Chapter 11 Surgical Treatment for Advanced or Recurrent Disease in Cervical Cancer

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Abstract In patients with locally recurrent cervical cancer, pelvic exenteration is a viable option with long-term survival in over one third of patients. Depending on the survival disease-free, the site and size of recurrence can be set 5-year survivals of 48–60%. Since it was first reported in 1948, pelvic exenteration has been used in the treatment of advanced pelvic cancers. The original procedure has been modified in an attempt to preserve urinary or fecal continence. The subclassification of the exenteration groups into type I (supralevator), type II (infralevator), and type III (with vulvectomy) is helpful to facilitate understanding of the extent of resection of the pelvic structures and the anatomical changes associated with each operation. Pelvic exenteration should only be undertaken by experienced surgeons at specialized centers. Restorative techniques for both urinary and gastrointestinal tracts can diminish the need for stomas and, along with vaginal reconstruction, can significantly improve quality of life for many patients afterexenteration. These advances in surgery and radiotherapy help make the procedure a viable option for patients with otherwise incurable elvic malignancy.

Keywords Exenteration • Recurrent cervical cancer • Type I (supralevator) • Type II (infralevator) • and Type III

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© Springer International Publishing Switzerland 2017 J.G. de la Garza-Salazar et al. (eds.), *Cervical Cancer*, DOI 10.1007/978-3-319-45231-9_11

11.1 Introduction

The term Pelvic Exenteration (PE) refers to an ultraradical procedure of en bloc resection of multiple endopelvic organs, followed by surgical reconstruction, in order to re-establish the abolished visceral and parietal functions. It has a curative, and local control goal in patients with gynecological cancer; its main indication is in recurrent cervix cancer (CC) patients that cannot be treated with less invasive procedures [1].

Between 1985 and 2015, at the National Cancer Institute of Mexico, 115 recurrent CC-related PE procedures were performed, with a disease-free period of 18 months. Of these women, 85 (73.9%) undertook total PE, and 19% suffered from complications. This is less than the international literature mean, which is between 22 and 32%, with a global survival of 18 months in a 2-year follow up. Currently, the procedure is designed for recurrent disease and is used in this way mainly in America. Nonetheless, it is used for both primary and recurrent disease in Europe.

11.2 Historical Perspective

The PE was first described in 1948 by Dr. Alexander Brunschwig, director of the Gynecology service of the New York Memorial Hospital, USA, as a palliative procedure for the abdominal perineal resection of recurrent or persistent gynecological tumors. In its beginnings, the procedure consisted of three steps: first the colostomy, second, the transcutaneous nephrostomies, and third, the pelvic viscera scission. However, after the disappointing results obtained, this procedure was replaced by a one-step resection included the rectosigmoids, the genital tract, and bladder, including the suspensory structures, regional lymph nodes of these organs, the ureter, anus, and vulva, with the implantation of the ureters to the Colon, and terminal colostomy; temporarily packing the empty pelvis with gauze, and closing the wound with adaptation of the tissues. Dr. Brunsshwig performed the procedure in 22 patients, reporting 5 perioperative deaths (23% of the series), four late deaths, and 14 patients who survived up to 8 months [2].

Complications on the long run mainly consisted of infections of the urinary tract, hyperchloraemic acidosis, and difficulty in the management of stomas and fecescollection devices [1].

Later, Ernest M. Bricker importantly improved the technique, with the development of an ileal conduit that separated the urinary and fecal stomas, thus avoiding hyperchloraemic acidosis and reducing the risk of pyelonephritis and renal failure [3]. This way, the procedure purpose changed from palliative to potentially curative, in adequately selected patients [4].

The experience in this procedure, such as the advances in radiotherapy and chemotherapy, allowed its adjustment to each particular case, making it possible to preserve some pelvic organs that had no evidence of tumoral affection and, in

some cases, to extend the surgery to include the pelvic wall. As a result, different types of partial PE were developed (supraelevator, anterior, posterior), as well as extensions towards the sacrum and coccyx in some cases, such as colorectal tumors [5, 6].

