

Less Radical Surgery for Fertility Preservation in Patients with Early-Stage Invasive Cervical Cancer Contemporary Problematics

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Abstract

Cervical cancer, is a middle age women's disease. Nowadays, because of the postponement of childbearing at older age, women younger than 45 years old who are diagnosed with cervical cancer, have a strong desire for preserving fertility. For this reason, Radical Trachelectomy (Vaginal and Abdominal) is used worldwide.

In this article, we review data on procedures for fertility preservation, namely Radical Trachelectomy, less invasive procedures and Neoadjuvant Chemotherapy, based on the literature over the past 12 years. Oncological and Obstetrical outcomes are analyzed.

In conclusion, Radical Trachelectomy, is an oncologically safe procedure for women with early invasive cervical cancer. However, a number of considerations regarding the selection criteria, patient's information and especially the complications and the postoperative quality of life, should be taken into account.

Keywords: Cervix; Cancer; Radical; Trachelectomy; Fertility; Abdominal; Vaginal

Introduction

Cancer of the cervix, holds the second place among the most common gynecological cancers in developing countries and the seventh in developed world. Approximately 520000 new cases of invasive cervical cancer are recorded worldwide every year [1]. Cervical cancer, can affect women in all ages. The average patient age of cervical cancer diagnosis, is 50 years [2]. However, it is estimated that a percentage of 25-30% of all cases are diagnosed in women younger than 40 years. Because of the postponement of childbearing to older age, women <45 years old who are diagnosed with cervical carcinoma have a strong demand for preserving fertility.

The recommended surgical treatment for early cervical cancer (stage IA2-IB1), is Radical Hysterectomy (RH) with bilateral pelvic lymphadenectomy. However, radical surgeries do not spare fertility. The alternative surgical treatments include Radical Vaginal Trachelectomy (RVT), Abdominal Radical Trachelectomy (ART), large conization and simple trachelectomy, as well as Neoadjuvant chemotherapy.

This paper reviews our knowledge of fertility-sparing options in early cervical cancer, based on the literature over the past 12 years.

Selection Criteria

The selection of patients is of utmost importance to the management of fertility sparing surgery. The candidates need to be entirely informed about the preoperative procedures, surgery, late complications and especially the potential outcome (oncologic and obstetric). All patients must be aware that there is no guarantee of fertility after a radical trachelectomy, and that the risk of premature delivery is increased. Also, it should be emphasized that the radical hysterectomy remains the standard treatment for early-stage cervical cancer. Therefore, it is essential to provide the patient with a detailed informed consent.

Tumor size

RT, should be the treatment option for patients with tumors of FIGO stage IA1 with lymphovascular space invasion, IA2 and IB1 [3]. Tumor size, is the most important risk factor for recurrence. For this reason the majority of centers do not include stage IB1 tumors >2 cm. Many studies have described those lesions >2 cm have an increased

risk of recurrence. However, it has become evident that patients with exophytic tumor >2 cm in size but with little stromal invasion could still remain reasonable candidates for VRT [1,4].

Cervical stromal infiltration

Many clinicians have proposed that the appropriate candidates for fertility sparing surgery, should have less than half of the cervical stroma infiltrated for a safe trachelectomy, because it is necessary to have at least 1 cm of free margin, while other suggest margins of only 5-8 mm [2,4]. A good proportion of healthy stroma after thachelectomy, increases the chance of a successful pregnancy, and decreases the risk for cervical incompetence, ascending infection, premature rupture of membranes, and premature delivery.

Histological type

Squamous cell, adenocarcinoma, and adenosquamous carcinoma are acceptable for RT, while small-cell neuroendocrine carcinoma is not suitable, because it has the worst prognosis of all types due to its association with lymph node metastases, Lymphovascular Space Involvement (LVSI) and local and distant relapse [3]. For this type of cancer, the standard treatment includes RH followed by chemoradiotherapy. In lymph node negative patients, overall recurrence and mortality for patients with squamous cell carcinoma less than 2 cm in diameter with stromal invasion less than 10 mm and without LVSI seems to be similar to the outcome achieved with standard radical hysterectomy and pelvic lymphadenectomy. Tumor size greater than 2 cm and LVSI were identified as the major predictive

