

Clinical use of PGE2 (dinoprostone) and cervical ripening balloon catheter during delivery induction in patients with a Bishop score of ≤ 4 with vertex presentation

Bishop skoru ≤ 4 olan vertex geliş hastalarda doğum indüksiyonunda PGE2 (dinoproston) ve servikal olgunlaştırıcı balon kateterin klinik kullanımdaki yeri

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ABSTRACT

Aim: We aimed to compare the clinical use of PGE2 (dinoprostone) and cervical ripening balloon catheter for delivery induction in patients with a Bishop score of ≤ 4 with vertex presentation.

Material and Methods: This study was retrospectively conducted and included the induction of labor between January 2014 and January 2017 at Eskişehir Osmangazi University, Department of Obstetrics and Gynecology. There was a total of 60 patients in the study and 30 patients were given dinoprostone and 30 patients were given birth by double balloon catheter. We compared the clinical results of the patients. Multivariable regressions were used to identify odds of induction success.

Results: There was no significant difference between the demographic characteristics of the patients. When the clinical results of the patients were compared, there was no difference between the vaginal delivery rate and the delivery time between the two groups. The duration of active labor in the balloon catheter group was statistically significantly longer ($p = 0.036$). The amount of postpartum hemorrhage in the balloon catheter group was also significantly higher ($p = 0.008$).

Conclusion: The ideal agent to be used in cervical pregnancy is still a controversial issue. In this regard, more work needs to be done with the patient.

Keywords: PGE2, Double balloon catheter, induction of labor, cervical ripening

ÖZ

Amaç: Bu çalışmada Bishop skoru ≤ 4 olan vertex geliş hastalarda doğum indüksiyonunda PGE2(dinoproston) ve servikal olgunlaştırıcı balon kateterin klinik kullanımdaki yerini karşılaştırmak amaçlandı.

Gereçler ve Yöntem: Bu çalışma retrospektif yapılmış olup Eskişehir Osmangazi Üniversitesi Kadın hastalıkları ve Doğum Anabilim Dalında Ocak 2014 -Ocak 2017 tarihleri arasında yapılan doğum indüksiyonlarını kapsamaktadır. Çalışmada toplam 60 hasta mevcut olup 30 hastaya dinoproston ile 30 hastaya ise çift balon katater ile doğum indüksiyonu yapılmıştır. Hastaların klinik sonuçları karşılaştırılmıştır. İndüksiyon sonucuna etki edebilecek faktörler lojistik regresyon modeli ile analiz edildi.

Bulgular: Hastaların demografik özellikleri arasında anlamlı fark yoktu. Hastaların klinik sonuçları karşılaştırıldığında ise her iki grup arasında vajinal doğum oranı ve doğum süreleri arasında fark saptanmadı. Balon katater grubunda aktif doğum eylemi süresi istatistiksel olarak anlamlı ölçüde uzun saptandı ($p=0,036$). Balon katater grubunda postpartum kanama miktarı anlamlı ölçüde fazlaydı ($p=0,008$).

Sonuç: Servikal olgulaşmada kullanılacak ideal ajan hala güncel bir tartışma konusudur. Bu konuda daha fazla hastayla yapılacak çalışmalara ihtiyaç duyulmaktadır.

Anahtar Kelimeler: PGE2, Çift balon katater, doğum indüksiyonu, servikal olgunlaşma

Cite as: Şerbetçi H, Velipaşaoğlu M, Tanır HM. Clinical use of PGE2 (dinoprostone) and cervical ripening balloon catheter during delivery induction in patients with a Bishop score of ≤ 4 with vertex presentation. Jinekoloji-Obstetrik ve Neonatoloji Tıp Dergisi 2025;22(2):158–162.

Geliş/Received: 18.10.2024 • **Kabul/Accepted:** 09.12.2024

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Çevrimiçi Erişim/Available online at: <https://dergipark.org.tr/tr/pub/jgon>

INTRODUCTION

Induction of labour is a fundamental practice in modern obstetrics. The intravenous administration of oxytocin for the purpose of inducing labour is currently the most commonly employed method (1). In this regard, intravaginal PGE₂, which represents one of the most recently introduced methods for labour induction in clinical practice, is being employed with increasing frequency (2, 3).

