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Prospective comparison of cervical ripening with double balloon Cook catheter, misoprostol or dinoprostone in term singleton pregnancies

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ABSTRACT

Objectives: Induction of labor is indicated if the risk of continuing pregnancy is higher (either for fetus or mother) than the risk associated with the induction itself. The purpose of the present study was to compare the effectiveness of the double balloon Cook catheter and pharmacological preparations — prostaglandins (PGE), in our case it was misoprostol (PGE1) or dinoprostone (PGE2) for cervical ripening in pregnant women with gestational age at term.

Material and methods: The prospective observational study was conducted from March 2017 to December 2018. We used mechanical and pharmacological methods for cervical ripening. We compared the efficiency of methods and time to delivery from start of cervical ripening. We also evaluated the neonatal complications by Apgar score and neonatal intensive care unit admission in three different groups.

Results: Two hundred and nine women were chosen for cervical ripening. Double balloon Cook catheter and misoprostol were equally efficient in achieving vaginal delivery (76%). The shortest time for cervical ripening and successful vaginal delivery was shown in misoprostol (PGE1) group. In conclusion, no significant differences were found between groups in all neonatal outcomes.

Conclusions: Currently, many methods of delivery preinduction exist and the prevalence of their usage varies considerably between countries. As yet, there is no literature comparing these three methods for the preparation of cervix.

Key words: Bishop score; cervical ripening; prostaglandins

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INTRODUCTION

Induction of labor is one of the most common obstetric interventions. Its incidence is increasing worldwide [1]. The International Institute for Health and Care Excellence (NICE) from 2015 states that around 20% of women in the UK undergo the induction of labor each year [2]. Between 1990 and 2018, the overall frequency of induction of labor in the United States almost tripled, increasing from 9.5% in 1990 to 27.1% in 2018 [3].

At our department the average frequency of labor induction varied between 20–22% during last ten years.

Recent evidence shows that elective labor induction at term in low-risk nulliparous women is associated with lower risk of caesarean delivery, with no increase in adverse perinatal comorbidities [4]. Cervix maturation is a key to successful induction of labor. In absence of mature cervix, successful vaginal delivery is less likely [5]. To increase the success of vaginal delivery in adverse vaginal findings (usually defined as Bishop score < 6), we use effective mechanical and pharmacological methods. The use of oxytocin or artificial rupture of the membranes (ARM) is less likely to induce labor successfully in the absence of a favorable cervix. In such circumstances cervical ripening methods that soften, thin, and dilate the cervix are often needed to induce labor [6]. The ideal substance for cervical ripening should be effective, safe and easy to use [7].

Currently, many methods of delivery preinduction exist, and the prevalence of their usage varies considerably between countries. The purpose of the present single center prospective observational study was to compare the effectiveness of the double balloon Cook catheter with pharmacological preparations — prostaglandins, in our

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Table 1. Indications — Comparison by Fisher's exact test

	Group	
	Cervical ripening	
	Count	%
Post-term pregnancy	66	31.58%
Growth restriction	36	17.22%
Pregestational DM	2	0.9%
Gestational DM	33	15.79%
Chronic hypertension	5	2.3%
Gestational hypertension	30	14.35%
Pre-eklampsia	13	5.9%
Intrahepatic cholestasis	7	3.2%
HDFN	23	10.5%
Stillbirth	5	2.3%
SGA	9	4.1%
Programmed childbirth	10	4.6%
Previous cesarean delivery	19	9.1%

case it was misoprostol (PGE1) or dinoprostone (PGE2) for cervical ripening in pregnant women with gestational age at term. As yet, there is no literature comparing these three methods for the preparation of cervix.

MATERIAL AND METHODS

In 2017 the double balloon Cook catheter was introduced to our clinical practice.

The aim of this prospective observational study was to show the non-inferiority of the double balloon Cook catheter compared to our standard of care represented by pharmacological methods. All eligible singleton pregnancies were grouped into double balloon Cook group (n = 72), misoprostol group (n = 67) and dinoprostone group (n = 70).

The study was approved by the Ethical Committee of University Hospital Olomouc. The informed consents were obtained from all participants before cervical ripening.

The study included 230 singleton pregnancies in the third trimester without signs of labor. Inclusion criteria were as follows: (1) 18–46 years old; (2) 37 + 0 to 42 + 1 weeks of pregnancy; (3) cervical Bishop score < 6; (4) singleton pregnancy; (5) head presentation; (6) no premature rupture of membranes; (7) physiological cardiotocograph monitoring before cervical ripening. The exclusion criteria were as follows: (1) any contraindication for vaginal delivery; (2) fetal anomaly; (3) multiple gestations; (4) non cephalic presentation; (5) history of two or more caesarean sections; (6) planned caesarean deliveries.

