

Fertility-Sparing Surgery for Early Cervical Cancer—Approach to Less Radical Surgery

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Objective: To evaluate whether certain patients with early-stage cervical cancer are candidates for less radical surgery when considering fertility-sparing surgery.

Design: Prospective cohort study.

Setting: Two gynecologic cancer centers (St Thomas' Hospital, London; and West Kent Gynaecological Cancer Centre, Maidstone).

Population: Women with early-stage cervical cancer (n = 66) undergoing fertility-sparing surgery, either simple (SVT) or radical vaginal trachelectomy (RVT).

Methods: Prospective clinical data collection and review of patient notes, pathology and radiology data, and pregnancy outcomes.

Main Outcome Measures: Postoperative complications, surgical specimen histologic analysis, follow-up data, and obstetric outcome.

Results: A total of 66 women underwent either SVT (n = 15) or RVT (n = 51), with pelvic lymphadenectomy, for stage IA2 or IB1 cervical cancer. There was no residual disease in the SVT specimen in 53% versus 29% after RVT. Clear surgical margins in 100% of SVT specimens with residual disease versus 94% after RVT. Two patients had positive lymph nodes after RVT; one of these declined adjuvant treatment until after egg harvesting and subsequently died of disease (1.5%). Median follow-up was 96 months (range, 12–120 months). One patient had a mid vaginal recurrence (1.5%). Twenty-four women have tried to conceive to date, with 14 women having 17 live births. Live birth pregnancy rate was 70.8%.

Conclusions: It is possible to select patients for a less radical fertility-sparing procedure through identification of measurable low-risk factors and thus reduce the morbidity caused by conventional RVT. The selection criteria should be stringent and applied within the setting of a cancer center.

Key Words: Trachelectomy, Pregnancy, Fertility, Cervical cancer

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In the UK, there has been an increase in the incidence of invasive cervical cancer in young women aged 25 to 34 years.^{1,2} This increase has been seen in both screen-

detected and symptomatic early-stage invasive cancers of the cervix. It seems that as the mean age of first intercourse has decreased the national screening program's peak

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incidence of screen-detected cervical carcinoma has moved to a lower age group. In addition, in Western countries, the maternal age at first pregnancy has increased such that more women with a diagnosis of cervical cancer have not yet completed their families. As a result of these changes, fertility-sparing surgery for early cervical carcinoma has become more desirable during the course of the last 2 decades.

For more than a century, the standard treatment for early-stage cervical cancer has been radical hysterectomy (abdominal or vaginal) with pelvic lymphadenectomy. This procedure involves removal of the uterus with or without the adnexa, part of the parametrium, upper vagina, and uterosacral ligaments and renders a woman infertile.^{3,4} Burghardt and Holzer⁵ in 1977 questioned the therapeutic necessity of removal of the uterine corpus and the adnexa in the management of small-volume cervical tumors. He later described 16 women with small-volume stage IB cervical cancer (old staging) managed conservatively with cone biopsy or simple hysterectomy alone with no recurrences.⁶ In the 1990s, Dargent et al⁷ addressed the fertility of young women with cervical carcinoma and described a modification entailing conservative surgery without compromising fertility and at the same time treating cancer with acceptable oncologic efficacy. He named this procedure "radical trachelectomy," which represents a compromise between conservative treatment (cone biopsy or simple hysterectomy) and radical hysterectomy (radical abdominal or radical vaginal hysterectomy) with pelvic lymphadenectomy in the surgical treatment for invasive cervical cancer. Subsequently, he published 48 cases treated by this new technique with 10-year follow-up and reported 2 recurrences.⁸

Since the introduction of radical trachelectomy by Dargent, several case series have been published using his technique or modification of his technique via an abdominal approach. In these publications, the surgical resection has been described to be similar in extent to Dargent's technique irrespective of the size of the primary cervical lesion.^{9–11} A recent study by Frumovitz et al¹² demonstrated that cervical cancers of 2 cm or smaller with no lymphovascular space invasion (LVSI) have no parametrial invasion. Schmeler et al¹³ reviewed several studies demonstrating that parametrial involvement in cervical carcinomas less than 2 cm is less than 1%. This observation supports the concept of less radical surgery for this group of patients in the form of simple trachelectomy or cone biopsy. In their series of 26 patients, Rob et al¹⁴ presented their experience with less radical fertility-sparing surgery in this patient cohort.

