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A prospective randomized study comparing vaginal dinoprostone plus oxytocin versus oxytocin alone for labor induction in nulliparous women with unripe cervix

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ABSTRACT

Aims: To compare the effectiveness and outcomes of two medications (oxytocin and dinoprostone) used for cervical ripening and labor induction.

Methods: Term nulliparous pregnant women with Bishop score <4 who received labor induction indication were divided into two groups. The first group received vaginal dinoprostone followed by oxytocin. The second group received only oxytocin only. Labor onset times, delivery duration, Bishop scores, contraction frequencies every 10 minutes, cesarean rates, and Apgar scores of newborns were compared between the two groups.

Results: Although there was no statistically significant difference in terms of active labor onset time between the dinoprostone and oxytocin groups, a significant difference was observed regarding the time to delivery. (dinoprostone: 873.5±219.12 minutes; oxytocin: 637.4±339.3 minutes; p=0.0001). A significant difference was also found between the two groups in terms of mean Bishop scores at 2, 4, 6, 8, and 10 hours. (p=0.0001, p=0.0001, p=0.008, p=0.033, respectively). Similarly, there was a significant difference between the two groups regarding contraction frequency per 10 minutes in the first 2 hours of induction. (dinoprostone: 0.22±0.42/10 minutes; oxytocin: 0.72±0.88/10 minutes; p=0.0001) No statistically significant difference was found between the two groups in terms of cesarean rates. However, it was determined that the oxytocin group had a 2.06 times higher probability of undergoing cesarean section compared to the other group. OR:2.06 (0.83-5.10, 95% CI). The mean 1st minute Apgar score of babies in the dinoprostone group was 6.49±0.19 and the 5th minute Apgar score mean was 9.10±0.11. The mean 1st minute Apgar score of babies in the oxytocin group was 6.80±0.17 and the 5th minute Apgar score mean was 8.80±0.15, with no statistical significance detected between the two groups (p>0.05).

Conclusion: Dinoprostone can be preferred as a method to reduce cesarean rates; however, oxytocin may be preferred in clinics with high patient density due to its faster effect and quicker completion of delivery.

Keywords: Cervical ripening, labor induction, oxytocin, dinoprostone

INTRODUCTION

Cervical ripening and labor induction are frequently utilized obstetric interventions in cases where spontaneous labor has not commenced or needs to be initiated early due to medical reasons. Labor induction is performed in approximately 20% of term pregnancies, with 25-50% of these applications being conducted due to post-term pregnancy.[1,2] Timely initiated induction has critical importance in terms of reducing maternal and fetal morbidity and mortality.[3]

The choice of labor induction method depends mostly on the cervical ripeness status, and this condition is usually evaluated clinically with the Bishop score. In cases with Bishop score <4, induction failure and cesarean rates increase.[4,5] Therefore, cervical ripening before labor induction is an important step in patients with an unripe cervix. One of the most commonly used agents for this purpose is dinoprostone, which is a prostaglandin E_2 analog. Oxytocin, on the other hand, has also been widely used for many years to initiate and advance labor.[6]

In the literature, there are numerous studies comparing the effectiveness of dinoprostone and oxytocin in labor induction. However, there is no clear consensus on which agent is superior, especially in nulliparous pregnant women with an unripe cervix.[7,8] In clinical practice, agent selection depends not only on effectiveness but also varies according to various

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factors such as induction duration, time to delivery, cesarean rates, fetal outcomes, and patient load of the healthcare institution.

The aim of this study is to comparatively evaluate the differences between dinoprostone followed by oxytocin application and oxytocin infusion alone in term nulliparous pregnant women with an unripe cervix (Bishop score <4) in terms of induction success, labor duration, cesarean rate, and neonatal outcomes.

METHODS

Ethics

This prospective, randomized, and controlled study was conducted between May 2005 and May 2006 at the 2nd Department of Obstetrics and Gynecology of Şişli Etfal Training and Research Hospital. Ethical approval was not required for this thesis study in accordance with national regulations in effect at the time of data collection (2005–2006). Institutional approval was obtained. The dataset originates from a completed medical thesis archived under thesis number 659197 at the ULAKBİM National Thesis Center. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

The study population consisted of term nulliparous pregnant women with an indication for labor induction and an unripe cervix (Bishop score <4). Inclusion criteria included post-term pregnancy, preeclampsia, oligohydramnios, and gestational diabetes mellitus. In contrast, patients with conditions such as multiple pregnancy, placenta previa, breech presentation, cephalopelvic disproportion, and premature rupture of membranes were excluded from the study.

