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Comparison of dinoprostone versus oxytocin with dinoprostone for the induction of labor: A retrospective case-control study in a tertiary clinic in Türkiye

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Abstract

Aim: Even though the number of inductions is still rising, limited information is available about the results of subsequent pregnancies following induction. The current study was aimed at comparing the effectiveness of dinoprostone and low-dose oxytocin with dinoprostone in the induction of laborlabor for term pregnancies to assess the need for additional uterotonic agents.

Materials and Methods: In this retrospective case-control study, 99 patients with full-term pregnancies (completed 37 weeks or more of pregnancy) who had unripe cervixes underwent laborlabor induction for different reasons were evaluated. BISHOP score was performed to predict the patient who required laborlabor induction. All participants were given either only a sustained-release dinoprostone vaginal insert or low-dose administration of oxytocin to the dinoprostone. Two patient groups' clinical characteristics were compared.

Results: No statistically significant differences were found between the two groups based on age, gravity, parity, and gestation weeks. However, there was a significant difference between the two groups in terms of the duration of the active phase of laborlabor and time from admission until the end of the second stage of laborlabor ($p=0.04$). Labor and birth occurred in a significantly shorter time in the dinoprostone + oxytocin group. Common indications for induction of laborlabor were post-term pregnancy (77.14%). The cesarean section ratio was found to be similar in both groups ($p=0.084$). There was no statistically significant difference between the two groups in terms of adverse events such as tachysystole and hyperstimulation of the uterus and infant outcomes ($p>0.05$).

Conclusion: Sustained-release dinoprostone and dinoprostone with low-dose oxytocin were both found to be effective augmentations in the management of delay in labor. Our results supported that administration of oxytocin with dinoprostone vaginal insert dramatically shortened induction to delivery times, and no significant increase of cesarean section rate had been found.

Introduction

The main aim of obstetrics is to deliver a healthy fetus with minimal trauma to the mother by giving birth. Induction of laborlabor in women with an immature cervix at term continues to be of importance to obstetricians. In cases where the cervix is not suitable, induction of labor is often difficult and takes a long time. This increases the rate of attempted birth and cesarean section and may have serious obstetric consequences for the mother and baby.

Oral or vaginal delivery of different types of exogenous prostaglandin and the administration of oxytocin are the main examples of pharmacological ripening agents. Oxytocin is a safe and effective initiator of uterine contractions, but success depends on the condition of the cervix at the time it is started [1]. It is reported that dinoprostone, a prostaglandin E2 agent, has been found to be more efficacious than sole oxytocin in inducing laborlabor in late-term patients with a non-dilated cervix [2]. Even though standardized protocols for the use of augmentation of laborlabor have been recommended to reduce adverse neonatal outcomes, unstructured laborlabor management

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may result in hypertensive uterine contractions and reduce the incidence of cesarean (CS) which have been linked to adverse consequences on the developing fetus [3,4].

In this study, it was aimed to compare Dinoprostone (PGE2 -Propess®), one of the frequently used agents in laborlabor induction to ripen the cervix, and the addition of low-dose oxytocin to dinoprostone in terms of effectiveness, reliability and the presence of complications such as deterioration of maternal comorbidities and fetal distress in cases with an indication for pregnancy termination at 37 weeks and above.

Materials and Methods

This retrospective case-control study study was approved by the ethics committee of the University of Health Sciences, Bakirkoy Dr Sadi Konuk Education and Research Hospital, Istanbul, Türkiye (Protocol Number: 2013/46), and was performed in accordance with the Declaration of Helsinki. The patient files of all dinoprostone-administered patients who were admitted to our obstetric clinic for one year were enrolled in the study. Informed consent was obtained from all the participants included. A detailed history was taken and recorded. A general physical and a vaginal examination by ultrasound were performed, and findings were noted. All participants underwent cervical ripening either with only dinoprostone or dinoprostone and oxytocin.

Participants

A total of 99 women with singleton pregnancies of 37 weeks of gestation, and low Bishop scores ≤6 underwent labor induction were enrolled. Prenatal and demographic data were gathered from patient files, electronic data, and delivery charts. Patients were divided into two groups according to their treatment. Group 1 consisted of 66 pregnant women whose Bishop score was ≤6 and who underwent induction of laborlabor with a vaginal insert containing 10 mg dinoprostone, prostaglandin E2 (Propess©). Group 2 consisted of 33 pregnant women with a Bishop score ≤6 who underwent induction of labor with oxytocin time from induction to delivery and who in the end had a vaginal delivery.

