

At-risk twin pregnancies benefit from an intervention called cerclage

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Women carrying twins are at higher risk for premature birth and miscarriage—those whose cervix dilates before 24 weeks are at highest risk—and yet one common treatment is not recommended for this population. A new multi-center randomized-controlled trial from Thomas Jefferson University shows that cerclage, an intervention that



sutures a dilating cervix closed, can help prevent preterm birth and miscarriage. The findings could overturn existing guidelines.

The clinical trial was stopped early because of positive results in the <u>intervention group</u>. The researchers showed that <u>perinatal mortality</u> was significantly decreased in women receiving cerclage.

"For women with <u>twin pregnancies</u> and early signs of labor and cervix dilation, there was really very little we could offer," says first author, Amanda Roman, MD, Associate Professor in the Department of Obstetrics and Gynecology at Thomas Jefferson University. "This study provides powerful evidence that there is an <u>effective treatment</u> we can use."

The results were published online in the *American Journal of Obstetrics* and *Gynecology* (*AJOG*) on June 24th.

Women who showed signs of preterm labor, as confirmed by a cervical exam that indicates dilation, were enrolled in the study and randomized to either receive cerclage plus antibiotics and indomethacin (an anti-pain medication), or standard of care. Of the 30 women enrolled, 17 women were randomized to the cerclage group and 13 to non-cerclage. The women in both groups were similar in demographics including age, race, body-mass index and other factors for preterm birth.

The trial enrolled 30 patients across 8 medical centers over the course of four years. "The small number of participants reflects how rare this condition is among all pregnancies," says Dr. Roman. "But because women were randomized to treatment and non-treatment groups, the results are strong, as confirmed by the independent Data Safety Monitoring Board."

The analysis showed that in the group that received cerclage, gestation



was prolonged by an average of 5.6 weeks (with a range of 2.0 to 9.3 weeks), and reduced infant mortality by 77%.

"Cerclage is a heroic intervention in this group of women," says Dr. Roman. "The possibility of losing a pregnancy is devastating. So we're very encouraged by these results demonstrating a life-saving intervention for women with twins experiencing early asymptomatic cervical dilation."

"We've already incorporated this cerclage into our practice and have been able to offer this to pregnant mothers with twins with great success," says senior author Vincenzo Berghella, MD, Director of the Division of Maternal Fetal Medicine at Jefferson. "These results have the potential to change practice, and help many more women have healthy twin babies."

Dr. Roman and her collaborators are also exploring whether cerclage might prove effective for another subset of women carrying twins, specifically <u>women</u> whose cervical length has shortened, which is a precursor to cervical dilation, between 16 and 23 weeks. They have a clinical trial currently open. Women participating in the study will be randomized to receiving cerclage or no cerclage (ClinicalTrials.gov # NCT03340688).

More information: Amanda Roman et al, Physical Exam Indicated Cerclage in Twin pregnancy: a Randomized Controlled Trial, *American Journal of Obstetrics and Gynecology* (2020). DOI: 10.1016/j.ajog.2020.06.047

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