



## Effectiveness assessment of labor preinduction using a Foley catheter in patients with unripe cervixes

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### ABSTRACT

*Aim. The purpose of the study is to assess the effectiveness of labor preinduction using a Foley catheter in patients with unripe cervixes.*

*Methods. The study was based on the analysis of medical records of patients who underwent labor in the Maternity Ward of St. John of God Autonomous Public Provincial Hospital in Lublin (Poland). The course of labor was analyzed in 176 patients who had undergone Foley catheter labor preinduction.*

*Results. Mean increase in Bishop score –  $3.85 \pm 1.62$ ; mean increase in dilation –  $1.06 \pm 0.54$ ; mean change in effacement –  $0.82 \pm 0.52$ . The mean time between catheter removal and delivery was 6 hours 6 minutes.*

*Conclusion. Differences in values before and after preinduction are observed across all the components of the Bishop score. Using a Foley catheter in labor preinduction allows for a vaginal delivery, and does not increase the rate of cesarean sections or perinatal complications.*

### KEYWORDS :

#### INTRODUCTION

Ensuring safe delivery in women requiring labor induction presents a significant challenge in modern obstetric practice. The decision to induce labor should be taken with consideration, after a careful analysis of all the potential benefits and risks for the mother and the child resulting from the procedure [1,2]. The most common indications for labor induction include: post-term gestation, preeclampsia, IUGR and arterial hypertension [3,4,5]. The condition of the cervix before labor is a major factor influencing the success rate of elective labor induction [3,6].

An unripe cervix near term increases the risk of failed inductions and perinatal complications, as well as the percentage of deliveries by cesarean section. In such cases labor induction should be preceded by preinduction [5]. Currently, several perinatal cervical ripening methods are known. Pharmacological methods include the use of prostaglandins, oxytocin; mechanical methods include Foley catheter insertion, hygroscopic dilators [5,7-9].

An optimal cervical ripening method should induce changes in the cervix in a way that resembles, as closely as possible, the natural processes preceding labor. The method should not cause adverse side effects in the mother or the fetus, such as hyperstimulation of uterine contractions or disruption to fetomaternal circulation, nor should it endanger future pregnancies [3,7,9].

Women are qualified for labor preinduction based on an internal examination of the cervix using the Bishop score. Foley catheter labor preinduction acts through a complex and multidimensional mechanism. A saline-filled balloon constitutes the presenting part that presses against the internal orifice of the cervix and mechanically enhances dilation. A neuroendocrine reflex in the stimulated cervix causes a release of endogenous oxytocin. The stimulation also causes

reactions resulting in a release of endogenous prostaglandins [1,10]. The technique is recommended when the cervix is unripe, with a Bishop score lower than 6 [2,3,5].

The purpose of the study is to assess the effectiveness of labor preinduction using a Foley catheter in patients with unripe cervixes.

#### METHODS

The study was based on the analysis of medical records of patients who underwent labor in the Maternity Ward of St. John of God Autonomous Public Provincial Hospital in Lublin (Poland) between January 1 and July 1, 2011. The study used a diagnostic survey and an analysis of medical records. The course of labor was analyzed in 176 patients who had undergone Foley catheter labor preinduction. Preinduction was performed in patients with Bishop scores lower than 6. Inclusion criteria for the study were: a live, single fetus in cephalic presentation and an intact amniotic sac.

Analyzed data included: parity, gestational age, and cervical ripeness (Bishop score) before the insertion of the catheter and after its removal. Statistical analysis was performed for intervals between: catheter insertion and removal or expulsion; catheter insertion and delivery; induction and delivery; rupture of membranes and delivery. Other analyzed data included: the mode of delivery, indications for cesarean section, and the condition of the newborn.

Statistical analysis was performed for all outcomes. Differences or correlations of  $p < 0.05$  were considered statistically significant.

#### RESULTS

In the study time frame, 1172 labors were managed in the Maternity Ward of St. John of God Autonomous Public Provincial Hospital in Lublin. In 178 cases (15.18% of the total) labor preinduction was per-

formed. 2 of the preinduced patients were excluded from the study, as membranes were ruptured during catheter insertion.

