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ORIGINAL ARTICLE

Foley catheter induction of labor as an outpatient procedure

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OBJECTIVE: The aim of our study was to introduce outpatient induction of labor by Foley catheter, and to compare outcomes and preferences between in-patients and outpatients.

STUDY DESIGN: This clinical cohort study was conducted in Helsinki University Hospital between January 2011 and January 2012. A total of 485 women scheduled for induction of labor by Foley catheter were included. The main outcome measures were cesarean delivery rate, and maternal and neonatal infectious morbidity. Maternal satisfaction of outpatients was measured after delivery.

RESULTS: Two hundred and four (42.1%) women were managed as outpatients and 281 (57.9%) women as in-patients. The rates of cesarean delivery, and maternal or neonatal infections did not differ between outpatients and in-patients. Of the outpatients, 85.3% were satisfied.

CONCLUSION: Induction of labor by Foley catheter appears suitable for outpatients, and resulted in no differences in cesarean delivery or infection rates compared with in-patients. Most women were satisfied with the outpatient induction.

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INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention with significant impact on the individual woman and health services.[1] More than 20% of women undergo IOL in developed countries.[2,3] There is a worldwide interest in outpatient care. Evidence from previous studies suggest that in-patient and outpatient induction have comparative maternal and fetal outcomes.[4–7] Outpatient setting may have implications for maternal satisfaction and costs.[8] Multiple studies have attempted to perform cervical ripening in the outpatient setting using prostaglandin E2 preparations,[9,10] but, as highlighted in the recent Cochrane review, there are few studies on Foley catheter in outpatient settings. IOL by Foley catheter has previously been shown to result in comparable vaginal delivery rate as prostaglandin in term women with unfavorable cervix, associated with low risk of maternal and neonatal adverse events.[11] A similar efficacy and safety of Foley catheter has been demonstrated in outpatient settings by one previous study.[1] Thus, the Foley catheter, appears to be a tempting option for outpatient IOL.[6,7,12,13]

Our aim was to introduce outpatient IOL by Foley catheter in our clinic. We wanted to evaluate outcomes and maternal preference between in-patients and outpatients, and to potentially improve patient care.

METHODS

This clinical cohort study comparing outpatient and in-patient IOL by Foley catheter consisted of women from the Department of Obstetrics and Gynecology, Helsinki University Hospital, Finland, between January 2011 and January 2012. We included women with uncomplicated singleton pregnancy, intact amniotic membranes, cephalic presentation, $\geqslant 37$ gestational weeks and Bishop score <6 [ref. 14] scheduled for IOL. Duration of pregnancy was defined by the fetal crown-rump length measurement at the time of first trimester ultrasound screening. The database contained information on 485 women. Nulliparous and multiparous women were analyzed separately. The study protocol was approved by the Ethical Committee (No. 268/13/03/03/2012) and the Hospital District of Helsinki and Uusimaa.

At the start of the study, the outpatient procedure was introduced to obstetricians and midwives by presentations and staff meetings. Written information and training on the use of Foley catheter was offered. The setting of IOL was decided by both the obstetrician and maternal preference. At the start of IOL all women were examined, underwent an ultrasonographic assessment of fetal biophysical profile including amniotic fluid volume, and had a reassuring nonstress test for a minimum of 20 min. The women were offered an option for outpatient IOL by the obstetrician in charge when the decision on IOL was made. The women received written and oral information about the study, and an informed consent was obtained by the obstetrician in charge. Women with preference for outpatient IOL were discharged after having received counseling regarding the catheter, discomfort, pain relief, and probability for the balloon falling out. Women were given oral and written 24-h contact information and instructions to immediately contact the delivery unit in case of bleeding, severe pain, fever, ruptured membranes or decreased fetal movements, or otherwise the latest after 24 h from catheter insertion.

