Katarzyna Suffecool*, Barak M. Rosenn, Stefanie Kam, Juliet Mushi, Janelle Foroutan and Kimberly Herrera

**Labor induction in nulliparous women with an unfavorable cervix: double balloon catheter versus dinoprostone**

**Abstract**

**Objective:** We sought to compare the efficacy of the double-balloon catheter and dinoprostone for induction of labor among nulliparous women with an unfavorable cervix.

**Study design:** Nulliparous women with a Bishop score <6 were randomized to receive a 10-mg intravaginal dinoprostone insert or a double-balloon catheter. Primary outcome was time to delivery. Statistical analyses were performed by intention to treat using the chi-square, Fisher’s exact, and Student’s t-test, as appropriate.

**Results:** The mean induction-to-delivery time was shorter in the double-balloon group as compared to the dinoprostone group (17.9 ± 5.8 vs. 26.3 ± 9.7 h) as was the time from induction to vaginal delivery (19.13 ± 5 vs. 24.45 ± 8.7 h, respectively). More women in the catheter group were delivered within 24 h compared to the dinoprostone group (87.1% vs. 47.4%). Approximately 50% of women in both groups delivered by cesarean section.

**Conclusion:** Induction of labor with the double-balloon catheter in nulliparous women with an unfavorable cervix is associated with a shorter time to delivery compared to dinoprostone.

**Keywords:** Double-balloon catheter; labor induction; prostaglandins.

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**Introduction**

The overall rate of induction of labor in the United States has more than doubled since 1990, with more than 22% of all gravid women undergoing induction of labor in 2006 [7]. When the cervix is unfavorable, as determined by the Bishop pelvic scoring system [1], labor induction is associated with a higher incidence of prolonged labor, operative vaginal delivery, and cesarean delivery. Under these circumstances, agents for cervical ripening may be used to soften, thin, and dilate the cervix, in order to reduce the induction-to-delivery time and to decrease the likelihood of a failed induction.

There is little consensus on the best method for cervical ripening and induction of labor, and published studies have proposed various induction protocols and methods. Most of these studies present data that include induction in both nulliparous and multiparous women. The purpose of this study was to compare two methods of labor induction in nulliparous women with an unfavorable cervix. The study was designed to test the hypothesis that using a double-balloon catheter for cervical ripening in these women will significantly shorten the induction-to-delivery time compared to cervical ripening using a dinoprostone (prostaglandin E₃) 10 mg vaginal insert.

**Material and methods**

This prospective randomized study was conducted between February 2011 and September 2012. The study was approved by the institutional review board of St. Luke’s–Roosevelt Hospital Center. The included patients were nulliparous pregnant women at age 18 years or older with term (37 completed weeks or more) singleton gestations in vertex presentation and intact membranes and a cervical Bishop score <6, admitted for cervical ripening and induction of labor. Women with contraindications for a vaginal delivery (i.e., placenta previa, nonvertex presentation), presence of ruptured membranes, severe preeclampsia, suspected fetal growth restriction with abnormal Doppler studies, presence of a uterine scar, and a nonreassuring fetal heart tracing requiring immediate intervention were excluded.
from the study. Gestational age was determined by last menstrual period or, in cases of discrepancy with early ultrasound, by first- and second-trimester ultrasound.

Eligible patients who were admitted to the Labor and Delivery Unit for induction of labor and signed informed consent were randomized to one of two cervical ripening protocols: either 10-mg controlled-release dinoprostone vaginal insert or double-balloon cervical catheter (Cook Cervical Ripener Balloon; Cook OB/GYN, Spencer, IN, USA). Randomization was obtained via a computer-generated schedule with 1:1 allocation for each arm of the study. The allocation of assignment was concealed by placement in sequentially numbered, opaque, sealed envelopes. The envelopes were kept in the Labor and Delivery Unit and drawn in consecutive order.

Prior to randomization, the following data were recorded: medical and gynecological history, physical and vaginal examination, an initial Bishop score, ultrasonography of the fetal position, fetal weight estimation, and the amniotic fluid index.

For women randomized to dinoprostone, the vaginal insert was placed in the posterior fornix of the vagina per routine protocol. The dinoprostone insert was removed either 12 h after insertion or if the patient had more than five contractions in a 10-min interval (tachysystole) or a nonreassuring fetal heart rate tracing. In case of involuntary expulsion of the insert, a new dinoprostone insert was placed. Vaginal examination of the cervix was performed at the time of removal of the insert.