Table 1. presents the characteristics of the 176 subjects, with the majority of women classified as: 26-30 years old (33.5%) or 21-25 years old (33.0%), resident in urban areas (61.4%), at 40 weeks of gestation (58.5%), and nulliparous (69.3%).

**Table 1. Participants' characteristics**

Information on the respondents		n	%
Age	< 20 y/o	12	6.8
	21-25 y/o	58	33.0
	26-30 y/o	59	33.5
	31-35 y/o	27	15.3
	> 30 y/o	20	11.4
Residence	urban	108	61.4
	rural	68	38.6
Gestational age	< 39 weeks	21	11.9
	39 weeks	18	10.2
	40 weeks	103	58.5
	41 weeks	31	17.6
	> 41 weeks	3	1.7
Parity	nulliparous	122	69.3
	primiparous	46	26.1
	multiparous	8	4.5

The most common indications for preinduction were: a low fetal biophysical profile score (79.0%), arterial hypertension and preeclampsia (27.8%), and post-term gestation (19.3%). In 10 cases (5.7%) preinduction was performed because of intrauterine growth restriction, and in 8 cases (4.5%) because of abnormal CTG readings. Most patients had multiple indications for labor preinduction.

Table 2. summarizes the analysis of cervical examination results before the insertion of the catheter and after its removal. Significant changes were found in each score component before and after preinduction, which contributed to an overall change in the total Bishop score. The difference in the total Bishop scores for cervical ripeness in the cervical examinations before and after catheterization was 3.85 points (see Table 2).

**Table 2. Bishop scores before and after Foley catheterization**

Parameter	Before catheter insertion	After catheter removal
Dilation	0.78 ± 0.48	1.84 ± 0.63*
Effacement	0.85 ± 0.5	1.67 ± 0.52*
Fetal station	0.87 ± 0.45	1.22 ± 0.49*
Consistency	0.46 ± 0.58	1.13 ± 0.56*
Position	0.51 ± 0.46	1.48 ± 0.52*
Total	3.47 ± 1.23	7.32 ± 1.75*

\* p < 0.00001

Mean increase in Bishop score – 3.85 ± 1.62; mean increase in dilation – 1.06 ± 0.54 ; mean change in effacement – 0.82 ± 0.52.

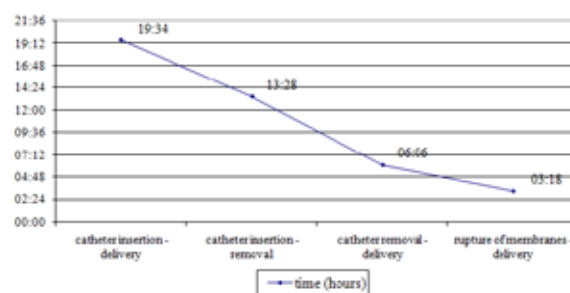
Upon removal of the Foley catheter, labor was induced by administering oxytocin in 152 patients (86.4%). The remaining 24 patients (13.6%) were not administered oxytocin, as spontaneous uterine contractions occurred.

In the next stage of the study the data were analyzed in terms of the mode of delivery: vaginal or cesarean. A significant majority, 123 patients (69.9%), had a vaginal delivery. The remaining patients

(30.1%) underwent cesarean section. Among patients requiring a cesarean section, a significant majority were nulliparous (86.8%); only 7 (13.2%) of those unable to deliver vaginally were parous (p<0.00000). The most common indications for cesarean section were: failure to progress in labor – 40 cases (75.5%) and imminent intrauterine asphyxia – 23 cases (43.4%). In six cases (11.3%) asynclitic presentation of the fetus was found, and in two (3.8%) there was cervical dystocia.

The mean time from catheterization to delivery was 19 hours 34 minutes, with a mean preinduction time of 13 hours 28 minutes. The mean time between catheter removal and delivery was 6 hours 6 minutes. The time between the rupture of membranes and delivery was also calculated, with a mean of 3 hours 18 minutes (see Figure 1).

**Figure 1. Labor preinduction results**



The condition of the newborn was evaluated using the Apgar score at 1, 3 and 5 minutes. All scores were between 9 and 10.

