

Pelvic Exenteration - Past, Present and Future

Laura Duduș^{1,2}, Corina E. Minciună^{1,2}, Ștefan Tudor^{1,2}, Monica Lăcătuș^{1,2}, Cătălin Vasilescu^{1,2*}

¹Department of General Surgery, Fundeni Clinical Institute, Bucharest, Romania

²Carol Davila University of Medicine and Pharmacy, Bucharest, Romania

*Corresponding author:

Professor Catalin Vasilescu
Department of General Surgery
Fundeni Clinical Institute
258 Fundeni Street, Bucharest
022328, Romania
E-mail: catvasilescu@gmail.com

ORCID iDs:

Laura Duduș
<https://orcid.org/0000-0002-3051-7081>
Corina Minciuna
<https://orcid.org/0000-0002-4074-8967>
Ștefan Tudor
<https://orcid.org/0000-0003-2933-2060>
Monica Lacatus
<https://orcid.org/0000-0002-5192-3396>
Catalin Vasilescu
<https://orcid.org/0000-0003-0194-8779>

Synopsis

The most frequent diseases treated with pelvic exenteration, in terms of the histological type, were gynecological malignancy and squamous cell carcinoma. Even though open approach is favored to minimally invasive one, hospitalization and morbidity are reduced when choosing the latter. R0 and lymphnode status are important predictors for overall survival, as well as major early postoperative complications.

Rezumat

Exenterația pelvină - istoric, actualități, perspective

Introducere: Ținând cont de faptul că procedura deschisă este deja validată de multiple studii, articolul își propune să demonstreze că exenterația pelvină practică prin abord minimal invaziv poate oferi șanse de supraviețuire crescute și să identifice factori de prognostic pentru evoluția acestor pacienți.

Metode: Date privind clasificările actuale și indicațiile operatorii sunt prezentate succint. Studiul este unul retrospectiv.

Rezultate: Cea mai frecventă patologie întâlnită la pacientele studiate sunt cancerul ginecologic, respectiv carcinomul scuamocelular din punct de vedere histologic. Boala recurentă a fost descoperită în 68.2% din paciente iar rezecția R0 a fost posibilă în 72.7% din cazurile abordate minimal invaziv și 73.7% din cazurile abordate deschis. Morbiditatea peri-operatorie a fost raportată la 56.6% pentru intervențiile clasice și 18.1% pentru cele minimal invazive. Intervalul DFS a fost calculat la 20.15 luni, variind între

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1.5 și 70.3 luni, iar supraviețuirea generală a fost de 38.1 luni (0.33- 1508), până în Noiembrie 2023. *Concluzii:* Exenterația pelvină este o procedură chirurgicală în continuă evoluție, abordul clasic fiind de multe ori preferat celui minimal invaziv. Pe de altă parte, morbiditatea și zilele de spitalizare sunt reduse în cea de-a doua variantă. R0 și absența ganglionilor pozitivi sunt factori importanți ai creșterii supraviețuirii generale, precum și absența complicațiilor majore imediat post-operator. În concluzie, exenterația pelvină este o intervenție promițătoare atunci când vine vorba de prelungirea vieții pacientelor în stadii avansate de boala pelvină.

Cuvinte cheie: exenterația pelvină, boala pelvină avansată, cancer pelvin recidivat, cancer pelvin

Abstract

Background: Bearing in mind that the open procedure is already validated by multiple studies, the article aims to prove that pelvic exenteration performed in a minimally invasive fashion might offer better survival and to potentially identify prognostic factors for the outcome of these patients.

Materials and Methods: Data regarding past and present classifications and surgical indications are presented. Patient data were collected retrospectively.

Results: The most frequent diseases treated with pelvic exenteration, in terms of the histological type, were gynecological malignancy and squamous cell carcinoma. Recurrent pelvic disease was found in 68.2% of patients. R0 resection was achieved in 72.7% of patients in the MI group, and in 73.7% of patients in the OP group. Peri-operative morbidity was reported to be 56.6% for open surgery, and 18.1% for minimally invasive. Average DFS was 20.15 months, ranging from 1.5 to 70.3 months, while the OS was calculated to be 38.1 months (0.33 – 1508) up until November 2023.

Conclusion: Pelvic exenteration is a continuously improving surgical procedure, open approach being favored to minimally invasive one. On the other hand, hospitalization and morbidity are reduced when choosing the latter. R0 and lymph node status are important predictors for overall survival, as well as major early postoperative complications. All in all, pelvic exenteration is still a promising surgical procedure to extend cancer patients' lives.

