative, 1-year and 5-year survival after PE were 76.9% (SE 11.7%) and 46.2% (SE 13.8%), respectively, and in patients with positive margins they were 22.2% (SE 13.9%) and 11.1% (SE 10.5%), respectively.

COMPLICATIONS		GRADE	
CHARACTERISTIC	NUMBER OF PATIENTS	GRADE	NUMBER OF PATIENTS (%)
Urinary incontinence	2	I	2 (9.1)
Pyelonephritis	5	II	5 (22.7)
Lymphocyst	1	IIIa	2 (9.1)
Vesicovaginal fistula	1		
Stricture of the uretero-cystic anastomosis	1	IIIb	1 (4.5)

Table 2 Late postoperative complications (greater than 30 days after surgery) according to the classification of Clavien-Dindo [7].

PREDICTORS	RISK RATIO OPTIONS		
	RR	95% CI RR	P-VALUE
Age, years: ≥50/<50	2.043	0.69–6.05	0.197
Concomitant diseases: yes/no	1.67	0.57–4.9	0.354
N1 (positive pelvic nodes)/N0 (negative pelvic nodes)	3.33	1.18–9.42	0.024
Tumor Grade: G3/G2/G1	0.82	1.17–3.85	0.796
Histology: squamous/adenocarcinoma	1.5	0.423–5.345	0.529
Margin status: positive/negative	4.36	1.51–12.563	0.006
Surgery type: total PE vs. anterior PE and/or posterior PE	1.142	0.15–8.94	0.9

Table 3 Univariate analysis of survival rate.

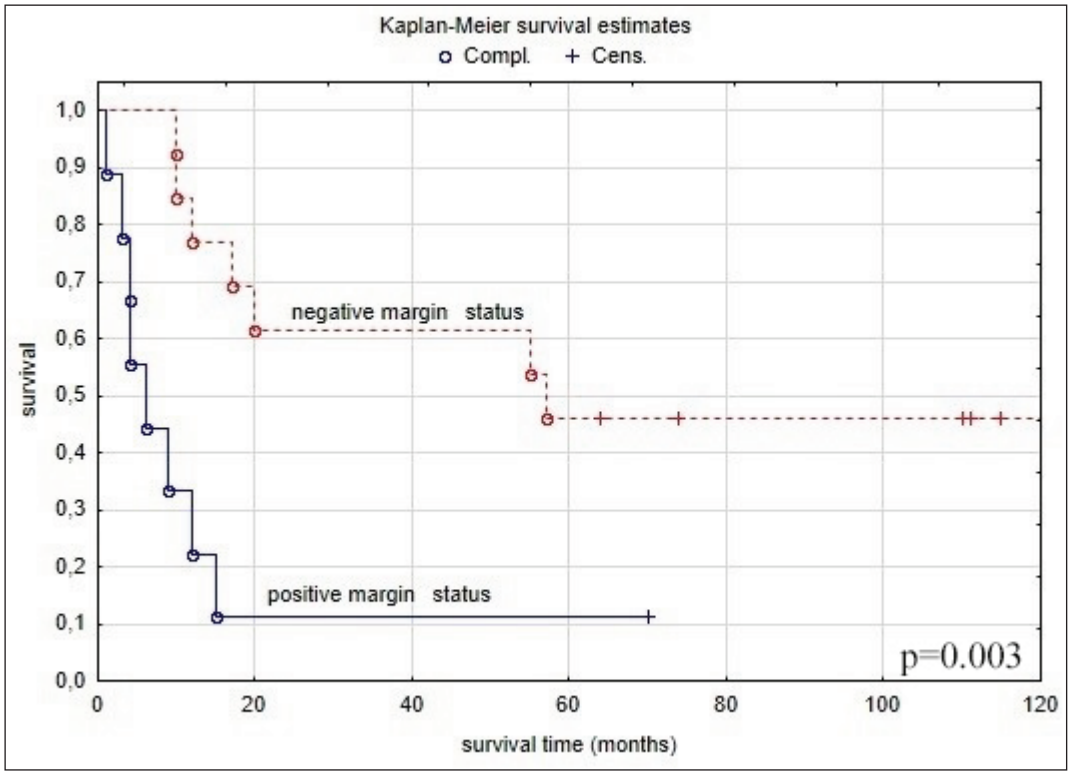

Figure 1 The survival in patients based on surgical margin status.

