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GYNECOLOGIC ONCOLOGY

Pelvic exenteration as ultimate ratio for gynecologic cancers: single-center analyses of 37 cases

N. de Gregorio[1] · A. de Gregorio[1] · F. Ebner[2] · T. W. P. Friedl[1] · J. Huober[1] · R. Hefty[3] · M. Wittau[4] · W. Janni[1] · P. Widschwendter[1]

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Abstract

Background Pelvic exenterations are a last resort procedure for advanced gynecologic malignancies with elevated risks in terms of patients' morbidity.

Methods This single-center analysis reports surgical details, outcome and survival of all patients treated with exenteration for non-ovarian gynecologic malignancies at our university hospital during a 13-year time period. We collected data regarding patients and tumor characteristics, surgical procedures, peri- and postoperative management, transfusions, complications, and analyzed the impact on survival outcomes.

Results We identified 37 patients between 2005 and 2013 with primary or relapsed cervical cancer (59.5%), vulvar cancer (24.3%) or endometrial cancer (16.2%). Median age was 60 years and most patients (73%) had squamous cell carcinomas. Median progression-free survival was 26.2 months and median overall survival was 49.9 months. The 5-year survival rates were 34.4% for progression-free survival and 46.4% for overall survival. There were no significant differences in progression-free survival and overall survival with regard to disease entity. Patients with tumor at the resection margins (R1) had a nearly significantly worse progression-free survival (median: 28.5 vs. 7.3 months, HR 2.59, 95% CI 0.98–6.88, $p=0.056$) and a significantly worse overall survival (median: not reached vs. 10.9 months, HR 4.04, 95% CI 1.40–11.64, $p=0.010$) compared to patients with complete tumor resection (R0). In addition, patients without lymphovascular space invasion had a significantly better progression-free survival ($p=0.017$) and overall survival ($p=0.034$) then patients with lymphovascular space invasion. We observed complications in 14 patients (37.8%), 10 of those were classified as Clavien–Dindo 3 or 4. There was a trend to worse progression-free survival in patients that suffered complications ($p=0.052$). Median total amount of transfused blood products was 4 (range 0–20).

Conclusion Pelvic exenteration is a procedure that provides substantial progression-free survival and overall survival improvement and—in selected patients—can even achieve cure in otherwise hopeless clinical situations. Patients need to be offered earnest counseling for sufficient informed consent with realistic expectations what to expect.

Keywords Pelvic exenteration · Advanced gynecologic malignancy · Cervical cancer · Endometrial cancer · Vulvar cancer

Introduction

For almost 50 years, pelvic exenteration has been used as a last resort for patients with advanced or relapsed gynecologic malignancies. Depending on the surgical extend an anterior, posterior or complete exenteration is differentiated. The anterior exenteration is defined as the removal of the uterus, tubes, ovaries, parametrium, vagina, urinary bladder and urethra. In case of a posterior exenteration, the bladder and urethrae are spared and the rectum is removed instead. A complete exenteration comprises all of those organs. A further variation is the removal of the perineal compartment,

✉ N. de Gregorio
Nikolaus.de-gregorio@uniklinik-ulm.de

[1] Department of Obstetrics and Gynecology, University of Ulm, Prittwitzstr. 43, 89075 Ulm, Germany

[2] Department of Obstetrics and Gynecology, Amper Hospital Dachau, Dachau, Germany

[3] Department of Urology, Klinikum Heidenheim, Heidenheim an der Brenz, Germany

[4] Department of General Surgery, University of Ulm, Ulm, Germany

mostly performed in cases of a relapsed vulvar or vaginal carcinoma. Here, myocutaneus skin flaps are used to reconstruct pelvic floor defects in the perineal region.

Survival rates after exenteration tend to be poor due to the often advanced stages of the diseases, but sometimes even cure can be achieved in case of a complete resection with tumor-free margins. Ultraradical surgical concepts like the lateral extended endopelvine resection (LEER) have been introduced to improve complete resection rates in the last years [1]. A LEER procedure extends the resection margin to the osseous pelvic side wall which includes a resection of the internal iliac vessels and their branches. Even in very experienced centers, those procedures still tend to be risky with high rates of perioperative morbidity (> 50%) and even mortality (up to 5%) [2]. In addition, the patients' quality of life has been reported to be significantly reduced within the first 3 months after the procedure [3].

