

Simple vaginal trachelectomy in women with early-stage low-risk cervical cancer who wish to preserve fertility: the new standard of care?

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Received 30 March 2020
Revised 13 May 2020
Accepted 14 May 2020
Published Online First
3 June 2020

HIGHLIGHT

- Following simple trachelectomy and node sampling, the 5-year progression-free survival in patients with low-risk cervical cancer is 97.5%
- The obstetrical outcome is excellent following simple trachelectomy with 75% of pregnancies reaching >36 weeks
- Simple trachelectomy is a safe fertility-preserving option for women with low-risk small size lesions (<2 cm)

ABSTRACT

Objective There is a trend toward less radical surgery in women with small-volume disease who wish to preserve fertility. The objective of our study was to evaluate the oncologic and obstetrical outcome of simple vaginal trachelectomy and lymph node assessment in patients with low-risk early-stage cervical cancer (<2 cm).

Methods From May 2007 to January 2020, 50 patients underwent a simple vaginal trachelectomy/conization with laparoscopic sentinel lymph node mapping±complete pelvic node dissection. Patients underwent loop electrocautery excision (LEEP), cone/cervical biopsies, or simple trachelectomy. A preoperative pelvic MRI with gadolinium contrast was systematically performed in all cases. The size of the lesion was established by review of the LEEP, cone or trachelectomy specimen, MRI, and clinical examination. Data was collected prospectively in a computerized database. Descriptive statistics and the Kaplan–Meier estimate were used for analysis.

Results The median age was 29 years (range: 21–44) and 35 (70%) patients were nulliparous. As per FIGO 2009 classification, 11 patients had stage IA1 with lymphovascular space invasion (LVSI), 13 patients had stage IA2, and 26 patients had stage IB1. Twenty-six patients had squamous histology, 20 patients adenocarcinoma, and four patients other histologies. On final pathology, lymph nodes were negative in 46 patients (92%), three patients had isolated tumor cells, and one patient had micrometastasis. Thirty patients (60%) had either no residual disease in the trachelectomy specimen (22) or residual dysplasia only (eight). With a median follow-up of 76 months (range: 1–140), only one local recurrence occurred which was treated initially with chemoradiation. She recurred again locally and underwent a pelvic exenteration: the patient progressed again and died of disease. The 5-year progression-free survival and overall survival was 97.9% and 97.6%, respectively. There were 40 pregnancies: five (12.5%) ended in the first trimester, one (2.5%) in the second trimester, and three (7.5%) were late preterm: all the others (30 or 75%) delivered >36 weeks and one pregnancy is ongoing.

Conclusion Simple trachelectomy/conization and lymph node assessment is an oncologically safe fertility-

preserving surgery in well-selected patients with low-risk early-stage cervical cancer (<2 cm). Obstetrical outcomes are comparable to the general population.

INTRODUCTION

There has been a definitive trend toward less radical surgery in the management of early-stage cervical cancer over the past 30 years.¹ The radical trachelectomy procedure is now considered standard of care for women with cervical cancer who wish to preserve fertility, although the safety has mostly been demonstrated for lesions <2 cm (NCCN guidelines).² The current literature indicates that the recurrence and mortality rates after radical trachelectomy are <5% and 2%, respectively for tumors under 2 cm.³ The ideal candidates for radical trachelectomy procedure would be women with tumors <2 cm, and without deep stromal invasion, lymph node metastasis, or high-risk histology. Patients with these characteristics have a better outcome and are less likely to require conversion to hysterectomy or need adjuvant treatment.^{4,5}

Although oncologic outcomes are good following radical trachelectomy, fertility and obstetrical outcome can be compromised. For instance, obstetric outcomes and pregnancy complications were frequently observed after radical trachelectomy.⁶ Following abdominal radical trachelectomy, up to 60% of patients had complications which affected fertility such as cervical stenosis, ovarian insufficiency, and Asherman's syndrome.⁷ In a large series of 360 abdominal trachelectomies, 57% of patients encountered fertility issues mostly related to cervical stenosis and fallopian tube obstruction.⁸

In recent years, several retrospective studies have indicated that the probability of parametrial infiltration in small lesions (<2 cm) is very low (<1%), suggesting that a simple hysterectomy might be adequate surgery in such cases.⁹ Tseng et al. compared 1764 modified



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To cite: Plante M, Renaud M-C, Sebastianelli A, et al. *Int J Gynecol Cancer* 2020;**30**:981–986.

