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Original Article

Prostaglandin E2 induction of labor and cervical ripening for term isolated oligohydramnios in pregnant women with Bishop score ≤ 5

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Abstract

Background: We aimed to evaluate the efficacy and safety of dinoprostone for cervical ripening and labor induction in patients with term oligohydramnios and Bishop score ≤ 5.

Methods: This was a prospective case−control study, which included 104 consecutive women with a Bishop score ≤ 5. Participants were divided into two groups. Women with term isolated oligohydramnios and Bishop score ≤ 5 underwent induction of labor with a vaginal insert containing 10-mg timed-release dinoprostone (prostaglandin E2; Group A, $n = 40$). The control group, Group B, consisted of 64 cases of pregnancy with normal amniotic fluid volume (amniotic fluid index ≥ 5 cm) and Bishop score ≤ 5, and was matched for patient's age and parity. The primary outcome was time from induction to delivery; the secondary outcomes were the caesarean section (CS) rate, uterine hyperstimulation, rate of failed induction, and neonatal complications.

Results: The mean time interval from induction to delivery was not different between the two groups ($p = 0.849$), but there was a statistically significant difference between the groups in terms of the CS rate ($p = 0.005$). There were no differences between the groups in neonatal outcome or perinatal morbidity or mortality.

Conclusion: Dinoprostone appears to be a safe alternative for induction of labor in pregnancies with oligohydramnios. Induction of labor with dinoprostone in term pregnancies with isolated oligohydramnios is associated with increased rate of CS but there is no higher risk of perinatal complications.

Keywords: caesarean section rate; cervical ripening; dinoprostone; induction of labor; oligohydramnios

1. Introduction

Oligohydramnios complicates 0.5−5% of all pregnancies. The prevalence of oligohydramnios depends largely on the definition and criteria used for distinguishing it from others.[1] The common etiological factors associated with oligohydramnios are ruptured membranes, congenital abnormalities, and placental insufficiency. It is thought to be associated with increased maternal and fetal morbidities. The perinatal morbidity and mortality are due to a high risk of caesarean deliveries owing to fetal distress, low Apgar scores, and meconium aspiration syndrome in the fetus.[2]

Fluid volume is a biophysical parameter with particular significance in high-risk pregnancies, as it provides valuable information about fetal well-being and for decision-making for induction of labor. Because oligohydramnios has been circumstantially associated with a variety of poor pregnancy

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outcomes, obstetricians have increasingly resorted to induction of labor in pregnancies complicated by decreased amniotic fluid volume.[3]

The ideal method to induce labor should be safe, painless, inexpensive, comfortable, and effective. However, such a perfect method does not exist at present. Most of the currently available methods for labor induction try to mimic the physiological sequence of cervical effacement and dilatation followed by uterine contraction, but the majority achieve only part of the natural progression. Oxytocin, misoprostol, and dinoprostone are the most often used agents for cervical ripening and labor induction.[4]

In this study, we aimed to compare the efficacy and safety of dinoprostone for cervical ripening and labor induction in term pregnancies with isolated oligohydriamnios.

2. Methods

This prospective study was conducted at the Zekai Tahir Burak Woman's Health, Research and Education Hospital, Ankara, Turkey between April 2009 and August 2009. The study was approved by the local Ethics Committee of the hospital, and an informed consent was signed by all patients before treatment, as in all cases of labor induction at our institution. Forty consecutive women with term isolated oligohydramnios and Bishop score ≤ 5 underwent induction of labor with a vaginal insert containing 10-mg timed-release dinoprostone (prostaglandin E2; Group A). Oligohydramnios was defined as an amniotic fluid index (AFI) of < 5 cm.[2] The control group, Group B, consisted of 64 cases of pregnancy with normal amniotic fluid volume (AFI ≥ 5 cm) and Bishop score ≤ 5, and was matched for patient's age and parity. The criteria of inclusion were women with a singleton live cephalic presentation between 37 weeks and 42 weeks, intact amniotic membranes, and reassuring fetal heart rate (FHR). The exclusion criteria were multifetal gestation; noncephalic presentation; premature rupture of membranes; suspicious or ominous nonstress test result at admission; placenta previa; suspected macrosomia over 4000 g; a history of uterine scarring or pregnancies complicated by evidence of fetal congenital malformations, gestational diabetes, hypertension, intrauterin growth retardation, or chronic illness; and any other contraindication to vaginal delivery. Patients with contraindication to prostaglandins administration (allergy, severe asthma, or pre-existing cardiac or cardiovascular disease), renal or hepatic dysfunction, and parity > 5 were also excluded. None of the women in the study received epidural or other modes of analgesia.