Pregnant women with the indication of a dead fetus and pregnant women with premature outflow of amniotic fluid before the due date were excluded from the study. Out of a total of 230 pregnant women, 209 women continued the study.

Two hundred and nine pregnant women in our study were fully informed of the advantages and disadvantages of diferent methods of cervical ripening.

According to the hospital protocol, all procedures were documented and the choice of pharmacological cervical ripening agent was made by individual provider, which resulted in an even distributive of both pharmacological agents in our study population. (dinoprostone in 33.49%, n = 70, misoprostol in 32.06% of cases, n = 67)

For high-risk pregnant women with a history of previous caesarean section, fetuses with growth restriction, small fetuses and suspect cardiotocograph monitoring cases we chose mechanical method, represented by double balloon Cook catheter (n = 72, 34.45% of cases).

In pregnant women with normal cardiotocograph monitoring, obese women, women with simple postmaturity, gestational hypertension, gestational diabetes mellitus, pre-eclampsia we chose one of two pharmacological methods.

The most common indications for cervical ripening were: postmaturity in 31.58% (n = 66), associated indications (2 or more) in 20.1% (n = 42), fetal growth restriction in 17.22% (n = 36), gestational diabetes mellitus in 15.79% (n = 33), gestational hypertensive disease in 14.35% (n = 30) and conditions after previous caesarean section in 9,1% (n = 19) (Tab. 1).

The double balloon Cook catheter was inserted into the cervix, each balloon on external and internal os was instilled with normal saline (80 mL). The proximal end of catheter was fixed to patient's thigh. If the spontaneous expulsion of catheter did not happen 24h after insertion, the catheter was removed artificially and Bishop score was assessed [8].

The vaginal insert misoprostol (PGE1) in dose of 200 µg withdrawal tape, was placed high in the vaginal posterior fornix and left there for a maximum of 24h, with a release rate of approximately 7 µg/h. The vaginal insert was removed with the onset of active labor (≥ 3 regular contractions/10 min) or painful contractions, cervical dilation of 2 cm or after the completion of maximum insertion time of 24 h [9].

Dinoprostone (PGE2) was inserted at the starting dose of 3 mg (1 tablet) high into the posterior vaginal arch. The second tablet was introduced after 6–8 hours if labor did not occur. The maximum daily dose was 6 mg.

Statistical analysis

quantitative data were expressed as mean, standard deviation (SD), minimum and maximum, and median. Due to big range of samples, the comparison of two independent samples in quantitative quantities was performed using two-sample t-tests. Comparison of several independent groups was per-

Table 2. Results of Kruskala-Wallis for maternal characteristics — age, body mass index (BMI), parity, epidural analgesia and success of vaginal labor

		Methods of cervical ripening						p
		Double balloon Cook catheter (n = 72)		Misoprostol (n = 67)		Dinoprostone (n = 70)		
		Count	%	Count	%	Count	%	
Age	< 35	48	66.70%	52	77.60%	52	74.30%	0.246[a]
	35–40	18	25.00%	14	20.90%	16	22.90%	
	> 40	6	8.30%	1	1.50%	2	2.90%	
BMI	< 25	47	65.30%	39	58.20%	36	51.40%	0.198[a]
	25–29.9	15	20.80%	19	28.40%	18	25.70%	
	30–34.9	7	9.70%	4	6.00%	10	14.30%	
	> = 35	3	4.20%	5	7.50%	6	8.60%	
Parity	0	37	51.40%	49	73.10%	47	67.10%	0.013[a]
	1	23	31.90%	15	22.40%	16	22.90%	
	2	10	13.90%	3	4.50%	5	7.10%	
	3	1	1.40%	0	0.00%	2	2.90%	
	4	1	1.40%	0	0.00%	0	0.00%	
Epidural analgesia	NO	36	50.00%	32	47.80%	36	51.40%	0.910[b]
	YES	36	50.00%	35	52.20%	34	48.60%	
Delivery	SC	17	23.60%	16	23.90%	28	40.00%	0.168[b]
	vaginal	50	69.40%	44	65.70%	38	54.30%	
	VEX	5	6.90%	7	10.40%	4	5.70%	

formed (due to big differences in file sizes) by non-parametric Kruskal-Wallis ANOVA. The correlation of quantitative quantities was verified by Pearson's correlation coefficient. Comparison of groups in qualitative quantities was performed using Fisher's exact test. The probability of vaginal delivery in time was plotted by using Kaplan-Meier curves. All tests were performed at the level of statistical significance of 0.05. IBM SPSS Statistics for Windows, Version 23.0 Armonk, NY: IBM Corp. statistical software was used for statistical processing.