Original research

radical surgery vs 807 less radical surgery and found no difference in the 10-year disease-specific survival, also suggesting that in low-risk patients, radical surgery may not be necessary.¹⁰ A group from The Netherlands has recently published an extensive review of their surgical treatment of early-stage cervical over a 30-year period.¹¹ Their data showed that radicality of the hysterectomy had no influence on survival in patients with lesions <2 cm, whereas the importance of the parametrectomy was significant in patients with lesions >2 cm.¹¹ All these studies are based on retrospective data. Results of the SHAPE/CX5 trial, a prospective international randomized trial comparing radical hysterectomy and nodes with simple hysterectomy in patients with lesions <2 cm will provide level 1 evidence as to the safety (or not) of less radical surgery in these patients. Results are awaited in 2023.¹²

In parallel, the concept of simple trachelectomy also emerged as a less radical surgical option for women with low-risk disease wishing to preserve fertility in order to improve the obstetrical outcome following fertility-preserving surgery.¹³ Although there are no clearly defined criteria for the definition of low-risk cervical cancer, it generally refers to patients with tumor size <2 cm, squamous, adenocarcinoma, or adenosquamous carcinoma histology, and no evidence of lymphovascular space invasion (LVSI).⁹ Shim et al conducted a systematic review of the literature on stage IA1/LVSI and concluded that simple trachelectomy/cone could safely be performed but this recommendation was based on a small number of non-randomized studies.¹⁴ Tseng et al compared the outcome of 2592 non-uterine-preserving surgery (hysterectomy) with 125 uterine-preserving surgery (cone/trachelectomy) in young women with stage IB1 disease and concluded that the latter was not associated with a higher risk of death.¹⁵

In a systematic review, Bentivegna et al summarized data from 228 patients who underwent simple trachelectomy/cone for stage IB1 disease and reported four recurrences (1.8%).¹⁶ Importantly, large literature reviews and meta-analysis confirm that obstetrical outcome following simple trachelectomy/cone are clearly superior compared with radical trachelectomy.^{17, 18} Emerging data would suggest that simple trachelectomy may be an interesting option as fertility-preserving surgery in young women with small lesions, when weighing oncologic safety and obstetrical/fertility outcome.¹⁹ However, this is based on fairly limited data with less than 300 published cases.²⁰ The aim of our study is to present our updated series of 50 simple trachelectomy cases with the emphasis on oncologic, obstetrical, and fertility outcome.

METHODS

This is a retrospective review of a prospective series of 42 consecutive simple vaginal trachelectomies and eight conizations in patients with early-stage low-risk cervical cancer wishing to preserve their fertility from May 2007 to January 2020. All records were kept prospectively in a computerized database. This protocol has received approval by our institutional review board. Inclusion criteria are identical to those previously reported for radical trachelectomy and are as follows: women desiring to preserve fertility, age under 45, lesions measuring <2 cm, adenocarcinoma and squamous histology, all grades, and LVSI allowed.²¹ Review of patients' medical chart, operative records, and pathology reports

was conducted and detailed oncologic outcome and obstetrical information were obtained from patients and referring physicians. Diagnostic loop electrocautery excision procedure (LEEP)/cone/cervical biopsies as well as the trachelectomy specimen were reviewed by a gyn-pathologist with special attention to the depth of invasion, presence of LVSI, and margin status. A preoperative pelvic MRI with gadolinium contrast was systematically performed or reviewed at our institution in all cases. The size of the lesion was established by review of the LEEP/cone specimen, MRI, and clinical examination.

