SUMMARY

Background: Radical vaginal trachelectomy (RVT) is a fertility-preserving operation for young women who have cervical cancer in an early stage and want to have children. The demand for RVT is increasing, because more than 40% of all cases of cervical carcinoma affect women under the age of 44. Women are increasingly having their first child at later ages.

Methods: We present the results of RVT in more than 300 patients whom we operated on, review pertinent literature retrieved by a selective PubMed search, and evaluate treatment recommendations.

Results: The literature contains data on more than 1000 women treated with RVT and nearly 300 pregnancies after RVT. The 5-year recurrence and mortality rates are 2%–5% and 3%–6%, respectively. RVT is an oncologically safe treatment for women who want to have children. The main criteria for treatment with RVT are that the tumor should be no greater than 2 cm in diameter and that the lymph nodes should be histopathologically free of tumor tissue. The laparoscopic-vaginal technique is the best operative approach to assure a high rate of healing. Only one-third of all patients want to have children a short time after RVT. Their pregnancy rates resemble those of women in the general population. 50% of the children are born prematurely, mainly because of premature rupture of the membranes. Thus, pregnancies after RVT are considered high-risk pregnancies.

Conclusion: As many as 48% of women with early-stage cervical carcinoma meet the criteria for RVT. RVT is an oncologically safe method that enables women with early-stage cervical carcinoma to become pregnant and have children. Pregnancy after RVT is associated with an elevated risk of preterm birth and should be managed according to standardized procedures.

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In addition, a selective literature search in Medline via PubMed was done and the current recommendations of the Arbeitsgemeinschaft Gynäkologische Onkologie (Working Group on Gynecological Oncology) are incorporated.

In addition to our results, personally communicated recommendations as well as results of discussions of the Task Force Fertility Preservation of the European Society of Gynaecological Oncology (ESGO) have been included in the analysis.

**Development of radical trachelectomy**

As early as 1973 operations were reported that were similar to the later radical trachelectomy (RVT) (21). The first formal operation plan of a radical vaginal trachelectomy was developed by Daniel Dargent (11). His method to treat women with early cervical carcinoma in FIGO stage IA1 to IIA with radical vaginal trachelectomy combined with laparoscopic removal of pelvic lymph nodes was published in 1994. Since then, the indications, the adjuvant and neoadjuvant therapy, the choice of patients, the pre-operative staging, the surgical technique and the post-operative follow-up have been continuously critically evaluated and improved. Most data relating to RVT is collected retrospectively in specialized gynecological oncology treatment centers. The quality of the surgery and the experience of the surgeon are of great importance for the oncological results and the outcome of subsequent pregnancies (14, 17, 21, 22). There are no randomized controlled trials regarding oncological outcomes of RVT compared with radical hysterectomy. Participating in a study of this kind is not feasible for women who wish to preserve fertility (16).

**Current indications and oncological safety**

In the current recommendations of the German Society for Gynecology and Obstetrics (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe, DGGG), RVT is mentioned as a treatment option for patients with squamous cell carcinoma or adenocarcinoma of the cervix in FIGO stage IA1 L1 V0, stage IA2 V0 or stage IB1 V0 ≤ 2 cm who wish to conceive. Neuroendocrine cervical cancer is more often associated with recurrence, distant metastasis and lower five-year survival rates and is therefore not suitable for RVT. This is similar if histopathological examination has shown that the tumor has invaded the blood vessels. In addition, a pre-condition for RVT is to prove that the pelvic lymph nodes are free of cancer by histopathological examination (Figure 1). Adhering to these inclusion criteria is very important for oncological safety. In the early stages of the development of the RVT it was assumed that tumors up to FIGO stage IIA can be treated in this way. It soon became clear that the size of the tumor is of great importance for oncological safety (15). Studies in recent years have shown that oncological safety of RVT regarding recurrence rates and mortality are comparable to the more radical

<table>
<thead>
<tr>
<th>TABLE 1</th>
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<tr>
<td><strong>Overview of literature on oncological results post RVT</strong>*</td>
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<table>
<thead>
<tr>
<th>RVT</th>
<th>n</th>
<th>Median follow-up Time (month)</th>
<th>Recurrence rate</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marchiole (15)</td>
<td>118</td>
<td>95 (31–234)</td>
<td>7 (5.9%)</td>
<td>5 (4.2%)</td>
</tr>
<tr>
<td>Plante (31)</td>
<td>72</td>
<td>60 (5–145)</td>
<td>3 (5%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Shepherd (19)</td>
<td>112</td>
<td>45 (1–120)</td>
<td>3 (3.3%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Hertel (14)</td>
<td>100</td>
<td>29 (1–128)</td>
<td>4 (4%)</td>
<td>2 (2%)</td>
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<tr>
<td>Covens (13)</td>
<td>93</td>
<td>30 (1–103)</td>
<td>7 (7.5%)</td>
<td>4 (4.3%)</td>
</tr>
<tr>
<td>Sonoda (20)</td>
<td>36</td>
<td>21 (3–60)</td>
<td>1 (2.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Schlaerth (26)</td>
<td>10</td>
<td>48 (28–84)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dargent (28)</td>
<td>95</td>
<td>76 (4–176)</td>
<td>4 (4.2%)</td>
<td>3 (3.1%)</td>
</tr>
<tr>
<td>Mathevet (39)</td>
<td>109</td>
<td>76 (4–176)</td>
<td>4 (3.6%)</td>
<td>3 (2.7%)</td>
</tr>
<tr>
<td>Burnett (27)</td>
<td>21</td>
<td>31</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lanowska (22)</td>
<td>212</td>
<td>37 (0–171)</td>
<td>8 (3.8%)</td>
<td>4 (1.9%)</td>
</tr>
</tbody>
</table>