The Foley catheter (Rüsch two-way single balloon Foley Couvelaire tip catheter size 22 Ch; Teleflex Medical, Athlone, Ireland) was placed by the obstetrician in charge. The catheter was introduced into the endocervix, and the space between the amniotic membrane and the lower uterine segment either blindly or by direct visualization. The balloon reservoir was inflated with 40 to 50 ml of saline and retracted so that it rested on the internal os. Transvaginal ultrasound examination was routinely performed to assure balloon placement. Light traction was applied and the catheter was taped on the inner thigh.

The balloon was left in place for a maximal of 24 h. Women in the outpatient setting were asked to contact the delivery unit and return after balloon expulsion. If the balloon was expulsed during the night, outpatients were asked to return the following morning, unless they had any concerns. If balloon expulsion did not occur within 24 h after insertion, the balloon was removed and further management considered by the obstetrician in charge. After spontaneous expulsion of the balloon, the cervix was assessed. If the cervix was ripened to a Bishop score $\geqslant 6$, amniotomy was performed and continuous fetal cardiotocography for a minimum of 1 h was started. If the cervix remained unripe with a Bishop

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Table 1. Characteristics of the study population ($n = 485$)

	Outpatient group (n = 204)		*In-patient group (n = 281)*		P-*value*
	n	%	n	%	
Maternal age $\geqslant 37$ years	28	13.7	32	11.4	0.44
Nulliparous	131	64.2	181	64.4	0.96
Previous cesarean section	31	15.2	46	16.4	0.73
IVF	6	2.9	10	3.6	0.71
Smoking	26	12.7	43	15.3	0.43
BMI (kg m^{-2}) $\geqslant 30$ kg m^{-2}	32	15.7	42	14.9	0.82
Gestational diabetes	26	12.7	30	10.7	0.48
Bishop $\leqslant 3$ at the start of IOL	88	44.9	104	37.0	0.09
Gestational age $\geqslant 42$ weeks	32	15.7	95	33.8	< 0.001
Sequential use of Foley catheter and misoprostol[a]	19	9.3	24	8.5	0.77

Abbreviations: BMI, body mass index; IOL, induction of labor; IVF, *in vitro* fertilization. χ^2 test. [a]Excluded before the final analysis.

score < 6 after balloon expulsion, cervical ripening was continued with intravaginal misoprostol and these ($n = 43$) women are reported separately. After amniotomy, the women waited in the ward for regular contractions to start. In the absence of spontaneous contractions, oxytocin induction was started 2 to 12 h after amniotomy at the discretion of the obstetrician in charge, and depending on our delivery unit capacity. Oxytocin augmentation and continuous cardiotocography during labor were routinely used.

Data on the characteristics of the study population and maternal antenatal risk factors, such as maternal age, body mass index in early pregnancy, *in vitro* fertilization, parity, Bishop score, smoking and gestational diabetes were obtained and collected from the hospital records. Women with prolonged pregnancy (gestational weeks $\geqslant 41^{+5}$) had a routine antenatal appointment during which the decision on IOL or expectant management was made. Post-term pregnancy was defined as gestational weeks $\geqslant 42^{+0}$. All women were induced the latest by 42^{+1} gestational weeks. Data on the delivery and neonatal outcomes were collected from the hospital records. The maternal and neonatal outcomes included cesarean deliveries, postpartum hemorrhage, umbilical cord arterial pH values, Apgar scores and maternal and neonatal infections. When there was more than one indication for cesarean delivery, the primary indications were categorized by using the following hierarchy: fetal distress, infection and failure to progress.