RESULTS

From March 2017 to December 2018 we proceeded to cervical ripening in 209 women (4.8% out of all deliveries). With respect to gestational age in our study group 41 patients (19.62%) were in 37 weeks of pregnancy, 37 patients (17.7%) were in 38 weeks of pregnancy, 31 patients (14.83%) were in 39 weeks of pregnancy, 38 patients (18.18%) were in 40 weeks of pregnancy, 66 patients (31.58%) were in 41 weeks of pregnancy and one patient (0.48%) was in 42 weeks of pregnancy.

Seventy-two patients (34.45%) were allocated to the double balloon Cook catheter group, 70 patients (33.49%) into the dinoprostone (PGE2) group and 67 patients (32.06%) to misoprostol (PGE1) groups respectively. The demographic characteristics of the groups are shown in Table 2.

In double balloon Cook catheter group 48 patients (66.7%) were younger than 35 years, 18 patients (25.0%) were in the age group 35–40 years and 6 women (8.3%) were older than 40 years.

In misoprostol (PGE1) group 52 women (77.6%) were younger than 35 years. Between 35–40 years were 14 women (20.9%) and 1 woman was older 40 years (1.5%).

In Dinoprostone (PGE2) group 52 patients (74.3%) were younger 35 years, 16 patients (22.9%) were in the group 35–40 years and 2 women were older 40 years (2.9%).

The mean age of women was 31 (SD ± 5.31) years. There was no statistically significant difference in age categories between groups.

In double balloon Cook catheter group 47 patients (65.3%) had Body Mass Index (BMI) under 25 years old, 15 patients between 25–29.9 (20.8%), 7 patients (9.7%) between 30–34.9 and three patients (4.2%) had BMI 35 or more.

In misoprostol (PGE1) group 39 women (58.2%) had BMI under 25, nineteen women (28.4%) betweeen 25–29.9, 4 patients (6.0%) between 30–34.9 and 5 patients (7.5%) BMI 35 or more.

In dinoprostone (PGE2) group 36 women (51.4%) had BMI below 25 years old, 18 women (25.7%) between 25–29.9 years old, 10 women (14.3%) between 30–34.9 and 6 women (8.6%) 35 or more. Mean BMI was

Table 3. The time periods from the start of cervical ripening to first contractions (hours)

		The time from the start of cervical ripening to the start of first contraction (hours)					p
		Mean	SD	Minimum	Maximum	Median	
Methods of cervical ripening	Double ballon Cook catheter	22.89	14.28	4.00	76.00	23.25	0.005
	Misoprostol	15.68	11.03	3.50	47.50	13.25	
	Dinoproston	22.06	17.35	4.00	72.00	15.00	

The Kruskal-Wallis test showed statistically significant differences, p = 0.005. Subsequent post hoc tests with Bonferroni correction showed that there was a statistically significant difference only between the double balloon Cook catheter and misoprostol groups, p = 0.003.
The differences between the other pairs of groups are statistically insignificant

25.29 (SD ± 5.86). There was no statistically significant difference in age categories between groups. Mean gestation age at cervical ripening was 39.44 (SD ± 2.0 weeks).

In double balloon Cook catheter group 37 women (51.4%) were nulliparous, rest of cases were multiparous (n = 35, 48.6%).

In misoprostol (PGE1) group 49 patients (73.1%) had first pregnancy, in 18 cases (26.9%) it was a repeated pregnancy.

In dinoprostone (PGE2) group 47 women (67.1%) were nulliparous, rest of cases were multiparous (n = 23, 32.9%). There was statistically significant difference in age categories between groups — nulliparity and multiparity. (p = 0.013).

An epidural catheter was used in 105 cases (50.2%). In double balloon catheter group epidural catheter was inserted in 36 women (50.0%), of them 28 women (77.8%) had vaginal delivery, 6 women (16.7%) had caesarean section and 2 women (5.5%) operative delivery. In misoprostol (PGE1) group an epidural catheter was inserted in 35 women (52.2%), of them 23 women (65.7%) gave birth vaginally, 8 women (22.9%) had caesarean section and 4 women (11.4%) had operative delivery. In Dinoprostone (PGE2) group 34 women (48.6%) were treated with epidural analgesia (EDA), of them 18 patients (52.9%) gave birth vaginally, 12 patients (35.3%) by caesarean section and 4 patients (11.8%) by extraction vaginal delivery. The relationship between preinduction methods and EDA has not been shown.

We also chose a double-balloon Cook catheter in 26 cases of cervical ripening due to growth restriction of the fetus, where 23 women (88.5%) gave birth by vaginal delivery, 3 women by caesarean section (11.5%), also in conditions after caesarean section (n = 15), where 8 women gave birth spontaneous (53.3%) and 7 women had a caesarean section (46.7%).

