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Induction of Labor with a Transcervical Foley Catheter in an Outpatient Setting in a Low-Risk Population: A Retrospective Cohort Study

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Abstract

Background: Induction of labor (IOL) is one of the most common obstetric interventions. While in previous years IOL has primarily been performed in an inpatient setting, outpatient approaches have gained increasing interest in recent years. Since October 2019 the insertion of a Foley catheter in an outpatient setting is the first-line choice for IOL in low-risk situations in our department. If labor cannot be induced within 24 hours, IOL will be continued in an inpatient setting with oral misoprostol or oxytocin and amniotomy, depending on the Bishop score. The aim of this study was to evaluate our standard IOL regimen concerning effectiveness and safety. **Methods:** Data were collected retrospectively from all deliveries in our department from October 2019 until December 2020 that had primarily been induced with a Foley catheter in an outpatient setting. Effectiveness was evaluated by assessment of the time interval between Foley insertion and delivery and the need for further induction methods after the Foley catheter. Safety was evaluated by assessment of the presence of adverse events at time of hospitalization after outpatient IOL with the Foley catheter such as pathological CTG, uterine hyperstimulation, vaginal bleeding or chorioamnionitis. In addition, general maternal and neonatal outcome parameter were evaluated. **Results:** We included a total of 120 women in our analysis. Among the women, 66.7% were primiparous, 24.2% delivered their second child, and 9.1% their third or fourth. The main indications for IOL were late-term or postterm pregnancy (32.5%), suspected fetal macrosomia (12.5%) and oligohydramnios (10.8%). At time of hospitalization, there were no pathological changes in fetal heart rate, vaginal bleeding, chorioamnionitis or uterine hyperstimulation in any of the cases analyzed (upper limit of 95% CI 3.0%). No further induction method after the Foley cath-

eter was needed in 20.8% (95% CI 13.9 - 29.1%). 26.7% of the women (95% CI 18.9% - 35.5%) did not require misoprostol to achieve the onset of labor. Vaginal delivery was achieved in 75.8% of the women (95% CI 67.2% - 83.2%), 24.2% (95% CI 16.9% - 32.8%) sustained a caesarean section. The mean time interval between insertion of the catheter and delivery was 38.1 hours and the mean time of inpatient stay 4 days. There occurred no serious neonatal or maternal adverse events directly related to the IOL with the Foley catheter in our cohort. **Conclusions:** In this retrospective cohort of low-risk pregnancies, IOL with an outpatient Foley catheter was associated with favorable maternal and neonatal outcomes and no observed serious adverse events directly related to the Foley catheter. These findings provide descriptive information on the implementation of an outpatient Foley catheter induction regimen in clinical practice. Further studies with comparative designs are needed to evaluate the effectiveness and safety of this approach further and to determine its possible applicability beyond low-risk situations.

Keywords

Outpatient Induction of Labor, Cervical Ripening, Balloon Catheter, Foley Catheter, Misoprostol

1. Introduction

Induction of labor (IOL) is one of the most common obstetric interventions, currently occurring in approximately 25% of all pregnancies in high-income countries [1]-[3]. Given the increase in high-risk pregnancies as well as the potential benefit of an IOL at 39 weeks compared to expectant management in low-risk pregnancies in reducing the caesarean section rate, as shown in the ARRIVE trial, the number of IOL will continue to rise [4].

The methods of IOL include the vaginal or oral administration of prostaglandins, the intravenous administration of oxytocin (with or without amniotomy) and the use of mechanical methods, most frequently a transcervical balloon catheter [3] [5]. While in previous years IOL has primarily been examined in an inpatient setting, in recent years the option of an outpatient treatment has become increasingly popular. Several studies have shown advantages of the outpatient IOL compared to the inpatient setting, such as higher patient satisfaction and potential for cost reduction [1] [2] [6]-[19]. Because balloon catheters have been proven to be both effective and safe, they are considered for outpatient management in several guidelines, e.g. the British NICE-guideline, the American ACOG-guideline and the German, Swiss and Austrian AWMF-guideline [20]-[22]. However, the guideline in the German-speaking countries [22] is still very cautious and recommends an outpatient management only in carefully selected cases.

Since October 2019, the insertion of a Foley catheter in an outpatient setting is the first-line choice for IOL in the low-risk population in our department, a tertiary perinatal center. If labor cannot be induced within 24 hours IOL will be con-

tinued in an inpatient setting with oral misoprostol or intravenous oxytocin and amniotomy, depending on the Bishop score.

