

COMPARISON OF FOLEY CATHETER AND PROSTAGLANDIN E2 TABLETS FOR THE INDUCTION OF LABOR AT TERM*Ana Daneva Markova¹, Marija Hadži-Lega¹, Milan Stefanović²*

The aim of the paper was to assess success rates and associated maternal and fetal risks, to determine the different methods of induction for labor at term, compare induction with Foley catheter and induction with naturally occurring prostaglandin E2 (PGE2) tablets in women with gestational age at term.

Two hundred and twelve women at term were included into the study, one group with Foley catheter, the second group with PGE2 tablets, with a maximum of two doses. The primary outcome measures were the admission-to-delivery interval and the induction-to-delivery interval. Secondary outcomes included cesarean section rate, mode of delivery, and maternal and neonatal safety outcome. Results were calculated by applying the Fisher's exact test, c²-test, t-test and calculating the P-value using an alpha level of 0.05 for Type I errors.

The mean time from admission to delivery was 13.53h in the Foley catheter group and 12.30h in the PGE2 group (P=0.090). The induction-to-delivery interval was also comparable between the groups (10.75h vs 9.37h), while the cesarean section rate did not differ significantly between them (7.61% vs 15.30%). More women in the misoprostol group had an instrumental delivery (12.38% vs 2.94%). The only significant difference in neonatal outcome was a larger number of babies born with Apgar score < 7 at 1 min in the Foley group. Maternal outcomes were not significantly different, except for a higher number of digital examinations in the Foley group.

Foley catheter is equally efficacious in labor induction and demonstrates a similar fetal and maternal safety profile to PGE2. *Acta Medica Medianae 2013;52(4):21-26.*

Key words: *induction of labor, Foley catheter, Prostaglandin E2, neonatal outcome*

Ss. Cyril and Methodius University, University Clinic of Obstetrics and Gynecology, Medical Faculty, Skopje, Republic of Macedonia¹
University of Niš, Medical Faculty, Department of Obstetrics and Gynecology, Niš, Serbia²

Contact: Ana Daneva Markova
Department of Obstetrics and Gynecology
State University Hospital of Skopje
Skopje, Macedonia

Introduction

Induction of labor refers to the iatrogenic stimulation of uterine contractions before the onset of spontaneous labor to accomplish vaginal delivery. It is a commonly performed procedure in obstetrics, with an incidence ranging from 5 to 30 % of all pregnancies (1). It is performed when the perceived benefits of delivery outweighs the risks associated with labor induction.

In the late nineties, the rate of induction of labor was 19% in the US (2), 23% in Australia (3), and 21% in the UK (4). In the UK, the rate of cesarean delivery nearly tripled during the 1970s and the 1980s (5), and in 2000, 22% of pregnant women were delivered by cesarean (4). In the US, cesarean delivery rates increased from

17% in 1980 to 24% in 1990 (6), and this trend continues presently (7).

The major concern over labor induction is a failure to achieve vaginal delivery, when emergency cesarean section becomes the only option. The risk of emergency cesarean section in women undergoing labor induction has been reported to be 25% for nulliparous and 6% for multiparous women (8). However, the effects of labor induction on childbirth, in general, are still the subject of considerable controversy (9). According to different publications, inducing labor has been found to both increase and decrease the risk of cesarean delivery (3,10,11).

The decision to induce labor in less imminent situations is often difficult. If the induction fails, an emergency cesarean delivery will be indicated. It is well established that maternal risks are greater in emergency cesareans when compared to vaginal deliveries or to elective cesarean deliveries (12). Often a decision to induced labor is made, because vaginal delivery is considered safer and more beneficial than an elective cesarean delivery for both mother and child (13). This risk, however, is related to various factors, including the indications for induction, the cervical status and the methods

used. However, the recurring dilemma is that if the induction is unsuccessful, the intention to accomplish a safe beneficial delivery is not realized.

Identifying those pregnancies that can be induced with low failure risk should be of utmost importance. Previous studies have found that null parity and a low Bishop score increase the rate of failed induction and of a cesarean delivery (10, 11). However, our knowledge of factors influencing the risk of emergency cesarean delivery in women undergoing labor induction is still limited. Moreover, there is no available data on this topic in the Republic of Macedonia.

In this study, we evaluated the different indications for labor induction, the different methods used and success rates associated with maternal and fetal risks.

