Dinoprostone Versus Double Balloon Catheter for Cervical Ripening in Patients with Isolated Oligohydramnios

İzole Oligohidramnios Hastalarında Servikal Olgunlaşma için Dinoproston ile Çift Balon Kateterin Karşılaştırılması

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ABSTRACT

Objective: To compare the labor characteristics and neonatal outcome of dinoprostone vaginal insert and double balloon catheter in pregnancies with isolated oligohydramnios at term.

Methods: All pregnant women with isolated oligohydramnios and immature cervix at term that underwent labor induction with either the dinoprostone vaginal insert or double balloon catheter between 08 September 2016 and 08 September 2017 at a tertiary centre were included in the study. Data regarding the characteristics of parturition, including the period of time from insertion of the ripening agent to vaginal delivery, caesarean section rate, distribution of caesarean indications, need for augmentation, change in haemoglobin, new-born birth weight, meconium-stained amniotic fluid, 5-minute Apgar score and neonatal intensive care unit admission, were extracted from medical records.

Results: The cesarean section rates were 29% versus 48.8% in the dinoprostone and balloon catheter groups, respectively (p = 0.03). The other intrapartum, postpartum characteristics and neonatal outcome were comparable between groups.

Conclusion: Dinoprostone vaginal insert is a more efficient way of cervical ripening compared to the double balloon catheter in patients with isolated oligohydramnios. Both agents are comparable for neonatal outcome.

Key Words: PGE2, cook balloon catheter, cervical ripening, isolated oligohydramnios, amniotic fluid index, caesarean section rate

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ÖZET

Amaç: Miadında izole olarak oligohidramnios izlenen gebeliklerde dinoproston vajinal ovül ile çift balon kateterin doğum özelliklerini ve yenidoğan sonuçlarını karşılaştırmayı amaçladık.

Yöntem: Üçüncü basamak bir merkezde 08 Eylül 2016 - 08 Eylül 2017 tarihleri arasında dinoproston vajinal ovül veya çift balon kateter ile doğum indüksiyonu öncesi servikal olgunlaşma uygulanan izole oligohidramnios tanılı tüm gebe kadınlar çalışmaya dahil edildi. Hastane kayıtlarından bu gebelere ait olgunlaşma ajanının yerleştirilmesinden vajinal doğuma kadar geçen süre, sezaryen oranı, sezaryen endikasyonlarının dağılımı, augmentasyon ihtiyacı, hemoglobin değişikliği, yeni doğan doğum ağırlığı, mekonyumlu amniyotik sıvı, 5 dakika Apgar skoru ve yenidoğan yoğun bakım ünitesine kabul dahil doğum ve yenidoğan özellikleri ile ilgili veriler çıkarıldı.

Bulgular: Dinoproston ve balon kateter gruplarında sezaryen doğum oranları sırasıyla % 29 ve % 48.8 idi (p = 0.03). Diğer intrapartum, postpartum özellikler ve yenidoğan sonuçları gruplar arasında benzerdi.

Sonuç: Dinoproston vajinal ovül, izole oligohidramnioslu hastalarda çift balon katetere kıyasla servikal olgunlaşmanın daha etkili bir yoludur. Her iki ajan neonatal sonuçlar açısından benzerdir.

Anahtar Sözcükler: PGE2, cook baloon kateter, servikal olgunlaşma, izole oligohidramnios, amniyotik sıvı endeksi, sezaryen doğum oranı

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INTRODUCTION

The amniotic fluid index (AFI) assessment is an essential part of antenatal tests of fetal well-being including biophysical profile and modified biophysical profile. Oligohydramnios, as stated by the American Congress of Obstetricians and Gynecologists (ACOG), has an AFI ≤ 5 cm or single deepest pocket (SDP) ≤ 2 cm measured with ultrasound (1). In the literature, the presence of oligohydramnios is associated with poor pregnancy outcome such as non-reassuring fetal heart rate traces with cord compression, fetal growth restriction, meconium aspiration syndrome and stillbirth (2, 3).