The aim of this study was to evaluate our standard IOL regimen in low-risk situations with an outpatient Foley catheter concerning effectiveness and safety.

2. Methods

We performed a retrospective cohort study with data collection from all women delivered in our department from 1st October 2019 until 31st December 2020 that had primarily been induced with a Foley catheter in an outpatient setting. Patients who signed the hospital's general consent were included in this analysis. In most cases, signed general consent was already available. In case of missing consent, we contacted the patients and asked for their participation. Those patients who refused to sign the general consent were excluded from the analysis.

In our department, the outpatient IOL management with a Foley catheter is offered to women with a singleton fetus in cephalic presentation, a gestational age of ≥ 36 + 0 weeks of gestation, a maximum of three previous deliveries without prior cesarean section, a placenta ≥ 4 cm above the internal cervical os, a cervical dilatation < 2 cm, intact membranes and a distance to the hospital < 30 minutes by car. Additionally, the indication for IOL has to be a low-risk condition such as late-term or postterm pregnany (gestational age > 40 + 0 weeks of gestation), maternal age > 40 years, smoking, isolated oligohydramnios (amniotic fluid index < 5 cm or single deepest pocket < 2 cm), gestational diabetes without fetopathy and insulin dose < 40 IU/24 h or suspected fetal macrosomia/large-for-gestational-age (estimated fetal weight > 4000 g or > 95th percentile). The Foley catheter, an 18 CH single-balloon catheter, is inserted transcervically by a physician under sterile conditions using a speculum. The balloon is inflated with 50 ml of sterile saline and, after performing transvaginal ultrasound examination to assure the correct balloon placement, the catheter is taped without traction to the inner thigh. Prior to the insertion the fetal well-being is examined by 30 minutes cardiotocogram (CTG) and afterwards by ultrasound of fetal heart rate. In case of normal findings (physiological fetal heart rate, no significant vaginal bleeding, no painful contractions or other concerning symptoms) the patient is discharged, provided with the 24 h-phone number of our labor ward as well as with instructions regarding the symptoms for which to present to our department earlier than the scheduled admission time after 24 hours (e.g. spontaneous dislocation expulsion of the catheter, vaginal bleeding, rupture of membranes, onset of labor, discomfort, decreased fetal movements or other concerning signs or symptoms). If labor cannot be induced within 24 hours IOL will be continued in an inpatient setting with oral misoprostol (max. 8 × 25 mcg every 2 hours) or intravenous oxytocin (max. 8 hours) and amniotomy, depending on the Bishop score, which is evaluated by a midwife at time of hospitalization (Bishop score ≤ 6: IOL continuation with misoprostol, Bishop score > 6: IOL continuation with oxytocin and amniotomy).

The parameter "effectiveness" was evaluated by measurement of the primary

outcome of our study, which was defined as the time interval between insertion of the Foley catheter and delivery in hours ("insertion-to-delivery interval"), and the assessment of the need for further induction methods after the Foley catheter (need for misoprostol and/or oxytocin or no need for further induction method) as one of the secondary outcomes. The parameter "safety" of the outpatient management was evaluated by assessment of the presence of the following adverse events at time of hospitalization after outpatient IOL with the Foley catheter as secondary outcomes: the presence of pathological CTG according to FIGO classification, uterine hyperstimulation (defined as uterine tachysystole with > 5 contractions in 10 minutes or uterine hypertonus with contractions lasting > 2 minutes), vaginal bleeding or chorioamnionitis (based on clinical criteria: maternal fever ≥ 38˚C plus one of the following: maternal leukocytosis (white blood cell count > 15,000 cells/mm^3), fetal tachycardia (>160 beats per minute) and/or purulent vaginal discharge). In addition, the following general maternal and neonatal outcome parameter were evaluated as secondary outcomes: delivery mode, chorioamnionitis, pathological intrapartum CTG according to FIGO classification, blood loss/occurrence of postpartum hemorrhage (blood loss > 500 ml in case of vaginal delivery or >1000 ml in case of caesarean section), total inpatient stay, arterial pH, 5-minute APGAR, meconium staining, CPAP-therapy, neonatal infection/sepsis, admission to neonatal care unit or neonatal intensive care unit (NICU).