We present our data on patients with early cervical cancer treated by fertility-preserving surgery. The objective of this study was to evaluate whether certain patients with early-stage cervical cancer are candidates for even less radical surgery when considering fertility-sparing surgery.

MATERIALS AND METHODS

This paper reports a series of 66 patients treated with fertility-preserving surgery over a period of 15 years (1995–2010) in 2 cancer centers in the South East of England (St Thomas' Hospital, London and the West Kent Cancer

Centre, Maidstone, UK). Surgery has been standardized by all participating surgeons performing this procedure at both centers. We performed 2 types of procedure as fertility-sparing surgery for early cervical carcinoma. Since 2003, for low-risk patients (tumor size <1 cm diameter, no LVSI, and tumor grade 1 or 2) we performed simple vaginal trachelectomy (SVT). For high-risk cases (tumor diameter <2.5 cm, LVSI positive, and all grade 3 tumors) patients underwent radical vaginal trachelectomy (RVT). The procedure incorporates the term *vaginal* to differentiate from the abdominal approach described by others.¹¹

All patients expressed their desire to preserve fertility and were counseled about the limited experience worldwide with these procedures and the risk of possible subsequent hysterectomy in the event of involved margins. Informed consent was obtained from all patients. Preoperative work-up included a magnetic resonance imaging with or without a computed tomographic scan of the abdomen and pelvis, an examination under anesthesia (EUA), and cystoscopy for clinical staging of the disease as recommended by the International Federation of Gynecology and Obstetrics. The histologic findings, radiological imaging, and the EUA findings were reviewed at a multidisciplinary meeting (MDM) before offering the patient fertility-sparing surgery either by SVT or RVT, and pelvic lymphadenectomy. The decision relied heavily on pathologic criteria as specified earlier.

The RVT procedure used was an almost identical technique to that previously described by Dargent et al,⁷ with the difference that less parametrium was taken (1–2 cm), and less uterosacral ligaments (1–2 cm). Simple vaginal trachelectomy involved removal of the cervix only. Circumferential incision around the cervix was made first with macroscopically clear margins of at least 1 cm. The bladder was mobilized and pushed proximally with the tissue around the cervix dissected as for a vaginal hysterectomy. The main uterine arteries were preserved, and only descending branches were ligated. The cervix was transected below or at the internal cervical os to allow safe placement of a cerclage suture (No. 1 nylon). The vaginal vault was then sutured to the resection edge of the lower uterine segment covering the cervical cerclage suture. The criteria used for selecting the patients for SVT were as follows:

- LLETZ LOOP or cone biopsy specimen with tumor-free margins
- Tumor not larger than 1 cm in biggest diameter
- No LVSI
- Only grades 1 and 2 tumors
- All other tumors required an RVT

At the start of the series, we performed open extra-peritoneal pelvic lymphadenectomy through a transverse suprapubic incision. Since 2002, laparoscopic transperitoneal lymphadenectomy was introduced for lymph node dissection. Nineteen patients had laparoscopic sentinel node (SLN) detection followed by formal lymphadenectomy. In this group, one patient had 2 positive lymph nodes, and both nodes were identified as SLNs.

We did not routinely use frozen section (FS) to assess the resection margins intraoperatively. We believe that if

parametrial margins are positive in the surgical specimen, the treatment of choice is chemoradiation and not radical hysterectomy. When the proximal cervical margin is involved, then either a radical hysterectomy or simple hysterectomy is advised depending on the site and size of the residual tumor in the surgical specimen. We do not use a 2-stage procedure to assess the SLN, as we cannot justify 2 procedures most of the patients; neither do we send the SLN for FS, as some tissue is wasted during the FS cutting, which may result in microscopic disease being missed. We used FS only in cases of bulky lymph nodes for confirmation of metastatic tumor involvement; and in these cases, we aborted surgery in favor of chemoradiation as the first choice of treatment. All surgical specimens were reviewed by dedicated gynecologic oncology pathologists. Table 2 shows the details of the surgical specimens.