In spite of an overall decreasing incidence, relapsed cervical cancer accounts for the majority of cases in recently published studies regarding exenterative surgery, followed by endometrial cancer and infrequently vulvar or vaginal carcinomas [4]. Even for colorectal carcinomas, exenteration is used as a salvage procedure, with lower morbidity compared to gynecologic malignomas (50% vs. 75%) and at the same time significantly improved 5 year overall survival (92.9% vs. 58%) [5].

Widely accepted patient selection criteria for an exenteration are the possibility of complete resection, no distant metastases, unavailability of less radical alternatives, willingness of the patient to accept the drastic body modifications and patients' general condition that allow a procedure of this magnitude. While a multidisciplinary approach (including lower GI surgeons and urologists) is mandatory, this procedure also requires a very experienced gynecologic surgeon and an adequate institutional infrastructure in terms of a blood bank and an intensive care unit.

This study reports the institutional experience of the department of obstetrics and gynecology of the University Hospital Ulm with the conduction of exenterations over a 12-year time interval.

Materials and methods

Patient characteristics and variable selection

Data from all patients having the documented procedures "Exenteration" and/or "LEER" at our Department of Gynecology and Obstetrics at the University Hospital Ulm between January 1st, 2005 and February 28th, 2018 were retrospectively reviewed. We identified 37 cases with complete datasets for further analysis.

Data regarding age, weight, body height, initial tumor stage, tumor type and subtype, grade, time interval since last treatment and staging procedures were collected; in addition, the histological factors tumor size, vascular and lymphovascular space invasion and resection margin (negative/positive and location of residual tumor) were documented. To be able to comprehensively assess the surgical procedures, we collected data on all previous lines of treatment, time in the operating theater, methods of bowel and bladder reconstruction, intra- and postoperative complications (classified after Clavien–Dindo) [6], progression-free and overall survival, estimated blood loss, number of transfused blood product (thrombocytes, frozen–fresh plasma, packed red blood cells), total length of hospital stay and any adjuvant treatment.

All data were extracted from the available archived patient's documents and subsequently anonymized. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional committee. Ethical approval of the ethics committee of the University Ulm was given (73/18).

Statistical analysis

Categorical variables are summarized and described using absolute and relative frequencies, while ordinal and continuous variables are described using medians, interquartile ranges and ranges. As the data distribution of most of the continuous variables was significantly different from normal distribution (Shapiro–Wilk test), non-parametric statistical tests were used for all analyses presented here. Correlation tests were performed using Spearman's rank correlation coefficient r. Progression-free survival (without deaths) and overall survival data were analyzed using the Kaplan–Meier method and summarized using medians, 95% confidence limits (95% CI) and Kaplan–Meier survival plots. All time-to-event intervals were measured from the date of surgery to the date of the event. If no event was documented, the data were censored at the date of the last adequate follow-up. Between group comparisons of progression-free survival and overall survival were performed with the log-rank test and hazard ratios (HR) were calculated based on univariable cox regression models. All statistical analyses were performed using the SPSS statistical software package, version 24 (IBM, New York, NY, USA). All statistical tests were two-sided, and p values below 0.05 were considered significant (no adjustment of significance levels for multiple testing).

Results

Patient characteristics

The median age in the patients' collective was 60 years, ranging from 24 to 83 years, and median BMI was 23.9 kg/m^2 (range 16.2–46.7 kg/m^2). 59.5% of patients had a cervical carcinoma, followed by vulvar cancer (24.3%) and endometrial cancer (16.2%). Most patients (73%) had squamous cell carcinomas, all but two patients had pT3 or pT4 tumors and approximately two-thirds had a grade 3 tumor. 73% had relapsed disease and in four patients an exenterative procedure was done despite the presence of distant oligometastatic disease. Patients with relapsed disease had a median time interval of 7 months after the last therapy prior to progression which led to exenteration, and 18 of them entered surgery because of the first relapse. 5 patients had any type of neoadjuvant therapy, and in three cases a platinum-based chemotherapy was given. For detailed patients' characteristics, see also Table 1.