The wellbeing of patients after Foley catheterization was assessed by means of obstetric observation. The vast majority of patients (86.4%) tolerated the cervical ripening procedure well. Several patients (5.1%) reported lower abdominal pain and spot bleeding that subsided following water immersion.

The analysis of the patients' medical records showed fever in just two patients (1.1%), reaching 38.2 and 38.6 °C, in the early postpartum period.

During the Foley catheter labor preinduction, complications occurred in 2 patients, with the amniotic sac rupturing upon catheter insertion.

**DISCUSSION**

Labor induction is one of the most common interventions in pregnant patients. In the last decade the percentage of induced labors has doubled, reaching 20-30% [5,11]. Ongoing research is devoted to finding a safe, effective and simple procedure that would be acceptable to patients and to medical personnel, as well as economically reasonable [2,12].

In recent years, many papers were published that compared the effectiveness and safety of different labor preinduction methods, including Foley catheter insertion. The factors analyzed included the following: changes resulting from the use of a given method, time from preinduction to delivery, the mode of delivery, the condition of the newborn and any complications during labor preinduction and induction [2,9,13-15].

The purpose of the study was to assess the effectiveness of Foley catheterization as a labor preinduction method. The inclusion criteria used yielded a very heterogeneous study group in terms of patient age, residence, gestational age, parity, comorbidities (or lack thereof), and indications for preinduction. Foley catheter insertion was the labor preinduction technique chosen for all patients. The most common indication in the group was a low biophysical profile score (Manning score). Other indications for preinduction included: post-term gestation, arterial hypertension and preeclampsia, IUGR and comorbidities. This is in line with reports by other researchers, naming post-term gestation and arterial hypertension as indications for preinduction [13,14,16].

An analysis of the course of preinduction indicates that the insertion

of a Foley catheter and filling it with saline significantly increases cervical ripeness. A change was observed in all the components of the Bishop score. An examination performed after the removal or spontaneous expulsion of the catheter showed a significant change in the total Bishop score, with a mean difference of 3.85 points ( $p < 0.00001$ ). The most significant changes were observed in cervical dilation and effacement ( $p < 0.00001$ ). The significant change observed in the cervical examination was similar to results reported in other studies [2,14,15,17,20]. Moreover, studies comparing the effectiveness of Foley catheterization and prostaglandin administration as preinduction methods reported that cervical ripening was faster in the Foley group than in the prostaglandin group [13,18,19]. Similar results were reported by Sciscione et al (2004) [10]. In their conclusions, the authors state that Foley catheter insertion is the superior method, resulting in a shorter preinduction-to-delivery time, lower cesarean section rates, and fewer complications and side effects compared to the use of prostaglandins. They also emphasize that if no spontaneous uterine contractions occur after preinduction, labor induction with oxytocin can be started directly following catheter removal. In the case of prostaglandin administration, induction can only be started 6 hours after the last dose (in compliance with ACOG guidelines). The author admits this may be the reason for the longer preinduction-to-delivery time in this group [10,18].

The enhanced cervical ripening undoubtedly contributed to higher success rates and shorter times of labor inductions. In the group studied, the mean induction-to-delivery time was 6 hours 6 minutes. Similar results were reported by Owolabi et al (2005) and Lin et al (2007) [8,20]. In the group studied, the mean preinduction-to-delivery time was 19 hours 34 minutes. In comparable studies, delivery occurred on average in less than 24 hours [1,2,16].

An important issue is whether catheter preinduction (mechanical dilation) could adversely affect the condition of the cervix and its function in future pregnancies. Sciscione et al (2004) proved that the use of a Foley catheter does not increase the risk of pre-term delivery in subsequent pregnancies [10]. Many comparable studies assessing the effectiveness of various labor preinduction techniques report that the cesarean section rate after Foley catheter preinduction is similar or even lower than with other methods, such as prostaglandin or oxytocin administration [8,9,10,14]. The present study seems to confirm these reports. Following preinduction, 123 patients (70.0%) had a vaginal delivery, and 53 patients (30.0%) had a cesarean section. It is likely that some of the indications for labor induction, e.g. a low biophysical profile score or arterial hypertension, could have resulted in

complications during induction and a surgical delivery. The majority of cesarean sections were performed on nulliparous patients (86.8%); only 7 (13.2%) of those requiring surgical delivery were parous. This observation is reinforced by the literature, indicating that the risk of failed labor inductions is the highest in nulliparae [2].

