



Reproductive and oncologic outcome following robot-assisted laparoscopic radical trachelectomy for early stage cervical cancer



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HIGHLIGHTS

- A high fertility rate of 81% was seen following robotic radical trachelectomy.
- Robotic radical trachelectomy was associated with a low rate of preterm deliveries.
- Cancer recurrence after robotic radical trachelectomy equals alternative techniques.

ARTICLE INFO

Article history:

Received 26 November 2015

Received in revised form 27 January 2016

Accepted 31 January 2016

Available online 1 February 2016

Keywords:

Robot
Trachelectomy
Fertility
Pregnancy outcome
Recurrence

ABSTRACT

Objective. To investigate the reproductive and oncologic outcome following robotic radical trachelectomy for early stage cervical cancer.

Methods. All women with early stage cervical cancer planned for fertility-sparing robotic trachelectomy between December 2007 and April 2015 at two tertiary referral centers in Sweden were identified. Perioperative- and follow-up data was retrieved from prospective databases used for all robotic procedures at the respective institution and an additional review of computerized patient files was performed. Reproductive outcome evaluation was restricted to women with ≥ 12 months follow-up and an active wish to conceive. Oncological outcome was evaluated for all patients.

Results. Fifty-six women (3 stage IA1, 14 stage IA2 and 39 stage IB1) were included. The median age was 29 years (range 23–41). Median follow-up was 24 months (range 1–89). Seven trachelectomies were aborted in favor of a radical hysterectomy and/or chemoradiation due to nodal metastases or insufficient margins; two distant recurrences occurred in these women. A local recurrence was seen in two of the 49 women (4%) in whom the procedure was completed as planned. Seventeen of the 21 women (81%) in the reproductive follow-up group conceived - 16 naturally and one following IVF. Sixteen women (94%) delivered in the third trimester, 12 women (71%) in gestational week ≥ 36 . One (6%) second trimester delivery occurred.

Conclusion. The high fertility rate, low rate of premature deliveries and an acceptable rate of recurrence support the feasibility of robotic fertility-sparing radical trachelectomy in women with early stage cervical cancer.

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1. Introduction

Vaginal radical trachelectomy (VRT) in conjunction with laparoscopic pelvic lymphadenectomy to preserve fertility in women with early stage cervical cancer was first described by Dargent in 1994 [1]. Alternatively, a radical trachelectomy can be performed abdominally as an open or laparoscopic procedure [2–8]. More than 1200 cases of fertility-sparing trachelectomies have been published of which over 900 using the vaginal approach and over 250 live births have been reported in women following this procedure [9–11]. Radical trachelectomy is

considered as safe as a radical hysterectomy if strict selection criteria are applied [9, 11–14]. Fertility rates following the procedure are reported to be in the range of 50–80% while the proportion of prematurity is reportedly in the range of 48–60% [2–8, 10, 15].

Selection criteria include stage IA2 and IB1 cervical squamous, adenosquamous epithelial cancer or adenocarcinomas with a tumor size ≤ 2 cm. In addition, selected cases with stage IA1 cancer may be suitable for a radical trachelectomy. A more restrictive policy is recommended in case of high-risk histology such as clear cell or neuroendocrine cancer [9, 11–14].

The tumor should be possible to resect with sufficient margins while still allowing for the remaining cervix to be of an adequate length. There are no studies evaluating the risk of premature labor in relation to the length of the remaining cervix following RRT, but some authors suggest

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that the remaining cervix should be at least 10 mm long [13, 16]. A pre-operative magnetic resonance imaging (MRI) scan or a vaginal ultrasonography to measure the length of the cervix are important for the surgeon to plan the procedure and to select the minority of stage 1A1 patients where a RRT is preferable to a repeated conization.

Robotic radical trachelectomy (RRT) was first described in 2008 [17]. Since then, 58 cases and five pregnancies have been reported in English language literature [10, 18–23]. Vieira et al. reported 22 cases of RRT but follow-up was too short to evaluate pregnancy outcomes adequately [22]. A study on the reproducibility and accuracy of the procedure suggested that robotic surgery allows for an equal level of cervical resection, and superior positioning of the cervical cerclage compared to vaginal trachelectomy [19]. The fertility rates following abdominal and laparoscopic trachelectomies are reported to be lower (53–59% and 50–56% respectively) than after a vaginal approach (67–80%) and as RRT is comparable to these procedures to the extent of increased intra-abdominal surgery compared to VRT, fertility following RRT may potentially be impaired compared to the vaginal alternative [2–4, 6, 7, 10, 15].

Skåne University Hospital (SUH) and Karolinska University Hospital (KUH) are tertiary referral centers for gynecological oncologic surgery in Sweden. So far, more than 3000 women, with primarily gynecological cancers, have undergone robotic surgery at the two institutions. After having implemented robot assisted radical hysterectomies as a standard procedure, the first RRT was performed in December 2007 [17]. The aim of this study was to evaluate fertility, obstetric outcome and cancer recurrence following RRT.

