



Vaginal Radical Trachelectomy for early stage cervical cancer. Results of the Danish National Single Center Strategy



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HIGHLIGHTS

- An unselected national danish single Center series of Vaginal Radical Trachelectomy
- Complete follow up and presentation of valid oncologic and reproductive outcome
- We show an extensive need of fertility treatment after Vaginal Radical Trachelectomy
- Centralization of this rare and complex procedure increases safety

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ABSTRACT

Objective. To present and evaluate an unselected national single center strategy with fertility preserving trachelectomy in cervical cancer.

In 2003 nationwide single-center referral of women for trachelectomies was agreed upon between all Danish departments performing cervical cancer surgery with the purpose of increasing volume, to increase surgical safety and facilitate follow-up.

Methods. Prospective data were recorded in the Danish Gynecological Cancer Database of all Vaginal Radical Trachelectomies (VRT) performed in Denmark between 2002 and 2013. Oncologic, fertility and obstetrical outcomes of 120 unselected consecutive VRTs were assessed.

To obtain complete follow-up about fertility treatment, pregnancy and obstetric outcome the women filled out an electronic questionnaire. Median follow-up: 55.7 months.

Results. 85.8% of the patients had stage IB1 disease, 68.3% squamous cell carcinomas, 30.0% adenocarcinomas and 1.7% adenosquamous carcinomas.

Six recurrences (5.1%) and 2 deaths (1.7%) occurred. Four women with adenocarcinomas (10.5%) had recurrences, compared to two women with squamous cell carcinomas (2.5%).

Seventy-two women (60.0%) desired to conceive and 55 women obtained a total of 77 pregnancies. Of the 72 women 40 were referred to fertility treatment.

First and second trimester miscarriage rates were 21.6% and 2.7%, respectively.

A total of 53 children were born of which 41 were delivered after gestational week 34.

Conclusion. This unselected national single center referral study confirms the oncological safety of Vaginal Radical Trachelectomy.

The complete follow-up regarding reproductive data, reveals a surprisingly extensive need of fertility treatment and due to the rate of prematurity, these pregnancies must be regarded as high-risk pregnancies.

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1. Introduction

Cervical cancer is the fourth most common cancer in women worldwide, with an estimated 528,000 new cases in 2012. The vast majority, around 85%, occurs in developing countries, where it accounts for almost 12% of all female cancers [1,2]. In these countries high-cost surgery such as robotic assisted trachelectomy will not be

accessible in the foreseeable future, making fertility preservation by radical vaginal trachelectomy for early stage cervical cancer a feasible surgical procedure.

According to Surveillance, Epidemiology and End Results (SEER), approximately 42% of all cervical cancer patients are diagnosed prior to the age of 40 years [3].

The psychosocial impact of cancer-related infertility is significant. However, up to 48% of women within reproductive age with early stage cervical cancer, formerly treated by radical hysterectomy, may be eligible for fertility preserving surgery [4].

Since Dargent first introduced Vaginal Radical Trachelectomy with pelvic lymphadenectomy (VRT) in 1994 [5], several studies have been published focusing on oncologic safety of VRT, with recurrence rates and disease free survival to be on par with radical hysterectomy, although the possible impact of adenocarcinoma histology continues to be uncertain [6–22].

In this study, we present our first series of 120 VRT performed between 2002 and 2013. The series represents all Danish cervical cancer patients treated by VRT, as the procedure was centralized to Copenhagen University Hospital Rigshospitalet from the onset of this procedure. The patients were examined and operated by a few specialists in gynecologic oncology. The objective is to evaluate the oncologic and reproductive outcomes.

2. Methods

From 2002 to 2013, 123 consecutive women with early stage cervical cancer planned for Vaginal Radical Trachelectomy were included. All pre-, intra- and post-operative data were prospectively recorded in a computerized database: The Danish Gynecological Cancer Database.

The surgical technique of VRT has been described in detail before [5,8]. Shortly, complete laparoscopic pelvic lymphadenectomy was performed to exclude lymph node metastases. When no macroscopic disease was found, the vaginal part of the operation continued by dissecting a 2 cm vaginal cuff, preserving about 1 cm of the cervix. The specimen was sent for immediate pathological examination, aiming for a free endocervical margin. Finally, a permanent cerclage was performed followed by the vagino-isthmic anastomosis [23].