From 1950 to 1965, the surgical mortality rate reduced from 13.4 to 1.8% with a mortality rate of 7.8% in patients with CC after radiotherapy. Total mortality of the series was 10%. A literature review of that times that included 932 patients reported a surgical mortality rate of 17% and 5 year survival rates of 21% [7].

During the 1970s and the 1980s, with the purpose of solving morbidities, such as abscess formation and fistulae in the empty pelvis (mainly associated to radiotherapy and intestinal obstruction) the use of non-radiated tissue flaps was implemented as major omentum, made of muscular-cutaneous flaps from the hips or the abdominal wall. These were transposed into the interior pelvis or perineum, thus reducing the procedure morbidity [7, 8].

During the 1990s, the main PE advances were in the area of reconstruction, mainly of the deep colorectal anastomoses, the formation of new continent urinary reservoirs, and the formation of neo-vaginas, with the use of muscular-cutaneous flaps [1].

11.3 PE Classification

The original classification divided the PE in three main groups: total, anterior, and posterior (Fig. 11.1); it depended on the position and type of resected pelvic organs. Thus, the anterior included the bladder, uretra, and genital tract; the posterior included the genital tract, and rectum sigmoids; and the total included the genital tract, bladder, uretra, and rectum sigmoids. Among the PE, there is another subtype: the PE with lateral endopelvic extended resection (LEER) which refers to a total PE that includes resection of the internal obturator muscle, pubococcygeus and iliococcygeus muscles [1].

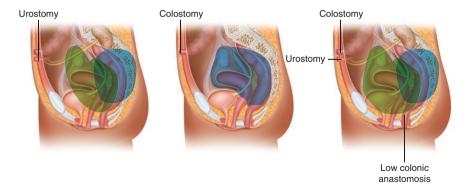


Fig. 11.1. Types of pelvic exenteration ((a) Anterior. (b) Posterior. (c) Total)

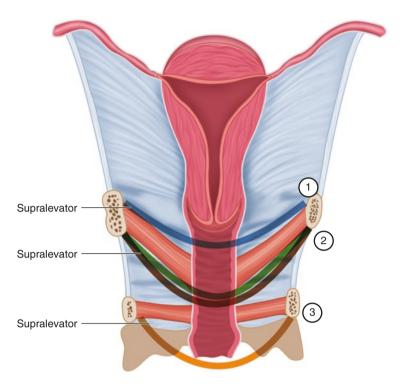


Fig. 11.2. Types of pelvic exenteration. (I. Supralevator, II: Infralevator, III, with vulvectomy)

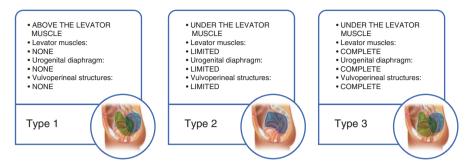
Notwithstanding, this classification was considered very restricted, since it is based on the nature of the resected organs, without providing an estimated level of resection, the preservation or scission of the elevator muscles of the anus, the size of the resection of the urogenital diaphragm and of the vulvoperineal tissues, or the removal of other pelvic or extrapelvic structures [9].

As a result, in the year 1990, a classification dividing the PE in three different types was published: I (supraelevator), II (infralevator), and III (including vulvectomy) in relation to the resected tissue extension and the anatomic changes in each PE group (Fig. 11.2); likewise, the group "extended PE" was added, which refers to the PE that include additional procedures (bone resection, small intestine, groin, paraortic nodes, soft tissues) [6]. The anatomical differences between the types of exenterative procedures are described by structures involved in the Table 11.1.

11.4 Indications and Contraindications in Pelvic Exenteration

EP is an ultra-radical procedure which shall must only be used as "the last chance", other options implying less morbidity must always be considered before choosing this procedure, since it has the highest morbidity and mortality, while its reported

Table 11.1 Types of pelvic exenteration



curation rates do not exceed 45% [10]. The most common indication (70%) for PE is in recurrent or persistent CC, followed by advanced colorectal cancer (20%), and 10% in other gynecologic cancers [1].