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factors for the adverse outcome in lymph node, negative patients [3]. Although LVSI is a negative prognostic factor for recurrence and nodal metastasis, the presence of LVSI alone, does not necessarily exclude the possibility of RVT. Several clinicians have the opinion that LVSI alone in the absence of other poor prognostic factors is not considered an absolute contraindication for RVT, similar to how LVSI as the sole unfavorable prognostic factor does not justify adjuvant therapy post-Radical Hysterectomy. Patients should be informed of the risk of recurrence if LVSI is extensive [5]. In literature only 5% of patients with LVSI in their preoperative assessment, had positive lymph node on specimen examination [5].

Clinical eligibility criteria for RT are listed below (Table 1).

Preoperative procedures

To assess the exact size of the tumor, preoperative examinations are essential. Colposcopy is the first basic procedure before the surgery, because is very helpful in assessing the diameter of exocervical tumor and the degree of spreading in the vagina [6-8]. MRI volumetry is of utmost importance for determination the precise size of the tumor, amount of cervical stroma infiltration, amount of healthy stroma (determination of tumor growth in anteroposterior, craniocaudal, and transverse directions), and the involvement of paracervical tissues. Although MRI and CT scans are insufficient for evaluation the microscopic pelvic lymph node infiltration, a new generation of PET-CT and MRI, use ultra-small iron particles, could be helpful for the assessment of the lymph node [9,10]. Finally, the vaginal or rectal ultrasonography, can provide information about the volume of the tumor with high sensitivity.

Intraoperative assessment

The intraoperative assessment is very important too. During surgery, extrauterine spread of the disease to the lymph nodes and the proportion of healthy stroma should be assessed. Perioperative pathological examination should be performed, because when extrauterine spread or infiltration of the cranial part of the specimen is diagnosed, it is necessary to radicalize surgery or initiate chemoradiotherapy. Perioperative assessment of regional lymph nodes is used repeated frozen sections. Recently, this assessment has been replaced in many centers by detection of sentinel lymph nodes (SLNs) [2,8,11]. The technique of SLNs, may be helpful in localize aberrant nodal metastasis spread and identify micrometastases (<2 mm), that have been missed with conventional histopathology [1,5].

Surgical Techniques

RT, may be performed either vaginally or abdominally depending on surgeon's preference and level of expertise. Details about the performance of these techniques are well described elsewhere [2,4,12-17].

RVT

It includes laparoscopic pelvic lymphadenectomy and subsequent radical trachelectomy by the vaginal route. The main points of this

procedure, are the remaining proportion of the cervix and the size of the tumor [5,7, 12,13,18]. The usual recommendation is to remain about 1cm of healthy cervix although some clinicians suggest that 5-8 mm are adequate [8,13,19,20]. If the margin on the final pathology is shown to be too close, 5 mm is considered the minimum acceptable margin. Involvement of paracervical tissue is an exception and is an indication for chemoradiotherapy. It is considered that the greater the portion of the healthy stroma after trachelectomy is, the better the result of a future pregnancy. The most important limitation of the RVT, is the size of the tumor. RVT, is a risky procedure for tumors >2 cm. Literature reports a percentage of recurrence of about 21% compared to 3% for tumors <2 cm [1-3].

ART

ART, is a modification of the classical abdominal radical-hysterectomy. Since the procedure is familiar to most surgeons, due to its similarity with the classical radical-hysterectomy, it has been demonstrated that ART provides a wider parametrial resection and lower intraoperative complications rates, compared to RVT. Unfortunately, this may result in more pelvic adhesions which could potentially cause postoperative subfertility. The first step in this procedure is pelvic lymphadenectomy, with or without SLN identification and radical cervix extirpation follows [14-16,21,22]. "Classical" ART provides standard radical resection of the parametria with complete resection of the uterine artery, although modifications of ART with preservation of uterine artery have been described. It remains to be proved in the future, if uterine artery preservation could play an important role in future pregnancies after RT. However, many pregnancies have occurred after uterine artery resection during RT.

