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MATERNAL-FETAL MEDICINE

Induction of labor in nulliparous women with unfavorable cervix: a comparison of Foley catheter and vaginal prostaglandin E_2

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Abstract
Purpose To compare maternal and neonatal outcomes of two methods of labor induction in nulliparous women with unfavorable cervix.
Methods A case–control study was performed on nulliparous women with a cervical Bishop score < 6, who underwent induction of labor with either extra-amniotic Foley catheter (Foley catheter study group) or vaginal tablets of prostaglandin E_2 (PGE_2 control group). The control group was matched for gestational age and for the indication to induce labor.
Results A total of 346 nulliparous women were included. Similar rates of cesarean delivery were found in the Foley catheter and the PGE_2 groups (25.4 vs. 24.2 %, respectively, $p = 0.8$), without differences in maternal or neonatal adverse outcomes. In the Foley catheter group, induction to delivery interval was shorter compared with the PGE_2 group (25.1 vs. 36.6 h, respectively, $p < 0.001$), and more women delivered within 24 h (55.0 vs. 40.4 %, respectively, $p = 0.01$).
Conclusion Induction of labor with Foley catheter in nulliparous women with unfavorable cervix is associated with shorter induction to delivery interval, but with similar rates of cesarean deliveries and adverse pregnancy outcomes, as compared with vaginal tablets of PGE_2.

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Introduction

Induction of labor is one of the most common obstetrical procedures, performed in up to 23 % of pregnancies in the United States [1]. The goal of labor induction is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor [2]. The modified Bishop score is a system widely used to assess the readiness of the cervix for induction of labor [3]. Originally developed to assess the likelihood of labor in parous women, it has since been applied to nulliparous women undergoing induction of labor as well [4]. Unfavorable cervix is defined by the American College of Obstetrics and Gynecology (ACOG) as a cervical Bishop score of less than 6 [2].

If induction of labor is indicated for medical reasons and the status of the cervix is unfavorable, agents for cervical ripening may be used. Common cervical ripening agents include mechanical agents, such as extra-amniotic catheter balloon, and biochemical agents, such as dinoprostone (PGE_2) and misoprostol (PGE_1) [2]. Comparison between different methods of labor induction has been studied thoroughly, without demonstrating any difference in the rates of vaginal delivery (VD) or cesarean delivery (CD) [5].

Induction of labor in nulliparous women poses an obstetrical challenge. Several studies have demonstrated high rates of failed induction and CD in this population [6–10]. It has also been shown that nulliparous women require multiple doses of PGE_2 compared to parous women in order to achieve a successful VD [11]. Only few compared mechanical methods to prostaglandins for cervical ripening

in nulliparous women, with conflicting results regarding the induction to delivery time interval [12–15], which has great clinical and economical significance. Thus, the preferred method for labor induction in this population is still unclear. Our aim was to compare maternal and neonatal outcomes in nulliparous women with unfavorable cervix, undergoing induction of labor with Foley catheter and vaginal tablets of PGE_2.

Methods

The medical records of all nulliparous patients, with an unfavorable cervix, defined as a cervical Bishop score of <6, who delivered from January 2013 to December 2014, following induction of labor, in a single tertiary medical center, were reviewed. Maternal and fetal indications for induction of labor included: prolonged pregnancy (defined as pregnancy $> 41 + 0$ weeks of gestation), pregestational diabetes mellitus, gestational diabetes mellitus (GDM A1 and A2), hypertensive disorders (chronic hypertension, gestational hypertension, preeclampsia), suspected fetal macrosomia (defined as estimated fetal weight > 4000 g), suspected intrauterine growth restriction (IUGR, defined as estimated fetal weight $<$ 10th percentile using the updated Israeli growth charts [16]), and presence of ACOG category II non-reassuring fetal heart rate (NRFHR) pattern [17]. Excluded were patients with multiple pregnancy, premature rupture of membranes, stillbirth and major fetal anomalies.

For the purpose of the study, eligible patients were divided into two groups; the study group included all patients who underwent induction of labor with Foley balloon catheter (Foley catheter group) and the control group included the consecutive patients undergoing labor induction with vaginal tablets of PGE_2 group (PGE_2), matched for gestational age and for the indication to induce labor. Gestational age was calculated according to the last menstrual period, confirmed by first-trimester ultrasonography. The study was approved by the local Institutional Review Board.