The sentinel lymph node (SLN) mapping technique was introduced in our center in October 2000. The procedure has been described in our previous publication.¹⁹ Briefly, the procedure begins with laparoscopic SLN mapping. Frozen section of the SLN was performed in all cases. A complete lymph node dissection was performed early in the series, but omitted more recently when bilateral SLN were identified and negative on frozen section. The simple vaginal trachelectomy technique was described previously.¹⁹ A frozen section of the trachelectomy specimen was performed in patients with visible lesions to ensure clear surgical margins by at least 5 mm, otherwise an additional slice of cervix is removed to clear a safer oncologic margin. In patients with no visible lesions, the specimen was kept intact and sent for final pathology. An endocervical curettage was systematically performed. Patients were followed every 3–4 months for the first 2 years, every 6 months for the next 3 years, and then yearly, with a colposcopic evaluation and a Pap test. Additional investigations were performed as required according to symptoms or findings such as cervical biopsies, pelvic ultrasound, or MRI. On the second postoperative visit, an HPV-DNA test was performed and all patients were encouraged to receive HPV vaccination. Patients were asked to keep us informed in the event of a pregnancy.

Descriptive statistics were performed. The primary endpoint was progression-free survival calculated from the date of surgery to the date of recurrence or last available follow-up visit. The Kaplan–Meier survival estimate was calculated using the STATA version 13.1 software (Stata Corp., College Station, Tx).

RESULTS

A simple vaginal trachelectomy was performed in 42 patients and a large cold knife cone in eight patients with early-stage cervical cancer according to surgeon preference. [Table 1](#) summarizes patient and tumor characteristics. The median age was 29 years (range: 21–44) and 35 (70%) patients were nulliparous. Eleven patients had stage IA1 with LVSI, 13 patients had stage IA2, and 26 patients had stage IB1. All tumors measured <2 cm (based on MRI measurements, clinical examination, and tumor size dimension measured from the diagnostic specimen) except in three patients whose lesions were confined to a polyp. The majority (n=26) of patients had squamous histology, 20 patients had adenocarcinomas, and four patients had other histologic subtypes (adenosquamous, clear cell x 2, and undifferentiated). Over half of the patients (58%) had grade 1 lesions and the majority (66%) did not have LVSI.

In terms of the diagnostic procedure, 30 (60%) patients had a LEEP, 11 patients a conization, six patients a cervical biopsy, and three patients an excision of a polyp that turned out to be

Table 1 Patients' and tumor characteristics (n=50)

Age	
Median (range)	29 (21-44)
Gravida	
G0	35 (70%)
G1	15 (30%)
Stage	
IA1 + LVSI	11 (22%)
IA2	13 (26%)
IB1	26 (52%)
Histology	
Squamous	26 (52%)
Adenocarcinoma	20 (40%)
Adenosquamous	1 (2%)
Clear cell	2 (4%)
Undifferentiated	1 (2%)
Grade	
1	29 (58%)
2	13 (26%)
3	8 (16%)
LVSI	
No	33 (66%)
Yes	15 (30%)
Suspicious	2 (4%)
Diagnostic procedure	
LEEP	30 (60%)
Cone	11 (22%)
Cervical biopsy	6 (12%)
Excision polyp	3 (6%)
Margins diagnostic procedure	
Positive	42 (84%)
Negative	6 (12%)
Unknown	2 (6%)

LEEP, loop electrocautery excision ; LVSI, lymphovascular space invasion.

malignant. Eight patients had negative margins on the diagnostic specimen: four subsequently underwent a therapeutic cone, four a trachelectomy, and none had residual disease in the final specimen. Conversely, margins of the diagnostic specimen were positive for either invasive or preinvasive disease in 42 (84%) patients. Despite that, there was no residual cancer in the trachelectomy specimen in 60% of patients: 22 (44%) patients had no residual disease and eight (16%) patients had only preinvasive residual disease. Margins of the trachelectomy specimen were negative in 49 (98%) patients (Table 2). One patient had positive endocervical margins. She was offered definitive hysterectomy but she elected to have a second trachelectomy which showed only residual low-grade lesion with negative margins.