Gestational age was established by the last reported menstrual period and first-trimester ultrasound measurements. Ultrasonography was performed on all patients to assess presentation of fetus, estimated fetal weight, placental site, and amniotic fluid volume. The amniotic fluid volume was estimated according to the four-quadrant technique.[5] The uterus was divided into four quadrants, by the umbilicus transversely (into upper and lower halves) and by the linea nigra (into right and left halves). The maximum vertical diameter of the largest pocket in each quadrant without an aggregate of cord or fetal extremities was measured in centimeters. The sum of the largest vertical pocket in the four quadrants was the AFI. A depth of 0–5 equated with oligohydramnios.

The dinoprostone insert was left *in situ* for 12 hours, if possible, or removed at the onset of active labor. Active labor was considered to begin when cervical dilatation was 4 cm.[6] All cases were followed by continuous electronic fetal monitoring. A partogram was drawn to follow the progress of labor. Artificial rupture of membranes was done at 5-cm dilatation, and color of amniotic fluid (liquor amnii) was noted. At the 12^{th} hour from the start of treatment, the Bishop scores were re-evaluated. For patients whose Bishop score was still < 5 (i.e., not exhibiting regular uterine contraction), a vaginal application of dinoprostone was performed and they were induced with low-dose oxytocin infusion. Oxytocin augmentation was applied in the second stage, if necessary.

Tachysystole was defined as six or more than five contractions in 10 minutes, averaged over a 30-minute window. Hyperstimulation was described as a tachysystole with late FHR decelerations or fetal tachycardia ($>$ 160 beats/min) or other worrying FHR changes.[7] In the event of hyperstimulation, the vaginal dinoprostone insert was removed, and fetal resuscitation (and tocolysis, if needed) was done. Nonreassuring FHR patterns were defined as persistent or recurring episodes of severe variable decelerations, late decelerations, prolonged fetal bradycardia, or a combination of decreased beat-to-beat variability and a decelerative pattern.

Demographic and antenatal data were collected from the delivery chart, computerized data, and patient files. The primary outcome measures were time from induction to delivery and incidence of vaginal delivery; the secondary outcomes were the caesarean section (CS) rate, side effects, rate of failed induction, the incidence of admission to the neonatal intensive care unit, and neonatal complications.

All statistical analyses were performed using SPSS software (version 15; SPSS Inc., Chicago, IL, USA). Continuous data are expressed as mean (standard deviation) and were analyzed with two independent-samples tests. Chi-square and Fisher's exact tests were used for categorical data. The significance boundary (p) was given as 0.05.

3. Results

A total of 148 patients who satisfied the trial criteria were recruited into the study; of these, 44 patients declined to participate, and thus 104 patients [patients with oligohydramnios ($n = 40$) and control patients ($n = 64$)] completed the study (Fig. 1). The demographic variables of the patients in Groups A and B are presented in Table 1; age, parity, and Bishop scores were insignificant between the groups ($p > 0.05$ for all). Gestational age was significantly different between the groups ($p = 0.001$).

Table 2 summarizes the obstetric and neonatal outcomes. The mean time intervals from induction to delivery were 21.76 ± 4.49 hours and 20.86 ± 4.04 hours for the oligohydramnios and control groups, respectively ($p > 0.05$). CS rate

