

# Radical Trachelectomy for Early Stage Cervical Cancer

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Published online: 19 November 2018

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This article is part of the Topical Collection on *Gynecologic Cancers*

**Keywords** Early stage cervical cancer · Radical trachelectomy · Fertility sparing

## Opinion Statement

In patients with early-stage cervical cancer, radical hysterectomy and pelvic lymphadenectomy is the gold standard. However, this disease commonly affects women of child-bearing age; thus an option to spare fertility is ideal. This option came to fruition in the early 90s when the Dargent procedure or radical trachelectomy was first reported. The procedure has subsequently been modified as technology has improved and now may be performed via minimally invasive techniques. Additionally, with the advent of the sentinel lymph node procedure, the morbidity in this usually young patient population has continued to improve. There is a multitude of data to show that oncologic outcomes, concerning recurrence and mortality, are comparable to radical hysterectomy, as well as obstetrical outcomes are favorable. Data to support its acceptance within the gynecologic oncology community has led to radical trachelectomy being implemented into governing body guidelines and should be offered to appropriate candidates with early-stage cervical cancer who wish to preserve fertility.

## Introduction

About 13,240 new cases of cervical cancer will be diagnosed and approximately a third of these patients will die of their disease in the year 2018 [1]. Approximately 50% are diagnosed with early-stage disease, defined as tumors 4 cm or less that are confined to the cervix. Overall, women

diagnosed with cervical cancer have a 5-year survival rate of 66.2% [2]. Patients with localized disease have a much more favorable prognosis, with a 5-year relative survival rate of 91.7%. Unfortunately, in the USA, only 46% of women are diagnosed with locally confined disease.

Experience and randomized studies have demonstrated that patients with locally confined disease (stage IA2-IB1), without lymph node metastases, may successfully be treated with radical surgery. Surgery typically includes radical hysterectomy and bilateral pelvic lymphadenectomy. This requires removal of the uterus, cervix, and radical excision of the upper vagina and parametria, which eliminates the potential for child-bearing. However, as this disease commonly afflicts young women with approximately 38% of women being diagnosed at 45 years or less, these patients may be candidates for fertility-sparing options, such as radical trachelectomy [2].

Radical trachelectomy was developed in 1987 by French surgeon Dr. Daniel Dargent for the treatment of early invasive cervical cancer in order to preserve fertility. He reported on the first radical vaginal trachelectomy. Since that time, over 1000 procedures have reportedly been performed worldwide [3]. This procedure can be performed by multiple approaches including abdominally, vaginally, laparoscopically, and robotically.

In this article, we will review pre-operative considerations, the surgical technique, and common post-operative complications. Additionally, we will review the recent literature with regard to oncologic and fertility outcomes.

## Patient selection and pre-operative assessment

Criteria used to determine appropriate candidates for radical trachelectomy have remained similar to when the procedure was first described, and include the following:

- Reproductive age, typically < 40–45 years of age
- Squamous carcinoma or adenocarcinoma histology; rare histologies (small cell neuroendocrine, gastric type adenocarcinoma, and adenoma malignum) are not considered suitable for fertility-sparing surgery
- Stages IA1 with lymphovascular space invasion, IA2, or IB1
- Tumor size 2 cm or less
- No evidence of lymph node spread
- No history of fertility impairment
- Strong desire to preserve fertility
- Imaging (pelvic MRI) to rule out upper endocervical involvement

Using these criteria, Sonoda and colleagues evaluated 186 patients < 40 years of age who had undergone radical hysterectomy and determined that 48% would have been eligible for a radical trachelectomy [4]. However, in approximately 14% of cases, the procedure would need to be abandoned because of unexpected disease spread. Criteria for aborting the procedure include a positive endocervical margin not amenable to further resection, positive lymph nodes, or a lesion that is larger than originally anticipated, although this is less likely given improvements in pre-operative imaging techniques.

Pre-operative imaging is crucial in the assessment of tumor size and location with respect to its distance from the internal os, as well as assessing the presence of distant metastases. Magnetic resonance imaging (MRI) plays a vital role in the pre-operative assessment of potential candidates for radical trachelectomy as it allows determination of tumor size, extension into the endocervical canal, and the length of the canal. The reported staging accuracy of MRI compared to physical exam ranges from 75 to 99%, but the superiority of MRI truly lies in its ability to detect the tumor-free distance from the internal os. MRI has a high

specificity of 98% and positive predictive value of 95% for predicting the distance between the tumor and the internal os of less than or equal to 5 mm [5].