Accordingly, indications for PE [11–13] are as follows:

- Recurrent or persistent CC, after central level radiotherapy (with previous hysterectomy)
- Primary metastatic CC

The indications of this procedure as a palliative treatment are controversial due to its per se high morbidity.

The following must be considered:

- Resectability of the tumor and ability to obtain negative margins
- Tumor localization
- Previous treatments, such as pelvic radiotherapy

The contraindications of this procedure are:

Absolute

- Pelvic wall involvement
- Sacral plexum or sciatic nerve involvement
- Large vessel affection
- Extrapelvic metastases (40–50% detected during the approach)
- Poor functional study

Relative

- Obstructive unilateral or bilateral uropathy
- Advanced age
- Major systemic disease
- Psychologic distress
- Impossibility to take care of stomas
- Morbid obesity and malnutrition

The clinical unresectability triad must be considered [8]:

- Unilateral obstructive uropathy
- Inferior ipsilateral member edema
- Edema and pain in the ipsilateral inferior member

Brunschiwg and Barber define certain unresectability criteria based upon clinical and imaging studies [5]:

- Pelvic wall lesion
- Recurrence in previously radiated nodes
- Paraortic positive lymph nodes
- Evidence of intra-abdominal tumor

In 2006, Michael Hökel, made a systematic review of 21 previous studies on gynecologic cancer, and found that 40–63% of the patients who undertook PE were suspended because of unresectability. As for theoretical results, only 50 out of 200 recurrent patients will be candidate to a radical procedure with curative purposes [1].

11.5 Recurrent Cervical Cancer

The main PE indication in gynecological cancer in is recurrent CC, which is the most common site of recurrence at the local level. At the level of the vaginal vault, it represents 30–45% in patients who previously undertook radical hysterectomy, or to pelvis, without lateral pelvic wall affection. In patients who received radiation therapy, with uterus conversion, the recurrence sites are, ordered by frequency: 43% parametria and pelvic wall, 27% cervix, uterus and superior third of the vagina, and 16% distant sites.

Candidates to surgical resection must be carefully selected, taking into consideration that disease-free minimum acceptable time is 12 months, and the size of the tumor less than 3 cm, to achieve 5 year success rates of 50–60% [13].

11.6 Palliative Pelvic Exenteration

Its use is still controversial. In the series of published cases, 2-year survival rate is 10.5–47%. The objective is not only to obtain margins, or increase its overall survival, but to improve patients' quality of life. The use of neoadjuvant chemotherapy, with the goal of reducing tumor size, but very few series of patients have been published on this subject [14].

The main indications of palliative PE are:

- Intestinal or uretral obstruction
- Recto-vaginal or vesico-vaginal fistulae
- Post-radiotherapy cistitis or proctitis

11.7 Diagnosis and Selection of the Patient

In the preoperative evaluation, the adequate selection of the patient consists of three crucial principles:

- Medical evaluation
- Psychological apects
- Imaging studies

Medical Evaluation

Adequate medical condition for a long surgical procedure, with the changes that can occur during the transoperative, as well as the right liquid management, possibility to need blood transfusions, and nutritional help are vital considerations to take in account; thus, the presence of chronic diseases must also be considered.

Studies published by the MD. Anderson suggest that chronologic age and obesity must not be considered as a contraindication to a curative surgical procedure, since such factors do not affect the duration of the surgery, blood loss, hospital stay or complexitions [15, 16].

The objective of the medical evaluation (full history and a physical examination, laboratory and imaging studies) is to find evidence of unresectable or metastatic disease. The presence of one or two of the clinical previously mentioned unresectability triad signs suggests pelvic lateral wall metastatic disease, which makes it unresectable, as well as the presence of palpable lymph nodes.

