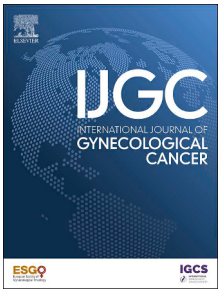
ORIGINAL RESEARCH

Complications and recurrence after pelvic exenteration for gynecologic malignancies: Analysis of surgical complications from the COREPEX study



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ABSTRACT

Objective: This study aimed to assess intra-operative, short-term, and long-term morbidity and develop a score predicting post-operative complications after pelvic exenteration for gynecologic cancer.

Methods: This was a retrospective, multi-center, international study conducted in tertiary referral centers for gynecologic oncology. The inclusion criteria included cervical, vaginal, vulvar, or endometrial cancer; anterior/total pelvic exenteration performed between January 2005 and March 2023; curative/palliative intent; with or without laterally extended endopelvic/pelvic resection. Logistic regression adjusted for co-variables and a score predictive of severe post-operative complications based on the multi-variable analysis were developed.

Results: A total of 862 patients were included. Seven patients (0.8%) had severe intra-operative complications, and no patient experienced intra-operative death. A total of 225 patients (26.1%) had severe early post-operative complications and 27 (3.1%) died within 30 days. The most frequent severe early post-operative complications were pelvic abscess/collection (23.4%) and urostomy leak/fistula (13.4%). A total of 87 patients (10.1%) had severe late post-operative complications, and 16 patients (1.8%) died between 31 and 180 days. The most frequent severe late post-operative complications were pelvic abscess/collection (21.6%) and benign ureteric stricture (13.5%). Risk factors independently associated with severe early and late post-operative complications were no previous recurrences, American Society of Anesthesiologists score >1, total pelvic exenteration, infra-levator pelvic exenteration, laterally extended endopelvic/pelvic resection; and infra-levator pelvic exenteration and laterally extended endopelvic/pelvic resection, respectively. The COREPEX predictive score identified 4 groups with significantly different risk of severe post-operative complications ($p < .001$).

WHAT IS ALREADY KNOWN ON THIS TOPIC

Studies with large sample size reporting on morbidity from patients undergoing anterior/total pelvic exenteration for gynecologic malignancies come from national cancer databases and lack detailed information on peri-operative complications. Moreover, a predictive score aiming to develop a comprehensive model that allows to understand the risk of major post-operative complications is currently missing.

WHAT THIS STUDY ADDS

Pelvic exenteration was associated with a low risk of intra-operative complications (0.8%) and a remarkable risk of major post-operative complications (26.1% early and 10.1% late). No intra-operative death was recorded, and 3% of patients died of post-operative complication. Most frequent intra-operative and post-operative complications were vascular injury and infection, respectively. Variables independently associated with major post-operative complications were included in the predictive models, identifying 4 risk groups for early and late morbidity.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

Future research might need to focus on the prevention of the most frequent peri-operative complications. The

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Conclusions: Patients undergoing anterior or total pelvic exenteration have a low risk of intra-operative but a remarkable risk of major post-operative complications. No intra-operative death was recorded, and post-operative mortality was low. The COREPEX score predicting the risk of post-operative complications can be used to counsel patients and for future studies.

COREPEX score predicting the risk of major early and late post-operative complications can be used to counsel patients and for future studies.

Keywords:
Pelvic Exenteration; Complications; Morbidity; Gynecologic Cancer; Post-Operative; Predictive Model

ORIGINAL RESEARCH

INTRODUCTION

Pelvic exenteration is a radical operation which involves the en bloc resection of the pelvic organs, including the genital, urinary, and bowel tracts, and is characterized by important psychological and quality of life impact and high hospitalization costs.[1-4] Pelvic exenteration aims to remove the tumor with free oncologic margins and is usually performed in the salvage situation, representing the last curative option in recurrent gynecologic cancers previously treated with radiotherapy.[1,5-7] In selected patients in whom this surgical procedure is performed with curative intent, overall survival can reach 60% to 70% at 5 years.[6-8] However, pelvic exenteration has been associated with significant surgical morbidity, with high incidence of severe complications in the early and late post-operative period.[9-11] For these reasons, patient selection is crucial. However, because pelvic exenteration is a rare procedure, the majority of data reported to date are single-center, with relatively small numbers of patients and/or heterogeneous (not only gynecologic) groups of patients or reporting data from national cancer databases with limitations in variables included in the analyses.[3,9-11]

With the COREPEX study, we intended to establish a large European database reflecting contemporary surgical practice of pelvic exenteration in gynecologic malignancies.[12]

The primary aim of this study was the 30-day incidence of post-operative complications. Secondary aims were intra-operative morbidity, 30-day mortality, late morbidity/mortality, type of complications, and development of a score to predict post-operative complications.

METHODS

Patient Selection

This was an international, multi-center, retrospective study. The COREPEX study consortium consisted of 20 tertiary cancer centers from Europe. Imaging modalities used for clinical staging included: magnetic resonance imaging (MRI) scan as well as computed tomography (CT) and/or positron emission tomography (PET)/CT scan.

Requirements for a center to join the study were the following: availability of imaging modalities for pre-operative work-up and follow-up (MRI scan, CT scan or PET/CT, or PET scan), national referral centers for gynecologic oncology (tertiary referral unit with specialist expertise in gynecologic oncology surgery), all pelvic exenteration cases discussed by a multi-disciplinary team in the pre-operative and post-operative period, availability of updated patients database; surgery performed by experienced gynecologic oncology surgeons, pathology performed by a dedicated gynecologic oncology pathologist, and institutional follow-up was performed by physicians.