Our study hypothesis was that immediate induction with Foley catheter will result in a significant shortening of the induction-to-delivery time in comparison to immediate induction with vaginal PGE2 tablet.

We evaluated, retrospectively, all labor inductions which occurred in the past two years (2010-2012) at the University Clinic of Obstetrics and Gynecology, Skopje. Our center is the largest birth center in the country, and the only tertiary, university affiliated center in the country.

Materials and Methods

Study design

This is a retrospective database study. Data related to all labor inductions from January 2010 to January 2012 was analyzed. Our center is the largest birth center in the country, and the only tertiary, university affiliated center in the country.

We included in our analysis all deliveries requiring labor induction during the time period mentioned above. Mothers with multiple pregnancies, previous cesarean section, no cephalic presentation at birth, stillbirths and preterm deliveries (less than 37 completed weeks of gestation) are excluded. Women were excluded from the study if they were in labor (the onset of labor was defined as regular contractions occurring twice in 10 min by non-stress test, or if there was a contraindication to the induction of labor (such as placenta previa or meconium staining of the amniotic fluid).

Treatment schedule

On admission to the delivery room complex if the inclusion criteria were met, informed consent for inclusion in the study was requested by the medical staff and no woman refused it. At the time of diagnosis, Bishop's scoring was also done, uterine contractions and fetal heart rate were monitored using electronic fetal monitoring for 1h. If the fetal heart rate was normal and if

contractions were not present, the woman was randomly allotted to either the group undergoing immediate induction with Foley catheter (Group 1) or that undergoing immediate induction with PGE2 tablets (Group 2).

Women assigned to Group 1 were treated with a Foley catheter in the cervical channel instilled with 70ml NACL 0, 9%. Women in Group 2 were given 0.5mg PGE2 tablets instilled in the posterior vaginal fornix every 6h, for up to a maximum of two doses. The medications were administered by the trainee residents and application of the inducing agents was stopped if the woman was found to be in the active phase of labor (cervical dilatation 3cm and uterine contractions 3/10min). If the contractions subsequently became inadequate, an oxytocin infusion was used to augment labor so that three contractions were obtained in 10min or a maximum dose of oxytocin (32mIU/min) was achieved. The women were carefully monitored every half an hour for side effects and the onset and progress of labor. Vaginal examination was performed every 4h to assess the progress of labor. Abnormal labor was defined very specifically. Failure to progress in the latent phase was defined as a period of 24h in primigravidas and 14h in multigravidas without progress. Failure to progress in the active phase of labor was defined as failure of further cervical dilatation after 3cm dilatation or failure of descent of the presenting part after 2h of adequate uterine contractions. Failure to progress in the second stage of labor was defined as the absence of further descent of the presenting part over a period of 2h in primigravidas and 1h in multigravidas in spite of adequate uterine activity. At delivery the Apgar scores were determined. Babies in both groups had a blood sample taken for white cell counts and culture within 24h of birth and before treatment with antibiotics. Other tests and treatment given to the babies were determined by visiting pediatricians.

Outcome measures

Our primary outcome measures were the induction to-delivery and admission-to-delivery intervals. Secondary outcome measures were the caesarean section rate, maternal morbidity, neonatal morbidity and mortality. The fetal heart rate was monitored by using electronic fetal monitoring during 1h of observation and for the first 2h after the administration of inducing agents. Intermittent auscultation was performed every hour before the onset of labor and every half an hour during labor. If the fetal heart rate was abnormal during intermittent auscultation, continuous electronic fetal monitoring was performed throughout labor. The changes in fetal heart rate that were considered abnormal included persistent decelerations (early, late, or variable decelerations), fetal tachycardia (fetal

heart rate >160beats/min), fetal bradycardia (fetal heart rate <100beats/min), or reduced short term variability (<5beats/min). Failure of induction was defined as no onset of labor after 24h following the initiation of induction of labor. Tachysystole was defined as at least six contractions in 10min. Hyperstimulation was defined as the presence of tachysystole associated with fetal tachycardia, late decelerations, or loss of beat-to-beat variability. Recognized episodes of hyper stimulation were managed with a change in the maternal position, oxygen administration. Hyper tonus was defined as a uterine contraction lasting at least 2min. The occurrence of chorioamnionitis (maternal fever usually associated with maternal and fetal tachycardia, uterine tenderness and peripheral leukocytosis) and postpartum endometritis (the presence of maternal fever and uterine tenderness, leukocytosis and foul-smelling lochia) was evaluated in all patients. Sepsis in the neonate was defined as at least one positive blood culture believed not to be a contaminant. The physicians who managed labor were not blinded to the study group allocation.