Histologic confirmation is vital before decision making, since clinical findings may be done, that can be considered as tumoral activity data, such as post-radiation therapy fibrosis, cellulites, and endometriosis.

Clinical studies to be performed in addition to general examination, electrolytes test, and uroanalysis, are a viral detection panel that includes hepatitis virus and HPV, as well as renal and hepatic function assessment.

Cytoscopy and rectosigmoidoscopy are exclusive for patients who will undertake less radical resections (anterior or posterior exenteration).

Psychological Aspects

Nowadays, the role of psychologic support in a patient undertaking PE has been underscored. Candidate patients must be capable of accepting important changes in her body's shape that occur despite the strongest surgeon's efforts in anatomical reconstruction. Moreover, the patient must have intact mentales faculties, and have access to continuous medical and psychological assistance, stoma care. Furthermore, she must be aware of alterations that will take place in her sexual function, possible complications of the disease, and long hospital stays [17].

Moreover, the patient must also be familiar with the notion that the PE operative mortality rate is of 3-5%. On the other hand, the surgeon must be aware of the psychological syndromes that may arise in this kind of patients. Psychological support is crucial, not only during the preoperative, but also in the immediate and long-term postoperative.

Reported psychiatric syndromes, according to a study by Danielle Turns in 2001 are [17]:

Postoperative syndromes Delirium, depression, and brief reactive psychosis.

Long-term syndromes Post-traumatic stress, somatoform disorders, and sexual dysfunction.

Imaging Studies

Imaging studies have the purposes of evaluating local recurrence and distant metastasis.

Abdominal and pelvic Computerized Axial Tomography (ACT) has the goal of valuaing lesion resectability and extension.

Pelvic Magnetic Resonance Imaging (MRI) is the study of choice to determine tumor size and anatomic extension to adjacent organs. This imaging technique has an invasion-evaluation sensitivity of 88–92% in the bladder, 81–96% to the rectum, and 87–97% to the pelvic wall, and a specificity of 66.7–77.6% [18].

Positron Emission Tomography with FDG (PET-CT-FDG) has currently gained a significative value in the detection of distant metastasis, with a sensitivity of 100%, and specificity of 73% [19].

Apart from conventional studies, medical evaluation and physical examination under anesthesia, laparoscopic exploration has an additional value to identify the disease, to determine its exact location and extension, and to exclude peritoneal carcinoma.

11.8 Surgical Procedure

Generally, the surgical procedure can be divided in three steps: exploration, ablation, and reconstruction [1].

Exploration Step

The exploration step is traditionally performed through an incision in the middle line. If the presence of peritoneal carcinomatosis or liver metastasis is ruled out, the retroperitoneum must be reviewed in a creanial-caudal direction, starting by a systematic dissection of the paraortic lymph nodes to rule out the presence of disease at such level, since their involvement constitutes a contraindication to the procedure: it is considered to decrease survival [20, 21].

Lateral resectability is also valuated during the exploration step: if the disease is extended to the pelvic wall, the procedure must be aborpted [22]. Nonetheless, Hockel described in 1994 the lateral extended endopelvic resection, which implies the en bloc resection of muscular structures and lateral endopelvic fascia; this allows for the resection of tumors fixed to the pelvic wall, giving enough free-margin (R0) in up to 96% of the cases, with over 61% survival rates [23].

Laparoscopic exploration has also been used to substitute laparotomy: Kohler showed, in 41 candidates of PE, a 95.2% sensitivity, 100% specificity, 95.2%

negative predictive value, thus avoiding unnecessary laparatomies, diminishing morbidity and decreasing patient recovery. However, the exploration provides limited access to evaluate the caudal portion of the parametrium, which is exclusively accessible during the procedure [24].

But still, lateral resectability pre-surgical evaluation can be achieved by means of exploration under anesthesia, or by imaging methods, such as MRI.

Ablative Step

In 2006, Höckel stated that the ablative step must be performed with two main goals: enhance the control over the pelvic tumor, which increases survival; and decrease treatment-associated morbidities as much as possible [1].