Inclusion criteria were laboring patients' aged 18 years or older women with the unfavourable condition between 37 and 42 weeks of gestation with a singleton pregnancy, occipital presentation, no contraindication for vaginal delivery, and Bishop score ≤6. Patients with placental anomalies such as placenta accreta spectrum and uterine anomalies were excluded. Additionally, patients with contraindications or hypersensitivity to prostaglandin and oxytocin, ruptured membranes, a history of uncontrolled hypertension and coronary artery disease, use of another primary induction agent such as Foley catheter, hygroscopic dilators, cervical balloon, and oral misoprostol were excluded.

Procedures

Routine physical examinations and obstetric histories of the patients (gestational age, indication for laborlabor induction, physical examination findings, obstetric examination findings, hemogram, blood type, a complete blood count (CBC), complete urinalysis and obstetric ultrasonography findings) were investigated from their patient files. Fetal heart traces and uterine contractions on cardiotocography were evaluated. Bishop scores of the patients at initial or entering active laborlabor were recorded.

The presence of hypertension and proteinuria were used as criteria for the diagnosis of preeclampsia in both groups. Patients with blood pressure of 140/90 mmHg and above and proteinuria of 300 mg/dl or more protein in 24-hour urine were diagnosed with preeclampsia. None of the patients in the study had eclampsia or HELLP syndrome.

The basal fetal heart rate was accepted as 110-160 beats/min. Above 160 beats/min was considered as fetal tachycardia. Tachysystole was defined as 6 or more uterine contractions in 10 minutes in 2 consecutive periods. Hyperstimulation was defined as deceleration in heartbeats along with tachyptole.

Abnormal fetal heart tracing was defined as long-term severe bradycardia, tachycardia, late decelerations, long-term loss of variability, and deep variable decelerations associated with bradycardia. Patients with these findings were first turned into the left lateral decubitus position, oxygen was administered through a nasal mask, and a bolus of 500 mg crystalloid solution was administered intravenously. Dinoprostone pessary was removed. At the same time, in the group receiving low-dose oxytocin infusion, the infusion was stopped. The follow-up period was determined according to the severity of fetal distress and uterine hyperstimulation. At the end of this period, dinoprostone pessaries were reapplied to patients whose symptoms improved. When it was determined that clinically reassuring findings continued, the infusion was continued in the patient group receiving oxytocin infusion. Patients who did not improve in abnormal findings or who were initially diagnosed with signs of severe fetal distress underwent emergency cesarean section.

The American College of Obstetricians and Gynecologists' (ACOG) recommended dose and frequency of use for uterotonics was followed. After administration, uterine contractions and cervical changes were carefully noted.

Patients were split into two groups based on the type of treatment they received;

1. Dinoprostone Group (Group 1): It consisted of 63 patients who were indicated for pregnancy termination at 37 weeks and above. For each patient, 10 milligrams of dinopostone was placed in the posterior vaginal fornix to be used within 12 hours. The pessary was a hydrogen polymer containing 10 mg of prostaglandin E2 (PGE2) (Propess® pessary, 10 mg, VITALIS, UK). Fetal monitoring was provided by constantly keeping the patients on a cardiotocograph. Dinoprostone 10 mg was administered for 12 hours unless cervical maturity was achieved or complications developed. The second dose was used in pregnant women for whom the first dose was not sufficient and there was no change in the Bishop score at the 12^{th} hour.

2. Dinoprostone + Oxytocin Group (Group 2): It consisted of 36 patients in whom oxytocin infusion was started immediately after the dinoprostone vaginal insert was withdrawn. 5 units of synpitan® ampoules in 500cc 5%

dextrose were infused intravenously, starting at a dose of 2 mu/min and increasing by 2 mu/min every 20 minutes until effective contractions were achieved. Oxytocin infusion was not increased unless the frequency of contractions decreased. The maximum allowable dose of oxytocin was 36 mU/min. The patients were followed by vaginal examination and cardiotocograph, and the traces were recorded.

The variables examined for the comparison of each treatment method in this study were as follows:

1. Bishop score changes
2. Vaginal birth times
3. Vaginal and cesarean birth rates
4. Time from drug administration to vaginal labor
5. Side effects and complications for the mother and baby.

Statistical analysis

For statistical analyses of differences between groups Number Cruncher Statistical System (NCSS, Kaysville, UT, USA) statistical package was used. The sample size was determined based on several factors, including the desired power of the statistical tests. PASS Power analysis was used to establish formulas specific to calculate the required sample size in this study. The chi-square (χ^2) test and the t-test were used to analyze the data for descriptive statistics. The normality distribution of the data was evaluated by the Kolmogorov–Smirnov test. A difference was considered significant if the p-value was < 0.05.