Data collection

Maternal and neonatal data were collected from the computerized medical records. The primary outcome was CD rate. Secondary outcomes included the mode of delivery, induction to delivery interval, meconium stained amniotic fluid, use of oxytocin augmentation, and adverse maternal and neonatal outcomes. Adverse maternal outcomes included intra-partum or post-partum fever (defined as body temperature $\geq$ 38 °C), perineal tears grade 3 or 4, shoulder dystocia, early postpartum hemorrhage (within the first 24 h), and the need for blood transfusion. Composite adverse maternal outcome was defined as one or more of the above. Adverse neonatal outcomes included: 5 min Apgar score < 7, sepsis or bacteremia, blood transfusion, phototherapy, respiratory distress syndrome (RDS), other respiratory complications (transient tachypnea of the newborn, mechanical ventilation, oxygen enrichment), intraventricular hemorrhage (IVH), seizures, hypoxic–ischemic encephalopathy (HIE), necrotizing enterocolitis (NEC), or death. Composite adverse neonatal outcome was defined as one or more of the above. Tachysystole was defined according to ACOG guidelines as more than five contractions in 10 min, averaged over a 30-min window [17].

Induction of labor protocols

Our departmental protocol for induction of labor with Foley catheter included the trans-cervical insertion of a 22F Foley catheter under visualization, filled with 80 ml of normal saline. The catheter was attached to the patient's inner thigh without traction and removed after 24 h or after spontaneous rupture of membranes, if spontaneous expulsion had not occurred. After the removal of the catheter, or after its spontaneous expulsion, the patient was transferred to the labor ward, where oxytocin infusion and/or artificial rupture of membranes were commenced if active labor had not occurred.

For induction of labor with prostaglandins, a dinoprostone tablet (3 mg, Prostin E_2 ®, Pfizer, Belgium) was placed in the posterior fornix of the vagina. A repeated dose was administered every 8 h, up to a total of three doses, unless the Bishop score was greater than 6, or regular painful contractions <5 min apart had commenced. Afterwards, the patient was transferred to the labor ward, where oxytocin infusion and/or artificial rupture of membranes were commenced if active labor had not occurred. The time interval between last tablet administration and the initiation of oxytocin infusion was at least 6 h. In cases in which Bishop score remained $\leq$2 after three doses of PGE_2, cervical ripening continued with Foley catheter. These patients were included in the PGE_2 group, based on an intention-to-treat analysis.

The decision whether to induce labor with Foley catheter or with PGE_2 tablets was made originally according to the preference of the attending obstetrician. During labor, analgesia was administered at maternal request. According to our local protocol, failed induction was defined as cervical dilatation of <4 cm, after artificial rupture of membranes, when possible, and oxytocin infusion with adequate contractions for at least 12 h.

Statistics

Data were analyzed using Epiinfo 7 (Centers for Disease Control and Prevention, Atlanta, GA). Continuous variables were analyzed by *t* test and categorical variables by Chi square test or by Fisher exact test, as appropriate. Analysis was performed on an intention-to-treat basis. A *p* value of <0.05 was considered statistically significant. A preliminary analysis showed a CD rate of approximately 25 % in nulliparous women who underwent induction of labor in our institute. Given this, a sample size of 154 women in each group was sufficient to attain 80 % power to detect a 50 % reduction in the CD rate from 25 to 12.5 %.

Results

During the study period a total of 10,048 women gave birth at our institute. Of them, 1362 underwent induction of labor (13.5 %). CD rate was significantly higher in nulliparous women who underwent induction of labor, compared with parous women who underwent induction of labor (24.0 vs. 6.5 % respectively, $p < 0.001$). Out of 658 nulliparous women, 173 underwent induction of labor with Foley catheter (Foley catheter group) and these were matched with 173 women, who underwent induction of labor with vaginal PGE_2 (PGE_2 group). Mean maternal age was 27.3 ± 4.9 years and mean gestational age was 40.2 ± 1.3 weeks. The main indications for labor induction, according to which groups were matched, were prolonged pregnancy (39.3 %), suspected of IUGR (10.9 %), maternal hypertensive disorders (10.4 %), category II NRFHR (8.9 %), suspected fetal macrosomia (5.2 %), and maternal diabetes (2.8 %).

The mean number of PGE_2 tablets administered in the PGE_2 group was 1.54 ± 0.84. In 25 women in this group, Bishop score remained very low (≤2) after the administration of three tablets of PGE_2, and ripening was continued with Foley catheter. There were no cases in which PGE_2 tablets were used after cervical ripening with Foley catheter.

Table 1 presents the baseline and obstetrical characteristics of the study population. There were no differences between study groups in terms of maternal age, Body mass index (BMI), gestational age, deliveries < 37 weeks, neonatal birth weight, rate of SGA, rate of macrosomia, or the use of epidural analgesia.

