



Radical trachelectomy in early-stage cervical cancer: A comparison of laparotomy and minimally invasive surgery



Marcelo A. Vieira^a, Gabriel J. Rendón^b, Mark Munsell^c, Lina Echeverri^b, Michael Frumovitz^d, Kathleen M. Schmeler^d, Rene Pareja^b, Pedro F. Escobar^d, Ricardo dos Reis^a, Pedro T. Ramirez^{d,*}

^a Department of Gynecologic Oncology, Barretos Cancer Hospital, Barretos, Brazil

^b Department of Gynecologic Oncology, Instituto de Cancerología – Las Américas, Medellín, Colombia

^c Department of Biostatistics, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

^d Department of Gynecologic Oncology and Reproductive Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

HIGHLIGHTS

- Radical trachelectomy via MIS results in less blood loss and a shorter hospital stay.
- Oncologic outcomes between open and MIS radical trachelectomy are similar.
- Pregnancy rate is higher for open radical trachelectomy.

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ABSTRACT

Objectives. Radical trachelectomy is considered standard of care in patients with early-stage cervical cancer interested in future fertility. The goal of this study was to compare operative, oncologic, and fertility outcomes in patients with early-stage cervical cancer undergoing open vs. minimally invasive radical trachelectomy.

Methods. A retrospective review was performed of patients from four institutions who underwent radical trachelectomy for early-stage cervical cancer from June 2002 to July 2013. Perioperative, oncologic, and fertility outcomes were compared between patients undergoing open vs. minimally invasive surgery.

Results. A total of 100 patients were included in the analysis. Fifty-eight patients underwent open radical trachelectomy and 42 patients underwent minimally invasive surgery (MIS = laparoscopic or robotic). There were no differences in patient age, body mass index, race, histology, lymph vascular space invasion, or stage between the two groups. The median surgical time for MIS was 272 min [range, 130–441 min] compared with 270 min [range, 150–373 min] for open surgery ($p = 0.78$). Blood loss was significantly lower for MIS vs. laparotomy (50 mL [range, 10–225 mL] vs. 300 mL [50–1100 mL]) ($p < 0.0001$). Nine patients required blood transfusion, all in the open surgery group ($p = 0.010$). Length of hospitalization was shorter for MIS than for laparotomy (1 day [1–3 days] vs. 4 days [1–9 days]) ($p < 0.0001$). Three intraoperative complications occurred (3%): 1 bladder injury, and 1 fallopian tube injury requiring unilateral salpingectomy in the MIS group and 1 vascular injury in the open surgery group. The median lymph node count was 17 (range, 5–47) for MIS vs. 22 (range, 7–48) for open surgery ($p = 0.03$). There were no differences in the rate of postoperative complications (30% MIS vs. 31% open surgery). Among 83 patients who preserved their fertility (33 MIS vs. 50 open surgery), 34 (41%) patients attempted to get pregnant. Sixteen (47%) patients were able to do so (MIS: 2 vs. laparotomy: 14, $p = 0.01$). The pregnancy rate was higher in the open surgery group when compared to the MIS group (51% vs. 28%, $p = 0.018$). However, median follow-up was shorter in the MIS group compared with the open surgery group (25 months [range, 10–69] vs. 66 months [range, 11–147]). To date, there has been one recurrence in the laparotomy group and none in the MIS group.

Conclusions. Our results suggest that radical trachelectomy via MIS results in less blood loss and a shorter hospital stay. Fertility rates appear higher in patients undergoing open radical trachelectomy.

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* Corresponding author at: Department of Gynecologic Oncology & Reproductive Medicine, Unit 1362, The University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd., Houston, TX 77030, USA.

E-mail address: peramire@mdanderson.org (P.T. Ramirez).

1. Introduction

Radical trachelectomy is now considered a standard treatment for women diagnosed with early-stage cervical cancer wishing to preserve

fertility [1]. To date more than 1000 cases of vaginal radical trachelectomy (VRT) have been published, with a global pregnancy rate (total number of women who conceived of all who retained fertility) of 24% [2], and a relapse and death rate of 4.2% and 2.9%; respectively [3]. The abdominal radical trachelectomy (ART) is an alternative approach to this procedure and offers an advantage to surgeons who are not proficient in vaginal radical surgery. In a recent review that included 485 abdominal radical trachelectomies, the reported pregnancy rate was 16.2%, and relapse and death rates were 3.8% and 2.9%, respectively [2].