Table 2 Pathology results (n=50)

Trachelectomy specimen	N (%)
No residual disease	22 (44%)
Preinvasive disease	8 (16%)
Invasive disease	20 (40%)
Margins	
Negative	49 (98%)
Positive	1 (2%)

Lymph node assessment was performed laparoscopically in all patients. Thirty-five (70%) patients had a complete pelvic lymph node dissection with a median of 15 lymph nodes per patient (range; 7–33). Fifteen (30%) patients had SLN mapping alone (median of four nodes, range, 2–8) provided bilateral SLN identified at surgery and negative frozen section (Table 3). All SLN were submitted for ultrastaging on final pathology. Three patients had isolated tumor cells and one had a micrometastasis. They were all located in the SLN (one patient had isolated tumor cells in two SLN). All occurred in patients who also had complete lymph node dissection and all the other lymph nodes were negative. Interestingly, the two patients with clear cell histology had positive SLNs.

The median follow-up time was 76 months (range, 1–140). The progression-free survival and overall survival at 5 years were 97.9% and 97.6%, respectively (Figure 1). Only one patient was lost to follow-up. There was one recurrence previously reported.²¹ Briefly, this patient presented a pelvic recurrence post-trachelectomy for which she received chemoradiation. A hysterectomy was performed afterwards for intractable pain and showed only endometriosis on pathology. The patient recurred 6 months' later and underwent a total pelvic exenteration but eventually died of disease. Another patient died of metastatic breast cancer: her cervical cancer follow-up was normal. A 21-year-old patient had clear cell carcinoma. A micrometastasis was identified in a SLN on final pathology (negative on frozen section). She received two cycles of adjuvant chemotherapy (carboplatin/paclitaxel) but she refused to continue because of toxicity. On follow-up, a cervical biopsy showed low-grade lesion and surprisingly a focus of LVSI.

Table 3 Lymph node evaluation (n=50)

	N (%)	Node count median (range)
Lymph node assessment		
SLN mapping + BPLND	35 (70%)	15 (7–33)
SLN mapping alone	15 (30%)	4 (2–8)
Lymph node status		
Negative	46 (92%)	
Positive	4 (8%)	
Isolated tumor cells	3	
Micrometastasis	1	

BPLND, bilateral pelvic lymph node dissection; SLN, sentinel node mapping.

Original research

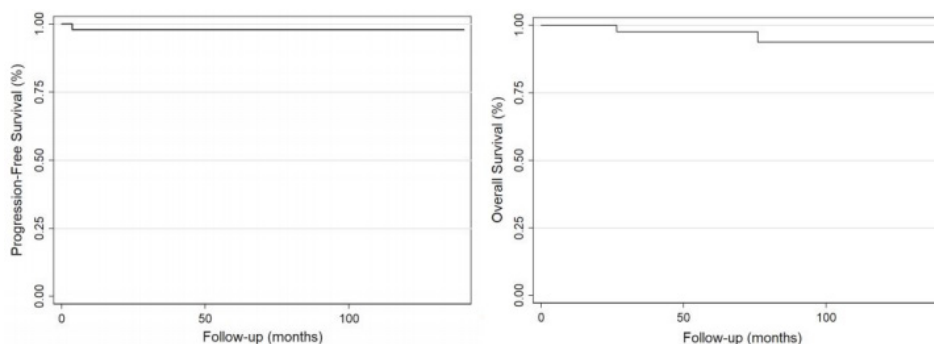


Figure 1 5-year progression-free and overall survival.

Definitive radiation therapy was offered but declined. So far, she remains without evidence of disease.

