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ORIGINAL ARTICLE

Intra-vaginal prostaglandin E2 versus double-balloon catheter for labor induction in term oligohydramnios

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OBJECTIVE: Compare mechanical and pharmacological ripening for patients with oligohydramnios at term.
STUDY DESIGN: Fifty-two patients with oligohydramnios ⩽5 cm and Bishop score ⩽6 were randomized for labor induction with a vaginal insert containing 10 mg timed-release dinoprostone (PGE2) or double-balloon catheter. The primary outcome was time from induction to active labor. Time to labor, neonatal outcomes and maternal satisfaction were also compared.
RESULT: Baseline characteristics were similar. Time from induction to active labor (13 with PGE2 vs 19.5 h with double-balloon catheter; $P=0.243$) was comparable, with no differences in cesarean rates (15.4 vs 7.7%; $P=0.668$) or neonatal outcomes. The PGE2 group had higher incidence of early device removal (76.9 vs 26.9%; $P=0.0001$), mostly because of active labor or non-reassuring fetal heart rate. Fewer PGE2 patients required oxytocin augmentation for labor induction (53.8 vs 84.6% $P=0.034$). Time to delivery was significantly shorter with PGE2 (16 vs 20.5 h; $P=0.045$)
CONCLUSION: Intravaginal PGE2 and double-balloon catheter are comparable methods for cervical ripening in term pregnancies with oligohydramnios.

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INTRODUCTION

Ultrasound estimation of amniotic fluid volume is an important component of prenatal surveillance, used to detect fetuses at high risk for an adverse outcome.[1] Decreased amniotic fluid (oligohydramnios) is an indicator of poor fetal outcome and an important marker of placental function.[2]

Calculating the amniotic fluid index (AFI) by using ultrasound to measure the sum of the deepest pockets of amniotic fluid in the four quadrants of the maternal uterus is the most common and most efficient method of quantifying amniotic fluid volume.[1,3] Oligohydramnios, defined as AFI < 5 cm, is associated with adverse obstetrical outcomes. When oligohydramnios is present, the risks of stillbirth, fetal heart rate decelerations during labor and cesarean delivery due to fetal distress are increased.[2,4,5]

Induction of labor for patients with oligohydramnios at term is advocated to reduce perinatal morbidity and mortality. The outcome of term induction of labor due to oligohydramnios is similar to that of patients with normal amniotic fluid levels who are induced for other indications.[6]

Various agents can be used for cervical ripening.[7,8] The Foley catheter and prostaglandins are two common methods for labor induction. There are no significant differences between the two devices in duration of induction,[9] as well as in the incidence of meconium, chorioamnionitis, low APGAR scores, induction failures or cesarean deliveries.[8,10] When comparing mechanical to pharmacological methods for labor induction, contradictory results have been reported for primiparous women in terms of labor duration and safety.[11,12]

The preferred mode of cervical ripening for patients with oligohydramnios has not been determined. Mechanical devices (the double-balloon catheter) induce labor with fewer contractions and might decrease the risk of cord compression and variable decelerations in patients with oligohydramnios. Prostaglandins better mimic the natural course of labor and might have an advantage in cervical ripening. However, they induce uterine contractions that might cause fetal heart rate decelerations. The aim of this study was to compare mechanical and pharmacological ripening methods for patients with oligohydramnios at term.

METHODS

We conducted a randomized clinical trial comparing the efficacy of a vaginal insert containing 10 mg of dinoprostone in a timed-release formulation (PGE2; Propess, Ferring Pharmaceuticals, Saint-Prex, Switzerland) with an Atad double-balloon catheter (double-balloon catheter) (Cook Cervical Ripening Balloon; Cook Incorporated, IN, USA) for induction of labor in patients with term oligohydramnios and an unripe cervix. Inclusion criteria were a singleton, term gestation (⩾37 weeks), cephalic presentation, intact membranes, an unfavorable cervix (Bishop score ⩽6), presenting to our labor and delivery unit for labor induction secondary to oligohydramnios, defined as AFI ⩽5 cm. Women with a multifetal gestation, fetal malpresentation, spontaneous labor, contraindication to prostaglandins or a vaginal delivery (e.g., placenta previa), non-reassuring fetal heart rate tracing, a fetus with major anomalies or previous cesarean delivery were excluded.

