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Transcervical Foley Catheter with Vaginal Misoprostol for Induction of Labor in Women with Poor Bishop Score

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ABSTRACT

Objective: *To study the effect of transcervical Foley catheter on labor induced with misoprostol.*

Methods: *This analytic prospective cohort study was carried out between 1st March associatedand 31st August 2025. Pregnant women ≥37th week' gestation with poor Bishop scores whose labor were induced with 50 µg misoprostol (inserted vaginally) and an inflated transcervical Foley catheter (group A) or with 50 µg misoprostol alone (group B) were recruited and followed up till delivery. The mothers and newborns were followed up till their discharge from the hospital. The main variables recorded included labor progression, mode of delivery, Apgar score, maternal and perinatal outcomes. Fisher exact test and t-test were used for comparison. P<0.05 was considered statistically significant.*

Results: *We recruited 35 women in group A and 43 in group B. The main indications for labor induction were prolonged pregnancies and hypertensive diseases of pregnancies. Women of group A had significantly less labor augmentation (P=0.003), shorter labor duration (P<0.001), reduced cesarean section risk (P=0.001), best 5th minute Apgar score (P=0.013) and less neonatal asphyxia (P=0.015).*

Conclusion: *The association of inflated transcervical Foley catheter with misoprostol for labor induction significantly reduces labor duration and risk of cesarean section and also improves neonatal outcomes.*

Keywords

Cesarean section rate, Inflated transcervical Foley catheter, Labor duration, Labor induction, Poor Bishop score.

Introduction

Labor induction (LI) is the initiation of uterine contractions before its natural onset in order to deliver the fetus vaginally. Its prevalence is on the rise worldwide with frequencies usually varying nowadays from 20% to 34.6% [1-3]. Nevertheless, in many hospitals in sub-Saharan Africa, the prevalence remains low as 1.4 - 6.8% [4].

LI is associated with some maternal complications such as uterine overstimulation, amniotic fluid embolism, uterine rupture, postpartum hemorrhage and maternal death as well. Perinatal complications associated with LI include abnormal fetal heart rate

patterns, fetal or birth asphyxia as well as fetal or neonatal death [5].

LI is also associated with high risk of cesarean section (CS) mainly for failed induction especially observed in cases of poor Bishop score [1,6,7]. CS carries some risk of complications, albeit small, such as hemorrhage, injury of neighboring organs, maternal death as well as uterine rupture during next deliveries [8]. These complications are more found with difficult CSs [9]. CS also has a cost especially in low-income countries where many women are poor and, therefore, have no health insurance. CS rate is increasing worldwide with rates ranging from 5% (sub-Saharan Africa) to 42.8% (Latin America) [10].

In our daily practice many women request labor induction for termination of term pregnancies. Induction with misoprostol alone carries high rate of failed induction [1]. Reducing the rates of failed induction leads to reduced CS rates and consequently to less maternal and perinatal complications. A few studies revealed that associating misoprostol to transcervical Foley catheter inflated with a liquid reduces the rate of failed induction and the rate of CS as well [11,12]. The magnitude of the effect of inflated transcervical Foley catheter might be different in sub-Saharan Africa where cervical dystocia is frequently observed in our daily practice.

No such study has been carried out in our country. The aim of this study, therefore, was to evaluate the efficacy of an inflated transcervical Foley catheter inserted just before labor induction with intravaginal misoprostol.

Methods

This analytic prospective cohort study was carried out between 1st March and 31st August 2025 in two University Teaching Hospitals. Pregnant women ≥37th week of gestation with a poor Bishop score (<6) and whose labor had to be induced were recruited. Inductions of labor were done at the convenience of the obstetrician either with a prior insertion of an transcervical Foley catheter inflated with 70 ml of a normal saline solution and 50 µg of misoprostol (Cytotec®, Pfizer, Paris, France) inserted vaginally (group A) or with misoprostol alone (group B).

Before insertion of Foley catheter, the vulva, vagina and exo cervix were cleaned with a hexamidine solution, then a Collins speculum was placed and the catheter was introduced in the cervical canal with a sterile sponge holding forceps and thereafter inflated. Finally, the catheter was taped to the inner thigh. As concerns misoprostol, it was inserted with a sterile glove in the posterior pouch of Douglas 4 hourly until the uterine contractions were good enough (3 or 4 in 10 minutes lasting 40 to 60 seconds). Thereafter, in cases of uterine hypokinesia, five milli units of oxytocin given every minute (in a 5% dextrose solution) were used initially and augmented at the same dose every 30 minutes if necessary until the uterine contractions were efficient. The labors of all the parturients were followed up from insertion of misoprostol with or without Foley catheter till the delivery. Thereafter all women and their newborns were followed up till their discharge from the hospital.

Women who refused to participate to this survey and those with premature rupture of membranes were excluded as well as those with contra-indications to induction of labor. A written informed consent was obtained from each woman. This study was approved by the two institutional ethics committees.

The variables recorded in both groups on a tested pre-established questionnaire included maternal age and parity, marital status, gestational age at induction (confirmed by an ultrasound scan performed before 20 weeks' gestation), time interval between induction and active phase beginning, time interval between induction beginning and delivery, mode of delivery, the indication of CS if any, birth weight, sex of newborn, Apgar scores, maternal and neonatal outcomes. Additional variables recorded in women of group A were the time that elapsed between insertion and spontaneous expulsion of the Foley catheter and the cervical dilatation at Foley catheter expulsion.

