ZKTB

ORIGINAL RESEARCH

Factors Associated with Success of Induction of Labor with Dinoprostone Vaginal System and Outcomes

Vajinal Dinoproston Sistemi ile Yapılan Doğum İndüksiyonunda Başarıyı Etkileyen Faktörler ve Sonuçları

Mehmet B. Şentürk [1], Mehmet Şükrü Budak [2], Yusuf Çakmak [3], Halit Ataç [3]

1. Zeynep Kamil Maternity and Training Hospital, Obstetrics and Gynecology Clinic, İstanbul, Türkiye
2. Diyarbakır Women and Children Hospital, Obstetrics and Gynecology Clinic, Diyarbakır, Türkiye
3. Batman State Hospital, Obstetrics and Gynecology Clinic, Batman, Türkiye

ABSTRACT

Objective: *The aim of this study was to evaluate factors associated with success of induction of labor with dinoprostone vaginal system and assess maternal and fetal outcomes.*

Material and Method: *One hundred and three patients were evaluated retrospectively. Primary outcomes were considered proportion of women achieving vaginal delivery within 24 hours. Secondary outcome measures were assessed as tachysystole, hyper stimulation, oxytocin requirement, cesarean section rate, fetal distress, meconium stained liquor, postpartum hemorrhage, cervical-vaginal tears, fetal death and vaginal birth achieved post hours, and side effects such as hyperprexia, vomiting, and diarrhea. The factors associated with success of dinoprostone use were evaluated comparing between vaginal birth and cesarean section groups, and fetal outcomes were also assessed.*

Results: *The success rate of vaginal birth within 24 hours after induction was 28.2%. Age, parity and cervical opening were associated factors with success of achieving vaginal birth within 24 hours ($p<0.01$). There were no differences between two groups in terms of maternal and fetal outcomes ($p>0.05$). Apgar scores also were not different between two groups. The maternal and fetal complications which might be attributed to dinoprostone use were rare.*

Conclusion: *Age, parity and cervical opening were associated factors with success of induction of labor with dinoprostone with rare maternal and fetal complications.*

Keywords: *delivery, obstetric; dinoprostone; oxytocin; outcome assessment (Health Care); apgar score*

ÖZET

Amaç: *Bu çalışma dinoproston vajinal sistem ile yapılan doğum indüksiyonunda, başarıyı etkileyen faktörleri, maternal ve fetal sonuçları araştırmayı hedeflemektedir.*

Gereç ve Yöntem: *Bu retrospektif çalışmada 103 hastanın sonuçları incelendi. Primer sonuç; dinoproston indüksiyonu yapılmış hastaların 24 saat içinde vajinal doğum oranları olarak kabul edildi. Sekonder sonuçlar ise taşisistoli, hiperstimülasyon, oksitosin gerekliliği, sezeryan gerekliliği, fetal distress, mekonyumla boyalı amnion mayisi, diğer yan etkiler hiperprexi, kusma, ishal, postpartum kanama, cervikal ve vaginal yırtık ile 24 saatten sonraki vajinal doğum olarak değerlendirildi. Dinoproston indüksiyonu sonrası 24 saat içerisinde vajinal doğum başarısı ile ilişkili faktörler ile fetal ve maternal sonuçlar değerlendirildi.*

Bulgular: *Dinoproston sonrası 24 saat içerisinde vaginal doğum başarısı % 28,2 olarak bulundu. Yaş, parite ve servikal açıklık başarı ile ilişkili faktörler idi ($p<0.01$). Sezeryana alınan grup ile vajinal doğum yapan grup arasında maternal ve fetal yan etkiler ile komplikasyonlar arasında fark görülmedi ($p>0.05$). Apgar skorları benzerdi, maternel ve fetal komplikasyonlar nadirdir.*

Sonuç: *Yaş, parite ve servikal açıklık dinoprostonla yapılan doğum indüksiyonu başarısını etkileyen faktörlerdir. Maternal ve fetal komplikasyonlar ise nadir olarak görülmektedir.*

Anahtar Kelimeler: *doğum, obstetrik; dinoproston; oksitosin; sonuç değerlendirmesi (Sağlık Bakımı); apgar skoru*

Contact:
Corresponding Author: Mehmet B. ŞENTÜRK
Address: Zeynep Kamil Maternity and Training Hospital, Obstetrics and Gynecology Clinic, İstanbul, Türkiye
Tel: +90 541 773 7176
E-mail: dr.baki77@gmail.com
Submitted: 14.04.2014
Accepted: 24.11.2015
DOI: http://dx.doi.org/10.16948/zktb.08796