Staging

26 (71%) patients had a CT scan and 27 (73%) a pelvic MRI, while 17 (45%) had both. In eight cases (21%), a PET-CET was performed prior to surgery. All but four patients had both a cystoscopy and a sigmoidoscopy.

Surgical intervention

Table 2 shows details regarding surgical management and treatment outcomes. Anterior exenteration was performed in 17 cases; 6 of these patients had a perineal compartment resection and in 1 patient, a LEER was added. Posterior exenteration was performed in six patients, and two of these patients had a perineal compartment resection. A total exenteration was performed in ten patients, and one of these was subjected to an additional vulvar resection. A LEER-only procedure was performed in four patients. 15 (40.5%) patients underwent a pelvine and/or paraaortic lymphadenectomy (mostly in patients with primary diagnosis), with a median of 34 removed nodes (range 12–77). Nodal involvement was present in eight (53.3%) of these patients, with a median number of seven involved nodes (range 1–32).

For all patients with a posterior or total exenteration, a permanent proximal end colostomy was applied ($n = 16$). Patient with an anterior or total exenteration ($n = 27$) had for urinary diversion either an ileal conduit ($n = 17$), an urostomy ($n = 9$) or in one case of a 28-year-old cervical cancer patient, an ileal neobladder. In four patients with a LEER, a partial bladder resection was performed with a

Table 1 Baseline characteristics of 37 women with exenteration or LEER

Variable	
Age (years)	
Median	60
Interquartile range	47.5–67.5
Range	24–83
Body mass index (kg/m^2)	
Median	23.9
Interquartile range	21.7–29.3
Range	16.2–46.7
Histological grade	
II	11 (29.7%)
III	25 (67.6%)
Missing	1 (2.7%)
Tumor type	
Cervical	22 (59.5%)
Vulvar	9 (24.3%)
Endometrial	6 (16.2%)
Histological subtype	
Squamous	27 (73.0%)
Adeno	7 (18.9%)
Others	3 (8.1%)
Vascular space invasion	
No	17 (45.9%)
Yes	5 (13.5%)
Missing	15 (40.5%)
Lymphovascular space invasion	
No	7 (18.9%)
Yes	15 (40.5%)
Missing	15 (40.5%)
Primary diagnosis or relapsed disease	
Primary diagnosis	10 (27.0%)
Relapsed disease	27 (73.0%)
Time interval since last relapse ($n = 27$)	
< 10 months	19 (70.4%)
≥ 10 months	8 (29.6%)
Tumor stage	
pT2	2 (5.4%)
pT3	11 (29.7%)
pT4	24 (64.9%)
Histological tumor size (mm)	
Median	45.0
Interquartile range	33.5–62.5
Range	10–110
Distant metastases present at time of operation	
Yes	4 (10.8%)
No	33 (89.2%)
Number of lines of previous therapy	
0	16 (43.2%)
1	17 (45.9%)
2	3 (8.1%)
Missing	1 (2.7)

Table 2 Surgical management and outcome in 37 women with exenteration or LEER

Variable	
Type of surgical procedure	
Anterior exenteration	10 (27.0%)
+ Perineal compartment	6 (16.2%)
+ LEER	1 (2.7%)
Posterior exenteration	4 (10.8%)
+ Perineal compartment	2 (5.4%)
Total exenteration	9 (24.3%)
+ Perineal compartment	1 (2.7%)
LEER only	4 (10.8%)
Additional lymphadenectomy	15 (40.5%)
Duration of surgery (h)	
Median	8.5
Interquartile range	7.5–10.75
Range	5–15
Number of transfused packed red blood cells	
Median	2
Interquartile range	2–4
Range	0–10
Number of transfused fresh–frozen plasma	
Median	2
Interquartile range	0–4
Range	0–10
Number of transfused platelet concentrates	
Median	0
Interquartile range	0–0
Range	0–2
All blood products	
Median	4
Interquartile range	2–9
Range	0–20
Resection status	
R0	28 (75.7%)
R1	9 (24.3%)
Postoperative complications	
No	23 (62.2%)
Yes	14 (37.8%)
If yes ($n=14$)	
Clavien–Dindo < 3	4 (10.8%)
Clavien–Dindo ≥ 3	10 (27.0%)
Total retention time (days)	
Median	21
Interquartile range	14.5–26.5
Range	9–92
Adjuvant treatment	
No	18 (48.6)
Yes	19 (51.4)
If yes ($n=19$)	
Radiation	6 (16.2%)
Chemotherapy	7 (18.9%)
Chemoradiation	6 (16.2%)