Patients were followed up at 3, 6, and 12 months after surgery and annually thereafter with clinical and cytologic examination. The maximum follow-up was for 10 years, and the minimum was for 12 months (median, 96 months). Patients were advised to wait 12 months before trying to conceive and encouraged to try naturally for at least 12 months before resorting to infertility investigation or referral to an assisted conception unit. Patients who conceived were initially seen by the gynecologic oncologist after confirmation of a viable intrauterine pregnancy by transvaginal ultrasound and were then referred to an obstetrician. The obstetrician regularly communicated with the gynecologic oncologist, and the patient was managed as high risk under the care of the obstetric consultant team. None of our patients were given prophylactic antibiotics during their pregnancy. Throughout the antenatal period, ultrasound assessment of the lower uterus

was performed to check the cerclage suture. Prophylactic oral tocolytics were given to patients from 24-week gestation until 38 weeks up until 1999 to prevent premature labor, but this practice was discontinued from 2000. All our patients were delivered by elective cesarean delivery between 37 and 38 weeks. Patients returned for oncology follow-up between 6 to 8 weeks after delivery.

RESULTS

A total of 66 consecutive patients wanting fertility preservation were referred to the 2 cancer centers with stage IA2 and stage IB1 cervical cancer and were treated with either SVT (23%) or RVT (77%) and pelvic lymphadenectomy. Fertility was preserved in 62 patients (93.9%), whereas 2 patients had hysterectomy for positive margins on trachelectomy specimen and 2 patients received RT for involved pelvic lymph nodes. Patients' characteristics are shown in Table 1. Of the 15 women who underwent SVT, 5 were stage IA2 and 10 had stage IB1 (6 had adenocarcinoma and 9 squamous cell carcinoma; 8 were grade 1; 7 were grade 2, and none had LVSI). The initial tumor size in patients who underwent SVT and pelvic lymphadenectomy was 6 to 10 mm (mean, 8 mm). Fifty-one patients underwent RVT and pelvic lymphadenectomy for stage IA2 in 2 patients and stage IB1 in 49 patients (24 patients had adenocarcinoma, 2 patients had adenosquamous, and 25 patients had squamous cell carcinoma: 4 were grade 1; 38 were grade 2; 9 were grade 3 tumors, with LVSI negative in 17 and LVSI positive in 34 patients). The tumor size at initial presentation in the patients who underwent RVT ranged between 7 and 25 mm (mean, 18 mm).

TABLE 1. Patients' characteristics

		SVT (n = 15)	RVT (n = 51)
Age, mean (range), yrs	28 (20–40)	—	—
FIGO stage	—	—	—
IA2	—	5	2
IB1	—	10	49
Tumor size, mean (range), mm	—	8 (6–10)	18 (7–25)
Histologic subtype	—	—	—
Squamous cell carcinoma	34	9	25
Adenocarcinoma	30	6	24
Adenosquamous carcinoma	2	0	2
Grade of tumor	—	—	—
1	12	8	4
2	45	7	38
3	9	0	9
Lymphovascular space involvement (LVSI positive)	34	0	34
Size of primary lesion on MRI, mean (range), mm	—	—	—
Squamous cell cancers (n = 34)	14.5 (8–26)	—	—
Adenocarcinoma (n = 30)	10 (6–20)	—	—
Adenosquamous (n = 2)	18, 21	—	—

TABLE 2. Details of the surgical specimens

	SVT (n = 15)	RVT (n = 51)
Size of surgical specimen		
Mean (range), mm	20 (15–24)	38 (32–45)
Residual disease in surgical specimen, n (%)		
No residual disease	8 (53)	15 (28)
Residual disease present	7 (47)	36 (71)
Resection margins in patients with residual disease		
Clear of tumor	7	34
Involved with tumor	0	2*
Lymph node status		
Number of lymph nodes removed, mean (range)	22 (18–32)	28 (18–54)
Patients with positive nodes	0	2†
Patients with negative nodes	15	49

The second patient had micrometastases in 2 nodes and had chemoradiation and is disease free 12 months later.

*Of the 2 patients with involved margins, one had adenocarcinoma with involved margin at the lower uterine end and had a subsequent hysterectomy, which showed no residual tumor. The second patient had squamous cell carcinoma at the uterine end of the margins and subsequently, had a radical hysterectomy. Both women are well and disease free 3 and 8 years after treatment.