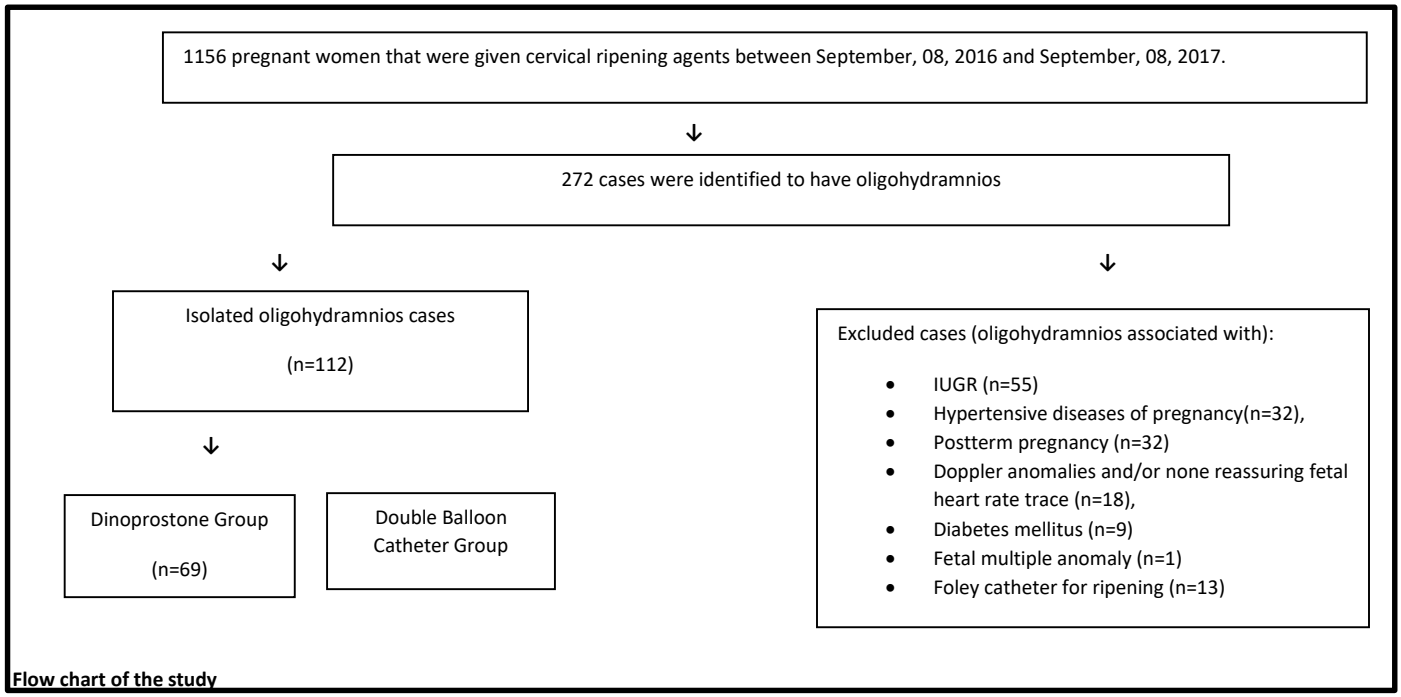
Due to the proven relationship of oligohydramnios with fetal morbidity and mortality, many centers, including ours, prefer to induce labor beyond the 37 gestational week in such pregnancies. For more than 50 years, cervical maturity, as determined by the Bishop score, is known to have a significant effect on the success of labor induction (4). There are plenty of studies in the literature comparing the effectiveness of different cervical ripening methods for the unfavourable cervix. The majority of these studies ignore the integral risks of pregnancy subgroups, such as postmaturity, preeclampsia and oligohydramnios, however, the problem is not only confined to failed induction of labor without cervical ripening. The impact of these subgroups on labor outcome is highlighted by a meta-analysis by Chauhan et al. which concluded; in pregnancies with oligohydramnios there is a 2.2-fold increased risk of caesarean delivery for foetal distress and a 5.2-fold increased risk for a low Apgar score (5). Thus, there is a selection bias of study populations in contemporary literature regarding the safety of ripening agents.