Patients were included if they met the following inclusion criteria: histologically confirmed cervical, vaginal, vulvar, or endometrial cancer; anterior or total pelvic exenteration performed between January 2005 and March 2023; curative or palliative intent; with or without laterally extended endopelvic resection[13]; and laterally extended pelvic resection.[14] Patients were excluded if they underwent posterior pelvic exenteration only or if pre-operative CT scan, PET/CT, or PET scan was not performed.

The protocol was approved by the institutional review board of the lead institution (Fondazione Policlinico Agostino Gemelli IRCCS) on March 25, 2021 (Protocol ID: 3879, No. 0011322/21). Institutional review board approval at the participating sites was a prerequisite for participation. The study was performed in accordance with the Declaration of Helsinki and followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.

Outcome Measures

The primary aim of this study was 30-day incidence of post-operative complications defined as any deviation from the normal post-operative course that occurred between the time the patient left the operating room and 30th post-operative day since pelvic exenteration. Post-operative complications were graded according to the Clavien–Dindo classification system.[15] Secondary aims were the following: incidence of intra-operative complications (defined as any deviation from the ideal intra-operative course, which occurred between skin incision and the time the patient leaves the operating room and graded according to Common Terminology Criteria for Adverse Events[16]), 30-day mortality (defined as death due to surgery-related complication within 30 days from the pelvic exenteration), late post-operative complications (defined as any deviation from the normal post-operative course that occurred between 31st and 180th post-operative day since pelvic exenteration), late mortality (defined as death due to surgery-related complication between 31st and 180th post-operative day since pelvic exenteration), type of complications, and development of a model predictive of post-operative morbidity. Minor complication was defined as grade 1 to 2, whereas major/severe complication as grade 3 to 5.

Data Collection and Clinicopathological Variables

Data were collected from each institution's principal investigator and entered in the COREPEX study electronic database using the RedCap software. The database is held by Policlinico Agostino Gemelli IRCCS, Rome, Italy. Data of included patients were pseudonymized in the COREPEX database and the code key kept at each institution according to Good Clinical Practice and Local Regulations.

Clinicopathological variables included age at pelvic exenteration, body mass index, Eastern Cooperative Oncology Group performance status, primary site of disease, histology, previous radiotherapy, time from diagnosis to pelvic exenteration, pelvic exenteration intent (curative vs palliative [defined as presence of para-aortic/inguinal node metastasis, distant metastasis, peritoneal carcinomatosis]), timing of pelvic exenteration (naïve, persistence [defined as lack of complete remission of the tumor in its primary site], recurrence [defined as cancer that has come back after a period of time during which the cancer could not be detected]), type of pelvic exenteration (anterior only or total), pelvic exenteration approach (laparotomy, laparoscopic, robot, or conversion), laterally extended surgery, pelvic exenteration classification (supra-levator, infra-levator, infra-levator with vulvectomy),[17] lymphadenectomy (pelvic, para-aortic, inguinal), length of hospitalization, metastatic lymph node(s), surgical margins, pathologic tumor diameter, lymph-vascular space invasion, perineural invasion, and adjuvant chemotherapy. The empty pelvis syndrome was defined as a spectrum of post-exenteration complications, including the presence of pelvic collection and/or perineal small bowel fistula and/or perineal/vaginal/vulvar wound dehiscence (according to PelvEx collaborative consensus[18]). Analysis of complications rates according to period was performed by dividing the study period in 2 parts (2005-2014 and 2015-2023).

Statistical Analysis

Demographics and clinical data were summarized using absolute counts and percentages. Continuous data were summarized using median and interquartile range (IQR). Univariable and multi-variable analyses were performed using the logistic regression models, and odds ratios were reported with their 95% confidence intervals (CIs). Only variables which resulted significant at

univariable analysis were selected for multi-variable analysis. Logistic regression analysis was not performed if complications were less than 10. A stepwise selection, based on the likelihood ratio, was used to select variables in the multi-variable approach, with 0.05 and 0.10 as enter and remove limits, respectively. The area under the curve (AUC) was used to assess discriminating power of each model. A score was built re-proportioning the regression coefficients to sum up to 100(%), using the β coefficients derived from each final model. In detail, the β coefficients from the multi-variable model (statistical coefficients representing the influence of each parameter) were converted into risk points to create a scoring system. This scoring system helps to quantify the risk associated with each parameter for an individual patient; based on these risk points, patients were divided into risk groups with significantly different risk of complications. Four groups were considered based on risk score (0% to 25%; 26% to 50%, 51% to 75%, and 76% to 100%). IBM SPSS statistical software v. 27.0 and R v. 4.1.2 were used.

In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centers, if such is requested.

RESULTS

Data from 904 patients was retrieved. Of these, 21 (2.3%) were excluded because pelvic exenteration was abandoned for intra-operative findings of distant metastasis (including para-aortic lymph node metastasis) and 21 (2.3%) were excluded because they underwent laterally extended endopelvic/pelvic resection with no pelvic exenteration, leaving a total of 862 patients included for the analysis (Fig. S). Table 1 shows the clinical and pathologic characteristics of the included patients. Majority of patients were diagnosed with cervical cancer ($n = 572$, 66.3%) and squamous cell carcinoma ($n = 581$, 67.4%). The median time from diagnosis to pelvic exenteration was 17 months (IQR 8.5-40.1). The number of patients who underwent pelvic external beam radiotherapy before pelvic exenteration was 646 (74.9%). Most of the pelvic exenterations were performed with curative intent ($n = 759$, 88.1%), at time of recurrence ($n = 648$, 75.2%), and by laparotomy ($n = 779$, 90.4%). Total pelvic exenteration was performed in 510 (59.2%) and infra-levator pelvic exenteration in 343 cases (39.8%). Laterally extended endopelvic/pelvic resection was associated with pelvic exenteration in 301 patients (34.9%). The median operative time was 383 minutes (IQR 300-510), and the median estimated blood loss was 700 mL (IQR 500-1200). The median length of hospitalization was 18 days (IQR 12-27). A total of 121 (14.0%) and 53 (6.1%) had positive pelvic and para-aortic lymph nodes, respectively. Surgical margins were free from tumor in 676 patients (78.4%). A total of 198 patients (23.0%) received adjuvant chemotherapy.