For women randomized to the double-balloon catheter, the device was inserted into the cervix using ring forceps, with both deflated balloons inserted proximal to the internal os. While holding the device in place, the uterine balloon was inflated with 80 mL of saline above the level of the internal os and then pulled back against the internal os. Following this step, the speculum was removed and the vaginal balloon was inflated with 80 mL of saline to apply pressure on the vaginal side of the cervix. The balloon catheter was removed either following self-expulsion or after 12 h of insertion. Vaginal examination of the cervix was performed at the time of catheter removal.

Patients who received dinoprostone and who did not enter spontaneous labor were managed with oxytocin infusion starting 60 min after removal of the insert in accordance with the unit’s policy and procedure. In patients who had the double-balloon catheter inserted, oxytocin infusion was started 6 h after placement of the catheter in accordance with the unit’s policy and procedure.

Oxytocin was administered per protocol to all patients who did not have at least three contractions in 10 min. Oxytocin was administered by an infusion pump system beginning at 2 mIU/min and increased by 2 mIU/min every 20 min until regular uterine contractions were established, defined as three to five contractions in a 10-min interval.

In patients having regular contractions, a cervical examination was performed every 2-3 h. Continuous fetal heart rate monitoring and uterine activity monitoring were performed on all patients.

Active labor was defined as cervical dilatation of 5 cm or more in the presence of regular uterine contractions. Amniotomy was performed during the active phase of labor.

Failed induction was diagnosed when women did not progress into the active phase of labor despite an adequate contraction pattern, after amniotomy, and following at least 12 h of oxytocin infusion. Failure to progress was defined as an unchanged cervical examination in a 4-h interval despite oxytocin infusion and a sustained uterine contraction pattern or no descent after 2 h during the second stage of labor.

The primary outcome was time from insertion of the ripening device to delivery. Secondary outcomes included delivery rate within 24 h, cesarean delivery rate, time to active labor, rate of operative vaginal delivery, and occurrence of maternal or fetal adverse events.

Planned sample size calculation was based on detection of a 25% difference between the two methods of cervical ripening in mean time from induction to delivery. Based on our own historical data, the time from insertion of dinoprostone to delivery in nulliparous women is 22.5±7 h (mean±SD). A sample size of 26 women per group had an 80% power to detect a 25% difference allowing an alpha error of 5% and using a two-tailed t-test. To account for a protocol violation rate of 5%, 28 patients were planned to be enrolled in each arm of the study.

Statistical analyses were performed by intention to treat. The Student’s t-test and the Mann-Whitney U-test were used to compare continuous variables. The χ² and the Fisher’s exact test were used for analysis of categorical variables; P<0.05 was considered statistically significant. Analysis of the proportions of women who remained undelivered over time was performed by plotting Kaplan-Meier survival curves.

Results

Over the study period, 10,567 women delivered at our institution and, of these, 1,275 deliveries followed labor induction. Two hundred and forty women who met the inclusion criteria were approached, and, of these, 62 consented to participate in the study (Figure 1). In the dinoprostone group, two women had the insert left intravaginally for more than 12 h. This was considered a protocol deviation; however, data from these two subjects were included in the analysis.

Failure to place the double-balloon catheter occurred in two women randomized to the catheter group: one had a closed cervix that did not admit the ripening device and the other was found to have the cervix 3 cm dilated and oxytocin was started without catheter placement. In one woman, the catheter was left in place for longer than 12 h. None of these women were excluded from analyses.

Demographics and baseline characteristics in both groups were similar (Table 1). All study participants received oxytocin for induction or augmentation of labor.

Table 2 depicts the outcome of induction and labor characteristics in the two groups.

In both groups, the majority of women (>80%) successfully transitioned into the active phase of labor following the induction.

The mean (±SD) time from induction to delivery was significantly shorter in the catheter group compared to the dinoprostone group (17.9±5.8 vs. 26.3±9.7 h, respectively) as was the time from induction to vaginal delivery.
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The proportion of women who were delivered within 24 h was significantly higher in the catheter group compared to the dinoprostone group (87.1% vs. 48.4%).

Uterine tachysystole occurred in eight (25.8%) of the patients in the dinoprostone group, but in none of the patients in the catheter group. The vaginal insert and the catheter were removed because of fetal heart rate changes in two patients in each group. None of these cases required an emergency cesarean delivery following removal of the induction agent.

Approximately 50% of women in both groups delivered by cesarean section. Indications for cesarean section did not differ significantly between the groups (Table 2). Figure 2 depicts the Kaplan-Meier survival curves that include all women who delivered vaginally and illustrates the fraction of women who remained undelivered at any given time after initiation of induction.