Most of the women who visit our emergency triage during the third trimester of pregnancy are undergoing a routine evaluation that includes a non-stress test and a biophysical profile including AFI measurement. When term oligohydramnios is detected, induction of labor is recommended. After signing an informed consent, patients were randomized for double-balloon catheter or slow-release prostaglandin induction, using computer-generated, random sequences.

Detailed demographic information was extracted from patients' computerized medical records including maternal age, maternal body mass index, medical and surgical history, gestational age, gravidity, parity, chronic hypertension, preeclampsia toxemia, gestational diabetes mellitus, pre-gestational diabetes, smoking, AFI, and Bishop score which includes: cervical dilatation, effacement, consistency and position as well as the station of the fetal head in the pelvis.

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Pregnancies were dated by the last menstrual period and confirmed with first trimester ultrasound using standard criteria. The PGE2 was inserted into the posterior fornix during a vaginal examination. The double-balloon catheter was inserted under direct visualization of the uterine cervix following manufacturers' instructions.

Uterine activity and fetal heart rate patterns were monitored three times a day. The first time was 2 h after beginning the ripening or when contractions started, whichever happened first. The patient was monitored continuously when she reached the active stage of labor.

Information regarding the labor course, birth weight, regional anesthesia, fetal heart rate, mode of delivery and complications was recorded. Questionnaires regarding the patients' personal impressions were completed after delivery, all by the same recorder. Categorical variables were compared using parametric tests and continuous variables were compared using nonparametric statistics (*t*-test, Mann–Whitney test and χ^2 test, according to the type of variable).

The primary outcome was defined as the time from induction to active labor (defined as cervical dilation of at least 5 cm). Secondary outcomes were induction to delivery time, cesarean section and operative delivery rates, the percentage of patients who needed oxytocin augmentation following the ripening procedure, the percentage of patients who developed uterine tachysystole (defined as greater than five uterine contractions in 5 min), meconium passage, and fetal heart rate changes. APGAR scores and maternal satisfaction were also evaluated. The study was approved by the local Helsinki committee.

The trial was registered as a clinical trial at Clinicaltrials.gov. Identification number NCT00815542

RESULTS

A total of 52 patients with oligohydramnios who were admitted to the antepartum unit were enrolled; 26 were randomized for induction of labor with vaginal PGE2 and 26 for induction with the double-balloon catheter. The groups were comparable regarding demographic and pregnancy characteristics (Table 1). There were no significant differences in parity, average AFI or the use of regional anesthesia. All participants had a Bishop score $\leqslant 6$ upon randomization to the study.

The time from induction to active labor (median 13 h with PGE2 and 19.5 h with double-balloon catheter; $P = 0.243$), was not significantly different between the groups (Table 2). However, the time from induction to delivery was shorter in the PGE2 group (median 16 h for PGE2 vs 20.5 h for double-balloon catheter; $P = 0.045$) and women induced with the double-balloon catheter were more likely to require oxytocin augmentation (Table 2).

More fetuses had fetal heart rate decelerations during ripening with PGE2 compared with the double-balloon catheter (34.6 vs 0%; $P = 0.002$). Induction was stopped earlier than planned in 76.9% of the PGE2 group and 26.9% of the double-balloon catheter group ($P = 0.0001$), mostly because of progression to active labor, but also because of non-reassuring fetal heart rate, which led to stopping the induction. No differences in mode of delivery or in early neonatal outcomes were found (Table 2). Maternal fear and inconvenience were reported less often with PGE2 (Table 3).