The database was maintained using Microsoft Excel, and statistical analyses were conducted using Stata software (Stata SE 16). Descriptive statistics were performed. Continuous variables are presented as mean and standard deviation (SD) or as median and interquartile range (IQR), as appropriate. Categorical variables are presented as frequencies and percentages. Exact 95% confidence intervals for the main categorical outcomes were calculated using the Clopper-Pearson method. For outcomes with no observed events, the upper limits of the 95% confidence intervals were reported. Missing data were not imputed. All analyses were performed using available cases for each outcome, and denominators are reported where data were incomplete.

The study was approved by the local ethics committee (Project-ID 2020-01713).

3. Results

Of the 190 pregnant patients, who were primarily induced with a Foley catheter in an outpatient setting in our department from 1st October 2019 until 31st December 2020, we included a total of 120 patients in our analysis. 69 patients with unsigned general consent and 1 patient in whom IOL was discontinued on patient's request due to fatigue were excluded (see **Figure 1**).

In our population, 66.7% of the women were primiparous, 24.2% delivered their second child and 9.2% their third or fourth. The main indications for IOL were late-term or postterm pregnancy (32.5%), suspected fetal macrosomia/large-for-gestational-age (12.5%) and oligohydramnios (10.8%). The median gestational

age at start of IOL was 284 days (40 + 4 weeks of gestation) and at delivery 285 days (40 + 5 weeks of gestation). Baseline characteristics are described in Table 1.

Table 1. Baseline characteristics.

	median (q1 - q3) or n (%)	min	max
Parity			
1	80 (66.7%)		
2	29 (24.2%)		
3 or 4	11 (9.2%)		
Indication for IOL			
Late-term or postterm pregnancy*	39 (32.5%)		
Suspected fetal macrosomia/ large-for-gestational-age**	15 (12.5%)		
Oligohydramnios***	13 (10.8%)		
Gestational diabetes (with insulin)	11 (9.2%)		
Decreasing fetal movements	9 (7.5%)		
Maternal exhaustion	7 (5.8%)		
Maternal age ≥ 40 years	7 (5.8%)		
Gestational diabetes (without insulin)	5 (4.2%)		
Maternal request	4 (3.3%)		
Late flattening	3 (2.5%)		
IVF/ICSI	2 (1.7%)		
Cholestasis of pregnancy	2 (1.7%)		
Other	3 (2.5%)		
Gestational age at start of IOL (days)	284 (276 - 288)	256	293
Gestational age at delivery (days)	285 (278 - 289)	258	294
Maternal age (years)	32 (29 - 35)	21	45
BMI (kg/m^2) (n = 110)	28.1 (25.4 - 32.4)	19.2	46.1
Obesity (BMI ≥ 30 kg/m^2) (n = 110)	43 (39.1%)		
Fetal weight (g)	3520 (3215 - 3775)	2470	4585
Fetal weight > 4000 g	17 (14.2%)		
Fetal head circumference (cm)	35 (34 - 36)	30	39
Fetal sex			
male	65 (54.2%)		
female	55 (45.8%)		
Streptococcus agalactiae colonization	19 (15.8%)		

n = 120, BMI/obesity: n = 110; * late-term or postterm pregnany was defined by a gestational age > 40 + 0 weeks of gestation; ** Fetal macrosomia/large-for-gestational-age was defined by an estimated fetal weight > 4000 g or > 95th percentile, respectively; *** Oligohydramnios was defined by an amniotic fluid index < 5 cm or a single deepest pocket < 2 cm.

The primary outcome, the median time interval between insertion of the Foley catheter and delivery, was 39.7 hours (IQR 26.5 h - 49.5 h) (mean 38.1 hours (SD ± 16.3 h)) (see Table 2). Spontaneous vaginal delivery (median 34.4 h) was associated with a shorter time interval compared to instrumental vaginal delivery (median 43.4 h) or caesarean section (median 49.5 h) (see Table 2).