VRT was performed if the patient had a wish for fertility-preserving surgery and the following selection criteria were met; histologically confirmed squamous, adenosquamous, or adenocarcinoma, stage IA1 with lymphovascular space involvement [LVSI], IA2 or IB1 of no more

than 2 cm, no evidence of spread to pelvic lymph nodes or any distant metastases on PET/CT.

All women underwent a preoperative PET/CT and if this revealed suspicion of spread to lymph nodes a two-step procedure was offered. Initially a laparoscopic lymphadenectomy was performed to clarify if the suspicious nodes were caused by reactive inflammation or tumor spread and followed by either trachelectomy or hysterectomy. In case of additional spread adjuvant of radiotherapy and concomitant chemotherapy treatment was offered.

Stages were according to the International Federation of Obstetrics and Gynecology (FIGO) and all patients except three, had a diagnostic cone before VRT, to confirm the stage and safety of the procedure. The time frame between the diagnostic cone and the trachelectomy was 6 weeks to ease surgical conditions at the time of trachelectomy.

Following detailed information about the risk of recurrence, postoperative complications and reproductive prognosis, written informed consent was obtained from all patients. Additionally, prior to surgery, the women had accepted that if more advanced disease – as evidenced by lack of free proximal margin – was found during surgery, a radical hysterectomy would be performed. In case that lymph node involvement was found and confirmed by frozen section, the operation would be interrupted and the patient would be referred to chemo-radiation therapy. Finally, patients were advised that if the postoperative pathology report demonstrated risk factors of recurrence, such as multiple micro metastases, lymph node metastases or lack of free endocervical margin, additional adjuvant treatment would be recommended.

Women with clear cell carcinoma or small cell neuroendocrine tumors were advised against trachelectomy.

In order to obtain complete follow-up on reproductive outcome, we performed an electronic questionnaire, including data on menstruation patterns, detailed information about fertility treatment, pregnancy attempts and obstetric outcome. The questionnaire was sent out 6 months before the final analysis. Reproductive information from non-responders was obtained from medical files and telephone interviews. At each follow-up visit, planned every 4 months for 2 years, followed by every 12 months for a total of 5 years, gynecological examination, cytology and vaginal ultrasound were performed.

3. Statistics

Fisher's exact test and Mann Whitney rank sum test were used to compare baseline characteristics. Recurrence free survival was calculated from the date of surgery and survival rates were compared with the use

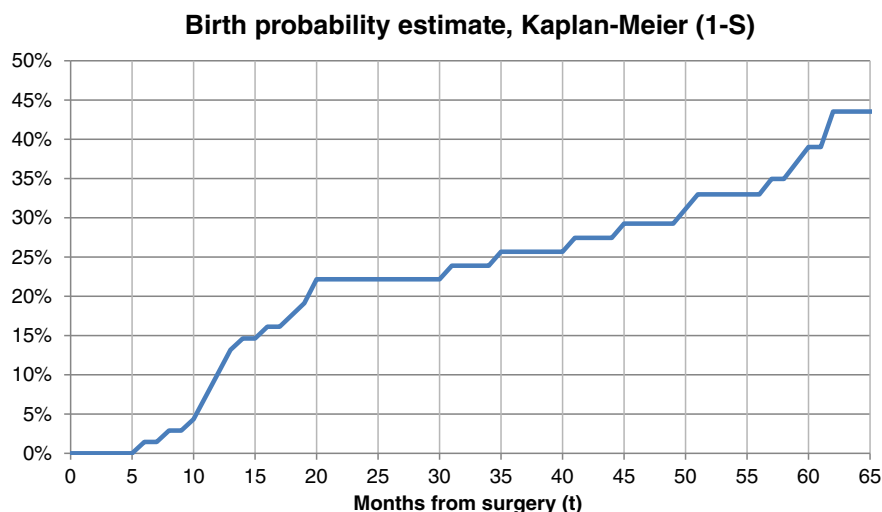


Fig. 1. The curve demonstrates the cumulative birth probability of the first delivery, of the women in the study who wished for pregnancy – and shows a probability of 39% of giving birth within 60 months from the VRT date.

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