

Research Article

Evaluation and Comparison of Efficacy and Safety of Foley Catheter with and without Traction in Preinduction of Labour

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Abstract

The aim of the study was to evaluate the efficacy and safety of labour preinduction rate with the use of the Foley catheter with and without traction. Main outcome measures were cesarean section and assisted labour rate, duration of preinduction, the time from intervention to birth, time of the first labour period

Methods: Two cervical ripening study arms were used: Foley catheter with traction (105 women) and Foley catheter without traction (92 women). The catheter was removed if it did not fall out spontaneously, when regular contractions appeared or on patient's request. Lack of spontaneous onset of labour was followed by induction of labour.

Results: The cesarean section rate was significantly higher in the Foley catheter without traction group (Foley catheter without traction 52% vs. 44% in the Foley catheter with traction group, $p < 0,05$), as well as assisted labour rate (12% vs. 3%, $p < 0,05$). The mean preinduction time (until the beginning of labour) with the Foley catheter alone lasted longer than the one with traction (795 min vs. 266 min, $p < 0,5$) but there was no significant difference in duration of labour. However mother's comfort was improved by shortening the time of preinduction.

Conclusions: Both Foley catheter with traction and without traction are useful methods of labour preinduction. However, Foley catheter with traction seems to be a safer method because of significantly shorter time of preinduction, lower cesarean section and assisted labour rates as well as higher efficacy in leading to labour without induction.

Keywords: Mechanical ripening, Unfavorable cervix, Preinduction of delivery

Introduction

Labour induction is an obstetric procedure used in up to 30% of all labours in Europe [1,2]. Most common indications for labour induction are: post-term pregnancy, fetal intrauterine growth restriction, maternal arterial hypertension and preeclampsia [3]. Therefore labours requiring induction are connected with significantly higher risk of complications and cesarean section. Successful induction depends mainly on maturity of cervix. Consequently, the preinduction - meaning the procedures aiming at acceleration of the cervix ripening - increases the chances of natural birth and good condition of both the mother and the newborn [3]. Maturity of the cervix is estimated with the Bishop score. Score smaller than 6 points indicates that the cervix is immature and requires preinduction [4,5].

Methods of preinduction can be divided into two groups: pharmacological and non-pharmacological. Foley catheter belongs to the non-pharmacological (mechanical) methods. Its main advantages are: higher chances for successful labour induction, low costs, easy storage and lack of disadvantages associated with application of prostaglandins (e.g. uterus hyper stimulation). At the same time

the efficacy is comparable to that in pharmacological methods [6]. Beside mechanical effects, Foley catheter triggers local prostaglandin production by pressing on the lower part of uterine [7].

Mechanical methods of preinduction include Foley catheter, Foley catheter with extra-amniotic saline infusion (EASI), two-balloon Atad catheter, hygroscopic dilators, membrane sweeping and stripping, amniotomy and others [6,8]. Up to now the Foley catheter has undergone many changes since Antoine Mattei first used a dilator filled with air [9]. To enhance the effectiveness of mechanical preinduction, 0,9% NaCl infusion into the extra amniotic space, traction, cyclical catheter pulling and additional weight at the end of the catheter have been introduced [10,11].

Pharmacological methods are also various e.g. prostaglandins, hyaluronidase, relaxin [12,13]. Ability to choose an optimal preinduction method could give the chance of increasing the number of successful labour inductions, shortening the time of preinduction and in that way improving the patient's comfort.

Methods

The study group consisted of 197 patients hospitalized in

Table 1: Maternal characteristics and parity.

	Foley catheter with a traction	Foley catheter without the traction	P
	N = 105	N = 92	
Average maternal age	27,4	30,0	< 0,05
Average gestational age	41	40,3	0,006
Patients with single pregnancy	100%	100%	
Nulliparous	N = 94	N = 73	0,077
	-89%	-79%	
Multiparous	N = 11	N = 19	
	-11%	-21%	

Table 2: Assessment of Foley catheter efficacy.

	Foley catheter with attraction	Foley catheter without traction	P
	N = 105	N = 92	
Average Bishop score before preinduction	3,3	3,6	<0,05
Average Bishop score after preinduction	6,7	7,4	<0,05
Average change in Bishop score	3,38	3,78	0,099
Average time of of preinduction (min)	266,0	795,0	<0,05
Dilatation >3 cm after preinduction	80,2%	74,7%	0,312
Time of first labour period (min)	370,0	327,0	0,157
Time of second labour period (min)	28,5	38	0,108
Total time of labour (min)	398,0	365,0	0,313
Spontaneous vaginal delivery	0.53	0.36	0,275
Cesarean section	0.44	0.52	<0,05
Assisted vaginal labour	0.03	0.12	<0,05

Perinatology Department between 2013-2014 in whom the preinduction procedure with use of Foley catheter has been introduced. All the patients were at term of birth and with unripened cervix (Bishop Score <5, cervical dilatation <3cm).