There were no signifcant diferences in the spontaneous delivery rate in groups treated with different methods double balloon Cook catheter/misoprostol(PGE1)/dinoprostone (PGE2) (76.3% vs 76.1% vs 60%, p = 0.168) — or in rates of caesarean section (23.6% vs 23.9% vs 40.0%, p = 0.168).

Time to the first contractions from start of cervical ripening shows Table 3 and Figure 1. The Kruskal-Wallis test

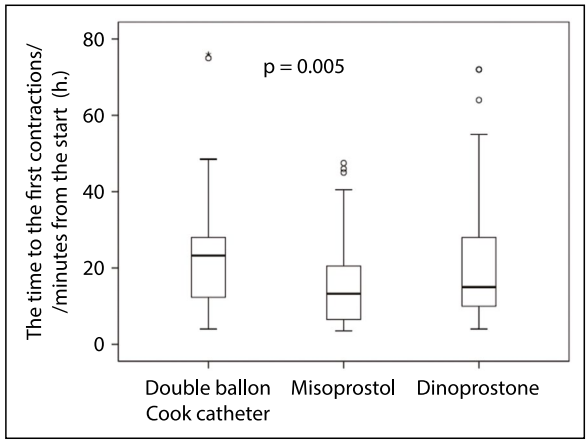

Figure 1. The time to the first contractions from the start in minutes
The distribution of the measured values was shown by a box graph. The horizontal line in the box shows the median value, the lower edge of the box the value of the 1st quartile (25th percentile), the upper edge the value of the 3rd quartile (75th percentile). The terminals show the maximum and minimum measured values. Outliers (values that are more than 1.5 times the interquartile range from the quartiles) are plotted in circles. Extremes (values that are more than 3 times the interquartile range from the quartiles) are plotted with asterisks

showed statistically significant differences, p = 0.005. Subsequent post hoc tests with Bonferroni correction showed that there was a statistically significant difference between the double balloon Cook catheter and misoprostol groups, p = 0.003. Dunn's test showed that time to delivery in double balloon Cook group (mean = 29.2 hours, median = 28.0 hours) was not different from the time in dinoproston group (mean 28.5 hours, median = 24.0 hours), but was longer than in misoprostol group (mean = 20.4 hours, median = 17.0 hours), p = 0.001 (Tab. 4 and Fig. 2).

Generally perceived advantages of mechanical methods over pharmacological ones include comparable efficacy, low risk of uterine hyperstimulation and fetal hypoxia, low risk of side effects such as nausea, vomiting, diarrhea, fever and potential economic and storage benefits [10, 11]. Side effects did not occur in our study.

Maternal complications or discomfort of mothers during cervical maturation with double balloon Cook catheter

Table 4. The time to delivery from start of cervical ripening (hours)

		Time to delivery from start of cervical ripening (hours)					p value
		Mean	SD	Min	Max	Median	
Methods of cervical ripening	Double balloon Cook catheter	29.19	14.85	4.50	77.00	28.00	0.001[d]
	Misoprostol	20.41	12.26	3.00	53.50	17.00	
	Dinoprostone	28.48	20.47	4.00	96.00	24.00	

Results of Kruskala-Wallis for time to delivery from start of cervical ripening. There was a statistically significant dependence of time to delivery on the methods of preinduction (p = 0.001)

were reported only in one percent of women. Postpartum infectious complications were not observed in any of the mothers. No cases of uterine rupture occurred during our study, but we reported three cases of scar dehiscence after catheter insertion were described perioperatively (0.5%) (Tab. 2).

As regards neonatological results in double balloon Cook catheter group the mean of birth weight was 2893 grams (g), median = 2930 g, in misoprostol group the mean of birth weight was 3383 g, median = 3440 g, in dinoprostone group the mean of birth weight was 3432 g, median = 3455 g (Tab. 3). There was a statistically significant difference between the groups due to preinduction of labor in small fetuses and fetuses with growth restriction by double balloon Cook catheter.

The median of pH of umbilical cord blood did not differ between groups (Tab. 5). Clinical status of newborns expressed as percentage of neonatal intensive care admissions did not differ between groups. We also evaluated the neonatal complications by Apgar score and neonatal intensive care unit admission in three different groups and no differences were found. In conclusion no significant differences were found between groups in all neonatal outcomes.

Comparison of mechanical (double-balloon Cook catheter) and pharmacological method — misoprostol (PGE1) revealed the same success of vaginal delivery (76.3% vs 76.1%), but more complications occurred with use of a pharmacological preparation due to more frequent occurrence of uterine hyperstimulation (n = 5, 2.39%) and fetal hypoxia (n = 31, 14.83%).

