Two methods of cervix ripening: intracervical Foley catether and dinoprostone – which one is actually more efficient?

ORIGINAL ARTICLE

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Abstract

OBJECTIVE: The aim was to evaluate which of the two analyzed methods of preinduction: intracervical Foley catether and intracervical dinoprostone is related to higher rate of successful vaginal delivery in shorter time and to shorter hospitalization after the delivery.

DESIGN: A retrospective analysis of 198 patients with unfavorable cervix for labor induction (Bishop score ≤ 6), hospitalized at 1st Department of Obstetrics and Gynecology, Medical University of Warsaw, was carried out. In 105 patients labor preinduction was conducted with Foley catheter (study group) and in 93 with intracervical dinoprostone (control group).

RESULTS: There were no significant differences regarding patients' age, body mass index (BMI), weight gain during the pregnancy, duration of pregnancy and parity between the groups. 68.6% of patients in the study group and 65.6% in the control group delivered vaginally ($p=0.65$). In the study group significantly less women developed spontaneous onset of labor (36.2% vs 66.7%; $p<0.001$). The time from preinduction to delivery onset and from preinduction to vaginal delivery were longer in the study group (780 min vs 489 min; 1682 min vs 920 min; $p<0.001$). The time of hospitalization after the delivery was significantly shorter in the study group (4.1 days vs 6.8; ($p<0.001$).

CONCLUSION: Both Foley catheter and dinoprostone seem to be equally effective in achieving vaginal delivery. In terms of time effectiveness Foley catheter preinduction is related to longer time from preinduction to delivery, nevertheless shorter time of hospitalization.

INTRODUCTION

Induction of labor is a common procedure in modern obstetrics. It is performed when the risk of continuing the pregnancy is higher than the risk related to the delivery. Nowadays up to 30% of all pregnancies are scheduled for labor induction due to medical indications (Barrilleaux *et al.* 2002; Pennell *et al.* 2009; Martin *et al.* 2012). It is well established that a cervix favorable for vaginal

delivery is the strongest positive predictive factor in the successful induction of labor (Sciscione *et al.* 1999). During the late third trimester of pregnancy there are several processes preparing the cervix for the delivery. The most important are cervical softening, effacement, anterior rotation and dilatation, which are the results of complex biochemical reactions, including collagen and glycosaminoglycan rearrangements and water content (Uldbjerg *et al.* 1983; Niromanesh *et al.* 2003; Carson 2014). When labor induction is indicated and cervix is unfavorable for the delivery, it is necessary to induce analogous changes in the cervix. In 1853 the use of the Foley catheter for the preinduction of labor was first described by Krause (Hamilton 1954). Nowadays there are two categories of artificial methods of cervical ripening: mechanical (like Foley catheter balloon and laminaria tents), and pharmacological (mostly prostaglandins) (Niromanesh *et al.* 2003). The efficacy of each method is well documented in the literature. As the induction of labor is widely used globally, there are two concerns facing modern obstetrics nowadays: achieving successful vaginal delivery in a reasonably short time and minimizing the risk of most frequent side effects or complications for both the mother and the neonate to avoid prolonged time of hospitalization after the delivery. Both concerns are closely related to the cost-effectiveness of obstetric procedures.

The aim of the presented study was to evaluate which of the two analyzed methods of preinduction: intra-cervical Foley catether and intracervical dinoprostone (PGE2) application, is related to higher rate of successful vaginal delivery in shorter time and also to shorter time of hospitalization after the delivery.

MATERIAL AND METHODS

A retrospective analysis of medical data of patients, hospitalized at the 1st Department of Obstetrics and Gynecology, Medical University of Warsaw, between 2008 and 2012 was conducted. In years 2008–2010 intracervical dinoprostone was the first-line method of labor preinduction in our Department. Since 2010 intracervical application of Foley catheter became the method of first choice in preinduction. No other medical procedures in labor induction were changed during the analyzed period. The study inclusion criteria were: term singleton pregnancy with cephalic presentation, no fetal anatomical abnormalities, intact membranes and unfavorable cervix. All analyzed patients were scheduled for labor induction due to medical indications. Unfavorable cervix for labor induction was defined as Bishop score ≤ 6. Women with vaginal bleeding, with a history of cesarean section or any other uterine scar, intrauterine fetal death, any contraindications for prostaglandin administration, allergy to latex or any contraindications for vaginal delivery were excluded from the study. The indications for labor induction included: post-term pregnancy (10 days or more), pregnancy complications (gestational diabetes and pregnancy induced hypertension at term, cholestasis of pregnancy, oligohydramnion and intrauterine growth restriction after completed 37 weeks of gestation).