The heterogeneity in a subgroup of pregnant women and also the definition of oligohydramnios, either AFI or SDP, makes the literature inconclusive about the most efficient method for cervical ripening in women with oligohydramnios. The aim of this study was to determine which of the ripening agents has the lowest caesarean delivery rate with the best neonatal outcome in pregnant women with the unique pathology of AFI ≤5 cm.

METHODS

This study was conducted in xxxx, Ankara, Turkey, following the Institutional Review Board approval at 25.08.2016 (Number: 211). The participants of the study were all pregnant women with isolated oligohydramnios and immature cervix at term that underwent labor induction with either dinoprostone 10 mg vaginal insert or double balloon catheter between 08 September 2016 and 08 September 2017.

An assessment of high-risk pregnancy intensive care department medical records in this period yielded 1156 pregnant women that were given cervical ripening agents (dinoprostone 10 mg vaginal insert, double balloon catheter or Foley catheter) for induction of labor. Among them, 272 cases were identified to have oligohydramnios. To view the impact of isolated oligohydramnios, the antenatal pathologies associating oligohydramnios that can cause low Apgar score or increase the caesarean rate were excluded from the study group. The excluded cases were intrauterine growth restriction with estimated birth weight less than 3% of gestational age (n = 55), hypertensive diseases of pregnancy (n = 32), post-term pregnancy (n = 32), Doppler anomalies and/or non-reassuring fetal heart rate trace (n = 18), diabetes mellitus (n = 9) and fetal multiple anomaly (n = 1). Cases of isolated oligohydramnios that were inserted Foley catheter for ripening (n = 13) were also excluded (Flowchart).



Flow chart of the study

In the study population, the gestational age was confirmed at the first-trimester ultrasound, AFI was measured on two occasions by a specialist with the technique described by Phelan et al. (6). The cervical examination, for the determination of the Bishop score, was performed just before insertion of the ripening agents. All patients signed an informed consent regarding induction with a ripening agent. The obstetricians were free to choose any of the ripening agents, however, these obstetricians were not included in the study and parturition follow-up. Whatever the choice of ripening agent, patients were continuously followed for fetal heart rate trace, uterine activity and maternal vital signs. The patients were allowed to take small sips of clear fluids during induction and go to the toilet when necessary. Oxytocin augmentation was administered in cases of labour arrest.

In the mechanical ripening group, a double balloon catheter was inserted through the cervix. First, the distal balloon was inflated with 50 ml of sterile saline and seated at the level of the internal os. The proximal balloon was then inflated with 50 ml of sterile saline in the external os and seated in the vagina. The catheter was kept in place for at most 24 hours or until spontaneous expulsion with cervical dilatation of 4–5 cm or prior to caesarean section.

In the pharmaceutical ripening group, dinoprostone 10 mg vaginal insert was applied to the posterior fornix of the vagina. The dinoprostone was kept in place for at most 24 hours or until active labor with cervical dilatation of 5 cm or prior to caesarean section.

The caesarean indications in study arms were acute fetal distress and failed induction. Acute fetal distress was defined as Category III of National Institute of Health Three-tier classification system. The caesarean section performed in latent phase was termed as failed induction. The latent phase was defined to begin following cervical ripening and start of oxytocin augmentation and rupture of membranes ending with cervical dilatation of 5 cm.

RESULTS

The demographic characteristics of patients that were extracted from electronic medical records included maternal age, parity, maternal body mass index, gestational age (weeks) and initial Bishop score (Table 1). The percentage of nulliparous women were higher in the dinoprostone group (p = 0.01).

The characteristics of parturition, including the period of time from the insertion of the ripening agent to vaginal delivery, caesarean section rate (CSR), distribution of caesarean indications, need for augmentation and change in haemoglobin, were extracted from medical records. The neonatal outcome including new-born birth weight, meconium-stained amniotic fluid, 5-minute Apgar score and neonatal intensive care unit (NICU) admission were also extracted from the medical records (Table 2).