†One patient who had positive lymph node had a grade 3 poorly differentiated squamous cell carcinoma and was advised chemoradiation but only received radical pelvic radiotherapy and died 30 months later with distant recurrence.

After surgery, the trachelectomy specimen underwent detailed histologic assessment for residual tumor and involvement of resection margins, and the lymph nodal tissue was also assessed to exclude metastasis. The histologic results are illustrated in Table 2.

There was no residual disease in the surgical specimen in 53% (8/15) after SVT versus 29% (15/51) after RVT. Surgical margins were clear in 100% of specimens with residual disease after SVT versus 94% after RVT. Of the 2 patients who had margins involved with tumor after RVT, one had adenocarcinoma at the proximal endocervical margin and was advised a simple hysterectomy with conservation of ovaries. The hysterectomy specimen had no residual tumor. The second patient was multiparous (one previous live baby) diagnosed with a grade 3 squamous cell carcinoma and underwent a radical hysterectomy, the surgical specimen contained a 3-mm residual disease. Both these patients are disease free 3 and 8 years, respectively.

Lymph node involvement was demonstrated in 2 patients who underwent RVT. One of these 2 patients had SLN detection, and 2 SLNs were harvested, both demonstrating microscopic tumor. This patient presented with vaginal discharge and bleeding at 16 weeks' gestation and was diagnosed with a stage IB1 squamous cell carcinoma with a tumor size of 26 mm, grade 2 with LVSI. She expressed a strong wish to preserve fertility. After lengthy counseling, she was advised to have medical termination of her pregnancy and subsequently had RVT and SNL detection followed by a pelvic node clearance. The second patient had one positive node of the 36 lymph nodes removed. This patient had a grade 3 squamous cell carcinoma, which was LVSI positive; and the size of the lesion was 20 mm. Both these patients were advised to have chemoradiation. One received chemoradiation and is alive and disease free 12 months after her treatment. The

TABLE 3. Postoperative outcomes

	SVT (n = 15)	RVT (n = 51)
Irregular vaginal bleeding	0	3 (5.9%)
Vaginal vault granulation causing postcoital bleeding	0	2 (3.9%)
Amenorrhea in immediate postoperative period	0	2 (3.9%)*
Late amenorrhea and hematometra (due to late stenosis of os)	0	2 (3.9%)†
Pelvic lymphocele	0	1 (1.9%)
Mild leg lymphedema	1 (6.6%)	0
Vaginal vault recurrence	0	1 (1.9%)‡
Death due to distant recurrence	0 (0%; 95% CI, 0.0%–21.8%)	1 (1.9%; 95% CI, 0.0%–10.4%)

Grade 2 adenocarcinoma FIGO stage IB1 (primary lesion, 10 mm) and had had no residual tumor in the radical trachelectomy specimen, with all 36 lymph nodes being negative. Treated with chemoradiotherapy and is disease free 5 years later.

*Of the 2 patients who had amenorrhea soon after operation, one had postpill amenorrhea and one had vaginal opening stenosis requiring the removal of the cerclage suture and dilation of the vaginal opening.

†Both cases of late stenosis and hematometra required hysterectomy. One had extensive vaginal scarring and closure of the opening 35 months after her RVT, whereas the other patient had scarring 84 months later, after a cesarean delivery.

‡The patient who had recurrence at the vaginal vault had had an RVT for a grade 2 adenocarcinoma FIGO stage IB1 (primary lesion, 10 mm) and had had no residual tumor in the radical trachelectomy specimen, with all 36 lymph nodes being negative. Treated with chemoradiotherapy and is disease free 5 years later.

CI, confidence interval.

TABLE 4. Obstetric outcome of fertility-sparing surgery

	SVT (n = 15)	RVT (n = 51)
No. patients who tried to conceive (24 [36%] of 66 patients) (%)	5 (33)	19 (37)
No. pregnancies resulting in a live birth out of total trying to conceive (≥38 weeks' gestation), (%)	4 (80)	14* (74)
Miscarriage <12 weeks' gestation	0	1 (after IVF)
Second trimester miscarriage (due to spontaneous rupture of membranes of IVF twin pregnancy at 22 weeks)	0	1
Ectopic pregnancy (after IVF)	0	1

*Three women had 2 children after radical trachelectomy.

second patient only had radical pelvic radiotherapy after ovarian stimulation and egg retrieval for subsequent surrogate pregnancy, which resulted in twin babies. Unfortunately, this patient had recurrent tumor in the left supraclavicular node 12 months later and died with recurrent disease 18 months later.

