

SHORT COMMUNICATION

Incorporating textbook outcomes in the audit of pelvic exenterations

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Abstract

Locally advanced pelvic tumors often require pelvic exenteration (PE) to achieve R0 resection, highlighting the critical role of specialized centers and nuanced metrics like textbook outcomes in assessing surgical performance and improving patient outcomes. This study aimed to audit our PE cases and compare the results with those reported by the PE Collaborative Group (PelvEx). Data were collected on patient demographics, tumor characteristics, diagnostic and treatment details, pathology findings, and outcomes. Both a direct audit and an evaluation based on the textbook outcomes were conducted. A comparison of our 23 PE cases with the PelvEx cohort, which exhibited comparable characteristics, revealed a higher rate of radicality in our cases but worse outcomes regarding hospital stay duration and mortality. However, approximately 65% of our patients achieved textbook outcomes, with over 90% meeting the criteria for both radicality and hospital survival. The incorporation of textbook outcomes into the audit of surgical procedures offers a valuable framework for clarifying the interpretation of direct audit results.

Keywords: Audit; Pelvic exenteration; Textbook outcomes; Morbidity; Mortality; Intraoperative radiotherapy

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1. Introduction

Locally advanced pelvic tumors (e.g., digestive, gynecological, and urinary) can invade the visceral peritoneum or infiltrate and adhere to adjacent organs or structures. This stage of the tumor, classified as T4 according to the American Joint Committee on Cancer classification (version 4.2022), often necessitates surgery involving *en bloc* resection of the affected organs to achieve oncologically adequate margins (R0 resection), with no residual tumor. This surgical intervention is known as pelvic exenteration (PE), and it may also be required in cases of recurrence of these tumors.

PE is a complex procedure, and the literature often emphasizes that only tertiary referral centers can provide the level of care required to assess and treat patients with advanced primary or recurrent cancer. The centralization of these cases in high-volume centers (HVs) is considered a key factor in improving outcomes and survival rates.^{1,2} However, comparisons between HVs (more than 20 PE cases annually) and

low-volume centers (LVs, fewer than 20 cases) suggest that organizational expertise, rather than volume, plays a significant role in improving patient outcomes.³ Recently, the concept of mixed-volume hospitals (MVHs) has emerged, wherein individual cancer surgeries may be low-volume, but total complex cancer operations are performed at high volumes. A study comparing outcomes between MVH and HV centers has demonstrated similar long-term survival rates for certain high-risk cancer surgeries.⁴

Any initiative to improve care requires a comprehensive audit of results. In addition, the concept of “textbook outcome” has gained popularity, referring to the proportion of patients who achieve all desired short-term outcomes following treatment.⁵

Motivated by these considerations, this article presents an audit of PE outcomes at our LV-MVH center and compares these results with those of the PE Collaborative Group (PelvEx), which serves as our reference group.

2. Data and methods

2.1. Direct audit

A retrospective, single-center study was conducted using a database that collects patient demographics, tumor characteristics, diagnostic and treatment details, as well as pathology and outcome information for patients undergoing PE. The first part of the audit involved directly comparing our results with those from the PelvEx cohort.⁶

2.1.1. Descriptions of direct audit

Total PE was defined as complete *en bloc* resection of the rectum, genitourinary viscera, internal reproductive organs, regional lymph nodes, and peritoneum. Partial PE included anterior, posterior, and/or modified PE. Anterior PE involved resection of the bladder with or without internal reproductive organs (uterus, vagina, cervix, prostate, seminal vesicles). Posterior PE included resection of the rectum with or without the internal reproductive organs while preserving the bladder. Modified PE was subdivided into cases requiring lateral sidewall compartment resection with or without neurovascular resection, or those requiring bony resection. The histopathological evaluation considered a resection to be R0 if all margins were >1 mm, R1 if there was microscopic residual disease defined (≤ 1 mm), and R2 if there was macroscopic residual disease.⁶

Our standard neoadjuvant regimen consists of XELOX (capecitabine 100 mg/m² and oxaliplatin 130 mg/m²) for five cycles, followed by chemotherapy (capecitabine 825 mg/m²) with concomitant radiotherapy.

According to our protocol, if there is any suspicion of tumor involvement in the presacral space, bone resection

must be performed. Dissecting between a suspected tumor and the bone contradicts the oncological surgical principles, as it could lead to intratumoral dissection, compromised margins, and local dissemination of tumor cells.