Results

Ninety-nine pregnant women were recruited in our study and were grouped into the dinoprostone receiving group (63.6%) and dinoprostone plus low-dose oxytocin infusion group (36.4%). Demographic characteristics of all participants, such as age, gravida, parity, and average gestational age, are presented in Table 1. There was no statistically significant difference in terms of age, gravida, parity and gestational age of the patients in both groups (p>0.05).

Table 1. Demographic characteristics of patients who received either Dinoprostone or Dinoprostone + Oxytocin.

Characteristics	Dinoprostone Group	Dinoprostone + Oxytocin Group	P value
Age	26.44±5.99	26.09±5.03	0.765*
Gravida	1.75±1.24	1.63±1.11	0.643*
Parity	0.67±1	0.54±0.92	0.547*
Average gestational age	39.6±2.56	39.97±2.2	0.099*

Data are given as mean ±Standart Deviation. * Independent Samples t-test.

Table 2. Indications for labor induction in cases.

Dinoprostone Indication	Dinoprostone Group	Dinoprostone + Oxytocin Group	P value
Oligohydramnios (n)	10 (15.87%)	1 (2.86%)	0.205*
Growth restriction (n)	5 (7.94%)	1 (2.86%)	
Intrauterine mort fetus (n)	6 (9.52%)	2 (5.71%)	
Postterm pregnancy (n)	33 (52.38%)	27 (77.14%)	
Diabetes mellitus (n)	3 (4.76%)	1 (2.86%)	
Preeclampsia (n)	6 (9.52%)	3 (8.57%)	

* Pearson chi-square test (χ^2 test).

Table 3. The average time between the cases' entry into labor and birth.

	Dinoprostone Group	Dinoprostone + Oxytocin Group	P value
Active labour (hour)	10.41±4.16	7.16±3.37	**0.04***
Delivery (hour)	15.77±6.43	11.5±3.75	**0.03***

* Independent Samples t-test.

Table 4. The average time from labor to birth for nulliparous and multiparous cases.

	Nulliparous	Multiparous	P value
Active labour (hour)	9.98±6.15	9.42±6.17	**0.793***
Delivery (hour)	17.22±6.33	11.03±6.87	**0.04***

* Independent Samples t-test.

Table 5. Comparison of the groups in terms of delivery method.

Delivery method	Dinoprostone Group (n=63)	Dinoprostone + Oxytocin Group (n=36)	Total cases (n=99)	P value
Normal Spontaneous Delivery (NSD) (n)	45 (71.43%)	26 (72.3%)	71 (71.71%)	0.415*
Cesarean (CS) (n)	18 (28.57%)	10 (27.7%)	28 (28.28%)	

* Pearson chi-square test (χ^2 test).

Table 6. Indications for dinoprostone remove between groups.

Indications	Dinoprostone Group (n=63)	Dinoprostone + Oxytocin Group (n=36)	P value
Fetal Distress	14 (22.23%)	6 (16.66%)	0.415*
Hyperstimulation	2 (3.17%)	2 (5.55%)	
Cervical Maturity	43 (68.25%)	27 (75.00%)	
Expiration of Treatment Period	4 (6.34%)	1 (2.77%)	

* Pearson chi-square test (χ^2 test).

Table 7. Cesarean section (CS) indications.

CS Indications	Dinoprostone Group (n=63)	Dinoprostone + Oxytocin Group (n=36)	P value
Fetal Distress	13(72.22%)	6(60.00%)	0.084*
Protracted labour	3(16.66%)	3(30.00%)	
Unsuccessful Induction	2(11.12%)	1(10.00%)	
Total number of patients	18	10	

* Pearson chi-square test (χ^2 test).

Table 8. The frequency of the occurrence of adverse events in groups.

Adverse events	Dinoprostone Group (n=63)	Dinoprostone + Oxytocin Group (n=36)	P value
Hyperstimulation	2 (3.17%)	2 (5.58 %)	>0.05*
Tachysystole	3 (4.76%)	2 (5.58 %)	
Presence of amnion with meconium	1 (1.58%)	1 (2.77 %)	
Need for neonatal intensive care	2 (3.17%)	1 (2.77 %)	
Postop/postpartum Atonia	0 %	0 %	
Uterine rupture	0 %	0 %	

* Pearson chi-square test (χ^2 test).