psoas hitch reconstruction. The median theater time was 8.5 h (5–15). In 28 (75.7%) patients, a complete resection with clear margins could be achieved, while in 9 cases (24.3%) a microscopically positive margin was found. Locations of this R1 resection were the pelvic wall ($n=5$), and in one case, each pelvic floor muscles, vaginal cuff, perineal skin and small bowel. Patients stayed for a median of 21 days in hospital (range 9–92).

Blood loss and transfusion

The median number of transfused blood products was 2 packed red blood cells (range 0–10 products), 2 FFPs (range 0–10) and 0 platelet concentrates (range 0–2), and the median total amount of blood products transfused was 4 (range 0–20). Both the number of transfused red blood cell units and the total amount of transfused blood products did not significantly correlate with theater time or total duration of hospitalization (Spearman rank correlation test, all $p > 0.05$).

Complications

We observed 14 patients (37.8%) with noteworthy complications, 10 of those we classified as Clavien–Dindo 3 or 4. Fistulas and wound infection were observed in four cases (10.4%) each. Two patients suffered from sepsis or peritonitis and we identified one case each of a lower leg compartment syndrome, a pulmonary embolism, hemorrhage due to an uretero-ileal fistula, a sciatic nerve injury and one urethral splint dislocation. No mortality was observed. Overall, six (16.2%) patients underwent revision surgery of any kind as a consequence of exenteration.

Adjuvant treatment

Chemotherapy with Platinum/Paclitaxel was administered as neoadjuvant therapy in four cases (10.8%), while one patient was treated with chemoradiation prior to surgery. Another 19 patients (51.4%) had at least 1 modality of adjuvant systemic treatment (6 patients with a combination of platinum/paclitaxel, 6 patients were treated with chemoradiation and another 6 patients had radiation only).

Survival

A median progression-free survival of 26.2 months was achieved with median overall survival being 49.9 months (Fig. 1). The 5-year survival rates were 34.4% for

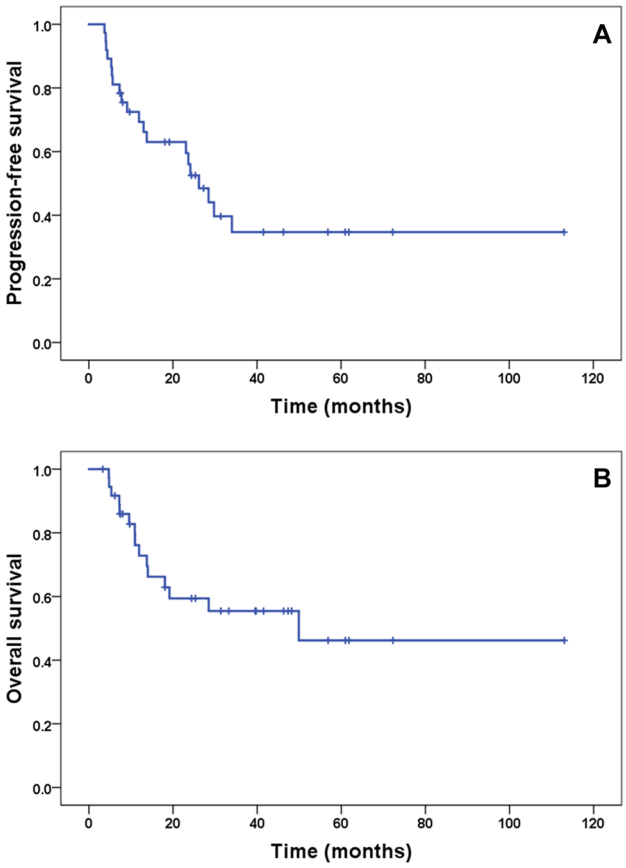

Fig. 1 **a** Progression-free survival and **b** overall survival for all patients with an exenteration ($n=37$)