Post-operative complications were classified according to the Clavien-Dindo system.⁷ In addition, major complications were defined as those classified as Clavien-Dindo Grade III or higher.

Post-operative mortality was defined as death within the hospitalization or within 90 days of resection. Radical resection was defined as a microscopic resection.

2.2. Textbook outcome audit

The second part of the audit involved analyzing the variables that constitute the textbook outcome. The textbook outcome was adapted to PE and assessed using five separate “desired outcome” measures: Hospital survival (no post-operative mortality), radical resection, no reintervention, no adverse outcomes, and a hospital stay of 17 days or less.

2.2.1. Description of “textbook outcome”

A “textbook” hospital stay was defined based on the PelvEx results as a hospital stay of 17 days or less. A “textbook outcome” was considered achieved when all five desired health outcomes were realized.⁵

2.3. Statistical analysis

Means were calculated using the free online software available at <https://calcular.io>. Chi-square tests were performed using AI tools (<https://chatgpt.com>) to compare the use of neoadjuvant therapy, the major complication rate, and mortality. In addition, a *t*-test was used to compare the length of surgery.

3. Results

3.1. Direct audit

A total of 23 PE cases were recorded, performed on 12 men and 11 women for rectal cancer (either locally advanced rectal cancer [LARC] or recurrent rectal cancer [LRRc]). The mean age of patients was 63.3 years (range 51 – 82), and the mean body mass index (BMI) was 24.6 kg/m² (range 21.8 – 31.7). The mean BMI in the PelvEx cohort was 25 kg/m². In the pre-operative assessment, 5% of our patients were classified as American Society of Anesthesiologists (ASA) 1, 70% as ASA 2, and the remaining 25% as ASA 3.

Treatment characteristics and outcome data are summarized in Table 1. To facilitate the interpretation of the direct audit, comparative variables from the PelvEx

Table 1. Treatment characteristics and outcomes

Parameter	CHPC	PelvEx	P-value
Number of patients	23	2186	-
Male: Female ratio	1.09:1	0.97:1	-
Age (mean [range] in years)	63.3 (51 – 82)	62 (51 – 70)	-
Neoadjuvant therapy (%)	81.8	71.2	0.32
PE type (%)			
Total	39.1	30.7	-
Partial/modified	60.9	69.3	-
Bone resection	43.4	30.7	-
Median length of surgery (minutes)	430	450	<0.05
Margin status (%)			
R0	96	78.2	-
R1	4	19.7	-
R2	0	0.5	-
Median length of hospital stay (days)	29	17.5	<0.05
Major complication rate (%)	30.4	23.5	0.91
90-day mortality (%)	8.6	2.5	<0.05

Abbreviations: CHPC: Consorcio Hospitalario Provincial Castellón;
PE: Pelvic exenteration; PelvEx: Pelvic Exenteration Collaborative Group.

results⁶ are also presented in Table 1. The most recent data from this registry (2017 – 2021) were used, with the mean calculated by combining data from both LARC and LRRC cases, as these were analyzed together in our study due to the small sample size.

Mortality (two patients) was attributed to medical causes: One patient died from nosocomial pneumonia due to bronchoaspiration in the inpatient ward, and the other from septic shock of respiratory origin in the intensive care unit. Abdominal complications were ruled out in both cases through a computed tomography (CT) scan. While other abdominal complications that could have contributed to the mortality of these patients (e.g., abdominal collections, intestinal fistula, and hemorrhage) were considered, they were unlikely to have been overlooked clinically, even with the use of CT scans.

Intraoperative electron radiotherapy (IOERT) was administered in 56.5% of our cases (Figure 1).

3.2. Textbook outcome audit

The textbook outcome was achieved in 30.4% of patients. An additional 34.7% of patients were close to achieving the textbook outcome, with four of the desired outcomes met. The most frequently achieved outcome was radical resection (95.6%), followed by hospital survival

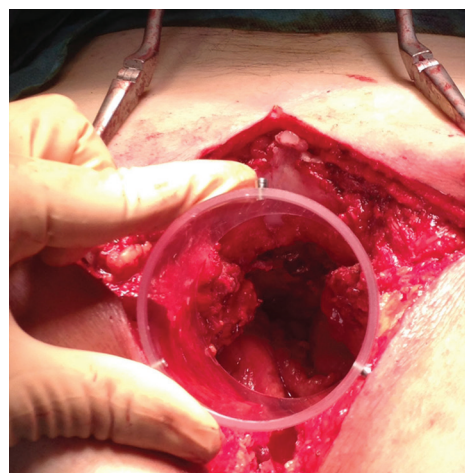


Figure 1. Total pelvic exenteration (posterior view, through sacral resection) and intraoperative electron radiotherapy field applicator.

