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Induction of labor methods in isolated term oligohydramnios

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Abstract

Objective To compare pregnancy outcomes following induction of labor with prostaglandins versus extra-amniotic balloon catheter indicated for term isolated oligohydramnios.

Study design Retrospective cohort study of all women who underwent induction of labor due to term isolated oligohydramnios at a university affiliated medical center (2007–2016). The cohort was divided into two subgroups, according to induction method: vaginal prostaglandins E2 versus extra-amniotic balloon catheter. Primary outcomes were successful cervical ripening, defined as a Bishop score ≥ 8, and vaginal delivery rate. Secondary outcomes were neonatal adverse events.

Results Five hundred and ten women were included, of whom 454 (89%) underwent induction by prostaglandins and 56 (11%) by extra-amniotic balloon. Cervical ripening success rate was significantly higher in the prostaglandins group (89.4 vs. 76.79%, $p = 0.006$), as was the rate of vaginal delivery (77.53 vs. 48.21%, $p < 0.0001$). Induction with prostaglandins remained superior to extra-amniotic balloon in vaginal delivery rate following adjustment to potential confounders (aOR 3.470, 95% CI 1.296–9.296, $p < 0.0001$). Neonates delivered following induction with extra-amniotic balloon catheter were more often admitted to the neonatal intensive care unit (14.55 vs. 3.39%, $p = 0.002$).

Conclusion Both prostaglandins and extra-amniotic balloon catheter are reasonable interventions for isolated term oligohydramnios. Prostaglandins were superior to extra-amniotic balloon both in cervical ripening success and in vaginal delivery rates.

Keywords Induction of labor · Oligohydramnios · Term · Prostaglandins · Extra-amniotic balloon

Abbreviations

AFI	Amniotic fluid index
PGE1	Prostaglandins E1
PGE2	Prostaglandins E2
EAB	Extra-amniotic balloon
NRFHR	Non-reassuring fetal heart rate
NICU	Neonatal intensive care unit

Introduction

Oligohydramnios is a possible indicator for placental insufficiency and was found to be associated with less favorable fetal outcome [1, 2]. Oligohydramnios in clinical practice is defined as an amniotic fluid index (AFI) measurement of less than 5 cm [3, 4]. Isolated oligohydramnios is the new appearance of low amniotic fluid volume estimated by ultrasound, with appropriate fetal biometry, no associated structural or chromosomal abnormalities and no maternal infection or illness [5]. The incidence of isolated oligohydramnios ranges between 0.5 and 5% in different studies [6, 7].

Induction of labor in women who present with isolated term oligohydramnios is an acceptable intervention, to reduce the risk of perinatal morbidity and mortality [8]. Oligohydramnios is more prevalent in post-date pregnancies that present higher rates of adverse perinatal outcomes and is independently associated with significant perinatal mortality [9]. Litigants to induction of labor argue that

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active management in isolated term oligohydramnios might result in inferior perinatal outcomes, as a result of the induction itself and not directly related to oligohydramnios [10]. However, others demonstrated that pregnancy outcomes are similar when comparing induction of labor due to term oligohydramnios to other indications with normal amniotic fluid volume [11].

Cervical ripening is the first step of labor induction in women with an unfavorable cervix defined as a Bishop score of 6 or less [12]. Its accomplishment provides a marker for vaginal delivery success [12]. Effective cervical ripening methods are either pharmacological or mechanical [13, 14], such as prostaglandins E1 (PGE1), E2 (PGE2) and extra-amniotic balloon (EAB) catheter. No major differences were reported neither in success rates nor in adverse outcomes when either of those methods are used [15]. Nevertheless, there is a paucity of information regarding the favorable method for cervical ripening, specifically for women diagnosed with isolated term oligohydramnios [16].

Therefore, the aim of our study was to compare birth outcomes following labor induction with PGE2 versus EAB, indicated by isolated term oligohydramnios.

