### **PRACE ORYGINALNE** położnictwo

## Risk factors for cesarean section after using the Foley catheter for labor induction

# Czynniki ryzyka porodu cięciem cesarskim po indukcji porodu cewnikiem Foley'a

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#### Abstract

**Objective:** The aim of the study was to investigate the value of the Bishop score and ultrasound examination of the cervix in predicting the success of labor induction with the use of the Foley catheter determined by the mode of delivery.

**Material and methods:** Foley catheter induction of labor was performed in 135 pregnancies between 38 to 42 weeks gestation. The study group was divided into two groups, depending of the mode of delivery: vaginal vs. cesarean.

**Results:** The Bishop score was significantly higher in the vaginal delivery group when compared to the caesarean section group (5.2; 95%CI: 4.4 – 6.2 vs. 3.9; 95%CI: 2.8-4.9). Cervical length was not statistically significantly different between the two groups. Multivariate logistic regression showed that patient-specific risk for caesarean section decreases with increasing maternal age and the Bishop score (Detection Rate [DR] of 52% at fixed False Positive Rate [FPR] of 10%).

**Conclusions:** Failure of labor induction with the use of the Foley catheter can be predicted by maternal age and pre-induction Bishop score.

#### Key words: Foley catheter induction / induction of labor / cervical ripening /

#### Streszczenie

**Cel pracy:** Celem pracy była ocena przydatności skali Bishopa oraz pomiaru ultrasonograficznego długości szyjki macicy przy szacowaniu skuteczności indukcji porodu cewnikiem Foleya.

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Otrzymano: 05.11.2012 Zaakceptowano do druku: 10.04.2013

Nr **05**/2013

Jarosław Beta et al. Risk factors for cesarean section after using the Foley catheter for labor induction.

**Materiał i metody:** Badanie objęło 135 kobiet między 38 a 42 tygodniem ciąży, u których wykonano indukcję porodu cewnikiem Foley'a. Grupa badana była podzielona na dwie podgrupy w zależności od sposobu ukończenia porodu.

**Wyniki:** Punktacja w skali Bishopa okazała się być istotnie wyższa w grupie kobiet, które urodziły drogami natury w porównianiu do grupy cięć cesarskich (5,2; 95%CI: 4,4 – 6,2 vs. 3,9; 95%CI: 2,8-4,9). Długość szyjki macicy nie różniła się w obu grupach. Analiza regresji pokazała, że ryzyko cięcia cesarskiego po indukcji cewnikiem Foley'a spada wraz ze wzrostem wieku matki oraz wzrastającą punktacją w skali Bishopa. Czułość 52% przy odsetku wyników fałszywie dodatnich 10%.

Wnioski: Niepowodzenie indukcji cewnikiem Foley'a można przewidzieć na podstawie wieku matki oraz badania szyjki macicy (skala Bishopa)

## Słowa kluczowe: indukcja porodu / indukcja porodu cewnikiem Foley'a / / preindukcja porodu /

#### Introduction

Spontaneous vaginal delivery is undoubtedly the best method of completing a pregnancy. However, in some clinical conditions labor induction is indicated. The first step in labor induction is ripening the cervix, which is usually formed, closed, firm and unfavorable. Pharmacological management (prostaglandins, hyaluronidase or relaxin) [1, 2] or mechanical ripening with the Foley catheter [3, 4, 5, 6] are used for cervical ripening during clinical trials. The latter method is based on inserting the catheter slightly above the internal os of the cervix and filling the balloon with normal saline. The induction is based not only on the mechanical ripening of the cervical canal, but also on separating the lower pole of the amniotic sac that leads to a cascade of neurohormonal reactions and a release of endogenous prostaglandins. In case of insufficient (or absent) uterine contractions, after removing the Foley catheter an intravenous oxytocin infusion is started. The main advantages of this method include safety - as it does not hyper-stimulate the fetus, efficiency and relatively low costs [3, 5, 7, 8, 9, 10, 11, 12].

The aim of the study was to analyze the pre-induction assessment of the cervix based on the ultrasound examination and the Bishop score as predicting factors for successful vaginal delivery after induction of labor (IOL) with the Foley catheter cervical ripening.