In group of 105 patients Foley catheter was inserted above the internal cervical os of cervix, filled with 40 ml of fluid and additionally weighted down with a 250 ml bag with saline water. Foley catheter without traction was used in group of 92 patients. If the catheter did not fall out spontaneously, it was pulled out when regular contractions appeared, usually the next day after insertion or on patient's request. If spontaneous onset of labour has not appeared, induction of labour was performed. In all the patients CTG had been done during the preinduction period to evaluate the state of the foetus. During the preinduction the patients were advised to walk as much as possible. In case of discomfort or pain the women could sit or lie down. A change of body position enabled to regulate the pressure on the cervix, relieving the pain, especially in patients with weighted down Foley catheter.

The obtained results were statistically analysed with t-Student and U Mann-Whitney test. As statistically valid we considered the correlations with $p < 0,05$.

Results

Overall 197 women with single pregnancy took part in our study (92 in no-traction group, 105 in Foley catheter with traction group).

Most of them were nulliparous (N=167). Table 1 shows maternal characteristics of group preinducted with Foley catheter with traction and without the traction.

The cervical maturity was assessed with a cervical dilatation and Bishop Score (including such elements as: consistency, position, effacement, dilation, fetal head station). There was no significant difference in Bishop score before preinduction in both groups (3,38 in traction group vs. 3,78 in no-traction group, $p=0,1$) (Table 2).

Foley catheter was spontaneously expelled more often in Foley catheter with traction group (83,8% vs. 9,89%, $p < 0,05$). Patients with Foley catheter with traction were the ones who asked for its removal more often than patients from the other group (16,2% vs. 3,29%) due to painful contractions.

In 38% of patients with Foley catheter with traction vs. 15% of Foley catheter without traction ($p < 0,05$) preinduction led directly to labour and no induction was required.

The preinduction with the Foley catheter alone lasted much longer than the one with traction (795min vs. 266min). On the other hand, there was no significant difference in duration of the whole labour as well as the first period and the second period of labour (Table 2).

In total 52% of women with Foley catheter without traction required cesarean section compared to 44% in the group of women with Foley catheter with traction ($p < 0,05$).

Table 3: Neonatal outcomes.

	Foley catheter with traction	Foley catheter without a traction	P
	N = 105	N = 92	
Meconium stained amniotic fluid	0.15	0.13	0,978
Average birth weight (g)	3482	3475	0,911
Apgar score >8 points	93,5%	92,9%	

Table 3 presents neonatal outcomes such as percentage of meconium-stained amniotic fluid, newborn birth weight and Apgar score which were all higher in Foley catheter with traction group.

Discussion

Efficacy

As induction of labour is becoming more and more common procedure in obstetrics (up to now it is carried out in 30% of pregnancies) an optimal method of this procedure has to be found [14,15]. A successful induction depends mostly on maturity of cervix [16]. An unfavourable cervix, which is closed, firm and difficult to distend, increases the risk of failure of induction, longer duration of labour and higher risk of caesarean section [17]. According to Steiner and Creasy the best way to achieve the cervix maturity is to cause biochemical changes as similar to natural ones as possible [18]. The perfect method should be effective, safe, easy in use, cheap and acceptable for the patient at the same time [6].

The aim of our study was to estimate and compare the efficacy and safety of labour preinduction using two methods: a single balloon Foley catheter with and without traction of 250 ml. Most studies compared Foley catheter without traction with PGE2 gel [11,17,19,20,21,22] and only few studies focused on comparison of Foley catheter alone and with traction [23].

In our study an unfavourable cervix is the most common indication of preinduction. In the research conducted by Patro-Malysza post-term pregnancy (47,7%) and lowered fetus biochemical profile (78,9%) were two most common causes. Most of the patients had more than one indication [6]. Study of Jagielska and colleagues brought similar conclusions concerning indications for preinduction/induction procedure: post-term pregnancy (55,05%), hypertension and preeclampsia (16,51%), decreased amniotic fluid volume (12,84%), gestational cholestasis (10,09%), IUGR (5,51%) [3].

Most published studies report Bishop Score, cervical length in USG and cervical dilatation as predictors of the cervix maturity. Some authors [24,25] point out that both cervical length and Bishop Score are reliable predictors determining success of induction. Consequently, in our study we focused on Bishop Score. In our data both methods proved to be effective in increasing the Bishop score (change from 3,32 to 6, and 72 in Foley without traction vs. 3, 62 to 7, 39 in Foley with traction). What is more, there was a significant difference in average change of Bishop Score (3,38 vs. 3,78, $p > 0,05$). Study conducted by Gibson gave similar results [23]. In other research in which only Foley catheter without traction was considered, for example in Patro-Malysza study the change of Bishop score was from 3,29 to 6,85 [6] that is similar to our results.