Radical trachelectomy can also be performed laparoscopically and, to date, there have been 230 cases published in the literature, with a pregnancy rate of 23.9% and a relapse and death rate of 6% and 1.7%; respectively [4]. Another previously described minimally invasive approach is the robotic radical trachelectomy [5]. A total of 36 robotic radical trachelectomies have been published in the literature thus far [6–9], with 4 reported pregnancies, and one relapse without death.

To date, there are limited data comparing the outcomes of patients undergoing radical trachelectomy based on the surgical approach. The goal of this study is to compare operative, oncologic, and fertility outcomes in patients with early-stage cervical cancer undergoing open vs. minimally invasive radical trachelectomy.

2. Methods

Institutional Review Board approval was obtained from the University of Texas MD Anderson Cancer Center, Instituto de Cancerología – Las Americas in Colombia, Cleveland Clinic and the Barretos Cancer Hospital in Brazil. Data were collected retrospectively from all patients' records that underwent open, laparoscopic or robotic radical trachelectomy for early-stage cervical cancer from June 2002 to July 2013. Open radical trachelectomies were performed from June 2002 to February 2013 and minimally invasive radical trachelectomies were performed concurrently with open procedures from October 2008 to July 2013. In none of the institutions did patients undergo radical vaginal trachelectomy. All patients met the standard criteria for radical trachelectomy (Table 1).

The surgical technique of open, robotic or laparoscopic radical trachelectomy has been described elsewhere [5,10,11]. All trachelectomy specimens were submitted for frozen section. When the surgical margin was grossly positive or close (<5 mm) for invasive cancer, the patient underwent resection of additional tissue, and if this was not possible, then immediate conversion to radical hysterectomy was performed. The surgical approach was based on surgeon training and patient preference.

Patients who underwent conversion to radical hysterectomy were excluded from the portion of the analysis pertaining to surgical and fertility outcomes, and the patients with hysterectomy during follow-up subsequent to the radical trachelectomy were excluded from the fertility outcome analysis. Data extracted from the medical record included patients' age at diagnosis, race/ethnicity, body mass index, pregnancy history, preoperative imaging, and preoperative pelvic examination findings. Operative reports were reviewed and operative times, estimated blood loss, sentinel lymph node mapping, preservation of uterine

Table 1

Radical trachelectomy recommended criteria.

| |
|--|
| Strong desire to preserve fertility |
| Histologic diagnosis of invasive squamous, adenocarcinoma or adenosquamous cervical cancer |
| Stage IA1 with LVSI, IA2 or IB1 |
| Ideal tumor size less than 2cm ^a |
| Pelvic MRI, ruling out upper endocervical involvement |
| Resolution of acute inflammation (4–6 weeks after conization) |
| No extracervical involvement |
| Age less than 40 years ^a |
| No previous fertility impairment ^a |

^a According to surgeons' and centers' experience and patient preferences.

arteries, device used to avoid cervical stenosis, use of cerclage, blood transfusions, length of hospital stay, length of follow-up, and incidence of intraoperative complications were recorded. Pathologic data included tumor histologic subtype and grade, residual tumor, surgical margin, parametrial involvement, presence or absence of lymph vascular space invasion, number of lymph nodes removed and nodal status. We also recorded the need of adjuvant treatment. Serious morbidity was defined as readmission, reoperation or need for second procedure, anemia necessitating a blood transfusion, venous thromboembolism, ICU admission, death, or loss of fertility (need for postoperative radiotherapy). We also included the following as postoperative morbidities: urinary tract infections with symptoms such as dysuria and/or fever and positive urine culture, voiding dysfunction with residual urine greater than 100 mL at the time of voiding trial, and lymphocyst associated with abdominal pain and/or fever diagnosed by radiological exam. All postoperative morbidities were detailed and dichotomized as early (occurring less than 30 days) or late (occurring greater than 30 days but within 1 year of surgery) morbidities. Postoperative pregnancy rates were also determined. In addition, patient status and disease status at the time of the last follow-up were recorded.