Data are presented as number (%), median (range), or mean±SD.

### Table 1  Demographic characteristics and indications for induction of labor.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dinoprostone (n=31)</th>
<th>Double-balloon catheter (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age, years</td>
<td>28±7.1</td>
<td>27.5±6.4</td>
</tr>
<tr>
<td>Gestational age on admission, weeks</td>
<td>40.2±1.45</td>
<td>40.9±1.1</td>
</tr>
<tr>
<td>Baseline Bishop score</td>
<td>2 (1–5)</td>
<td>2 (0–5)</td>
</tr>
<tr>
<td>Indication for induction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postterm pregnancy (&gt;41.0 weeks)</td>
<td>12 (38.7%)</td>
<td>12 (38.7%)</td>
</tr>
<tr>
<td>Hypertensive disorders</td>
<td>8 (25.8%)</td>
<td>5 (16.1%)</td>
</tr>
<tr>
<td>Oligohydramnios</td>
<td>7 (22.5%)</td>
<td>6 (19.3%)</td>
</tr>
<tr>
<td>Polyhydramnios</td>
<td>1 (3.2%)</td>
<td>1 (3.2%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1 (3.2%)</td>
<td>1 (3.2%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (6.4%)</td>
<td>6 (19.3%)</td>
</tr>
</tbody>
</table>

(19.1±5.0 vs. 24.4±8.7 h, respectively).
Neonatal outcomes were similar in both study groups (Table 3). No newborn was admitted to the neonatal intensive care unit due to suspected sepsis or had a culture-proven sepsis.

**Discussion and conclusions**

Our findings suggest that induction of labor with a double-balloon catheter in nulliparous women with an unfavorable cervix significantly shortens labor, with no apparent change in cesarean delivery rate. Additionally, a greater percentage of women induced with the catheter delivered within 24 h of initiating induction. The two groups were comparable in terms of the proportion of women who achieved active labor as well as those who had a failed induction. The time interval from labor induction to onset of active labor, however, was significantly shorter by an average of 7 h in the catheter group.

These two methods of cervical ripening have been previously compared in a randomized study. The study by Cromi et al. [3] found that patients induced with a double-balloon catheter were more likely to deliver within 24 h as compared to the group induced with a 10-mg dinoprostone vaginal insert, but in contrast to our own study, there was no difference between the two groups with respect to the time interval from induction to delivery. This discrepancy between the studies may be the result of the different

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**Table 2  Induction and labor outcomes.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dinoprostone (n=31)</th>
<th>Double-balloon catheter (n=31)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of active labor, %</td>
<td>26 (84%)</td>
<td>25 (81%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Time to onset of active labor, h</td>
<td>19.1±8</td>
<td>12.3±3.7</td>
<td>0.0001</td>
</tr>
<tr>
<td>Time to delivery, h</td>
<td>26.3±9.7</td>
<td>17.9±5.8</td>
<td>0.0001</td>
</tr>
<tr>
<td>Time to vaginal delivery, h</td>
<td>24.4±8.7 (n=15)</td>
<td>19.1±5.0 (n=14)</td>
<td>0.05</td>
</tr>
<tr>
<td>Delivery within 24 h, %</td>
<td>15 (48.4%)</td>
<td>27 (87.1%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Time to delivery excluding CS for nonreassuring fetal heart rate tracing, h</td>
<td>26.7±9.5 (n=26)</td>
<td>20±5 (n=23)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

**Mode of delivery**

- Vaginal-overall: 15 (48.4%) vs. 14 (45.2%) P=0.8
- Assisted vaginal delivery: 4 (12.9%) vs. 2 (6.4%) P=0.6
- Cesarean section: 16 (51.6%) vs. 17 (54.8%) P=0.9

**Indication for cesarean section**

- Failed induction: 3 (9.7%) vs. 4 (12.9%) P=0.9
- Arrest of labor: 8 (25.8%) vs. 5 (16.1%) P=0.5
- Nonreassuring FHR tracing: 5 (16.1%) vs. 8 (25.8%) P=0.5

Data are presented as number (%) or as mean±SD.

