Thieme

Induction of Labour with a Double Balloon Catheter – Comparison of Effectiveness of Six Versus Twelve Hours Insertion Time: a Prospective Case Control Study

Geburtseinleitung mithilfe eines Doppelballonkatheters – Effektivitätsvergleich zwischen 6-stündiger und 12-stündiger Platzierung: eine prospektive Fallkontrollstudie

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Key words
cervical ripening, cervical ripening balloon, double-balloon catheter, induction of labour, time to delivery

Schlüsselwörter
Zervixreifung, Ballonkatheter zur Zervixreifung, Doppelballonkatheter, Geburtseinleitung, Zeitspanne bis zur Entbindung

received 25.5.2023
accepted after revision 14.9.2023

Bibliography
Geburtsh Frauenheilk 2023; 83: 1500–1507
DOI 10.1055/a-2177-0290
ISSN 0016-5751

Georg Thieme Verlag KG, Rüdigerstraße 14,
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ABSTRACT

Introduction
Induction of labour is a common obstetric procedure to initiate or augment contractions when labour is delayed or uncertain. The double balloon catheter is a safe and effective mechanical method for cervical ripening during induction of labour. This study evaluates the effectiveness of reducing double balloon catheter insertion time from 12 to 6 hours.

Methods
248 women undergoing induction with a double balloon catheter at term were divided into two groups: catheter placed for 12 hours at 8 pm in the first half of 2021 (P12) and catheter placed for 6 hours at 7 am in the second half of 2021 (P6). T-tests, chi-squared tests, and Wilcoxon signed rank test were used for statistical analysis. Primary and secondary endpoints included induction to delivery interval, prostaglandin to delivery interval, mode of delivery, and maternal and neonatal outcomes.

Results
The P6 group had a significantly reduced induction to delivery interval of 558 min (P6: 1348 min, P12: 1906 min, $p < 0.01$, 95 % CI: 376–710) within demographically comparable groups. Multiparous women also showed a significant reduction in prostaglandin to delivery interval of 260 min (P6: 590 min, P12: 850 min, $p = 0.038$, 95 % CI: 9–299). There were no significant differences in mode of delivery, maternal blood loss, or neonatal outcome.

Conclusion
Reducing double balloon catheter placement time from 12 to 6 hours resulted in almost 9 hours less induction to

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delivery interval without adverse effects on maternal and neonatal outcome.

ZUSAMMENFASSUNG

Einleitung
Die Geburtseinleitung ist eine häufig eingesetzte geburtshilfliche Maßnahme, welche die Wehentätigkeit einleiten oder verstärken soll, wenn sich diese verzögert hat oder unsicher ist. Der Doppelballonkatheter ist eine sichere und effektive mechanische Methode zur Beschleunigung der Zervixreifung während der Geburtseinleitung. Ziel dieser Studie ist es, die Effektivität eines Doppelballonkatheters zu prüfen, wenn die Verweildauer des Ballonkatheters von 12 auf 6 Stunden verkürzt wird.

Methoden
Eine Kohorte von 248 Frauen, bei denen die Geburt beim errechneten Geburtstermin mithilfe eines Doppelballonkatheters eingeleitet wurde, wurde in 2 Gruppen unterteilt: in der ersten Hälfte des Jahres 2021 (P12) wurde bei den entbindenden Frauen ein Ballonkatheter um 8 Uhr abends für 12 Stunden eingesetzt; in der zweiten Hälfte des Jahres 2021 (P6) wurde der Ballonkatheter um 7 Uhr morgens für 6 Stunden eingesetzt. Die statistische Analyse wurde mittels t-Test, Chi-Quadrat-Test sowie Wilcoxon-Vorzeichen-Rang-Test durchgeführt. Primäre und sekundäre Endpunkte waren die Zeitspannen zwischen der Geburtseinleitung und der Entbindung und zwischen der Prostaglandin-Gabe und und der Entbindung, der Entbindungsmodus sowie das mütterliche und neonatale Outcome.