Both in RVT and ART, if all frozen sections are benign in histopathology examination, and at least a 5 mm clear margin is obtained on the endocervical edge, a permanent cerclage with #0 Ethibond (knot tied posteriorly) may be placed prior to the reconstruction. The uterus is reconstructed to the upper vagina with 6 to 8 #2-0 absorbable sutures. The point of consideration is the time of cerclage. Many centers support that primary cerclage might reduce fertility by inducing subsequent cervical stenosis, erosions, and chronic discharges [15,23]. Also, some surgeons prefer the prophylactic permanent cerclage whereas others recommend it only during pregnancy [14-16,24].

Follow-Up (F-Up) and Complications

In literature, there are no guidelines for the F-Up of patients who underwent RT. However, the vast majority of the centers recommend that patients should be followed-up every 3-6 months for the first 2 years, then every 6 months for 3 years, and thereafter every year as in general screening. F-Up for the first 2 years is the most important, because typically more than 75% of relapses occur in that period [25-29]. F-Up is also significant for recording the complications and sub-sequent pregnancy rates. Postoperative monitoring includes colposcopy and Papanicolaou smear [2].

After RT patients should be aware of complications, because some

1. A strong desire for fertility preservation.
2. Age \leq 45 years old.
3. A proven diagnosis of cervical cancer: squamous, adenocarcinoma or adenosquamous.
4. FIGO stage IA1 with lymphovascular space involvement, IA2, and IB1.
5. Lesion size <2 cm.
6. No previous documentation of infertility.
7. Tumor limited to the cervix as confirmed by preoperative MRI.
8. No evidence of pelvic lymph node metastasis and/or other distant metastasis.

Table 1: Selection criteria for RVT.

of these symptoms, such as abdominal or pelvic pain, lemphedema, vaginal bleeding or discharge, urinary symptoms and weight loss, may be signs of relapse.

The most common complications intraoperative and postoperative, are listed on Table 2, and seem to be similar for RVT and ART.

Oncological and Obstetrical Outcome

The oncological outcome after RT depends on the characteristics of the tumor. Recurrence, is significantly higher in tumors >2 cm (25%-30%) [3]. Adenocarcinoma, may be associated with a higher rate of relapse, although the association is not statistically significant. Additionally, the presence of LVSI and stromal invasion >1 cm, are associated with a poor outcome. After RT, five-year free survival rate is reported to be about 93-96% of total patients compared to a rate of 100% after RT [2,3].

As of 2012, a total of about 1000 patients have been reported to have undergone RT. Two recent literature reviews [1,3], provide us with a thorough summary of the results in these patients (Tables 3 and 4).

A total of 985 patients represented in 11 studies. As it shows in Tables 3 and 4, the number of RVT performed is significantly higher than the number of ART (78% and 22% respectively).

The percentage of relapses is almost similar for the two methods: 4.3% for RVT and 3% for ART. In some instances after RT, patients are recommended to receive additional treatment with radiation or chemotherapy. This is mainly due to the presence of positive lymph nodes, histological subtype and positive upper margins of the removed cervix. Even after careful selection of the patients, a percentage of about 10-12% [1] will require additional treatment.

As far as fertility is concerned, it might be impaired after RVT or

Intraoperative	Postoperative
Range between 0%-9%.	
1. Urinary tract injury	1. Dysmenorrhea (24%)
2. Blood vessel injury	2. Excessive vaginal discharge (14%)
3. Lymphocele	3. Chronic pelvic pain (10%)
4. Parametrial bleeding	4. Dyspareunia (20%)
5. Suprapubic or valcar hematoma	5. Menstrual abnormalities (17%)
	6. Vulvar edema (12%)
	7. Recurrent candidiasis (14%)
	8. Bladder hypotonia (4-16%)
	9. Lymphocele (3-11%)
	10. Amenorrhea (7%)
	11. Lymphedema (3%)
	12. Isthmic stenosis (10%)
	13. Vulvar hematoma (7%)
	14. Suprapubic hematoma(4%)
	15. Urinary tract infection (2%)
	16. Femorocutaneous nerve palsy (1%)

Table 2: Complications after Radical-Trachelectomy [3].