A total of 100 nulliparous pregnant women who met the eligibility criteria and gave consent to participate in the study were randomized into two equal groups. The randomization was based on the protocol number assigned to each patient by the hospital's registration system at admission. Patients with an odd protocol number were assigned to the dinoprostone+oxytocin group, and those with an even protocol number were assigned to the oxytocin group. Group 1 (n=50) received oxytocin infusion following vaginal dinoprostone application, while group 2 (n=50) was followed with only intravenous oxytocin infusion.

Intervention Protocols and Monitoring

For patients in group 1, a 10 mg intravaginal pessary with a hydrogel matrix structure that releases 0.3 mg dinoprostone per hour was placed in the posterior fornix. This pessary was equipped with a 15 cm long string for easy removal when necessary. The application was performed as a single dose, and patients were not allowed to mobilize for the first hour after application, and continuous cardiotocographic (CTG) monitoring was provided. For patients in both groups, oxytocin was prepared as a 1% solution in 0.9% NaCl. The infusion was started at 4 mU/min and was titrated by increasing by 2 mU/min every 30 minutes until regular uterine contractions were achieved. Induction was continued without exceeding the recommended maximum dose and was maintained until delivery occurred.

Throughout the study, vaginal examinations were performed by the same obstetrician to reduce subjective differences in evaluation. Amniotomy was performed in both groups when patients entered the active phase of the first stage of labor. The bishop score was recorded through vaginal examination at the beginning of induction and then at specific hourly intervals (2nd, 4th, 6th, 8th, 10th, 12th, 14th, 16th, 18th, 20th, and 22nd hours). Uterine contraction frequency was evaluated and recorded from CTG at 10-minute intervals. All patients were monitored with CTG from the beginning of induction until delivery. The 1st and 5th minute Apgar scores of newborns after delivery were also recorded as important parameters.

Statistical Analysis

Quantitative data were presented as mean±standard deviation (X±SD). The independent sample t-test was used for comparisons between groups, the Chi-square (χ^2) test for categorical variables, and the McNemar test when necessary. Statistical analyses were performed using SPSS v.13.0 software, and $p<0.05$ was considered statistically significant.

RESULTS

The mean age, body-mass index, and gestational week (in days) of all patients included in the study are presented in Table 1. There was no statistically significant difference between patients in the two groups in terms of age, body mass index, and gestational week (all p values >0.05).

Table 1. Demographic data

Clinical information	Dinoprostone+ oxytocin	Oxytocin	t	p
Age	26.42±4.7	24.86±4.27	1.73	0.085
BMI	24.76±1.39	25.22±1.34	-1.64	0.102
Gestational day	288.02±7.3	286.84±8.03	0.77	0.444

BMI: Body-mass index

The distribution of patients in the oxytocin and dinoprostone+oxytocin groups according to labor induction indications is presented in Table 2.

Table 2. Labor induction indications

Indication	Dinoprostone+oxytocin		Oxytocin	
Postterm pregnancy	35	70.0%	34	68.0%
Oligohydramnios	5	10.0%	3	6.0%
Diabetes mellitus	2	4.0%	6	12.0%
Preeclampsia	8	16.0%	7	14.0%
Total	50		50	

The majority of labor induction indications in patients in both groups consisted of postterm pregnancies.

The mean labor onset and time to delivery of patients in both groups are presented in Table 3. While no statistically significant difference was found in terms of labor onset times in the dinoprostone+oxytocin group (p=0.148), a significant

difference was detected in terms of time to delivery. The mean delivery time in the dinoprostone+oxytocin group was 873.5±219.12 minutes, while it was found to be 637.4±339.3 minutes in the oxytocin group (p=0.0001).

Table 3. Labor onset and time to delivery

	Dinoprostone+ oxytocin (min)	Oxytocin (min)	t	p
Labor onset	357.8±169.67	301.2±215.74	1.46	0.148
Time to delivery	873.5±219.12	637.4±339.3	4.13	0.0001

Min: Minimum

The Bishop scores of the dinoprostone+oxytocin and oxytocin groups during labor monitoring are presented in Figure 1.

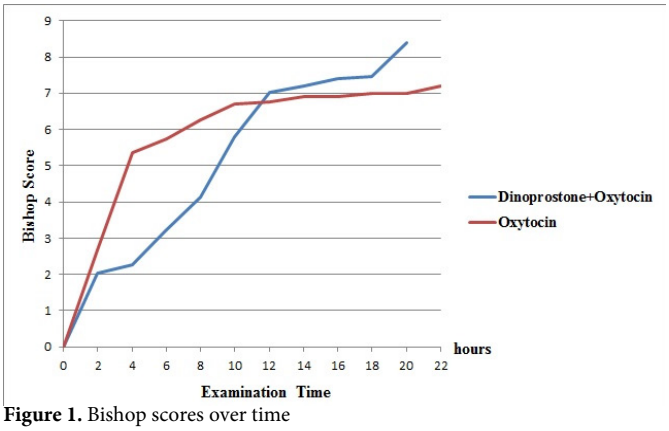

Figure 1. Bishop scores over time

Especially in the early hours of induction (2nd, 4th, 6th, 8th, and 10th hours), it was observed that the Bishop score increased faster in the oxytocin group compared to the dinoprostone+oxytocin group, and this difference was statistically significant (p=0.0001, p=0.0001, p=0.008, p=0.033, respectively). At the 12th, 14th, and 16th hours, no significant difference was found between the groups in terms of the Bishop scores (p>0.05).