Induction of labour with a balloon catheter, which is a mechanical method, is a relatively novel technique, and there is a paucity of studies on the subject in the literature. In a study in which clinical experiences obtained with balloon catheter were compared with the existing literature, it was reported that the use of a balloon catheter for induction resulted in a lower rate of caesarean section than other induction methods (4).

In a separate evaluation, it is asserted that the utilisation of a balloon catheter during the induction phase offers a number of advantages, including simplicity, cost-effectiveness and the absence of significant adverse systemic effects (5). Furthermore, a study comparing the use of prostaglandin, oxytocin and balloon catheter applications concluded that induction with a balloon catheter resulted in a reduction in caesarean section rates and a shorter duration of labour (6). In one study, it was shown that tachysystole and uterine hyperstimulation developed at higher rates with the use of prostaglandin compared to balloon catheterisation and that the use of prostaglandin in addition to balloon catheterisation did not provide additional benefit (7).

In the light of these findings, the aim of this study was to compare the clinical outcomes of patients who underwent balloon catheterisation and PGE₂ (dinoprostone) administration.

There are studies directly comparing the results of balloon catheterisation and PGE₂ (dinoprostone) administration. In our study, we aimed to compare the effect of balloon catheter and dinoprostone on cervical maturation and clinical outcomes in patients with Bishop score ≤ 4 .

MATERIALS AND METHODS

This study was designed as a retrospective observational study comprising women with term pregnancies who underwent induction of labour between January 2014 and January 2017 at the Department of Obstetrics and Gynaecology, Eskisehir Osmangazi University. The study population was divided into two groups: the first group (n=30) underwent cervical ripening with a balloon, while the second group (n=30) underwent cervical ripening with dinoprostone.

Vaginal bleeding, multiple pregnancy, anomalies of presentation, contraindications for vaginal delivery (placenta previa, genital herpes, genital chonduloma), caesarean section or uterine surgery, estimated fetal weight of 4500 g or more were excluded.

The demographic characteristics (age, gravida, etc.) and obstetric ultrasonography findings of all patients selected for the study and control groups were recorded on special forms. The patients were then taken to the gynaecological table, where the genital area, vagina and cervix were examined. Bishop scoring was performed for each patient. Patients with a Bishop score of ≤ 4 were included in the study, while patients with a Bishop score above 4 were excluded.

Among 60 pregnant women, 30 pregnant women underwent cervical ripening balloon and the other 30 pregnant women underwent cervical ripening and dilatation with dinoprostone. After obtaining informed consent from both groups, cervical ripening and dilatation with cervical ripening balloon in one group and cervical ripening and dilatation with dinoprostone in the other group were performed. Each balloon of the double-balloon cervical ripening balloon was inflated with 80 ml saline. After the procedure, both groups of pregnant women were compared in terms of the time between the start of induction and delivery, need for additional oxytocin, duration of active labour (from 4cm opening to delivery), uterine hyperstimulation, mode and outcome of delivery, rate of caesarean section due to fetal distress in labour, rate of non-progressive labour, amount of postpartum haemorrhage, postpartum APGAR scores 1, 5, minutes, rates of amniotic fluid with meconium and reasons for induction. The weight of blood-soaked objects is calculated to estimate the loss of blood in millilitres.

Statistical Package for the Social Sciences (SPSS) for Windows 24.0 was used for statistical calculations and comparisons. The conformity of the data to normal distribution was tested by Shapiro-Wilk test. Pearson exact chi-square, Pearson chi-square, Continuity correction chi-square and Fisher exact chi-square tests were used in statistics. Independent samples t test was used for parametric samples. In addition, non-parametric Spearman correlation coefficient was used. Data were presented as arithmetic mean and standard deviation and $p < 0.05$ was considered statistically significant.

RESULTS

There was no statistically significant difference between the demographic characteristics of the study and control groups (Table 1).

While 13 (43%) of the patients in the balloon catheter group delivered vaginally, 18 (60%) of the patients in the dinoprostone group delivered vaginally. 17 (56.7%) of the patients in the balloon catheter group and 12 (40%) of the patients in the dinoprostone group underwent caesarean section. There was no significant difference in the rates of caesarean section ($p=0.301$) (Table 2).