During follow-up, 11 (22%) patients had an abnormal Pap test (low-grade intraepithelial lesion, atypical glandular cells, and atypical squamous cells), but none developed a cancer recurrence. Two patients have low-grade lesions followed conservatively. Three patients chose to have a definitive hysterectomy, none had residual disease. In addition, 46 (92%) patients had a HPV-DNA test during follow-up and all tested negative except in one case. A permanent cerclage was placed in 24 (48%) patients. The decision to place the cerclage was left to surgeon discretion according to the amount of residual cervical tissue after the trachelectomy. Eight patients developed cervical stenosis, four were symptomatic, and only one required dilatation in the operating room. The other three patients were managed conservatively and placed on continuous oral contraceptives.

In terms of obstetrical outcome, 27 patients have become pregnant for a total of 40 pregnancies (Table 4). First trimester miscarriage occurred in five (12.5%) patients and one patient miscarried early in the second trimester at 15 weeks. Three patients delivered with prematurity at 34.4, 35, and 35 weeks without complications and all the other pregnancies (30 or 75%) ended >36 weeks. One pregnancy is still ongoing. One patient required opening of the cervical os with a small LEEP in the operating room. An intra-uterine catheter was left in place and she successfully got pregnant following intrauterine insemination through the catheter. Six patients without a cerclage attempted vaginal deliveries: four were successful and two had a Cesarean for failure to progress. All the other patients had elective cesarean section.

Eight (16%) patients have experienced fertility problems. One was not investigated but has asymptomatic cervical stenosis, one had failed two in-vitro fertilization attempts prior to the trachelectomy (endometriosis) and failed again twice following surgery. Two patients had infertility related to male factors: one attempted

unsuccessfully in-vitro fertilization x four and the other patient failed seven intrauterine insemination attempts. One had tubal blockage and attempted in-vitro fertilization unsuccessfully. Three patients with fertility issues got pregnant with the help of assisted reproductive technology: one was diagnosed with stage 2 endometriosis at the time of the trachelectomy but was able to conceive after intrauterine insemination. One infertility was possibly due to a 6 cm fibroid: she got pregnant with intrauterine insemination and ovulation induction. Lastly, one patient age 46 was successful in getting pregnant following in-vitro fertilization and delivered at term.

DISCUSSION

Oncologic outcome

Our study showed that the 5-year progression-free and overall survival were 97.9% and 97.6% respectively, with only one cancer recurrence and death (2%). To our knowledge, this is the largest single center series on simple trachelectomy in early-stage cervical cancer. Our oncologic data compares very favorably with the literature and supports the concept of less radical surgery in patients with lesions <2 cm who wish to preserve their fertility.¹⁶ A group from Turkey recently reported a small series of 14 simple trachelectomies and none have recurred.²⁰ They reviewed the literature on 291 cases and showed an overall recurrence rate of 4%, while two other reviews reported rates of 1.6% and 1.8%.^{16 19 20}

In our series, one patient (2%) was found to have lymph node micrometastasis and three had isolated tumor cells. All were in the SLN only group and all were missed on frozen section. The two patients with clear cell histology had lymph node involvement (one isolated tumor cell and one micrometastasis), emphasizing that this histologic subtype is associated with higher risk. The management of low-volume lymph node metastasis is controversial in cervical cancer and is particularly challenging in young women who wish to preserve fertility and ovarian function.²² Indications for adjuvant treatment in patients with intermediate risk factors following surgery is a matter a debate. Recently, Cibula et al compared two cohorts of patients with the “Sedlis criteria” who received adjuvant radiation following radical hysterectomy to a cohort of patients followed conservatively without adjuvant treatment, and found no significant differences in outcome.²³ In the future, one interesting avenue would be to explore the role of adjuvant chemotherapy in node positive patients, particularly in young women, in order to preserve ovarian and uterine function. Lee et al reviewed two

Table 4 Obstetrical outcome (n=40)