Table 2. Primary outcome: insertion-to-delivery interval (hours).

	n (%)	median (q1 - q3)	min	max	mean	sd
Overall	120 (100%)	39.7 (26.5 - 49.5)	4.5	82.1	38.1	16.3
Spontaneous	66 (55.0%)	34.4 (20.0 - 43.2)	4.5	64.6	33	15.1
Instrumental	25 (20.8%)	43.8 (34.6 - 48.0)	18.8	82.1	43.9	15
Caesarean section	29 (24.2%)	49.5 (33.5 - 56.8)	7.3	72.2	44.6	16.8

In more than half of the patients (56.7%), the Foley catheter remained in situ until the scheduled admission time to our labor ward after 24 hours leading to a median time interval from Foley insertion to expulsion of 24 hours (IQR 12 h - 24 h) and a mean time interval of 18.4 hours (SD ± 7.6 h). At time of hospitalization, there were no pathological changes in fetal heart rate, vaginal bleeding, chorioamnionitis or uterine hyperstimulation in any of the cases analyzed (upper limit of 95% CI 3.0%). No further induction method after Foley catheter was needed to achieve the onset of labor in 20.8% of the cases (95% CI 13.9% - 29.1%), 73.3% (95% CI 64.5% - 81%) required additional misoprostol (± oxytocin and amniotomy) and 5.8% (95% CI 2.4% - 11.6%) only additional oxytocin (± amniotomy) after removal of the Foley catheter. Spontaneous vaginal delivery was achieved in 55% of the women (95% CI 45.6% - 64.1%), 20.8% (95% CI 13.9% - 29.1%) needed vaginal-operative assistance and 24.2% (95% CI 16.9% - 32.8%) sustained a caesarean section. The median blood loss was 400 ml (occurrence of PPH in 16.7% of the cases (95% CI 10.5% - 24.6%)) and the median inpatient stay 4 days. There were no serious maternal adverse events recorded. All maternal outcomes are displayed in Table 3 and Figure 1.

Table 3. Secondary outcome: maternal outcome.

	median (q1 - q3) or n (%)	min	max	mean	sd
Reason for Foley expulsion					
Removal after 24 hours	66 (55%)				
Contractions	30 (25.0%)				
Spontaneous	22 (18.3%)				
Rupture of membranes ± contractions	2 (1.7%)				

Continued

Time Foley-insertion to expulsion (hours)	24 (12 - 24)	1.5	24	18.4	7.6
Delivery mode					
Spontaneous vaginal	66 (55.0%)				
Instrumental	25 (20.8%)				
Caesarean section	29 (24.2%)				
Main indication for caesarean section					
Pathological CTG*	11 (38.0%)				
Arrest during 1st stage of labour	8 (27.6%)				
Arrest during 2nd stage of labour	3 (10.3%)				
Maternal request**	3 (10.3%)				
Non-responding to IOL	1 (3.5%)				
Other	3 (10.3%)				
Main indication for instrumental vaginal delivery					
Pathological CTG*	16 (64%)				
Prolonged 2nd stage of labour/arrest during 2nd stage of labour	8 (32%)				
Chorioamnionitis***	1 (4%)				
Epidural anesthesia					
Yes	64 (53.3%)				
No	56 (46.7%)				
Intrapartum CTG*					
Normal	65 (54.2%)				
Suspect	21 (17.5%)				
Pathological	34 (28.3%)				
Chorioamnionitis***	2 (1.67%)				
Blood loss (ml)	400 (300 - 500)	200	1440	457	210
Postpartum hemorrhage (PPH)****	20 (16.7%)				
Total inpatient stay (days)	4 (3 - 5)	1	8	4.1	1.2

n = 120, duration labour stages: n = 91; IOL = induction of labour; * CTG was evaluated according to FIGO-classification; ** Caesarean section was requested due to maternal fatigue; *** Chorioamnionitis was diagnosed based on clinical criteria (maternal fever ≥ 38 ˚C plus one of the following: maternal leukocytosis (white blood cell count > 15,000 cells/mm^3), fetal tachycardia (> 160 beats per minute) and/or purulent vaginal discharge); **** Postpartum hemorrhage was defined as a blood loss > 500 ml in case of vaginal delivery and > 1000 ml in case of caesarean section.