INTRODUCTION

In the past decades there has been an increase in the incidence of induction of labor (1). Data from World Health Organization (WHO) Global survey on maternal and perinatal health has shown that all over the world 9.6% of deliveries required labor induction (2). In the developed countries the incidence of labor induction is as high as 25% (2). Prostaglandin E2 (PGE2) causes softening and dilatation of the cervix and subsequently produces uterine contractions which may induce labor (3). Dinoprostone, a PGE2 analogue has long been used for cervical ripening and labor induction and is efficacious safe (1).Propess™ (Ferring, Germany) is slow release PGE2 with a retrieval system, which allows immediate withdrawal if the situation demands (4). In southeastern Anatolia there are an increasing number of pregnant women and the induction of labor is increasing in parallel. Hence, the complications related labor or induction of labor (such as fetal demise, uterine rupture neonatal or maternal death) causes concern. In this retrospective study we evaluated the factors associated with success of induction of labor and outcomes of Propess™ (Ferring, Germany) vaginal insertion system.

MATERIAL AND METHOD

This was a retrospective cohort study. Ethics committee approval was not required because of the retrospective design of the study. The study was performed at Batman Women and Children hospital. This is a non-tertiary center with more than 7000 deliveries per year. Between 2011 February and 2012 January, we investigated files of 103 patient. The study population comprised of nulliparous and multiparous women with singleton cephalic presentations and unfavorable cervix (with Bishop's score <6). The 10 mg vaginal dinoprostone insert (Propess™, Ferring, Germany) was used for induction of labor. Fetal heart rate and uterine activity were monitored before insertion. A polymer matrix containing dinoprostone was placed intravaginally in posterior fornix. As hyper stimulation may occur after placement of the insert, fetal heart rate and uterine activity were monitored continually. The insert was removed by pulling the cord when active labor was achieved or after 12 hours of insertion. The insert was removed and oxytocin infusion was begun for patients who have inadequate uterine contractions. Uterine hyper stimulation and fetal distress were noted as ''distress'' and ''hyper stimulation'' in patients' files. The factors associated with success of induction of labor were investigated between vaginal birth and cesarean section groups. The primary outcome was defined as the proportion of women achieving vaginal delivery within 24 hours. The factors related to success of achieving vaginal delivery within 24 hours were investigated. These factors were age, parity, cervical opening, position and length, bishop scores, level of fetal head, fetal weight, cervical consistency, and membrane status. Secondary outcome measures assessed were tachysystole, hyper stimulation, requirement of oxytocin, incidence of cesarean section, fetal distress, meconium stained liquor and side effect like hyper stimulation, hyperpyrexia, vomiting, diarrhea, postpartum hemorrhage, cervical-vaginal tears, fetal death and vaginal birth beyond 24 hours. Fetal outcomes were assessed in terms of birth weight, asphyxia, APGAR scores at 1st and 5th minutes, admission to neonatal intensive care unit (NICU), and fetal death.

To investigate factors associated with success of achieving to vaginal birth, Student t Test, Yates' Continuity Correction Test, Fisher's Exact test, and Mann Whitney U Test was used. To compare outcomes between vaginal and cesarean birth groups, Yates' Continuity Correction Test, Fisher's Exact test, and Fisher-Freeman-Halton test were applied. Pearson Chi-Square test was used for evaluation of oxytocin requirement. P value <0.01 and <0.05 was considered as significant.

RESULTS

Patients' characters and apgar scores were shown in Table 1.The success rate of vaginal birth within 24 hours after induction was % 28.2. The totally vaginal birth rate was 35.9%. Age, parity and cervical opening were significantly higher in vaginal birth group (p<0.01). Cervical length, position, consistency, bishop score, fetal weight and membrane status were not different between two groups (p>0.05) (Table 2). There were no differences between two groups in terms of maternal and fetal outcomes (p>0.05) (Table 3). Table 4 has shown that apgar scores were not different between two groups.

Table 1: Patients' character and apgar scores.

	Min-Max	Mean±SD
Age (years)	16-49	28.3±6.7
Gestational Age (weeks)	25-42	38.8±2.9
Parity	0-8	2.3±2.3
Cervical length (cm)	1-3	1.5±0.6
Cervical opening (cm)	0-3	1.6±0.7
Bishop score	0-5	3±1.1
Apgar 1 min.	0-8	7.5±1.5
Apgar 5 min.	0-10	9±1.7

Table 2: Comparison of vaginal birth group to cesarean group.