Obstetrical outcome	N (%)
First trimester loss	5 (12.5%)
Second trimester loss (15 weeks)	1 (2.5%)
Premature deliveries (< 36 weeks)	3 (7.5%)
Term deliveries (> 36 weeks)	30 (75.0%)
Ongoing pregnancies	1 (2.5%)

randomized trials and 11 observational studies comparing adjuvant chemoradiation to adjuvant chemotherapy alone after radical surgery for cervical cancer.²⁴ They concluded that adjuvant chemotherapy showed similar survival outcomes and appeared to reduce distant recurrence.

There are two important ongoing prospective cohort studies on conservative management of early-stage cervical cancer. GOG 278 is a prospective quality of life study looking at bladder, bowel, and sexual function following conservative surgery and whether it is associated with better physical function and less toxicity. It is nearing completion and data should be available soon.²⁵ Preliminary data from the ConCerv trial out of MD Anderson Cancer Center have been presented at the IGCS meeting in Rio de Janeiro in September 2019.²⁶ This is a phase II prospective study of 100 patients undergoing simple hysterectomy/cone with SLN mapping alone in patients with cervical cancer measuring <2 cm. Despite very rigorous patient selection and central pathology review (excluding grade 3 adenocarcinoma and presence of LVSI), five patients (5%) had lymph node metastasis. With a median follow-up of 25 months (range, 5–60), four recurrences have been identified: one locally on the residual cervix 3 months' post cone, one in the pelvis and lungs 11 months' post-inadvertent simple hysterectomy, one in an inguinal lymph node 10 months' post-inadvertent simple hysterectomy, and lastly, one in the pelvis 7 years' post-cone.²⁶ So, recurrences can occur even in carefully selected and carefully managed patients.

A recent study analyzing data from the National Cancer Database in the United States reported worrisome results, suggesting a 55% increase in mortality (corresponding to a 5-year survival difference of 2.9%) in women with stage IB1 disease who underwent a simple compared with a radical hysterectomy.²⁷ This study suffers from significant and serious biases, including the fact that up to 33% of patients who underwent a simple hysterectomy did not have any lymph node assessment (compared with 4.7% in the radical hysterectomy group, $P < 0.001$). Not surprisingly, statistically more simple hysterectomy patients received adjuvant radiation and chemotherapy ($P < 0.001$). As suggested in the accompanying Editorial, important prognostic variables based on histo-pathological features were missing or incomplete, and more importantly, information on how tumor size was established is lacking.²⁸ According to the authors, simple hysterectomy was more likely to have been performed in older women, black women, and in non-academic centers which could be a reflection of healthcare disparity. Lastly, the nature of the database precludes complete data on recurrence rate, site of recurrence, or cause of death, and type of surgeon performing the surgery. Nevertheless, despite its weaknesses, this study reminds us that meticulous preoperative evaluation of the tumor size by imaging and rigorous pathological evaluation of the diagnostic specimen is critical to ensure safe oncological outcome following less radical surgery.

Follow-up

Long-term follow-up by experienced colposcopists/gyn oncologists following fertility-preserving surgery is essential. In a 10-year follow-up study of conization in early stage cervical cancer, Tomao et al reported that six of seven recurrences were local and occurred on the residual cervix.²⁹ We believe that HPV testing is important in the follow-up of those patients and we strongly encourage patients to receive HPV vaccination to hopefully reduce the risk of HPV re-infection.