Authors	Number of cases	Recurrence	Deaths	Pregnancies	Miscarriage	Deliveries	
						Preterm	Term
Covens [20]	91	6	4	18	6	6	12
Shepherd and Milliken [19,28]	138	3	4	NA	34	10	37
Burnett et al. [35,36]	18	0	0	3	1	1	1
Schlaerth et al. [32]	10	0	0	4	2	1	1
Sonoda et al. [37]	36	1	1	11	3	0	4
Hertel et al. [33]	106	4	2	18	3	8	4
Plante et al. [23]	125	6	2	58	29	19	58
Mathevet et al. [38]	95	4	3	33	22	5	29
Pahisa et al. [39]	13	2	1	3	0	0	1
Dargent et al. [13]	118	7	5	33	22	5	29
Chen et al. [12]	16	0	0	5	2	1	1
Total	766	33	22	186	124	56	177

Table 3: Literature review on Oncological and Obstetric outcome after RVT.

Authors	Number of cases	Recurrence	Deaths	Pregnancies	Miscarriage	Deliveries	
						Preterm	Term
Li et al. [29]	62	0	0	2	0	0	1
Nishio et al. [16]	61	6	NA	4	0	2	2
Olawaie et al. [22]	10	0	0	3	1	1	1
Abu Rustum et al. [14,21]	15	NA	0	2	1	0	0
Pareja et al. [15]	14	0	0	3	0	1	2
Ungara et al. [17]	30	0	0	13	4	1	5
Cibula et al. [11]	17	1	NA	6	1	2	3
Yao et al. [40]	10	0	0	2	0	1	1
Total	219	7	0	35	7	8	15

Table 4: Literature review on Oncological and Obstetric outcome after ART.

ART due to adhesion, cervical stenosis and loss of cervical function. Data on fertility and obstetric outcomes are based mainly on results after RVT, partially as a result of less experience with ART, and also due to recommendations of some clinicians to wait about 2 years prior to conception after ART [1,17].

As it shows in Tables 3 and 4 the rate of women achieved pregnancy after RVT is significantly higher compared to that of women underwent ART (24% and 16% respectively). The rate of miscarriages seems to be similar to that in RVT, and the percentage of preterm labor is slightly bigger after ART.

It is believed that the difference between the number of pregnancies after RVT and ART is based on the differences between their respective techniques. In RVT the blood supply from the main uterine arteries is not affected, while in ART the uterine artery is usually transected. However, there are reported cases in literature which contradict this theory.

After RT, about 20-25% of patients are infertile, with a prevalence of cases that underwent ART. In 70-75% of the cases, the cervical factor appears to be the cause of infertility. Assisted reproduction techniques, are associated with good results in these women. Miscarriages in first and second trimester are usual. The percentage of first-trimester miscarriage is almost the same as in general population, but in the second-trimester the rate is increased [6]. First trimester complete abortions can be managed conservatively without removing the cerclage and no curettage. In case of second trimester miscarriage or incomplete abortion, use of prostaglandins, cervical laminaria insertion, or removal of the cerclage is suggested, followed by adequate procedure (curettage) if necessary [3].

There is no clear consensus on the interval waiting time for pregnancy after RT. Complete healing of the tissue may last more than 3-6 months, and the larger the interval, the lower the risk of recurrence. Some clinicians suggest 6 months to 1year interval time before attempting pregnancy, while others consider a minimum of 2 years.

Less Radical Procedures and Neoadjuvant Chemotherapy

It has been reported in the literature, that about 40% to 65% of patients who underwent a diagnostic cone, do not have any residual cancer in the trachelectomy specimen. Additionally, the rate of parametrial involvement is only 0.6% in patients with tumor size < 2 cm, negative pelvic nodes, and ≤10 mm depth of invasion [1,2,4]. This raises the question as whether a large conization could be used instead of RVT. More and more centers suggest less radical procedures for "low-risk" patients (low-risk histology, tumor size <2 cm, and absence of lymph vascular space invasion). Until today, widely accepted protocols, include pelvic lymphadenectomy first, and if there are no positive nodes, a large conization or simple trachelectomy follows.