Performing preinduction with use of Foley catheter follows many different protocols and schemes depending on the study and the

clinical center where it takes place [26].

This may lead to different results and conclusions what we observe in our study. One of the most significant outcomes of our study was the difference in duration of preinduction between the groups (13h 15 min in no-traction vs. 4h 26min in Foley with traction group). In Patro-Malysza research total time of preinduction with no-traction Foley catheter was 15h 35min, whereas in Pettker's it was 10h 24min and in Anthony C. Scisione's - 9h 54 min [6,27]. As mentioned before, such differences may originate in different preinduction schemes and preparation of cervix before pre-induction.

Another analysed factor was time between catheter expulsion and beginning of labour. In our research the results were as following: 23 h 9 min. for Foley catheter without traction vs 18 h 14 min. for Foley catheter with traction. We compared the data with the results obtained by Patro-Malysza and colleagues: 8 h 27 min \pm 4 h 10min (Foley without traction) [26].

Safety

The secondary outcome of our study was the assessment of safety of both preinduction methods: Foley catheter with and without a traction. We can consider this issue dually: first – the safety of mother and the safety of newborn.

The safety of the mother is mainly conditioned by the risk of cesarean section. In our study 52% of women with Foley catheter without traction required cesarean section compared to 44% in the group of women with Foley catheter with traction ($p < 0,05$). The risk of cesarean section considerably increases if induction has to be performed, at least in nulliparous women [8]. In 38% of patients with Foley catheter with traction and 15% of Foley catheter without traction preinduction led directly to labour and no induction was required.

Maternal or neonatal infection is also a predictor of particular methods' safety. However, it has not been proved that Foley catheter increases the risk of infection at all [18,19]. That is the reason why in our study we did not assess any indicators of infections e.g. temperature $> 38^{\circ}\text{C}$, tachycardia > 120 bpm, leukocytosis $> 16,000$ WBC/mL, mandated administration of intravenous antibiotics, vaginal swab colonization, like it was done in another series [8]. So we cannot assume that the longer Foley catheter placement in cervix (13h 15 min no-traction vs. 4h 26 min with traction), the greater was risk of infection.

Neonatal outcomes did not reveal significant differences in safety of the newborns. In our research 92,9% of newborns in no-traction group and 93,5% of newborns in traction group achieved Apgar score above 8 points. Whereas in the analysis done by Jagielska and colleagues the average Apgar score was 9,5, by Patro-Malysza (2011)-consequently 9,48 assessed in the third and 9,6 in the fifth minute

[3,6]. Another parameter describing the newborns' state – the arterial and venous pH- 7,25 (Foley with traction) vs 7,24 in our groups vs. 7,3 in Jagielska's research [3]. Meconium –stained amniotic fluid occurred in 15% (Foley with traction) and in 13% (Foley without traction) of newborns. In Patro-Malysza (2010) clear waters were present in 89,6% of all patients [26]. Newborns' weight (3475, 06 g no-traction vs. 3482, 21 g with traction) was comparable to other results in Polish population (3454 g - Patro-Malysza 2011) [6].

Comfort

The patients' comfort was also taken under consideration in the study. In the traction group not only the preinduction time was shorter, but the catheter was expelled spontaneously in 83,8% of patients (vs. 9,89% in no-traction group). However, the catheter was removed on patient's wish due to pain and discomfort in 16,2% cases – comparably, only 3,29% in no-traction group asked for catheter removal. In study of Jagielska and colleagues, where only no-traction Foley was used, the rate was 10,09% [3].

Conclusions

Both Foley catheter with traction and Foley catheter without traction are useful methods of labour preinduction. However, Foley catheter with traction seems to be a safer method because of significantly shorter time of preinduction, lower cesarean section rate and assisted delivery rate as well as higher efficacy leading to labour without induction.