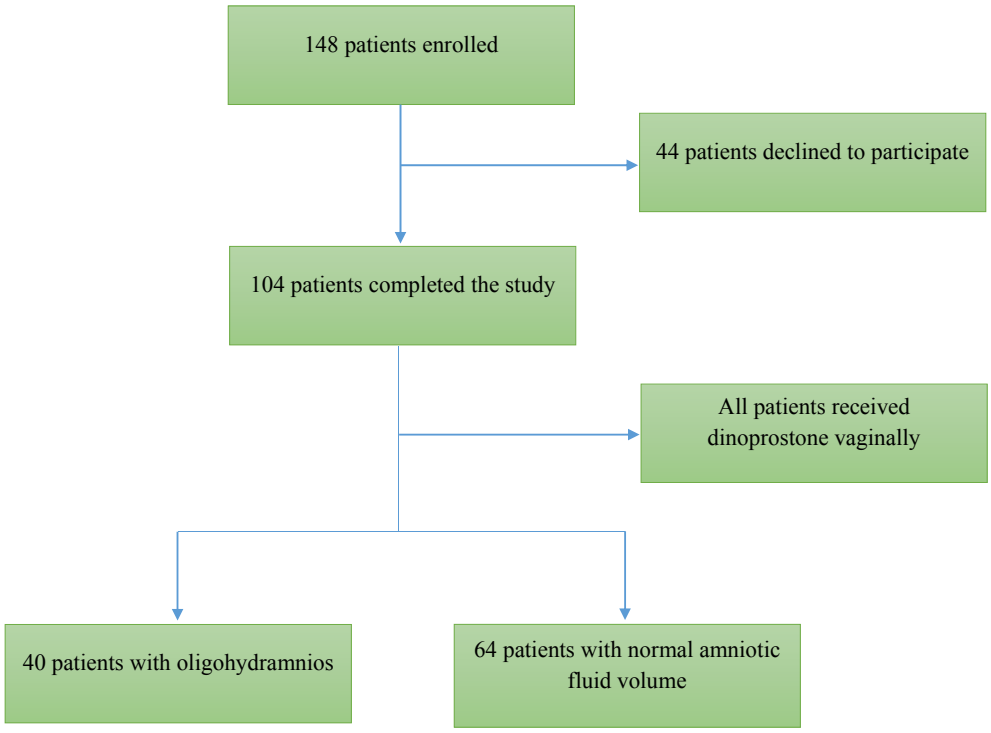

Fig. 1. Flowchart of study profile.

was significantly different between the groups, 40.0% and 15.6% for the oligohydramnios and the control groups, respectively ($p = 0.005$). Hyperstimulation occurred in four of 40 patients in the oligohydramnios group and in one of 64 patients in the control group, without reaching statistically significant difference.

Of the patients in Groups A and B, 7.5% (3/40) and 3.1% (2/64), respectively, needed admission to neonatal intensive care unit within 24 hours after delivery ($p > 0.05$). There was no statistically significant difference in the 5th-minute Apgar score and postpartum hemorrhage between the groups ($p > 0.05$). There were no uterine ruptures, infectious complications, or other major maternal complications.

Table 1
Demographic characteristics.

	Oligohydramnios ($n = 40$, 38%)	Control group ($n = 64$, 62%)	p
Age (years)	25.55 ± 5.2	25.75 ± 5.3	NS
Gestational age (wk)	39.8 ± 1.03	40.7 ± 0.78	0.001*
Parity	1 (0–5)	1 (0–4)	NS
Nulliparous	25 (62.5)	37 (57.8)	NS
Bishop score	3.40 ± 0.6	3.53 ± 0.6	NS
0–2	6 (15)	8 (12.5)	NS
3–5	34 (85)	56 (87.5)	NS
Labor induction for			
Oligohydramnios	40 (100)	0	
Post-term pregnancy	13 (32.5)	38 (59.3)	
Suspected fetal surveillance	0	15 (23.4)	
Social reasons	0	11 (17.1)	

Data are presented as n (%) or mean ± standard deviation.
* $p < 0.05$, significant.
NS = nonsignificant.

4. Discussion

Our study regarding the efficacy and safety of dinoprostone for cervical ripening and labor induction in term pregnancies with a Bishop score ≤ 5 between patients with isolated oligohydramnios and normal amniotic fluid revealed that dinoprostone did not decrease the mean time interval from

Table 2
Cervical ripening, labor, delivery, and neonatal outcomes of patients.