At the time of the study, a risk-group-based Streptococcus agalactie B screening was used, and thus not all participants were tested. Administration of antibiotics to Streptococcus agalactie B-positive women was started after 18 h from spontaneous or artificial rupture of membranes, or at the start of regular contractions. This was applied to both groups. Maternal infections were categorized as intrapartum or postpartum (from delivery to discharge). The criteria for intrapartum infection were maternal fever ($\geqslant$38 °C) during labor, fetal tachycardia ($\geqslant$160 b.p.m.), uterine tenderness, purulent amniotic fluid or vaginal discharge, and total white cell count $> 20 \times 10^9$/l. At least two of these criteria had to be met in combination with administration of antibiotics. Postpartum infections included endometritis (by the criteria listed above), wound infection (cesarean wound or episiotomy) and puerperal fever of unknown origin (defined as maternal fever ($\geqslant$38 °C with elevated white cell count, negative blood culture and no other focus of infection). The neonatal infections were categorized into blood culture-positive sepsis, clinical sepsis and suspected sepsis. Neonatal clinical sepsis was defined as blood culture-negative infection with symptoms and signs consistent with sepsis (respiratory distress, apnea, tachycardia, poor perfusion, low blood pressure, fever, hypoglycemia or hyperglycemia, irritability, feeding problems, lethargy, convulsions), abnormal blood values (C-reactive protein (> 20 mg l^{-1}), leukocytosis or leucopenia, increased neutrophil precursors and thrombocytopenia) and positive reaction to a minimum of 5-day antibiotic treatment. The cases of suspected sepsis had at least one symptom and at least one abnormal laboratory test value, and a positive response to antibiotic treatment.

Table 2. Reason for contacting delivery unit during outpatient IOL ($n = 204$)

	n	%
Balloon expulsion[a]	121	59.3
Pain[b]	4	2.0
Contractions	14	6.9
Vaginal bleeding	3	1.5
Rupture of membranes	4	2.0
Suspected rupture of membranes	3	1.6
24 h from balloon insertion[c]	50	24.5
Decreased fetal movements[d]	2	1.0
Rupture of the balloon	1	0.5
Difficulty urinating	2	1.1

Abbreviation: IOL, induction of labor. Sequential use of Foley catheter and misoprostol: a, $n = 10$; b, $n = 1$; c, $n = 7$; d, $n = 1$.

Interval times, presented as minutes, were calculated from the hospital records. The time from insertion of Foley catheter to expulsion was defined as the time from balloon insertion to spontaneous expulsion or removal. The start of regular contractions was defined as contractions in every 3 to 5 min with cervical dilation of 3 cm. The interval from induction to delivery was defined as the time from insertion of the balloon to delivery.

Maternal satisfaction of outpatient IOL and experience of contacting the delivery unit according to the instructions were measured after delivery by standard questionnaire with ratings 1 to 5 (very negative, negative, no opinion, positive and very positive).

All calculations were carried out using the Microsoft Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) for Windows v.18.0. Categorical variables were compared by the χ^2 test and Fisher's exact test when appropriate. Data with continuous variables were performed by *T*-test when the data followed normal distribution and by Mann–Whitney *U*-test if the data did not follow normal distribution. We performed a multivariate logistic regression analysis to estimate relative risks represented by odds ratios with 95% confidence intervals. The risk factors (maternal age $\geqslant 37$ years, parity, previous cesarean section, *in vitro* fertilization, smoking, body mass index $\geqslant 30$, gestational diabetes, post-term pregnancy, Bishop score $\leqslant 3$ at the start of IOL, need for oxytocin for induction, outpatient/in-patient setting) for cesarean section, maternal infection and neonatal infection were assessed separately for nulliparous and multiparous women. A *P*-value < 0.05 was considered statistically significant.

RESULTS

During the study period, 42.1% ($n = 204$) of the women underwent outpatient IOL and 57.9% ($n = 281$) in-patient IOL by Foley catheter. Table 1 shows the characteristics of the study population. There were more post-term pregnancies in the in-patient group ($P < 0.001$) (Table 1). The median gestational age at the start of IOL was 41.7 gestational weeks (s.d. $\pm$ 0.9) in both groups ($P = 0.97$). The most common indication (89.7%) for IOL was prolonged pregnancy, consisting 89.2% ($n = 182$) in outpatients and 90% ($n = 253$) in in-patients ($P < 0.001$). In 7.4% ($n = 36$) of the cases, the indication for IOL was maternal exhaustion, fear of labor or history of stillbirth, and in 2.9% ($n = 14$) a large (non-diabetic) fetus for gestational age.

The most common reasons for contacting the delivery unit during outpatient IOL were expulsion of the balloon (59.3%, $n = 121$) and reaching 24 h from insertion of the balloon (24.5%, $n = 50$) (Table 2). There were no cases of heavy bleeding, placental abruption, intrauterine fetal death, severe pain or sign of intrapartum infection among women with outpatient IOL. No deliveries occurred outside the hospital.