PE is the combination of three different monovisceral radical diseases (abdomino-perineal resection, hysteron-colpectomy, and cystectomy). With the use of conventional techniques, only central tumors are resectable with free margins. In spite of the exclusion of patients with pelvic wall extension, positive margins are present in the pathological definitive report in 10–20% of the cases [1]. It is widely recognized that accomplishing negative margins correlates with survival. In an attempt to determine the correct margin amplitude to achieve local control, Westin et al. confirmed the importance of the negative margin. However, they were unable to define such amplitude; most studies, on the other hand, define positive margins as those between >1 and 10 mm, and negative margins as those > 10 mm [25, 26].

As previously mentioned, lateral extended endopelvic resection has allowed for the resection of tumors fixed to the pelvic wall. This procedure is characterized by the en bloc scission of the pelvic visceral compartment with some of the following parietal structures: para-visceral fat, internal iliac vessels, internal obturator muscle, pubococcygen, iliococcygen, or coccygen. Nonetheless, it is associated to an elevated morbidity of up to 70%, most commonly implying wound dehiscence, and anastomosis leak [27].

Complications resulting from the ablative step are reported in 51–82% of the cases. The most common of them are bleeding, infection, and dehiscence (the most frequent in up to 39% of the cases), urinary or intestinal fistulae formation, obstruction, pulmonary embolism, among others. Surgical re-intervention is reported in up to 31% of the cases. The patients that most commonly present such complications are those that have undergone radiation therapy (61% vs 33.5%) [28].

In 2014, Chinatera et al. described and classified by frequency the complications presented by the patients: in the case of infectious complications (18.7%) the most common are originated in the abdomen, followed by pulmonary infections. As for the complications related to the surgical procedure on itself, the colorectal anastomosis leakage is present in 20% of the cases, followed by wound dehiscence in 17% of them [28].

Thanks to the careful selection of patients, improvement in surgical technique and postsurgical care, and the use of antibiotics, the procedure-associated mortality has decreased by 37%, presenting rates of 2–3% in the first series of the last decade [27].

Currently, the use of laparoscopy combined with perineal or vaginal access, followed by mini-laparotomy to reconstruct the pelvic functions has reported perioperative morbidity reductions, including a lower amount of blood loss, early roaming and early hospital exit, less scars, and better cosmesis, without compromising pelvic control or surival [29, 30].

Reconstruction Step

There are multiple techniques to re-establish the pelvic functions lost during the exenteration. One of the main issues concerning the reconstruction are, the unpredictable cicatrization capacity of the radiated tissues, and the determination of the balance between increasing the complication risk versus the potential benefit of the use of complex reconstruction techniques.

As for the rectal function, if the anal sphincter cannot be preserved, a terminal colonostomy is required. In case of anal sphincter preservation with the use of supraelevator exenteration, the intestinal continuity can be preserved in some occasions, and may be restored with the use of colorectal or co-anal anastomosis, when technically possible. Nevertheless, anastomosis failure is as high as 30–40% despite good technical maneuvers, mainly due to radiation therapy-related side effects. The use of stoma has not reduced the risk of fistula formation, but rather allows a more benign course: in some studies a decrease in the number of interventions and a higher rate of recoveries from fistulae have been reported. Thus, the use of colorectal anastomosis is not recommended in radiated tissue [31, 32].

As for the vesico-uretral function restitution, one of the options is the use of an orthotopic neo-bladder, supra-vesical urinary diversion, through a continent bag, or an incontinent conduct. Among such options, the conducts present less technical complexity but require the patient to permanently use a urinary bag, resulting in a negative impact on her image and quality of life.

Diverse surgical techniques have been described and validated for the formation of a urinary reservoir, with the use of a segment of ileum or colon. The poor methodology of the studies comparing both techniques up to date make it difficult to make any conclusions on the superiority of any specific technique in terms of complications, functional results, or quality of life.

