

Position Paper of the Task Force for Obstetrics and Prenatal Medicine (AGG – Section Preterm Birth) on the Placement, Removal and Surveillance of the Arabin Cervical Pessary in Patients at Risk for Spontaneous Preterm Birth

Positionspapier der Arbeitsgemeinschaft Geburtshilfe und Pränatalmedizin (AGG – Sektion Frühgeburt) zur Platzierung, Entfernung und Überwachung von Arabin-Zervixpessaren bei Patientinnen mit erhöhtem Frühgeburtsrisiko




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ABSTRACT

This position paper describes clinically important, practical aspects of cervical pessary treatment. Transvaginal ultrasound is standard for the assessment of cervical length and selection of patients who may benefit from pessary treatment. Similar to other treatment modalities, the clinical use and placement of pessaries requires regular training. This training is essential for proper pessary placement in patients in emergency situa-

tions to prevent preterm delivery and optimize neonatal outcomes. Consequently, pessaries should only be applied by healthcare professionals who are not only familiar with the clinical implications of preterm birth as a syndrome but are also trained in the practical application of the devices. The following statements on the clinical use of pessary application and its removal serve as an addendum to the recently published German S2-consensus guideline on the prevention and treatment of preterm birth.

ZUSAMMENFASSUNG

Dieses Positionspapier beschreibt klinisch wichtige praktische Aspekte der Zervixpessartherapie. Zur Beurteilung der Zervixlänge und um Patientinnen auszuwählen, die von einer Pessartherapie profitieren könnten, wird standardmäßig trans-

vaginaler Ultraschall eingesetzt. Wie bei anderen Behandlungsmodalitäten auch, ist es wichtig, regelmäßig Schulungen zum klinischen Einsatz und zur Pessarplatzierung durchzuführen. Diese Schulungen sind unerlässlich, um eine korrekte Platzierung von Pessaren im Notfall zu gewährleisten, Frühgeburten zu verhindern und die neonatale Ausgangssituation zu optimieren. Pessare sollten nur von medizinischen Fachleuten eingesetzt werden, die nicht nur mit den klinischen Implikationen einer Frühgeburt als Syndrom vertraut sind, sondern auch in der praktischen Anwendung von Pessaren geschult sind. Die folgenden Aussagen zum klinischen Einsatz von Pessaren und deren Entfernung dienen als Ergänzung der vor Kurzem veröffentlichten deutschen S2-Richtlinie zur Prävention und Therapie der Frühgeburt.

Introduction

In 2014, the German Society of Obstetrics and Gynecology (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe [DGGG]) formed an obstetrical task force (Arbeitsgemeinschaft Geburtshilfe und Pränatalmedizin [AGG]) to promote the implementation of guidelines. Recently, an S2-consensus guideline on the prevention and treatment of preterm birth [1, 2] was published which included indications for the Arabin pessary. This position paper adds important clinical recommendations on technical aspects such as pessary insertion and removal as well as clinical and ultrasound surveillance recommendations for patients receiving pessary treatment.

The Arabin pessary has been approved for the prevention of preterm birth in Europe (CE0482/EN ISO 13485:2003 annex III of the council directive 93/42 EEC). In the US and Canada, the pessary was given an FDA Investigational Device Exemption (IDE) and Medical Device Investigational Testing Authorization, respectively, to permit its use in studies [3]. Large trials and a prospective meta-analysis are being conducted worldwide. Clinical use of the cerclage pessary, which may stay in the vagina for >28 days, is regulated by the Medical Device Regulation (MDR) which has legal implications within the European Union [2].

The MDR demands that the manufacturer provides instructions including guidelines on clinical use, labeling and warnings. These instructions must be followed by physicians who should give concrete reasons in the patient's records (e.g., leave the pessary in place in patients with premature rupture of membranes during transportation). This paper has considered the most recent version of these instructions (Rev. 2018) and additionally considered the answers to frequently asked questions (FAQs) provided for physicians and patients in several languages by the manufacturer of the Arabin pessary. Both are documented on the website [3, 4].

The instructions are revised by the medical team and the notifying body (MedCERT) of the manufacturer on an annual basis based on completed studies and post-surveillance procedures; the revisions are numbered. Since pessaries with instructions are

sometimes held in stock for a while, the latest versions can also be downloaded from the corresponding website [3].

Clinical Items to Be Considered Before Pessary Application

Size of the pessary

Multiple sizes of pessaries are available. The inner upper diameter of the Arabin pessary, which surrounds the cervix, is usually 32 mm. Pessaries with an inner upper diameter of 35 millimeters can be used in a wide cervix with funneling. The outer lower diameter varies between 65 and 70 mm. The height of the available pessaries is 17, 21, 25 and 30 mm. This allows physicians to take an individual approach and adapt the choice to specific situations such as discomfort (shorter sizes), multiple pregnancy or mild genital prolapse (larger sizes). Arabin and Alfirevic [4, 5] provide a guide to assist in size selection. Meanwhile, an app on the website [3] helps to choose the right sizes for different clinical situations.

