20th World Congress in Fetal Medicine

The Arabin cervical pessary for the prevention of preterm birth in TTTS

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Objective

We investigated the use of the cervical pessary to reduce preterm birth before 32 weeks in monochorionic diamniotic twin pregnancies after fetal surgery for twin-twin transfusion syndrome.

Methods

In this open-label multicenter randomized trial pregnant women carrying monochorionic diamniotic twins requiring fetoscopic laser coagulation for twin-twin transfusion syndrome were randomly assigned in a 1: 1 ratio to pessary placement or conservative management. The primary outcome was birth before 32 weeks. Secondary outcomes were birth before 28, 30, 34 or 37 weeks, preterm rupture of membranes, fetal and neonatal survival, and a composite of maternal and neonatal complications. The estimated sample size was 364 patients, with 182 cases in each arm of the study. The analysis was performed according to the intention-to-treat principle. Two interim analyses were planned.

Results

The trial was stopped prematurely after the first planned interim analysis for futility. One hundred thirty-seven women were included in the analysis, 70 in the conservative management and 67 in the pessary group. A preterm birth before 32 weeks occurred in 27 women (40.3%) in the pessary group and in 25 women (35.7%) in the conservative management group (aOR, 1.19; 95% CI, 0.58-2.47, P=.63). No significant differences between groups were observed in the rate of deliveries before 28, 30, 34 and 37 weeks, respectively. Overall survival to delivery was 91.2% (125/137) for at least one twin and 70.8% (97/137) for both twins, with no differences between groups. Neonatal survival at 30 days was 76.5% (208/272). There were no differences between groups in maternal or neonatal morbidity.

Conclusion

In monochorionic diamniotic twin pregnancies requiring fetal therapy for twin-twin transfusion syndrome, routine use of cervical pessary did not reduce the rate of preterm delivery before 32 weeks.