References

- EURO-PERISTAT Project. European Perinatal Health report 2010.
- Centre THaSCI. NHS maternity statistics, England: 2012-13 – the health and social care information centre 2013.
- Jagielska I, Kazdepka-Ziemińska A, Janicki R, et al. Evaluation of the efficacy and safety of Foley catheter pre-induction of labor. *Ginekol. Pol.* 2013 ; 84: 180-185.
- Oleszczuk J, Leszczyńska-Gorzela B, Poniedziałek-Czajkowska E, Indukcja porodu [W]: Rekomendacje postępowania w najczęstszych powikłaniach ciąży i porodu. 2006. Wydanie II. D. Bifolium, Lublin
- Poniedziałek-Czajkowska E, Leszczyńska-Gorzela B, Oleszczuk J, Indukcja porodu. *Klin. Perin. i Gin.* 2005; 41: 35-40.
- Patro-Malysza J, Leszczyńska-Gorzela B, Marciniak B, Zastosowanie cewnika Foleya do preindukcji porodu *Perinatologia, Neonatologia i Ginekologia*, tom 4, zeszyt, 143-148, 2011
- Leduc D, Biringer A, Lee L, Dy J, Induction of Labour, Society of Obstetricians and Gynaecologists of Canada Clinical Practice Guideline No. 296, 2013. *J Obstet Gynaecol Can.* 2013; 35: 840-857.
- Maslovitz S, Lessing JB, Many A, Complications of trans-cervical Foley catheter for labor induction among 1,083 women, *Arch. Gynecol. Obstet.* 2010; 281: 473-477.
- Mattei A, Essai sur l'accouchement physiologique. Paris, France: Victor Masson 1855.
- Sherman DJ, Frenkel E, Tovbin J, Ripening of the unfavorable cervix with extraamniotic catheter balloon: clinical experience and review, *Obstet. Gynecol. Surv.* 1996; 51: 621-627.
- Baczyńska M, Kazmierak W, Skoczylas M. Porównanie skuteczności preindukcji porodu za pomocą cewnika Foleya z obciążeniem z preindukcją przy użyciu żelu z PGE2, *Perinatologia, Neonatologia i Ginekologia.* 2013; 6: 34-39.
- Jagani N, Schulman H, Fleischer A. Role of the cervix in the induction of labour, *Obstet. Gynecol.* 1982; 59: 21-26.
- Surita F, Cecatti J, Parpinelli M. Hyaluronidase versus Foley catheter for cervical ripening in high-risk term and post term pregnancies. *Int. J. Gynaecol. Obstet.* 2005; 88: 258-264.
- Laws PJ, Sullivan EA, Australia's Mothers and Babies 2002. AIHW Cat. No. PER 28. Sydney: AIHW National Perinatal Statistics Unit (Perinatal Statistics Series No. 15) 2004.
- National Collaborating Centre for Women's and Children's Health, Induction of labour. London, UK: RCOG Press 2008.
- Cocks DP, Significance of initial condition of cervix uteri to subsequent course of labour, *Br. Med. J.* 1955, 1:327-328.
- Pennell CE, Henderson JJ, O'Neill MJ, Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel, *BJOG.* 2009; 116: 1443-1452.
- Cromi A, Ghezzi F, Tomera S, Cervical ripening with the Foley catheter, *Int. J. Gynecol. Obstet.* 2007; 97: 105-109.
- Jozwiak M, Oude Rengerink K, Benthem M, Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. *Lancet* 2011; 378: 2095-2103.
- Jozwiak M, Oude Rengerink K, Ten Eikelder ML, Foley catheter or prostaglandin E2 inserts for induction of labour at term: an open-label randomized controlled trial (PROBAAT-P trial) and systematic review of literature. *Eur. J. Obstet. Gynecol. Reprod. Biol.* 2013
- Sciscione AC, McCullough H, Manley JS, A prospective, randomized comparison of Foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. *Am. J. Obstet. Gynecol.* 1999; 180: 55-60.
- Dalui R, Suri V, Ray P. Comparison of extraamniotic Foley catheter and intracervical prostaglandin E gel for preinduction cervical ripening, *Acta Obstet. Gynecol. Scand.* 2005; 84: 362-367.
- Gibson KS, Mercer BM, Louis JM, Inner thigh taping vs. traction for cervical ripening with a Foley catheter: a randomized controlled trial, *Am. J. Obstet. Gynecol.* 2013; 209: 272.
- Tan PC, Vallikkannu N, Suguna S, Transvaginal sonographic measurement of cervical length vs. Bishop score in labor induction at term: tolerability and prediction of Cesarean delivery. *Ultrasound Obstet Gynecol.* 2007; 29: 568-73.
- Stupar ZT, Mikić AN, Bogovac M, Prediction of labour induction outcome using different clinical parameters. *Srp. Arh. Celok. Lek.* 2013; 141:770-774.
- Patro-Malysza J, Marciniak B, Leszczyńska-Gorzela B, Effectiveness of intracervical catheter as a labor preinduction method. *Ginekol. Pol.* 2010; 81: 31-36.
- Pettker CM, Pocock SB, Smok DP. Transcervical Foley catheter with and without oxytocin for cervical ripening. A randomized controlled trial. *Obstet. Gynecol.* 2008. 111:1320-1326.