The incidence of peri-operative complications is reported in Table 2. Seven patients (0.8%) experienced severe (grade 3 to 4) intra-operative complications, and no patient experienced intra-operative death. Details of intra-operative complications are shown in Table S1. The most frequent intra-operative complication was iliac vein injury in 17 of 61 cases (27.9%) (15 grade 1, 1 grade 2, and 1 grade 3).

A total of 225 patients (26.1%) had severe early post-operative complications. Twenty-seven (3.1%) patients died of post-operative complications within 30 days (23/27, 85.2% curative; 4/27, 14.8% palliative). Details of early post-operative complications are shown in Table 3. The median number of complications per patient who had at least one early complication was one (range; 1-7). The most frequent early post-operative complication was infective (304/746, 40.7%), followed by surgical site (146/746, 19.6%), gastrointestinal (90/746, 12.1%), urinary (85/746, 11.4%), and vascular (49/746, 6.6%). Other complications were reported in 72 of 746 (9.6%). The most common infective complications were urinary tract infections in 123 (40.5%) and pelvic abscess/collection in 108 cases (35.5%). The most frequent grade 3 to 4 early post-operative complications were pelvic abscess/collection (63/269, 23.4%) and urostomy leak/fistula (36/269, 13.4%) (Table 3).

Seventy-four patients (8.6%) were re-admitted after hospital discharge and 190 (22.0%) underwent re-operation within 30 days from pelvic exenteration. The incidence of severe early post-operative complications was higher in the second study period than in the first (31.4% vs 23.1%, $p = .019$). The risk factors independently associated with development of severe early post-operative complications were no previous recurrences, American Society of Anesthesiologists (ASA) score >1, total pelvic exenteration, infra-levator pelvic exenteration (with or without vulvectomy), and laterally extended surgery (Table 4).

Eighty-seven patients (10.1%) had severe late post-operative complications. Sixteen patients (1.8%) died of post-operative complications between 31 and 180 days (12/16, 75% curative; 4/16, 25% palliative). Details of late post-operative complications are shown in Table 3. The median number of complications per patient who had at least one late complication was two (range; 1-10). The most frequent late post-operative complication was infective (149/282, 52.8%), followed by gastrointestinal (49/282, 17.4%), urinary (31/282, 11.0%), surgical site (20/282, 7.1%), and vascular (14/282, 5.0%). Other complications were reported in 18 of 282 (6.4%). The most common infective complications were urinary tract infections in 70 (47.0%) and pelvic abscess/collection in 50 (33.5%) cases. The most frequent grade 3 to 4 late post-operative complications were pelvic abscess/collection (24/111, 21.6%) and benign ureteric stricture (15/111, 13.5%) (Table 3).

A total of 149 patients (17.3%) were re-admitted after hospital discharge and 85 (9.9%) underwent re-operation 31 to 180 days from pelvic exenteration.

There was no difference in the incidence of late severe post-operative complications when comparing the first and second study periods (11.3% vs 12.2%, $p = .82$). The risk factors independently associated with development of severe late post-operative complications were infra-levator pelvic exenteration (with or without vulvectomy) and laterally extended surgery (Table 4).

The incidence of empty pelvis syndrome was 141 of 862 patients (16.4%). No intra-operative technique to prevent empty pelvis syndrome was adopted in 351 patients (40.7%) (data missing from $n = 15$, 1.7% patients). The use of any technique (details in Table S2) to prevent empty pelvis syndrome in 496 (57.5%) patients did not reduce the incidence of this complication (preventive methods $n = 76$ [8.8%] vs no prevention $n = 62$ [7.2%], respectively, $p = .40$).

The score to predict intra-operative complications was not built because the total number of patients experiencing major intra-operative complications was seven. The scoring system to predict early post-operative complication was based on the following variables: number of previous recurrences, ASA score, type of pelvic exenteration, pelvic exenteration classification, and laterally extended surgery Figure 1 Early A). The β-coefficients of the multi-variable model were consequently converted into the risk points. The AUC of the resulting model for risk of major early complications was 0.64 (95% CI 0.59 to 0.69). The histogram for the respective risk score groups is shown in Figure 1 Early B. Four risk groups significantly differing in incidence of major early complications were identified, with a risk of 21% (95% CI 14 to 27) for patients scoring 0% to 25%, 25% (95% CI 21 to 30) for patients scoring 26% to 50%, 48% (95% CI 39 to 56) for patients scoring 51% to 75%, and 86% (95% CI 60 to 100) ($p < .001$) for patients scoring 76% to 100%.