Ergebnisse
Die Zeitspanne zwischen Einleitung und Entbindung in der P6-Gruppe betrug im Mittel 558 Minuten und war somit signifikant kürzer (P6: 1348 min, P12: 1906 min, $p < 0{,}01$, 95 %-KI 376–710), obwohl die Gruppen demografisch vergleichbar waren. Bei Multiparen war die Zeitspanne zwischen der Prostaglandin-Gabe und der Entbindung signifikant kürzer und betrug nur 260 Minuten (P6: 590 min, P12: 850 min, $p = 0{,}038$, 95 %-KI 9–299). Es gab keine signifikanten Unterschiede im Entbindungsmodus, mütterlichen Blutverlust oder neonatalen Outcome zwischen den Gruppen.

Schlussfolgerung
Die Verkürzung der Verweildauer des Doppelballonkatheters von 12 auf 6 Stunden führte zu einer Verkürzung der Zeit zur Entbindung um fast 9 Stunden, ohne nachteilige Auswirkungen auf das mütterliche oder neonatale Outcome.

Introduction

Approximately 22 % of births in Germany are induced each year [1]. Medication is the main method used, but mechanical, sequential mechanical-medical, and other methods, such as induction with castor oil, are also used [2, 3, 4, 5, 6].

Oxytocin and prostaglandins are available as drugs for induction [7, 8]. Prostaglandin E2 (PGE2 – dinoprostone) and prostaglandin E1 (PGE1 – misoprostol) have a cervical ripening and labour-inducing effect, which is why, unlike oxytocin, they are also used in cases of immature cervical findings. Especially at the beginning of induction, there are often painful uterine contractions without cervical ripening, which has reduced general acceptance by the pregnant women. An alternative is sequential induction with first mechanical cervical ripening followed by PGE1/2 [7]. Such a sequential approach using misoprostol in combination with a double balloon catheter (DBC) was similarly effective in primiparae and shortened the prostaglandin delivery interval (PDI) [9].

Mechanical methods of induction of labour (IOL) include iatrogenic amniotomy, hydroscopic dilators, and cervical single and double balloon catheters. Amniotomy is not suitable as a standalone procedure and should only be used in the presence of mature cervical findings [7]. Dilators and balloon catheters have been used for cervical ripening for decades [10, 11]. Dilation of the cervix results in the endogenous release of prostaglandins, leading to cervical ripening and myometrial contractions. IOL with double balloon catheters is associated with low rates of uterine hyperstimulation [12] and low maternal and neonatal morbidity [3]. The resulting rate of caesarean section appears to be comparable to that following drug induction with dinoprostone [9]. The effectiveness of the balloon catheters is equivalent to that of IOL with dinoprostone [3, 13, 14] and misoprostol [3, 15], although a recent meta-analysis by Zhao et al. shows the superiority of vaginal misoprostol with respect to the induction-delivery interval (IDI) [16].

The German guideline for induction of labour 2020 [7] recommends the use of a DBC for 12 hours, as prolonging the balloon insertion time from 12 to 24 hours showed no additional effect on IDI [17].

More recent studies have found no difference in effectiveness, but a reduction in IDI when the balloon placement time was shortened further [18, 19].

This prospective case-control study tests the effectiveness of shortening the DBC insertion time from 12 to 6 hours in everyday clinical practice.

Methodology

Study population

In this prospective case control study, a total of 259 pregnant women were recruited from January to December 2021 at the Department of Obstetrics, University Hospital Jena. The study was approved by the Ethics Committee of the Friedrich Schiller Univer-

sity of Jena (no. 2021–2365). Women with a term pregnancy (gestational age ≥ 37 + 0 weeks of gestation) were included if they were induced with a DBC (Cook Medical, Bloomington, Indiana, USA). Exclusion criteria were age below 18 years, premature rupture of membranes, and suspicious/pathological fetal heart rate pattern at the time of labour induction. A total of 248 women with IOL were included in the study (▶ **Fig. 1**). Incomplete data sets result in different case numbers, as indicated in the tables.