Statistical analyses were performed using SAS 9.3 for Windows (Copyright © 2002–2010 by SAS Institute Inc., Cary, NC). Associations between categorical variables and modality of radical trachelectomy (open vs. MIS) were determined using Fisher's exact test. Nonparametric continuous variables were summarized and compared using the Wilcoxon rank sum test. All tests were two-sided, and a p-value <0.05 was considered statistically significant.

3. Results

One hundred patients (fifty from MD Anderson Cancer Center [MIS = 23, open = 27]; thirty-three from Instituto de Cancerología [MIS = 10, open = 23]; eight from Cleveland Clinic [open = 8] and nine from the Barretos Cancer Hospital [MIS = 9]) with early-stage cervical cancer were scheduled to undergo radical trachelectomy. The median age was 30 years (range, 21–40.6). The median body mass index was 23.5 kg/m² (range, 18–45). Sixty-one women were nulliparous. The majority of patients were Hispanic (58%). Fifty-eight patients underwent open radical trachelectomy and 42 patients underwent MIS (22 robotic and 20 laparoscopic). The most common stage was IB1 (69%) and the most common histologic subtype was squamous cell carcinoma (49%). Twenty-five (25%) patients had evidence of lymph vascular space invasion (LVSI) (Table 2).

On preoperative pelvic examination 26 patients had a visible lesion in the cervix, 9 patients in the MIS group and 17 patients in the open surgery group (p = 0.49). The median tumor size in the 26 patients with a visible lesion was 2 cm (range, 0.5–3.5). Preoperative magnetic resonance imaging (MRI) was obtained in 59 patients; ten patients (17%) had visible tumor and 14 (24%) had suspicion of tumor in the cervix on preoperative MRI, none had suspicious nodes on MRI. Thirty-one patients underwent a CT scan and 2 of these were noted to have an enlarged pelvic lymph node and underwent fine-needle aspiration (FNA). These were negative for carcinoma in the biopsy, but one patient had a positive lymph node in the lymphadenectomy specimen. Twenty-four patients had a PET/CT performed and none had evidence of metastatic disease.

Patients undergoing MIS radical trachelectomy had significantly lower median blood loss than patients undergoing open surgery (50 mL (range, 10–225) vs. 300 mL (range, 50–1100); respectively, p < 0.0001). Nine patients required a blood transfusion, all in the open surgery group (p = 0.010). There was no difference in operative time (MIS: 272 min [range, 130–441] vs. open: 270 min [range, 150–373], p = 0.78) (Table 2). Twenty-two patients had uterine artery preservation (MIS: 2 vs. open: 20, p = 0.0005).

Excluding the patients that underwent radical hysterectomy, there were three intraoperative complications (3%) and two of these were

Table 2
Patient characteristics by surgical approach.

| | MIS (n = 42) | Open (n = 58) | p-Value |
|--|------------------|----------------|---------|
| Age ^a | 30.1 (25.4–40.6) | 29.3 (21–40.3) | 0.68 |
| Race | | | 0.96 |
| White | 15 (35.7%) | 22 (37.9%) | |
| Black | 1 (2.4%) | 2 (3.5%) | |
| Hispanic | 25 (59.5%) | 33 (56.9%) | |
| Asian | 1 (2.4%) | 1 (1.7%) | |
| BMI ^a | 23.4 (18.8–45) | 23.5 (18–33.4) | 0.93 |
| History of previous pregnancy | | | 0.84 |
| Yes | 17 (40.5%) | 22 (37.9%) | |
| No | 25 (59.5%) | 36 (62.1%) | |
| Tumor stage | | | 0.65 |
| IA1 + LVSI | 3 (7.1%) | 3 (5.2%) | |
| IA2 | 12 (28.6%) | 13 (22.4%) | |
| IB1 | 27 (64.3%) | 42 (72.4%) | |
| Tumor histology | | | 0.58 |
| Squamous | 20 (47.6%) | 29 (50%) | |
| Adenocarcinoma | 20 (47.6%) | 22 (37.9%) | |
| Adenosquamous | 2 (4.8%) | 5 (8.6%) | |
| Mixed | 0 | 2 (3.5%) | |
| Estimated blood loss (mL) ^a | 50 (10–225) | 300 (50–1100) | <0.0001 |
| Rate of perioperative transfusion | 0 (0%) | 9 (15.5%) | 0.010 |
| Operative time (min) ^a | 272 (130–441) | 270 (150–373) | 0.78 |
| Length of hospital stay (days) | 1 (1–3) | 4 (1–9) | <0.0001 |
| Nodal counts | 17 (5–47) | 22 (7–48) | 0.03 |
| Lymph vascular space invasion | 11 (26.2%) | 14 (24.1%) | 0.99 |
| Presence of residual disease | 15 (35.7%) | 27 (46.6%) | 0.52 |
| Rate of conversion to hysterectomy | 5 (11.9%) | 3 (5.2%) | 0.27 |
| Follow-up (months) ^a | 25 (10–69) | 66 (11–147) | <0.0001 |
| Recurrence | 0 | 1 | NA |
| Death from disease | 0 | 1 | NA |