In the balloon catheter group, 5 (16.6%) of the pregnant women underwent caesarean section for fetal distress and 10 (33.3%) for non-progressive labour; in the probe group, 3 (10%) of the pregnant women underwent caesarean section for fetal distress and 9 (30%) for non-progressive labour. Although the number of pregnant women undergoing caesarean section for non-progressive labour was higher in the balloon group than in the dinoprostone group, the difference was not statistically significant ($p=0.1$). Although the number of pregnant women who underwent caesarean section for fetal distress was higher in the balloon group than in the dinoprostone group, no statistically significant difference was found. ($p=0.706$). 2 patients in the balloon catheter group underwent caesarean section for unexplained vaginal bleeding. Placental abruption was suspected.

No uterine hyperstimulation was observed in both double balloon catheter and dinoprostone groups. It was also observed that there was no statistically significant difference between the postnatal apgar scores and birth weights of both groups in the study (Table 3).

The mean amount of postpartum haemorrhage was 318 ± 219 ml in the balloon catheter group and 201 ± 60 ml in the dinoprostone group. The balloon catheter group was found to be significantly higher among the postpartum haemorrhage amounts ($p=0.008$). In the balloon catheter group, three out of 30 patients experienced a uterine atony complication. Conversely, no instances of uterine atony were observed in the dinoprostone group. However, no statistically significant difference was identified between the two groups in terms of uterine atony ($p=0.237$).

The incidence of meconium-stained amniotic fluid detected during labour was one case in the dinoprostone group and no instances of meconium-stained amniotic fluid were observed in the balloon catheter group. No statistically significant difference was observed between the two groups in terms of meconium-stained amniotic fluid ($p=0.1$).

Table 1. Demographic comparison of the patient groups

Labour Induction Form			P value
	Baloon Cathater	Dinoprostone	
Number of Patients	30	30	-
Age	28.76 \pm 6.10	26.23 \pm 3.87	0,061
Gravidity	1(1-7)	1(1-11)	0.689
Parity	1(0-3)	1(0-10)	0.629
Gestational week of birth	38.4 \pm 1.2	37.8 \pm 0.9	0.051

* $p<0.05$ was considered statistically significant

Table 2. Comparison of balloon catheter and dinoprostone groups in terms of delivery modes and C/S indications

Labour Induction Form				P value
		Baloon Cathater	Dinoprostone	
Type of birth	Vaginal	13(%43,3)	18(%60)	0.301
	Cesarean	17(%56,7)	12(%40)	
Indications for C/S				
	Fetal distress	5(%16,6)	3(%10)	0.706
	Non-progressive labor	10(%33,3)	10(%30)	0.1
	Placental abruption	2(%11)	0	0,077

* $p<0.05$ was considered statistically significant

Table 3. Comparison of groups in terms of labor duration and clinical outcomes

Labour Induction Form			P value
	Baloon Cathater	Dinoprostone	
Apgar 1 st minute	9(8-9)	9(8-9)	0,606
Apgar 5 th minute	10(9-10)	10(9-10)	0,985
Birth weight	2899±519	2971±490	0.556
Postpartum haemorrhage (ml)	318±219	201±60	0.008
Duration of labor (hour)	16.50 ± 8.35	13.75 ± 8.52	0.212
Duration of active labour (hour)	6.54 ± 4.08	4.45 ± 1.73	0.036

*p<0.05 was considered statistically significant

The mean time between the induction of labour and the onset of labour was 16.50 ± 8.35 hours in the balloon catheter group and 13.75 ± 8.52 hours in the dinoprostone group. No statistically significant difference was observed between the two groups ($p=0.212$). A comparison of the duration of active labour revealed that it was 6.54 ± 4.08 hours in the balloon catheter group and 4.45 ± 1.73 hours in the dinoprostone group. The duration of active labour in the balloon catheter group was found to be significantly longer than that observed in the dinoprostone group ($p=0.036$) (Table 3).