Of the women, 43 (8.9%) had an unripe cervix (Bishop score < 6) after balloon expulsion or removal and IOL was continued with intravaginal misoprostol at the discretion of the treating obstetrician. Nineteen (44.2%) women were in the outpatient group and 24 (55.8%) women in the in-patient group ($P = 0.77$) (Table 1). The cesarean section rate among these women was 51.2% ($n = 22$).

Table 3. Maternal and neonatal outcomes of nulliparous women ($n = 278$)

	Outpatient group (n = 115)		*In-patient group (n = 163)*		P-*value*
	n	%	n	%	
Prophylactic antibiotic	56	48.7	109	66.9	0.002
Oxytocin for labor induction	37	33.0	69	45.4	0.09
Epidural/spinal analgesia	100	87.0	145	89.0	0.61
Fetal scalp blood sampling	33	29.7	66	40.5	0.04
Cesarean delivery	44	38.3	64	39.3	0.87
Fetal distress	11	25.0	31	48.4	0.007
Infection	4	9.1	4	6.3	0.58
Failure to progress	28	63.6	28	43.8	0.02
Other	1[a]	2.3	1	1.6	1.00
Postpartum hemorrhage ⩾ 1000 ml					
Vaginal delivery	8	11.3	15	15.2	0.47
Cesarean delivery	17	38.6	22	34.4	0.65
Intrapartum infection	8	7.0	9	5.5	0.62
Postpartum infection	7	6.1	4	2.5	0.21
Endometritis	4	57.1	3	75.0	
Urinary tract infection					
Wound infection	2	28.6			
Fever of unknown origin	1	14.3	1	25.0	
Male	61	53.0	91	55.8	0.65
Apgar 1 min < 7	12	10.4	16	9.8	0.87
Apgar 5 min < 7	5	4.3	7	4.3	0.98
Umbilical artery pH < 7.05	3	2.7	2	1.3	0.65
Umbilical artery BE $\leqslant -12.0$	3	2.7	4	2.6	1
Neonatal infection	12	10.4	13	8.0	0.48
Suspected sepsis	11	91.7	8	61.5	
Clinical sepsis	1	8.3	5	38.5	
Admission to NICU	2	1.7	5	3.1	0.49
Admission to neonatal ward	18	15.7	19	11.7	0.33

Abbreviations: BE, base excess value; NICU, neonatal intensive care unit. χ^2 test, Fisher's exact probability test or *T*-test, women with sequential use of Foley catheter and misoprostol excluded. [a]Umbilical cord prolapse.

Table 4. Maternal and neonatal outcomes of multiparous women ($n = 164$)

	Outpatient group (n = 70)		*In-patient group (n = 94)*		P-*value*
	n	%	n	%	
Prophylactic antibiotic	21	30.0	29	30.9	0.91
Oxytocin for labor induction	26	37.1	28	31.3	0.32
Epidural/spinal analgesia	61	87.1	81	86.2	0.86
Fetal scalp blood sampling	2	8.0	2	9.1	1.00
Cesarean delivery	15	21.4	19	20.2	0.85
Fetal distress	6	40.0	6	31.6	0.61
Infection	1	6.7	1	5.3	0.86
Failure to progress	8	53.3	10	52.6	0.97
Other	1	6.7	2[a]	10.5	0.49
Postpartum hemorrhage ⩾ 1000 ml					
Vaginal delivery	7	12.7	6	8.0	0.38
Cesarean delivery	3	20.0	5	26.3	1.00
Intrapartum infection	4	5.7	2	2.1	0.40
Postpartum infection	2	2.9	2	2.1	1.00
Endometritis	1	50.0			
Urinary tract infection	1	50.0	1	50.0	
Wound infection			1	50.0	
Fever of unknown origin					
Male	30	42.9	35	37.2	0.47
Apgar 1 min < 7	7	10.0	5	5.3	0.26
Apgar 5 min < 7	3	4.3	3	3.2	0.71
Umbilical artery pH < 7.05	3	4.4	3	3.4	0.74
Umbilical artery BE $\leqslant -12.0$	2	2.9	2	2.2	1
Neonatal infection	0		5	5.3	0.07
Suspected sepsis			5		
Clinical sepsis					
Admission to NICU	2	2.9	0	0	0.25
Admission to neonatal ward	4	5.7	8	8.5	0.50