Key words: pelvic exenteration, advanced pelvic disease, recurrent pelvic disease, pelvic malignancy

Introduction

Starting with Brunschwig's first description in 1948 (1) and continuing through today's surgical practice, pelvic exenteration has always been considered a radical solution meant to increase life expectancy for cancer patients (2,3). Whether it was intended as a palliative or a curative treatment, the procedure is regarded as mutilating and associated with high morbidity levels, therefore doctors and patients alike have always avoided its practice on a large scale (4-6).

The present paper points out the evolution

of the pelvic exenteration technique, either open or minimally invasive, in patients with recurrent or locally invasive pelvic cancer (3,7,8). Even though oncological treatments have extended their use and are currently indicated in all stages of cancer, in selected cases surgical intervention might offer better overall survival (9). The study aims to show that minimally invasive approach is a feasible alternative to open procedure that is already validated by current guidelines in certain specific situations and to potentially identify prognostic factors for the outcome of these patients.

Materials and Methods

Definition

“Exenteration” is the term used to describe the emptying of a cavity and therefore “pelvic exenteration” (PE) implies all pelvic organs are removed surgically - the bladder and urethra, the anus and rectum and the reproductive system in women ($\pm$ vulva) or the prostate in men (9). Nonetheless, according to some authors, depending on the extent of the organs involved, a classification of pelvic exenterations into anterior, posterior and total has emerged. Therefore the anterior exenteration spares the bowel system, while the posterior one spares the urinary tract (10).

Data Accrual

The study is a retrospective analysis of selected cases, set between 2008 and 2018. Fundeni Clinical Institute Patient Data System was searched and the following were selected: patients with open pelvic exenteration and patients with minimally invasive pelvic exenteration, all consecutive cases, one selection criteria only. To ensure homogeneity of the patient lot and standardise the extent of the resection, bearing in mind that different types of cancers were treated using the same surgical procedure, only female patients were selected. All patients signed an informed consent prior to the surgical intervention and were informed of the possibility of a later study being conducted using their data.

Types of Cancers

PE was first described as a palliative surgical treatment for “advanced pelvic carcinoma”(1). Even though our knowledge about different types of cancers has greatly improved, it is now safe to say that Brunschwig was not far from the truth. PE is a solution for a variety of advanced or recurrent malignancies pertaining to either genitourinary or colorectal systems (7,9). Despite different malignancies having different outcomes and survival rates,

the advanced form of all pelvic cancers has the same pattern of evolution and therefore can be labelled as “advanced pelvic disease” (3,9). The surgical intervention that was designed to treat this “advanced pelvic disease” is PE and its technique was improved through the years by the addition of minimally invasive surgery and different types of surgical reconstructions, all undergone in an attempt to minimize the psychological impact on patients (11).

Selected cases include gynecological pathology - cervix, uterine, vulvar and ovarian cancer, urinary tract malignancies, locally advanced or recurrent rectum and anal cancers and pelvic tumors presented as emergency (either hemorrhagic or obstructive) that do not have a prior biopsy (7,10).

Open Surgery

The surgical steps include an abdominal time and a perineal time. After the patient is placed in a Trendelenburg position on the operating table, a midline incision is performed and the exploration of the abdominal cavity begins. Mobilization of the bladder after prior incision of the peritoneum is followed by the ligation of the ureters. Dissection on the anterior wall is carried down to the pelvic floor, including the prostate in men or the urethra $\pm$ vulva in women, depending on the type and the extension of the cancer. In preparation of the sigmoid transection, the mesosigmoid is divided and the rectum is fully mobilized down to the coccyx. The mobilization continues laterally to reach the anterior line of dissection in order to ensure that the specimen is resected en-block. The perineal time involves an elliptic incision of the perineal skin which extends posteriorly to the coccyx and anteriorly either to the scrotum (in men) or to the vulva (in women), including the letter whether the situation requires to do so. The dissection is then continued upwards to the pelvic floor, transecting the muscles and making sure careful hemostasis is undergone. Finally, the specimen can be removed (10).

Of course, if the perineal defect is extensive, reconstruction of the pelvic floor is required.

This can either be done in an alloplastic fashion or using myo-cutaneous flaps of the abdominus rectus muscle. Otherwise, an omental patch can be placed in order to avoid the “empty pelvic syndrome” (3).