Methods of induction of labour

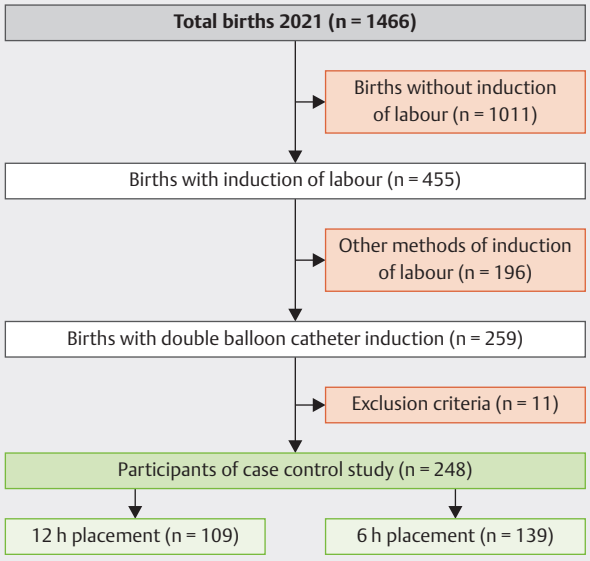
The DBC was inserted under visual control according to the manufacturer's instructions [10]. In the P12 group, the balloon was inserted at approximately 8 pm according to the hospital's internal Standard Operating Procedure (SOP) and usually removed at 8 am the following day. In the P6 group, the balloon was inserted at around 7 am and removed at 1 pm on the same day, unless the DBC spontaneously fell out. If the balloon insertion failed to induce labour, IOL was continued with misoprostol (initially 50 µg p.o., then 100 µg p. o. every 4 hours according to vaginal findings, manufactured by the Jena University Hospital pharmacy) or a vaginal insert containing dinoprostone (Propess, Ferring Arzneimittel, Kiel, Germany). As the clinical situation may required, oxytocin (5 IU oxytocin, Hexal, 5 IU in 500 ml whole electrolyte solution, start with 2 mIU/min, increase infusion rate by 2 mIU/min every 20–30 min, if necessary) was administered. The selection of IOL method for a participant following a prior caesarean section was made through a process of shared decision with her, excluding the use of misoprostol [7].

Endpoints

The primary endpoint of this study is the induction to delivery interval following induction of labour using the DBC. Secondary outcomes are the need for sequential drug induction of labour, prostaglandin delivery interval (PDI), mode of delivery, maternal outcomes as blood loss and uterine rupture, and neonatal outcomes, including arterial umbilical pH, base excess, neonatal acidosis < 7.1, APGAR score 5' < 7, pathological CTG, and meconium-stained amniotic fluid.

Data management

A paper-based case report form was created for the participants' patient files. It outlined the study's workflow and contained a specialized form for study specific data. Relevant descriptive clinical routine data were extracted from primary clinical documentation. Demographic data were collected on admission and the fetal condition was assessed by cardiotocography (CTG). Data with clinical relevance for IOL procedures were carefully chosen. This encompassed anamnestic factors that impact IOL, such as participant's age, co-morbidities, BMI, parity, history of previous caesarean section, gestational age, and the rationale behind IOL initiation. Moreover, details delineating pregnancy, childbirth, and neonatal outcomes were selected to comprehensively describe the efficacy and safety of labour induction. This included the sequential progression of IOL, utilization of epidural anesthesia, mode and rationale of delivery, instances of uterine rupture, APGAR scores, and neonatal intensive care unit (NICU) admissions.



▶ **Fig. 1** Study population. Inclusion criteria: GA ≥ 37 + 0, singleton pregnancy, induction with double balloon catheter; exclusion criteria: age < 18 years, path./susp. CTG at the start of induction, premature rupture of membranes.

