Silicone pessaries in women with a multiple pregnancy

A randomised controlled trial finds that silicone cervical pessaries do not reduce poor perinatal outcomes in women with a multiple pregnancy, although pessaries might be of some benefit in those with a short cervix.

Overview: Women with a multiple pregnancy are at increased risk of preterm delivery. Around 60% of twin pregnancies result in spontaneous birth before 37 weeks' gestation, and about 75% of triplet pregnancies result in spontaneous birth before 35 weeks' gestation. Prematurity is the biggest cause of adverse neonatal and infant outcomes among twins and triplets compared with singletons, including higher levels of long-term neurodevelopmental problems.

Progesterone, delivered either by injection or vaginally, is effective at preventing preterm birth in women with a singleton pregnancy but has not been shown to be effective in women with a multiple pregnancy. Other approaches, such as prophylactic use of cervical cerclage, are not effective either. Silicone cervical pessaries might help prevent preterm birth by relieving pressure on the internal cervical ostium and preventing premature dilation of the cervix.

Silicone ring (Arabin) pessaries seem to be effective at preventing preterm delivery in women with a singleton pregnancy and a cervical length of 25 mm or less (Goya et al. 2012).

Current advice: NICE guidance on multiple pregnancy warns that women with twin pregnancies have a higher risk of spontaneous preterm birth if they have had a spontaneous preterm birth in a previous singleton pregnancy. Cervical length (with or without fetal fibronectin testing), fetal fibronectin testing alone, and home uterine activity monitoring should not be used to predict the risk of spontaneous preterm birth in twin or triplet pregnancies.

The guidance does not make any recommendations specifically on whether cervical pessaries should be used to prevent preterm birth. However, it states that bed rest (at home or in hospital), intramuscular or vaginal progesterone, cervical cerclage, and oral tocolytics (alone or in combination) should not be used routinely to prevent spontaneous preterm birth in twin or triplet pregnancies.

The NICE Pathway on multiple pregnancy brings together all related NICE guidance and associated products on the condition in a set of interactive topic-based diagrams.

New evidence: Liem et al. (2013) conducted a multicentre, open-label, randomised controlled trial to establish whether cervical pessaries could prevent poor perinatal outcomes in women with a multiple pregnancy. The cervical pessaries for prevention of preterm birth in women with a multiple pregnancy (ProTWIN) study recruited pregnant women at 40 hospitals in the Netherlands who were between 12 and 20 weeks' gestation and had a multiple pregnancy. Participants were randomly assigned to receive a cervical silicone Arabin pessary or to a control group. The primary outcome was a composite of poor perinatal outcomes comprising: stillbirth; periventricular leucomalacia; severe respiratory distress syndrome; bronchopulmonary dysplasia; intraventricular haemorrhage; necrotising enterocolitis; proven sepsis; and neonatal death.
A total of 403 women were assigned to receive the cervical pessary (although 23 women [6%] did not have a pessary inserted) and 410 women were assigned to the control group. In an intention to treat analysis, a similar proportion of women in the pessary group and the control group had a poor neonatal outcome (53 women [13%] versus 55 women [14%], respectively, relative risk=0.98, 95% CI 0.69 to 1.39). The two groups also had a similar median gestational age at delivery (36.7 weeks versus 36.4 weeks, respectively, hazard ratio [HR]=0.91, 95% CI 0.76 to 1.09). The pessary was removed before 36 weeks’ gestation in 186 women (46%) because of adverse events.

The authors concluded that cervical pessaries are not effective in preventing poor perinatal outcome or preterm birth in women with a multiple pregnancy. The intervention might be effective in women with a cervical length of less than the 25th percentile, although this finding was a secondary outcome in a small group of women (n=133).

Commentary: “This new evidence demonstrates that the Arabin pessary does not prevent preterm birth in an unselected population of women with twin pregnancy. However, it provides some support for the intriguing hypothesis that the pessary could prevent preterm birth (and improve composite neonatal outcome) in women with a twin pregnancy and a short cervix.

“A ‘short cervix’ in the ProTwin study was a cervical length of the 25th centile or less, which in ProTwin was 38 mm or less. This measure contrasts with what used a large UK observational study (n=1000), where the 25th centile of cervical length measurement in women with twins was between 25 and 30 mm (To et al. 2006). This discrepancy in cervical length profiles between women in ProTwin and those in the UK raises concerns about both generalisability of the ProTwin results to other populations and uncertainty about the appropriate threshold of cervical length at which the pessary is effective.

“There is a significant unmet need for strategies that prevent preterm birth in both twin and singleton pregnancies in the UK. If the results of ProTwin are upheld in further studies, the Arabin pessary could be a cheap and effective intervention for a subset of women with twin pregnancy. This cervical pessary is relatively inexpensive, at around £40 per pessary. Given that the additional NHS costs associated with care of a preterm child compared with care of a child born to term is £22,885 per preterm child surviving to 18 years (2006 prices, Mangham et al. 2009), clinical efficacy of the pessary (if confirmed) is highly likely to be accompanied by cost effectiveness.” – Professor Jane E Norman, Professor of Maternal and Fetal Health, Tommy’s Centre for Maternal and Fetal Health, Medical Research Council Centre for Reproductive Health, University of Edinburgh.

Professor Norman is lead for a proposed UK multicentre trial of the Arabin pessary in women with a twin pregnancy and a short cervix and is Chair of the Guideline Development Group for the NICE clinical guideline on preterm labour and birth

Study sponsorship: The Netherlands Organisation for Health Research and Development.