NA, not available.

^a Median (range).

in the MIS group. One patient suffered from bladder injury that was managed by the MIS approach and one patient suffered an injury to the fallopian tube because of grasper traction requiring unilateral salpingectomy. There was one vascular injury in the left external iliac artery during lymphadenectomy in the open group and this patient lost 800 mL of blood and required a 2 unit blood transfusion. The median length of stay (LOS) was shorter in the MIS group than in the open group (one day [range, 1–3] vs. 4 days [range, 1–9], respectively, $p < 0.0001$) (Table 2).

The median number of lymph nodes retrieved was 20 (range, 5–48), and was lower in the MIS group compared to the open group (17 [range, 5–47] vs. 22 [range, 7–48] respectively; $p = 0.036$). Fourteen patients (7 in the laparotomy cohort and 7 in the MIS cohort) underwent intraoperative lymphatic mapping, and all had identification of sentinel lymph nodes and all sentinel nodes were negative for disease on final pathology. Two patients had positive non-sentinel lymph nodes on final pathology, one for each group, and required adjuvant treatment. Eight patients were converted to radical hysterectomy secondary to a close (<5 mm) or involved surgical margin in frozen section (MIS: 5 vs. open: 3, $p = 0.27$). Forty-two patients had residual disease in the cervical specimen, and this finding did not differ by type of technique. Sixty-three patients (68%) had placement of cerclage at the time of surgery. In order to prevent cervical stenosis, some surgeons chose to use pediatric Foley catheters (57/92, 62%) versus others who chose to use a Smit sleeve (Elekta AB, Stockholm, Sweden) (23/92, 25%) or none in 12 cases (13%). Of all the patients who had a pediatric Foley for cannulation of the cervical os, six (10.5%) developed cervical stenosis. Among patients who had a Smit sleeve placed to maintain patency of the cervical os, one (4.3%) patient developed cervical stenosis and one (8.3%) patient with no catheter at all developed cervical stenosis.

Excluding patients that underwent radical hysterectomy, the most common morbidities within 30 days of surgery included urinary tract

infections (10/92 – 11%), voiding dysfunction (5/92 – 5.4%) and lymphocyst formation (4/92 – 4%). Excluding another five patients who underwent hysterectomy during follow-up (after 30 days from the surgery), the most common long-term (>30 days) morbidities were cerclage erosion (11/63 – 17.5%) and cervical stenosis (8/87 – 9%) (Table 3).

A total of 5 patients in the MIS group experienced one or more serious morbidities, 3 patients underwent hysterectomy, one because of uterine necrosis, another because of peritonitis and one because of chronic pelvic pain. One patient developed a vesico-vaginal fistula 8 days after surgery and it was managed conservatively by placing a Foley catheter for 6 weeks. Another patient developed a left uretero-vaginal fistula 13 days after surgery and it was managed with a Foley catheter for four months and then she underwent ureteral re-implantation.