When evaluating the effect of lymph nodes status on survival, the median survival in patients with negative lymph nodes was 55 months in comparison with 6 months for patients with positive lymph nodes. The difference in the survival of patients from these two subgroups was clinically and statistically significant too (p = 0.016). One-year and 5-year survival in patients without pelvic lymph nodes metastasis were 71.4% (SE 12.1%) and 42.9% (SE 13.2%), and in patients with N1 were 25.0% (SE 15.3%) and 12,5% (SE 11.7%), respectively.

Figure 2 shows that survival in the group of patients with persistent disease after chemoradiotherapy is lower than in the group of patients with relapse of the disease (8.6 vs. 17.3 months). One-year survival was 42% (SE 14.2%) versus 80% (SE 12.6%) in persistent and recurrent CC respectively, 5-year survival was 17% (SE 10.8%) and 40% (SE 15.5%), respectively. However, these differences in survival did not reach statistical significance (p = 0.140), possibly due to the small sample size.

As we established earlier, the long-term results of treatment in patients after PE which was performed with negative or positive resection margins are categorically different, type of PE (negative margins vs. positive) overshadowed effect of clinical differences between groups. PE with negative surgical margins was performed in 50% (6 out of 12 patient) in the group with persistent CC after chemoradiotherapy, in 70% (7 out of 10 patients) with recurrent disease. This conclusion is clearly illustrated in ***Figure 3***, which shows the survival curves in the group of persistent patients based on the surgical margin status (p = 0.019). As shown in ***Figure 3***, none of the 6 patients with positive surgical margins survived for more than 13 months, while the survival with negative surgical margins was 8.6 months, 9.5 months, 20.2 months, and 57.6 months respectively. Two patients are alive more than 5 years after surgery.

DISCUSSION

Although PE was originally introduced as a palliative technique [5], currently it is indicated for curative treatment of patients with persistent or recurrent cervical cancer who have previously undergone primary treatment with radiotherapy or chemoradiotherapy [11–14]. Recurrent CC is the most common diagnosis leading to PE [11–15]. High morbidity and mortality following PE discourage both patients and surgeons from attempting this procedure and special consideration should be given to whether to proceed with PE based on patient pathological and physiological status, and experience and coordination of surgical team and other specialists. Studies published previously reported overall 5-year survival following PE in patients with recurrent CC between 24% and 54%, in patients with primary locally advanced cancer between 40% and 78% [15–18].

Overall, in the present study the rate of negative surgical margins in a series of 22 patients was 59.1%. This rate is relatively low compared to work by other authors where negative postoperative margins were observed in 67% to 93% [15 18–21] of patients. The potential for complete resection with PE approach differed between