The SPSS statistical package v.11.5 was used for data analysis. Data were tested for normal distribution with a Shapiro–Wilk test. Normally distributed variables were expressed as the mean ± standard deviation or as median (minimum to maximum) and nominal data as the number of cases (percentages), where applicable. A p value < 0.05 was considered significant.

The CSR was higher in the double balloon group (p = 0.03). When CSR was analyzed according to parity, dinoprostone group had lower CSR (p = 0.013) in nulliparous women. None of the neonates had a 5-minute Apgar score of less than 7 and none of them required NICU admission.

In the dinoprostone group, 2 patients were re-hospitalized for episiotomy complications (infection) and 1 patient required transfusion due to postpartum hemoglobin of 7 g/dL (prepartum hemoglobin level: 11.3 g/dL). No episiotomy complication or requirement for transfusion occurred in the balloon catheter group.

Data expressed as mean ± standard deviation, median (minimum – maximum) or number (%) where applicable. p value <0.05 considered significant. a: t-student test, b: chi-square test, c: mann withney – u test.

Table 1: Initial characteristics of groups.

Characteristics	Double Balloon Catheter Group (n=43)	Dinoprostone Group (n=69)	p value
Maternal age [a] (years)	26.95 ± 5.3	25.1 ± 5.1	.073
Parity[b], n (%)			.01
Nulliparous	27 (62.8)	58 (84.1)	
Parous	16 (37.2)	11 (15.9)	
Body mass index [a] (kg/m^2)	28.2 ± 3.3	28.6 ± 3.1	.572
Gestational age [a] (weeks)	38.9 ± 1.2	38.8 ± 1.1	.931
Initial Bishop score[c]	0 (0-1)	1 (0-1)	.367

Table 2: Characteristics of parturition and neonatal outcome.

Characteristics	Double Balloon Catheter Group (n = 43)	Dinoprostone Group (n = 69)	p value
Insertion to vaginal delivery time [a] (hour)	24.0 ± 10.8	22.9 ± 10.1	.69
Cesarean section rate[b] n (%)	21 (48.8)	20 (29.0)	**.034**
Cesarean indications			
Acute fetal distress	9 (20.9)	8 (11.6)	.181
Failed induction	12 (27.9)	13 (18.8)	.262
Need for augmentation[b] n (%)	21 (48.8)	31 (44.9)	.687
Change in hemoglobin[c]	0.4 (2.3)	0.7 (3.8)	.522
Newborn outcome			
Birthweight [a] (grams)	3101 ± 412	3148 ± 339	.528
MSAF[d] n (%)	2 (4.7)	3 (4.3)	.64

MSAF: meconium stained amniotic fluid, NICU: neonatal intensive care unit. Data expressed as mean ± standard deviation, median (minimum – maximum) or number (%) where applicable. p value <0.05 considered significant. a: t-student test, b: chi-square test, c: mann withney – u test, d: fisher's exact test.

DISCUSSION

In this study pregnant women with isolated oligohydramnios (AFI<5cm) at term were compared for parturition characteristics and neonatal outcome during ripening with a dinoprostone vaginal insert or double balloon catheter. In our study, we first report that isolated oligohydramnios cases had a higher caesarean rate, which was comparable to other high-risk pregnancies. Secondly, in isolated oligohydramnios, dinoprostone was found to be a significantly better induction agent compared to double balloon catheter in nulliparous women with lower CSR, however both agents were comparable in parous women. Third, the neonatal outcome of both cervical ripening agents was comparable.

Amniotic fluid functions as a shield to protect the growing fetus from external factors, such as trauma and cold, and also provides the means to practice breathing, swallowing and movement, which are essential for the maturation of respiratory, gastrointestinal and skeletal systems, respectively (7). Normal AFI requires the functional integrity of maternal factors, placenta and fetal organ systems.