*Summary of all studies, retrospective data except Lanowska et al. and Hertel et al. (prospective); RVT, radical vaginal trachelectomy
treatment with radical hysterectomy in patients with a tumor diameter of ≤ 2 cm and invasion of the connective tissue of less than 10 mm without invasion of the lymph nodes (Table 1) (14, 17, 18, 22–28). The recurrence rates are in the range of 2% to 5% and the mortality rates are 3% to 6% and are different in different groups. All data were collected retrospectively (14, 22). In contrast to the data of other groups, we evaluated the cohort of women post RVT prospectively. It seems that adenocarcinomas have a higher rate of recurrence but so far it has not been possible to prove this with statistical significance (13). In this study, the five-year survival rate without recurrence following RVT is 95% and for radical hysterectomy 100%, if the cervix carcinoma was FIGO stage IB1.

RVT in combination with laparoscopic removal of lymph nodes is currently the standard operation for fertility-preserving surgery for cervical cancer and worldwide more than 1000 operations have been performed (10). One of the important factors for survival without recurrence is the expertise of the surgeon. The RVT should be performed in a center specialized in this technique to ensure the best possible peri- and postoperative care for the patient (14). One problem with existing studies was the lack of follow-up of these young, mobile patients. We had a cohort of 225 patients post RVT (up until 03/2010) and could follow up 212 women (95%) prospectively and obtained data regarding oncology and fertility. All patients had the standard surgery (14, 17, 20, 22) and standard follow-up (22). The standard follow-up includes a review every three months for the first two years after surgery, and then every six months for the next three years. After five years, an annual follow-up is recommended. The follow-up is usually done by the gynecologist and in our trachelectomy follow-up clinic using a follow-up protocol developed by our team (colposcopy, HPV-swab etc.).

**Fertility and pregnancy**

Examining fertility and pregnancy data shows that patients and professionals are uncertain about pregnancy following trachelectomy.

Of the 212 patients treated by us, 76 patients (35.8%) were planning a pregnancy at the time when the data was collected (0–5 years following surgery) (29). According to this, most patients were not planning a pregnancy at this stage. Professionals and patients are unsure about the prognosis of a pregnancy. It was also shown that, as a result of the cancer diagnosis, planning a pregnancy became a secondary consideration for patients, despite receiving fertility-preserving surgery.

The patients under our care show no decline in fertility following RVT: 50 out of 76 women who were trying to conceive were successful (65.8%) (29). The pregnancy rate for all patients following RVT is 24% which is comparable with the pregnancy rate in Rob et al. of 30% (11). The really important number, however, is how many patients would like to be pregnant and it is this number which shows the true success rate following

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**FIGURE 2**

**a**

FIGO

IA1

Loop excision, R0

Desire to conceive

Control

If appropriate, hysterectomy

Loop excision or RVT, pelvic and parametrial LN

No desire to conceive

b

FIGO

IA2

Desire to conceive?

No desire to conceive

Nerve-conserving laparoscopic radical hysterectomy, pelvic and parametrial LN

RVT, pelvic and parametrial LN

Loop excision, pelvic LN

No desire to conceive

c

FIGO

IB1

Tumor <2 cm no RF

Desire to conceive

RVT, pelvic and parametrial LN, large vaginal cuff

Tumor <2 cm + significant RF;

Tumor ≥ 2 cm

desire to conceive

Nerve-conserving laparoscopic radical hysterectomy, pelvic and parametrial LN

Treatment for cervical cancer in early stages according to stage; modified according to AWMF online—S2-Leitlinie Onkologie/Gynäkologie: Zervixkarzinom Nr: 32/033

LN, sentinel lymph node resection under study conditions or complete pelvic lymph node resection; RVT, radical vaginal trachelectomy; RF, risk factors
trachelectomy (30, 34). In the unselected population 85.4% will conceive within 12 months if they are trying to conceive (4).