Labor and delivery outcomes are presented in Table 2. CD rate was similar between the Foley catheter group and the PGE_2 group ($p = 0.8$), as was the rate of operative deliveries ($p = 0.53$). No difference was found regarding the indications to perform CD. Among the 39 patients who underwent CD due to NRFHR, 5 (12.8 %) presented with tachysystole (one in the Foley catheter group and four in the PGE_2 group). Patients induced by Foley catheter were more likely to undergo augmentation of labor with oxytocin ($p = 0.005$), had a shorter induction to delivery interval ($p < 0.001$), and had a higher rate of deliveries within less than 24 h ($p = 0.01$). The induction to delivery interval remained significantly longer in the PGE_2 group, even after omitting cases in which cervical ripening with PGE_2 was unsuccessful and ripening continued with Foley catheter.

Adverse maternal and neonatal outcomes did not differ between study groups (Tables 3, 4). There were no cases of shoulder dystocia, perinatal mortality, RDS, IVH, seizures, HIE, or NEC. Mean cord pH was slightly lower in the PGE_2 group compared with the Foley catheter group ($p = 0.02$). However, there were no cases of cord pH less than 7.1 and there were no cases of 5 min Apgar score < 7.

Table 1 Baseline and obstetrical characteristics of nulliparous women undergoing induction of labor with Foley catheter and PGE_2

	Foley catheter $n = 173$	PGE_2 $n = 173$	p value
Maternal age (years)	26.9 ± 4.4	27.6 ± 5.4	0.18
BMI (kg/m^2)	20.7 ± 9.3	21.6 ± 9.0	0.57
Gestational age (days)	281.9 ± 9.2	281.6 ± 9.6	0.76
Hypertensive disorders	19 (10.9)	20 (11.5)	0.87
Diabetes mellitus	9 (5.2)	12 (6.9)	0.49
Oligohydramnios	45 (26.0)	38 (21.9)	0.39
Births < 37 weeks	2 (1.1)	4 (2.3)	0.41
Birth weight (g)	3224 ± 547	3228 ± 518	0.94
SGA infants[a]	31 (17.9)	25 (14.4)	0.38
Birth weight > 4000 g	18 (10.4)	13 (7.5)	0.34
Epidural analgesia	130 (75.1)	118 (68.2)	0.15

Data are reported as *n* (%) or mean ± SD

PGE_2 prostaglandins E_2, *BMI* body mass index

[a] *SGA* small for gestational age, defined as neonatal weight below 10th percentile for gestational age

Table 2 Labor and delivery outcomes after induction of labor with Foley catheter and PGE_2 in nulliparous women

	Foley catheter $n = 173$	PGE_2 $n = 173$	p value
Mode of delivery			
Vaginal delivery	107 (61.8)	105 (60.6)	0.8
Operative delivery	22 (12.7)	26 (15.0)	0.53
Cesarean deliveries	44 (25.4)	42 (24.2)	0.8
Indication for cesarean section			
NRFHR	19 (10.9)	20 (11.5)	0.86
Failed induction	15 (8.6)	13 (7.5)	0.69
Labor dystocia	7 (4.0)	5 (2.8)	0.55
Patient request due to maternal exhaustion	1 (0.5)	3 (1.7)	0.62
Suspected placental abruption	2 (1.1)	1 (0.5)	>0.99
Induction to delivery interval (h)[a]	25.1 ± 13.7	36.6 ± 26.9	<0.001
Delivered < 24 h[a]	71/129 (55.0)	53/131 (40.4)	0.01
Second stage duration (h)[a]	1.52 ± 1.1	1.55 ± 1.1	0.8
Oxytocin augmentation	168 (97.6)	157 (90.7)	0.005
Meconium stained amniotic fluid	37 (21.3)	24 (13.8)	0.06

Data are reported as n (%) or mean ± SD

PGE_2 prostaglandins E_2, *NRFHR* non-reassuring fetal heart rate

[a] Cesarean deliveries not included

Table 3 Adverse maternal outcomes of nulliparous women undergoing induction of labor with Foley catheter and PGE_2

	Foley catheter $n = 173$	PGE_2 $n = 173$	p value
Intra-partum fever	12 (6.9)	10 (5.7)	0.65
Post-partum fever	8 (4.6)	8 (4.6)	>0.99
Severe perineal tears	0	2 (1.1)	0.49
Early PPH	8 (4.6)	12 (6.9)	0.35
Blood transfusion	9 (5.2)	9 (5.2)	>0.99
Composite adverse maternal outcome	29 (16.7)	30 (17.3)	0.88

Data are reported as n (%)

PGE_2 prostaglandins E_2, *PPH* post-partum hemorrhage

Table 4 Neonatal outcomes in nulliparous women undergoing induction of labor with Foley catheter and PGE_2