## Surgical technique

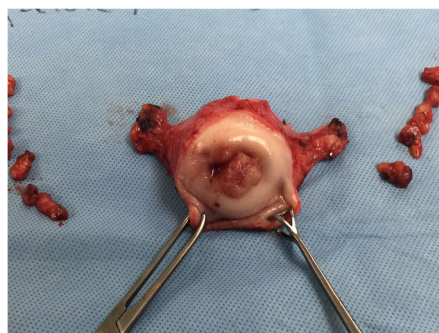
### Vaginal approach

As discussed previously, the vaginal approach has been well documented [6]. Retroperitoneal or laparoscopic pelvic lymphadenectomy is first performed, as in all approaches, consisting of the removal of the lymph node bearing tissue between the distal one-half of each common iliac artery, the anterior and medial aspect of the proximal half of the external iliac artery and vein, and the distal half of the obturator fat pad anterior to the obturator nerve. The pelvic lymph nodes may be assessed with a complete lymphadenectomy or via sentinel lymph node mapping, which will be discussed in a subsequent section.

Once the pelvic lymph nodes have been excised, the vaginal approach begins with the excision of 1–2 cm of vaginal mucosa around the cervix. The anterior and posterior edges are then used to cover the cervix in the midline. The vesicovaginal space is developed anteriorly and the paravesical spaces laterally to identify the bladder pillars. The ureters are palpated and identified. The posterior cul-de-sac is opened and the pararectal spaces are identified and the proximal uterosacral ligaments are excised. After relocation of the ureters, the parametrial tissue up to the level of the isthmus is excised. The cervical or descending branch of the uterine artery is ligated. The radical trachelectomy specimen with pelvic nodes is excised approximately 1 cm below the internal os [Fig. 1]. In order to keep the canal patent and prevent canalicular stenosis, a Foley or Malecot catheter may be placed into the uterus and sutured in place. An endocervical cerclage is placed and the vaginal mucosa is reapproximated to the new ectocervix with either interrupted or running sutures.

### Abdominal approach

The abdominal radical trachelectomy was described in 1997 by Smith et al., but has subsequently been modified [7, 8]. Entry into the abdomen may be via a midline vertical incision or transverse abdominal incision with a Maylard or Cherney incision to have adequate access to the pelvis. After excising the pelvic lymph nodes, the paravesical and pararectal spaces are developed. The round ligaments in most instances are divided, but may be preserved. The round



**Fig. 1.** Radical trachelectomy specimen with pelvic nodes

ligaments are grasped with Kelly clamps for uterine manipulation and the vesicocervical space is developed to dissect the bladder off the cervix. Care is taken to preserve the infundibulopelvic and utero-ovarian vessels as this is the main blood supply for the remaining uterus. Once a complete ureterolysis is performed to the tunnel of Wertheim, the uterine vessels are divided at their origin from the hypogastric vessels. The parametria and paracolpos are mobilized with the trachelectomy specimen. The posterior cul-de-sac is incised and the uterosacral ligaments are divided at their origin. The vagina is then incised to perform an anterior colpotomy, 1–2 cm distal to the external cervical os. This is then carried circumferentially until the specimen is completely separated from the vagina. This step may be facilitated with the use of a vaginal delineator, such as a McCartney tube™ or other vaginal cylinder. The lower uterine segment is estimated and clamps are placed at the level of the internal os. The cervix is then incised with a knife approximately 5 mm below the internal os. As in the vaginal approach, patency of the remaining cervical canal may be achieved with the use of a Foley or Malecot catheter followed by the placement of an endocervical cerclage. The lower uterine segment is then sutured to the vaginal mucosa via interrupted or continuous sutures.

### Minimally-invasive (laparoscopic and robotic) approach

The steps with either a laparoscopic or robotic approach are the same with regards to the abdominal approach. However, advances in minimally invasive surgery have allowed the performance of many procedures with the advantages provided by this approach. Namely, minimally invasive surgery has allowed for reduced length of hospital stay, reduced blood loss, decreased analgesic requirements, decrease in blood transfusion rates, decrease in complication rates, earlier recovery of physiological functions, and improved esthetic outcomes [9].

In addition to improvements in post-operative recovery, it differs by the ability to identify the ascending and descending branches of the uterine artery given the improved visualization provided by the laparoscope. This allows individual ligation of the descending branches to preserve blood supply of the isthmic portion of the uterus.