Obstetrical outcome

Our data shows excellent obstetrical outcome, with a total of 40 pregnancies, only five first trimester loss, and one second trimester loss (15 weeks). Only three pregnancies ended with mild prematurity (34–35 weeks), and all the others (75%) ended beyond 36 weeks of gestation. Most women delivered by elective cesarean section, although four delivered vaginally. Interestingly, most patients without a cerclage were delivered by Cesarean section, probably because of the fear of obstetrical complications, namely issues with cervical dilatation from the short, often stenotic and scarred cervix. A meta-analysis concluded that conization seems to result in better pregnancy outcome compared with radical trachelectomy with similar rates of recurrence and mortality.¹⁷ Similarly, Bentivegna reviewed the literature on 944 pregnancies and noted that prematurity was significantly lower after simple trachelectomy and cone compared with radical trachelectomy.¹⁸ Fokom Domgue et al recently conducted an extensive literature review and concluded that following conization/simple trachelectomy, nearly 75% of conceptions have resulted in the birth of a living newborn.¹⁹ The same results have been reported by Demirkiran et al.²⁰ In the ConCerv trial, nine pregnancies have been reported, with 75% delivering at term.²⁶ Altogether, the above data would suggest that in low-risk patients, the balance of obstetrical outcome is in favor of a simple trachelectomy.

As outlined by Fokom Domgue et al, there are no criteria by which to decide between a cone and a simple trachelectomy.¹⁹ We agree that in general, more cervical tissue is removed with a trachelectomy and it is probably a better option in patients with more extensive and visible lesions, whereas conization may be sufficient in patients with no evidence of residual disease. In our series, up to 60% of patients had either no residual disease or only pre-invasive lesions in their trachelectomy specimen. Routine cerclage may not be necessary in all cases, particularly following a conization or when a sufficient amount of residual cervix is present following trachelectomy. However, the exact amount of residual cervix that would be considered sufficient for not placing a cerclage is not well defined, and should be further studied. One of the advantages of not placing a cerclage is the possibility of allowing vaginal deliveries.

Fertility outcome

In our series, eight patients had fertility issues, some of which were not directly related to the trachelectomy itself (male factor in two, prior history of infertility, endometriosis, and fibroid). Three patients have been able to conceive following the support of reproductive technologies. Cervical stenosis remains a significant problem following the trachelectomy procedure. In our series, eight patients had cervical stenosis, four of which were symptomatic. In one patient, the stenosis was clearly the cause of infertility. We were able to open the cervical os with a small LEEP under anesthesia, and introduced a pediatric Foley catheter in the uterine cavity. Two weeks' later, the patient was inseminated and got pregnant. In a recent review, Shah et al concluded that up to 74% of patients suffer some type of complications following radical trachelectomy, and that cervical stenosis is the most common problem in up to 33% of cases.³⁰ Authors concluded that a significant proportion of women do not receive adequate reproductive counseling prior to the trachelectomy.

In summary, based on our data, we believe that in carefully selected patients with low-risk small size disease (<2 cm), a simple trachelectomy and lymph node assessment is a safe oncologic option for

young women who wish to preserve fertility. Obstetrical outcomes are superior compared with more radical procedures. Larger prospective studies are needed to confirm the safety of this approach, to help better define preoperative selection criteria, and obtain more data on oncologic and obstetrical outcome. We believe it will become the new standard of care for these patients, although a randomized trial comparing a simple trachelectomy vs radical trachelectomy is unlikely to be done. Standardization of the simple trachelectomy technique (compared with a conization) would also be useful. Lastly, review of all the preoperative diagnostic procedures (such as LEEPs and cone) by expert gynecologic pathologists is of paramount importance to estimate as precisely as possible the size of the lesion. This is particularly challenging when patients have had several procedures, sometimes removed in several pieces, making margin status and lesion size evaluation very difficult. In addition, high-quality pelvic MRI with diffusion study and review of the films with expert radiologists is essential prior to surgery. All these measures will ensure that only patients with truly low-risk small-volume disease are offered this ultraconservative treatment option. Therefore, these patients should be thoroughly evaluated and only managed by experienced gynecologic oncologists.

Contributors Study design, writing: MP. Data analysis: MP, JG. Data collection, review, editing: MCR, AS, JG, MP.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Participants' data are de-identified and collected in a database available upon request from Dr Marie Plante: marie.plante@crrhdq.ulaval.ca.

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