The scoring system to predict late post-operative complication was based on the following variables: pelvic exenteration classification and laterally extended surgery (Figure 1 Late A). The β coefficients of the multi-variable model were consequently converted into the risk points. The AUC of the resulting model for risk of major late complications was 0.63 (95% CI 0.58 to 0.69). The histogram for the respective risk score groups is shown in Figure 1 Late B. Four risk groups significantly differing in risk of major late complications were identified, with a risk of 5% (95% CI 2 to 8) for patients scoring 0% to 25%, 15% (95% CI 10 to 19) for patients scoring 26% to 50%, 16% (95% CI 11 to 20) for patients scoring 51% to 75%, and 24% (95% CI 7 to 41) ($p < .001$) for patients scoring 76% to 100%.

DISCUSSION

Summary of Main Results

With this study, we showed that, in a cohort of patients undergoing anterior or total pelvic exenteration for gynecologic cancer, the risk of major intra-

Table 1 Clinical and Pathological Characteristics of the Included Patients

Clinical characteristic	All patients *n* = 862
Age at pelvic exenteration, y (median, IQR)	56 (47-65)
Body mass index, kg/m^2 (median, IQR)	24.6 (21.0-28.9)
ECOG	
0	370 (42.9)
1	292 (33.9)
2	86 (10.0)
3	61 (7.1)
4	13 (1.5)
Missing	40 (4.6)
Primary site	
Cervix	572 (66.3)
Endometrial	140 (16.2)
Vulva	79 (9.2)
Vagina	70 (8.1)
Other[a]	1 (0.1)
External beam pelvic radiotherapy before pelvic exenteration	646 (74.9)
Time from diagnosis to pelvic exenteration, months (median, IQR)	17.0 (8.5-40.1)
pelvic exenteration intent	
Curative	759 (88.1)
Palliative	103 (11.9)
Timing of pelvic exenteration	
Naive	72 (8.4)
Persistence[b]	142 (16.5)
Recurrence	648 (75.2)
Type of pelvic exenteration	
Anterior only	352 (40.8)
Total	510 (59.2)
Pelvic exenteration approach	
Laparotomy	779 (90.4)
Laparoscopy	48 (5.6)
Robot	23 (2.7)
Conversion laparoscopy to laparotomy	9 (1.0)
Conversion robotic to laparotomy	3 (0.3)
Laterally extended surgery	
No	561 (65.1)
Laterally extended endopelvic resection	119 (13.8)
Laterally extended pelvic resection	74 (8.6)
Missing	108 (12.5)
Pelvic exenteration classification	
Supra-levator	343 (39.8)
Infra-levator	343 (39.8)
Infra-levator with vulvectomy	157 (18.2)
Missing	19 (2.2)
Lymphadenectomy	
No	433 (50.2)
Pelvic only	199 (23.1)
Para-aortic only	38 (4.4)
Pelvic and para-aortic	132 (15.3)
Inguinal only	22 (2.6)
Pelvic and inguinal	18 (2.1)
Pelvic, paraaortic and inguinal	13 (1.5)
Others	7 (0.8)
Estimated intraoperative blood loss (mL) (median, IQR)	700 (500-1200)
Operative time (min) (median, IQR)	383 (300-510)
Length of hospitalization, d (median, IQR)	18 (12-27)
Adjuvant therapy	
Chemotherapy	198 (23.0)
Radiotherapy	49 (5.7)
Pathological characteristic	**All patients *n* = 862**
Histotype	
Squamous cell	581 (67.4)
Adenocarcinoma	122 (14.2)
Adenosquamous	15 (1.7)
Endometrioid	58 (6.7)
Serous	10 (1.2)
Clear cell	11 (1.3)
Undifferentiated	5 (0.6)
Endometrial Stromal Sarcoma	6 (0.7)
Leiomyosarcoma	9 (1.0)
Carcinosarcoma	7 (0.8)
Mixed	3 (0.3)
Others	18 (2.1)
Missing	17 (2.0)
Positive pelvic lymph node	121 (14.0)
Positive aortic lymph node	53 (6.1)
Positive inguinal lymph node	28 (3.2)
Surgical margins	
Negative	676 (78.4)
Micro	145 (16.8)
Macro	32 (3.7)
Missing	9 (1.0)
Maximum pathologic tumor diameter, mm	43 (30-60)
LVSI	
Negative	391 (45.4)
Positive	328 (38.1)
Missing	143 (16.6)
Perineural invasion	
No	132 (15.3)
Yes	177 (20.5)

Table 1 (*continued*)

Clinical characteristic	All patients $n = 862$
Not reported	505 (58.6)
Missing	48 (5.6)

Abbreviations: IQR, interquartile range; LVSI, lymph-vascular space invasion; MRI, magnetic resonance imaging; PET, positron emission tomography.
Data are reported as absolute counts and percentages, in brackets, unless otherwise specified.
[a] Urothelial cancer in patients with previous diagnosis of cervical cancer undergoing pelvic exenteration according to MRI scan and PET scan findings.
[b] Persistence defined as continued evidence of the original tumor at the end of primary treatment.

operative, early post-operative, and late post-operative complications was 0.8%, 26.1%, and 10.1%, respectively. No patient died during surgery, and the 30-day post-operative mortality due to complications was 3.1%. The most frequent intra-operative complication was injury of external iliac vein (grade 1 in 88.2% of cases), whereas the most frequent severe post-operative complication was pelvic abscess/collection. The incidence of severe early post-operative complications was higher in the second study period than in the first. Lastly, a score to predict the risk of post-operative complications was developed and identified 4 groups at different risks of early and late post-operative morbidity.