2. Material and methods

All women with stage IA2 and stage IB1 cervical cancer planned for RRT between December 2007 and April 2015 were included using the same criteria throughout the study period. Women with stage IA1 cervical cancer were included only if at least one of the following criteria were met: lymphovascular space invasion, multifocal invasive lesions including patients with both squamous cell carcinoma and adenocarcinoma, or a cone biopsy with positive margins. Two consultant surgeons (JP and HF) performed the majority of the procedures. All women gave their informed consent and were operated in a single session, at one of the institutions (SUH) with the aid of lymphatic mapping for detection of sentinel lymph nodes (SLNs), either as a part of a closed study [24] or an ongoing study comparing radiocolloid with indocyanine green as tracers (adding approximately 20 min of operative time). According to the respective protocols, all pelvic lymph nodes were removed even if SLNs are found negative on frozen section with the exception of IA1–IA2 cervical cancers where only the SLNs are removed provided a bilateral distinct radiotracer or dye uptake is present [25].

The technique of RRT, with the preservation of the uterine arteries, has been described previously [17]. SLNs as well as the trachelectomy specimen were sent for frozen section adding time for the procedures. In case of a positive SLN, the RRT was abandoned in favor of a robotic radical hysterectomy and an oophorectomy with subsequent radiochemotherapy. In case of positive proximal margins of the trachelectomy specimen, an intraoperative evaluation was made whether an additional removal of the remaining cervix was possible or if a radical hysterectomy should be performed. The trachelectomy procedure was not abandoned based only on an estimated short remaining cervix during surgery apart from one case where the remaining cervix intraoperatively was considered too damaged by a previous large cone biopsy. At SUH, a 0-Prolene® suture (Ethicon GmbH., Norderstedt, Germany) was used as permanent cerclage throughout the study period while either an Ethibond Excel® 2-0 suture (Ethicon LLC., Livingston, Scotland) or a Gore-Tex® CV-2 suture (W.L. Gore & Associates LTD., Dundee, Scotland) were used at KUH (Table 2). Patients were controlled at least three times annually for the first two years, and then every six months for a minimum of five years post-surgery. Perioperative and postoperative

complications were recorded with special attention to cerclage erosion, cervical stenosis, and associated secondary problems. Postoperative complications were graded according to the Clavien-Dindo scale [26]. A Pap smear was taken at each follow-up. Additional investigations (biopsies, CT scan, PET CT, or MRI) were performed when indicated by symptoms. A measurement of the length of the remaining cervix and the position of the cerclage in relation to the inner cervical os was performed at postoperative follow-up. By gently pressing a standard vaginal ultrasonography probe against the cervix/vaginal apex, thus defining the distal margin, the remaining cervix, the inner cervical os and the cerclage were visualized. The mid inner cervical os was used as the proximal border [17]. The ultrasonographic cervical measurement was used as a parameter of surgical quality and to provide data on the potential effect of the cervical length on prematurity and fertility.

According to local treatment protocols, a free margin of 8 mm (SUH) or 5 mm (KUH) on a formalin fixed specimen was considered adequate.

In case of an isolated insufficient proximal cervical margin, a complete hysterectomy was recommended. External beam radiation (EBR), pelvic field (26 × 1.8 Gy) and concomitant weekly Cisplatin (4–6 × 40 mg/m²) was administered to node positive patients and/or patients with any other insufficient margins. One patient with insufficient circumferential margins in whom a hysterectomy was not performed received chemoradiation consisting of vaginal brachytherapy (5 × 5 Gy) and EBR with a total dose of 50.4 Gy and concomitant Cisplatin. Chemoradiation at occurrence was individualized.

Reproductive outcome was evaluated among women with at least 12 months follow-up who stopped taking contraceptive measures with an active intention and attempt to get pregnant, including assisted reproductive measures.

All women who became pregnant following RRT at SUH were prescribed prophylactic oral metronidazole (400 mg × 2) from gestational week (GW) 15 + 0 to 21 + 6. Women with a physically strenuous job (jobs including lifting and primarily standing and walking, i.e. health care and manufacturing industry) were prescribed sick leave from GW 20–25. At SUH sexual intercourse was prohibited throughout the pregnancy. All women were planned for a Cesarean delivery at GW 36–38.

An Institutional Review Board approval was obtained at both institutions.

For statistical analyses, we used the Chi square test and the Fischer's exact test. A *p*-value of <0.05 was considered significant.

3. Results

Fifty-six consecutive women (28 at SUH and 28 at KUH) with early stage cervical cancer (3 stage IA1, 14 stage IA2, and 39 stage IB1) were included in the study (Fig. 1). In seven cases, the planned RRT procedure was converted to a radical hysterectomy or aborted in favor of chemoradiation due to lymph node metastases or inadequate margins. One woman underwent a hysterectomy 19 months postoperatively due to prolonged bleeding. The remaining 48 patients were eligible for analysis. Patient characteristics and surgical data are described in Table 1. Median follow-up was 24 months (range 1–89 months). At KUH, one of the uterine arteries was sacrificed in two patients due to technical problems. Two early postoperative complications occurred at KUH; one vesicovaginal fistula and one compartment syndrome. The former was managed conservatively and a decompressive fasciotomy was performed in the latter. A long operative time of 472 min was believed to be a contributing factor. No further postoperative complications (<30 days) grade III or higher on the Clavien-Dindo scale occurred. One woman developed postoperative cervical stenosis and erosion of the cerclage was noted in four women (Table 1).

Twenty-one of the 32 (66%) women with minimum one-year follow-up (median 37, range 12–84 months) attempted to conceive, 16 (76%) succeeded through natural conception and one (5%) after in vitro fertilization (IVF) (Table 2). Of the four women who failed to conceive, one woman had a previous history of sub/infertility. The

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