In the group examined by us, 50 women had a total of 60 pregnancies and 45 live births during the study period (29). Other authors report similar rates (30, 31, 35) (Table 2). Of the women who were planning to conceive, only those who had already had fertility problems or failed to conceive prior to trachelectomy had problems afterwards. Possible changes that might influence fertility which are caused by the surgery itself are: reduced cervical mucus; adhesions; reduced blood flow through the uterus, fallopian tubes and ovaries; or cervical stenosis (30–36). The reduction in fertility caused by the surgery itself seems minimal.

Of the 60 pregnancies in our study, five resulted in miscarriage in the first trimester; one woman had an ectopic pregnancy. The rate of first trimester miscarriages following RVT was lower than the rate in the unselected population (8.4% versus 14–20%). In the second trimester, miscarriage was more common—three patients had a late miscarriage—and this rate is comparable with rates in the unselected population (5% post RVT versus 4% in the normal population) (34). In the group studied by Shepherd et al. (37) the rate of early miscarriage was notably higher (22/88). Also the number of late miscarriages was markedly increased (12/88) (Table 2). The data published by Plante et al. (30, 31, 38) is similar to ours. There is no suggestion that hormonal treatment to improve fertility alters the oncological results after RVT (39, 40). Two pregnant patients chose to terminate the pregnancy.

The greatest challenge post RVT is not to achieve pregnancy but to reduce the increased rate of preterm labor (29–34).

Nearly 50% of patients post trachelectomy reached the 37th week of gestation and had therefore a term delivery (29–32). Of the live births, three were before the 28th week of gestation and 15 women had their babies between the 28th and 36th weeks of gestation (29). Most of the preterm deliveries therefore occurred after the 32nd week of gestation. Following RVT only 10% of babies were born before the 28th week of gestation. The main reason for preterm delivery was premature rupture of the amniotic membranes with chorioamnionitis.

The babies examined by us were in good health and had no additional problems resulting from their prematurity or the RVT undergone by their mothers. Postnatal morbidity compared to a control group was slightly reduced which might be explained by the intensive antenatal care (e1).

### Recommendations in pregnancy

To standardize and simplify antenatal care for women after radical vaginal trachelectomy (RVT) of the cervix, we developed an 18-point recommendation to support health professionals and patients (Box 2). These recommendations go further than the recommendations based on three case studies by Knight et al. in 2010 (e2).

All pregnancies following RVT are high-risk pregnancies. Women should wait at least three months after RVT before a pregnancy to allow complete healing of the wounds. Despite the incidence of recurrence of the cancer being higher in the first two years post surgery, there is currently no indication that a pregnancy is a contributory factor. The patient must be made aware by the surgeon that a delivery can only be done by Cesarean section which should be done in a perinatology unit.

Antenatal care should be offered according to the antenatal care guidelines of the Bundesausschuss der Ärzte und Krankenkassen (German National Committee of Physicians and Health Insurers). Dental treatment should not be undergone in pregnancy to avoid bacteremia. Because of the mechanical manipulation and the increased rate of urinary tract infections and vaginal infections, the couple should be
advised not to have vaginal sexual intercourse between the 14th and 34th weeks of gestation.

All patients should be offered psychooncological counseling.

The patient should be shown how to check her own vaginal pH to test the function of the vaginal flora as a barrier against infection. The pH value should be between 4 and 4.5.

Gynecological examinations should be done under sterile conditions. For pregnant women post RVT we recommend weekly speculum examinations and vaginal ultrasound to measure the length of the remaining cervix. Swabs to check for bacterial and fungal infections and a microscopic film should be done every four weeks. In the case of abnormal results, systemic treatment according to resistance is recommended.

Digital vaginal examinations should be avoided.

The indications for total occlusion of the cervix are previous preterm birth or recurrent miscarriage, similar to other pregnancies. These patients should also be offered an abdominal cerclage—if not pregnant, by a laparoscopy or, if pregnant, by laparotomy (bikini-line incision). This seems reasonable despite the fact that all patients received a permanent cerclage during the RVT to support the remaining cervix. A general recommendation for total occlusion of the cervix is not supported by current data.

We recommend time off work from the 12th week of gestation onwards unless the patient has a stress-free office job. Until the 20th week of gestation the patient should avoid physical strain (no sport, no heavy lifting >2 kg, but not bed rest). Between the 20th and 28th weeks of gestation this should be intensified which means mainly bed rest, walking to the toilet is permissible.

No vaginal sexual intercourse during pregnancy.

No vaginal sexual intercourse between the 14th and 34th week of gestation.

Simultaneous psychooncological counseling, if necessary and wanted by the patient.

If the remaining cervix is <1cm, after previous premature delivery or recurrent miscarriages: abdominal cerclage—before the pregnancy with a laparoscopy, if already pregnant with laparotomy (bikini-line incision) and complete closure of cervical os (preferably with CO2 laser technique).