	Vaginal delivery		
	Yes (n=37)	No (n=66)	
	Mean±SD (Median)	Mean±SD (Median)	*P*
Age (years)	23.8±4.8 (23)	30.8±6.32 (30)	[a]*0.001***
Parity	0.00±0.00 (0)	3.61±1.97 (3.5)	[b]*0.001***
Cervical opening (cm)	1.00±0.74 (1)	1.82±0.68 (2)	[b]*0.001***
Level of the fetal head	-3±0 (-3)	-3.00±0.00 (-3)	[b]*1.000*
Cervical length	1.7±0.6 (2)	1.47±0.61 (1)	[b]*0.084*
Bishop score	2.9±1.3 (3)	3.02±0.95 (3)	[b]*0.899*
Cervical consistency			
Midlle	29 (78.4)	59 (89.4)	[c]*0.219*
Firm	8 (21.6)	7 (10.6)	
Cervical position			
Midlle	31 (83.8)	60 (90.9)	[d]*0.342*
Retrovert	6 (16.2)	6 (9.1)	
Membrane status			
Intact	28 (75.7)	50 (75.8)	[d]*1.000*
Ruptured	9 (24.3)	16 (24.2)	
Fetal Weight (kg)	3264±503 (3200)	3113±653 (3200)	[a]*0.227*

*[a] Student t Test, [b] Mann Whitney U Test, [c] Yates' Continuity Correction Test, [d] Fisher's Exact test, * p<0.05, ** p<0.01.*

Table 3: Outcomes between two groups.

	Vaginal delivery		
	Yes (n=37), n (%)	No (n=66), n (%)	
			P
Changes of FHR	18 (48.6)	30 (45.5)	[c]*0.956*
Fetal Distress	7 (18.9)	17 (25.8)	[c]*0.586*
Aysphyxia	0 (0)	1 (1.5)	[d]*1.000*
Meconium stained liquor	1 (2.7)	5 (7.6)	[d]*0.416*
Maternal adverse effect	14 (37.8)	22 (33.3)	[c]*0.807*
Tachysystolia	13 (35.1)	20 (30.3)	[c]*0.776*
Hyperstimulation	12 (32.4)	28 (42.4)	[c]*0.431*
Maternal complication	13 (35.1)	17 (25.8)	[c]*0.436*
Neonatal outcomes			
Good	36 (97.3)	63 (95.5)	[e]*0.227*
Death	0 (0)	3 (4.5)	
NICU	1 (2.7)	0 (0)	
Oxytocin requirement			
Yes	14 (37.8)	36(55.4)	[f] 0.088
No	23(62.2)	29(44.6)	
Delivery within 24 hours	Yes	No (beyond 24 hours)	
Vaginal	29 (78.4)	50 (75.8)	[c]*0.953*
C/S	8 (21.6)	16 (24.2)	

*[c] Yates' Continuity Correction Test,, [d] Fisher's Exact test, [e] Fisher-Freeman-Halton Test, [f] Pearson Chi-Square, * p<0.05, FHR: Fetal heart rate, NICU: Neonatal intensive care unit, C/S: Cesarean section.*

Table 4: The changes of apgar scores between two groups.

	Vaginal delivery		
	Yes(n=37)	No (n=66)	
Apgar	Mean±SD (Median)	Mean±SD (Median)	*p*
1 th minute	7.76±0.72 (8)	7.42±1.74 (8)	[b] *0.689*
5 th minute	9.16±0.60 (9)	8.95±2.06 (9)	[b] *0.214*

[b] Mann Whitney U Test.

DISCUSSION

This current study demonstrated that age, parity, cervical opening were associated factors the success of achieving of vaginal birth within 24 hours and maternal and fetal outcomes were not different between vaginal birth and cesarean section group. Treatment success in our study was 28.12%. This success rate is lower than reported studies before. This may be due to our study contains small number of patients. In these studies, cervical ripening was defined as an increase in the Bishop score of 2 or more, or the achievement of vaginal delivery within the defined observation period, 8 or 12 hours. Gestational age ranged from 37 to 42.

The success of induction with dinoprostone changed between 50% and 92% (3). Parity was an important factor which associated with success in this study. MacKenzie reported that the success rate were 85% in nulliparous women and 93% in multiparous women respectively (5). Authors also reported that there was a lower incidence of oxytocin use in multiparous women and multipara had earlier median times for onset of labor or delivery. This is consistent with another reported studies (6-8). Age was another factors associated with success of induction. But this may due to increasing of parity. Bishops' score may be most important factor of success.

In this study Bishops' score was not different in achieved vaginal birth and cesarean section groups. Only cervical opening was higher in the group which achieved vaginal birth within 24 hours, another parameters of Bishops' score were not different. We thought that this was due to small size of study. It has been reported that cervical opening is most important part of Bishops' score and the success rate of induction increases as cervical opening increases (9, 10).

