

Primary pelvic exenteration for locally advanced pelvic malignancies

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Abstract

Background: Pelvic exenteration can be performed in selected patients with large pelvic malignancies as a primary treatment with curative intention. This study aimed to share our experience of primary pelvic exenterations, which were performed in a single institution between November 2011 and July 2020, enrolling 23 patients with different types of pelvic cancers.

Results: The patients mean age was 55 years (range: 43-72 years) and the oncological indications were: stage IVa cervical cancer (11 cases, 48.9%), stage IVa endometrial cancer (1 case, 4.3 %), stage IVa vaginal cancer (6 cases, 26%), stage IIIb bladder cancer (3 cases, 13%), stage IIIc rectal cancer (1 case, 4.3%) and undifferentiated pelvic sarcoma (1 case, 4.3%). Total, anterior, and posterior pelvic exenterations have consisted of 34.4%, 56.5% and 13% of cases, respectively. Related to levator ani muscle, 13 (56.5%) pelvic exenterations were supralevatorian, 10(43.5%) infralevatorian, and 5 (21.7%) were infralevatorian with vulvectomy. No major intraoperative complications have occurred. Seven patients (30.5%) have developed early complications, and 4 of them (17.4%) have required reoperation. One (4.3 %) perioperative death caused by a pulmonary embolism was recorded and one patient had a late complication represented by a urostomy stenosis. Over a median follow-up period of 35 months, 8 (34.8%) patients have died. The median overall survival (OS) was 33 months (range 1-96 months). The 2-year and 5-year survival rates were 72% and 66% respectively. Univariate analysis showed that margin status was the only factor significantly associated with disease-free survival (DFS) ($p=0.016$).

Conclusion: Primary pelvic exenteration can be related with various postoperative complications, without high perioperative mortality and with long-term survival.

1. Introduction

In patients with advanced primary or recurrent gynecologic, urologic or rectal cancers without metastatic disease, extensive aggressive surgery such as pelvic exenteration may be necessary for curative intent treatment [1, 2]. Brunschwig was the first to describe in the 1940s pelvic exenteration [3]. Initially considered as a palliative procedure for patients with extensive pelvic cancers, with a very high perioperative mortality rate of 23%. After a significant progress related to patients selection, improvements in operative techniques and intensive care, the mortality rate have decreased to 3-9% in recent studies [4, 5], and a 5-year survival rate between 20% and 60% [6-14] with a good quality of life [15].

Primary pelvic exenteration is considered as first line radical surgical procedure for patients with advanced pelvic malignancies, prior to any oncological treatment. It could be performed in patients with stage IVa gynecological cancers [1], tumor-associated urogenital or rectogenital fistulas, and in some cases, when the histology of the disease (soft tissue sarcomas, neuroendocrine tumors) predicted chemoradiation therapy resistance [13]. This procedure could be also performed in rare malignant conditions such as synchronous pelvic cancers [16]. The procedure may be classified as total (removal of the tumor together with uterus, vagina, urinary bladder and rectum), anterior (bladder, uterus and vagina)

and posterior (rectum, uterus and vagina). In relation to levator ani muscle, the procedure is classified as supralelevatorian, infralelevatorian or infralelevatorian with vulvectomy. The surgical procedure includes an exenterative phase followed by a reconstructive phase consisting of a continent or incontinent urinary diversion, definitive end colostomy or low rectal anastomosis or and vaginal and pelvic floor reconstruction [17, 18].

The aim of this study was to analyze our primary pelvic exenteration experience from a single institution in patients with locally advanced primary pelvic malignancies.