DISCUSSION

Induction of labor in the presence of term oligohydramnios is accepted practice. The main concern with using PGE2 for labor induction in this situation is an increased likelihood of excessive uterine contractions, which might cause cord compression, non-reassuring fetal heart rate and consequently, a cesarean delivery. Therefore, some clinicians avoid its use. However, it is considered safe and effective for inducing labor in patients with a low Bishop score.[7,8,12] To add to the current knowledge regarding this controversy, we compared outcomes of two modes of labor induction for term patients with oligohydramnios, prostaglandins and a mechanical method. The mechanical, double-balloon catheter causes fewer contractions and therefore, less of the associated concerns when oligohydramnios is present.

We found a statistically significant difference in the time from induction to delivery when comparing PGE2 and the double-balloon catheter for induction of labor in term parturients with oligohydramnios. Although the other time parameters measured were shorter with the prostaglandins, the differences did not reach statistical significance. This could be related to the relatively low number of study participants. These findings are consistent with several prior studies that compared pharmacologic and mechanical methods for induction of labor.[8,10,13–15]

Moreover, we did not find any differences in mode of delivery or in early neonatal outcomes between the study groups, also in accordance with similar studies.[8,10]

Our data show that while inducing labor in patients with term oligohydramnios and an unfavorable cervix, the use of PGE2 resulted in a higher rate of discontinuing the induction process, mostly because of the onset of active labor. Although not statistically significant, PGE2 showed a trend toward attaining initial cervical dilation and the active stage of labor more rapidly. Although induction with PGE2 was also discontinued more often compared with the double-balloon catheter because of

Table 1. Demographic and baseline characteristics of the participants

Characteristic	*PGE2* (N = *26*)	*Double-balloon catheter* (N = *26*)	P
Maternal age (years), median (range)	28.5 (18–39)	28.5 (20–40)	0.883
Maternal BMI (kg m^{-2}), median (range)	23.4 (18–35)	24.7 (17–41)	0.275
Obese (BMI > 30 kg m^{-2}), *n* (%)	2 (9.1)	6 (26.1)	0.243
Parity			
Primiparous *n* (%)	13 (50)	13 (50)	1
Multiparous *n* (%)	13 (50)	13 (50)	1
Chronic hypertension/PET, *n* (%)	5 (20)	1 (3.8)	0.099
Diabetes/GDM, *n* (%)	1 (3.8)	1 (3.8)	1
Smoker, *n* (%)	3 (11.5)	2 (8)	1
AFI (cm), median (range)	4 (2–5)	4.25 (0–5)	0.664
Admission cervical dilation (cm), median (range)	0.5 (0–1.5)	0.5 (0–2)	0.475
Gestational age (weeks), median (range)	40 (37–41)	40 (37–42)	0.618
Birth weight (g), median (range)	3185 (2145–4040)	3012 (2270–3500)	0.137
Macrosomia (birth weight > 4000 g), *n* (%)	1 (3.8)	0	1
Regional anesthesia (%)	22 (84.6)	23 (88.5)	1

Abbreviations: AFI, amniotic fluid index; BMI, body mass index; GDM, gestational diabetes mellitus; PET, preeclampsia toxemia; PGE2, prostaglandin E2.

Table 2. Labor profiles and outcomes

Characteristic	*PGE2* (N = *26*)	*Double-balloon catheter* (N = *26*)	P
Ripening time (h), median (range)	13 (1–26)	12 (3–32)	0.155
Time to active labor (h), median (range)	13 (3–43)	19.5 (3–51)	0.243
Time to delivery (h), median (range)	16 (5–47)	20.5 (5–55)	0.045
Time to transfer to the delivery room (h), median (range)	10.5 (1–28)	14 (3–30)	0.664
Oxytocin augmentation, *n* (%)	14 (53.8)	22 (84.6)	0.034
Non-reassuring fetal heart rate during ripening, *n* (%)	9 (34.6)	0	0.002
Tachysystole, *n* (%)	2(7.7)	0	0.49
Remove ripening device early, *n* (%)	20 (76.9)	7 (26.9)	0.0001
Reason for early removal			
Active labor, *n* (%)	10 (38.5)	3 (11.5)	0.052
NRFHR, *n* (%)	6 (23.1)	0	0.023
Mode of delivery			
Normal vaginal delivery, *n* (%)	21 (80.8)	23 (88.5)	0.703
Operative vaginal delivery, *n* (%)	1 (3.8)	1 (3.8)	1
Cesarean section, *n* (%)	4 (15.4)	2 (7.7)	0.668
Need for pediatrician, *n* (%)	8 (32)	6 (23)	0.475
Meconium-stained amniotic fluid, *n* (%)	6 (23.1)	3 (11.5)	0.465