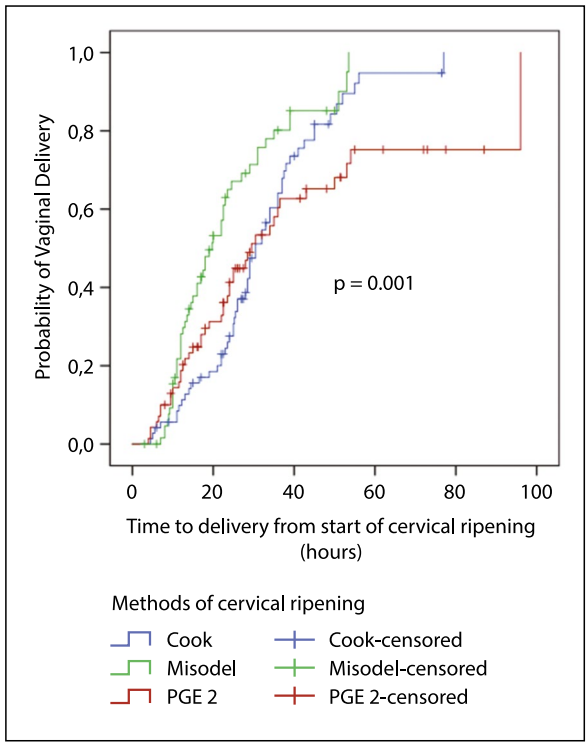

Figure 2. Kaplan-Meier curves ilustrating time to delivery from start of cervical ripening in hours

DISCUSSION

This prospective observational single-center study focuses on obstetrical and neonatal outcomes after cervical ripening with double balloon Cook catheter, misoprostol and dinoprostone and compares their efficacy and probability of vaginal delivery. Induction of labor is indicated if the risk of continuing of pregnancy is higher (either for fetus or for mother) than the risk associated with the induction itself [12].

Induction of vaginal delivery is generally associated with a decrease in caesarean sections regardless of gestational week, parity, or evaluation of vaginal findings. Maternal results reported fewer infectious complications, shoulder dystocia, and perineal injuries. Neonatal morbidity was reduced in induced births between 38 and 40 weeks [13]. The published work from 2017 states that induction of childbirth after the 39th week can reduce the risk of stillbirth. On the other hand, induction may be associated with increased hospitalization costs, reduced patient satisfaction, and slower onset of breastfeeding [14].

The use of cervical maturation methods has been shown to reduce the necessity of caesarean section when compared to initiating oxytocin induction in women with unfavorable cervix [15]. Induction of labor in the terrain of unfavorable cervix is associated with prolonged labor when compared to spontaneous onset of labor or induction of labor in a favorable cervix [16, 17].

Several methods have been proposed for cervical maturation, which are mainly divided into two groups —

Table 5. Newborns' characteristics and methods of cervical ripening

	Methods of cervical ripening															p
	Double balloon Cook (n = 70)					Misodel (n = 65)					PGE 2 (n = 70)					
	Mean	SD	Min	Max	Median	Mean	SD	Min	Max	Median	Mean	SD	Min	Max	Median	
birth weight (g)	2950	567	1940	4050	2945	3409	469	2200	4700	3440	3432	531	2340	4660	3455	< 0.0001
APGAR 1	9.09	1.73	1.00	10.00	10.00	9.25	1.48	4.00	10.00	10.00	9.07	1.54	3.00	10.00	10.00	0.564
APGAR 5	9.71	0.84	6.00	10.00	10.00	9.80	0.81	4.00	10.00	10.00	9.84	0.63	6.00	10.00	10.00	0.538
APGAR 10	9.96	0.20	9.00	10.00	10.00	9.98	0.12	9.00	10.00	10.00	10.00	0.00	10.00	10.00	10.00	0.180
PH	7.24	0.09	6.98	7.40	7.24	7.23	0.09	7.00	7.44	7.24	7.24	0.09	7.09	7.59	7.25	0.633
Lactate	5.06	2.19	0.40	10.90	4.70	5.05	2.54	0.50	11.80	4.40	4.66	2.02	0.50	9.60	4.50	0.663

Children born by the double balloon Cook method had significantly lower weight than newborns born by the misoprostol and dinoprostone methods ($p < 0.0001$)

mechanical and pharmacological. The ideal method should not be associated with adverse side effects neither in mother nor in fetus during cervical preparation 18].

The safety of prostaglandins for induction of labor in women with a preceding caesarean section has been questioned [19]. In 2001, Lydon Rochelle et al. described significantly more cases of uterine rupture in women whose birth was induced by prostaglandins after a prior caesarean section. Balloon catheters have been shown to be effective and safe even in women with a history of past caesarean section. According to Scandinavian authors in the publication from 2019, the success rate of vaginal delivery (using this method) ranges between 55.7–71.0% [20].

