Use of cervical pessary to prevent preterm birth

Insertion of a safe, low-cost cervical pessary during the midtrimester of pregnancy in women who are at a high risk for preterm birth (those with a short cervix) could prevent premature delivery (The Presario Cervical para Evitar Prematuridad [PECEP] trial). Confirmatory research is required.

Overview: Spontaneous preterm birth occurs in approximately 5-13% of pregnancies and is the leading cause of illness and death in newborns. It can also result in lifelong health problems including learning difficulties, cerebral palsy, blindness, and breathing problems.

A short cervix, less than 25 mm, is a major risk factor for preterm birth. Cervical pessary is a silicone device that has been used for 50 years to prevent preterm birth (Cross, 1959). The smaller diameter of the pessary is fitted around the cervix and the larger diameter faces the pelvic floor, thus rotating the cervix to the posterior vaginal wall and correcting the cervical angle.

Current advice: NICE does not have any guidance on the use of cervical pessary to prevent preterm birth. NICE guidance on antenatal care states that routine screening for preterm labour should not be offered. However, additional care will be required for women who have experienced preterm birth in previous pregnancies. A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.

The NICE pathway on antenatal care brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

New evidence: The Presario Cervical para Evitar Prematuridad (PECEP) trial is the first randomised trial to investigate the use of a pessary to prevent premature birth. Undertaken in 5 hospitals across Spain between June 2007 and June 2010, the trial investigated whether the insertion of a cervical pessary in women with a short cervix, identified by use of routine transvaginal scanning at 20-23 weeks of gestation, reduces the rate of early preterm delivery (Goya et al. 2012). Cervical length was measured according to the criteria of the Fetal Medical Foundation (To et al. 2001).

The research team invited 18,235 women with single pregnancies to have transvaginal ultrasonic measurement of cervical length during the second trimester scan. Nearly 11,875 agreed and out of these 726 were found to have a cervical length of less than 25mm. Of these 341 declined to participate in the study and 5 were lost to follow-up.

The remaining eligible women were randomly assigned to a cervical pessary or expectant management without a pessary, with 190 women in each group. The primary outcome was spontaneous preterm birth before 34 weeks (238 days) of gestation. Masking the study was impossible because of the nature of the intervention. However, neither the recruiters nor the trial co-ordinator had access to the randomisation sequence.

The results showed that spontaneous birth before 34 weeks...
gestation was significantly higher in the expectant management group (6% in the pessary group compared with 27% in the expectant management group, 95% CI 0.08-0.37). No serious side effects were reported, and women in the pessary group experienced a significantly reduced rate of low birthweight (less than 2500 g), respiratory distress syndrome, and treatment for sepsis.

The authors conclude that the pessary is an affordable (38 Euros per pessary), safe, and reliable alternative for prevention of preterm birth in a population of appropriately selected at-risk pregnant women who have been screened for cervical length assessment at the midtrimester scan. However, the precise mechanism by which a pessary confers a benefit is not known and more trials with much larger samples are needed.

**Commentary:** "Cervical pessary has been variably used in a number of countries to prevent preterm birth, but no quality data of efficacy has previously been available. Therefore the uptake has been sporadic. Currently 2 interventions are used in women with a short cervix: ultrasound-indicated cerclage or vaginal progesterone. Both these have shown some benefit in extending gestation but usually in women with prior history of a preterm delivery. Interventions in women without a prior history, even if the cervix shortens, have not shown to be beneficial, including cerclage. Low risk women are not currently screened for cervical length, and implementation of widespread screening would have a substantial impact on maternity services. Although this evidence is promising, such a change in practice, that is, cervical routine screening of the antenatal population, would not be justified unless harder outcomes of baby wellbeing were established (rather than just prolonged gestation). The findings need to be replicated, as the very high preterm delivery of less than 34 weeks gestation in the placebo arm (27%) is far higher than normally expected in women routinely identified with a cervix less than 25 mm, and a type 1 statistical error needs to be excluded. The role of such a pessary in high risk women with a prior history needs to be evaluated, as screening these women is likely to be far more efficient and cost effective." – Andrew Shennan, Professor of Obstetrics, Kings College London.

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