The study group consisted of patients hospitalized between 2011 and 2012, in whom preinduction of labor was conducted with intracervical Foley catheter. The control group consisted of women hospitalized between 2008 and 2010, who were pre-induced with intracervical dinoprostone. All the pregnancies were dated according to the last menstrual period and verified by the crown-rump length measured in the first trimester. All the women had reassuring fetal heart trace during hospitalization and routine ultrasound scan performed, assessing fetal biometry. Foley catheter preinduction was conducted in 105 patients. It was inserted through the cervical canal and the balloon was filled with 70–80 ml of 0.9% NaCl above the internal os. After 24 hours the catheter was removed and subsequently labor induction was carried out, if spontaneous uterine contractions had not occurred earlier. In the control group 93 women had a single dose of dinoprostone in the form of a gel applied for labor preinduction (Prepidil gel 0.5 mg/3g; Pharmacia Corporation). The drug was inserted into the cervical canal after visualizing it in vaginal speculum. The application was followed by a 2-hour intensive cardiotocographic monitoring. If spontaneous regular uterine contractions or rupture of membranes did not occur, all patients were subsequently scheduled for labor induction, performed 24 hours after Foley catether/dinoprostone application. Routine labor induction was performed with intravenous infusion of oxytocin (5 units of oxytocin in 50 ml 0.9% NaCl with increasing flow from 1.2 ml/h to 6.8 ml/h every 20 minutes till regular uterine contractions occurred, then the adequate flow was provided) and amniotomy when regular uterine contractions were observed.

The efficacy of labor preinduction with both methods was evaluated. Further analysis of use of epidural analgesia during labor, hemoglobin levels after the delivery, loss of blood, newborns' general condition according to Apgar score in the first and fifth minute of life and the time of hospitalization after the delivery was performed.

Several preinduction and induction complications were defined. *Tachysystole* was diagnosed when there were at least 5 contractions during 10 minutes for at least 20 minutes; *hypertonus* – as a single contraction lasting over 2 minutes; *hyperstimulation* – the presence of tachysystole or hypertonus associated with an abnormal fetal heart rate pattern. Cervical dystocia was identified when there was no progress in cervical ripening within 4 hours , despite an adequate contraction pattern, after amniotomy, and a minimum of 4 hours of oxytocin infusion.

Statistical analysis was performed with Mann-Whitney U-test for continuous variables and chi-squared

test for categorical variables. A Kaplan-Meier curve was used to visualize time courses. Statistica 10.0 was used for statistical analyses. The *p*-values <0.05 were considered significant and all tests were two-tailed.

RESULTS

There were no significant differences regarding patients' age, body mass index (BMI), weight gain during the pregnancy, duration of pregnancy and parity between the groups. The characteristics of both analyzed groups are shown in table 1. All patients in both groups had unfavorable cervix described as below 6 points according to Bishop's scale.

Table 2 contains data characterizing the course of preinduction and induction of labor in both groups. 63.8% of women in the study group and 33.3% in the control group required labor induction with intravenous oxytocin and amniotomy (*p*<0.001). Almost half of patients, who spontaneously developed regular uterine contractions during the preinduction of labor, required oxytocin administration during the first or second stage of labor anyway (47.4% in the study group vs 43.6% in the control group; *p*=0.93). 68.6% of patients in the study group and 65.6% in the control group delivered vaginally (*p*=0.65).

Tab. 1. Maternal characteristics in both groups.

	study group n=105		control group n=93		*p*-value
	mean / %	±SD	mean / %	±SD	
age	30.4	3.9	29.8	4.1	0.3
BMI	28	4.1	28.3	4.2	0.68
weight gain	15.4	6.9	16	12.9	0.42
weeks of gestation	39.6	1.1	39.6	1.2	0.79
primiparity*	73		76		0.63
Bishop score	5.3	1.4	4.9	1.9	0.73

*- percentages
BMI – body mass index

In about one third of all cases indications for cesareans section during labor preinduction or induction appeared. The most common were fetal distress and cervical dystocia during the first or second stage of labor. There were no cases of tachysystole, hypertonus and hyperstimulation or uterine muscle rupture in both groups. Epidural anesthesia during labor was used with similar prevalence in both groups (52.4% in the study group and 42.4% in the control group; *p*=0.16). A non-significant difference in hemoglobin level after the delivery was observed between the groups (12 ±1.4 G/dL in the study group vs 11.5 ±3.2 G/dL in the control group; *p*=0.72). Blood loss during the parturition was equal in both groups (study group average 455 ±401 mL vs control group 454 ± 417 mL; *p*=0.93).