In our study, double balloon Cook catheter was most often used in the following indications: history of previous cesarean section (n = 19), intrauterine fetal growth restriction (n = 36). Our data showed 76.3% success rate of vaginal delivery (including extraction delivery). Spanish authors of a retrospective cohort study from 2017 state a 75.86% success rate of vaginal delivery in women with fetal growth restriction [21]. Our data showed 88.5% success rate of vaginal delivery in cases with fetal growth restriction, although this was a small subgroup.

A 2020 meta-analysis comparing vaginal misoprostol, dinoprostone, and a balloon catheter in small fetuses and growth-restricted fetuses states that mechanical methods are associated with lower incidence of adverse outcomes during pregnancy. However, there is limited evidence of the optimal type of labor induction in pregnancies with small fetuses [22].

Another parameter was the evaluation of the time from the start of induction to delivery.

In our study, the time from insertion of a double balloon Cook catheter to delivery was 29.19 ± 14.85 hours and sucess of vaginal delivery was 76%.

According to Chinese authors in a randomized study from 2019, time from double balloon catheter insertion to delivery was 21.8 ± 9.8 hours and success of vaginal delivery within 24 h from catheter insertion 52.8%, and within 48 h from catheter insertion 64.2% [8]. There was a significant difference in the time from double balloon catheter insertion to delivery due to the different length of catheter retention in situ. Chinese authors inserted the catheter for 12 hours, while we inserted it for 24 hours, but with higher success rate of vaginal labour.

Peng and al. in their retrospective study from 2021 compared the effects of double-balloon catheter within 12 h and within 12–24 h for the induction of labour in mid-trimester pregnancy. They found that the success rate of induction of labour was higher in the double balloon catheter group within 12–24 h (96.3%, 29/31) than in the double balloon catheter group within 12 h (71.0%, 18/27). Authors stated the time from induction to delivery in the 24h group was shorter than that in the 12 h group (median time, 27.0 h vs 29.8 h), but the difference was not statistically significant ($p > 0.05$). However, the time from double balloon catheter removal to delivery in the 12 h group (median time, 17.8 h) was longer than that in the 24 h group (median time, 3.0 h), indicating a significant difference ($p < 0.05$) [23].

Prostaglandins are the most used pharmacological agents in labor induction. Misoprostol (PGE1) and dinoprostone (PGE2) were shown to be equally effective in delivering success in case of preinduction. It is generally known that the use of PGE is associated with higher risk and earlier onset of uterine hyperstimulation and adverse changes in fetal heart rate [24].

Misoprostol is an often-used synthetic analog of PGE1 due to its low cost and ease of storage. Several publications have shown that the vaginal route of misoprostol is an effective method of inducing vaginal delivery comparable to oxytocin [25]. In the retrospective cohort study from 2020, Gornisiewicz et al. showed the success rate of vaginal delivery in 68.8% cases and time from vaginal misoprostol application to delivery to be 14.5 hours [26].

In our study, vaginal misoprostol (PGE1) administration resulted in successful vaginal delivery in 75.1% of cases ($p = 0.168$), and the time to delivery was 20.44 hours.

In the retrospective observational study of Mlodawski et al. [27] patients with misoprostol vaginal insert had significantly higher risk of caesarean section when compared to a Foley catheter cervical ripening (45.19% vs 27.72%, $p < 0.001$). The most common indication for operative delivery was, in cases of misoprostol use, nonreassuring fetal heart rate tracing.

Also, Nazanin et al. in a randomized controlled trial from 2021 described higher vaginal delivery success in Foley catheter group when compared to vaginal misoprostol group (85.0% vs 73.3%).

In their retrospective cohort study, Gornisiewicz et al. [26], authors reported 76.9% probability of vaginal delivery with dinoprostone gel use and time from drug application to delivery (vaginal and caesarean section) to be 35.6 hours.

In our study the success rate of vaginal delivery using dinoprostone tablets was 60% and time to delivery was 28.48 hours. In contrast with Gornisiewicz et al., where they were using dinoprostone gel, delivery success was highter in compare with our dinoprostone tablet.

According to Scottish authors from 2004, who compared dinoprostone gel with dinoprostone tablets, the success rate of vaginal delivery was equal (55.9% vs 50.3%) and time from start of induction to delivery was 25.2 hours versus 25.7 [28].

Papanikolaou et al. showed in misoprostol group more women delivered within 12 h in compared with dinoprostone tablets group (57.5% vs 32.5%, $p < 0.01$). The induction-delivery interval was significantly shorter in the misoprostol group (11.9 h vs. 15.6 h, $p < 0.001$) [29].