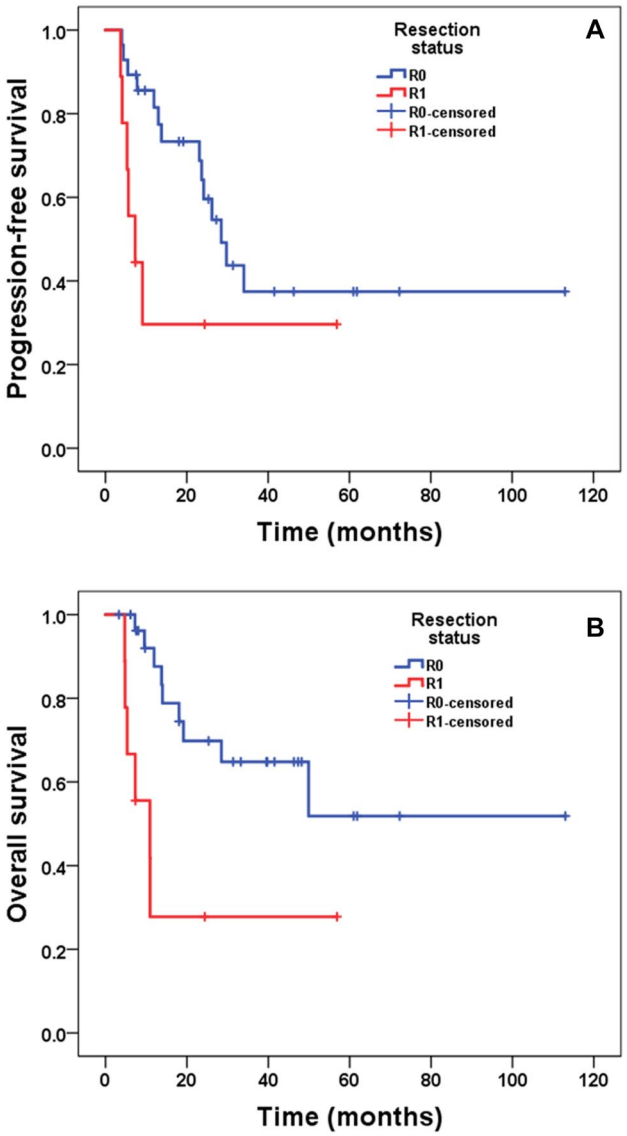

Fig. 2 **a** Progression-free survival and **b** overall survival for all patients with an exenteration according to resection status ($n=37$)

progression-free survival and 46.4% for overall survival. Progression-free survival and overall survival showed no significant difference with regard to the origin of the disease (cervix vs. endometrial vs. vulvar; $p=0.98$ and $p=0.88$, respectively). Patients with tumor at the resection margins (R1) had a nearly significantly worse progression-free survival (median progression-free survival: 28.5 vs. 7.3 months, HR 2.59, 95% CI 0.98–6.88, $p=0.056$; Fig. 2a) and a significantly worse overall survival (median overall survival: not reached vs. 10.9 months, HR 4.04, 95% CI 1.40–11.64, $p=0.010$; Fig. 2b) than patients with R0 resection.

Interestingly, the four patients that had oligo distant-metastatic disease (three cases with locally confined peritoneal carcinosis, one with a single possible pulmonary lesion) did not have a significant worse progression-free survival ($p=0.35$) or overall survival ($p=0.58$) than patients with no metastatic disease.

