Various Labor Induction Methods Put to the Test

BY SUSAN LONDON

FROM THE ANNUAL MEETING OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

SAN FRANCISCO – In women with term pregnancies and an unfavorable cervix, different methods of labor induction have their pros and cons, according to the results of a pair of randomized trials reported at the meeting.

INTRODUCING

A trial conducted in the Netherlands found that roughly one-fifth of women eventually had a cesarean section whether labor was induced with a Foley catheter or with vaginal prostaglandin gel. But there was less maternal and neonatal morbidity with the former.

And a trial conducted in Canada found that a Foley catheter plus oxytocin or misoprostol was associated with a higher rate of delivery within 24 hours than misoprostol alone. However, the misoprostol methods were associated with a lower cesarean rate.

Dutch Trial

U.S. and Dutch guidelines indicate that both prostaglandin E analogues and Foley catheters are options for inducing labor, said Dr. Marta JóŸwiak, an obstetrician at the Groene Hart Hospital in Gouda, the Netherlands. As a result, clinical practice varies. Although these methods have been compared, questions remain about their relative benefits and drawbacks, including complications and their costs.

Dr. JóŸwiak and her coinvestigators conducted a trial called PROBAAT (Prostaglandins or Balloon for Induction of Labor at Term) in 819 women with a term pregnancy who had a vital singleton fetus in cephalic presentation, intact membranes, and an unfavorable cervix, defined as a Bishop score of less than 6. The women were 31 were old on

The women were 31 years old, on average, and 81% were white. The

Major Finding: The combined rate of cesarean and vaginal instrumental deliveries specifically for fetal distress was significantly lower in the 411 women in the

Foley catheter group, compared with the 408 women who received vaginal prostaglandin gel (12% vs. 18%), while the former group had less maternal and neonatal morbidity. In the other trial, the rate of delivery within 24 hours was highest in the Foley plus oxytocin group of 92 women, at 94%. It was statistically similar at 87% in the Foley plus misoprostol group of 85 women, but significantly lower at 74% in the misoprostol-only group of 88 women.

Data Source: Two randomized controlled trials involving 819 pregnant women and 265 pregnant women, respectively. The women in both groups were at term with an indication for labor induction and an unfavorable cervix.

Disclosures: Dr. JóŸwiak and Dr. Dionne did not report any relevant financial disclosures.

median gestational age was 40 weeks. Two-thirds were nulliparous, and most (83%) had a Bishop score of 3 or less. The leading indications for labor induction were postterm pregnancy (36%) and hypertensive disorders (34%). Patients were excluded from the study if they had had a cesarean delivery, or had placenta previa, a fetus with congenital anomalies, or hypersensitivity to either of the products used for labor induction.

The investigators randomized the women in equal numbers to nonblinded treatment with a transcervical Foley catheter or vaginal prostaglandin E2 gel. Analyses were based on 411 women in the former group and 408 in the latter group.

Trial results showed that the rate of cesarean section, the primary outcome, was 23% in the Foley catheter group and 20% in the prostaglandin gel group, a difference that was not significant, Dr. JóŸwiak reported.

The rate of vaginal instrumental delivery did not differ, but the combined rate of cesarean and vaginal instrumental deliveries specifically for fetal distress was significantly lower in the Foley group (12% vs. 18%). The rate of *Continued on following page*



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maternal infection during labor also was lower in that group (2% vs. 4%).

The groups were similar with respect to rates of other maternal outcomes (hyperstimulation, postpartum hemorrhage, and blood transfusion). There were two cases of uterine rupture, both in the prostaglandin group.

In terms of neonatal outcomes, neonates in the Foley group were significantly less likely than their counterparts in the prostaglandin group to be admitted to the ward (12% vs. 19%), while rates of intensive care unit admission were identical.

The groups were similar with respect to rates of other neonatal outcomes, such as Apgar scores, umbilical cord blood pH, reasons for admission, and length of admission.

Subgroup analyses are still ongoing, according to Dr. JóŸwiak, but preliminary results suggest that the Foley catheter was the more successful of the two methods in nulliparous women, who are more likely to have trouble with labor induction.

"Induction with a Foley catheter is, in terms of cesarean section, as effective as induction with prostaglandin E2 gel, with less neonatal and maternal morbidity," she concluded.

"We recommend considering the Foley catheter as a first choice for induction of labor at term in women with an unfavorable cervix," Dr. JóŸwiak said.

Canadian Trial

Elective induction of labor now occurs in 21%-30% of all births, noted Dr. Marie-Danielle Dionne, a fetal-maternal medicine specialist at the University of Montreal. "An improved Bishop score before induction increases the rate of vaginal birth."

She and her coinvestigators enrolled women with a normal singleton pregnancy at term who had intact membranes and an unfavorable cervix, with a Bishop score of 5 or less. Women were ineligible if they had prostaglandin hypersensitivity, previous uterine surgery, a noncephalic fetal presentation, or nonreassuring fetal cardiac monitoring.

The women were randomized in equal numbers to nonblinded treatment with a Foley catheter plus intravenous oxytocin infusion, a Foley catheter plus intravaginal misoprostol, or intravaginal misoprostol alone.

The trial was stopped early because of an elevated rate of cesarean deliveries in the first group, according to Dr. Dionne.

Intention-to-treat analyses were based on 92 women in the Foley plus oxytocin group, 85 women in the Foley plus misoprostol group, and 88 women in the misoprostol-only group.

On average, the women were 30 years old, and the median gestational age was 40.5 weeks. About three-fourths of the women were nulliparous. The mean Bishop score was 3. The leading indications for induction were a postdate pregnancy (54%) and diabetes (27%).

Trial results showed that the rate of delivery within 24 hours, the primary

outcome, was highest in the Foley plus oxytocin group at 94%, Dr. Dionne reported. It was statistically similar in the Foley plus misoprostol group at 87%, but significantly lower in the misoprostolonly group at 74%.

However, the rate of cesarean delivery was 44% in the Foley plus oxytocin group. It was significantly lower in both the Foley plus misoprostol group at 24%, and in the misoprostol-only group at 28%.

The three groups did not differ with respect to rates of maternal complications (postpartum hemorrhage, hyperstimulation, receipt of antibiotics, and placental retention) and fetal and neonatal outcomes (Apgar scores, cord blood arterial pH, admission to the neonatal intensive care unit, meconium in amniotic fluid, receipt of antibiotics, and nonreassuring fetal monitoring).

"We can say that in our institutions, the use of a Foley catheter is associated with more deliveries within 24 hours," said Dr. Dionne.

"This is mostly due to a smaller delay from induction to labor," she said.

"Misoprostol use significantly reduced the rate of c-section, with or without a

Foley catheter," she further noted.

Dr. Dionne speculated that the higher rate of cesareans with the Foley catheter plus oxytocin, despite the more rapid delivery, was due to inadequate cervical ripening in the face of contractions. "There is a small change in the cervix and there are regular contractions, but it is probably not as physiological as with the misoprostol," she said.

"So we have to decide which is best: more deliveries within 24 hours or more vaginal births," Dr. Dionne concluded. "The answer is easy for me: We think more vaginal births is better."

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