Minimally Invasive Surgery

Minimally invasive (MI) approach includes laparoscopic or robotic procedures. After the insufflation of the abdominal cavity and the placement of the trocars, a thorough exploration takes place. If robotic procedure is pursued, the Da Vinci is now docked and prepared. As far as the abdominal time is concerned, the surgical steps are the same, even though there are teams, such as Prof. Vasilescu's team that prefer beginning with the dissection of the lymph nodes (LN). Otherwise, the surgery is conducted in the same way as it would have been in an open fashion, up until the point of the pelvic floor incision. The specimen is retrieved through the vaginal opening if an anterior pelvic exenteration is performed. Apart from that, the perineal incision and all the following steps are thereby conducted (12,13).

Other Data

Histological examination via biopsy was obtained for both locally advanced cancers and recurrent ones, except 2 cases that were presented with life threatening symptoms (bleeding and bowel obstruction). Complete imaging assessment was performed prior to the surgery and patients were included in a treatment plan that involved either neo-adjuvant oncological treatment or post-procedure chemotherapy, according to the scheme that was available at the year of practice.

An important step was to determine if the pelvic disease was developed either centrally or laterally, since laterally extended disease is not typically amenable to minimally invasive approach. However, patients in our lots were not subjected to any selection criteria before surgery.

Operating time was calculated as the time

between first incision to final suture, excluding docking time and other minimally invasive specific preparations. Blood loss was estimated with the help of the blood suction device. Length of hospital stay was appreciated as the number of days between surgery day and discharge day.

Postoperative complications were classified as minor and major (Clavien Dindo score), short and long-term (a different admission than that of the surgery).

Categorical variables were reported as frequencies and percentages. Continuous variables were presented as mean $\pm$ standard deviation (SD) or median and interquartile range, after checking for normality. Overall survival (OS) represented the time interval between surgery and the death of the patient or the date of last follow-up if the patient was alive at that moment. The OS rates were estimated with Kaplan-Meier method, and they were compared between different groups by Log-rank test. Univariate analysis and multivariate analysis have been performed to assess the prognostic factors associated with OS using Cox regression analysis. All variables associated with a p value ≤ 0.10 in univariate analysis were included in multivariate analysis, taking into consideration the size of the database. The differences with a p-value < 0.05 were considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics for Windows (version 23.0, IBM, Chicago, IL).

Results

Between the years 2008 and 2018, 110 female patients were admitted for pelvic exenteration. Eleven cases were operated in a MI fashion, either laparoscopic or using the Da Vinci robotic system and 99 cases were offered a classical procedure (open procedure – OP). Average age for the MI group was 58.18 years (40-73), while for the OP was 53.65 years (29-81).

Gynecological malignancy was the most frequent disease to be treated. 87.9% (n = 87) of the open procedures were carried out for

such a diagnosis, while MI surgery was offered exclusively for this type of pathology. In accordance, most frequent histological type of cancer was squamous carcinoma – SCC (75.5%), followed by 12.7% of cases of adenocarcinoma – ADK (digestive tract and also cervical cancer) and 11.8% of other histological types (cystadenocarcinoma, papilliferous carcinoma, adenosquamous carcinoma, endometrioid carcinoma, urotelial carcinoma, sarcoma and high dysplasia/metaplasia) (*Table 1*).

Thirty-two (32.3%) of the OP cases and five (45.5%) of the MI cases are locally advanced cancers, while 68.2% of all patients were diagnosed with recurrent malignancies. Recurrency was found after an average interval of 31 months (2-272 months) following prior surgery or curative intent oncological treatment (*Table 2*).

A total pelvic exenteration (TP) was performed in 87.9% of OP cases and 50% of MI surgery. Only 3 posterior pelvic exenterations were undergone, all in a classical approach.

The mean operating time for open TP was 337 ± 10.6 min versus minimally invasive procedure 440 ± 40.7 min, while open AP time was 259 ± 10.2 min and minimally invasive 360 ± 30.7 min respectively. The operating time for PP was 307 ± 15.8 min.

Estimated blood loss was calculated to be 537 ± 40.2 mL for the classical approach and 350 ± 35 mL for MI pelvic exenteration. While for the minimally invasive surgery no blood transfusion was needed, 12.7% of the patients operated in an open fashion were administered 1 or more blood units.

Length of hospital stay was different between the two groups- 11 days for MI vs 18 days for the OP.