DISCUSSION

Medical or obstetric complications during pregnancy may require cervical ripening and induction of labour. Induction of labour is required in approximately 20-30% of all pregnancies (8, 9). There are numerous techniques that may be employed to induce labour. In term pregnancies, if the onset of labour is not occurring in a normal manner and a caesarean section is not indicated, it is necessary to facilitate the ripening of the cervix. A variety of methods have been employed for this purpose. In the present era, prostaglandin derivative drugs are frequently employed for the purpose of cervical maturation and labour induction. Oxytocin is a safe and effective agent for the induction of uterine contractions. Nevertheless, the efficacy of this approach is frequently contingent upon the condition of the cervix at the outset of labour induction (1).

In a study comparing balloon catheter and misoprostol in the literature, the amount of postpartum haemorrhage was found to be similar with both methods (10). In our study, balloon catheter application caused a significant increase in the amount of postpartum haemorrhage compared to induction with dinoprostone. The reason for this was the development of uterine atony and consequently postpartum haemorrhage in 3 patients in the balloon catheter

group. There is no study in the literature showing a relationship between balloon catheter and uterine atony.

In a prospective randomised controlled trial of 210 patients comparing dinoprostone and double balloon catheter, the rate of uterine tachysystole was significantly higher in the dinoprostone group (11). The reason why uterine tachysystole was not observed in our study may be due to the relatively small number of patients.

A comparison of the patients in the study revealed that eight individuals in the dinoprostone group and 13 in the balloon group received oxytocin for a mean duration of 3.87 ± 2.58 and 4.34 ± 1.99 hours, respectively, to facilitate labour induction. No significant difference was observed in the need for additional oxytocin between the two groups. In a separate study comprising a larger patient cohort, it was observed that the requirement for supplementary oxytocin was markedly elevated in the double balloon catheter group relative to the dinoprostone group during labour induction in women with a Bishop Score below 6 (12).

When the duration of active labour was compared, it was calculated as 6.54 ± 4.08 hours in the balloon catheter group and 4.45 ± 1.73 hours in the dinoprostone group. The duration of active labour in the balloon catheter group was significantly longer than that in the dinoprostone group ($p=0.036$). In contrast, in a study conducted with nulliparous women with a Bishop Score below 6, it was found that the duration of labour with double balloon catheter was shorter than in the dinoprostone group (13). However, more studies with a larger number of patients are needed in this field.

It is known that a mature cervix is associated with an increased amount of oxytocin receptors in the myometrium. Therefore, although multiparous patients give birth faster, the lack of increase in the amount of postpartum uterine atony and bleeding may also be related to this situation. It is also possible to obtain the effects mentioned above with direct protoglandin administration,

but uterine tachysystole is a condition that should be carefully observed during labour induction. If this condition is observed, induction should be stopped or the dose should be reduced, but oral or vaginal misoprostol administration is not easily reversible. In addition, one study showed that increasing the dose of prostoglandin administered did not change the success of labour induction, although it shortened the duration of labour (14). In the light of these data, the balloon method, which is more physiological and relatively easier to reverse, may be a more rational choice.

Although it was not calculated in this study, the lower cost of balloon application, especially considering that it is reusable, can be considered as a reason for preference compared to other methods.

In our study, no significant difference was observed between the 1st and 5th minute APGAR scoring of the newborns in both groups and it is thought that the balloon catheter does not have a negative effect on postnatal outcomes.

The principal objective of this study was to assess the utilisation and clinical efficacy of a balloon catheter, which is not a commonly employed device in our country. The balloon catheter appears to be a viable option in terms of reusability and cost-effectiveness. The markedly elevated incidence of postpartum haemorrhage in comparison to dinoprostone can be attributed to the occurrence of uterine atony observed in the balloon catheter cohort. Further studies with larger patient populations are required to fully demonstrate the clinical efficacy of this approach in our country. If the findings of larger studies confirm that induction with a balloon catheter results in fewer systemic side effects, a lower incidence of caesarean section, and reduced costs, it could be offered as the preferred method for inducing labour in suitable patients.

Ethics Committee Approval

The study protocol received approval from the relevant institutional ethics committee on 30/06/2017 (reference number 201).

Author Contributions

H.S.: Conception and design of the study; analysis and interpretation of the data and writing-review. M.V.: Conception and design of the study; analysis and interpretation of the data. M.T: Methodology, supervision.

Conflict of Interest

The authors have no conflicts of interest relevant to this article.

Funding:

None

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