Furthermore, the results of neonatal examinations show that the Foley catheter preinduction technique is safe for the fetus and the newborn. All newborns in the study had Apgar scores of 9 or 10, with similar outcomes reported by Niromanesh et al (2003), Owolabi et al (2005), Cromi et al (2007) and Prager et al (2008) [1,8,14,19]. The results are particularly meaningful since the study included high-risk pregnancy patients (with hypertension, diabetes mellitus, cholestasis, IUGR).

Increased risk of infections is a common argument against Foley catheter labor preinduction. In the present study, fever in the early postpartum period (38.2-38.6°C) that required the administration of antibiotics was observed in just 2 patients (1.1%); both patients delivered by cesarean section). A study by Maslovitz reported complications in 7.6% of the patients studied; however, this was a study of catheterization with extra-amniotic saline infusion (EASI), which may have increased the complication rate [21]. Dalui et al (2005) assessed the influence of catheter insertion and PGE2 on the vaginal microflora in preinduced patients, and confirmed that the use of a Foley catheter does not produce significant changes in the flora [13]. Similar results were reported in other studies, which confirms the safety of this labor preinduction technique [12,15,20,22,23].

Foley catheter insertion is a simple procedure that does not require specialized equipment or patient preparation; an additional advantage being its cost-effectiveness [7,9,13,17,24].

The present study confirms the effectiveness and safety of the labor preinduction technique used.

## CONCLUSIONS

Foley catheter insertion accelerates cervical ripening.

Differences in values before and after preinduction are observed across all the components of the Bishop score.

Using a Foley catheter in labor preinduction allows for a vaginal delivery, and does not increase the rate of cesarean sections or perinatal complications.