Table 1. Cancer histology

	Open surgery (N)	Minimally invasive surgery (N)
SCC	N=73	N=10
ADK	N=14	N=0
Other	N=12	N=1
Total	99	11

As far as R0 resection is concerned, it was achieved in 72.7% of patients in the MI group and in 73.7% of patients in the OP group respectively. Mean number of harvested lymph nodes was the same for both groups and was calculated to be 21 ± 8 . Following the histology report, N0 was found in 8 patients for the MI group and 64 for the OP group.

Peri-operative morbidity (short-term complications) was reported to be 56.6% for OP and 18.1% for MI surgery. Minor post-operative complications included wound infections-either abdominal or perineal and urological or pneumological infections that did not require intensive care admission. Twenty-five patients developed such issues in the laparotomy group and 1 patient in the minimally invasive group respectively. Clavien Dindo score 3-4 complications were reported in 31.3% of OP patients and 9.1% of MI patients and included infectious issues, urinomas or urinary diversion leakages, re-interventions for ileus, fistulas or bleeding, heart failure, MODS and sepsis. Mortality of MI group was 0 and of OP group was 9.1%.

Long-term complications were mainly related to urinary diversions- acute pielonephritis and hydreonephrosis. Six patients (54.5%) in the MI group and 37 patients (36.3%) in the OP group have developed at one point a type of urinary pathology. Other long-term issues

Table 2. Cancer site and type for open surgery cases

	Gynecologic				Urinary Tract	Digestive Tract (Rectum and Anus)	Other
	Cervix	Endometrium	Ovary	Vulva			
	N=67 (67.7%)	N=8 (8.1%)	N=9 (9.1%)	N=3 (3%)	N=2 (2%)	N=8 (8.1%)	N=2 (2%)
Recurrent cancer	N=46	N=6	N=9	N=1	N=2	N=5	NA

Table 3. Post-operative complications according to classification and type of surgery performed

		OP (n=99)			MI (n=11)	
Minor short-term		25			1	
Major short-term	31	Reinterventions	5	1	Reinterventions	
		Other	26		Other	1
Minor long-term	48	Urologic	36	8	Urologic	6
		Other	12		Other	2
Major long-term	13	Reinterventions	7	3	Reinterventions	1
		Other	6		Other	2

were diagnosed in 14.5% of all patients and were represented by thrombotic events, vascular fistulas, bowel obstructions and complications due to adjuvant chemotherapy sessions. Moreover, 7.3% of cases needed a late re-intervention (*Table 3*).

Average DFS was 20.15 months, ranging from 1.5 to 70.3 months, while the OS was calculated to be 38.1 months (0.33 – 1508) up until November 2023. Ten patients are still alive.

Because of the small number of patients enrolled in the MI group, survival analysis

was only possible for the OP group. While age, tumor and histological type are variables that do not statistically influence the outcome of patients, R0 and lymphnode status (LN ±) are important predictors for overall survival, as well as major early postoperative complications (*Table 4*). According to multivariate-analysis, nodal status and early major complications turned out to be independent factors to influence the overall survival.

Bearing in mind that survival data was only available for 78 patients, 5-year survival was 4 times higher for R0 patients compared

Table 4. Survival Analysis: Univariate and multivariate analysis of risk factors associated with OS

	Univariate analysis			Multivariate analysis		
	HR	95% CI	p-value	HR	95% CI	p-value
Age (years)	0.998	0.977-1.020	0.886			
Type of exenteration						
Other	1					
Total pelvic exenteration	1.136	0.562-2.295	0.722			
Tumor type						
Primary tumor	1					
Recurrence	1.064	0.638-1.773	0.812			
Histopathological type						
Other	1					
Squamous cell carcinoma	1.104	0.643-1.896	0.719			
Type of resection						
Palliative (R1/2)	1					
Radical (R0)	1.149	0.638-2.069	0.643			
Lymph Nodes						
Negative	1					
Positive	1.533	0.930-2.537	0.094	2.240	1.325-3.788	0.003
Early major Complications						
No	1					
Yes	177.84	23.063-1371.317	0.000	235.83	29.83-1864.38	0.000
Late major complications						
No	1					
Yes	1.494	0.796-2.803	0.212			

against palliative ones. Lymphnode status is also important since survival chances for LN- patients are almost two times as high as for LN+ patients after the first year and up to seven times higher after 5 years. Moreover, LN- patients that survived past the first year have higher chances of remaining alive throughout. Early major complications also significantly influence the OS because no patient having registered such an issue made it past the first twelve months (*Fig. 1*).

