Society for Maternal-Fetal Medicine

SMFM Statement

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The role of cervical pessary placement to prevent preterm birth in clinical practice

Q2 Society for Maternal-Fetal Medicine Publications Committee

There has been renewed interest in the use of the cervical pessary as an intervention to prevent preterm birth (PTB) in women at high risk for preterm birth. Multiple randomized clinical trials (RCTs) have been published in the last several years, with conflicting results. The purpose of this statement is to summarize the findings of recent RCTs studying the use of the cervical pessary to prevent PTB and to provide guidance regarding the role of cervical pessary use in clinical practice.

Placement of a cervical pessary to treat cervical shortening was initially proposed in the late 1950s and early 1960s.[1-3] Most recently, the Arabin pessary has been studied as a possible alternative to cerclage and/or vaginal progesterone therapy. The mechanism of action for pessary in the prevention of PTB is postulated to be an alteration of the uterocervical angle such that the force from the weight of the uterine contents is directed away from the internal os.[4,5]

The low cost and relative ease of insertion and removal as well as avoidance of medication exposure or operative procedure have been factors driving further investigation of its effectiveness.[6,7] Because the Arabin pessary is constructed in such a way that the caudal portion of the device encircles the cervix, some have postulated that the Arabin pessary may provide additional benefit (compared with other pessaries), preventing cervical dilation, deterioration of the mucous plug, and exposure of the membranes.[8]

The Arabin pessary appears to be associated with low rates of major complications. Most reported side effects are minor and include discomfort with placement and removal.[7] In several studies, the most common side effect is an increase in vaginal discharge. Approximately 15–20% of women treated with an Arabin pessary had an amount of discharge requiring medical evaluation to exclude infection or membrane rupture.

In RCTs the rates of actual vaginal infection are similar in women with and without cervical pessary.[9,10] It is unknown whether pessary exposure alters the vaginal microbiome and has an impact on the long-term maternal and/or neonatal or child outcomes. Serious adverse events (eg, cervical ischemia) are rare. Reported side effects from other pessaries, including other ring devices and the Smith-Hodge lever design, are limited but appear similar to those trials involving the Arabin pessary.[11]

Cervical pessary in singleton gestations

Two large RCTs have recently been performed in singleton gestations, with conflicting results. The Pesario Cervical para Evitar Prematuridad trial studied women undergoing cervical length screening at 18–22 weeks of gestation and allocated those with a cervical length ≤25 mm to the Arabin pessary (n = 192) or expectant management (n = 193).[9] The mean cervical length and gestational age at randomization were 19 mm and 22.3 weeks, respectively. Overall, 11% of women had a prior PTB. There was a significant reduction in the rate of spontaneous PTB with pessary placement (6% vs 27%, relative risk [RR], 0.18, 95% confidence interval [CI], 0.08-0.37) as well as a reduction in the occurrence of composite adverse neonatal outcomes (3% vs 16 %; RR, 0.14; 95% CI, 0.04–0.39).

In contrast, a multinational study enrolled 924 women across 16 hospitals and studied women with a cervical length of ≤25 mm at 20–24 weeks of gestation and were randomly allocated to pessary (n = 460) or expectant management (n = 464).[10] The mean cervical length at entry was 20 mm. Women with a cervical length <15 mm were also treated with 200 mg of vaginal progesterone nightly, regardless of treatment group assignment, with 45% of overall participants receiving progesterone. Overall, 17% of the participants had a history of prior PTB. While per protocol the pessary was to remain in place until 37 weeks of gestation, in 47 women (11%), the pessary was removed prior to 34 weeks of gestation because of vaginal discharge, discomfort, or bleeding. The rate of spontaneous PTB at <34 weeks of gestation were similar with pessary and without (12.0% vs 10.8%; RR, 1.12; 95% CI, 0.75–1.69).

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Cervical pessary in multiple gestations

Pessary use has been studied for prematurity prevention in unselected multiple gestation populations and in the subgroup of women with a short cervix.[12-15] The largest RCT to date was conducted across 12 countries and included 1180 women with unselected twin pregnancies who received an Arabin pessary or expectant management. The rate of PTB at <34 weeks was not different between groups (13.6% for cervical pessary vs 12.9% in the expectant management [RR, 1.05; 95% CI, 0.79-1.4]).[13]

Q1 The ProTWIN study, conducted in The Netherlands, was an RCT involving 808 women with twin or triplet pregnancies who received pessary or expectant management. In this trial, there were also no differences in PTB at <32 weeks (10% vs 12%; RR, 0.86; 95% CI, 0.65–1.15) or composite poor perinatal outcome (13% vs 14%; RR, 0.98; 95% CI, 0.69–1.39).[12]

The only RCT published to date that focused on twins with a short cervix studied 137 women in Spain with a twin gestation and cervical length ≤25 mm.[15] Of women who underwent cervical length screening, 6.7% had a cervical length of ≤25 mm. Women who received cervical pessary had lower rates PTB at <34 weeks (16.2% vs 39.4%; RR, 0.41; 95% CI, 0.22–0.76) as well as a longer interval from randomization to delivery (hazard risk, 0.50; 95% CI, 0.41–0.62).

In a post hoc subgroup analysis of the trial by Nicolaides et al,[13] the incidence of PTB at <34 weeks of gestation among the 106 women with a cervical length of <25 mm randomized to pessary was 31%, compared with 26% in the 108 women in the expectant management group (RR, 1.2; 95% CI, 0.8–1.8). In contrast, a subgroup analysis of women from the ProTWIN study with a short cervix, defined as a cervical length of <38 mm, the women demonstrated a reduction in PTB at <32 weeks of gestation (14% vs 29%; RR, 0.49; 95% CI, 0.24–0.97) and adverse neonatal outcomes (12% vs 40%; RR, 0.40; 95% CI, 0.19–0.83) in those women treated with an Arabin pessary.[16] A systematic review and meta-analysis that combined data from 3 trials (n = 481 subjects) involving women with twin gestation and a short cervix did not find a benefit of cervical pessary to decrease spontaneous PTB or perinatal outcomes.[14]

Society for Maternal-Fetal Medicine recommendations

As of Dec. 15, 2016, there are >20 open studies examining cervical pessary (either alone or in combination with other treatments) to prevent PTB (listed at ClinicalTrials.gov). It will be important for future trials to carefully define and better differentiate between spontaneous PTB and any PTB at <34 and <37 weeks of gestation as clinical outcomes. This lack of specificity and clarity has created challenges in the interpretation of published RCTs involving cervical pessary as well as a concern for bias.

Currently no cervical pessary device is Food and Drug Administration approved in the United States for the prevention of PTB or treatment of cervical shortening. Though several pessaries are Food and Drug Administration approved for indications of pelvic organ prolapse and incontinence, the use of these devices during pregnancy for PTB prevention is off label. Currently the Arabin pessary is not approved for sale in the United States for any indication; it may be used in the United States only under an investigational device exemption as part of ongoing clinical trials.

At this time there is inconclusive evidence that cervical pessary use, including the Arabin pessary, decreases the rate of PTB or improves maternal or fetal outcomes for women at high risk for PTB. While one RCT suggested a benefit in singleton pregnancies with a short cervix and one in twins with a short cervix, replication and study in a US population is needed before routine adoption into clinical practice.

At this time, the Society for Maternal-Fetal Medicine recommends that placement of cervical pessary in pregnancy to decrease PTB be used only in the context of a clinical trial or research protocol. Such diligence will avoid implementation of an intervention prior to adequate testing that may later be found to be ineffective or even harmful.[17]

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