The mean number of contractions per 10 minutes observed on cardiotocography in patients in both groups during labor monitoring is presented in Figure 2.

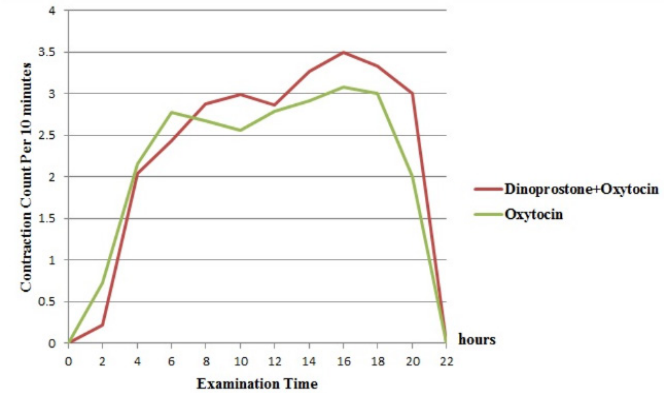

Figure 2. Contraction monitoring during labor (number of contractions per 10 minutes)

In the first two hours of induction (0-2 hours), a significant difference was found between the two groups in terms of the number of contractions per 10 minutes on cardiotocography (dinoprostone+oxytocin: 0.22±0.42/10 minutes; oxytocin: 0.72±0.88/10 minutes; p=0.0001). No significant difference was observed between the groups in the subsequent hours.

In the dinoprostone+oxytocin group, the pessary was removed in 27 patients because 12 hours had passed, in 10 patients because active labor had started, in 10 patients because fetal distress occurred, and in 3 patients due to transient maternal reactions such as nausea, vomiting, hypotension, and tachycardia. In 2 patients in the Oxytocin group, induction was considered unsuccessful because the first stage of labor did not begin within 12 hours; these patients underwent cesarean section after their systemic and obstetric examinations were re-evaluated and induction was attempted again the next day.

The percentages (%) of patients who delivered according to time intervals are presented in Figure 3.

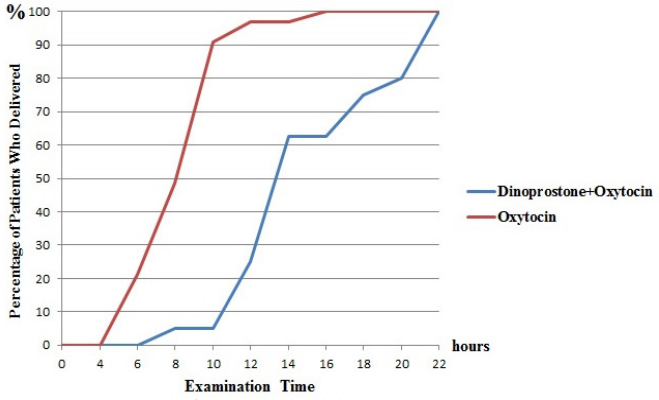

Figure 3. Percentage of patients who delivered

While 7 patients (21.2%) in the Oxytocin group delivered at the 6th hour and 16 patients (48.5%) at the 8th hour, in the dinoprostone+oxytocin group, no delivery had occurred at the 6th hour, and only 2 patients (5%) delivered at the 8th hour.

Cesarean delivery occurred in 20% (n=10) of the dinoprostone+oxytocin group and in 34% (n=17) of the oxytocin group.

The total cesarean rates are presented in Table 4.

Table 4. Cesarean rates

	Dinoprostone+oxytocin		Oxytocin	
Cesarean section	10	20.0%	17	34%
Vaginal delivery	40	80.0%	33	66%

p=0.177 (Chi-square test)

While all cesarean sections in the dinoprostone+oxytocin group were performed due to fetal distress (n=10), 15 of the cesarean sections in the oxytocin group were due to fetal distress and 2 were performed as a result of repeated unsuccessful inductions. Although there was no statistically significant difference between the two groups in terms of cesarean rates (p=0.177), it was determined that the oxytocin group had a 2.06 times higher probability of undergoing cesarean section than the dinoprostone group (OR: 2.06; 95% CI: 0.83-5.10).