Abbreviations: BE, base excess value; NICU, neonatal intensive care unit. χ^2 test, Fisher's exact probability test or *T*-test, women with sequential use of Foley catheter and misoprostol excluded. [a]Maternal request for fear of labor, failed attempt to use vacuum extraction.

The maternal outcomes are shown in Tables 3 and 4. There were no differences in the rates of cesarean delivery ($P = 0.87$, $P = 0.85$), postpartum hemorrhage ⩾ 1000 ml ($P = 0.47$, $P = 0.38$ in vaginal delivery and $P = 0.65$, $P = 1.00$ in cesarean delivery, respectively), maternal intrapartum infection ($P = 0.62$, $P = 0.40$) or postpartum infection rates ($P = 0.21$, $P = 1.00$) (Tables 3 and 4). Among nulliparous women, antibiotic prophylaxis was more often used in in-patient IOL (66.9% vs 48.7%; $P = 0.002$) (Table 3). Fetal scalp blood sampling was more common in in-patient IOL among nulliparous women compared with outpatient induction (40.5% vs 29.7%; $P = 0.04$) (Table 3). Nulliparous women in in-patient IOL delivered more often by cesarean section because of fetal distress (48.4% vs 25%; $P = 0.007$) and those in outpatient IOL because of failure to progress (63% vs 43.8%; $P = 0.02$) (Table 3). By multivariate logistic regression analysis, outpatient induction was not associated with cesarean delivery. The only significant risk factor for cesarean delivery was history of prior cesarean section (odds ratio 66.9; 95% confidence interval: 7.9 to 632.9; $P < 0.001$). Similarly, maternal or neonatal infections were not associated with outpatient induction (data not shown).

Gestational age at birth was similar among nulliparous and multiparous women in both groups ($P = 0.138$, $P = 0.805$). Neonatal outcomes did not differ between the groups (Tables 3 and 4).

The induction to delivery interval was longer in women with outpatient IOL (1842 min (range 258 to 4930) vs 1486 min (range 170 to 4285); $P < 0.001$). There were no differences between the groups of outpatient and in-patient IOL in duration of I stage of labor (nulliparous 525 min (range175 to 1620) vs 500 min (range 130 to 1750); $P = 0.72$ and multiparous 325 min (range 70 to 1510) versus 340 min (range 26 to 890); $P = 0.85$) or II stage of labor (nulliparous 26 min (range 0 to 89) vs 27 min (range 1 to 97); $P = 0.86$ and multiparous 11 min (range 0 to 64) vs 12 min (range 2 to 93); $P = 0.73$).

Of the 112/204 women who returned the questionnaire, 96 (85.3%) were satisfied with outpatient induction (very positive 70.7%, positive 14.6%, no opinion 9.8%, negative 0%, very negative 4.9%) and 90.7% (very positive 74.4%, positive 16.3%, no opinion 2.3%, negative 2.3%, very negative 4.7%) found contacting the delivery unit safe and easy.

DISCUSSION

We found that outpatient IOL by Foley catheter was safe and feasible. Several outpatient induction protocols have been described in observational studies, suggesting that outpatient IOL is feasible and acceptable.[15,16] Owing to low risk of adverse maternal and neonatal outcomes, the Foley catheter has already been introduced into outpatient management.[1,4,5,7,12] However, the recent Cochrane review highlights the insufficient evidence relating to Foley catheter IOL in outpatient setting.[5] We are aware

of only one previous study comparing in-patient and outpatient Foley catheter IOL.[1]