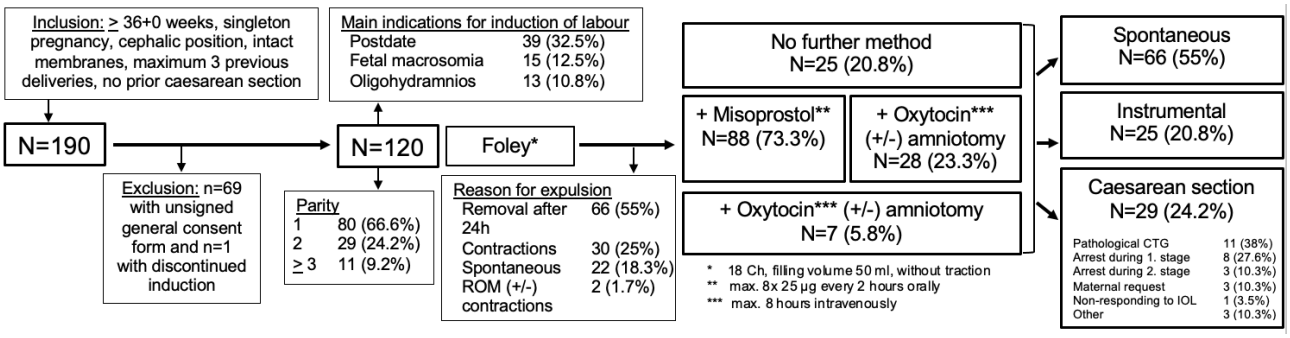

Figure 1. Flowchart.

Regarding the neonatal outcome, the median arterial umbilical cord pH was 7.27 (7.20 - 7.31) based on available data from 117 newborns. The median 5-minute APGAR was 9 (8 - 10). An arterial pH < 7.1 occurred in 4.3% of the newborns (95% CI 1.4% - 9.7%), a 5-minute APGAR < 7 in 1.7% (95% CI 0.2% - 5.9%). There were 2 cases (1.7%) with clinical suspicion of chorioamnionitis, one of which (0.8%) led to clinical diagnosis of neonatal early onset sepsis, although without detection of a pathogen in the blood cultures. In this case, IOL was continued after 24 hours Foley catheter and intact membranes with misoprostol. During labor, spontaneous rupture of membranes occurred and later the patient developed fever and fetal tachycardia, leading to a secondary caesarean section. A total of 5 newborns (4.2%, 95% CI 1.4% - 9.4%) were admitted to the neonatal care unit, 4 due to respiratory distress syndrome and 1 due to the early onset sepsis mentioned above. Except for that one case of neonatal sepsis, no serious neonatal adverse events were recorded. All neonatal outcomes are summarized in Table 4.

Table 4. Secondary outcome: neonatal outcome.

	median (q1 - q3) or n (%)	min	max
Arterial pH (n = 117)	7.27 (7.20 - 7.31)	7.05	7.41
Arterial pH < 7.1 (n = 117)	5 (4.3%)		
5 min APGAR	9 (8 - 10)	5	10
5 min APGAR < 7	2 (1.7%)		
Pathological intrapartum CTG*	34 (28.3%)		
Meconium-stained amniotic fluid	20 (16.7%)		
CPAP	10 (8.3%)		
Neonatal infection/sepsis	1 (0.8%)		
Admission to neonatal care unit	5 (4.2%)		

n = 120, arterial pH: n = 117; * CTG was evaluated according to FIGO-classification.

4. Discussion

The outpatient Foley catheter appears to be an advantageous choice as primary method for IOL in low-risk situations. Apart from one case with clinical diagnosis

of early onset sepsis without detection of a pathogen in the blood cultures and without direct relation to the IOL with the Foley catheter, there occurred no serious neonatal or maternal adverse events in our cohort. Additionally, the Foley catheter seems to be effective given that in 1 of 5 patients in our cohort the onset of labor was achieved using only the Foley catheter for IOL and further IOL with prostaglandins was not required in 1 of 4 patients.

Our study has several limitations, mainly its retrospective single-center design and the lack of a control group. To assess the effectiveness of an intervention, a study design with a comparison group is generally preferable to our descriptive retrospective design. But since we introduced a new IOL standard regimen in our department in October 2019, it was not useful to compare our study cohort to a historical control group as the IOL regimen was previously different, and likewise, it was not useful to compare our study cohort to patients with inpatient Foley catheter from our department because they belong to a different collective, as almost all low-risk patients are induced with outpatient Foley catheter and all high-risk patients with inpatient Foley catheter. In addition, when interpreting the results of our study, a potential selection bias due to the exclusion of a significant number of women without signed general consent must be considered. Furthermore, regarding our outcome parameter "effectiveness", a potential bias due to a possible difference in the Bishop score before Foley insertion between different patients must be taken into account, as this can have an impact on the time interval between Foley insertion and delivery and the need for further induction methods. The Bishop score before insertion of the Foley catheter was not consistently recorded in the patient files of our cohort, making an adequate evaluation impossible. Moreover, it was therefore not possible to use the difference in the Bishop score before the Foley insertion and after its removal as a parameter for the assessment of effectiveness. However, the "induction-to-delivery interval" and the need for further induction methods, which we chose instead, were also suitable parameter and for the purpose of this study - to evaluate our new standard IOL regimen regarding effectiveness and safety - our general study design is appropriate. Furthermore, our study includes a relatively large cohort of pregnant women, when comparing the sample size with those in other studies (see **Table 5**).