Study related and clinical data was combined into one data sheet. The analysis was conducted according to the intention-to-treat principle.

Descriptive statistics are presented as the median (interquartile range) or number (percentage) for numeric and categorical variables. Baseline statistical analysis was performed using a Student's t-test and a Fisher's chi-squared or exact test. The Wilcoxon signed rank test was used to determine the significance of the IDI and the PDI in the two groups [20]. All calculations were performed using R (version 4.2.1) [21, 22, 23, 24] and a p-value < 0.05 was considered statistically significant.

Results

During the study period, 109 women with IOL were recruited to the P12 group and 139 to the P6 group. The two groups were comparable in terms of their demographics (▶ **Table 1**). The median age of the participants was 31–32 years, they were normal to slightly overweight (P12: BMI 24.7 kg/m^2, P6: 25.9 kg/m^2), predominantly primiparous (P12: 65.1%, P6: 66.2%), and with a median gestational age of 40 weeks at balloon insertion. Furthermore, the observed anamnestic conditions entail no significant differences. These include previous caesarean sections (P12: 14.68%, P6: 6.47%, p = 0.055), multiple pregnancies (P12: 2.75%, P6: 0.88%; p = 1.00), hypertension in pregnancy (P12: 2.8%, P6: 1.5%; p = 0.657), and gestational diabetes (P12: 19.4%, P6: 25.6%; p = 0.329) in pregnancy. The comparability of those factors across both groups obviates the necessity for statistical adjustments.

▶**Table 1** Demographic description.

	P12		P6		p-value
	N	median (IQR) or n (%)	N	median (IQR) or n (%)	
Age [years]	109	31 (29–34)	139	32 (28–35)	0.914
Diabetes	108	21 (19.4%)	137	35 (25.6%)	0.329
Hypertension in pregnancy	108	3 (2.8%)	137	2 (1.5%)	0.657
BMI before pregnancy [kg/m^2]	109	24.7 (21.9–30.5)	137	25,9 (22–30.1)	0.898
BMI at birth [kg/m^2]	109	29.6 (27.4–35.4)	136	31,2 (27.2–34.9)	0.94
Gravidity	109	1 (1–2)	139	1 (1–2)	0.373
Parity	109	0 (0–1)	139	0 (0–1)	0.9
▪ primipara		71 (65.1%)		92 (66.2%)	
▪ multipara		38 (34.9%)		47 (33.8%)	
Prior caesarean section	109	16 (14.68%)	139	9 (6.47%)	0.055
Multiples	109	3 (2.75%)	139	4 (2.88%)	1.000
Weeks of gestation at IOL	109	40 (38–40)	139	40 (39–40)	0.304
Indication for IOL	109		139		0.403
▪ fetal		42 (38.5%)		61 (43.9%)	
▪ post term		42 (38.5%)		40 (28.8%)	
▪ maternal		19 (17.4%)		31 (22.3%)	
▪ on patients demand		6 (5.5%)		7 (5.04%)	

IOL = induction of labour; IQR = interquartile range; N = number of cases; n = number of cases with complete information; P6/P12 = balloon placement 6 and 12 h

Primary endpoint: induction to delivery interval

The primary endpoint is the induction to delivery interval. In the P6 group, this is significantly shorter by 558 min (about 9 h) compared to the P12 group (1348 min vs. 1906 min; $p < 0.01$) (▶ **Fig. 2a**). The significance remains when primi- ($p < 0.01$) and multiparous women ($p < 0.01$), and women with ($p = 0.02$) and without previous caesarean section ($p < 0.01$) are considered separately. The time to delivery is shortened not only by the six-hour reduction in balloon placement time, but by an additional 3 hours.

Secondary endpoints: prostaglandin to delivery interval, pregnancy and neonatal outcome

Furthermore, the PDI between the first prostaglandin administration after balloon removal and delivery in multiparous women was significantly shortened by 260 min (approximately 4.3 h) in the P6 group compared to the P12 group (590 min vs 850 min, $p = 0.001$) (▶ **Fig. 2b**).