	Oligohydramnios ($n = 40$, 38%)	Control group ($n = 64$, 62%)	p
Interval to delivery (h)	21.76 ± 4.49	20.86 ± 4.04	NS
No. of success with 12 h of priming	21 (52.5)	35 (54.6)	NS
No. of success with 24 h of priming	29 (72.5)	50 (78.1)	NS
Use of oxytocin	9 (22.5)	17 (26.5)	NS
Vaginal delivery	24 (60)	54 (84.3)	NS
Caesarean delivery for, n (%)	16 (40)	10 (15.6)	0.005*
Fetal distress	8 (50)	3 (30)	
Cephalopelvic disproportion	5 (37.5)	4 (40)	
Failed induction	3 (12.5)	3 (30)	
Uterine tacysystole	4 (10)	2 (3.1)	NS
Neonatal birth weight (g)	3256 (2410–4210)	3370 (2650–3990)	NS
Apgar score at the 5th min <7	3 (7.5)	2 (3.1)	NS
Neonatal intensive care unit admission	3 (7.5)	2 (3.1)	NS
Postpartum hemorrhage (≥500 mL)	1 (2.5)	2 (3.2)	NS

Data are presented as n (%) or mean ± standard deviation.
* $p < 0.05$, significant.
NS = nonsignificant.

induction to delivery. In addition to these results, the rate of CS in patients with oligohydramnios was higher than in those with normal amniotic fluid.

Induction of labor is a widely used procedure for various maternal and fetal indications, one of which is oligohydramnios. In many cases, the cervix may not be ripened enough, especially in primigravidas. Therefore, there is a need to prepare the cervix for a likely vaginal birth. Various techniques have been used for this purpose, with vaginal dinoprostone administration being one of the most commonly used methods of all.[8] In this prospective study, dinoprostone administered by the standard once-daily regimen demonstrated a significantly higher rate of labor success within 24 hours in the oligohydramnios and control groups (72% vs. 78%), and the rate of oxytocin use was similar in both groups. Venturini et al[9] and Stefos et al[10] studied dinoprostone gel action vaginally and concluded that it was noneffective in lessening the duration of labor. The primary outcomes of our study also supported the previous results.

Classically, oligohydramnios has been related to increased neonatal mortality and morbidity in high-risk pregnancy status.[11] However, some investigators have found an association between an active induction of labor in term low-risk pregnancy with isolated oligohydramnios and an increased rate of cesarean section without causing any detrimental neonatal outcomes, when compared with normal AFI.[12−16] A meta-analysis done by Chauchan et al[17]indicated that there was no association between olygohydramnios and neonatal acidosis, even though acidosis resulted in AFI < 5 with an increased risk of CS due to fetal distress and lower Apgar score. However, this analysis involved high-risk and preterm pregnancies. Some retrospective studies of term pregnancies with isolated oligohydramnios reported no differences in Apgar score, requirement of neonatal intensive care unit, fetal acidosis, or perinatal death from normal AFI pregnancies with induction of labor.[12,18,19] Similarly, we also found an increased rate of cesarean section in patients with oligohydramnios without an increase in adverse perinatal outcomes. By contrast, in a retrospective study by Danon et al,[20] patients with uncomplicated oligohydramnios at term underwent induction of labor with prostaglandin E2; the investigators concluded that the induction of labor for oligohydramnios was an overtreatment, and proposed close surveillance to lower the rate of CS.

Dinoprostone has been administered either vaginally or intracervically, rather successfully and without serious side effects in normal pregnancies.[13] The most important adverse reaction of dinoprostone is uterine hyperstimulation. The incidence of uterine hyperstimulation ranged from 5% to 16% in patients treated with controlled-release dinoprostone.[21] This condition generally resolves within 15 minutes after removal of the insert, and patients experiencing hyperstimulation gave birth to healthy babies without requiring a CS. Cardiotocographic abnormalities are monitored in 3−10% of women receiving dinoprostone; most of these abnormalities also resolve quickly after insert removal.[21] With regard to dinoprostone administration and uterine hyperstimulation frequency, results of our study are similar to others.

In conclusion, a single dose (10 mg) of controlled-release dinoprostone administered vaginally appears to be a safe for induction of labor in patients with oligohydramnios. Increased rates of CS is the detrimental effect of dinoprostone but it does not have a negative impact on neonatal outcomes. Prospective, randomized controlled clinical trials with large numbers of patients are needed to compare dinoprostone in term pregnancies with isolated oligohydramnios.

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