Abbreviation: NRFHR, non reassuring fetal heart rate; PGE2, prostaglandin E2.

Table 3. Maternal impression (scale 1–5)

Variable	*PGE2* (N = *26*)	*Double-balloon catheter* (N = *26*)	P
Parturient fearful of induction, mean (s.d.)	2.33 (1.3)	3.76 (1.2)	0.002
Parturient is uncomfortable with the insertion of the induction, mean (s.d.)	2.33 (1.2)	3.59 (1.1)	0.004
Parturient uncomfortable during hospitalization for induction, mean (s.d.)	2.67 (1.2)	3.29 (1.5)	0.241
Pain during induction, mean (s.d.)	3.89 (1.2)	3.59 (1.3)	0.492
Satisfaction with induction process, mean (s.d.)	3.33 (1.2)	3.41 (1.3)	0.860

Abbreviation: PGE2, prostaglandin E2.

non-reassuring fetal heart rate, there was no higher rate of cesarean deliveries in that group.

Both prostaglandins and double-balloon catheters were effective in promoting cervical ripening and induction of labor, with no differences in modes of delivery or maternal and early neonatal complications. Additional oxytocin was required less often when inducing labor with PGE2. Higher maternal satisfaction rates were reported with PGE2.

Previous studies have demonstrated that intravaginal or intracervical ripening with PGE1 and PGE2 in the presence of oligohydramnios was not associated with poorer perinatal outcomes compared with pregnancies with adequate amniotic fluid.[16,17]

In agreement with our results, a recently published study comparing the use of a double-balloon catheter and PGE2 for induction of labor in term patients with oligohydramnios, did not find any differences in cesarean delivery rates or in change of Bishop scores. However, they found an increased number of newborns with umbilical cord arterial blood pH < 7.1 when PGE2 was used to induce labor.[14] Those differences could be attributed to different study populations or to different treatment protocols.

In our study, as well as in that of Wang *et al.*,[14] more patients induced with the mechanical method compared with the PGE2 group needed an additional intervention of oxytocin. This did not affect the maternal and neonatal outcomes and therefore this less importance factor in decision making.

The results of this study suggest that both PGE2 and the double-balloon catheter may be used to achieve timely and safe delivery in the presence of term oligohydramnios and an unfavorable cervix. This study was a randomized clinical trial from one medical center with a uniform labor management protocol. Women induced with PGE2 and the double-balloon catheter had similar baseline characteristics and detailed patient information, which controls for possible confounders and strengthens the results.

There are limitations that should be considered when interpreting our results. Although this was a randomized controlled study, the small numbers weaken the results and therefore they should be interpreted carefully. This should be considered a pilot study and additional, larger studies are indicated.

In conclusion, we found that the prostaglandins were associated with a trend toward shorter interval from induction to active labor than the double-balloon catheter, although the differences were not statistically significant. Moreover, although more tachysystole and non-reassuring fetal heart rates were observed in the prostaglandin group, these patterns were not significant enough to influence the mode of delivery or neonatal outcomes. Therefore, we cautiously state that based on the results of this pilot study, the two methods are comparable for induction of labor in term oligohydramnios patients. Taking into consideration maternal preferences toward prostaglandins, these results should be cautiously incorporated when counseling patients with term oligohydramnios. Future studies with sufficient power are indicated to assess significant maternal and neonatal outcomes.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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