As in most cases, the round ligament is preserved, the decision to utilize a uterine manipulator is individualized given the patient and tumoral characteristics, but can ease manipulation of the uterus. The use of a colpotomizer also allows easy delineation of the vagina, improved development of the vesicocervical and vesicovaginal spaces, and provides assistance when determining the distance from the external os when performing the upper vaginectomy [Fig. 2].

Trocar placement for a laparoscopic radical trachelectomy approach typically can be accomplished with 5 mm trocars, although some may prefer a 12 mm midline trocar for a use of 10-mm camera. A central supra-umbilical trocar and three accessory trocars should suffice and the arrangement is similar to a traditional robotic hysterectomy [Fig. 3].

### Other surgical considerations

#### Frozen section

Frozen section of the trachelectomy specimen is advocated to ensure an acceptable tumor-free margin has been obtained [10–12]. The recommended

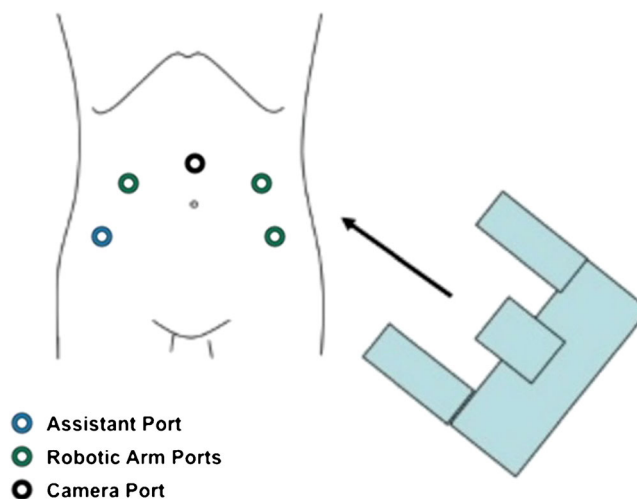


**Fig. 2.** Upper vaginectomy—margin

tumor clearance is at least a 5 mm margin [13]. If this is not achieved, either additional cervical tissue may be excised, if anatomically feasible, or a completion hysterectomy would need to be performed. Frozen section of any suspicious pelvic nodes should be performed prior to beginning a radical trachelectomy to ensure there is no metastatic disease as this would be an indication to abort a fertility-sparing procedure.

### Sentinel lymph nodes

Evaluation of the pelvic lymph nodes in patients with early stage cervical cancer should be performed. In these patients, the risk of nodal metastasis is as high



**Fig. 3.** Trocar placement for a laparoscopic and/or robotic radical trachelectomy

15–20% and pelvic lymphadenectomy is generally sufficient, as the risk of para-aortic nodal metastases is small [14]. More recently and increasing in favor is the use of sentinel lymph node mapping and biopsy to decrease post-operative morbidity in patients up to stage IB1 disease. The SENTICOL study was a multicenter prospective evaluation of patients with stage IA1 disease with lymphovascular space invasion to stage IB1 to assess the accuracy of this procedure [15]. The sentinel lymph node mapping procedure in the 136 patients had a 98.2% negative predictive value, and in the patients who mapped bilaterally, there was a 0% false-negative rate. Emphasis must be placed on the fact that if a hemi-pelvis does not map, a side specific complete lymphadenectomy should be performed to maintain these high rates of reliability, as well as any suspicious lymph nodes, regardless of mapping, should be removed. Additionally, although this technique has been used in tumors up to 4 cm, the best detection and mapping rates are from patients with tumors that are 2 cm or less. Although frozen section should be performed on suspicious lymph nodes to determine if a fertility-sparing procedure should be continued, frozen section on sentinel lymph nodes has poor diagnostic value [16]. Nonetheless, the sentinel lymph node procedure should be considered in this cohort of patients undergoing fertility-sparing surgery for early stage cervical cancer [17].

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## Cerclage

Cervical cerclage following radical trachelectomy has not always been considered standard [18]. It is now well established that placement of a cervical cerclage at the time of radical trachelectomy plays an important role in preventing premature dilatation of the residual uterine cervical canal and the subsequent occurrence of preterm premature rupture of membranes (PPROM) [19]. The type of suture used to perform the cerclage varies among different reports, including braided and non-braided sutures. No randomized trials have evaluated the optimal suture material. Braided sutures are notable for their strength and ease of removal. Unfortunately, the braided material provides an environment for bacterial incorporation, which is a known contributor to preterm birth [20]. In contrast, non-braided suture exhibits less tissue reactivity and some data may suggest improved successful pregnancy rates with non-braided sutures (e.g., Nylon® and Prolene®) [21]. In addition, conventionally, the knot of the cerclage is tied posteriorly to avoid a theoretical risk of erosion into the bladder, but this also has not been evaluated in a randomized trial.