Neoadjuvant Chemotherapy (NAC) for cervical cancer (Table 5) has an essential role mainly in the treatment of advanced or recurrent disease. Women with a cervical lesion >2 cm, have a higher risk of relapse. Some authors recommend the use of neoadjuvant chemotherapy prior to the surgery for downstaging tumors >2 cm, in

order to follow a more conservative cervical resection, diminish the risk of relapse and improve the obstetrical results. Many clinicians support that NAC is potentially capable of reducing localized lesion, improving parametrial involvement and increase the surgical resection rate. It is also beneficial in combination with radiotherapy for the control or elimination of pelvic micrometastases, while others have reported that there is no significant difference between NAC - combined with surgery and surgery alone. Also, the side effects of Chemotherapy should be taken under consideration as the most of them are so distressing for the patients that some of them refuse further treatment. The most common side effects are anemia, neutropenia, thrombocytopenia, alopecia, nausea and vomiting, neurotoxicity, liver and renal dysfunction. In rare cases allergy has been described.

Although it appears to have promising results, Neoadjuvant Chemotherapy combined with more conservative surgery, is still an experimental method, and its oncological safety has not been established yet. Our view is that neoadjuvant chemotherapy followed by less radical surgery, may result in histological distortion - indistinguishable surgical margins affected by the surgical specimen. This is a very important disadvantage of neoadjuvant chemotherapy and needs to be clarified in the future. Additionally, the gonadotoxic effects of chemotherapy, as is of concern.

Discussion

An increased demand for fertility sparing treatments in young women with early-stage cervical cancer has resulted in the introduction of 2 procedures: RVT and ART. Shepherd et al. [28], reported that the complications and relapse rates after RVT, were low, compared to those following RH and ART. RVT offers the advantage of a shorter hospitalization, shorter postoperative recovery and possibly a lower incidence of bladder and bowel dysfunction due to the limited parametrial resection [16]. However, the main limitation of this procedure remains the adequate training on the vaginal radical approach, of the gynecologic oncologist who will perform the procedure.

Patient selection is one of the most critical parts of the preoperative evaluation process. Tumor size is the most important factor for recurrence. The ideal candidates should have a tumor <2 cm, to be offered this procedure. The question is whether the patients with tumor >2 cm are eligible for RT. Plante et al. [23] and Dargent et al. [13], both reported by their experience from RVT that tumor size >2 cm was statistically significant for the risk of relapse. Li et al. [29] suggest that carefully selected patients with lesion between 2 and 4 cm in size could be eligible for these procedures and especially for ART. This practice is also supported by other studies [14,21]. In our opinion, there is a need for further studies. Until then, it is essential to be very strict in patient selection.

The importance of informed consent process is highlighted in literature. However, it is not reported the percentage of women who were eligible for RT, but refused the procedure after a complete information. The informed consent of the patient must contain information about the relative risk of recurrence, which is not increased by fertility preserving surgery per se, but may influence the decision

1) cisplatin 75 mg/m ² plus ifosfamide 2 g/m ² every 10 days.
2) cisplatin 75 mg/m ² plus doxorubicin 35 mg/m ² every 10 days.
3) TIP: paclitaxel 175 mg/m ² plus cisplatin 75 mg/m ² plus ifosfamide 5 g/m ² .
4) TEP: paclitaxel 175 mg/m ² plus cisplatin 75 mg/m ² plus epirubicin 80 g/m ² every 21 days

Table 5: Chemotherapy Protocols [1,3].

of the patient to choose standard surgery. According to some authors, it should be emphasized to the patient that the only well established treatment for early stage cervical cancer, remains radical-hysterectomy [1,19,23,28]. Furthermore, studies do not clarify how young women, who do not desire preservation of fertility, are treated. Approximately 48% of patients <40 years of age with operable Stage-I cervical cancer, may be eligible for fertility-sparing RT according to the commonly accepted inclusion criteria [21]. But, a lot of women do not desire to preserve their fertility. Their exact percentages as well as the use of hysterectomy as a routine procedure are two parameters with no specific answer in literature.