Results in the Context of Published Literature

The low occurrence of major intra-operative complications and the absence of any intra-operative death represent important arguments to support the performance of such complicated surgery in tertiary referral centers; in fact, one previous study reported that a higher surgical volume of pelvic exenteration was associated with lower peri-operative mortality.[19]

The incidence of early post-operative complications in our study is in line with previous reports that assessed 30-day morbidity.[3,11,20-23] On the other hand, although we report a 30-day mortality rate of 3.1%, other studies reported rates ranging from 0% to 1.9%;[3,20,21] nevertheless, we must acknowledge that we included also patients who underwent pelvic exenteration for palliative purpose and with poor performance status (18.6% of our patients had Eastern Cooperative Oncology Group performance status $\geq$2). We are aware that including these patients might have negatively impacted the overall results, but we aimed to provide a "real-life" outcome on all patients undergoing pelvic exenteration. Regarding the pattern of complications, we reported infective to be the most frequent early and late post-operative ones. This is also in line with previous reports, with pelvic abscess/collection being the most frequent severe post-operative complication.[21-24] This is part of the so-called empty pelvis syndrome, which is mainly characterized by pelvic collections, perineal surgical site complications, and small bowel complications, such as fistulae, obstruction, and adhesions.[18] The incidence of empty pelvis syndrome in our cohort was similar to those from other reports;[25,26] however, we were not able to prove that preventive methods (Table S2) were associated with a reduction in the incidence of this complication. One systematic review on reconstruction techniques and their associated complications concluded that given the low quality of the evidence with small number of patients, strong conclusions in favor of a certain technique to prevent empty pelvis syndrome remain challenging.[25] On the other hand, a recent Delphi consensus was performed by the PelvEx collaborative and agreed on the definition and core data set for empty pelvis syndrome also reached a consensus on preventive methods.[18]

Factors associated with increased risk of severe post-operative were no previous recurrences, ASA score >1, total pelvic exenteration, infra-levator pelvic exenteration (with or without vulvectomy), and laterally extended surgery. Co-morbidities and extent of surgery (total and laterally extended pelvic exenteration) are variables that were already suggested by other authors in different models.[3,11,23,24] Instead, the number of previous recurrences being a protective factor toward complications has not been described and we might ascribe that to the fact that patients operated at first diagnosis were those with larger tumor extent (causing increased local inflammation) and/or palliative indications, such as bowel/bladder fistula (which prevent primary radiotherapy) and might increase the risk of infections (the most frequently reported complications). Finally, different studies reported low pre-operative hemoglobin levels to be associated with higher incidence of post-operative complications, but this was not the case in our series.[11,23]

Table 2 Incidence of Peri-Operative Complications (Highest Complication Per Patient Is Reported)

Complication	All patients $n = 862$
Intra-operative	
No	801 (92.9)
G1-G2	54 (6.3)
G3-G4	7 (0.8)
G5	0
Post-operative (early)	
No	379 (44.0)
G1-G2	222 (25.8)
G3-G4	225 (26.1)
G5	27 (3.1)
Grade missing	9 (1.0)
Post-operative (late)	
No	642 (74.5)
G1-G2	87 (10.1)
G3-G4	87 (10.1)
G5	16 (1.8)
Grade missing	30 (3.5)

Strengths and Weaknesses

This study has strengths. First are the large sample size including patients operated in referral centers with expertise in gynecologic oncology surgery (not deriving from national database samples), the recent inclusion time frame, and a similar collaboration was earlier developed by the PelvEx collaborative group, which published different international studies on the outcomes of pelvic exenteration performed for all pelvic cancers;[27,28] however, most of patients included in these studies were diagnosed with colorectal cancer. Second, to the best of our knowledge, it represents the first study developing a score of prediction of major surgical complication, which can be used for discussion with patients and for symptoms/signs monitoring during hospitalization and after discharge.

Limitations of the present study are the following: the retrospective nature of the study; incidence of complications might be underestimated (particularly, after patient discharge); we did not record the Charlson co-morbidity index (previously associated with incidence of post-operative complications[3]), even if we reported the ASA score, which is representative of patients health status; specific complications from plastic reconstructions were not described; no data on quality of life is reported; we did not report external validation of the score, limiting its clinical applications; the models presented in the scores had moderate discrimination ability; exclusion of posterior pelvic exenteration might be considered a further limitation, with consequent lack of morbidity analysis between anterior/total and posterior pelvic exenteration (however, we focused on a large number of surgeries

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Table 3 Details of Early and Late Post-Operative Complications[a]