In general, our results on effectiveness are difficult to generalize. This is mainly because the IOL regimens regarding the handling of the balloon catheter as well as additional IOL methods vary greatly between different hospitals ranging from removal of the catheter after 12 hours or not until 24 hours, filling volume of the balloon/the balloons between 30 ml and 80 ml, application of traction or no traction and continuation of IOL after the balloon catheter with oxytocin, amniotomy and/or different prostaglandins [9]-[19]. Therefore, the primary outcome of our analysis, the time interval between insertion of the Foley catheter and delivery, is hardly comparable with the time spans reported in other studies.

Table 5. Literature review of studies including outpatient balloon catheters for IOL: comparison of maternal and neonatal outcomes.

	Sciscione *et al.* [9]	Henry *et al.* [10]	Wilkinson *et al.* [11]	Policiano *et al.* [12]	Kruit *et al.* [13]	Kuper *et al.* [14]	Beckmann *et al.* [15]	Ausbeck *et al.* [16]	Haavisto *et al.* [17]	Hamdan *et al.* [18]	Wise *et al.* [19]	Our study
Study type	RCT single center	RCT single center	RCT single center	RCT single center	Cohort single center	RCT single center	RCT Multi-center	RCT single center	RCT single center	RCT Single center	RCT Multi-center	Cohort single center
Country, Year	United States, 2001	Australia 2013	Australia, 2015	Portugal, 2016	Finnland, 2016	United States, 2018	Australia, 2019	United States 2020	Finnland, 2020	Malaysia, 2021	New Zealand, 2023	Switzerland
Intervention/primary IOL method	Outpatient vs. inpatient Foley	Outpatient Foley vs. inpatient prostaglandin E2	Outpatient vs. inpatient Cook catheter	Outpatient vs. inpatient Foley	Outpatient and inpatient Foley	Outpatient vs. inpatient Foley+ oxytocin	Outpatient Cook catheter vs. inpatient prostaglandin E2	Outpatient vs. inpatient Foley	Outpatient vs. inpatient Cook catheter	Outpatient vs. inpatient Foley catheter	Outpatient Foley vs. Inpatient prostaglandin E2	Outpatient Foley catheter
N in the outpatient balloon catheter group	61	50	33	65	204	65	215	63	53	82	539	120
Caesarean section	29%	34%	18.2%	28%	28.9%	3.1%	32.6%	23.8%	22.6%	12.2%	40.7%	24.2%
Unassisted vaginal birth	NR	30%	48.5%	NR	NR	89.2%	51.2%	66.7%	64.2%	82.9%	39%	55%
PPH	NR	16%	18.1%	NR	13.5% *	0*	30.4% **	6.3%	NR	13.4% **	40.6% **	16.7%
Chorioamnionitis	NR	NR	NR	NR	5.9%	4.6%	NR	22.2%	NR	NR	4.8%	1.7%
Neonatal infection/sepsis	NR	NR	NR	NR	5.9%	NR	NR	NR	NR	NR	NR	0.8%
Meconiumstained amniotic fluid	NR	NR	12.1%	NR	NR	12.3%	NR	20.6%	NR	NR	NR	16.7%
Arterial pH < 7.1	NR	7%	NR	NR	NR	1.5%	3.5%	9.5%	5.7%	NR	4.0%	4.3%
5 min APGAR < 7	NR	NR	6.1%	NR	3.9%	0	NR	1.6%	0	0	3.3%	1.7%
Admission to NICU	2.2%	NR	3.0%	2%	2%	7.7%	NR	9.5%	NR	NR	NR	0
Admission to neonatal care unit/nursery	NR	16%	36.4%	NR	10.8%	10.8%	12.6%	NR	NR	2.4%	8.2%	4.2%

NR = not recorded, PPH = postpartum hemorrhage (blood loss > 500 ml in case of vaginal delivery and > 1000 ml in case of caesarean section), NICU = neonatal intensive care unit. * In this study, PPH was defined as blood loss > 1000 ml in both vaginal and caesarean deliveries. ** In this study, PPH was defined as blood loss > 500 ml in both vaginal and caesarean deliveries.