In the laparotomy group, eight patients experienced one or more serious morbidities, 2 patients underwent hysterectomy secondary to utero-vaginal anastomosis dehiscence with secondary uterine corpus necrosis. Another patient developed an utero-vaginal dehiscence following intercourse 3 months postoperatively. She was taken to the operating room and noted to have disruption of the posterior vaginal to uterine anastomosis, which was revised. Three weeks following secondary closure of the vaginal cuff, she developed a pelvic abscess and was again readmitted, initiated on intravenous antibiotic therapy, and underwent CT-guided drainage of the abscess without further complication. Five patients developed anemia, necessitating blood transfusion in the immediate postoperative period.

Four patients underwent postoperative adjuvant therapy. Two underwent radiation alone. One patient was treated because of disease at the margins and parametrium and another patient because of parametrial disease; a third patient had a positive lymph node, and underwent concurrent chemotherapy and radiation. All of these patients were without evidence of disease at the last follow-up. The fourth patient had one right pelvic lymph node (1/29) positive for disease in the final pathology and refused to undergo radiation due a strong desire to preserve fertility and underwent chemotherapy alone (4 cycles each 21 days of cisplatin 75 mg/m² and paclitaxel 175 mg/m²). At 23 months of follow-up, the patient was without evidence of disease and attempting to get pregnant.

In total, 17 (9 [21%] MIS vs. 8 [13.7%] open) patients were unable to maintain their fertility either secondary to a positive or close surgical margin necessitating conversion to hysterectomy (9/17), need for postoperative adjuvant therapy (4/17), a surgical complication (2/17), recurrence of disease (1/17) or ovarian dysfunction (1/17). Among the patients that underwent trachelectomy excluding patients unable to maintain their fertility, 34 (41%) of 83 patients had attempted to get pregnant. Sixteen (47%) patients were able to do so (MIS: 2 vs. laparotomy: 14, $p = 0.01$). Three women (18%) each had 2 pregnancies. A total of 19 pregnancies have resulted in 4 (21%) first trimester losses, 1 (5.3%) second trimester loss, 9 (47.4%) pre-term deliveries, 1 (5.3%) term delivery and 4 (21%) ongoing pregnancies (Table 4).

Excluding patients that underwent hysterectomy ($n = 13$) and the patients lost to the follow-up ($n = 7$), the median time of follow-up was 51 months [range 10–147] for the entire cohort with

Table 3
Postoperative complications.

| | MIS (n = 42) | Open (n = 58) | p-Value |
|---------------------------------|--------------|---------------|---------|
| Morbidity <30 days from surgery | | | |
| Urinary tract infection | 4 (9.5%) | 6 (10.3%) | 0.99 |
| Voiding dysfunction | 1 (2.3%) | 4 (6.8%) | 0.64 |
| Lymphocyst | 2 (4.7%) | 2 (3.4%) | 0.99 |
| Morbidity >30 days from surgery | | | |
| Cerclage erosion | 5 (11.9%) | 6 (10.3%) | 0.74 |
| Cervical stenosis | 3 (7.1%) | 5 (8.6%) | 0.99 |

MIS, minimally invasive surgery.

Table 4

Fertility outcomes comparing MIS versus open surgery.

| | MIS (n = 42) | Open (n = 58) |
|-----------------------------------|--------------|---------------|
| Women with fertility preservation | 33 (78.6%) | 50 (86%) |
| Women attempting pregnancy | 7 (21.2%) | 27 (54%) |
| Achieved pregnancy | 2 (28.6%) | 14 (51.8%) |
| Pregnancies | 3 | 16 |
| First trimester miscarriage | 1 (33.3%) | 3 (18.8%) |
| Second trimester deliveries | 0 (0.0%) | 1 (6.2%) |
| Third trimester deliveries | 1 (33.3%) | 9 (56.2%) |
| Pre-term | 1 (33.3%) | 8 (50%) |
| Term | 0 (0.0%) | 1 (6.2%) |
| Ongoing | 1 (33.3%) | 3 (18.8%) |

a significantly shorter median time of follow-up for MIS vs. open cases (25 months [range, 10–69] vs. 66 months [range, 11–147], $p < 0.0001$) (Table 2).