Discussion

Brunschwig first described it in 1948 and almost a decade later, promoters of the pelvic exenteration technique demonstrated it can be undergone for curative purposes also. Later on, in 2003, Pomel et al. performed the surgery in a laparoscopic fashion (14), followed by a robot- assisted procedure in 2009 (15) and an entirely robotic pelvic exenteration with extended lymphadenectomy described by Vasilescu et al. in 2011 (12).

In the light of surgical and anesthetic

advances pelvic exenteration performance has become safer and mortality and morbidity have now lower rates than before. On the other hand, oncological treatment gaining ground has placed surgery in an unfavorable position, especially this type of extensive procedure (16). Therefore, the main condition for pelvic exenteration to be performed is to achieve curative status- R0 resection, palliative surgery having been determined not to generally improve quality of life and returning poor results in survival rates (9,17).

Over the years, experienced centers have reported a tendency towards treating more recurrent cancers rather than primary ones. Once again as the procedure became even more standardised and effective from an oncological standpoint, surgeons were able to offer this solution for more complex cases. The technique now includes options for anterior extension - pubic bone resection, for posterior extension - sacrectomy and for lateral extension- the possibility to perform vascular, neural or muscular resection of the pelvic side wall (18,19). Moreover the share of gynecological

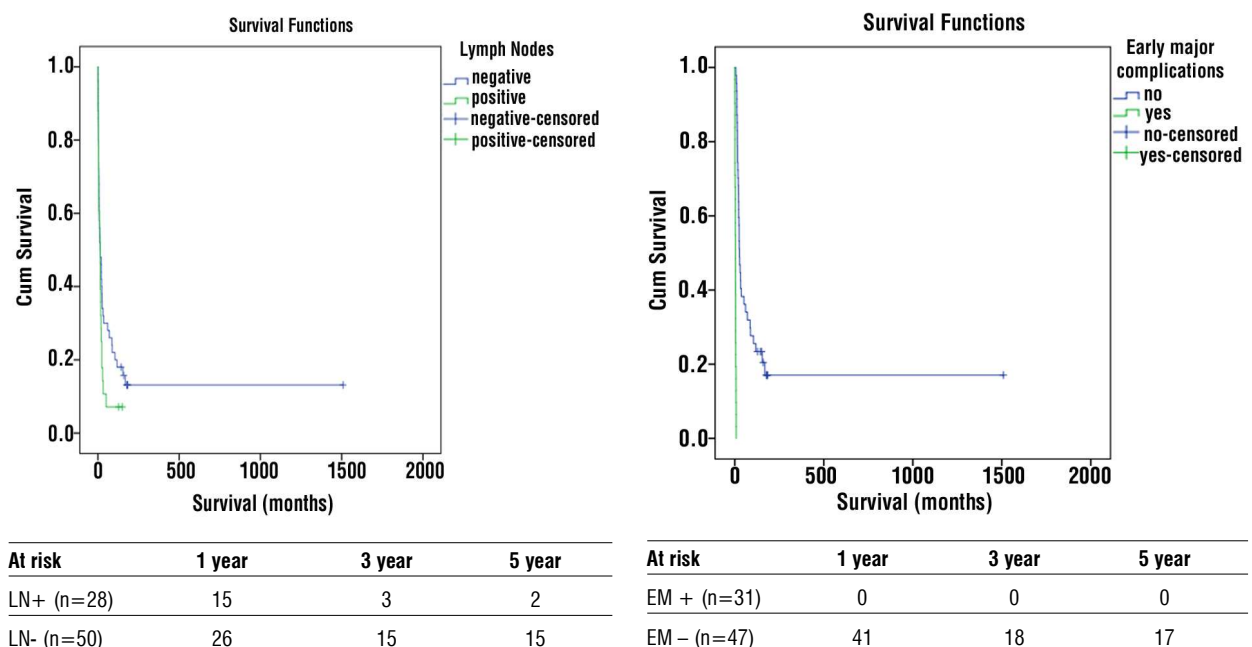


Figure 1. Survival Data - Lymph node status and Early Major Complications

malignancies treated with pelvic exenteration has decreased over the years in favour of GI tract malignancies, owing to better screening policies applied especially for cervical cancer (19). An improvement in survival was also noticed in connection to a shift in hystological types, from squamous carcinoma to adenocarcinoma, knowing that ADK patients have better survival chances than SCC ones (9,19). Patients in our groups follow the same tendency as far as recurrent cancers are concerned, while unfortunately gynecological malignancies and therefore SCC tumors maintain dominancy over the time.

The average time of recurrence after primary treatment- oncological or surgical- was reported in literature between 15 and 23.7 months. The time calculated for our series was a little higher, the reason being that there were 2 patients in the MI group that were presented with a recurrence after more than 10 years.