The maternal or fetal adverse of dinoprostone are rare. The mean incidence of uterine hyper stimulation following induction of labor with dinoprostone was 3.5% and mean incidence of fetal distress was 4.2% (3). In this study mean incidence of hyper stimulation and fetal distress were higher when compare literature. This was due to variable definition of hyper stimulation and fetal distress between midwifes or obstetricians. But true asphyxia was seen only in one neonatal and three fetal death were seen. When we consider fetal death and neonatal asphyxia as true fetal distress, the rate was 3.88% and consistent with literature (3). But three fetal death were actually intrauterine mort de fetuses and this was indication of induction of labor. Thus although these were not true outcomes we considered as seconder outcomes. In addition meconium stained liquor (MSL) was seen in 6 (5.8%) cases. Of course MSL always does not reflect fetal distress but in this study, the lower rate of MSL can reflect that definition has not changed from obstetrician to obstetrician like fetal distress or uterine hyper stimulation.

There were no differences between vaginal birth and cesarean section group in terms of fetal distress and hyper stimulation rates. The median apgar scores of 1 minute was 7.54 and of 5th. minute was 9.03. This results also are consistent with literature (3). The median values at five minutes confirm that induction using dinoprostone insert does not have an adverse effect on neonatal condition at birth. The maternal adverse effect of dinoprostone has been reported as vomiting, nausea, diarrhea, backache, abdominal pain and headache in previously (3). The rates of these adverse effects were changed from 2 to 2.5 percent (3). In this study the rate of maternal adverse effect was 29.12%. This is very high and could be due to variable definition between obstetricians and midwifes. Because ıt can be difficult to assess which side effect is drug related especially like backache.

This study includes limitations. The small number of cases and retrospective design are limitations. Moreover some outcomes cannot be correctly defined. But when considering the objective outcomes such us fetal asphyxia and MSL, dinoprostone vaginal insert seems to be safe. The factors associated with success of induction were age, parity and cervical opening.

Conflict of interest: The Authors declared that there is no conflict of interest.

Acknowledgement: We want to thanks to archive workers of Batman State Hospital. This study was not supported by any company or institutions.

REFERENCES

1. Madaan M, Agrawal S, Puri M, Nigam A, Kaur H, Trivedi SS. Is low dose vaginal misoprostol better than dinoprostone gel for induction of labor: a randomized controlled trial. J Clin Diagn Res. 2014;8(9):OC31-4.

2. WHO recommendations for Induction of labor. World Health Organization 2011. Available from: whqlibdoc. who.int/publications/2011/9789241501156_eng.pdf.

3. A Calder And I Z Mackenzie A. Review of Propess- a controlled release dinoprostone (prostaglandin E2) pessary. J Obstet Gynaecol. 1997;17 Suppl 2:S53-67.

4. Mukhopadhyay M, Lim KJ, Fairlie FM. Is propess a better method of induction of labour in nulliparous women. J Obstet Gynaecol. 2002;22(3):294-5.

5. MacKenzie I. Z. (1995a) Induction of cervical ripening : Evaluation of the prostaglandin E2 release from `Propess' and clinical efficacy and safety in the induction of labour in women with unfavorable and partially favourable cervix. In: Propess-RS ‹ A Clinica l Review, edited by A. A. Calder , M. J. N. C. Keirse and I. Z. MacKenzie , pp. 11±15. Haslemere, Euromed.

6. Westgate J. and Williams J. A. (1995) Evaluation of`Propess-RS' : Evaluation of the efficacy, safety and convenience of `Propess-RS' in the induction of labour . In:Propess-RS ‹ A Clinica l Review, edited by A. A. Calder , M. J. N. C. Keirse and I. Z. MacKenzie, pp. 29±35. Haslemere, Euromed.

7. Browning J. J., Bidgood K. A., Calder A. A., et al. (1995). Propess PMS study: post-marketing surveillance study of the efficacy and safety of `Propess ' when administered for the induction of labour at 16 UK centres . Data on: Ferring Pharmaceutical s Ltd., U.K.

8. Mowat K. J., Carty M. J. and Chat® eld W. R. (1995) Propess-RS PMS study. Post-marketing surveillance study of the efficacy, acceptability and safety of `Propess-RS' at three UK centres . Data on File: Ferring Pharmaceutical s Ltd., U.K.

9. Riboni F, Garofalo G, Pascdi I, Vitulo A, Dell'avanzo W, Battogliarin G, Paternorter D. Labor induction at term: Clinical, biophysical and molecularpredictive factors. Arch Gynrcol Obstet. 2012;28(5):1123-9

10. Crare JM. factors predicting labor inductions success: a critical analysis. Clin Obstet Gynecol. 2006;49(3):573-84.