#### Material and methods

#### **Study population**

It was an observational study on induction of labor. The approval of the Hospital Ethics Committee was obtained. The study group consisted of 135 women who underwent cervical ripening with the Foley catheter. All subjects signed an informed consent. The inclusion criteria were: normal pelvic anatomy, cephalic presentation with ultrasound fetal weight estimates of  $\leq$  4000g. All women underwent an ultrasound examination of the cervix according to the Fetal Medicine Foundation criteria, performed by a certified sonographer. The Bishop score was assessed immediately before the procedure. None of the patients had a history of caesarean sections. All data, including patient demographics and medical history, were recorded in the database directly before the induction.

The Bishop score was performed immediately before the induction by assessing one of the five components (Table 1) on vaginal examination with the total score being stored in the database.

#### Induction technique

The Foley catheter of 16F filled with sterile solution of normal saline was used for the IOL. Average balloon volume was 52.68ccm (median 60ccm). In 91 cases (81%), after the removal of the catheter, the oxytocin intravenous infusion pump was prescribed (5 IU diluted in 50 mL of Ringer lactate; initial

#### Table I. Bishop scoring.

Cervix	Bishop Score			
	0	1	2	3
Consistency	Firm	Medium	Soft	-
Position	Posterior	Mid-Position	Anterior	-
Effacement	>4cm	3-4cm	1-2cm	0cm
Dilation	Closed	1-2cm	3-4cm	5cm
Fetal Head Station	-3	-2	-1	+1, +2

Subtract 1 point for nulliparity, postdate pregnancy and premature rupture of membranes

#### Table II. Maternal characteristics and obstetric history.

Characteristics	Cesarean section (N=51)	Vaginal delivery (N=84)	
Maternal age in years, median (IQR)	30.0 (27.5 – 32.5)	33.0 (29.0 – 36.0)*	
Maternal weight, median (IQR)	85.0 (79.8 – 91.0)	77.0 (69.0 – 85.0)	
Maternal height in cm, median (IQR)	166.0 (163.5 –171.3)	166.0 (165.0 – 170.0)	
Cervical length, median (IQR)	28.6 (22.9 - 31.7)	25.0 (17.0 – 31.0)	
Time of labor in minutes, median (IQR)	555 (225 – 900)	920 (415 – 1065)*	
Oxytocin use, n (%)	39 (76.5)	51 (60.7)*	
Racial origin			
Caucasian, n (%)	51 (100)	84 (100)	
Cigarette smoker, n (%)	9 (17.6)	3 (3.6)	
Conception			
Spontaneous, n (%)	51 (100)	84 (100)	
Ovulation drugs, n (%)	0	0	
Parity			
Nulliparous, n (%)	45 (88.2)	63 (75.0)	
Parous, n (%)	6 (11.8)	21 (25.0)*	

Comparisons between the groups were performed by Chi-square or Fisher's exact test for categorical variables and by Mann Whitney-U test for continuous variables. \* p<0.05

velocity 1.2ml/hr). The Foley catheter was removed after 12 hours from insertion unless it fell out due to cervical effacement and dilation. The study group was divided into two subgroups depending on the mode of delivery (caesarean section vs. vaginal delivery).

#### Statistical analysis

Comparisons between the vaginal and caesarean section delivery groups were done by  $\chi^2$ -test or Fisher's exact test for categorical variables and by Mann Whitney- U test for continuous variables. Additionally, multiple and logistic regression analyses were performed. The statistical software package SPSS 16.0 (SPSS Inc., Chicago, IL) was used for data analyses.

#### Results

Maternal characteristics of the vaginal and caesarean delivery groups are compared in Table II.

Multivariate logistic regression analysis demonstrated that significant independent contribution for caesarean section was provided by maternal age or/and Bishop score (R2=0.326; p=0.004) but not by ultrasound examination of the cervix (p=0.099), weight (p=0.123), height (p=0.088), smoking status (p=0.666), parity (p=0.567), use of oxytocin (p=0.904) or time of labour (p=0.267).