In general:

- The inner upper diameter should usually be 32 mm when treating average cervical shortening and, in rare cases, 35 mm (in patients with an unusually edematous wide cervix or U-shaped funneling) to avoid compression with further secretion of atypical interleukins and cytokine production [5, 6].
- The outer lower diameter should be 65 mm for nulliparous or women of small constitution and 70 mm for multiparous or tall women.
- The height of the curvature should be 17 mm in rare cases, possibly only during the first trimester; otherwise the height should be 21 mm for singleton pregnancies and smaller women, 25 mm for multiple pregnancy and taller women, rarely 30 mm in women with a mild degree of genital prolapse.

These are patient-related features which can be modified to adapt to individual patients. Pessaries are delivered with perforations of

the silicone ring for the easier release of vaginal discharge from the upper fornix of the vagina.

STATEMENT

There is no absolute indication for a specific size. Different sizes allow an individual approach according to the patient's characteristics.

Vaginal swabs and pH measurements

The indications for obtaining a vaginal or cervical sample do not differ from those for other patients at risk of spontaneous preterm birth. This means that in patients with a high risk for preterm birth, specific multi-resistant bacteria or streptococcus should be excluded in a timely manner. Romero et al. stated that the vaginal microbiome is not associated with the microbiome in the intra-amniotic cavity or an inflammation of the amniotic membranes, and not necessarily with preterm birth (PTB) [6, 7].

Consequently, systematic administration of antibiotics is not indicated and may be harmful. Vaginal discharge is a common side effect of pessaries and should not be treated with antibiotics. Vaginal pH measurements have never been evaluated in terms of their sensitivity and specificity for detecting PTB and cannot be recommended before or during pessary treatment.

STATEMENT

Vaginal swabs or pH measurements are not necessary before pessary insertion and their use should be restricted to specific indications, e.g. intraamniotic sludge. Antibiotic therapy based solely on vaginal discharge is contraindicated.

Speculum examination

Patients with sonographic cervical shortening below the 25th, 10th, or 3rd centile according to the ultrasound curves of Salomon et al. [7] may have an indication for pessary treatment [8].

Before insertion, a speculum examination is indicated in patients with a history of conization or trachelectomy, a history of cervical lesions, a suspicion of uterus duplex with the possibility of two cervixes and in cases where it is difficult to interpret the findings of transvaginal sonography (TVS). A pessary can be placed in any patient with sufficient cervical tissue to hold the pessary, including patients who are status post cervical surgery.

During pessary treatment, a speculum examination is indicated in cases with discomfort and suspicion of dislocation, vaginal bleeding as well as suspicion of premature preterm rupture of membranes (PPROM).

STATEMENT

Speculum examination before insertion is indicated in mothers who are status post cervical surgery or lesions and during pessary placement or treatment in patients with discomfort, suspicion of dislocation, vaginal bleeding or PPRM.

Training

Similar to other treatment modalities, the success rates of pessary treatment increase with the experience of the treating physician and/or department [8, 9].

The European Guidelines on Preterm Birth recommend proper and continuous training in pessary placement [9, 10].

Pessary placement in technically difficult situations requires experience. Difficulties may arise due to:

- maternal size, anatomy, parity and culture
- pre-existing cervical shortening/thickness, opening of the internal/external cervical os
- sensitivity to vaginal procedures including vaginismus, experience of discomfort or pain
- specific anatomic or obstetric situations (e.g. bicornuate uterus, placenta previa, etc.)
- the degree of genital prolapse or additional urinary incontinence
- incidental or sudden occurrence of preterm contractions or bleeding during treatment
- the degree and kind of discharge, differential diagnosis: PPRM/urinary incontinence
- the degree of cervical edema before removal due to contractions/pressure

STATEMENT

Adequate provider training is a prerequisite for pessary placement and treatment. Cervical pessaries should only be applied by healthcare professionals who have been trained in the pathophysiology and clinical symptoms of PTB syndrome, who are trained in transvaginal ultrasound (TVS) and/or have participated in a training course.

Communication and Practical Items to Be Considered During Insertion of the Pessary

Insertion

Communication is an essential part of treatment. The indication, evidence and most common side effects such as vaginal discharge should be discussed with the patient. Patients at risk of genital prolapse should know that the pessary might descend with the cervix during pushing. In addition, patients should receive instructions on how to proceed in case they are admitted to a hospital where doctors are not familiar with the therapy. The size and charge number should be documented in the patient's chart. Once the patient has been informed in detail and re-assured and the documentation has been completed, the pessary can be inserted (with the patient usually in a semi-recumbent position).

The pessary should be folded with the smaller diameter pointing upwards so that the device can be directed towards the top of the posterior fornix. During insertion the pessary stays folded until the upper vaginal fornix is reached; it is then gently placed as high as possible with the smaller diameter completely around the cervix. The anterior rim may be gently pushed towards the sacrum



► **Fig. 1** QR code for the video providing information on pessary insertion (<https://www.youtube.com/watch?v=5x2g6Eg2f0o&feature=youtu.be>).

so that the cervix is rotated, with the entire cervix engaged in the pessary. An easier and less painful insertion can be achieved by covering the pessary with gel. After placement, the pessary should not be “felt” by the patient. It is recommended that the patient stands up and reports whether she feels discomfort or a reduction of pressure. In case of pain or discomfort, the size and position of the pessary should be considered. After insertion of the pessary, a sonographic evaluation may be performed to confirm proper placement.