Materials and methods

Study groups

A retrospective cohort study of all women carrying a singleton term gestation, who underwent labor induction due to isolated oligohydramnios, in a single university-affiliated tertiary medical center, between 1st July 2007 and 31st December 2016. We compared maternal and neonatal outcomes according to labor induction method: PGE2 and EAB. The following cases were excluded: contraindication to vaginal delivery such as more than one prior cesarean delivery, placenta previa, vasa previa and non-vertex presentation; non-reassuring fetal heart rate (NRFHR) tracing at admission to labor induction; major fetal anomalies diagnosed in anatomical scans or genetic analysis during pregnancy amongst: neural tube defect, cyanotic heart anomalies, cleft palate, limb anomalies and chromosomal aneuploidy; known placental insufficiency related conditions such as intra uterine growth restriction and pregnancy-induced hypertension; women with chronic illness such as inflammatory bowel disease, any diabetes mellitus, systemic lupus erythematosus; finally cases presented with oligohydramnios following membrane rupture were excluded.

Definitions

Oligohydramnios is defined by our departmental protocol, and in accordance with international guidelines [17] when AFI is measured below 5 cm [4]. Isolated oligohydramnios is diagnosed when no other fetal or maternal pathology was detected during antenatal care and follow-up (including first and second trimester screening for aneuploidy, anatomic surveys and third trimester estimated fetal weight) and following standard triage evaluation, for all referred term pregnancies, which includes detailed medical history, non-stress test, physical examination, fetal biophysical profile and AFI measurement.

Women with an unfavorable cervix (Bishop score of 6 or less) were considered for cervical ripening to achieve labor induction. No specific protocol exists for cervical ripening in isolated oligohydramnios, and the decision for induction and the choice of method, either PGE2 or EAB, is up to the attending physician's discretion.

Pharmacologic cervical ripening with prostaglandins is achieved by vaginally inserted PGE2 10 mg in a timed release formulation (Propess, Ferring Pharmaceuticals, Saint-Prex, Switzerland). The alternative mechanical method is EAB, using a Foley catheter which is inserted into the cervical canal and inflated proximally to the internal os with 80 ml saline solution.

Women undergoing cervical ripening were admitted for hospitalization in the maternal–fetal medicine ward. During hospitalization, routine assessment included non-stress test and cervical ripening progression, done at 12 and 24 h after commencing induction, and in any case of contractions, vaginal bleeding, rupture of membranes, decreased fetal movements or maternal request. Cervical ripening was defined as achieving a Bishop score of 8 or above. After cervical ripening has been achieved, the parturient was admitted to the delivery ward, where she was offered regional analgesia and fetal heart rate was monitored continuously until delivery, with oxytocin added as necessary. The usual labor augmentation protocol included administration of intravenous oxytocin starting with infusion rate of 2.5 mU/min. At 20 min intervals, the dose is gradually increased in increments of 2.5 mU/min until 3–5 contractions in 10 min have been established.

Data collection

Data were retrieved from our department's comprehensive computerized perinatal and delivery database. The following demographic and obstetric parameters were recorded: maternal age, gravidity, parity, use of assisted reproductive techniques, previous cesarean delivery, hypertensive disorders, diabetes mellitus during pregnancy, gestational age at induction, AFI measurement at admission and induction of labor method. Intra-partum characteristics and labor outcome included: cervical ripening success rate, use of regional anesthesia, time from labor induction to delivery, mode of delivery and the indication for cesarean delivery.

Neonatal outcome parameters included: birth weight, 5 min Apgar score, umbilical cord pH, and neonatal intensive care unit (NICU) admission rates. Birth weight was further analyzed into small or large for gestational age, defined as below the 10th percentile or above the 90th percentile, according to local reference values [18].

All outcomes were evaluated as independent outcomes or composites. Primary outcomes were cervical ripening success rates achieved within 48 h since induction commencement and vaginal delivery rates. Secondary outcomes were neonatal adverse outcomes. Respiratory complications were stratified to a respiratory composite outcome that included any one of respiratory distress syndrome, transient tachypnea of the newborn, mechanical ventilation and meconium aspiration syndrome.

Statistical analysis

Data analysis was performed with the Statistical Analysis Software version 9.4 (SAS, North Carolina, USA). Continuous variables were compared using General Linear Model. Chi-square and Fisher's exact tests were used for categorical variables, as appropriate. Differences were considered significant when p value was less than 0.05. Following the bivariate analysis, multivariate logistic regression was utilized to adjust outcomes for potential confounders.