The postoperative outcomes are shown in Table 3. Three patients had irregular vaginal bleeding after RVT and were treated with cyclical norethisterone after excluding recurrent disease by clinical, colposcopic, and cytologic examination. Two patients had vaginal vault granulation tissue confirmed on histologic finding after excision biopsy. Two women had amenorrhea soon after RVT. One was due to stenosis of the vaginal opening, which was treated by removal of the cerclage suture with dilatation of the uterine opening into the vault of the vagina with up to 7 Hegar dilator (this patient had adenocarcinoma, and the RVT specimen was 35 mm deep aiming to obtain a clear margin above the endocervical canal). This patient subsequently had regular menstruation and has been trying to conceive for 10 months. The second patient had postpill amenorrhea confirmed biochemically, and a transvaginal ultrasound showed inactive endometrium. The 2 patients after RVT had secondary amenorrhea (35 and 84 months after surgery). This was caused by scarring of the vaginal opening. Both patients required hysterectomy for hematometra. One patient had extensive paravaginal fibrosis and recanalization of the uterine cavity failed; hence, a hysterectomy was performed with the patient's consent. The second patient developed hematometra after a cesarean delivery and was found to have closure of the vaginal opening during the uterine wall repair at the time of her cesarean delivery. One patient who had RVT and extraperitoneal pelvic lymphadenectomy developed a moderate size pelvic lymphocele, which resolved spontaneously. Another patient developed mild lymphedema in both thighs after SVT and extraperitoneal lymphadenectomy.

One patient (1.9%) had recurrence in the vault of the vagina 30 months after RVT for a stage IB1 tumor, with a 10-mm initial tumor, grade 2 adenocarcinoma with no LVSI, and no residual tumor in the RVT specimen. The recurrent tumor was 5 mm at the mid vagina. She was treated with chemoradiation for her recurrent tumor and is disease free 5 years later.

Pregnancy Outcome

In our series, 24 women (36%) have tried to conceive to date, with 15 women having 18 live births. In the SVT group, 4 babies were born with 80% pregnancy rate; and in the RVT group, 14 babies were born with 74% pregnancy rate. All deliveries were at term with cesarean section. Table 4 shows the outcome of those women trying to conceive. There were no spontaneous second trimester miscarriages, but one patient required a hysterotomy to terminate her pregnancy at 22 weeks with chorioamnionitis. This patient had twin pregnancy after in vitro fertilisation (IVF) and had ruptured membranes at 22 weeks' gestation and developed signs of chorioamnionitis. This was the same patient who had a tubal ectopic pregnancy with her first attempt of IVF after her RVT for a 25-mm squamous cell carcinoma, grade 2, with no LVSI. She is currently considering a surrogacy. Four years later, she is disease free.

DISCUSSION

The reproductive results with RVT have shown to be satisfactory, although there seems to be a significant increase in premature deliveries^{8–10,15,16}; however, this has not been our experience. The rationale for less radical fertility-sparing surgery in women with early cervical cancer wanting fertility preservation has been debated by several gynecologic oncologists.^{12–14,17}

Several publications have attempted to identify low-risk cases of early cervical cancer by assessing both clinical and histologic parameters; and these women may be potential candidates for less radical surgery, such as large cone biopsy or simple trachelectomy.^{5,12,14,18–22} In our practice, these risk factors were assessed by initial clinical examination, review of the histology for low-risk factors (such as a lesion <1 cm, no LVSI, and histologic grades 1 and 2). Tumor volumetry might be a more precise way of assessing tumor size but needs further evaluation and standardization. By identifying these patients with low-risk factors (23%) before definitive surgery, we avoided extensive surgical dissection, reducing morbidity without compromising their oncologic outcome, but also retaining their reproductive potential. There is evidence to suggest that even with lesions up to 2 cm in diameter with other low-risk factors (no LVSI, grade 1 or 2 disease)

there is a very low risk of parametrial involvement ($<1\%$)¹³ and could be treated with SVT with 1-cm clear margins. Obviously, we did not want to compromise oncologic outcome and therefore conservatively used 1-cm tumor size for SVT in our series.