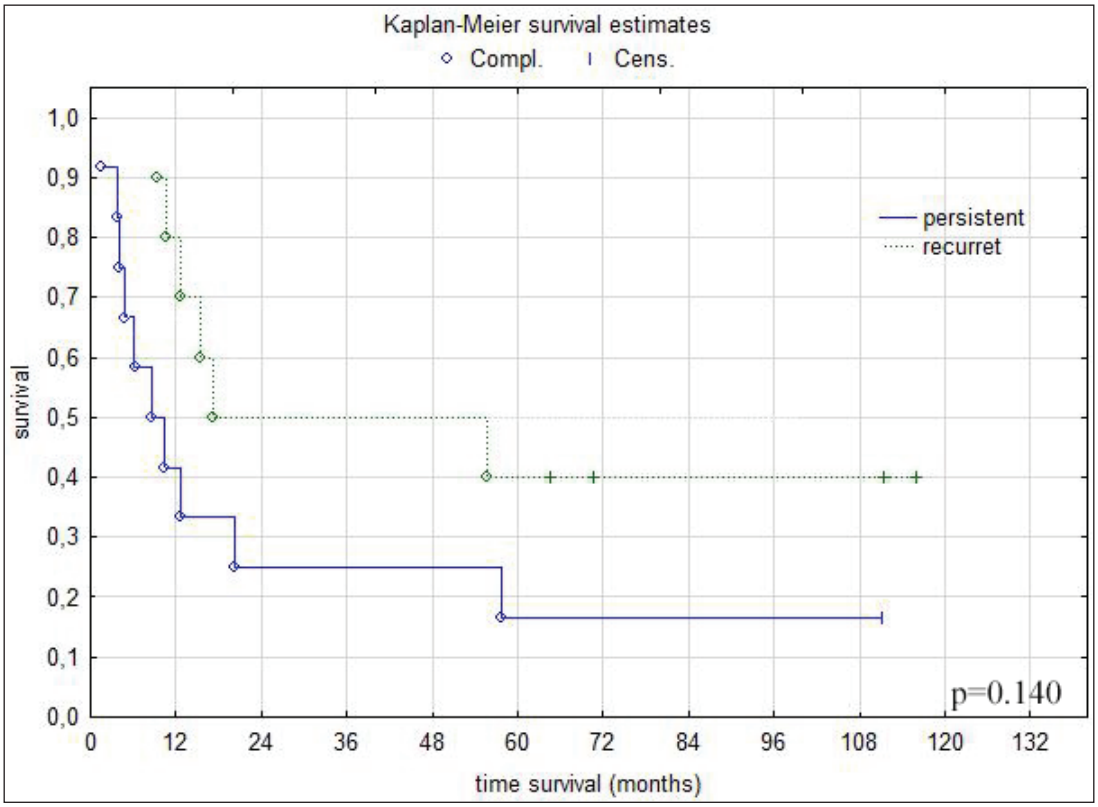

Figure 2 The survival of patients in persistent and recurrent groups.

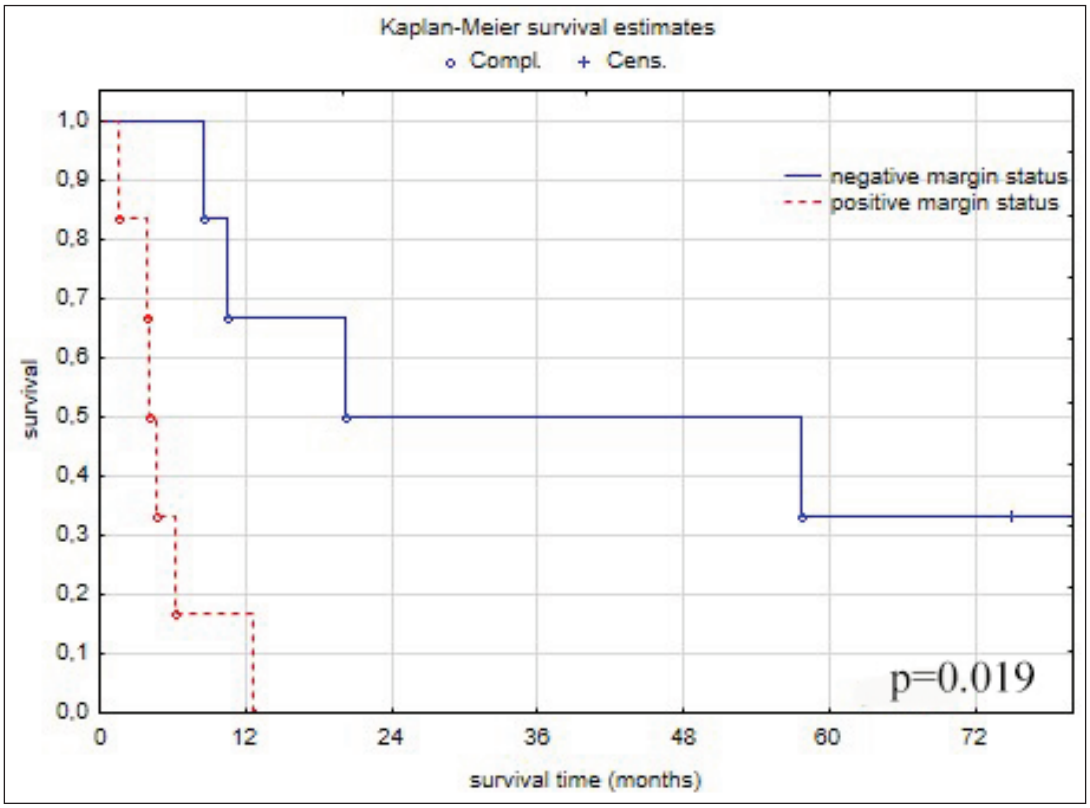

Figure 3 Comparison of survival in patients with persistent disease depending of the surgical margin status.

persistent and recurrent CC. Complete resection was achieved in 50% of the patients with persistent tumor and in 70% of the patients with recurrent CC. Primary resection of visceral fascia presented difficulties for complete resection in patients with recurrent cancer and therefore was limited to a select group of patients.