2. Materials And Methods

This study is a retrospective analysis of all patients who underwent primary pelvic exenteration for advanced pelvic cancer in a tertiary university hospital in Târgu Mures, Romania. The study was approved by the Ethical Medical Committee of our University Hospital (No. 27227). Twenty three primary exenterations were performed between August 2011 and July 2020. Informed consent was obtained in every case and all patients were evaluated by the anesthesiology team in order to evaluate their medical condition to support a complex surgical intervention. All procedures were performed with a curative intent, not for palliation purposes. No one of the patients submitted to primary pelvic exenteration has received neoadjuvant treatment. The exenteration was the first therapeutic approach. For exclusion of all oncological contraindications for pelvic exenteration and assessment of operability, the preoperative work-up included mandatory a transvaginal or transrectal echography plus magnetic resonance imaging or computed tomography. All patients proposed for a total or anterior exenteration underwent cystoscopy, or a colonoscopy for a total or posterior exenteration. Among the 27 patients identified, pelvic exenteration was abandoned in 4 due to oncological contraindications encountered during surgery: pelvic sidewall involvement of the tumor with extension to the bony structures and involvement of the neurovascular structures of the sciatic foramen in one patient, or the detection of peritoneal carcinomatosis in 3 cases, which had not been described in the preoperative imaging work-up. Data were collected from the medical records and consisted of patient demographics, types of malignancy, details on intraoperative management provided, postoperative complications and followed-up. The presence of postoperative complications were assessed according to Clavien- Dindo scale [19].

Collected data were analyzed using Microsoft Excel. Quantitative variables were presented by mean and median, while qualitative and categorical variables were expressed both as integer and percentage values. Survival curve and rates were calculated using the Kaplan-Meier method and univariate analysis was performed using Cox regression model.

3. Results

3.1. Epidemiological and preoperative clinical characteristics

Over a period of 9 years, 23 patients underwent primary exenterative surgery for locally advanced stages pelvic cancers in our department. The median age at the time of surgery was 55 years (range 43 - 72 years). The origin of the primary tumor was represented by stage IVa cervical cancer (11 cases, 48.9%), stage IVa endometrial cancer (1 case, 4.3 %), stage IVa vaginal cancer (6 cases, 26%), stage IIIb bladder cancer (3 cases, 13%), stage IIIc rectal cancer (1 case, 4.3%) and undifferentiated pelvic sarcoma (1 case, 4.3%).(Table 1). Ten out of the 17 patients with stage IVa cervical or vaginal cancer have already developed a vesico-vaginal (8 women) or recto-vaginal (2 women) fistula at the moment of surgery; also the patient with stage IIIc rectal cancer – a rectovaginal fistula.

Table 1. Demographic characteristics and intraoperative details.

<i>Mean age (years)</i>		53.5 (43-72)
<i>Origin of malignancy</i>	Stage	Histological type
Cervical	IVa	Squamous cell carcinoma
Endometrial	IVa	Adenocarcinoma
Vaginal	IVa	Squamous cell carcinoma
Bladder	IIIb	Urothelial carcinoma
Rectum	IIIc	Adenocarcinoma
Undifferentiated pelvic sarcoma		
		11 (48.9 %)
		1 (4.3 %)
		6 (26 %)
		3 (13 %)
		1 (4.3 %)
		1 (4.3 %)
<i>Type of exenteration regarding topography</i>		
Total		7 (30.5 %)
Anterior		13 (56.5 %)
Posterior		3 (13%)
<i>Type of exenteration regarding the levator ani muscle</i>		
Supralevatorian		13 (56.5%)
Infralevatorian		10 (43.5%)
Infralevatorian with vulvectomy		5 (21.7%)
<i>Type of urinary tract reconstruction:</i>		
Non-continent urinary conduit type Bricker		20 (87%)
<i>Type of bowel reconstruction</i>		
Colostomy		7 (30.5%)
Colorectal anastomosis		3 (13%)
<i>Length of surgery (min), median (range)</i>		364 (270-560)
<i>Estimated blood loss (ml), median (range)</i>		600 (300-2100)
<i>Transfusion volumes (ml), median (range)</i>		700 (0-1800)
<i>Hospital stay after PE (days), median (range)</i>		20 (11-75)

3.2. Procedures and complications of pelvic exenteration

As type of exenterative procedure, related to the tumor involvement of pelvic organs, 7 (30.5%) patients required total exenteration, 13 (56.5%) procedures were anterior and 3 (13%) were posterior exenterations. Regarding the levator ani muscle, with the aim to obtain tumor free resection margins 13 (56.5%) pelvic exenterations were supralelevatorian, 10 (43.5%) infralevatorian, and 5 (21.7%) were infralevatorian with vulvectomy.