For power analysis calculations, we assumed successful induction of labor rates of 80%, based on available literatures [11, 16]. Using Epi-Info™ software, to ensure an 80% power for detecting a difference of 10% in success in cervical ripening rates, that we defined as clinically significant, assuming prostaglandins group to be at least 75% of the cohort, a sample size of 671 women overall was needed.

Results

Overall, during the study period, 654 women were diagnosed with term isolated oligohydramnios and delivered in our institute. Of them, 144 women were excluded: 26 presented with an AFI larger than or equal to 6 cm, 76 had a Bishop score not requiring cervical ripening, 40 were induced with both PGE2 and EAB and 2 underwent cesarean delivery prior to induction of labor due to NRFHR. Eventually, 510 met the inclusion criteria and underwent labor induction due to isolated term oligohydramnios. Four hundred fifty-four (89%) women were induced with PGE2 and 56 (11%) were induced with EAB.

Baseline characteristics of the women in the study groups are presented in Table 1. Groups presented no significant differences in maternal age, gravidity, parity and assisted reproductive technologies. Previous cesarean delivery was more prevalent in the EAB group ($n=6$, 10.71%) than in the PGE2 group ($n=10$, 2.20%, $p=0.005$). Median AFI resembled between groups (4 mm in PGE2 group and 3 mm in EAB group, $p<0.001$).

Successful cervical ripening was significantly higher in the PGE2 group versus the EAB group (89.4% vs. 76.79%, $p=0.006$). Vaginal delivery rate was also significantly higher in the PGE2 group versus the EAB group (77.53% vs. 48.21%, $p<0.0001$). Time from induction commencement to cervical ripening was shorter in patients induced by EAB compared to those induced by PGE2 (14.5 vs. 17 h, $p=0.018$). However, time to delivery was shorter in the PGE2 than the EAB group (23.5 vs. 29 h, $p=0.029$). Operative vaginal delivery and cesarean delivery rates were significantly higher in the EAB versus PGE2 group (19.64 vs. 13.43%, $p<0.0001$ and 32.15 vs. 9.04%, $p<0.0001$, respectively). We demonstrated a trend toward higher cesarean delivery due to NRFHR in the EAB group (51.22 vs. 27.78%, $p=0.016$) (Table 2).

Neonatal adverse outcomes are presented in Table 3. Median birth weight was 148 g higher in the PGE2 group

Table 1 Baseline characteristics of the study groups

	Prostaglandins, $N=454$	Extra-amniotic balloon, $N=56$	p value
Gestational age, weeks	39.85 (± 1.08)	39.52 (± 1.18)	0.033
Age, years	30.12 (± 5.18)	30.32 (± 5.57)	0.847
Gravidity	2 (1–8)	2 (1–7)	0.893
Parity	0 (0–5)	0 (0–5)	0.572
Previous cesarean delivery	10 (2.2)	6 (10.71)	0.005
Assisted reproductive technology	15 (3.3)	4 (7.14)	0.145
Amniotic Fluid Index, cm	4 (0–5)	3 (0–5)	< 0.001

Values are presented as median (range) for continuous variables and as n (%) for categorical variables

Normally distributed continuous variables are presented as mean (± standard deviation)

(3128 vs. 2980 gr, $p=0.002$), with no difference in the rates of small or large for gestational. NICU admission was significantly higher when induction was conducted with EAB versus PGE2 (14.55% vs. 3.39%, $p=0.002$).