The groups did not differ in the secondary outcomes (▶ **Table 2**). In both groups, the IOL had to be continued with prostaglandins in 93.5% of cases. The different types for sequential IOL after removing the DBC – dinoprostone vaginally (P12: 25%, P6: 21.2%) and misoprostol orally (P12: 67.6%, P6: 66.2%) – were used equally in both groups.

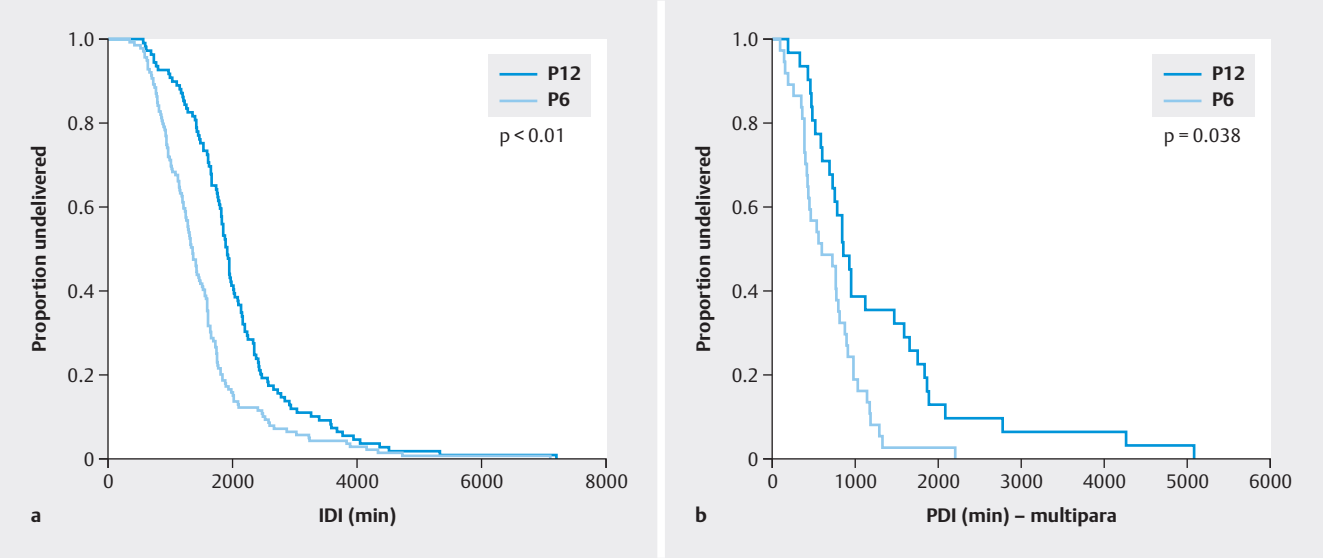
The rates of secondary caesarean section (P6: 27.5%, P12: 26.6%, $p = 0.57$) and blood loss at birth of 400–500 ml were equally distributed in the two cohorts. In the entire study population, there was only one case of uterine rupture in the P6 group. This was an attempted vaginal birth after caesarean section with DBC and dinoprostone vaginal insert. This approach was initiated in response to obstructed labour during the previous delivery. Subsequently, a pathological CTG reading indicated the repeat caesarean section. Intraoperatively, a rupture of the posterior uterine wall, independent of the previous caesarean scar, was encountered and sewn over without complications. The neonate was well (pH NA 7.22; APGAR 1'/7; 5'/8; 10'/9).

There were no significant differences in neonatal outcome as regards the frequency of pathological CTG sub partu (P12 and P6: 33% both), neonatal acidosis with umbilical arterial pH < 7.1 (P6: 6%, P12: 10%), amniotic fluid containing meconium (P6: 0%, P12: 1.8%) and APGAR 5' < 7 (P12 and P6: 3.6% both).