For the 10 patients with total or posterior pelvic exenterations, a low rectal anastomosis was performed in 3 cases and in 7 patients an end definitive colostomy due to insufficient unaffected rectal stump. Urinary diversion procedures were performed for all patients who underwent a total or anterior exenteration, tailoring a Bricker's ileal (in 15 patients) or sigmoid (in 5) incontinent conduit [20], technically easier to perform compared to other urinary diversion procedures and also associated with lower rates of postoperative complications. The option for an ileal or sigmoid urinary conduit after total exenteration (of course, in all anteriorexenterations an ileal conduit was performed) have depended of the remaining length of the sigmoid colon and of the avoidance of an unnecessary ileal anastomosis needed for the ileal conduit. All ureteric-ental anastomoses were adjusted on 'double J' ureteral stents in order to prevent a subsequent stenosis. All the patients were maintained in the Intensive Care Unit for more than 4 days for close monitoring due to the complexity of the procedure and antithrombotic prophylaxis, total parenteral nutrition, intravenous albumin, and prophylactic antibiotic treatment were given. On final pathology report, clear resection margins (R0) were achieved only in 19 out of 23 patients (86.2%). All 5 patients with positive margins were sent for adjuvant chemotherapy.

No major intraoperative complications have occurred. Postoperative complications were divided according Clavien-Dindo classification [19]. Seven patients (30.5%) have experienced early complications and one patient a late complication respectively [Table 2]. As early complications, one Clavien-Dindo grade V has been registered – a patient of 46 years old, referred to the hospital for stage IIIB bladder cancer, who underwent an anterior supralelevatorian exenteration with no intraoperative complications, has experienced a sudden death in the 16th postoperative day due to a pulmonary embolism, after patient's home discharge, despite prophylactic anticoagulant treatment. Four patients experienced Clavien-Dindo grade IIIb complications: enteric fistulas - 3 ileal fistulas with peritonitis and one entero-vaginal fistula, all necessitating re-laparotomies and ileum re-anastomosis. Two patients after an infralevatorian exenteration with vulvectomy have developed a perineal wound infection with tissue necrosis, necessitating prolonged local treatment (Clavien-Dindo grade II). Only one patient has experienced a late complication – a ureteric-ental stenosis solved finally by a unilateral permanent percutaneous nephrostomy.

Table 2. Early and late complications and survival after pelvic exenteration

<i>Early Complications</i>		7 (30.5%)
Clavien-Dindo grade II	Perineal wound infection	2 (8.7 %)
Clavien-Dindograde IIIb	Bowel fistula	4 (17.4 %)
Clavien-Dindograde V	Pulmonary embolism	1 (4.3 %)
<i>Late Complications</i>		
	Urostomy stenosis	1 (4.3 %)
<i>Survival outcomes</i>		
	Alive – free of disease	15 (65.2%)
	Deceased	8 (34.8%)

3.3. Recurrence and Survival outcomes

Over a median follow-up period of 35 months, 8 (34.8%) patients died. The median overall survival (OS) was 33 months (range 1-96 months) (Figure 3). The 2-year and 5-year survival rates were 72% and 66% respectively.

The median disease-free survival (DFS) time was 26.7 months. DFS and OS were analyzed in terms of exenteration type (total vs partial), type of tumor, bladder invasion, rectal invasion, resection margin status and age (as a continuous variable). Univariate analysis showed that status of resection margin was the only factor significantly associated with DFS ($p=0.016$).

Eight patients had recurrences following pelvic exenteration. The median time to recurrence was 7 months (range, 1-16 months). Five patients had distant recurrences and three had local recurrences. All of the patients with distant recurrences have died from the disease. Out of the 3 patients with local recurrences, 2 have received radiotherapy and one chemotherapy; one is alive and free of disease, the other 2 have died of disease. The median time from recurrence after surgery to death was 7.5 months (range 1-28 months).