The ilial conduct was the standard method for years, in which a piece of the distal ileum on which the ureters were anastomosed and later, a stoma was created towards the abdominal wall was firt described by Bricker in 1950 [3]. In a 131 patient analysis with ileum conduct, a complication rate of 66% was discovered, among which the most common was stenosis, para-estomal hernia, and bladder infection (24%, 24%, and 23%, respectively), reporting a renal function undermining of 27% [33].

There are multiple continent urinary derivation techniques described, like the Kock, Miami, Florida, Camey II, among others. These have a valve mechanism and thus, are useful when the uretra preservation is not possible [34].

One such technique was described in Miami University, and it uses the segment 12 cm–14 cm of the terminal ileum, ascendant colon, and proximal transverse colon. With this technique, ureteral stenosis has been reported in up to 22% of the cases, pyelonephritis in 16.9%, and gastrointestinal complications in 26% [35]. In one of

the largest series published about the Miami-type reservoir experiences, 90 patients were analyzed, 90% of which had radiation therapy records. The most common early complication was urinary duct infection (40%), followed by anastomosis (14%). Among the late complications, (>60 days) the most common was again urinary duct infection, followed by uretral stenosis (42 and 11%, respectively). The conclusion was that 80% of the complications can be solved in a conservative way, in addition of being a simple technique, effective even in patients with radiation therapy records, with which continence preservation can be achieved in 93% of the cases [36].

Pelvic and vulvovaginal structures reconstruction can be achieved using straight abdominal muscle flaps, major gluteus, or gracilis, with which the dead pelvic space is obliterated. As a result, small intestine hernias, and adherence or abscess formation are prevented. Additionally, the cicatrization process is improved thanks to the presence of healthy, vascularized tissue inside the radiated area. Otherwise, omentoplasty can be performed, which on its own, improves the cicatrization process. Among these, the vertical straight abdominal muscle is preferrable, since it has a larger volume, and is more vascularized, with a big pedicle. Furthermore, it does not interfere with the use of urinary or intestinal stomas, and can be obtained from the laparatomy's same vertical scission [8].

11.9 Prognostic Factors

In a retrospective study by Westin et al. it was shown that factors that impact the most on disease-free, and overall survival are the margin size, lympho-vascular invasion, peri-neural invasion, and the presence of positive lymph nodes [25]. Baiocchi et al. al reported a higher recurrence risk in patients with nodal affection and peri-neural invasion; higher risk of death in patients with grade three tumors, nodal affection, and the resection of more than three organs during the procedure. The lapse between primary treatment and exenteration had a significative impact on survival, if it was longer than 24 months; Moreover, it was also found that patients with endometrial pathology have a better 5-year global survival, when compared to cancer of the cervix (64.2% vs 23.1%) [12]. In 2007, Park discovered that tumor size, taking 4 cm as a cut-off value, significatively influences on recurrence, without having any significative impact on survival [37].

11.10 Global and Disease-free Survival

With the correct patient selection that takes in account the previously mentioned unfavorable prognostic factors, PE use as a primary or secondary procedure has been reported in 41–70% range, with 5-year survival rates of 20–73%. As a palliative treatment, 5-year global survival has been reported at 10–27% [8].

As for disease-free survival and recurrence, it has been steady, at 48–55% in spite of the years, and application of new surgical techniques and patient selection criteria [1].

Reference	Year	No. patients	Survival (%)
Rutledge et al	1977	296	42
Averette et al	1984	92	58
Lawhead e al	1987	65	23
Cuevas et al	1988	252	44
Morley et al	1989	100	66
Soper y et al	1989	69	40
Goldberg et al	1998	154	24
Total/Mean		1028	43

11.11 Quality of Life

Most of the studies that evaluate quality of life in patients with PE are retrospective, and report a decrease in quality of life, unless when it is used as a palliative procedure, where patients' quality of life actually improves. Recent prospective information on the evaluation of physical and psychological welfare report that after an initial decrease, there is a return to the basal state, in the 9–12 months. This suggests an adaptation process undertaken by the patient, to her new health state [38].

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