The data from researchers from various oncological centers around the world have varying long-term results

following the treatment of patients with CC after PE. In Western Europe and the USA, numerous systematic reviews and multicenter studies report a 5-year survival rate after PE for cervical cancer that ranges from 24.7% to 48%. A single cancer center in Switzerland (Zurich) reported on the largest European experience with PE in CC patients and included 282 patients who underwent PE with 5-year survival rate of 64% when it was a curative prosedure [22–31]. At the same time, at oncological centers in the countries of the Commonwealth Independent States (CIS), the 5-year survival rate of this category of patients after PE does not exceed 20%. In particular, Alieva R.A. (Azerbaijan) reported a 5-year survival rate of 15.2% [32], and Latypov V.R. et al. (Russia) reported a rate of 11% [33]. In our study the median survival was 17 months, 1-year survival was 63.6% (SE 10.6%), 3-year survival was 40.9% (SE 10.2%), and 5-year survival was 31.8% (SE 9.9%). Therefore, we believe that in the current series acceptable results were achieved in the treatment of this unfavorable category of patients using PE.

A number of clinical factors were reported to affect poor prognosis in the patients who undergo PE [9, 14, 25]. In our study it has been established that clinically and statistically significant risk factors for death are positive surgical margins and pelvic lymph node involvement. Negative resection margins were associated with reduced the risk of death 4.36 times (95% CI 1.51–12.56; p = 0.006), and increased 5-year survival from 11.1% (SE 10.5%) to 46.2% (SE 13.8%). Presence of lymph node metastases increase the risk of death 3.3 times (95% CI 1.18–9.418; p = 0.024), and decreased 5-year survival rate from 42.9% (SE 15.3%) to 12.5% (SE 11.7%). However, long-term treatment results of PE in patients with negative margins status cannot be considered satisfactory. This suggests that thorough evaluation of patients with full spectrum of available clinical diagnostic procedures as well as multidisciplinary specialists is necessary to select patients in whom radical tumor resection is achievable with high probability.

Thanks to the modern achievements of surgical techniques, anesthesia and perioperative support, according to the literature, early mortality after PE does not exceed 9%, and the incidence of early postoperative complications ranges from 16 to 53%, with late term morbidity being between 33 and 61% [22–30]. The results obtained in our study included the absence of intra- and postoperative mortality, and the frequency of early and late term complications (63.6% and 36.4%, respectively) is comparable with existing data in the literature and might be explained by more conservative patient selection for the PE.

The mean hospital stay was 40.1 days. Hospitalization was longer than in other studies and this may be due to a country-specific healthcare standard in our country [34]. Blood loss during surgery (700–2,200 ml) was less than reported by other groups [15, 19] and similar to that reported by Martinez and colleagues [35]. This might be the result of newer and better hemostatic devises being used in recent studies and the use of minimally invasive surgery for PE in recent years [35, 36].

CONCLUSIONS

We believe that an individualized treatment approach for each patient should be developed and implemented by a multidisciplinary team, with careful and rigorous selection of candidates for PE. We also recommend the availability of adequate perioperative monitoring and pain control to provide an acceptable incidence and severity of postoperative morbidity highlighting the need for performing such operations in specialized multidisciplinary cancer centers. Better patient selection was assured by thorough image studies and clinical prognostic workup.

This study is limited by its retrospective cohort analysis and being a single institution study with possible referral bias. However, our results remain in line with previous studies and highlight the importance PE as a curative option for carefully selected patients with persistent and recurrent cervical cancer.

COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTION

OPM performed data collection, was involved in the surgical treatment of patients, analysis and wrote the manuscript. KMS responsible for the data interpretation and manuscript editing. SLP, SAM and IAK were involved in the surgical treatment of patients. SAK responsible for the surgical treatment of patients, analysis, and manuscript editing. All authors had approval of the final version of the manuscript.

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