In the caesarean section group compared to the vaginal delivery group, the average Bishop score was lower (3.9; 95%CI: 2.8-4.9 vs. 5.2; 95% CI: 4.4 - 6.2; p=0.016.).

There was no significant difference in the pre-induction cervical length between the two sub-groups (27.2 vs. 25.5, p=0.926).

Patient-specific risk for cesarean section was calculated with the following formula:

odds/(1+odds), where odds =  $e^{Y}$  and Y was derived from the multivariate logistic regression analysis:

Y = 6.211432-0.19001\*Maternal Age (in years) – 2.26955 if Bishop score >4, otherwise 0

The estimated prediction of the cesarean delivery at fixed false positive rate (FPR) of 10% was 52.7% (AUROC 0.803 95%CI 0.673 – 0.932; p=0.001).

#### Discussion

The findings of the study demonstrate that patients with low Bishop score, as well as younger patients, are more likely to have caesarean section after the Foley catheter induction of labor. Additionally, the pre-induction ultrasound assessment of the cervix appears not to be useful in predicting the outcome of the Foley catheter induction of labor. The prediction model was based on maternal age and Bishop score only. For example, a 25-year-old woman with the pre-induction Bishop score of 3 has 89% chance of delivering by caesarean section following induction of labor with the Foley catheter, while a 37-year-old patient with Bishop score of 5 has only a 5%-chance for surgical delivery. The study of 5610 singleton pregnancies of nulliparous women between 37 and 42 weeks of gestation showed that the Bishop score itself is a reliable method of predicting vaginal delivery incidence [13]. In the presented data the ultrasound measurement was not included in the model. Some authors suggest however that the ultrasound evaluation of the cervix demonstrates significantly better predictive value in the prognosis of labor induction comparing to the Bishop score [14].

Interestingly, an analysis of 105146 prolonged pregnancies showed that the risk for cesarean section following induction of labor increases with maternal age, and doubles in women at the 35 years and older [15]. These results are contradictory to our findings, possibly due to a relatively small number of cases or the effect of statistical modeling of a very specific group of patients. The analysis showed that the number of cases was sufficient to regress the data into the model.

Our results showed that labor induction time interval was significantly shorter in women undergoing caesarean section, possibly due to the fact that the main causes for caesarean section were fetal distress (N=27), lack of progress (N=13) and threatening infection (N=8). Women undergoing caesarean section were less likely to be on the oxytocin drip (39 vs. 51, p=0.49). Again, our hypothesis is that it was associated with shorter time to delivery, what limited the options of augmenting the labor. Additionally, induction-delivery time and oxytocin use were not included in the regression model as this information is obviously not available at the time of counseling and risk assessment.

In the presented study, parous women had a two-fold higher chance of delivering vaginally when compared to nulliparous patients. This is fully consistent with other findings of the study as the parity itself increases the Bishop score.

Accurate pre-induction assessment of a woman and strict inclusion criteria appear to have an essential role in the induction of labor. It seems worthwhile to look for predicting factors for successful vaginal delivery or predictors for caesarean section. Population-based study of 9686 full-term pregnancies compared the outcomes after elective induction of labor and elective caesarean section with the outcomes after spontaneous labor. The authors suggested that the risk for emergency caesarean section was almost three times higher in women undergoing induction of labor [16].

In the presented data the overall caesarean section rate was 38%. Randomized study of 106 singleton pregnancies undergoing the Foley catheter induction of labor presented similar results [17]. Similarly, a randomized controlled trial of 330 nulliparous women with unfavorable cervix undergoing induction with double balloon, single Foley catheter balloon or prostaglandins, reported a 36% rate of cesarean sections after single balloon induction [18]. It is understood that all of those emergency deliveries were due to lack of progress (N=21) or fetal distress (N=30). Multivariate logistic regression model presented in the study could have potentially reduced this number to 18%. According to that model, women with high risk for caesarean section would not have been candidates for the Foley catheter labor induction. They might have been counseled for expectant management, other mode of induction or possibly, in the nearest future, elective caesarean section. To the best of our knowledge, there have been no reports supporting the hypothesis that some women would benefit from elective caesarean section instead of labor induction. A recently published review on women with a history of caesarean deliveries proved that there is not enough

evidence comparing benefits and disadvantages of elective caesarean section versus labor induction [19].