The Kaplan-Meier curves showing the percentage of patients who did not deliver in time in both groups are presented in Figure 1.

Newborns' general condition was assessed in the 1st and 5th minute of life according to Apgar scale (Table 3). Significantly more children were born in good general condition (Apgar score 8–10 points) in the study group (98.1% vs 89.2%, *p*=0.009). In the 5th minute all newborns in the study group and 98.9% in the control group were in good general condition.

The time of hospitalization after the delivery was significantly shorter in the study group and equaled 4.1 ± 3.2 days on average in comparison to 6.8 ± 5.2 in the control group (*p*<0.001).

DISCUSSION

In presented study the two different methods: mechanical and pharmacological were compared. According to presented results Foley catheter and dinoprostone were equally efficient in achieving vaginal labor. Over 60% of women in both analyzed groups delivered vaginally. The rate of natural labor is similar to reported in the literature. According to other authors the percentage of vaginal deliveries varies between 65–80% in both described methods (James *et al.* 1994; Sciscione *et al.* 1999; Niromanesh *et al.* 2003; Pennell *et al.* 1009;

Tab. 2. Preinduction and induction of labor.

	study group n=105		control group n=93		*p*-value
	mean / %	±SD	mean / %	±SD	
spontaneous onset of regular uterine contractions*	36.2		66.7		<0.001
time from the preinduction to the spontaneous onset of regular uterine contractions (min)	780	407	489	388	<0.001
spontaneous rupture of membranes *	35.9		53.8		0.012
time from the preinduction to the spontaneous rupture of membranes (min)	1260	863	685	417	0.039
time from the preinduction to vaginal delivery (min)	1682	2387	920	600	<0.001

*- percentages

Tab. 3. Newborns' general condition according to Apgar scale.

		study group %	control group %	*p*-value
1st minute Apgar points	8–10	98.1	89.2	
	4–7	1.9	8.6	0.009
	0–3	0	2.2	
5th minute Apgar points	8–10	100	98.9	
	4–7	0	1.1	0.94
	0–3	0	0	
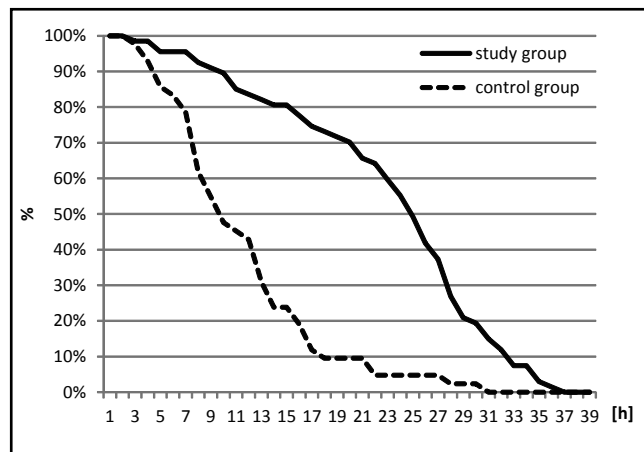
Fig. 1. The Kaplan-Meier curves showing the percentage of patients who did not deliver in time in both groups.

Mozurkewich *et al.* 2011; Jozwiak *et al.* 2012; Henry *et al.* 2013). Therefore, Foley catheter and dinoprostone are both preinduction methods of proven efficacy.

In moderns obstetrics the most important goal in labor induction is not only to deliver vaginally, but also to achieve it in the shortest possible time. The results of time effectiveness of Foley catheter and dinoprostone reported in the literature are different. According to Ghezzi there are no statistical differences in times from intervention onset to delivery, as well as to active phase of labor between Foley group and intravaginal PGE2 group (Ghezzi *et al.* 2001). Similar findings were also published by Henry (Henry *et al.* 2013). Several authors reported preinduction ripening time and total time from the start of preinduction to delivery to be shorter when Foley catheter was used (Thomas *et al.* 1986; Orhue 1995; Sciscione *et al.* 2001; Niromanesh *et al.* 2003; Moini *et al.* 2003; Edwards *et al.* 2014). On the other hand, there are publications proving that women preinduced with Foley catheter are more likely not to deliver within 24 hours (Yuen *et al.* 1996; Cromi *et al.* 2011; Sciscione *et al.* 2001; Mozurkewich *et al.* 2011; Jozwiak *et al.* 2012). In our study the time from preinduction to delivery was significantly shorter in the PGE2 group. The above mentioned differences reported in