Early post-operative complications

Type of complication	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4a	Grade 4b	Grade 5	Total
Gatro-intestinal	1 stoma ischemia 35 ileus 8 gastroparesis 1 diarrhea	1 small bowel-cutaneous fistula 1 gastric ulcer	1 bleeding of colorectal anastomosis 1 Miami pouch-vagina fistula 6 small bowel obstruction 2 duodenal ulcer 1 small bowel anastomosis dehiscence	13 colorectal anastomosis fistula 1 Bleeding of colorectal anastomosis 1 gastric ulcer 6 gastric/duodenal perforation 4 small bowel anastomosis dehiscence	2 colorectal anastomosis fistula		5 colon perforation	90
Urinary	2 ureterocutaneostomy avulsion 1 difficulty with catheterization 3 hydronephrosis	1 fistula anastomosis neobladder-urethra 3 acute kidney injury 1 ureteric stricture/			hydroureteronephrosis	15 urostomy leak/ dehiscence/ fistula 18 ureteric stricture/		
					hydroureteronephrosis 1 urostomy necrosis	20 urostomy leak/ dehiscence/ fistula 7 ureteric stricture/		
					hydroureteronephrosis 2 urostomy ischemia 1 renal lithiasis 1 urostomy prolapse 1 dialysis	1 urostomy necrosis 1 urostomy leak/ dehiscence/ fistula 1 ureteric stricture/		
					hydroureteronephrosis 2 acute kidney injury		3 urostomy leak/ dehiscence/ fistula	85
Infection (other than surgical site)	2 pelvic abscess/ collection	2 *C Difficile* infection 4 gastroenteritis 109 urinary tract infection 13 pneumoniae 41 pelvic abscess/ collection 40 fever/sepsis	12 urosepsis 2 pneumonia/pleural effusion 30 pelvic abscess/ collection 1 left flank abscess/ collection 1 dental osteitis 1 CVC infection	26 pelvic abscess/ collection	2 urosepsis 1 pneumonia 5 pelvic abscess/ collection 1 left flank abscess/ collection 2 sepsis	1 right leg necrosis with sepsis	4 pneumonia 4 pelvic/ abdominal abscess/ collection	304
Surgical site	19 midline wound dehiscence/infection 1 stoma wound dehiscence 1 subcutaneous hematoma	73 wound dehiscence/infection (8 requiring negative pressure wound therapy)	9 midline wound dehiscence/infection 5 perineal wound/ vaginal wound dehiscence	22 midline wound dehiscence/infection 1 fascial dehiscence 2 perineal wound/ vaginal wound dehiscence 3 subcutaneous hematoma 4 flap necrosis	2 midline wound dehiscence/infection 1 flap dehiscence/ infection	1 fascial dehiscence	2 wound dehiscence/ infection	146
Vascular/ lymphatic	2 orthostatic edema	14 DVT/VTE 1 arterial thrombosis 1 venous phlebitis 3 intraperitoneal bleeding	1 IVC filter 1 lymphocele	7 intraperitoneal bleeding 3 arterial thrombosis	4 intraperitoneal bleeding 2 arterial thrombosis	1 arterial thrombosis	5 intraperitoneal bleeding 2 VTE 1 pulmonary edema 1 compartmental syndrome upper limb	49
Other	1 pleural effusion 3 postoperative delirium 1 obstruction of urostomy output due to mucus 1 Posterior reversible encephalopathy syndrome 1 fascial dehiscence	53 blood transfusion 1 atrial fibrillation 2 chylous ascites 1 metabolic encephalopathy	3 pleural effusion		1 Takotsubo syndrome 2 respiratory distress syndrome 1 inhalation pneumoniae	1 acute liver dysfunction		72
Total	83	365	111	123	31	4	27	746

Late post-operative complications

Type of complication	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4a	Grade 4b	Grade 5	Total
Gatro-intestinal		3 small bowel-	1 colorectal anastomosis	10 colorectal anastomosis	1 colon ischemia/		2 colon	49

Table 3 (*continued*)

Late post-operative complications								
Type of complication	**Grade 1**	**Grade 2**	**Grade 3a**	**Grade 3b**	**Grade 4a**	**Grade 4b**	**Grade 5**	**Total**
		cutaneous fistula 1 hemorrhoids 6 small bowel obstruction 1 colorectal anastomosis fistula 1 high ileostomy output 1 gastritis	fistula 1 small bowel obstruction	fistula 3 large bowel obstruction 1 colon ischemia/necrosis 2 colostomy prolapse 6 small bowel perforation/ fistula 3 small bowel obstruction 1 colostomy obstruction 3 small bowel anastomosis dehiscence 1 small bowel-cutaneous	necrosis		perforation 1 small bowel fistula and short bowel syndrome	
Urinary	2 difficulty catheterization	1 acute kidney injury 2 ureteric stricture/ hydroureteronephrosis	2 urostomy leak/ dehiscence/fistula 1 urinary retention 1 ileal conduit bleeding ureteric 12 stricture/ hydroureteronephrosis	5 urostomy leak/dehiscence/ fistula 3 ureteric stricture/ hydroureteronephrosis	1 acute kidney injury		2 urostomy leak/ dehiscence/ fistula	32
Infection (other than surgical site)	1 pelvic abscess/ collection	1 *C. Difficile* infection 56 urinary tract infection 1 erysipelas pneumoniae 22 pelvic abscess/ collection 2 CVC infection 15 fever/sepsis	9 urosepsis 14 pelvic/abdominal abscess/collection	3 urosepsis 9 pelvic/abdominal abscess/ collection 1 peristomal abscess/ collection 1 infected lymphocele	1 pelvic/ abdominal abscess/ collection 3 sepsis 1 CVC infection		2 urosepsis 4 pneumoniae 3 pelvic/ abdominal abscess/ collection	149
Surgical site	1 incisional hernia 1 acute kidney injury	11 wound dehiscence/ infection (1 requiring negative pressure wound therapy)	1 midline wound dehiscence/infection 1 perineal wound/vaginal wound dehiscence 1 infected inguinal lymphocele	1 perineal wound/vaginal wound dehiscence 1 flap necrosis	2 midline wound dehiscence/ infection			20
Vascular/ lymphatic		8 DVT/VTE		2 arterial thrombosis	2 VTE		1 intraperitoneal bleeding 1 VTE pulmonary edema	14
Other	1 obturator nerve injury sequelae	14 blood transfusion 1 transient ischemic attack 2 electrolytes disorder						18
TOTAL	6	149	44	56	11	0	16	282

Abbreviations: CVC, central venous catheter; DVT, deep vein thrombosis; VTE, venous thrombo-embolism.
[a] One patient might have had more than one complication.