The concept of outpatient IOL, where cervical ripening occurs predominantly at home, is an option that may optimize delivery unit occupancy, shorten the hospitalization period and require less staff, thus decreasing health-care costs. At least theoretically, outpatient IOL may offer a number of advantages to both women and health-care services. Moving cervical ripening from in-patient to outpatient setting appears to decrease costs significantly[6,8] and may also increase maternal satisfaction.[1,4] Furthermore, at least 50% of all patients requiring the IOL may be eligible for outpatient cervical ripening.[8] In 2010, before starting the trial of outpatient cervical ripening, IOL was the most common reason for antenatal care admittance in our hospital explaining more than 30% of cases (unpublished data). Accordingly, episodes of antenatal care decreased by 16% during 2011 when we started outpatient IOL management in our hospital (unpublished data). However, health-care costs were not the main focus of our study. Instead, we concentrated on safety and feasibility.

Outpatient IOL is suitable for women without serious medical condition or pregnancy complications.[17] In our study, the most common indication for IOL was prolonged pregnancy. Evidence from randomized controlled studies suggest that in-patient and outpatient IOL by means of Foley catheter or prostaglandins achieve comparable maternal and fetal outcomes in prolonged pregnancy.[7]

One of the key questions regarding outpatient IOL has been the readmission rate to hospital after the initiation of outpatient cervical ripening. Sciscione *et al.*[1] demonstrated readmission rate of 8%. In our study, the return rate for reasons other than labor, rupture of membranes, balloon expulsion or reaching 24 h of home cervical ripening was the same. We believe this was due to thorough counseling and providing detailed written information. Women were advised on when to contact the delivery unit and also encouraged to contact the hospital if they had any other concern. In addition women were provided with 24-h contact information to delivery unit. More than 9 out of 10 women considered the process safe.

In our study cesarean delivery rates, or neonatal or maternal outcomes did not differ between in-patients and outpatients. This is in line with previous studies on cervical ripening in outpatient setting by means Foley catheter.[1,4–6] However, nulliparous women in the in-patient setting delivered more often by cesarean section because of fetal distress compared with those in the outpatient setting. This is likely due to the fact that the in-patient group included more women with post-term pregnancy, which highlights the importance of patient selection. Similarly, as in the present study, outpatient cervical ripening with a Foley catheter has not resulted in increased infectious morbidity compared with in-patient cervical ripening.[1,5,6] Moreover, admission of the newborns to neonatal ward or NICU was equally common in both groups, as also shown in the previous studies.[5]

One of the considerations for both the woman and the health-care service is the time involved in the process of IOL. The total time from the beginning of induction to birth was longer in outpatient induction, as noted also in a previous study.[1] This may be explained by the fact that women were asked to stay home even after the Foley was spontaneously expulsed and amniotomy was often scheduled for the next morning. In addition, women in in-patient IOL were perhaps more actively managed. However, there were no differences in the durations of I and II stage of labor between the groups. The total time spent in hospital care was shorter among outpatients. The longer duration from induction to delivery did not increase the rates of infection or cesarean delivery. Previous studies have shown that adverse neonatal outcomes are not increased even with prolonged induction to delivery interval.[18]

Importantly, most women were satisfied with the outpatient IOL in our study. Previous studies have also shown that women allocated to outpatient cervical ripening are more satisfied.[4,19,20]

We acknowledge the limitations of our study, such as lack of randomization and the selection bias of more post-term pregnancies ending up in the in-patient group. This was due to the preliminary nature of the study, in which we wanted to emphasize maternal preferences on the setting of induction. Also, we regret not having performed calculations on the economic impact of outpatient vs in-patient IOL. We were encouraged by this pilot study, and in future plan a radomised controlled trial to have exact analysis on clinical aspects, health-care cost and resource saving of the outpatient IOL by Foley catheter. The strengths of this study were that the groups were comparable, our extensive experience with Foley catheter IOL, standardized management protocols used, and systematic detailed data reporting.

In conclusion, the Foley catheter IOL appears to be an acceptable outpatient procedure. Although our experience with outpatient Foley catheter IOL are promising, further randomized trials are needed to substantiate our findings.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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