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17P Cuts Preterm Birth if No Cerclage

BY PATRICE WENDLING

CHICAGO — The effect of 17-alpha-hydroxyprogesterone caproate on preterm birth varies depending on the presence or absence of cerclage in high-risk women, according to a planned secondary analysis of the Vaginal Ultrasound Cerclage Trial.

In women with prior spontaneous preterm birth and a cervical length of less than 25 mm, the hormone had no

effect if cerclage was present, but significantly reduced preterm births at less than 24 weeks and perinatal mortality if cerclage was absent, Dr. Vincenzo Berghella reported at the annual meeting of the Society for Maternal-Fetal Medicine.

The use of 17-alpha-hydroxyprogesterone caproate (17P) had no effect on the

primary outcome of preterm birth at less than 35 weeks in either the cerclage or no-cerclage groups.

Among the 148 women randomized to cerclage, the primary outcome occurred in 30% of the 47 women receiving 17P and in 34% of the 101 women with no 17P (odds ratio, 0.84).

Among the 152 women with no cerclage, the primary outcome occurred in 39% of the 52 women who received 17P and in 44% of the 100 women with no 17P (OR, 0.80). Women given 17P in either group received an average of 11 injections, beginning at an average gestational age of 18-19 weeks (range, 16-28 weeks).

In the presence of cerclage, the use of 17P had no significant effect on the outcomes of preterm birth at less than 24 weeks (OR, 0.60); less than 28 weeks (OR, 0.46); less than 32 weeks (OR, 0.62); or less than 37 weeks (OR, 1.29). The use of 17P in the presence of cerclage also had no significant effect on perinatal death (OR, 0.62), said Dr.

Berghella, professor of ob.gyn. at Jefferson Medical College in Philadelphia.

In the absence of cerclage, the use of 17P had a significant effect only on preterm birth at less than 24 weeks, occurring in 2% of women given 17P vs. 20% with no 17P (OR, 0.08), and on perinatal death, occurring in 4% of women given 17P and 23% with no 17P (OR, 0.14).

Because cervical length was a significant predictor of preterm birth in

Major Finding: In women with a cervical length of 15-24 mm, 17P was associated with statistically significant decreases in both preterm birth at less than 24 weeks (OR, 0.11) and perinatal mortality (OR, 0.18). There was no significant effect of 17P in women with a cervical length of less than 15 mm.

Data Source: Secondary analysis of 300 patients in the Vaginal Ultrasound Cerclage Trial.

Disclosures: The study was funded by the National Institute of Child Health and Human Development. Dr. Berghella disclosed no conflicts of interest.

both groups in a logistic regression analysis, the researchers analyzed the effect of 17P using different cervical length cutoffs. In women with a cervical length of 15-24 mm, 17P was associated with statistically significant decreases in both preterm birth at less than 24 weeks (OR, 0.11) and perinatal mortality (OR, 0.18), while there was no significant effect of 17P in women with a cervical length of less than 15 mm, Dr. Berghella said.

During a discussion of the findings, an attendee said the study provides a clear clinical effect of 17P, but that the researchers may have "de-powered" the study by separately analyzing the women based on cerclage status. Dr. Berghella said the researchers felt that women who receive cerclage are different from those who do not, and that the design was influenced by the original analysis showing that cerclage had an influence on preterm birth (Am. J. Obstet. Gynecol. 2009;201: 375:e1-8).

Shape of Cervical Funnel Tied to Length of Gestation

BY PATRICE WENDLING

CHICAGO — The presence of a U-shaped cervical funnel was significantly associated with earlier birth in high-risk women in a planned secondary analysis of the Vaginal Ultrasound Cerclage Trial.

Women with a U-shaped funnel gave birth nearly 3 weeks earlier at a gestational age of 31.8 weeks, compared with 34.6 weeks for women with a V-shaped funnel and 34.7 weeks for those with no funnel, Dr. Melissa Mancuso

reported at the annual meeting of the Society for Maternal-Fetal Medicine.

The relationship was independent of cervical length in the women, all of whom had a prior spontaneous preterm birth and a shortened midtrimester cervical length of less than 25 mm.

Women with a U-shaped funnel also were found to have the greatest benefit from cerclage. During a discussion of the study, one attendee asked if the findings suggest that the benefit of cerclage is only in women with a U-shaped funnel.