Of all deliveries during the study period, 62.6% of participants were nulliparous women. Most of the indications for labor induction among patients in both groups were post-term pregnancies (77.14%).

Indications for labor induction of the cases according to their treatment groups are demonstrated in Table 2. No statistically significant difference was detected (p=0.205). There was no statistically significant difference between the initial Bishop scores of the patients in both groups. In addition, according to the Bishop scoring performed when propess was taken, no statistically significant difference was detected between the two groups in terms of Bishop 2 score (p=0.306). However, when compared to the initial Bishop score, the Bishop 2 score was found to increase significantly (p=0.01).

In the dinoprostone and dinoprostone+oxytocin groups, the duration of labor and the time until birth were evaluated. It was found that labor and birth occurred in a significantly shorter time in the dinoprostone + oxytocin group (p=0.03). Table 3 shows the average time between the cases' entry into labor and birth.

No statistically significant difference was found between the nulliparous and multiparous groups in terms of labor. However, as anticipated, a statistically significant difference was found when examining the period to birth, with multiparous having a shorter duration, (p=0.04). The average time from labor to birth for nulliparous and multiparous cases is demonstrated in Table 4.

A comparison of the groups in terms of delivery method is shown in Table 5. Caesarean section was performed in 18 patients (28.57%) in the dinoprostone group and 10 patients (27.77%) in the dinoprostone+oxytocin group for various reasons. There was no statistically significant difference in cesarean section rates between the two groups, (p: 0.415). Moreover, there was no significant difference between the nulliparous and multiparous groups in terms of cesarean section rates, (p: 0.537).

Indications for dinoprostone removal between groups are presented in Table 6. There was no statistically significant difference between the two groups in terms of indications for dinoprostone removal, (p=0.095).

Cesarean section indications and rates in our study are given in Table 7. No significant difference was observed between the two groups in terms of cesarean section indications. Fetal distress constituted most of the cesarean indications for patients in both groups, (p=0.84). Fetal distress developed in 14 patients in the dinoprostone group and 6 patients in the dinoprostone + oxytocin group. In these patients, dinoprostone was removed and intrauterine resuscitation was performed. Despite intrauterine resuscitation, fetal distress continued in 10 patients in the dinoprostone group and 4 patients in the dinoprostone + oxytocin group and required a cesarean section. Hyperstimulation developed in 2 patients in the dinoprostone group and 2 patients in the dinoprostone + oxytocin group. Although dinoprostone was removed and oxytocin was stopped, a cesarean section was performed because fetal distress continued in the patients. The probe of 4 patients in the dinoprostone group and 1 patient in the dinoprostone + oxytocin group was removed after the 12-hour treatment period expired. Patients in the dinoprostone-only group were administered dinoprostone again. Vaginal birth occurred in 2 of them. Others and the patient receiving dinoprostone + oxytocin underwent cesarean section due to induction failure.

The number of cases with serious events such as hyperstimulation, tachysystole, presence of meconium amnios, need for neonatal intensive care, postop/postpartum atony, and uterine rupture occurring in both groups are given in Table 8. There was no statistically significant difference between the two groups in terms of adverse events (p>0.05). No maternal treatment-related side effects were observed in either patient group. No maternal, fetal or neonatal mortality was encountered.

The average Apgar score at 1 minute and 5 minutes after birth did not show a difference between the groups (p= 0.692 and p=0.558, retrospectively).

Discussion

The current study compared the efficacy of two protocols that were designed for the management of labor to achieve cervical ripening in women with an unfavourable cervix. Based on the results of this study, dinoprostone with concurrent low-dose oxytocin shortened the duration of delivery. This investigation featured the use of dinoprostone or low-dose oxytocin concurrently with dinoprostone. We detected either regimen to be equally effective and safe, leading to the delivery promptly. The occurrence of adverse events in the two treatment groups was similar, and cesarean delivery rates were similar. The mean duration between the onset of labor and delivery in each case was significantly shorter in the dinoprostone with concurrent low-dose oxytocin group. The average time from labor to birth in nulliparous and multiparous cases was shorter in multiparous cases, as expected. When pregnant women are interviewed as to their expectations regarding childbirth, one of the main hopes for their labor is short duration [5,6]. Our findings show that the duration of induction of labor with low-dose oxytocin administration and dinoprostone insert seems to be shorter when compared to induction of labor with sole use of dinoprostone.

In our study, the rate of vaginal birth, which can be considered treatment success, was found in pregnant women who were given only dinoprostone and at a similar frequency to the cases in the oxytocin and dinoprostone group.