Table 4 Univariable and Multi-Variable Analysis for Risk of Early (Within 30 Days) and Late (31 to 180 Days) Post-Operative Complications

Early post-operative complications G3 to G5 $n = 251/862$		
Characteristics	**Univariable OR (95% CI)**	**Multi-variable ($n = 673$) OR (95% CI)**
Age at pelvic exenteration, years	1.01 (0.99 to 1.02)	
BMI, kg/sqm	1.01 (0.99 to 1.04)	
ECOG PS		
0	Ref.	
1	1.08 (0.76 to 1.51)	
≥2	1.39 (0.94 to 2.08)	
Primary site		
Cervix	Ref.	
Endometrial	0.97 (0.64 to 1.46)	
Vulva	1.19 (0.72 to 1.97)	
Vagina	0.86 (0.49 to 1.51)	
Time from diagnosis to pelvic exenteration	0.99 (0.99 to 1.00)	

(*continued on next page*)

Table 4 (*continued*)

Early post-operative complications G3 to G5 *n* = 251/862		
Characteristics	**Univariable OR (95% CI)**	**Multi-variable (*n* = 673) OR (95% CI)**
Previous EBRT		
No	Ref.	
Yes	0.96 (0.60 to 1.52)	
No. of previous recurrences		
0	**Ref.**	**Ref.**
1	**0.66 (0.43 to 1.00)**	**0.48 (0.28 to 0.82)**
≥2	**0.58 (0.36 to 0.93)**	**0.44 (0.25 to 0.79)**
Neoadjuvant chemotherapy		
No	Ref.	
Yes	1.10 (0.71 to 1.71)	
Fistula		
No	Ref.	
Yes	0.74 (0.50 to 1.10)	
Hemoglobin	1.00 (0.91 to 1.10)	
Creatinine	1.11 (0.93 to 1.33)	
ASA score		
1	**Ref.**	**Ref.**
2	**1.93 (1.06 to 3.52)**	**2.12 (1.14 to 3.94)**
3	1.50 (0.79 to 2.84)	1.52 (0.77 to 2.98)
4	**3.78 (1.47 to 9.70)**	**3.77 (1.19 to 11.88)**
Pelvic exenteration type		
Anterior only	**Ref.**	**Ref.**
Total	**1.44 (1.06 to 1.96)**	**1.58 (1.09 to 2.28)**
Pelvic exenteration approach		
Laparotomy	Ref.	
Laparoscopy	1.27 (0.76 to 2.12)	
Pelvic exenteration classification		
Supra-levator	**Ref.**	**Ref.**
Infra-levator	**1.63 (1.17 to 2.28)**	**1.68 (1.14 to 2.49)**
Infra-levator with vulvectomy	**1.51 (1.00 to 2.30)**	**1.62 (1.00 to 2.63)**
Laterally extended surgery		
No	**Ref.**	**Ref.**
Yes	**1.71 (1.22 to 2.41)**	**1.51 (1.00 to 2.28)**
Lymphadenectomy		
No	Ref.	
Yes	1.00 (0.75 to 1.34)	
Type of urinary diversion		
Bricker	Ref.	
Others	0.97 (0.71 to 1.32)	
Estimated blood loss, L	1.13 (0.94 to 1.36)	
Duration of surgery, hour	1.05 (0.99 to 1.11)	
Late post-operative complications G3 to G5 *n* = 103/862		
Characteristics	**Univariable OR (95% CI)**	**Multi-variable (*n* = 754) OR (95% CI)**
Age at pelvic exenteration, y	1.00 (0.98 to 1.02)	
BMI, kg/m^2	1.00 (0.96 to 1.04)	
ECOG PS		
0	Ref.	

Table 4 (*continued*)

Late post-operative complications G3 to G5 *n* = 103/862		
Characteristics	**Univariable OR (95% CI)**	**Multi-variable (*n* = 754) OR (95% CI)**
1	1.06 (0.66 to 1.70)	
≥2	1.05 (0.59 to 1.87)	
Primary site		
Cervix	Ref.	
Endometrial	0.62 (0.32 to 1.20)	
Vulva	1.53 (0.81 to 2.86)	
Vagina	0.93 (0.43 to 2.02)	
Time from diagnosis to pelvic exenteration	1.00 (0.99 to 1.00)	
Previous EBRT		
No	Ref.	
Yes	1.02 (0.54 to 1.94)	
N of previous recurrences		
0	Ref.	
1	1.36 (0.69 to 2.67)	
≥2	1.45 (0.70 to 2.98)	
Neoadjuvant chemotherapy		
No	Ref.	
Yes	0.65 (0.32 to 1.32)	
Fistula		
No	Ref.	
Yes	0.69 (0.39 to 1.23)	
Hemoglobin	1.02 (0.89 to 1.16)	
Creatinine	1.13 (0.91 to 1.40)	
ASA score		
1	Ref.	
2	1.25 (0.57 to 2.74)	
3	1.19 (0.51 to 2.75)	
4	1.48 (0.41 to 5.37)	
Pelvic exenteration type		
Anterior only	Ref.	
Total	1.27 (0.82 to 1.94)	
Pelvic exenteration approach		
Laparotomy	Ref.	
Laparoscopy	0.93 (0.43 to 2.00)	
Pelvic exenteration classification		
Supra-levator	**Ref.**	**Ref.**
Infra-levator	**1.84 (1.11 to 3.06)**	**1.67 (0.96 to 2.91)**
Infra-levator with vulvectomy	**2.76 (1.57 to 4.87)**	**2.65 (1.44 to 4.88)**
Laterally extended surgery		
No	**Ref.**	**Ref.**
Yes	**1.96 (1.25 to 3.07)**	**1.83 (1.12 to 3.00)**
Lymphadenectomy		
No	Ref.	
Yes	1.18 (0.78 to 1.78)	
Type of urinary diversion		
Bricker	Ref.	