#### Conclusions

In conclusion, maternal age and Bishop score seem to be reliable predictors of the labor induction failure by the Foley catheter. It is possible to predict the outcome of labor induction but further studies are needed to improve the accuracy of the model.

#### Conflict of interest None

#### References

- Jagani N, Schulman H, Fleischer A, [et al.]. Role of the cervix in the induction of labour. Obstet Gynecol. 1982, 59, 21-26.
- Surita F, Cecatti J, Parpinelli M, [et al.]. Hyaluronidase versus Foley catheter for cervical ripening in high-risk term and post term pregnancies. Int J Gynaecol Obstet. 2005, 88, 258-264.
- Thomas I, Chenoweth J, Tronc G, Johnson I. Preparation for induction of labour of the unfavourable cervix with Foley catheter compared with vaginal prostaglandin. *Aust NZJ Obstet Gynaecol.* 1986, 26, 30-35.
- Obed J, Adewole I. The unfavorable cervix: improving the Bishop score using the Foley catheter. Int J Gynaecol Obstet. 1995, 48, 211-212.
- Dalui R, Suri V, Ray P, Gupta I. Comparison of extraamniotic Foley catheter and intracervical prostaglandin E gel for preinduction cervical ripening. *Acta Obstet Gynecol Scand.* 2005, 84, 362-367.
- Marciniak B, Bartosiewicz J. Effectiveness of intracervical catheter as a labour preinduction method. *Ginekol Pol.* 2010, 81, 31-36.
- George S, Matthews J, Jeyaseelan L, Seshadri L. Cervical ripening induces labour through interleukin 1 beta. Aust N Z J Obstet Gynaecol. 1993, 33, 285-286.
- Poma P. Cervical ripening. A review and recommendations for clinical practice. J Reprod Med. 1999, 44, 657-668.
- Gelisen O, Caliskan E, Dilbaz S, [et al.]. Induction of labour with three different techniques at 41 weeks of gestation or spontaneous follow-up until 42 weeks in women with definitely unfavourable cervical scores. *Eur J Obstet Gynecol Reprod Biol.* 2005, 120, 164-169.
- Mozurkewich E, Chilimigras J, Berman D, [et al.]. Methods of induction of labour: a systematic review. BMC Pregnancy Childbirth. 2011, 11, 84.
- Jozwiak M, Rengerink K, Benthem M, [et al.]. 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.
- Norman J, Stock S. Intracervical Foley catheter for induction of labour. Lancet. 2011, 378, 2054-2055.
- 13. Laughon S, Zhang J, Troendle J, [et al.]. Using a simplified bishop score to predict vaginal delivery. *Obstet Gynecol.* 2011, 117, 805-811.
- Sieroszewski P, Banach R. Comparison of the predictive value of digital examination (Bishop's score) and ultrasound evaluation for labour induction success. *Ginekol Pol.* 2010, 81, 105-110.
- Roos N, Sahlin L, Ekman-Ordeberg G, Kieler H, Stephansson O. Maternal risk factors for postterm pregnancy and cesarean delivery following labour induction. *Acta Obstet Gynecol Scand*. 2010, 89, 1003-1010.
- Dunne C, Da Silva O, Schmidt G, Natale R. Outcomes of elective labour induction and elective caesarean section in low-risk pregnancies between 37 and 41 weeks' gestation. J Obstet Gynaecol Can. 2009, 31, 1124-1130.
- Dodd J, Crowther C. Elective repeat caesarean section versus induction of labour for women with a previous caesarean birth. *Cochrane Database Syst Rev.* 2006, 18: CD004906.
- Hill J, Thigpen B, Bofill J, [et al.]. A randomized clinical trial comparing vaginal misoprostol versus cervical Foley plus oral misoprostol for cervical ripening and labour induction. *Am J Perinatol.* 2009, 26, 33-38.
- Pennell C, Henderson J, O'Neill M, [et al.]. 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.