Tables 4 and 5 elaborate post hoc analysis following adjustment to potential confounders: maternal age, parity, assisted reproductive technology and previous cesarean delivery. PGE2 induction of labor demonstrated a positive, non-significant, trend in successful cervical ripening

Table 2 Outcomes for the study groups

	Prostaglandins, $N=454$	Extra-amniotic balloon, $N=56$	p value
Successful ripening	405 (89.4)	43 (76.79)	0.006
Time to ripening, hours	17 (1–48)	14.5 (0.5–33.5)	0.018
Time to Delivery, hours	23.5 (2–101.5)	29 (10–60)	0.029
Normal vaginal delivery	352 (77.53)	27 (48.21)	< 0.0001
Operative vaginal delivery	61 (13.43)	11 (19.64)	< 0.0001
Cesarean delivery			
Total	41 (9.04)	18 (32.15)	< 0.0001
NRFHR	21/41 (51.22)	5/18 (27.78)	0.016
Arrest of descent	14/41 (34.15)	10/18 (55.56)	0.016
Arrest of dilatation	6/41 (14.63)	3/18 (16.67)	0.016

Values are presented as median (range) for continuous variables and as *n* (%) for categorical variables

NRFHR Non-reassuring heart rate

Table 3 Neonatal complications

	Prostaglandins, $N=454$	Extra-amniotic balloon, $N=56$	p value
Birth weight, g	3128 (1958–4240)	2980 (1923–4016)	0.002
Small for gestational age[a]	36 (7.95)	6 (10.71)	0.443
Large for gestational age[b]	24 (5.3)	1 (1.79)	0.506
5 min Apgar score	10 (1–10)	10 (2–10)	0.667
Umbilical cord pH	7.32 (7.03–7.48)	7.33 (7.06–7.5)	0.446
Neonatal intensive care unit admission	15 (3.39)	8 (14.55)	0.002
Respiratory composite[c]	6 (1.32)	2 (3.57)	0.216

Values are presented as median (range) for continuous variables and as *n* (%) for categorical variables

[a]Small for gestational age—below 10th percentile according to local reference values[17]

[b]Large for gestational age—above 90th percentile according to local reference values[17]

[c]Respiratory composite outcome—including any of transient tachypnea of the newborn, respiratory distress syndrome, mechanical ventilation, and meconium aspiration

Table 4 Multivariable logistic regression analysis for successful ripening

	Crude OR (95% CI)	Adjusted OR (95% CI)	p value
Successful cervical ripening	2.594 (1.308–5.143)	3.070 (0.996–9.457)	0.0063
Parity[a]	2.101 (1.409–3.133)	2.689 (1.543–4.687)	0.0003
Age[b]	0.949 (0.887–1.014)	0.884 (0.817–0.956)	0.1221
Assisted reproductive technology	0.494 (0.158–1.539)	0.822 (0.224–3.017)	0.2236
Previous cesarean delivery	2.078 (0.270–16.018)	1.821 (0.178–18.630)	0.4826

Adjusted for (ripening method prostaglandins vs. extra-amniotic balloon, parity, age, assisted reproductive technology, previous cesarean delivery)

OR odds ratio, *CI* confidential interval

[a]The OR was calculated in 1 parity increments

[b]The OR was calculated in 1 year increments

Table 5 Multivariable logistic regression analysis for mode of delivery

	Crude OR (95% CI)	Adjusted OR (95% CI)	*p* value
Normal vaginal delivery	3.690 (2.090–6.515)	3.470 (1.296–9.296)	< 0.0001
Parity[a]	3.836 (2.611–5.635)	5.308 (3.091–9.118)	< 0.0001
Age[b]	1.015 (0.969–1.063)	0.931 (0.878–0.986)	0.5387
Assisted reproductive technology	0.460 (0.181–1.169)	0.844 (0.288–2.475)	0.1025
Previous cesarean delivery	0.753 (0.257–2.210)	0.240 (0.053–1.089)	0.6058

Adjusted for (ripening method prostaglandins vs. extra-amniotic balloon, parity, age, assisted reproductive technology, and previous cesarean delivery)

OR odds ratio, *CI* confidential interval

[a]The OR was calculated in 1 parity increments

[b]The OR was calculated in 1 year increments

rates with an adjusted odds ratio of 3.070 (95% confidence interval 0.996–9.457, $p = 0.0063$). PGE2 induction of labor remained independently superior to EAB regarding vaginal delivery rate with an adjusted odds ratio of 3.470 (95% confidence interval 1.296–9.296, $p < 0.0001$).