Statistical analysis

All data were collected in a preform prepared for the study. The data were analyzed with Epi info software and Microsoft Excel software (Redmond, WA, USA). Analyses were done using the modified intention to treat principle. The modified intention to treatment population comprised all women who were randomized to treatment and received at least one proper dose of study drug. We did not have a prespecified stopping rule based on superiority of regimen before the trial ended. Results were calculated applying Fisher's exact test, the c2-test and the t-test, and calculating the P-value using an alpha level of 0.05 for Type I errors.

Results

Of the 264 women eligible for admission into the study, 52 women were not included because of various reasons (gestational age <37 weeks, fetal distress, meconium-stained amniotic fluid, breech and compound presentation, and contractions started during observation). Following randomization, 110 women were included in the Foley group and 102 women in the PGE2 tablet group. Of 110 women in the Foley group, four had improper administration of Foley catheter and one refused the treatment with Foley catheter; they were excluded from the final analysis.

Primary outcome

Results for the primary outcome variable are presented in Table 2. As can be seen, there were no significant differences between the two treatments groups for the time interval from induction to the onset of labor, induction-to-delivery interval, time in hospital before delivery, however, women in Group II had a shorter duration of active labor.

Secondary outcome

Secondary outcome measures are shown in Tables 4 and 5. The rate of cesarean section did not differ significantly between groups (Table 4), but the operative vaginal delivery rate was significantly higher in Group I among nulliparous women (13% vs 3%, $P=0.022$). In Group I, three cesarean sections had to be carried out for failure of induction and five women had secondary arrest of labor in the active phase. In Group II, three women had failure of induction; six had fetal distress and six had secondary arrest of labor in the active phase.

Table 1. Baseline characteristics at the entry into the trial

Characteristics		Immediate induction with PGE2 gel (n = 102)	Immediate induction with Foley catheter(n = 110)	value
Maternal age (years) †		23.02±3.59	23.09±3.54	0.444*
Gestational age (weeks) †		38.40±0.85	38.26±0.87	0.119*
Parity	0	87	81	0.954**
	≥1	23	21	0.954**
Ultrasound needed to confirm gestational age		85	90	0.035**
Interval from rupture of membranes to admission (hours) †		4.22±2.36	4.46±2.66	0.245*
Methods of confirming rupture of membranes pooling of amniotic fluid on speculum examination		103	96	0.883**
Absence of membranes on digital examination		95	91	0.527**
Reduced liquor volume (AFI < 5) on ultra sonography		24	21	0.826**
Bishop score	≥6	38	42	0.319**
	<6	72	60	0.319**

* Using the t-test, ** Using the c2-test, † Values are mean _ SD, AFI - amniotic fluid index, PGE2 - prostaglandin E2

Table 2. Timing of events after induction

	Immediate induction with Foley (N=105)	Immediate induction with PGE2 gel (n = 102)	P value
Time to active labor††	5.36±4.54	4.59±3.87	0.123
Duration of active labor††	4.73±2.73	2.82±1.47	<0.001
Induction-to-delivery interval	10.75±6.69	9.37±5.48	0.0526
Time in hospital before delivery	13.53±7.45	12.30±5.55	0.090
Interval from membranes rupture to delivery	16.97±6.94	16.77±6.06	0.413

Values are mean \pm SD, * Using the *t*-test, † Three women in the Foley group who had induction failure and did not go into labor were excluded from the analysis

‡ Six women in the prostaglandin E2 (PGE2) group who had induction failure and six women who had fetal distress before the onset of active labor were excluded from the analysis