▶**Table 2** Course of birth and neonatal outcome.

	P12		P6		
	N	median (IQR) or n (%)	N	median (IQR) or n (%)	p-value
Course of birth					
Continuation of induction	109	102 (93.6%)	139	130 (93.5%)	1
Dinoproston vaginal insert	108	27 (25%)	137	29 (21.2%)	0.578
Misoprostol oral	108	73 (67.6%)	139	92 (66.2%)	0.923
▪ misoprostol [number of doses]		3 (2–4)		2 (2–4)	0.12
▪ misoprostol [dose µg]		250 (150–350)		175 (150–350)	0.132
Amniotomy	109	6 (5.5%)	139	15 (10.8%)	0.21
Epidural anaesthesia	109	52 (47.7%)	138	53 (38.4%)	0.181
Delivery					
Suspicious CTG sub partu	109	36 (33%)	139	46 (33.1%)	1
Position	108		137		0.573
▪ regular cranial position		101 (93.5%)		124 (90.5%)	
▪ irregular cranial position		5 (4.6%)		11 (8%)	
▪ breech position		2 (1.9%)		2 (1.5%)	
Oxytocin sub partu	109	62 (56.9%)	139	66 (47.5%)	0.18
Delivery mode	109		138		0.572
▪ spontaneous		66 (60.6%)		88 (63.8%)	
▪ vaginal operative		14 (12.8%)		12 (8.7%)	
▪ CS		29 (26.6%)		38 (27.5%)	
Indication for CS	41		44		0.41
▪ protracted ES		6 (14.6%)		2 (4.6%)	
▪ suspicious CTG		22 (53.7%)		26 (59.1%)	
▪ birth arrest DS		8 (19.5%)		7 (15.9%)	
▪ birth arrest in ES		5 (12.2%)		8 (18.2%)	
Blood loss	108	500 (300–600)	138	400 (300–600)	0.836
Uterine rupture	109	0 (0%)	139	1 (0.7%)	1
Neonatal outcome					
Meconium stained amniotic fluid	109	2 (1.8%)	139	0 (0%)	0.192
Birth weight	109	3430 (2995–3850)	139	3480 (3055–3910)	0.126
▪ SGA		15 (13.89%)		15 (10.95%)	
▪ AGA		78 (72.22%)		96 (70.07%)	
▪ LGA		15 (13.89%)		26 (18.98%)	
APGAR 1 min	109	9 (8–9)	139	9 (8–9)	0.349
APGAR 5 min	109	9 (9–10)	139	9 (9–10)	0.877
APGAR 10 min	109	10 (10–10)	139	10 (10–10)	0.332
UA ph	107	7.21 (7.16–7.28)	139	7,23 (7,17–7,27)	0.711
▪ UA ph < 7.1		11 (10.3%)		9 (6.5%)	0.397
Base excess	106	− 3.5 (− 6.5–− 1.4)	137	− 4 (− 6.2–− 1.5)	0.695
Transfer NICU	109	11 (10.1%)	139	14 (10.1%)	1

AGA = appropriate for gestational age; CS = caesarean section; CTG = cardiotocography; DS = dilation stage; ES = expulsion stage; IQR = interquartile range; LGA = large for gestational age; N = Number of cases; n = Number of cases with information; NICU = neonatal intensive care unit; P6/P12 = balloon placement 6 and 12 h; SGA = small for gestational age; UA = umbilical artery



▶ **Fig. 2** Proportions of undelivered birthing persons. **a** After induction of labour with double balloon catheter, **b** after first prostaglandin administration.

Discussion

We were able to show that reducing the duration of the double balloon catheter placement by six hours led to a more effective induction of labour, as indicated by a reduction in induction to delivery interval of an additional three hours to the shortened 6-hour double balloon catheter placement duration. We found this effect in both primi- and multiparous women, as well as in deliveries with and without previous caesarean section. The Prostaglandin-to-Delivery-Interval was also significantly reduced by more than four hours in multiparous women. Shortening of the induction to delivery interval was not associated with a higher rate of additional necessary sequential drug induction or more surgical deliveries, and there are no differences in the maternal and neonatal safety parameters studied.