the literature may be the consequence of different study protocols used by individual authors. Up till now there is no consensus on the time limitation for exposure to intracererivcal Foley catheter. St Onge reported the mean time of a balloon expulsion after cervical ripening to be about 10 hours (St Onge & Connors 1995). If the expulsion did not occur, most researchers removed the Foley catheter after an arbitrary time limit, which ranged from 6 to 24 hours. In our study if a patient did not develop a spontaneous active phase of labor, the balloon was also removed after 24 hours, in order that labor induction with oxytocin was performed identically in both groups. The proportion of women who deliver within 24 hours may be related to the time of Foley application.

In our study significantly more women in PGE2 group went into active phase of labor during preinduction (66.7% vs 36.2%). Both regular uterine contractions, as well as rupture of membranes occurred in more than half of patients when dinoprostone was used. Also the mean time from preinduction to spontaneous onset of labor was shorter in PGE2 group. These results are contrary to those published earlier by other authors. The rates of spontaneous delivery onset in the Foley preinduction group are similar to our finding (St Onge & Connors 1995; Dalui *et al.* 2005), but analogous rates in PGE2 preinduction reported in the literature are smaller. According to St Onge only 39% of women went into the active phase of labor spontaneously (St Onge & Connors 1995). Rates reported by other authors are even smaller: Atad *et al.* – 7%, Trofatter *et al.* – 37% and Dalui *et al.* – 8% (Trofatter *et al.* 1985; Atad *et al.* 1997; Dalui *et al.* 2005). The use of oxytocin for labor induction in the presented study resulted from the rate of patients, who did not develop regular uterine contractions during the preinduction. Therefore, it was much higher in the Foley group. As the labor begun, similar percentages of patients required oxytocin administration due to uterine contractions extenuation during the first or second stage of labor. A higher requirement of oxytocin when Foley catheter is used for labor preinduction was also reported in the literature (Jozwiak *et al.* 2012; Henry *et al.* 2013).

Presented results show a significantly higher rate of patients, who develop spontaneous regular uterine contractions during the preinduction with dinoprostone. That particular group also requires less oxytocin and achieve vaginal delivery in a significantly shorter time. Although patients in the Foley group delivered later (after 28 hours from preinduction onset on average), comparable rates of patients delivered vaginally in both groups. It seems that dinoprostone is faster in labor preinduction and induction, but finally both methods are equally effective.

Another time indicator, which should be taken into account, is the time of hospitalization. In the presented data hospitalization time from labor preinduction to discharge was significantly shorter in the Foley group.

Similar findings were also reported by Henry *et al.* (Henry *et al.* 2013).

In our study, perhaps due to the small number of patients included, there were no cases of tachysystole, hypertonus or hiperstimulation. The Cochrane meta-analysis, including 71 randomized trials (total 9722 women) proved that mechanical methods reduced the risk of hiperstimulation. Serious neonatal and maternal morbidity were rarely reported and did not differ between the groups of mechanical and PGE2 preinduction (Jozwiak *et al.* 2012). In the presented study, however, we observed better newborns' general condition according to 1st minute Apgar scale. According to Cochrane meta-analysis, PGE2 preinduction was associated with higher rates of fetal acidaemia in cord arterial blood collected after the delivery, with lower pH and pO2 values and higher pCO2 values compared to the mechanical methods (Jozwiak *et al.* 2012). The other problem mentioned in the literature, which may be related to Foley catheter preinduction, is the intra-uterine infection. A few studies addressed this issue and found this complication not to appear more often when mechanical agents were used for preinduction (Dalui *et al.* 2005; Jozwiak *et al.* 2012).

Both Foley catheter and dinoprostone seem to be equally effective in achieving vaginal delivery. In terms of time effectiveness, Foley catheter preinduction is related to a longer time from preinduction to delivery, but conversely shorter time of hospitalization. Since the average cost of Foley catheter preinduction is lower than dinoprostone, as are the expenses related to possible complications and hospitalization time, while the rates of cesarean section are comparable, with comparable cesarean section rates, but lower costs related to possible complications and hospitalization time, it seems that mechanical labor preinduction with Foley catheter is the most cost-effective method (van Baaren *et al.* 2013).

Conflict of interest: *None to declare*

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