Table 3. Mode of delivery

		Immediate induction with Foley (N=105)	Immediate induction with PGE2 gel (n = 102)	P value
Nulliparous	Cesarean section	08 (9.52%, 8/84)	15 (18.51%, 15/81)	0.105**
	Operative vaginal delivery	13 (15.47%, 13/84)	03 (3.70%, 3/81)	0.011***
	Spontaneous vaginal delivery	63 (75.00%, 63/84)	63 (77.77%, 63/81)	0.794
Total		84 (100%)	81 (100%)	
Multiparous	Cesarean section	0	0	-
	Operative vaginal delivery	0	0	-
	Spontaneous vaginal delivery	21 (100%, 21/21)	21 (100%, 21/21)	0.916
Total		21 (100%)	21 (100%)	

* Using the *c*²-test with Yates correction done where necessary, PGE2 - prostaglandin E2

** P = 0.095 when calculated in nulliparous women only, *** P = 0.011 when calculated in nulliparous women only

Table 4. Maternal outcome

Outcome measurement		Immediate induction with Foley (N=105)	immediate induction with PGE2 gel (n = 102)	P value
Clinical chorioamnionitis		0	0	
Analgesic use		63 (60%, 63/105)	52 (50.98%, 52/102)	0.191*
Abnormal fetal heart rate		03 (2.85%, 3/105)	06 (05.88%, 6/102)	0.644 **
Hypertonus		0	03 (2.85%, 3/105)	
Antibiotic used	Penicillin	52 (49.52%, 52/105)	58 (56.86%, 58/102)	0.290*
	Cephalosporin	53 (50.47%, 53/105)	44 (43.13%, 44/102)	0.290*
Number of vaginal digital examination	<4	53 (50.47%, 53/105)	76 (74.50%, 76/102)	0.0003*
	4-8	52 (49.52%, 52/105)	26 (25.49%, 26/102)	0.0003*
Post partum fever		01 (0.95%, 1/105)	01 (0.98%, 1/102)	0.743**

* Using the *c*²-test. ** Fisher's exact test one-tailed value,

† None of the women in either group vomited or had hyperstimulation, tachysystole or post partum hemorrhage, PGE2 - prostaglandin E2

Table 5. Neonatal outcome

Neonatal outcome		Immediate induction with Foley (N=105)	immediate induction with PGE2 gel (n = 102)	P value
Apgar score	<7 at 1 min	12 (11.42%, 12/105)	03 (2.94%, 3/102)	0.036*
	<7 at 5 min	01 (0.95%, 1/105)	01 (0.09%, 1/102)	0.743**
Ventilation after initial resuscitation		08 (7.61%, 8/105)	03 (2.94%, 3/102)	0.233*
Stay in intensive neonatal care unit		12 (11.42%, 12/105)	09 (8.82%, 9/102)	0.534*
Neonatal antibiotics		08 (7.61%, 8/105)	06 (5.88%, 6/102)	0.618*
Neonatal infection		03 (2.85%, 3/105)	03 (2.94%, 3/102)	0.644**
Neonatal seizure		01 (0.95%, 1/105)	01 (0.09%, 1/102)	0.743**
Neonatal death		01 (0.95%, 1/105)	01 (0.92%, 1/102)	0.743**

* Using the *c*²-test with Yates correction done whenever necessary, ** Fisher's exact test one-tailed value

We also examined the rate of cesarean section in the two groups considering Bishop's score at the time of randomizing to study groups. At randomization, in Group I there were 69 women (three women had been excluded) who had a Bishop score <6, and in them the rate of cesarean section was 4.3% (3/69). In Group II there were 60 women with a Bishop score <6 and the rate of cesarean section was 15% (9/60) (P=0.076). Maternal outcome in regard to clinical chorioamnionitis, analgesic use and postpartum fever were similar in both groups (Table 5), but the number of digital vaginal examinations was significantly higher in Group I than Group II (P=0.0003). Blood samples were taken for a white cell count and culture in more than 80% of babies in the two groups. The rate of neonatal infection did not differ between the groups (Table 6). A higher number of babies born in Group I had a low Apgar score at 1min, but this difference did not exist at 5min. One baby in Group II had a delivery with an Apgar score 4/6 at 38 weeks' gestation. The baby died 48h after birth and the cause of death was asphyxia. In Group II also one baby was delivered asphyxiated with Apgar scores of 3/4 and the baby died six days after delivery.