(*continued on next page*)

Table 4 (*continued*)

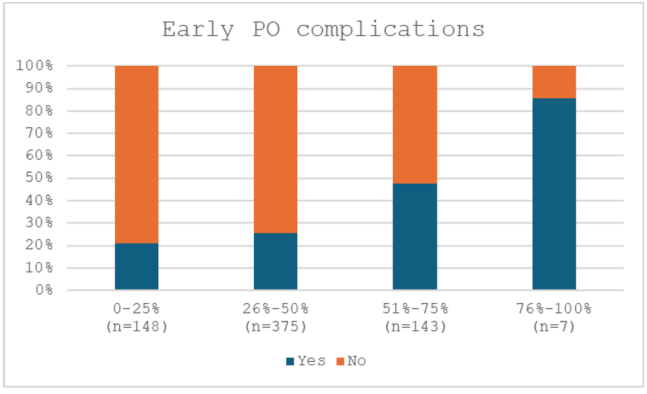
Late post-operative complications G3 to G5 *n* = 103/862		
Characteristics	**Univariable OR (95% CI)**	**Multi-variable (*n* = 754) OR (95% CI)**
Others	0.86 (0.55 to 1.35)	
Estimated blood loss, L	1.05 (0.82 to 1.33)	
Duration of surgery, h	**1.07 (1.00 to 1.15)**	**Not significant**
Adjuvant chemotherapy		
No	Ref.	
Yes	0.58 (0.33 to 1.02)	

bold values correspond to the statistically significant variables at univariable analysis and are tested in a multivariable analysis.
Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; EBRT, external beam radiotherapy; ECOG, Eastern Cooperative Oncology Group; OR, odds ratio; PS, performance status; Ref., reference.

A

Characteristic	Beta coefficient	Score Points (%)
No Previous Recurrence	0,823	23
Previous Recurrence 1	0,09	3
Previous Recurrence >1	0	0
ASA 1	0	0
ASA 2	0,75	21
ASA 3	0,417	12
ASA 4	1,326	37
PE type anterior	0	0
PE type total	0,457	13
PE supra-levatorial	0	0
PE infra-levatorial	0,521	15
PE infra-levatorial with vulvectomy	0,485	13
Laterally extended surgery no	0	0
Laterally extended surgery yes	0,413	12

A

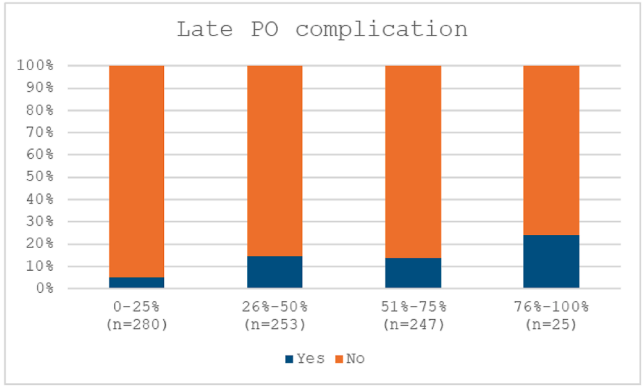


B

B

Characteristic	Beta coefficient	Score Points (%)
PE supra-levatorial	0	0
PE infra-levatorial	0,445	27
PE infra-levatorial with vulvectomy	0,99	61
Laterally extended surgery no	0	0
Laterally extended surgery yes	0,634	39

A



B

Figure EARLY**,** Predictive score (**A**) defining risk groups (**B**) associated with major early post-operative morbidity. The score is calculated by adding points in the yellow column according to the presence of different risks factors, the sum of which will give the total score (eg, patient who had 1 previous recurrence, ASA score 2, underwent total infra-levator pelvic exenteration with no lateral extension, has a score of 3 + 21 + 13 + 15 = 52% falling into the third risk group, carrying a risk of 48% of major early post-operative complications). LATE**,** Predictive score (**A**) defining risk groups (**B**) associated with major late post-operative morbidity. ASA, American Society of Anesthesiologists; PO, post-operative; PE, pelvic exenteration.

involving bladder removal, the one at highest risk of complications[29]); lastly, data on nutritional status (previously associated with peri-operative complications[11]) are also missing.

Implications for Practice and Future Research

Pelvic abscess or collection was the most common severe post-operative complication, underscoring the need for strategies in clinical practice and research to enable prevention and early detection. Likewise, urostomy leakage and benign ureteric stricture may be preventable through intravenous indocyanine green angiography, which allows assessment of tissue perfusion and optimization of surgical resection.[30]

The COREPEX complications score is a tool that gynecologic oncologists can use during pre-operative counseling to stratify the patients' risk of early or late severe post-operative complications. Thanks to pre-operative imaging, all characteristics included in the model can be predicted before surgery. Further research is needed to externally validate the complications score and prospectively assess the impact of the predictive model. In addition, artificial intelligence tools, such as smartphone applications,[31] could be integrated to monitor post-operative complications after pelvic exenteration, thereby

providing additional support to patients who live far from referral centers and require ongoing care.

CONCLUSIONS

Patients undergoing anterior or total pelvic exenteration for gynecologic cancers in tertiary referral centers have a low risk of intra-operative complications but have a remarkable risk of major post-operative complications. No intra-operative death was recorded, and 3% of patients died of post-operative complications. Most frequent intra-operative and post-operative complications were vascular injury and infection, respectively. Lastly, the COREPEX complications score to predict the risk of early and late post-operative complications was developed and can be used to counsel patients and for future studies.

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