Induction of labour is the most common obstetric intervention in Germany, accounting for more than 20% of inductions [1]. Mechanical induction using double balloon catheter is a routine procedure that has been clinically established for many years. Equivalent effectiveness and safety have been demonstrated for double balloon placement for 12 and 24 hours. Recent studies have reported comparable effectiveness even when the duration of placement was shortened to 6 hours [18, 19].

This effect can be explained by a higher endogenous prostaglandin release and a greater sensitivity to exogenous prostaglandins [25, 26].

The comparable studies by Bleicher et al. [18] and Lassey et al. [19] do not provide information on the timing of onset of the induction of labour. In our clinic, the start of the IOL using the double balloon catheter was changed from the evening hours at 8 pm for 12 hours to the morning at 8 am for 6 hours, so that the women were spared nighttime induction of labour. This adds valuable new insights to the previous work of Kehl et al. [27]. They found the evening application of the double balloon catheter with planned administration of misoprostol by maintaining the placement time to be favourable. In our clinical experience, overnight balloon induction often leads to sleep deprivation and early exhaustion caused by the onset of uterine contractions. A morning induction lasting only 6 hours could prevent this nighttime exhaustion and thus have a positive influence on the duration of induction. As a result, women and midwives may be more accepting and satisfied with their choice of induction method. While we did not extensively assess this aspect during our study, we received similar feedback at our centre subsequent to the transition to the 6-hour placement regimen in clinical practices.

Our study's primary emphasis rested on the evaluation of clinical feasibility. Consequently, we intentionally excluded the prospect of conducting a randomized trial, notwithstanding its inherent advantages. The strategic decision to implement the modification in double balloon catheter placement duration after a span of 6 months served as a foundational step in ensuring the comparability of our study cohorts. This assertion was substantiated through statistical comparisons encompassing anamnestic profiles, pregnancy, delivery, and neonatal outcomes. Particularly, this fostered the hypothesis that the use of supplementary sequential IOL methods (dinoprostone, misoprostol, and amniotomy) are equally safe and efficient for both maternal and neonatal well-being in both study cohorts. This confirms prior findings of improved efficacy by combining oral misoprostol and mechanical dilation [28].

Several considerations come into play when determining the optimal approach for labour induction [7, 27]. To include women with multiple pregnancies as well as prior caesarean section into our study cohort, was giving tribute to the clinical reality and contributes novel insights to existing literature. Our findings confirm the safety of mechanical induction of labour among women with prior caesarean section [29] within our study cohort, even when followed by vaginal prostaglandin application.

This study has some limitations such as a monocentric approach and unblinded design of the participants and study personnel. The strength of our study is the real-world design in daily clinical practice in a delivery ward, together with an intention-to-treat analysis. During the study period, the SOPs were not changed for obstetric practice and in clinical matters other than the study protocol.

Conclusion

We were able to demonstrate the superiority of shortening the duration of a double balloon catheter placement to six hours, both from the point of view of the women in terms of reducing the induction to delivery time by around 9 hours and from the point of view of hospital management, by optimizing procedures with comparable patient safety. As a result, the shortened procedure described above has been introduced into our clinical routine as SOP.

Clinical Trial

Registration number (trial ID): NCT05874024

Contributors' Statement

AK and ES developed the research question and study design.
YH and AK wrote the study and statistical analysis protocol and case report form. LS and AK were responsible for recruitment and data collection. YH and LS analysed the data. All authors participated in the drafting of this article.

Acknowledgement

The authors are particularly grateful for the support of the doctors and midwives in the delivery room, without whose help this study would not have been possible. Special thanks to Dr. Andrew Heidel for linguistic review and editing of the manuscript.

Conflict of Interest

The authors declare that they have no conflict of interest.

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