There was a trend for worse progression-free survival in patients who suffered complications ($p=0.052$), while no such trend was found for overall survival ($p=0.23$). No difference in survival was observed between patients with and without neoadjuvant and/or adjuvant treatment (progression-free survival: $p=0.12$; overall survival: $p=0.10$), between patients with and without revision surgery (progression-free survival: $p=0.14$; overall survival: $p=0.20$), between patients with primary vs. relapsed disease (progression-free survival: $p=0.45$; overall survival: $p=0.62$), between patients with grade 2 vs. grade 3 tumors (progression-free survival: $p=0.85$; overall survival: $p=0.87$), between patients with tumor stages pT2 vs. pT3 vs. pT4 (progression-free survival: $p=0.96$; overall survival: $p=0.68$), between patients with tumor size below or above 5 cm (progression-free survival: $p=0.14$; overall survival: $p=0.06$), or between patients with squamous vs. adeno vs. other carcinomas (progression-free survival: $p=0.90$; overall survival: $p=0.92$). In addition, progression-free

survival and overall survival did not differ between patients with a BMI below or above 25.0 kg/m^2 (progression-free survival: $p=0.11$; overall survival: $p=0.32$) or between patients below or above the age of 60 years (progression-free survival: $p=0.90$; overall survival: $p=0.49$). Similarly, we found no difference in survival between patients with a duration of surgery below or above 10 h (progression-free survival: $p=0.95$; overall survival: $p=0.84$) or between patients that stayed in the hospital for less or more than 20 days (progression-free survival: $p=0.35$; overall survival: $p=0.33$).

Lymphovascular space invasion and vascular space invasion were only reported for 22 patients, as the other patients had the operation before those parameters were routinely assessed in our center. Nevertheless, the seven patients without lymphovascular space invasion had a significantly better progression-free survival ($p=0.017$) and overall survival ($p=0.034$) then the patients with lymphovascular space invasion. In contrast, there were no significant differences in progression-free survival ($p=0.23$) or overall survival ($p=0.88$) between patients with and without vascular space invasion.

As we expected that patients with relapsed disease that had a long progression-free interval before the exenterative procedure might do better due to a less aggressive tumor biology, we compared survival between patients with relapsed disease ($n=27$) that had a progression-free interval below or above 10 months. While there was no difference in progression-free survival ($p=0.43$), patients with a longer progression-free interval before exenteration had a significant better overall survival ($p=0.020$).

Discussion

In patients with prior chemo radiation and isolated relapsed disease in the pelvis, chemotherapy is known to have poor response rates [7], which often leaves an exenteration as the only viable option. Due to the nature of the procedure, the potential complications and the expected surgical severity and morbidity, our center tends to be rather reluctant and cautious in performing such an ultraradical pelvic surgery. This might bias the presented results, as we could have selected only those patients assumed to have the maximum benefit from an exenteration (positive selection bias). Other limiting factors of our analysis are the retrospective character, the limited number of patients (i.e., non-significant results of statistical tests have to be interpreted with care), and the potential impact of the different (neo-) adjuvant therapies. However, due to rare occurrence of advanced non-ovarian gynecologic malignancies without distant metastases and the even lower number of physically suitable patients that are willing to undergo such a radical surgical procedure, the performance of a prospective randomized trial to investigate the benefits of a pelvic exenteration is very challenging. Thus, even small retrospective studies are important for reviewing the value of pelvic exenteration as ultimate ratio for gynecologic cancers.

As most authors agree, these procedures should only be done in the absence of less radical alternatives or a possibility of radiation therapy. In our study, we reported a number of patients without prior radiation. As all patients are first discussed in our interdisciplinary gyneco-oncological tumor conference with the presence of radio-oncologists, this finding might be related to special tumor and/or patients' characteristics such as large tumors (up to 11 cm in diameter) infiltrating into bladder or rectum, which leads to a high risk for developing fistulas, or tumor masses being close to small bowel loops, which limits the applicable radiation dose. From our perspective, one of the most difficult decisions for the selection of potential candidates for exenteration is the preoperative question whether or not clear resection margins can be achieved. Although the possibility of a LEER procedure somewhat offsets the limitation of pelvic wall involvement, we consider cases with involvement of the pelvic plexus nerves as inoperable. Therefore, awareness for clinical symptoms with characteristic pain in this area is essential for identification of patients with plexus involvement, especially as the role of imaging for detecting local organ involvement is controversial. MRI seems to outmatch CT scans [8, 9]. At least one imaging modality was used for all of our patients and we relied mainly on the detection of distant metastases. Importantly, we achieved clear margins in 75.7% of all patients, which compares favorably to the 45% reported in the largest analysis of over 1100 patients from the national Cancer Data base of the United States [10], and is in the range of previously reported results (82% Jäger et al. [4], 83% Kaur et al. [11], 72% Chiantera et al. [12]).