All steps are demonstrated in an online video provided by Professor Alfirevic, Liverpool UK: <https://youtu.be/5x2g6Eg2f0o>

Alternatively, ► **Fig. 1** depicts the QR code to be directly forwarded to this link.

STATEMENT

Informed patient consent and pessary education is essential prior to placement. The pessary should be gently inserted with the smaller diameter facing upwards. Instruction pamphlets from the pessary package should be given to the patient, and the size and charge number be documented.

Clinical Items to Consider During Pessary Treatment and Removal

Clinical examination

In asymptomatic patients with a low risk for PTB (sonographic length over the 3rd percentile), clinical examinations during the period of pessary treatment are used to confirm placement. At the first visit after placement, it should be confirmed that the cervix is still surrounded by the upper ring of the pessary. In follow-up visits, a vaginal digital examination may suffice to determine the position of the pessary. In patients with mild genital prolapse, the pessary and cervix may be smoothly redirected towards the upper vaginal vault – even by the patient herself if she feels the device after standing or pushing.



► **Fig. 2** Placement of the transducer “on the top of the pessary” and the upper cervical lip.

Ultrasound surveillance

During pessary treatment, TVS may be used to reconfirm the cervical length or to detect funneling. The cervical length can increase or decrease during treatment. Similarly, funneling may increase or decrease. It is recommended that the transducer is placed “on the top of the pessary” and the upper cervical lip (► **Fig. 2**) to avoid unnecessary manipulation and a change in the uterocervical angle with further false-positive evaluation of the cervical length. This technique eliminates the shadow of the pessary. Placing the transducer “in the pessary” as stated by Goya et al. [10] is associated with a de-sacralization of the pessary and a change in the uterocervical angle and consequently carries the risk of measuring the cervical length as too short.

STATEMENT

In patients with a pessary, TVS can be used to measure the cervical length and width of funneling during treatment. Placement of the transducer on top of the pessary avoids de-sacralization, unnecessary manipulation and a false-positive result of TVS.

Removal

This chapter discusses pessary removal < 34 weeks, between 34 and 37 and after the completion of 37 weeks.

Indications for preterm removal of a pessary < 34 weeks:

- Patients with regular contractions which cannot be prevented by IV tocolytics
- Severe vaginal bleeding
- Proven premature rupture of membranes (PPROM)
- Suspicion of chorioamnionitis (Triple I)

In cases with mild contractions and intact membranes, tocolytic treatment should be started with the pessary in place to provide the necessary time for effective treatment with corticosteroids.

If contractions persist, the pessary should be removed.

PPROM should be diagnosed with the aid of biochemical tests (cave: false-positive results) and ultrasound. If PPRM is proven, there are a few exceptions when the pessary should be left in place for a short time. This includes maternal transport to a perinatal center or cases at the limit of fetal viability when any manipulation increases the risk of more contractions. These patients should be carefully supervised by specialists. Since an early diagnosis of Triple I, as defined in the most recent version of the guideline, is difficult to establish, leaving the pessary in place should be the exception after obtaining informed consent from the patient and documenting this procedure in the patient's records.

> 34 weeks/<37 weeks

- Patients with regular painful contractions
- Severe vaginal bleeding
- Proven PPRM
- Suspicion of chorioamnionitis (Triple I)

When a patient is admitted with regular painful contractions after 34 weeks of gestation, the pessary should be removed.

≥ 37 weeks

The pessary should be removed at 37 weeks in all patients unless a cesarean delivery is scheduled. In cases of cesarean delivery, removal may be postponed until the day of the operation and should be performed following spinal anesthesia, before skin incision. The device must be removed in symptomatic patients and patients with PROM.

Technical aspects

In practice, the pessary can be removed by inserting a finger between the cervix and the upper or lower inner ring. Before removal, it is important to ensure that the cervix is pushed back through the inner ring of the dome. Patients with mild cervical edema should be informed that removal may be painful. In rare cases when the pessary is stuck due to contractions, severe cervical edema or progressive genital prolapse, it may be prudent to cut the pessary with episiotomy scissors instead of removing the pessary under anesthesia or by force.

Following removal from the cervix, the device can be squeezed (similar to insertion) and carefully removed.

Once the pessary is removed it should not be re-used since it is certified for single use only.

STATEMENT

The pessary should be removed in cases with proven PPRM. A pessary should routinely be removed when no risk of PTB remains at 37 weeks of gestation. If the device is stuck, it should be cut rather than removed by force, as this reduces the risk of lesions to soft cervical tissue.

Any severe events associated with pessary use should be reported to the manufacturer. To date, most claims were due to ignorance regarding the instructions or false handling. If possible, the size and charge numbers should also be reported.

Conflict of Interest

The authors declare that they have no conflict of interest.

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