The understanding of its importance has led to an amniotic fluid assessment as a part of routine antenatal testing in order to identify fetuses that have increased risk of perinatal morbidity and mortality. To determine the pathologic shortage or excess of amniotic fluid, Phelan et al. set AFI as the technique for its measurement in 1987. Later, in 1990, Moore et al. reported the normative data of AFI across gestational weeks (6, 8). The first studies, including reviews by Peipert and Donnenfeld in 1991, Chauhan et al. in 1999, and the Cochrane review by Nabhan and Abdelmoula in 2008, associate oligohydramnios with poor perinatal outcome and higher CSR (9, 5, 10). A symptomatic treatment – amnioinfusion – was put forward to prevent cord compression in an attempt to improve perinatal outcome and decrease CSR (11).

However, two recent meta-analyses by Rossi and Prefumo (12) and by Rabie et al. (13), reported a comparable neonatal outcome in patients with normal AFI and isolated oligohydramnios. In our study, the neonatal outcome was good with none of the neonates requiring NICU admission or with an Apgar score less than 7. The previous association of oligohydramnios with poor neonatal outcome and increased caesarean rate were attributed to comorbid conditions.

For this reason, we excluded the cases with comorbidities to observe the effect of oligohydramnios as a unique parameter. Following these recent evidence-based results, could a continuation of routine antenatal follow up without induction of labor in patients with isolated oligohydramnios at term be acceptable in the near future?

In our study, the CSR was 48.8% in the double balloon catheter group and 29% in the dinoprostone group, with a mean CSR of 36.6% in cases of oligohydramnios isolated at term. In the study period, our institutional primary CSR was 14.8% in uncomplicated pregnancies and 36.7% in high-risk pregnancies. The studies by Shechter-Maor et al., Wang et al. and Du et al. are a few examples of the studies comparing parturition and neonatal outcome of double balloon catheter and PGE2 in patients with oligohydramnios (14, 15, 16). The CSR in the dinoprostone group of these studies were 15.4%, 22% and 39.5%, while in the double balloon catheter group the CSR were 7.7%, 16.4% and 31.6%, respectively. It is possible to conclude that the CSR highly differs between studies. Continuous monitorization of the fetal heart rate trace during the whole process could be a reason for our high CSR.

In oligohydramnios, due to cord compression with uterine stimulation, one may assume a higher CSR in the dinoprostone group. In our study, contrary to this expectation, CSR was lower in the dinoprostone group. Our experience with mechanical ripening agents, including with the double balloon catheter and despite its pressure on the cervix from both directions, is that they dilate the cervix but do not result in effacement. However, dinoprostone not only ripens the cervix but also stimulates uterine contractions, which might activate the natural cascade of events during an unstimulated labor: shorter and stronger fundal fibers with longer and thinner lower segment fibers, which propel and passage the fetus, respectively. The concerns of both the patient and the physician – caused by the absence of uterine activity – in the balloon catheter group could be a reason for a higher CSR and failed induction. This reason might also increase CSR due to fetal distress with relatively earlier artificial rupture of membranes to shorten the delivery time (in an attempt to do something). Artificial rupture of membranes with an uneffaced cervix may result in asynclitism, which is probably another explanation for failed induction in the balloon catheter group.

There is concern that the mechanical ripening agents may have a tendency of increasing infectious morbidity (17). In our study, there were 2 episiotomy dehiscence cases in the dinoprostone group but none in the balloon catheter group. In these 2 cases, there were no signs of chorioamnionitis, endometritis or neonatal infection. We believe this might have happened coincidentally with individual patient factors. Since the wound cultures were negative and according to medical records, except for dehiscence, there were no signs of infection.

The strength and of this study lies beneath its quasi-randomization as the deciders of the ripening agent and the labor observers – deciders for the caesarean section are different obstetricians. The retrospective design was the limitation of the study which resulted a parity and size discrepancy in our study arms. To overcome this issue, we analyzed groups of dinoprostone and cook catheter in terms of CSR among parous and among nulliparous women; separately. Indeed, a double randomization is impossible with these two methods as they have different insertion characteristics.

In conclusion, we observed a lower CSR with dinoprostone compared to the double balloon catheter method for cervical ripening in patients with isolated oligohydramnios at term. The neonatal outcomes were similar. Further studies with this subgroup of patients are needed to clarify the subject.

Conflict of interest
No conflict of interest was declared by the authors.

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