When it comes to the type of exenteration performed, the open procedure is far more practiced than the minimally invasive approach (20). Also laparoscopy is favored to robotic approach, 82.8% of literature reports describing it as a first choice (16,21). Our series show that the open procedure is nine times more frequent than MI, while laparoscopy (25%) was less practiced than robotic (75%) surgery. TP exenteration is generally the most undergone type, especially when it comes to OP, while AP is usually associated with MI surgery (80% of the cases) (16,21). This is also the case in our study population. The slight differences in approach are however, due to the fact that Fundeni Hospital has had a DaVinci programme and more than one specialized team and therefore the learning curve was overcome easily and many procedures were performed this way.

Mean operating time and estimated blood loss for our cases have similar numbers to those of other publications. Of course open procedures are faster than MI ones, while blood loss and the need for transfusions are lower for this latter kind of approach. The length of hospital stay is also influenced by the

type of surgery performed. Both our groups- OP and MI- have registered similar results to literature (9,22).

R0 resection is the most important decision factor in choosing to perform pelvic exenteration. Palliative surgery is now only reserved for life threatening bleeding tumors or fistulas and in order to compensate for its higher morbidity and mortality rates, minimally invasive approach is advisable. Also, minimally invasive procedure is recommended to be pursued in a number of other situations- when tumor is less than 5 cm in diameter, when tumor is centrally developed rather than with lateral extension and when patients are unfit to withstand a big laparotomy. In our series, R0 was achieved in 73.6% of patients, higher than 70% reported in literature (9,17,23).

Studies show that perioperative morbidity ranges from 20% to 80%, with a median of 53.6%.(6,9) Our patients scored a comparable percent, both open and minimally invasive fashion included. The in-hospital mortality of the two groups combined (8.2%) was also comparable with the median of other reports (6.3%)(9). As other publications conclude urologic associated long-term morbidity is the most frequent and our study groups show a higher occurrence, compared against a maximum of 24% noted in literature (9,24). This high percentage could be explained by the type of urinary reconstruction routinely performed by our teams, which was a double-barrel ureterostomy instead of an ileal conduit.

Both short and long-term surgical reinterventions and minimally invasive procedures such as stent placement and percutaneous drainage were considered in 33% of cases as described in other studies (17).

DFS and OS are directly related to R0 resection (9,17,25). Patients with R0 resections have lower chances of developing a relapse and therefore higher chances of overall survival. That is precisely why, the primary endpoint for PE should be achieving R0 status, both by thorough pre-operative imaging assessment and intra-operative practice of extending the resection beyond

pelvic wall if necessary (6).

Another important OS predictor is the N0 result, although studies have analyzed its importance only in connection with gynecological malignancies. Indeed, it is true especially for cervical cancer, that recurrence usually involves the lymphatic tissue but relapse rates after combined surgical and oncological treatments generally remain high, so it does not come as a surprise to find large numbers of LN+ results in patients undergoing pelvic exenteration (3,26). Positive lymphnodes were found in 12 to 57% cases in literature (23), our patients having scored an overall 34.6% - all types of malignancy included. On the other hand, LN- patients have statistically increased chances of survival, with up to 7 times higher rates after 5-years time.

Major early events have an adverse effect on OS, complications such as heart-failure and sepsis usually leading to in-hospital mortality, while other severe conditions having been associated in our study with death in the first year after surgery. Other publications show the same results regarding CD 3-4 complications and advise on thoroughly select and prepare the patient beforehand, avoiding cases with unfavorable cardiopulmonary performance or nutritional status. (10,27)

Conclusion

In conclusion, PE surgery is advised for both locally advanced and recurrent pelvic cancers, especially with curative intent, according to multiple studies. Approached either open or minimally invasive, in the setting of attentive pre-operative selection and care and aiming for R0 resection, PE can offer improved overall survival. Lymphnode status and early major adverse effects are important prognostic factors.

Authors' Contributions

Laura Dudus: investigation, data curation, writing – original draft. Corina Minciuna: data analysis, writing – review & editing.

Stefan Tudor: resources, data curation, writing – review & editing. Monica Lacatus: resources, writing – review & editing.

Catalin Vasilescu: conceptualization, supervision, writing – review & editing.

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Conflict of Interest

Drs. Laura. Dudus, Corina Minciuna, Stefan Tudor, Monica Lacatus, Cătălin Vasilescu declare that they have no conflict of interest.

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