Discussion

In the current, study we aimed to investigate term pregnancies complicated by isolated oligohydramnios, who underwent labor induction, comparing PGE2 versus EAB. Our results demonstrate that PGE2 was associated with both shorter cervical ripening times and higher rates of vaginal delivery. Moreover, we found lower rates of neonatal adverse outcomes in this group.

Oligohydramnios has been related to adverse pregnancy outcomes including increased perinatal mortality rates, meconium-stained amniotic fluid, intra-partum fetal distress and low Apgar score [1, 19]. Recent studies question the necessity of labor induction for women with isolated term oligohydramnios, presenting similar outcomes in conservative management [20]. However, others show both increased rates of small for gestational age and NICU admission [21]. Elective term induction of labor has recently been proven to reduce chances of cesarean delivery, hypertensive disorders of pregnancy and neonatal respiratory complications [22] and was endorsed by international guidelines [23]. Hence, we presume induction of labor should remain a relevant treatment option for isolated term oligohydramnios.

Prostaglandins stimulate contractions and change the water and collagen components of the cervix. By doing so, enhance cervical shortening [24] and increase the likelihood of vaginal delivery within 24 h [25]. EAB exerts mechanical pressure on the cervix. This pressure is attributed to the release of endogenic prostaglandins, promoting cervical dilatation and effacement [26]. Adverse perinatal outcomes in oligohydramnios, following exclusion of confounding factors such as intra-uterine growth restriction and congenital malformation, are mainly related to umbilical cord compression and to some degree of uteroplacental insufficiency [2, 27]. Since these factors might result in reduced oxygen perfusion to the fetus during contractions, the best method for induction of labor should be considered carefully. Our data demonstrate that cervical ripening with PGE2 was associated with higher success rates of both cervical ripening and vaginal delivery. Drawbacks of induction by prostaglandins include increased risk of uterine hyperstimulation which might cause NRFHR [14]. We found higher rates of cesarean delivery due to NRFHR in the PGE2 group. Having said that, it is important to emphasize that this group was not associated with lower Apgar score or umbilical cord pH. Mechanical cervical ripening propagates an endogenous release of prostaglandins that produce lower rates of uterine contractions and hyperstimulation [28]. Our conflicting finding of shorter time to cervical ripening but longer to delivery in the EAB group can be settled by the physiologic mechanism of this induction method. In the mechanical induction, the cervix is being stretched with the EAB and an apparently good Bishop score is achieved. However, active labor lags, compared to exogenous prostaglandins treatment in which the ripening, is achieved simultaneously with contractions. An additional assumed advantage of prostaglandins is a reduction in the use of oxytocin for augmentation since prostaglandins promote myometrial contractility [29].

We found higher frequencies of NICU admission in the EAB group. This finding might be associated to the longer time to delivery found in this group. However, it could also be related to confounders such as previous cesarean delivery, lower birth weight and higher rates of cesarean delivery in the index pregnancy of this group [30]. No other significant differences in perinatal morbidity were observed.

The limitations of this study derive mainly from its retrospective nature, we were able to present only data that were accurately entered into patient's charts during hospital encounters. Data such as smoking history and obesity were lacking. We obtained a cohort close to the calculated sample size as elaborated in "Materials and methods". However,

the sample size was calculated for an assumed difference between groups of 10% in primary outcome. We obtained a larger (13%) difference adding power to our final sample size. With lack of specific protocol indicating the recommended induction method in cases of isolated oligohydramnios, the decision is left to the attending physician. Since prostaglandins is both more easily inserted and more frequently used in our institute, there is a significant leverage in case number in this group. However, study groups were similar in most baseline characteristics, and we overcame possible selection bias such as higher rates of previous cesarean delivery in the EAB induction group by conducting multivariate analysis. The strength of our study lay both in the relatively large cohort and specific labor details we were able to obtain.

In conclusion, our study provides important information that may help caregivers choose the most appropriate induction method when a diagnosis of isolated term oligohydramnios emerges. Data from our present study indicate prostaglandins to be a superior, with regard to success rates and adverse outcomes. Notwithstanding, a large double-blinded prospective study is of need for definite recommendations.

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Compliance with ethical standards

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

Ethical approval Study was approved by our local institutional review board (Approval No, 0278-17-RMC).

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors.

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