	Foley catheter $n = 173$	PGE_2 $n = 173$	p value
Cord pH[a]	7.31 ± 0.05	7.30 ± 0.05	0.02
Hospitalization duration (days)	3.3 ± 2.4	3.2 ± 2.0	0.7
NICU admission	20 (11.5)	16 (9.2)	0.48
Sepsis/bacteremia	2 (1.1)	0	0.49
Blood transfusion	1 (0.5)	0	>0.99
Phototherapy for hyperbilirubinemia	6 (3.4)	6 (3.4)	>0.99
Respiratory complications	13 (7.5)	6 (3.4)	0.09
Hypoglycemia	7 (4.0)	5 (2.8)	0.55
Composite adverse neonatal outcome	26 (15.03)	17 (9.8)	0.14

Data are reported as n (%) or mean ± SD

PGE_2 prostaglandins E_2, *NICU* neonatal intensive care unit

[a] Data are available for 327 cases

Discussion

In the present study, we found that cervical ripening with Foley catheter and vaginal tablets of PGE_2 in nulliparous women with unfavorable cervix yielded similar rates of vaginal, cesarean, and operative deliveries. There is little evidence regarding the preferred agent for labor induction in nulliparous women, and only few studies directly compared Foley catheter with prostaglandin E_2 in this population. Pennell et al. [15] compared double balloon catheter ($n = 107$), Foley balloon catheter ($n = 110$) and cervical PGE_2 gel ($n = 113$) for induction of labor in nulliparous women. There was no difference in CD rate between the groups. Aghideh et al. [18] also found similar rates of CD in nulliparous women induced with misoprostol, dinoprostone, and Foley catheter. Our findings are consistent with their observations.

Interestingly, we found that cervical ripening with Foley catheter achieved shorter induction to delivery interval and higher rate of deliveries within 24 h, compared with PGE_2. Shorter induction to delivery interval was shown to be associated with higher patient's satisfaction [19] and with lower medical costs [20]. Previous studies have shown conflicting results regarding the induction to delivery interval in nulliparous women. Pennell et al. [15], in contrast to our results, have shown no difference in the induction to delivery interval between the Foley catheter group and the PGE_2 group. Such a difference could be explained by different treatment protocols. Pennell et al. [21] used PGE_2 gel which was shown to be associated with shorter induction to delivery interval compared with PGE_2 tablets. On the contrary, others [13, 14] have shown shorter induction to delivery interval in nulliparous women induced by Foley catheter compared to misoprostol. Longer induction to delivery interval with prostaglandin administration may be attributed to the interrupted treatment protocol, requiring the intervention of the attending physician every few hours. Moreover, the longer interval may be the result of cases in which prostaglandin placement was delayed because of uterine contractions.

In the current study, we found that adverse maternal and neonatal outcomes did not differ between study groups. Although there are several reports of higher rates of chorioamnionitis with the use of trans-cervical Foley catheter [13, 22, 23], in our study, the rate of intra-partum and post-partum fever did not differ between the study groups. Indeed, we observed that mean cord pH was slightly lower in the PGE_2 group. Though clinically insignificant, this finding is consistent with another report [15], and may be secondary to the increased rates of uterine hyperstimulation seen with prostaglandins [5, 24], leading to increased rates of fetal acidemia. Nevertheless, other than this finding, there were no cases of 5 min Apgar scores < 7 and the rates of early neonatal complications did not differ between study groups. Women in the Foley catheter group were more likely to undergo augmentation of labor with oxytocin. This may be attributed to the continuous effect of PGE_2 on uterine contractility.

Several study limitations must be acknowledged. First, its retrospective design. Clinical follow-up was limited and maternal satisfaction from either method of induction could not be retrieved. Second, the study was not sufficiently powered to detect differences in adverse neonatal outcomes which are rare. Third, the decision whether to induce labor with Foley catheter or with PGE_2 tablets was made originally by the attending obstetrician. This might introduce a selection bias.

There are many reports comparing different methods of labor induction in pregnant patients [5]. However, the main strength of our study is the focus on nulliparous women with an unfavorable cervix, in whom induction of labor is challenging. Moreover, it has been shown that fetal indications for labor induction may significantly increase the risk of CD [25]. Thus, in order to eliminate confounding factors, the study groups were matched for gestational age and for the indication to induce labor as well.

In conclusion, labor induction with either Foley balloon catheter or vaginal tablets of PGE_2 results similar rates of cesarean delivery and adverse pregnancy outcomes in nulliparous women with unfavorable cervix. Foley catheter insertion was associated with shorter induction to delivery interval.

The study was approved by the local institutional review board.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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