(91.3%), absence of adverse outcomes (73.9%), and no reintervention (65.2%). The least frequently achieved outcome was a hospital stay of 17 days or less, achieved in only 34.7% of patients.

4. Discussion

In this article, we have presented our model for auditing PE. The direct audit provided initial conclusions, which were further refined by incorporating the audit based on the textbook outcomes.

First, we can affirm that both populations were comparable in terms of demographics and the inclusion of patients with LARC and LRRC. The distribution of PE types and surgical durations were also similar. Among the differences, our series included a higher proportion of patients treated with neoadjuvant therapy, and we performed more bone resections compared to the PelvEx cohort.

The direct audit reveals a mix of positive and negative results. A positive finding is the higher radicality in our cohort, with a greater percentage of R0 resections, fewer R1 resections, and no R2 resections. The increased use of neoadjuvant therapy (although without statistically significant differences) and bone resections may be associated with this improved radicality. In fact, the PelvEx group itself recognizes the administration of neoadjuvant therapy as a desirable practice for achieving more R0 resections.² Concerning bone resection, one study that exclusively used this technique reported 76% R0 resections,⁸ which is similar to the overall result in PelvEx, where 30% of cases utilized this approach. PelvEx has noted that centralization of care in HV centers has challenged traditional boundaries of resectability.² Although our

center is classified as an LV center, it is also an MVH, which may support the argument that organizational expertise plays a crucial role in achieving acceptable outcomes.

Regarding IOERT, despite the limitations of a small sample size, our only case of R1 resection experienced a local recurrence, despite being treated with this modality.

On the negative side, we must highlight the higher incidence of major complications (though without statistically significant differences) and mortality in our cohort. The incidence of major complications in single-center studies from LV hospitals ranges between 25% and 27%,^{9,10} while mortality rates in meta-analyses can reach up to 30.5%,¹¹ which is substantially higher than in the PelvEx registry. Another negative finding was the longer hospital stays in our cohort. This particular finding may be biased by the fact that more than 30% of our patients were referred from hospitals more than 200 km away, with an agreement that they would remain at our center for the entire late post-operative period.

The PelvEx guidelines outline a set of minimum standards for the care of patients with advanced pelvic malignancies:² A multidisciplinary team (which should include urologists), pre-operative staging (such as pelvic magnetic resonance imaging and positron emission tomography-CT), collaboration with radiologists to predict resectability, patient optimization (including nutrition and fitness), and the availability of neoadjuvant treatments (with intraoperative radiotherapy potentially advisable). These standards were met by our center. However, the direct audit raises questions about whether we met objectives related to the incidence of major complications and, though more debatable, mortality.

In addition, we developed the audit using textbook outcomes as a framework. Our unique aspect of the article is the adaptation of textbook outcomes to the context of PE. Specifically, the “no ostomy” criterion was removed, as ostomies are required for complete rectal and bladder resections, making it an impractical parameter for this audit. The “hospital stay” criterion was also adapted, with reference to the PelvEx median of 19 days. Approximately 65% of our patients achieved the textbook outcomes, with the hospital stay being the most common factor preventing the transition from four to five outcomes achieved. Given that the average textbook outcome for colon resections is 49% (range 26 – 71%),⁵ our result for these more complex surgeries appeared more satisfactory and comparable. This finding supports the argument that organizational expertise in MVH may help LV centers achieve acceptable outcomes. Furthermore, the fact that more than 90% of our patients underwent radical surgery and survived provides

valuable data for pre-operative discussions with patients and their families.

The primary limitation of our study is the inability to make direct comparisons with the larger PelvEx cohort due to the small sample size and the lack of statistical power. However, the main strength of our study lies in the utilization of a synoptic format for assessing outcomes, which could be applied to other organ sites as well.

5. Conclusion

The use of textbook outcomes has facilitated the auditing of our PE procedures, supporting the notion that MVH can achieve acceptable results, even if classified as LV centers.

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Conflict of interest

The authors declare that they have no competing interests.

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Ethics approval and consent to participate

The Ethics and Clinical Research Committee of Consorcio Hospitalario Provincial de Castellón has approved this study.

Consent for publication

Verbal consent was obtained from each participant to publish their data and/or images.

Availability of data

Data supporting our findings are available in the electronic patient records at Consorcio Hospitalario Provincial Castellón.

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