OBSTETRICS

A randomized trial of preinduction cervical ripening: dinoprostone vaginal insert versus double-balloon catheter

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OBJECTIVE: We sought to compare the efficacy of a double-balloon transcervical catheter to that of a prostaglandin (PG) vaginal insert among women undergoing labor induction.

STUDY DESIGN: In all, 210 women with a Bishop score ≤6 were assigned randomly to cervical ripening with either a double-balloon device or a PGE2 sustained-release vaginal insert. Primary outcome was vaginal delivery within 24 hours.

RESULTS: The proportion of women who achieved vaginal delivery in 24 hours was higher in the double-balloon group than in the PGE2 group (68.6% vs 49.5%; odds ratio, 2.22; 95% confidence interval, 1.26–3.91). There was no difference in cesarean delivery rates (23.8% vs 26.2%; odds ratio, 0.88; 95% confidence interval, 0.47–1.65). Oxytocin and epidural analgesia were administered more frequently when a double-balloon device was used. Uterine tachysystole or hypertonus occurred more frequently in the PGE2 arm (9.7% vs 0%, $P = .0007$).

CONCLUSION: The use of a double-balloon catheter for cervical ripening is associated with a higher rate of vaginal birth within 24 hours compared with a PGE2 vaginal insert.

Key words: double-balloon catheter, labor induction, mechanical method, prostaglandins, ripening time

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Over the past several decades, the incidence of labor induction has continued to rise to the point that in developed countries the proportion of infants delivered following induction of labor can be as high as 1 in 4. Induction of labor has a major health impact on the woman and on her baby, can affect the satisfaction with the birth experience, and places strain on the organization of care in labor wards. For all of these reasons the policies of induction, chiefly indications and methods, remain key priorities for research in obstetrics, with a view to improving the quality of care and outcomes.

Methods that have historically been applied to induction of labor in the presence of an unripe cervix can be classified into 2 categories: (1) mechanical methods that are thought to work by both directly dilating the cervix and by promoting endogenous prostaglandin (PG) release; and (2) application of pharmacologic ripening agents such as exogenous PGs. Over 50 years after discovery of pharmacologic preparations of PGE2 and several centuries after the first description of mechanical dilation of the cervical canal to achieve delivery, we continue to search for the optimal method that will modulate the unfavorable to favorable cervix, improving the ultimate outcome of labor and ideally eliminating risks to the mother and fetus.

Despite extensive studies, uncertainties remain about how best to apply vaginal PGs in terms of their vehicle, dosage, and timing.[1] Similarly, the evidence for the use of mechanical methods for inducing labor is confused by a large number of small studies using different comparators and protocols,[2,3] to the extent that highly reputed scientific societies came to opposite recommendations regarding the use of balloon catheters for iatrogenic cervical ripening in labor induction guidelines.[4,5] Interpretation of comparative data between mechanical devices and topical PGE2 is hindered by several factors including often underpowered trials, use of different measures of effectiveness (cervical change vs a variety of delivery outcomes), use of disparate regimens, and methods of induction either used alone or in combination.[2,3]

Controlled-release inserts have become the preferred vehicle for delivering vaginal PGs in many settings, probably due to reduced need of repeated vaginal examination, rapidity and ease of removal when active labor is established or when complications ensue, and the reported reduction in the need of instrumental vaginal deliveries and in the use of oxytocin augmentation compared to vaginal PGE2 gel or tablet.[1]

In view of the increased frequency of use of sustained-release pessaries and the very scarce comparative data between this device and mechanical methods, we decided to design a randomized study

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comparing this vaginal PGE2 preparation with a double-balloon device specifically developed and engineered for ripening the cervix and licensed for use in obstetric care.

Materials and Methods

Patients with unfavorable cervices, scheduled to undergo labor induction from August 2010 through October 2011 at the Obstetrics Department of University of Insubria, Varese, Italy, were screened for study inclusion. All recruited women presented with a singleton gestation, vertex presentation, Bishop score ≤6, intact membranes, gestational age ≥34 weeks, and reassuring fetal heart tracing on admission. Women with antepartum bleeding, intrauterine fetal death, prior uterine scars, positive vaginal or rectal group B streptococcus screening cultures, placenta previa, or any other contraindication to vaginal delivery were excluded. All the participants gave written informed consent and local institutional review board approval was obtained before the beginning of the study.