## REFERENCES

- Prager, M., Eneroth-Grimfors, E., Edlund, M. & Marions, L. (2008). A randomised controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labour induction. *BJOG-An International Journal Of Obstetrics And Gynaecology*, 115, 1443-1450. | 2. Patro-Malysza, J., Marciniak, B., Leszczyńska-Gorzalek, B., Bartosiewicz, J. & Oleszczuk, J. (2010). Effectiveness of intracervical catheter as a labor preinduction method. *Ginekologia Polska*, 81, 31-36. | 3. Bueno, B., San-Frutos, L., Salazar, F., Pérez-Medina, T., Engels, V., Archilla, B., Izquierdo, F. & Bajo J. (2005). Variables that predict the success of labor induction. *ACTA Obstetrica et Gynecologica Scandinavica*, 84, 1093-1097. | 4. Jagielska, I., Kazdepka-Ziemińska, A., Janicki, R., Formaniak, J., Walentowicz-Sadlecka, M. & Grabiec, M. (2013). Evaluation of the efficacy and safety of Foley catheter pre-induction of labor. *Ginekologia Polska*, 84, 180-185. | 5. Ten Eikelder, M.L., Neervoort, F., Oude Rengerink K., van Baaren, G.J., Jozwiak, M., de Leeuw, J.W., de Graaf, I., van Pampus, M.G., Franssen, M., Oudijk, M., van der Salm, P., Woiski, M., Pernet, P.J., Feitsma, A.H., van Vliet, H., Porath, M., Roumen, F., van Beek, E., Versendaal, H., Heres, M., Mol, B.W. & Bloemenkamp K.W. (2013). Induction of labour with a Foley catheter or oral misoprostol at term: the PROBAAT-II study, a multicentre randomised controlled trial. *BMC Pregnancy and Childbirth*, 13, 67. | 6. Sieroszewski, P. & Banach, R. (2010). Comparison of the predictive value of digital examination (Bishop's score) and ultrasound evaluation for labor induction success. *Ginekologia Polska*, 81, 105-110. | 7. Gelbert, S. & Sciscione, A. (2006). Mechanical methods of cervical ripening and labor induction. *Clinical Obstetrics and Gynecology*, 49, 642-657. | 8. Owolabi, A.T., Kuti, O. & Ogunlola, I.O. (2005). Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labor. *Journal of Obstetrics and Gynaecology*, 25, 565-568. | 9. Ziyauddin, F., Hakim, S. & Berawal, S. (2013). The transcervical Foley catheter versus the vaginal prostaglandin E2 gel in the induction of labour in a previous one caesarean section – a clinical study. *Journal of Clinical and Diagnostic Research*, 7, 140-143. | 10. Sciscione, A.C., Larkin, M., O'Shea, A., Pollock, M., Hoffman, M. & Colmorgen G. (2004). Preinduction cervical ripening with the Foley catheter and the risk of subsequent preterm birth. *American Journal of Obstetrics and Gynecology*, 190, 751-754. | 11. Jozwiak, M. & Dodd J.M. (2013). Methods of term labour induction for women with a previous caesarean section. *Cochrane Database of Systematic Reviews*, 28, 3: CD009792. | 12. Henry, A., Madan, A., Reid, R., Tracy, S.K., Austin, K., Welsh, A. & Challis D. (2013). Outpatient Foley catheter versus inpatient prostaglandin E2 gel for induction of labour: a randomised trial. *BMC Pregnancy and Childbirth*, 13, 25. | 13. Dalui, R., Suri, V., Ray, P. & Gupta I. (2005). Comparison of extraamniotic Foley catheter and intracervical prostaglandin E gel for preinduction cervical ripening. *ACTA Obstetrica et Gynecologica Scandinavica*, 84, 362-367. | 14. Cromi, A., Ghezzi, F., Tomera, S., Uccella, S., Lischetti, B. & Bolis, P.F. (2007). Cervical ripening with the Foley catheter. *International Journal of Gynaecology and Obstetrics*, 97, 105-109. | 15. Pettker, C.M., Pocock, S.B., Smok, D.P., Lee, S.M. & Devine, P.C. (2008). Transcervical Foley catheter with and without oxytocin for cervical ripening: a randomized controlled trial. *Obstetrics and Gynecology*, 111, 1320-1326. | 16. Levy, R., Kanengiser, B., Furman, B., Ben Arie, A., Brown, D. & Hagay, Z.J. (2004). A randomized trial comparing 30-ml and 80-ml Foley catheter balloon for preinduction cervical ripening. *American Journal of Obstetrics and Gynecology*, 191, 1632-1636. | 17. Surtita, F.G., Cecatti, J.G., Parpinelli, M.A., Krupa, F., Pinto, E. & Silva, J.L. (2005). Hyaluronidase versus Foley catheter for cervical ripening in high-risk term and post term pregnancies. *International Journal of Gynaecology and Obstetrics*, 88, 258-264. | 18. Adeniji, O., Olayemi, O., & Odukogbe, A. (2006). Intravaginal misoprostol versus transcervical Foley catheter in pre-induction cervical ripening. *International Journal of Gynaecology and Obstetrics*, 92, 130-132. | 19. Niromanesh, S., Mosavi-Jarrahi, A. & Samkhaniani, F. (2003). Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. *International Journal of Gynaecology and Obstetrics*, 81, 23-27. | 20. Lin, M.G., Reid, K.J., Treaster, M.R., Nuthalapaty, F.S., Ramsey, P.S. & Lu, G.C. (2007). Transcervical Foley catheter with and without extraamniotic saline infusion for labor induction. *Obstetrics and Gynecology*, 110, 558-565. | 21. Maslovitz, S., Lessing, J.B. & Many, A. (2010). Complications of trans-cervical Foley catheter for labor induction among 1083 women. *Archives of Gynecology and Obstetrics*, 281, 473-477. | 22. Heinemann, J., Gillen, G., Sanchez-Ramos, L. & Kaunitz, A.M. (2008). Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review. *American Journal of Obstetrics and Gynecology*, 199, 177-187. | 23. Mealing, N.M., Roberts, C.L., Ford, J.B., Simpson, J.M. & Morris, J.M. (2009). Trends in induction of labour, 1998-2007: a population – based study. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 49, 599-605. | 24. Chung, J.H., Huang, W.H., Rumney, P.J., Garite, T.J. & Nageotte, M.P. (2003). A prospective randomized trial that compared misoprostol Foley catheter, and a combination misoprostol-Foley catheter for labor-induction. *American Journal of Obstetrics and Gynecology*, 189, 1031-1035. |