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## Uterine artery preservation

One of the most frequently debated issues is whether uterine artery preservation should be the norm when performing radical trachelectomy or whether it is safe to transect the uterine vessels. Several authors have addressed uterine perfusion after radical trachelectomy. The first report, from Tang et al. [22], including 26 patients (the uterine arteries were preserved in 16 and ligated in 10 of them) who underwent computed tomography angiography (CTA), demonstrated 87.2% rate of unilateral or bilateral uterine artery occlusion when these vessels were spared.

More recently, Escobar et al. measured and analyzed uterine perfusion utilizing laser angiography with ICG during uterine artery sparing

and non-sparing radical trachelectomy. Based on real-time intraoperative angiography observations, the authors concluded that there is no need to preserve the uterine artery during radical trachelectomy to maintain uterine viability. [23•].

## Post-operative morbidity

Surgical outcomes of radical trachelectomy indicate that it is a safe procedure with comparable complication rates to radical hysterectomy. In a systematic review comparing peri-operative morbidity of laparoscopic radical trachelectomy ( $n = 143$ ) and hysterectomy ( $n = 186$ ), the rates of intraoperative and postoperative complications were similar for both groups (intraoperative complications 3.5 and 1.1%, respectively; postoperative complications 35.7 and 33.3, respectively) [24]. The only significant difference seen was in median operative time (155 vs 115 min, respectively). These findings are similar to other studies across all approaches of radical trachelectomy to radical hysterectomy [25–27, 28••].

A common complication of radical trachelectomy is the development of cervical stenosis, which is seen in up to 10–15% of patients [21, 27, 29, 30]. In a series of patients who underwent robotic radical or abdominal trachelectomy, the rate of cervical stenosis prior to the use of an intrauterine cannula (Smitt sleeve) was 14%, and after implementation, the rate was reduced to 0% [27]. In a review of 1547 patients undergoing radical trachelectomy, in whom 424 or 27% used anti-stenosis tools, the incidence of cervical stenosis was 4.6% with and 12.7% without, a significant difference [21]. The most frequently used tool to prevent stenosis was a catheter in 68% of patients. Most catheters are kept for a minimum of 3–5 days, but range to as long as 8 weeks. The use of anti-stenosis tools, most commonly a catheter, is advocated by the authors to prevent cervical stenosis.

**Table 1. Oncologic outcome following radical trachelectomy**

Authors	Number	Recurrences	Deaths
Plante [34] and Roy [35]	100	2 (2.0%)	1 (1.0%)
Steed [36] and Covens [37]	121	7 (5.8%)	4 (3.3%)
Shepherd et al. [38]	123	5 (4.1%)	2 (3.3%)
Hertel et al. [39]	100	4 (4.0%)	2 (2.0%)
Dargent [40] and Mathevet [41]	95	4 (4.2%)	3 (3.1%)
Ungar et al. [42]	91	2 (2.2%)	0
Diaz [43]	40	1 (2.5%)	1 (2.5%)
Wethington [44]	101	4 (4%)	0
Burnett et al. [45]	19	0	0
Schlaerth et al. [46]	10	0	0
Total	800	29 (3.6%)	13 (1.6%)

**Table 2. Obstetrical outcomes following radical trachelectomy**

Authors	Pregnancies	1st trimester miscarriage	Therapeutic abortion	2nd trimester miscarriage	3rd trimester miscarriage	Delivery < 32 weeks	Delivery > 32 weeks
Plante [34] and Roy [35]	59	10 (16%)	3 (4%)	2 (5%)	44 (75%)	3 (7%)	41 (93%)
Covens [37] and Bernardini [47]	45	8 (16%)	0	3 (7%)	34 (77%)	6 (18%)	28 (82%)
Shepherd et al. [38]	52	15 (29%)	2 (4%)	7 (13%)	28 (54%)	7 (25%)	21 (75%)
Hertel et al. [39]	14	1 (7%)	2 (14%)	0	11 (78%)	3 (27%)	8 (73%)
Dargent [40] and Mathevet [41]	56	11 (18%)	3 (5%)	8 (14%)	34 (61%)	5 (15%)	29 (85%)
Ungar et al. [42]	10	4 (40%)	0	0	6 (60%)	1 (17%)	5 (83%)
Kim et al. [48]	27	1 (4%)	3 (11%)	3 (12%)	20 (74%)	0	20 (100%)
Total	263	50 (19%)	13 (5%)	23 (9%)	177 (67%)	25 (14%)	152 (86%)



## Oncologic outcomes

There is a strong body of literature to suggest that the oncologic outcomes following radical trachelectomy are comparable to radical hysterectomy for tumors of similar size when meticulous surgical technique is used. Maintaining strict criteria for patient selection is of paramount importance as unusual recurrences are seen in patients with larger tumor sizes and unusual histologies [18, 31, 32].