In case of cervical ripening with dinoprostone, this method proved to be the least effective of all methods, because it led to more frequent caesarean deliveries (60% vaginal delivery versus 40% caesarean section).

Our results in misoprostol and dinoprostone group correspond to the data published.

In our study we have shown double balloon Cook catheter to have comparable results in labor induction as pharmacological agents (commonly used prostaglandins — dinoprostone, misoprostol).

CONCLUSIONS

We have shown, that double baloon catheter is safe and effective method in labor induction. The time to first contractions with double balloon catheter and the time to delivery was equal to results of dinoprostone group, but longer than in misoprostol group. Hovewer, the indications for double balloon catheter clinical use were different from pharmacological methods. We did not observe any maternal and neonatological complications during the study. The aim of study was to show the advantage of mechanical double balloon catheter in labor induction in specificy subgroups of patients (growth restriction, uterine scar), further studies are needed.

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Conflict of interest

The authors declare no conflict of interest.

REFERENCES

1. Stock SJ, Calder A. Induction of labour. In: Arulkumaran S, Robson MS. ed. Munro Kerr's Operative Obstetrics. 12th ed. Philadelphia: Elsevier Saunders, Phildelphia 2014.
2. Hawkins JS, Wing DA. Current pharmacotherapy options for labor induction. Expert Opin Pharmacother. 2012; 13(14): 2005–2014, doi: 10.1517/14656566.2012.722622, indexed in Pubmed: 22963686.
3. Martin JA, Hamilton BE, Osterman MJK, et al. Births: final data for 2018. Natl Vital Stat Rep. 2019; 68(13): 1–47, indexed in Pubmed: 32501202.
4. Grobman WA, Grobman WA, Rice MM, et al. Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network. Labor induction versus expectant management in low-risk nulliparous women. N Engl J Med. 2018; 379(6): 513–523, doi: 10.1056/NEJMoa1800566, indexed in Pubmed: 30089070.
5. Tenore JL. Methods for cervical ripening and induction of labor. Am Fam Physician. 2003; 67(10): 2123–2128, indexed in Pubmed: 12776961.
6. Xenakis E, Piper J, Conway D, et al. Induction of labor in the nineties: Conquering the unfavorable cervix. Obstetrics & Gynecology. 1997; 90(2): 235–239, doi: 10.1016/s0029-7844(97)00259-7, indexed in Pubmed: 9241300.
7. Abdelaziz A, Mahmoud AA, Ellaithy MI, et al. Pre-induction cervical ripening using two different dinoprostone vaginal preparations: A randomized clinical trial of tablets and slow release retrievable insert. Taiwan J Obstet Gynecol. 2018; 57(4): 560–566, doi: 10.1016/j.tjog.2018.06.016, indexed in Pubmed: 30122579.
8. Xing Y, Li Na, Ji Q, et al. Double-balloon catheter compared with single-balloon catheter for induction of labor with a scarred uterus. Eur J Obstet Gynecol Reprod Biol. 2019; 243: 139–143, doi: 10.1016/j.ejogrb.2019.10.041, indexed in Pubmed: 31704530.
9. Redling K, Schaedelin S, Huhn EA, et al. Efficacy and safety of misoprostol vaginal insert vs. oral misoprostol for induction of labor. J Perinat Med. 2019; 47(2): 176–182, doi: 10.1515/jpm-2018-0128, indexed in Pubmed: 30179853.
10. Jozwiak M, Bloemenkamp KWM, Kelly AJ, et al. Mechanical methods for induction of labour. Cochrane Database Syst Rev. 2012(3): CD001233, doi: 10.1002/14651858.CD001233.pub2, indexed in Pubmed: 22419277.
11. Gupta J, Chodankar R, Baev O, et al. Synthetic osmotic dilators in the induction of labour - An international multicentre observational study. Eur J Obstet Gynecol Reprod Biol. 2018; 229: 70–75, doi: 10.1016/j.ejogrb.2018.08.004, indexed in Pubmed: 30107363.
12. Levine LD, Valencia CM, Tolosa JE. Induction of labor in continuing pregnancies. Best Pract Res Clin Obstet Gynaecol. 2020; 67: 90–99, doi: 10.1016/j.bpobgyn.2020.04.004, indexed in Pubmed: 32527660.
13. Gibson KS, Waters TP, Bailit JL. Maternal and neonatal outcomes in electively induced low-risk term pregnancies. Am J Obstet Gynecol. 2014; 211(3): 249.e1–249.e16, doi: 10.1016/j.ajog.2014.03.016, indexed in Pubmed: 24631440.
14. Little SE. Elective induction of labor: what is the impact? Obstet Gynecol Clin North Am. 2017; 44(4): 601–614, doi: 10.1016/j.ogc.2017.08.005, indexed in Pubmed: 29078942.
15. Levine LD. Cervical ripening: Why we do what we do. Semin Perinatol. 2020; 44(2): 151216, doi: 10.1016/j.semperi.2019.151216, indexed in Pubmed: 31813539.