Once the decision to induce labor was made, women who whished to participate in the study were recruited by a staff physician. Participants were randomly allocated to preinduction cervical ripening with either a double-balloon catheter or a 10-mg controlled-release dinoprostone vaginal insert. The randomization sequence was created using a computer-generated randomization scheme with 1:1 allocation for each arm of the study. The random allocation sequence was concealed from those responsible for recruiting participants into the study (attending physicians) by keeping it in a file cabinet with access restricted to research staff. A research assistant disclosed the nature of the assignment only after enrollment.

In the group assigned to mechanical ripening, a double-balloon catheter (Cook Cervical Ripener Balloon; Cook OB/GYN, Spencer, IN) was inserted into the cervical canal under direct visualization during a sterile speculum examination. Once both balloons entered the cervical canal, the first (uterine) balloon was filled with 50 mL of saline above the level of the internal os and then pulled snugly back against the os. The second (vaginal) balloon was then inflated with 50 mL of saline to apply pressure on the vaginal side of the cervix. The external end of the device was taped without traction to the medial aspect of the woman's thigh. After completion of the device placement, patients underwent continuous fetal heart rate monitoring for 30 minutes and then were allowed to ambulate. The double-balloon device was left in place for approximately 12 hours, as per manufacturer's recommendation. Reasons for removing the catheter included: (1) the maximal time allowed for cervical ripening to take place had elapsed; (2) spontaneous rupture of membranes occurred; (3) the balloon was expelled spontaneously; (4) patients entered labor (defined as rhythmic, firm, adequate-quality uterine contractions occurring at a frequency of ≥4 in 30 minutes and lasting ≥40 seconds, with an effaced cervix and a cervical dilatation ≥3 cm); or (5) fetal distress was suspected.

In the group randomly assigned to pharmacologic ripening, the PGE2 slow-release vaginal insert was placed high in the vaginal fornix and patients were monitored for uterine activity and fetal heart rate for at least 1 hour and then allowed to ambulate. Primary reasons for discontinuation of the PGE2 insert included: (1) completion of maximum recommended dosing period (24 hours); (2) onset of labor; or (3) uterine contractile abnormalities or nonreassuring fetal heart rate patterns that prompted clinical intervention.

Soon after expulsion or removal of the double-balloon device or 1 hour (as per the manufacturer's recommendation) after completion of maximum recommended dosing period of the PG pessary, oxytocin was administered to those women who were not in labor. It is our policy to perform amniotomy before initiating induction of labor with oxytocin, unless the fetal station is considered too high to safely perform amniotomy or the cervix is closed. Oxytocin was administered using a standard dose regimen in all patients. The induction protocol at our institution specifies starting oxytocin at 5 mIU/min increasing incrementally by 5 mIU/min every 15 minutes to achieve 7 contractions in 15 minutes or up to a maximum infusion of 30 mIU/min. Once in active labor (cervix at least 5 cm dilated), standardized intrapartum management was carried out by the staff members in charge of the labor and delivery unit according to institutional protocols. Slow progress of labor was defined as ≤1 cm of cervical progress in 2 hours. If the membranes were intact, amniotomy was first performed. If there was still no progress 1 hour after amniotomy, augmentation by oxytocin infusion was started. Oxytocin was initiated immediately if the membranes were already ruptured and the cervix remained unchanged on 2 consecutive pelvic examinations conducted 2 hours apart. Oxytocin was also administered when the second stage of labor was >2 hours in nulliparous and 1 hour in multiparous women.

Tachysystole was identified when there were >5 contractions per 10 minutes for at least 20 minutes. Hypertonus was defined as a single contraction lasting at least 2 minutes. Failed induction was diagnosed when women did not progress into the active phase of labor despite adequate contraction pattern, after amniotomy and a minimum of 10 hours of oxytocin infusion. Failure to progress was defined as unchanged cervical dilatation in a 4-hour interval despite oxytocin augmentation and a sustained uterine contraction pattern or no descent after 1 hour during the second stage of labor. Bishop score was calculated prior to labor induction and after removal of the ripening devices by the attending physician or a member of the resident staff. Blood loss at vaginal delivery was estimated using an underbuttocks drape with a graduated pouch for measurement. Blood loss at cesarean delivery was estimated from the content of suction devices.

All outcome data were obtained concurrent with patient care and recorded by the investigators team. The primary outcome measure was vaginal delivery within 24 hours of the initiation of ripening. Other outcome variables included improvement in the Bishop score after ripening, cesarean delivery rates, ripening-to-delivery interval, oxytocin administration, epidural request, and neonatal outcomes (admission to the neonatal in-