We did not use a 2-stage procedure as described by Rob et al.¹⁴ They described a preliminary lymphadenectomy (SLN dissection) to assess risk before performing a large cone or a simple hysterectomy. They included patients with grade 3 tumors (5 patients) and positive LVSI (10 patients) and reported positive lymph nodes in 4 patients. By strictly adhering to low-risk prognostic factors mentioned in our series, none of our 15 patients that underwent the less radical SVT have had recurrent disease to date (mean follow-up, 64 months). In the absence of LVSI, the risk of lymph nodal involvement is low.^{23,24} In our practice, we do not perform FS assessment intraoperatively to check resection margins, as our magnetic resonance imaging assessment of tumor borders has been accurate with only 2 patients having involved margins as shown in Table 2. One had no residual tumor, and the second had 3-mm residual tumor in the subsequent hysterectomy specimens.

We routinely insert a cervical cerclage using nylon in all our patients whether they had SVT or RVT. None of our patients had premature labor. All women who had had babies reached 37 to 38 weeks' gestation. In the series reported by Rob et al,¹⁴ they did not use cervical cerclage in any of their patients and had a 13% second trimester miscarriage rate and a premature delivery rate of 27%. The theoretical risk of the cerclage suture introducing infection is very small. Despite not using prophylactic antibiotics during pregnancy, none of our patients suffered premature labor or puerperal sepsis with the cerclage suture in situ. One patient with an IVF twin gestation had ruptured membranes at 22 weeks, and it is possible that the suture may have contributed to the rupture of membranes with subsequent chorioamnionitis, thus resulting in termination of pregnancy by hysterotomy.

In our series of 66 patients treated with fertility-sparing surgery, there was a 1.5% recurrence rate and 1.5% death rate; and no recurrences and death were recorded in the SVT group. This oncologic outcome is comparable to previously reported series in the literature. The pregnancy rate in patients attempting pregnancy is comparable with other published data. The live birth pregnancy rate among the all patients trying to conceive was 75% (SVT, 80%; and RVT, 74%). Our series had low first and second trimester miscarriage rates (1 patient in each trimester). Our only second trimester pregnancy loss was due to premature rupture of the membranes in a twin pregnancy, with all the other pregnancies reaching the third trimester with a successful outcome at 38 weeks. These favorable obstetric results may be due to our tendency to aim for a 1-cm circumferential margin of normal tissue during the surgery and to tailor the dissection of the parametrium to individual tumor size.

The one patient who had a vaginal recurrence after 30 months after an RVT did not have any high-risk factors, that is, no LVSI or any residual tumor in the RVT specimen. In this patient, the recurrent lesion was in the mid vagina and may be explained by a possible implantation process. This

patient was treated with chemoradiation and is disease free for more than 5 years.

Our series of 66 patients with a mean follow-up of 8 years demonstrates that the radicality of fertility-preserving surgery can be reduced provided that certain pathologic low-risk factors are present. In addition, importantly, oncologic outcome was not compromised, whereas morbidity was reduced and obstetric outcome improved.

CONCLUSION

Radical trachelectomy continues to be the fertility-sparing treatment of choice for patients with early cervical cancer. However, through the identification of measurable low-risk factors in these women, it may be possible to select patients for an even less radical fertility-sparing procedure and thus reduce the morbidity caused by conventional RVT as originally described by Dargent. The selection criteria for less radical surgery should be stringent and be made only by a qualified multidisciplinary team in a cancer center. In those patients who request fertility-preserving surgery, the other key players in this decision-making process are an experienced gynecologic oncology pathologist, radiologist, and surgeon.

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Contribution of authorship: KSR, AJP, and OD conceived, designed and wrote the study as well as performed the surgery. SM performed the surgery and contributed to writing. MC and GC performed the histologic analysis and retrieved pathology data and contributed to writing. GM and MK retrieved the data from patients' notes and infoflex data system and contributed to writing.

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