No statistically significant difference was found between the groups in terms of 1st and 5th minute Apgar scores of newborns (all p values >0.05). The mean 1st minute Apgar score of new borns in the dinoprostone+oxytocin group was found to be 6.49±0.19 and the 5th minute Apgar score was 9.10±0.11. The mean 1st minute Apgar score of newborns in the oxytocin group was recorded as 6.80±0.17 and the 5th minute Apgar score was 8.80±0.15.

No serious maternal systemic side effects were observed in either patient group throughout the study. Additionally, no maternal, fetal, or neonatal mortality was encountered.

DISCUSSION

In this randomized controlled study, we compared the effectiveness and outcomes of dinoprostone followed by oxytocin application versus oxytocin application alone in pregnant women with an unripe cervix (Bishop <4) who had an indication for cervical ripening and labor induction.

In the meta-analysis conducted by Alfirevic et al.,[7] oxytocin was shown to have a lower effect on achieving delivery within 24 hours compared to vaginal dinoprostone. In our study, we also observed that delivery did not occur within 24 hours in 2 patients in the oxytocin group, while all patients in the dinoprostone group delivered within 24 hours.

In the Cochrane database study by Kelly et al.,[8] it is reported that the use of vaginal prostaglandin for labor induction in term pregnancy increases vaginal delivery rates. In our study, we found that vaginal dinoprostone pessary increased the vaginal delivery rate (**Table 4**).

In the study conducted by Kulhan and colleagues,[9] it was stated that regular contractions were achieved earlier in the oxytocin group, the desired contraction frequency was reached in 6-8 hours in the dinoprostone group, while this duration was 2-3 hours in the oxytocin group. In our study, when we examined the contraction frequency every 10 minutes with cardiotocography after starting induction, a significant difference in favor of oxytocin was observed in the first two hours of induction. No significant difference was observed between the groups in the following hours (**Figure 2**).

According to the Cochrane analysis conducted by Kelly and colleagues,[8] it was stated that the risk of cesarean section increased 1.44 times in the oxytocin group compared to the vaginal dinoprostone group OR: 1.44 (1.12-1.86). In our study, the risk of cesarean section in patients in the oxytocin group increased 2.06 times compared to the dinoprostone group [OR: 2.06 (0.83-5.10)] and is consistent with the literature.

In a similar study conducted with the same induction protocol,[10] the mean delivery time in the oxytocin group was 8.3 hours (498 minutes), while in our study, the mean delivery time in the oxytocin group was longer at 10.62 hours (637.4 minutes). This difference may be due to the inclusion of patients who underwent cesarean section in the statistical calculations in our study.

In the same study,[10] the mean Bishop score in the oxytocin group was found to be 7.5, while in our study, the mean Bishop score was found to be 6.2. This difference may similarly be due to the inclusion of patients who underwent cesarean section in the statistical calculations.

In the study conducted by Aghideh et al.,[11] they applied labor induction with oxytocin, misoprostol, dinoprostone, and balloon catheter methods, and stated that no significant difference was observed between these four groups in terms of Apgar scores of babies who delivered vaginally. Keskin and colleagues[12] showed that there was no significant difference between the two groups in terms of fetal blood gas parameters in term pregnancies that underwent labor induction with oxytocin and dinoprostone. Consistent with these studies, our study results also showed no significant difference between the Apgar scores of babies in the two groups.

Limitations

This study was conducted as a single-center study. Therefore, the generalizability of the findings to different clinical conditions or patient groups may be limited. The inclusion of only term nulliparous pregnant women in the study restricts the applicability of the results to multiparous or preterm pregnancies.

The relatively small number of participants may have prevented reaching statistical significance in some subgroups, particularly regarding cesarean rates. This situation can be considered as a factor that limits the statistical power of the study.

CONCLUSION

We examined the effects of oxytocin and dinoprostone used for labor induction on labor duration, time to delivery, Bishop score, cesarean rates, and Apgar scores of newborns. Both agents can be used for labor induction. Dinoprostone can be preferred as a method to reduce cesarean rates; however, oxytocin may be preferred in clinics with high patient load due to its faster effect and quicker completion of delivery. The choice of method will depend on the clinician's experience, hospital conditions, and the patient's condition.

ETHICAL DECLARATIONS

Ethics Committee Approval

Ethical approval was not required for this study in accordance with national regulations in effect at the time of data collection (2005–2006). The dataset originates from a completed medical thesis archived under thesis number 659197 at the ULAKBİM National Thesis Center.

Informed Consent

All patients signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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