In-patient admission if premature contractions, cervical incompetence, bleeding or difficult social circumstances.

Time off work (except light office work) from the beginning of the 12th week of gestation.

Avoidance of physical strain (no sport, no heavy shopping >2kg but not bed rest) until the 20th week of gestation.

Between the 20th and the 28th weeks of gestation this should be intensified which means mainly bed rest, walking to the toilet is permissible.

Primary elective Cesarean section from the 37th week of gestation onwards.

Delivery in a perinatology unit.

No elective dental work during pregnancy.

No vaginal sexual intercourse between the 14th and 34th weeks of gestation.

Simultaneous psychooncological counseling, if necessary and wanted by the patient.

No vaginal progesterone, oral progesterone if twins and if recurrent miscarriage—progesterone 200 mg three times a day from diagnosis of pregnancy until the 16th week of gestation, then slow reduction over 2 to 3 weeks.

Induction of lung maturing with betamethasone: between 23+6 and 34+0 if delivery is likely.

Prophylactic antibiotics only if premature rupture of amniotic sac or proven infection.

Chorionic villus sampling (CVS)/amniocentesis: indication same as for patients who did not have RVT.

* Developed from our clinical experience.

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**Recommendation for management in pregnancy after radical vaginal trachelectomy (RVT)**

- Every pregnancy after RVT should be considered a high-risk pregnancy and treated as such.
- Examination each week including:
  - measurement of remaining cervix (sterile vaginal sonography)
  - swabs and film (bacterial infections, fungal infections)
  - speculum (exclude funneling)
- Improve vaginal flora if pathological bacterial flora ($L$. acidophilus cultures supp., if appropriate hequetidin supp., if appropriate oral antibiotics)
- Vaginal pH measurements done by patient twice a week from 14th week of gestation onwards.
- No digital examination.
- If the remaining cervix is <1cm, after previous premature delivery or recurrent miscarriages: abdominal cerclage—before the pregnancy with a laparoscopy, if already pregnant with laparotomy (bikini-line incision) and complete closure of cervical os (preferably with CO2 laser technique).
- In-patient admission if premature contractions, cervical incompetence, bleeding or difficult social circumstances.
- Time off work (except light office work) from the beginning of the 12th week of gestation.
- Avoidance of physical strain (no sport, no heavy shopping >2kg but not bed rest) until the 20th week of gestation.

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Patients post RVT should have the same indication for choriionic villus sampling (CVS) or amniocentesis as women without carcinoma or surgery. The question of whether patients who had an RVT and have subsequently completed their family should have a secondary hysterectomy has not been fully answered.

**Conclusion**

Since it was first described by Daniel Dargent, radical vaginal trachelectomy in the hands of an experienced surgeon has been developed into an oncologically safe technique for women with early stage cervical carcinoma who wish to preserve fertility. Our team has operated more than 300 patients with this method and worldwide there are more than 1000 patients. There have been 300 pregnancies. Most babies were born after the 37th week of gestation. There is still a high percentage of preterm birth following trachelectomy.

There is a lack of information among doctors and patients about pregnancies following trachelectomy. Our recommendations are designed to help patients post trachelectomy who wish to conceive to feel more confident. They also should help to create the conditions for a successful pregnancy. The aim of the recommendation is to reduce the rate of preterm birth further by standardizing antenatal care. If complications occur during pregnancy after RVT these should be clearly documented and analyzed to improve knowledge about pregnancies after trachelectomy.

**Conflict of interest statement**

Prof Schneider has personal connections with Karl Storz Company. He received payments for consultancy work and support for the education of fellows in gynecological oncology from the Karl Storz Company. From GSK, Merck and Sanofi Pasteur he received payments for advice and presentations.

Dr Speiser, Prof. Köhler and Dr Mangler declare that no conflicts of interest exist.

**KEY MESSAGES**

- Radical vaginal trachelectomy (RVT) is a fertility-preserving surgical technique for young women with a desire to conceive who have been diagnosed with cervical cancer in the early stages.
- The oncological safety of the radical removal of the cervix is similar to that of radical hysterectomy.
- If trying to conceive, the rate of conception after RVT is only marginally below the rate of conception of the unselected population.
- Out of 1000 women worldwide who were treated with RVT, so far 300 pregnancies occurred. About 50% of the babies were born after the 37th week of gestation; 90% of the babies were born after the 28th week of gestation.
- Following the recommendations for management of pregnancies post RVT should further reduce the rate of pre-term deliveries.

**REFERENCES**


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For eReferences please refer to: www.aerzteblatt-international.de/ref1713
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A Fertility-Preserving Procedure in Early Cervical Cancer in Young Women

Dorothee Speiser, Christhardt Köhler, Achim Schneider und Mandy Mangler

eREFERENCES