A comparison of the surgical parameters in our study with that of another large single-center trial from UCLA [13] showed that duration of surgery (Ulm 8.5 h vs. UCLA 7.76 h), amount of blood transfusions (2 vs. 4.9) and length of hospital stay (21 vs. 23 days) were within the same range. Most patients with an above average length of stay in our cohort had a resection of the perineal compartment, which led to delayed wound healing and the necessity of secondary wound care.

The overall complication rate in our cohort was 37.4%, most of those related to infection. Comparison to existing data is difficult, as some author only report major complications, while others report all complication, e.g., Kaur et al. in 30.7% [11], Roos in 75% [14] and Jäger in 100% [4] of the cases. Although most revision surgeries were performed because of wound-healing issues, exenteration is a high-risk surgical procedure with a high overall rate for complications

and potentially fatal outcome. While mortality rates up to 5% have been reported [2], fortunately we saw no postoperative mortality in our patient cohort.

All of our procedures were performed through an abdominal midline incision; however, there are first reports of laparoscopic LEER procedures [15]. Although we do favor laparoscopic access for many situations, in our experience the reduced ability to control bleeding and to retrieve the specimen naturally limits the broad use of this technique for exenterations in advanced gynecological malignancies.

Although pelvic exenteration is an ultimate surgical procedure with highly elevated patient morbidity, we found a median progression-free survival of more than 2 years, and 5-year survival rates of 34.4% for progression-free survival and 46.4% for overall survival. Considering the mostly advanced tumor stages (UICC stage IV), these are impressing outcome data. Radical surgical treatment allows long-term survival for selected patients with initially worst prognosis and should thereby carefully be considered as potential treatment options in suitable patients. These interpretations are in line with the findings of other trials where often the 5-year overall survival and progression-free survival are reported. For example, Westin et al. found a 5-year RFS of 33% and a 5-year overall survival of 40% [16], which approximately mirrors our results. Comparing survival rates between different study populations is difficult due to large differences in tumor subtypes, stages, tumor size, adjuvant therapies, etc. Goldberg et al. reported an overall 5-year survival of 47% for patients with a pelvic exenteration, although their study excluded patients with positive nodes [17].

In our study, we had 15 patients where we performed a lymphadenectomy; in 8 (53%) cases, positive nodes were identified. Seagle et al. reported 63 months overall survival in the node-negative group and 17 months in the node-positive group [10].

Some authors consider larger tumor size itself (for example with a diameter over 5 cm) as exclusion criteria for exenteration [18]. Interestingly, we found no significant impact of the absolute tumor size on progression-free survival with only a trend to worse overall survival in patients with tumors > 5 cm. Therefore, we conclude that a large sized tumor should not be a strict contraindication for exenteration.

In addition, we also performed four procedures in patients with oligometastatic disease with decent outcome regarding PDS and overall survival. This is in line with a recent survey conducted among American gyneco-oncologists, where half of them stated that they would offer a pelvic exenteration even for palliative reasons [19].

Several authors have reported case series ranging over two or more decades. As there was no improvement in prognosis, they concluded that prognosis is predominantly determined by tumor biology (13–15). However, at least for perioperative management in the last decades an improvement can be assumed as we fortunately did not observe any case of mortality in our study.

In summary, we conclude that pelvic exenteration is a procedure that may provide substantial improvements in progression-free survival and overall survival and—in selected patients—can even achieve cure in otherwise hopeless clinical situations. Patients need to be offered earnest counseling what to expect and that prolonged survival might be accompanied by reduced quality of life and loss of sexual function.

Author contributions NdeG: conceptualization and writing original draft. AdeG: resources, review and editing. FEbner: review and editing. TWPF: data curation and formal analysis. JH: supporting and review. RH and MW: resources and review. WJ: supervision and review. PW: conceptualization, resources, review and editing.

Compliance with ethical standards

Conflict of interest We have no potential conflict of interest.

Ethical approval This study was approved by local ethics committee.

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