Numerous studies have proven that radical trachelectomy can obtain a similar death rate compared to radical hysterectomy and is a safe alternative for fertility conservation. Initial reviews of the procedure suggested recurrence rates of 4.5% and mortality rates of 3%. In the largest meta-analysis of oncologic outcomes in patients undergoing radical trachelectomy, which included 2479 patients, with regards to recurrence and mortality, the rates are similar at 2.3% and 0.7%, respectively [33••]. Follow-up ranged from 9 to 96 months and 81.4% of the patients had follow-up greater than 2 years. A sampling of the literature used to compose these numbers is included in Table 1.

## Fertility and obstetrical outcomes

There have been hundreds of pregnancies reported, mostly with the vaginal approach, but increasingly now with the abdominal approach. First trimester miscarriage rates are similar to the general population at under 20% [Table 2]. Interestingly enough, as many patients undergo this procedure for fertility preservation, a 5% elective termination rate is seen. Although the 2nd trimester miscarriage rate for patients undergoing radical trachelectomy is higher than in the general population, 10% vs 3%, respectively, almost 70% of pregnancies reach the 3rd trimester. Of those, 85% will result in delivery after 32 weeks gestation, with the majority reaching term (> 37 weeks gestation). In total, a large systematic review of the wide body of literature reporting on obstetrical outcomes in patients undergoing fertility-sparing surgery for early stage cervical cancer, aggregated rates of miscarriage and preterm labor are 24% and 26.6% with a pooled pregnancy rate of 20.5% [33••].

Various factors are associated with the high rates of miscarriage, preterm labor, and subsequent preterm premature rupture of membranes seen following radical trachelectomy in patients who achieve pregnancy. An initial theory pertained to the possibility that these complications could be a result of a lack of adequate blood flow to the uterus following transection of the uterine artery. However, Umemura and colleagues evaluated the uterine blood supply post radical trachelectomy using 3D CT scanning and showed that ligation of several supplying arteries to the uterus during radical trachelectomy actually induces new arterial vascularization and did not affect fetal growth or placental function [49]. This was also confirmed using contrast-enhanced MRI showing that there was no significant decrease of uterine enhancement rate following abdominal radical trachelectomy, suggesting that uterine function and fertility may be preserved after this procedure [50].

Additionally, a major etiology of 2nd trimester losses and preterm deliveries is likely due to mechanical changes to the remaining cervix and support to the growing lower uterine segment (i.e., short cervix). A short cervix prevents formation of a normal mucous plug, the main physiologic barrier to prevent

ascending infections and subclinical chorioamnionitis [38].

Maternal fetal medicine consultation is critical for these patients to ensure they are receiving adequate perinatal care with the most up to date guidelines for the management of a short cervix including ultrasound cervical lengths [51, 52]. Additionally, if these patients have recurrent 2nd trimester miscarriages, there is evidence to suggest that an abdominal cerclage may be preventative [53]. Patients who reach term should be delivered via cesarean section given the permanent cerclage.

## Conclusions

Radical trachelectomy for the treatment of early stage cervical cancer in women who desire to preserve fertility is a valuable alternative to radical hysterectomy. Its increasing acceptance and implementation have allowed for pooling of a wealth of retrospective data. The improvements over the past two decades with regards to laparoscopic and robotic surgery have revolutionized the surgical management of cervical cancer. Post-operative complications and oncologic outcomes are comparable to the gold standard, radical hysterectomy, in patients with similar-sized tumors. Although there is a high rate of miscarriage and early preterm birth, the majority of pregnancies reach > 32 weeks. The Dargent procedure, or radical trachelectomy, is one of the most important surgical advances in the treatment of early-stage cervical cancer. Future directions will push the envelope with respect to less radical procedures, but at this time, radical trachelectomy is a comparable and very valuable option for patients with early stage cervical cancer.

## Compliance with Ethical Standards

### Conflict of Interest

The authors declare that they have no conflict of interest.

### Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of major importance

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