There has been one recurrence in the open surgery group. The patient had stage IB1 adenocarcinoma and at the time of her surgery her margins were negative. During her second year of follow-up, the patient had a pelvic relapse confirmed with biopsy and was not deemed a surgical candidate and she received chemotherapy and radiation. Three months after therapy she was noted to have peritoneal carcinomatosis and biopsies confirmed metastatic adenocarcinoma. She died 29 months after her initial surgery (Table 2).

4. Discussion

Radical trachelectomy is feasible in appropriately selected patients in early-stage cervical cancer, and the MIS (robotic and laparoscopic) approach offers a number of advantages such as improved visualization, less blood loss, lower transfusion rates, and faster return to daily activities [4,7,9,12–16]. Nick et al. [7] have shown that robotic radical trachelectomy is safe and feasible. In their study, the authors showed that the robotic approach was associated with less blood loss and shorter hospital stay when compared to the open approach.

Obstetrical outcomes are higher in patients who underwent ART but likely due to short follow-up of MIS cases. However, one must consider that when evaluating pregnancy rates after radical trachelectomy, the data often does not reflect true pregnancy rates as this is impacted by a number of factors such as, but not limited to, number of patients actually attempting to get pregnant, time of follow-up, and lack of information on true fertility potential for each of these patients, as often, a thorough fertility evaluation is not routinely performed prior to radical trachelectomy. Published data demonstrate that ART preserves fertility and maintains excellent oncologic outcomes. Most women (74%) attempting pregnancy after ART are able to get pregnant and deliver in the third trimester (52%) [17]. Consistent with the current literature, our findings support the feasibility of radical trachelectomy through an MIS approach. Although the number of patients is small and follow-up times are short in our study, these data suggest that the MIS approach is feasible, and that the oncologic outcomes are also very similar to those in the open approach.

We noted no significant differences in early or late morbidities in patients undergoing trachelectomy by either the open or MIS approach. Despite the small number of patients in each surgical group, patients experienced similar numbers of postoperative urinary infections and cerclage erosions. Whether or not to place a cerclage immediately at the time of surgery is a decision that depends on the physician and institutional practices, and not all patients had it placed during surgery. The use of the Smit Sleeve or Foley catheter to prevent cervical stenosis is recommended for all patients undergoing radical trachelectomy regardless of the surgical approach. The uterine arteries were preserved in only 22 patients (2 in the MIS group and 20 in the open group). There were 6 pregnancies in the open surgery group with uterine artery preservation vs. 10 pregnancies in the open surgery group without preservation of

uterine arteries. Most studies published on radical trachelectomy do not advocate for uterine artery preservation [17,18]. Tang et al. showed by using computed tomography angiography that the benefit of preserving the uterine artery is limited given the fact that 87.5% of patients have occlusion of the uterine arteries after ART with uterine artery preservation [18].

The strengths of our study lie in the fact that this is the largest comparative series of open vs. MIS of radical trachelectomy. The study is composed of all patients who underwent radical trachelectomy at multiple institutions reflecting different levels of surgical expertise and different levels of a learning curve. We do recognize that our study also has the limitations of a retrospective study and it is susceptible to limitations and biases inherent in such a design, where criteria for surgical approach, surgeon expertise and skill, and details of postoperative care may not have been clearly defined. The data presented in this article represents a composite of multiple institutions and surgeons of varying degrees of surgical expertise performing radical trachelectomy. Although it would be ideal to provide an analysis of surgeons experienced in both open and minimally invasive radical trachelectomy, with surgeons involved with equal degrees of surgical expertise, this is not possible in the setting of a procedure that is performed rarely and by select centers; and for which data is subsequently collected in a retrospective manner. We also did not have details regarding fertility potential and therapy in those patients who underwent radical trachelectomy.

In summary, this study demonstrates the feasibility of radical trachelectomy through a minimally invasive approach. As anticipated, the MIS approach was associated with less blood loss and shorter length of stay. However, we did note that the complication rates were not insignificant perhaps reflecting the impact of an initial learning curve. We believe that a minimally invasive surgical approach should be considered for women undergoing radical trachelectomy.

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