However, although the perinatal outcome does not remain completely unaffected by additionally used IOL methods and the general intrapartum management in different hospitals, maternal and neonatal outcome parameters are comparable, and we therefore conducted a literature search reviewing several studies investigating IOL with an outpatient balloon catheter and compared them with our results (see **Table 5**). In general, adverse perinatal outcome rates were low in our cohort and are compared to those reported in other studies in the lower to middle range (e.g. caesarean section 24.2% vs. 12.2% - 40.7% [9]-[19], PPH 16.7% vs. 0% - 40.6% [10] [11] [13]-[16] [18] [19], chorioamnionitis 1.7% vs. 4.8% - 22.2% [13] [14] [16] [19], arterial umbilical cord pH < 7.1 4.3% vs. 1.5% - 9.5% [10] [14]-[17] [19], 5-minute APGAR < 71.7% vs. 1.6% - 6.1% [11] [13] [16] [19]). The comparison of the main maternal and neonatal outcome parameter is shown in detail in **Table 5**.

In contrast to a Cochrane review on outpatient IOL conducted in 2013 [23], in which the authors concluded that there is very limited evidence on this topic and there could not yet be determined whether IOL is effective and safe in an outpatient setting, followed by two other Cochrane reviews, one on mechanical IOL methods in 2019 [24] and one with comparison of outpatient versus inpatient IOL in 2020 [25], in which the authors encouraged more research on safety aspects and patients satisfaction, today there are many more high quality studies, mainly RCTs and additionally reviews and meta-analyses, that together have been able to demonstrate both the safety and effectiveness of outpatient balloon catheters [2] [9]-[19] [26]-[29]. Particularly, conflicting findings such as possibly higher infectious morbidity (chorioamnionitis, endometritis, neonatal or maternal infection/sepsis) or higher caesarean section rates with balloon catheters in comparison to other IOL methods could be refuted [1] [2] [26]-[30]. In contrast, in comparison to the use of balloon catheters in an inpatient setting, the outpatient management showed even lower caesarean section rates [1] [2]. This agrees with our data, finding a caesarean section rate in the lower range in comparison to other studies, a very low rate of chorioamnionitis and only one case with clinical diagnosis of neonatal early onset sepsis, but without invasive pathogen detection and without direct relation to the IOL with the Foley catheter. Additionally, in line with a review on complications during the period from insertion to expulsion of the balloon catheter in case of IOL [31], which found a low risk of adverse events in this period, there were no adverse events such as pathological changes in fetal heart rate, vaginal bleeding, chorioamnionitis or uterine hyperstimulation at time of admission to our labor ward after outpatient IOL with the Foley catheter. This emphasizes the safety of the outpatient management.

In general, today there is considerable evidence on outpatient IOL with balloon catheters, but like the collective in our study, other studies strictly address a low-risk population and therefore these data are only applicable to low-risk settings. Studies on outpatient IOL in other populations or conditions are missing so far.

5. Conclusions

In this retrospective cohort of low-risk pregnancies, IOL with an outpatient Foley catheter was associated with favorable maternal and neonatal outcomes. There were no serious neonatal or maternal adverse events directly related to the IOL with the Foley catheter observed. In 1 out of 5 cases the woman did not require further induction methods after the Foley catheter and in 1 out of 4 cases the woman did not require misoprostol to achieve the onset of labor. These findings suggest potential benefits of outpatient Foley catheter induction, such as a possible reduction or even avoidance of potentially harmful prostaglandins and potential for overall cost reduction due to a possibly shorter inpatient stay until delivery. However, these potential benefits require confirmation and further evaluation in comparative studies.

In general, there is a lot of data on outpatient IOL with a balloon catheter with demonstrated safety and efficacy in low-risk settings. However, evidence regarding its use in other clinical settings are missing so far. While staying at home for 24 hours without maternal or fetal monitoring is not possible in every high-risk setting, there are numerous settings in which the women or the fetus does not require continuous monitoring, but which are not represented in studies. Given its excellent safety profile, an outpatient Foley catheter may be an advantageous option here as well. Future research should therefore consider the use of an outpatient Foley catheter in other settings than exclusively low-risk ones.

Statement on Funding Sources and Conflicts of Interest

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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