Discussion

There are many studies that have compared either intravaginal application of Foley catheter or PGE2 tablets for induction of labor at and near term and found to be of benefit (5,6,12,13). Until now, Foley catheter has not been tested against PGE2 in a study designed exclusively for patients at term. Our study shows that Foley catheter was not associated with significant differences in time in hospital before delivery, induction delivery interval, caesarean section rate, or maternal and neonatal infectious morbidity when compared with vaginal PGE2 tablets. Foley catheter was associated with an increased need for operative vaginal delivery, a larger number of digital vaginal examinations and a larger number of babies born with an Apgar score <7 at 1min. Several investigators have

compared immediate induction with Foley catheter with immediate or delayed induction with oxytocin in women with PROM at term (12,13,15). These studies have shown Foley catheter to have equal efficacy and similar adverse effects to immediate induction with oxytocin (12,13) or to be more effective than expected treatment followed by oxytocin (15). The mean induction-to-delivery time of the Foley catheter group in our study and other secondary outcomes, such as caesarean section rate, and maternal and perinatal outcome, are in agreement with the Foley catheter group of these studies.

Several studies have been conducted that have compared 25mg vaginal misoprostol with PGE2 preparations (0.5 mg, 16 2mg, 17 3 mg18) for induction of labor in women without PROM and have found misoprostol to be equally effective (17) or more effective than PGE2 with similar maternal and neonatal outcomes (16). Our trial has compared immediate induction with Foley catheter to PGE2 tablets for induction of labor at term. The findings do not support the study hypothesis that Foley catheter results in a shorter time interval from induction to delivery than PGE2 tablets. Our study was not blinded because it was not financially or technically feasible. Neonatal caregivers were not masked to subject allocation, but bias would be unlikely to influence neonatal treatment decisions. Our primary outcome, the time interval to delivery, was unlikely to be influenced as the attending physicians at each birth had no vested interest in the study conclusion. In conclusion, our study was unable to demonstrate any advantage for Foley catheter over PGE2 tablets with regard to the induction-to-delivery interval and mode of delivery. Our findings support the relative safety of Foley catheter compared to PGE2 tablets.

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UPOREĐIVANJE FOLEY KATETERA I PROSTAGLANDIN E2 TABLETA KOD INDUKOVANOG POROĐAJA U TERMINU

Ana Daneva Markova, Marija Hadži-Lega, Milan Stefanović

Cilj ispitivanja bio je procena stope uspeha i rizika po majku i fetus, kao i utvrđivanje različitih metoda indukcija porođaja u terminu i upoređivanje indukcije pomoću Foley katetera i indukcije tabletama prostaglandina E2 (PGE2).

Ispitivanje je obuhvatalo 212 žena koje su se porodile u terminu, pri čemu su prvu grupu činile žene kod kojih je porođaj indukovao Foley kateterom, a drugu grupu žene kod kojih je porođaj indukovao PGE2 tabletama sa maksimalno dve doze. Primarne mere uspeha bile su period od trenutka prijema do trenutka porođaja i period od trenutka indukcije do trenutka porođaja. U sekundarne mere uspeha spadali su stopa carskog reza, način porođaja i bezbednost majke i novorođenčeta. Rezultati su dobijeni izračunavanjem i pomoću Fišerovog egzaktnog testa, c2-testa, t-testa kao i izračunavanjem P-vrednosti na alfa nivou od 0.05 za greške tipa I.

Srednje vreme od trenutka prijema do trenutka porođaja iznosilo je 13.53 h u grupi sa Foley kateterom i 12.30 h grupi sa PGE2 (P=0.090). Vršeno je upoređivanje od trenutka indukcije do trenutka porođaja (10.75 h vs 9.37 h), s tim što se stopa carskog reza nije značajno razlikovala između prve dve grupe (7.61% vs 15.30%). Većina žena u grupi sa mizoprostolom imala je instrumentalni porođaj (12.38% vs 2.94%). Jedina značajna razlika odnosila se na veći broj beba rođenih sa Apgar skorom <7 u 1 min u grupi sa Foley kateterom. Stopa uspeha porođaja kod majki nije se značajno razlikovala, osim što je veći broj pregleda prstima bio izvršen u grupi sa Foley kateterom.

Foley kateter je podjednako efikasan kod indukovano porođaja i pokazuje slični profil bezbednosti za majku i fetus kao i PGE2. *Acta Medica Medianae* 2013;52(4):21-26.

Ključne reči: indukcija porođaja, Foley kateter, prostaglandin E2, bezbednost novorođenčeta