4. Discussion

In our study, 11 out of the 23 patients (47.8%) with primary pelvic exenteration had urinary or rectal fistulas at the moment of surgery, a condition that will alter enormously their quality of life and that will not be solved by oncologic treatment. The 5-year overall survival after pelvic exenteration, which ranges between 20% and 60% in all studies, when the oncological indications and contraindications are respected [5-14, 22-26], is similar or higher compared to overall survival after chemoradiotherapy for these advanced pelvic cancers, considered separately. Kramer [25] reported that 22% of his patients who

underwent radiochemotherapy for locally advanced cervical cancer with curative intent have developed fistulas, and the 5 years survival rate was 18%. Moore [26] has reported fistulas appeared as complications of radiochemotherapy in 48% of his patients.

For all our primary pelvic exenteration patients, a 5-year survival probability of 66% was calculated, which is even higher to the rates found in other studies on exenteration [6-14, 27]. Also, the morbidity after exenteration was comparable: in our study, 4 patients (17%) of patients suffered a second surgery because of bowel fistulas. Other early minor complications in our series included 2 (8.7%) perineal wound infection. Late postoperative complications were found in one case (4.3%) of the patients, presenting an urostomy stenosis. The relatively high 5 years overall survival and low morbidity after procedure are strong arguments in favor of primary pelvic exenteration. The current series supports the increasing number of studies regarding the role of pelvic exenteration for selected patients with locally advanced primary pelvic malignancies [28].

In light of the associated morbidities, the intend of any exenterative surgery must be to strive to achieve tumor free margins. Existing tumors that are fixed to the lower pelvic side wall have long been regarded a contraindication for pelvic exenterations, but the role of laterally extended endopelvic resections (LEER) in the surgical treatment of pelvic malignancies has been proven by some reports [29, 30]. The only contraindication for LEER is the involvement of the sciatic nerve, but these pelvic side wall resections are technically difficult and may be associated with increased risks because of frequent anatomic anomalies [31]. Completeness of tumor resection was the only variable with a significant impact on survival according to Zoucas [32]. In our series, clear resection margins were achieved in only 82.6% of patients. The inferior resection line (urethra, vagina and rectum) has been proven to be the weak point for the majority of patients with positive microscopic resection line and this has to be pushed downwards as much as necessary to obtain clear margins.

An important element of every pelvic exenteration procedure, affecting the duration of surgery, the frequency and type of complications, and the postoperative quality of life, is the method used for urinary and/or fecal diversion. The Bricker procedure remains the most performed technique for urinary diversion [20]. In our study group, this method has been applied in all patients with anterior or total exenteration. But, in recent years, the low rectal anastomosis and orthotopic continent urinary diversions are more and more used after pelvic exenterations, mainly for patients more fit for a prolonged surgery and without tumor involvement of the bladder neck or lower rectum. These surgical techniques will avoid the need of external stomas and, subsequently, the patients' quality of life will improve significantly [33].

The learning curve for pelvic exenterations is long for the entire involved team (gynecologic oncologist surgeon, anesthesiologist, radiologist, urologist, etc.). Comparing the early period when pelvic exenteration was implemented in our department, in recent years, the tendency is to lower significantly the operative time, the blood transfusion volume and the complications rate.

Major biases of our study are the retrospective nature of the analysis, the heterogeneity of the advanced pelvic cancers and the relatively small number of patients but these factors are present in the majority of

series reported in the literature on pelvic exenteration. Despite these limitations, our study has contributed to an evidence that primary pelvic exenteration is a feasible surgical option for selected patients with locally advanced pelvic malignancies accompanied with acceptable long-term outcomes. It is imperative to adopt a multidisciplinary approach when performing such technically demanding operations to achieve better outcomes for the patients. In the near future, considering the new data regarding the safety of minimally invasive surgery in the treatment of cervical cancer [34], the exenterative and partially the reconstructive phase might be performed by laparoscopic or robotic surgery

5. Conclusions

Primary pelvic exenteration for locally advanced pelvic malignancies is accompanied with considerable morbidity, but with acceptable overall survival. The eligibility of patients for this radical surgical approach should be assessed by careful patients' selection, preoperative counseling and should be carried out only in surgical centers with well trained staff.

