

Cervical cerclage and pessary in women with cervical insufficiency

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Objective

Cervical insufficiency (CI), responsible for 8% of preterm births (PB), describes painless cervical dilation leading to recurrent pregnancy losses in the second trimester or preterm births in otherwise normal pregnancies. The structural weakness of cervical tissue has been thought to contribute to or cause these adverse outcomes. Cervical pessary and cervical cerclage are considered preventive treatments in cases of risk for PB. This study aimed to assess the feasibility of conducting a future randomized controlled trial (RCT), focused on evaluating the potential effectiveness of the cervical pessary compared with cerclage. The comparison was to be in terms of reducing the PB rate before 37 weeks of gestation in women with previous PB due to CI or due to having a short cervix in their current pregnancy. As a secondary outcome, we studied the morbidity of the pessary compared with the cerclage in women with CI and assessed the economic impact of using both devices in these women.

Methods

This was a prospective, multi-centre, open-label pilot RCT. Enrolees were women with singleton pregnancies who had previous PB caused by CI (primary intervention <16 weeks) or a previous PB and a short cervical length (≤ 25 mm) in their current pregnancy (secondary intervention <24 weeks). Women were randomized (1: 1) to either cervical cerclage or pessary. The primary outcome was the spontaneous PB rate before 37 weeks of gestation. The sample size was calculated based on the estimated population we would be able to recruit: 60 women, 30 for each group (cerclage and pessary), to ascertain whether the PB rate < 37 weeks would be reduced from 34% to at least 27% in the pessary group, similar to results from cerclage.

Results

The results of our study show indications that the pessary would have a similar effect to that of the cerclage in the reduction of the rate of PP <37 weeks. The rates of obstetric and perinatal complications are not modified according to the device used in our population of pregnant women. Insertion of cervical pessary had lower secondary effects compared with cerclage. Furthermore, the cervical pessary costs were lower than the cerclage.

Conclusion

Cervical pessary did not worsen the prognosis of pregnancy and had fewer secondary effects with a lower economic cost; therefore, it would be feasible to carry out a study of similar characteristics with a larger sample size in order to verify our results.