Additionally, in literature, there is no standardized F-Up time and procedures for the patients, and this is another questionable point. Many authors, support a period that ranges from 3 to 6 months for the first 2 years F-Up [1,20]. Taking into account that the vast majority of relapses occur in the first 2 years, the current F-Up interval of 6 months should be possible revised. Studies do not clearly demonstrate, if colposcopy should be performed at every F-Up visit, as some would suggest, or if a Pap-smear and gynecological examination is adequate (assuming the Pap-smear is normal) [22]. The most difficult follow-up based on the Pap-smear, is that of cervical adenocarcinoma, because the sampling devices used to obtain the cytology specimens often yield an abundance of crowded glandular cells [30]. The lower uterine segment cells display morphologic similarities to in-situ and invasive endocervical adenocarcinoma. However, characteristic differences have been widely published. Others even suggest yearly F-Up MRI [31], but this practice remains questionable. Finally, there is no study to report the percentage of women who lost or refused F-Up after RT and so we cannot have a clear assessment for the precise rate of obstetric and oncological outcomes.

We have also identified some pitfalls, including cervical stenosis and cerclage after RVT. Most patients do not suffer cervical stenosis after RVT. For the prevention of stenosis, many authors have suggested the placement of a catheter in the cervical canal for a few days following healing [32]. This method has not been determined to be effective. In our opinion, the catheter might be useful when it is used for 3 up to a maximum of 10 days, because the longer the catheter remains the higher the risk for ascending infections post-operatively is. Regarding the cerclage, it is not clear whether or not it should be performed, and remains to be determined. Li et al. [29], mentioned in their study that they prefer to perform isthmic cerclage at the time of vaginal trachelectomy. But, many others abandon this practice due to pelvic infections, bladder irritation, erosion and chronic discharge [15,23].

Another important point is the quality of life and more specifically of sexual life after RT. Many women after the operation suffer prolonged or irregular menstruation, pain, bleeding or spotting during or after intercourse, and dyspareunia. Dyspareunia, may be the most important and annoying problem for the patients. With the absence of the cervix the uterus and ovaries are much lower in the pelvis. Thus it makes logical anatomic sense that deep dyspareunia might occur as a result [29]. These problems have a significant impact not only in the sexual life of women, (as they became sexually secluded), but in their psychology as well. These two last points should be taken under serious and professional consideration before the surgery.

In terms of obstetrical outcome, there are encouraging data in literature. A percentage of 62% [12,23,29,33] is reported for deliveries among the patients who underwent RVT. The corresponding percentage for those underwent ART was 15% [11,22,27,29]. From this point of view, the number of pregnancies after ART was dramatically

lower compared to the number after RVT. This may be due to the more radical resection of the procedure in ART, and subsequent infertility. The cervical factor is the main cause of infertility after trachelectomy. Data on fertility outcomes demonstrate RVT as a more protective to fertility technique compared to ART. However, this conclusion is doubtful as the number of ART is too low to allow such a comparison.

Finally, it is crucial to mention the new approaches of cervical cancer treatment: Robotic-assisted and Laparoscopic abdominal RT. Robotic RT (RRT), is a similar technique to ART. The selection criteria for patients remain the same. The most important advantages of this minimally invasive surgery, have been well documented and include reduced length of hospitalization, decreased blood loss, diminished pain medication requirements, quicker restoration of bowel function and faster return to daily activities. The first reference of RRT was by Geisler et al. [26]. Recently, Ramirez et al. [27] reported their experience of RRT, and mentioned, as the most important feature of the procedure, that the robot offers excellent visualization of the vasculature and parametrial tissues, which must be isolated during this surgery. Similarly, Laparoscopic RT (LRT), first reported in literature by Lee et al. [34], is also a minimally invasive surgical technique with almost the same advantages of RRT. The main difference between these two procedures is that LRT is a more familiar process to surgeons, while RRT requires a more specific training. There are extremely few centers worldwide for this very new technique, compared to the training centers for Laparoscopy. The basic disadvantage for both techniques remains the high operative time, which is about 4-6 hours. Overall, the outcomes appear to be very similar when comparing a laparoscopic to robotics approach, however, it is too early to determine which the best, as continued research is and clinical trials are needed in terms of oncological outcome and patient's quality of life.

Conclusion

The treatment of cervical carcinoma has changed over the past years, to more conservative techniques, especially for young women who desire to preserve their fertility.

RT is now a well established safe and feasible procedure for tumors <2 cm. Both of them have good oncological and obstetrical outcomes, with low morbidity, recurrence, and mortality rates. Less radical procedures such as large conization and neoadjuvant chemotherapy before the surgery are being studied, and in the future more options will be safely available for the management of early cervical cancer.

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