Even, though it was encouraging to note that women who were induced or augmented with uterotonics in this study did not have uterine rupture and postoperative atonia, uterine hyperstimulation syndrome was existent in 4 out of 99 cases. In a trial by Bolnick et al, the authors investigated the comparison of dinoprostone with concurrent low-dose oxytocin and intermittent misoprostol with delayed high-dose oxytocin among women with a Bishop score 6 [7]. They found that the prevalence of uterine hyperstimulation syndrome was 0% and reported that two active management protocols appeared to be equally safe. Although this serious obstetric condition was seen in a small number of cases in our study, we think that it should be kept in mind as it is an important medical condition. An additional crucial point is that it is reported that despite the increased risk of hyperstimulation, prostaglandin vaginal insert is related to a probable protective effect on CS rate [8]. The rates of CS delivery in Bolnick et al's study were similar to ours.

Our results demonstrated that the use of these two protocols was equally safe and did not result in a difference in maternal and neonatal morbidity, such as tachysystole, uterine hyperstimulation, presence of amnion with meconium cesarean section rates and need for neonatal intensive care units as reported previously in the literature [9].

In a study by Ali et al, the effectiveness of vaginal prostaglandin E2 and oxytocin infusion for induction of labor for term pregnancy was evaluated [10]. They reported that more patients who had vaginally administered PGE2 delivered their babies vaginally within twenty-four hours. There are several methods available for inducing labor. The method of our research differed in the protocol selection as in our institute, it is routine to not use oxytocin alone. Lengthy labor is related to increased risks of maternal and neonatal infection; for this reason, more research on deciding on the proper protocol of labor induction in the presence of an unripe cervix in term patients is required clearly. Although it is well-known that PGE2 is extremely effective in increasing the birth rate within twenty-four hours of administration of the drug, our results support that using oxytocin and PGE together might be more effective than using PGE alone.

There are several randomized controlled trials for the comparison of different augmentation protocols for induction of labor. In a study by Liu et al, the authors compared controlled-release dinoprostone vaginal pessary and dinoprostone intravaginal gel [11]. They reported that dinoprostone was safer because of the lower incidence of uterine hyperstimulation and tachysystole. Ozkan et al explored the efficacy and safety of vaginal misoprostol versus dinoprostone vaginal insert in labor induction at term and reported that misoprostol and dinoprostone were equally safe [12]. Akay et al declared that according to their findings, oxytocin and dinoprostone seemed to have similar obstetric outcomes in post-term pregnancies with an unfavorable cervix [13]. To our knowledge, this is the first sample to explore the comparison of the dinoprostone or low-dose oxytocin concurrently with dinoprostone in women with an unfavorable cervix. Büyük et al. compared the use of oxytocin with dinoprostone in term multiparous pregnant women to ripen the cervix [14]. They found that dinoprostone increased the cesarean rate in terms and suggested that the use of oxytocin might be more ideal choice for cervical ripening in multiparous women. However, we found a similar cesarean rate between our study and control group. The difference on this subject might be due to selection of different participant population.

Various dosages and protocols of delivery have been suggested to determine the most effective method. In this study, we showed that low-dose oxytocin administration following dinoprostone application shortened the duration of birth without increasing CS rates, and at the same time, it did not affect neonatal outcomes. For these reasons, the administration of oxytocin after dinoprostone removal could be a reliable method in patients in whom labor induction is decided. This study can be regarded as a pilot study to carry out additional research because it can't yet demonstrate anything with great certainty. We believe that our study would contribute to the literature in standardizing the intravaginal PGE2 pessary and low-dose oxytocin application method. There were also some limitations. The effects of the treatment on maternal, fetal and newborn mortality were not examined. We did not investigate patient satisfaction. Short labor is one of the key goals for the expectations of pregnant women regarding childbirth. Further work might also include a comparison of uterotonic agents on female satisfaction.

Conclusion

This study was conducted to try and review current guidelines for the care of term pregnancies to prevent the prevalence of maternal and newborn morbidity. Our results demonstrated that the two active labor management protocols in the presence of an unfavourable cervix were safe and without life-threatening complications. Although the side effect profile of oxytocin is known, the important findings are that it shortens the duration of labor significantly compared to the other method and that it does not create a side effect profile greater than the complications that occur only with prostaglandin administration.

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.

Informed consent

Verbal and written informed consent form was obtained from patients.

Ethical approval

University of Health Sciences, Bakirkoy Dr Sadi Konuk Education and Research Hospital, Istanbul, Türkiye (Protocol No:2013/46).

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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