16. Villalain C, Quezada MS, Gómez-Arriaga P, et al. Prognostic factors of successful cervical ripening and labor induction in late-onset fetal growth restriction. Fetal Diagn Ther. 2020; 47(7): 536–544, doi: 10.1159/000503390, indexed in Pubmed: 31838473.
17. Ten Eikelder MLG, Neervoort F, Oude Rengerink K, et al. Induction of labour with a Foley catheter or oral misoprostol at term: the PROBAAT-II study, a multicentre randomised controlled trial. BMC Pregnancy Childbirth. 2013; 13: 67, doi: 10.1186/1471-2393-13-67, indexed in Pubmed: 23506128.
18. Razavi M, Farzaneh F. Comparison of the three methods of syntocinon, misoprostol, transcervical catheter plus syntocinon in labor induction. Zahedan J Res Med Sci. 2020; 22(2): e90332, doi: 10.5812/zjrms.90332.
19. Jozwiak M, van de Lest HA, Burger NB, et al. Cervical ripening with Foley catheter for induction of labor after cesarean section: a cohort study. Acta Obstet Gynecol Scand. 2014; 93(3): 296–301, doi: 10.1111/aogs.12320, indexed in Pubmed: 24354335.
20. Huisman CMA, Ten Eikelder MLG, Mast K, et al. PROBAAT-S project group. Balloon catheter for induction of labor in women with one previous cesarean and an unfavorable cervix. Acta Obstet Gynecol Scand. 2019; 98(7): 920–928, doi: 10.1111/aogs.13558, indexed in Pubmed: 30723900.
21. Duro-Gómez J, Garrido-Oyarzún MF, Rodríguez-Marín AB, et al. Efficacy and safety of misoprostol, dinoprostone and Cook's balloon for labour induction in women with foetal growth restriction at term. Arch Gynecol Obstet. 2017; 296(4): 777–781, doi: 10.1007/s00404-017-4492-8, indexed in Pubmed: 28831553.
22. Familiari A, Khalil A, Rizzo G, et al. Adverse intrapartum outcome in pregnancies complicated by small for gestational age and late fetal growth restriction undergoing induction of labor with Dinoprostone, Misoprostol or mechanical methods: A systematic review and meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2020; 252: 455–467, doi: 10.1016/j.ejogrb.2020.07.020, indexed in Pubmed: 32738675.
23. Peng J, Li R, Du S, et al. Induction of labour in mid-trimester pregnancy using double-balloon catheter placement within 12 h versus within 12-24 h. BMC Pregnancy Childbirth. 2021; 21(1): 17, doi: 10.1186/s12884-020-03513-7, indexed in Pubmed: 33407258.
24. Chodankar R, Sood A, Gupta J. An overview of the past, current and future trends for cervical ripening in induction of labour. The Obstetrician & Gynaecologist. 2017; 19(3): 219–226, doi: 10.1111/tog.12395.
25. Combination of misoprostol with transcervical foley's catheter compared to misoprostol alone for cervical ripening at term and labour induction in tertiary care hospital: a randomized trial. Indian Journal of Forensic Medicine & Toxicology. 2020, doi: 10.37506/ijfmt.v14i4.12696.
26. Gornisiewicz T, Kusmierska-Urban K, Huras H, et al. Comparison of misoprostol versus dinoprostone for delivery induction among pregnant women without concomitant disease. Ginekol Pol. 2020; 91(12): 726–732, doi: 10.5603/GP.2020.0119, indexed in Pubmed: 33447991.
27. Mlodawski J, Mlodawska M, Plusajska J, et al. Misoprostol vaginal insert and Foley catheter in labour induction — single center retrospective observational study of obstetrical outcome. Ginekol Pol. 2020; 91(11): 700–703, doi: 10.5603/GP.a2020.0118, indexed in Pubmed: 33301165.
28. Shetty A, Livingston I, Acharya S, et al. Vaginal prostaglandin E2 gel versus tablet in the induction of labour at term — a retrospective analysis. J Obstet Gynaecol. 2004; 24(3): 243–246, doi: 10.1080/01443610410001660706, indexed in Pubmed: 15203616.
29. Papanikolaou EG, Plachouras N, Drougia A, et al. Comparison of misoprostol and dinoprostone for elective induction of labour in nulliparous women at full term: a randomized prospective study. Reprod Biol Endocrinol. 2004; 2: 70, doi: 10.1186/1477-7827-2-70, indexed in Pubmed: 15450119.