**Table 3  Neonatal outcomes.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dinoprostone (n=31)</th>
<th>Double-balloon catheter (n=31)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight, g</td>
<td>3397±391</td>
<td>3474±441</td>
<td>0.5</td>
</tr>
<tr>
<td>Macrosomia (&gt;4000 g)</td>
<td>1 (3.2%)</td>
<td>3 (9.67%)</td>
<td>0.6</td>
</tr>
<tr>
<td>5-min Apgar score &lt;7</td>
<td>0 (0%)</td>
<td>1 (3.2%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Umbilical artery blood pH &lt;7.0</td>
<td>1 (3.2%)</td>
<td>1 (3.2%)</td>
<td>1</td>
</tr>
</tbody>
</table>

Data are presented as number (%) or as mean±SD.
induction protocols used. In our study, oxytocin infusion was started 6 h after placement of the double-balloon catheter, compared to 12 h in the study by Cromi et al. [3]. Similarly, in the dinoprostone group, our protocol dictated removal of the insert after 12 h, while in the Cromi et al. [3] study the insert was kept in place for up to 24 h before starting oxytocin infusion. It is noteworthy that, although the 10-mg dinoprostone slow-release insert is identical in the USA and in Europe, the manufacturer’s instructions on the US product state that it should be removed after 12 h, while the European instructions state that it should be removed after 24 h. Another important difference is that the study by Cromi et al. [3] included more than 25% multiparous women, as opposed to our own population of purely nulliparous women.

Mechanical methods for cervical ripening, such as the double-balloon catheter, promote cervical change while provoking little, if any, uterine activity, and most deliveries occur only after administration of oxytocin. In contrast, prostaglandins such as the dinoprostone vaginal insert may evoke uterine contractions within the 1 h of insertion and these may persist with an adequate contraction pattern in approximately half of all patients [6, 13]. Indeed, administration of oxytocin is contraindicated as long as the vaginal insert is in place for fear of evoking tachysystole or tetanic uterine contractions. Thus, by design, use of mechanical ripening methods allows earlier initiation of oxytocin infusion, contributing to the shortened induction-to-delivery time. In fact, it may be argued that oxytocin infusion can be initiated immediately after placement of the catheter. This may have led to an even greater number of women delivering within 24 h and to an even shorter induction-to-delivery interval in this group. Furthermore, each double-balloon catheter costs our hospital $35 compared with $190 for the dinoprostone vaginal insert. This, together with the savings related to shorter duration of labor, makes the double-balloon catheter a more cost-effective and more desired method for labor induction.

A prolonged course of induction and labor from admission to delivery has several important implications. The length of labor is directly correlated with increased risks of maternal chorioamnionitis, postpartum fever, and neonatal infection [5, 10]. Additionally, qualitative studies that examined how women perceive their birth experience in the setting of induction of labor have found that prolongation of the time interval required to achieve delivery was significantly associated with patient dissatisfaction with the birth process [9]. When pregnant women are interviewed as to their expectations regarding childbirth, they identify short duration and manageable pain as the main issues of concern [4]. In our study, the cesarean section rate was 50% in both arms, which is higher than the rate reported in some previous studies [2, 3]. One possible explanation stems from the fact that we included only nulliparous women with a low Bishop score as opposed to other studies that included both nulliparous and multiparous women. A low Bishop score is a well-established risk factor for cesarean section when labor is induced in nulliparous women.

In a retrospective review, women who required cervical ripening before labor due to a low Bishop score were two to three times more likely to undergo cesarean delivery as compared to those who were admitted in labor (41.3% vs. 13.9%) [11, 12].

An additional benefit from cervical ripening with the double-balloon catheter stems from the cost savings associated with the price differential between the dinoprostone insert and the catheter, as well as savings in manpower and ancillary expenses associated with the shortened time spent in labor. A cost analysis to quantify these savings is beyond the scope of this study.

The main strengths of our study are the randomized design and the inclusion criteria. Women enrolled in both arms of the study had comparable characteristics. By including only nulliparous women, we eliminated a major confounding factor (parity) and focused on the women who are most likely to have a prolonged induction or to fail induction altogether [8]. The limitations of the study are worth mentioning. Although we performed a priori sample size calculation to ensure adequate power to detect a meaningful difference in the length of labor from induction to delivery, the study was underpowered to detect small differences in secondary outcomes. Additionally, the nature of intervention did not allow blinding of caregivers or subjects. Furthermore, although we found no differences between the two groups with respect to neonatal outcome, this study was not powered to detect such differences.

In conclusion, this study supports the premise that mechanical methods of pre-induction cervical ripening, specifically the double-balloon catheter, have several advantages compared to a pharmacologic agent. A shorter duration from induction to delivery, cost savings, and patient satisfaction are all factors that should be taken into account when deciding on which method of induction to use.

**Disclosure:** None of the authors have conflict of interest.

Received June 24, 2013. Accepted August 29, 2013.
References


The authors stated that there are no conflicts of interest regarding the publication of this article.