"What we know from the parent randomized trial is that there is a benefit from cerclage and that benefit increases as your cervical length decreases," she said. "If there is a U funnel present, that benefit is increased further."

It's been nearly 2 decades since researchers first described dilation and effacement in normal, term pregnancies as a progression of the funnel- or T-shaped internal cervical os to a Y shape, then a V shape, and finally a U shape (J. Ultrasound Med. 1995;14:719-24). While funneling has been found to be a risk factor for preterm birth in some reports, controversy lingers over its clinical utility and whether the clinical implications of a U- and V-shaped funnel are the same.

Dr. Mancuso reported on 301 women who were randomized to cerclage or no cerclage and underwent serial vaginal ultrasound between 16 and nearly 23 weeks, revealing no funnel in 154 women, a V-shaped funnel in 99, and a U-shaped funnel in 48. At baseline, women with a U funnel had a significantly shorter mean cervical length of 13 mm, compared with

Major Finding: High-risk women with a U-shaped cervical funnel gave birth significantly earlier at 31.8 weeks' gestation, versus 34.6 weeks for women with a V-shaped funnel and 34.7 weeks for those with no funnel.

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Disclosures: The study was funded by the National Institute of Child Health and Human Development. Dr. Mancuso disclosed no conflicts of interest.

19 mm for women with a V funnel and 21 mm for those with no funnel, said Dr. Mancuso of the University of Alabama at Birmingham. Twice as many women with a U funnel were treated with cerclage vs. no cerclage (32 vs. 16), which was a significant difference.

In a univariate analysis, the presence of a U funnel, but not a V funnel, was significantly associated with an increased risk of preterm birth at all four time points measured. Preterm birth rates in the Ufunnel, V-funnel, and no-funnel groups were 23% vs. 6% vs. 8.4% at less than 24 weeks, 38% vs. 17% vs. 12% at less than 28 weeks, 60% vs. 34% vs. 32% at less than 35 weeks, and 73% vs. 50% vs. 47% at less than 37 weeks. There was no significant difference between the no-funnel and V-funnel groups.

After investigators controlled for baseline cervical length and cerclage, a Ushaped funnel remained significantly associated with preterm birth, with adjusted odds ratios ranging from 2.4 to 2.1, Dr. Mancuso said.

Because U-funnel outcomes appeared to be appreciably worse, the researchers investigated the possibility of an interaction between the U funnel and cerclage. Indeed, women with a U-shaped funnel gave birth a mean 4.9 weeks later in gestation with a cerclage than without a cerclage. This relationship remained significant, even after cervical length was controlled for, she said.

Session moderator Dr. Joshua Copel of Yale University in New Haven, Conn., described the findings as interesting and provocative.

Maternal Asthma Tied to Risk of Preeclampsia, Prematurity

NEW ORLEANS — Maternal asthma has a significant effect on several adverse pregnancy outcomes including preeclampsia, preterm delivery, and low birth weight, based on a meta-analysis of 30 studies.

Pregnant asthmatic women have been reported to have an overall increased risk of adverse perinatal outcomes, but study results are conflicting, Dr. Jennifer Namazy said at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

"Our meta-analysis was conducted to see whether the risks were real," said Dr. Namazy of Scripps Health in San Diego.

Dr. Namazy and her colleagues' review included prospective cohort studies and retrospective studies con-

ducted between 1975 and 2009, in which pregnancy outcomes were compared between women with asthma and nonasthmatic controls. The 30 studies included 8 studies involving asthma management.

Compared with control women without asthma, asthmatic women had a significantly increased risk of preeclampsia (relative risk, 1.54). Low birth weight (defined as 2,500 g or less) was significantly more likely in babies of women with asthma (RR, 1.46). Babies born prematurely (birth after less than 37 weeks' gestation) or small for gestational age were significantly more likely among women with asthma compared with controls (RR, 1.41 and 1.22). Neonatal death was significantly more likely in babies of women with asthma (RR, 1.49).

Perinatal mortality (stillbirth plus neonatal death) was significantly more likely in babies of women with asthma (RR, 1.25). No significant associations were seen between maternal asthma and an increased risk of congenital anomalies (RR, 1.08).

"The data suggest that active management may reduce some, but not other perinatal complications," she said. But active management may not ensure adequate asthma control, and more research is needed to specifically assess the effect of asthma control on perinatal outcomes.

—Heidi Splete

Disclosures: Dr. Namazy has served as a consultant for Genentech.