List Of Abbreviations

OS - overall survival

DFS - disease-free survival

LEER - laterally extended endopelvic resections

Declarations

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Author's Contributions

MG contributed to the conception and design of the study, analysis and interpretation of the patient data. MEC contributed to the conception and design of the study and was the leading surgeon for all the surgical procedure described in our report. ALC, SLK, RFB and MS contributed to the acquisition of the patient data, the analysis and interpretation data of the study and the writing of the article. AAM supervised the work and revised the article, contributed to the drafting of the work and its critical revision for important intellectual content. All authors read and approved the final manuscript and agree to be accountable for all aspects of the research in ensuring that the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Availability of data and materials

Data were collected from medical charts and are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was approved by the Ethical Medical Committee of the University Hospital of Târgu Mureş (protocol code 27227, 10/03/2020).

All enrolled patients gave written informed consent for the surgical procedures and data collection.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures



Figure 1

MRI scan. Stage IVa cervical cancer – large cervical tumor invading the bladder and rectum

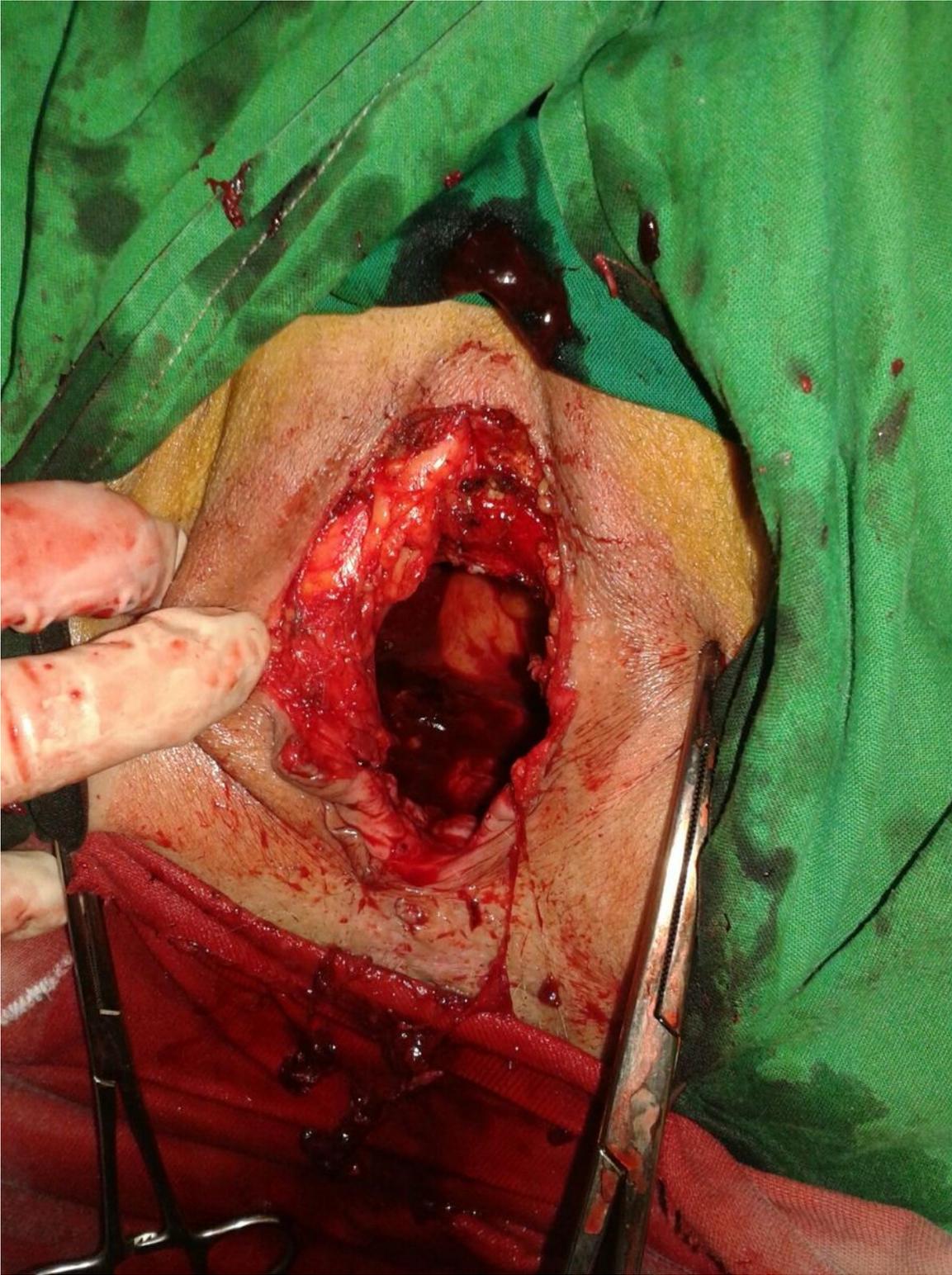


Figure 2

Total infralevatorian exenteration with vulvectomy.

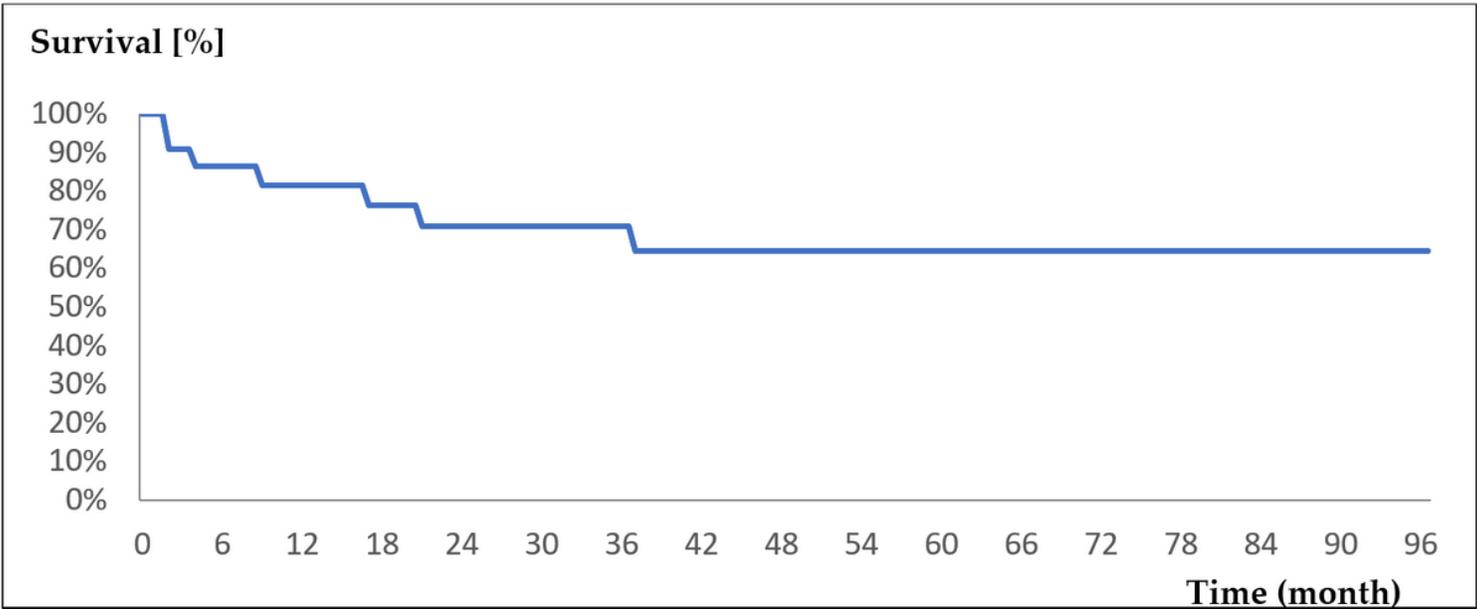


Figure 3

Overall survival of the study group