The minimum sample size was calculated as needing at least 31 cases in each group, using the following formula [13]:

$$N= 2\ (1/1\text{-}f)\frac{(p)(1-p)(Z\alpha+Z_{\beta})^2}{(P0-P1)^2},$$

where f is the percentage of women lost at follow-up (0%), Zα =1.65 corresponds to a type I error of 5%, Zβ =1.03 corresponds to a power of 85%, P0 the percentage of labor augmentation in women induced with both Foley catheter and misoprostol (31.4%) [14], P1 the percentage of labor augmentation in women induced with misoprostol alone (66.0 %) [14] and P is (P0+P1)/2. Data were analyzed using SPSS 26.0 (IBM, Armonk, NY, USA). Data of women of group A were compared to those of group B. Fisher's exact test was used to compare categorical variables and t-test to compare continuous variables. We used relative risks (RRs) with their 95% confidence intervals (CIs) to present the comparison between the two groups. P<0.05 was considered statistically significant.

Results

During the study period, we had a total of 115 pregnant women with poor Bishop scores. A total of 37 (32.2%) women were excluded, 28 (24.3%) for premature rupture of membranes and nine (7.8%) for other reasons. The remaining 78 women took part to this survey.

The indications for induction were prolonged pregnancy or post term in 32 cases (41.0%) (17 in group A vs 15 in group B), hypertensive diseases of pregnancy in 26 cases (33.3%) (13 in each group), IUFD in 12 cases (15.4%) (four vs eight), mild growth restriction in three cases (3.8%) (one vs two), self-request in three cases all in group B (3.8%) and fetal malformations in two cases all in group B (one renal and one cardiac malformations) (2.6%). Some sociodemographic and obstetrical variables are given in Table 1.

After insertion, Foley catheter was expelled for a time ranging

between 1 and 9 hours, with a mean of 3.8 ± 1.1 hours. The cervical dilatation when the catheter was expulsed ranged between 3 and 4 cm (mean 3.8 ± 0.4 cm). Failed induction were less found in group A, although statistically insignificant (P=0.053).

Before evaluating the indications for CS and perinatal outcome, the 12 cases of IUFD and the two cases of fetal malformations were excluded (Table 2).

Table 1: Some sociodemographic characteristics of the population under study.

Variables	Group A women (n=35) N (%)	Group B women (n=43) N (%)	RR	95% CI	P-value
Mother's age (y)	30.2 ± 4.1 (23-41)	28.0 ± 5.4 (17-41)	-	-	0.052
Parity	1.2 ± 1.3 (0-5)	0.9 ± 1.2 (0-5)	-	-	0.293
Bishop score	2.1 ± 1.3 (0-5)	2.1 ± 1.5 (0-5)			0.991
Misoprostol doses used	1.7 ± 0.8 (1-4)	2.2 ± 1.4 (1-8)	-	-	0.064
>2 doses used	2 (5.7)	8 (18.6)	0.31	0.07-1.35	0.085
Failed induction	2 (5.7)	9 (20.9)	0.27	0.06-1.18	0.053
Labor augmentation	4 (11.4)	18 (41.9)	0.27	0.10-0.73	0.003
Duration to active phase (h)	5.2 ± 1.9 (2-8)	10.9 ± 7.6 (2-30)	-	-	0.008
Duration of active phase (h)	3.2 ± 1.4 (2-6)	3.9 ± 1.2 (2-6)	-	-	0.020
Labor duration (h)	8.2 ± 2.7 (2-15)	14.9 ± 7.9 (4-36)	-	-	<0.001
Uterine overstimulation	0 (0)	8 (18.6)	-	-	0.006
Uterine atony	4 (11.4)	10 (23.3)	0.49	0.17-1.43	0.145
Puerperal infection	2 (5.7)	3 (7.0)	0.82	0.14-4.63	0.598

RR: Relative risk, CI: Confidence interval.

Table 2: Some sociodemographic characteristics of the population after excluding women with IUFD or fetal malformations.

Variables	Group A women (n=31) N (%)	Group B women (n=33) N (%)	RR	95% CI	P-value
Fetal heart rate anomalies	1 (3.2)	7 (21.2)	0.15	0.02-1.17	0.033
Cesarean delivery	11 (35.5)	25 (75.8)	0.47	0.28-0.78	0.001
1st min Apgar score	7.8 ± 0.8 (6-9)	8.2 ± 1.1 (4-10)	-	-	0.076
5th min Apgar score	9.1 ± 0.8 (6-10	8.5 ± 1.2 (4-10)	-	-	0.013
Mean birth weight (g)	3063.2 ± 738.0 (1000-4200)	2908.0 ± 856.0 (1130-4150)	-	-	0.400
Neonatal asphyxia	0 (0)	6 (18.2)	-	-	0.015
Neonatal infection	1 (3.2)	2 (6.1)	.53	0.05-5.58	0.524
Transfer to NICU	1 (3.2)	9 (27.3)	0.12	0.02-0.88	0.008

IUFD: Intra Uterine Fetal demise, RR: Relative risk, CI: Confidence interval, NICU: neonatal intensive care unit.

Table 3: Indications for cesarean sections amongst the study population.

Variables	Group A women (n=31) N (%)	Group B women (n=33) N (%)	RR	95% CI	P-value
Acute fetal distress	11 (35.3)	16 (48.5)	0.73	0.40-1.32	0.212
Cervical dystocia	0 (0)	5 (15.2)	-	-	0.031
CPD	0 (0)	2 (6.1)	-	-	0.261
Cord prolapse	0 (0)	1 (3.0)	-	-	0.516
Severe pre-eclampsia	0 (0)	1 (3.0)	-	-	0.516
Total	11 (35.5)	25 (75.8)	0.47	0.28-0.78	0.001

RR: Relative risk, CI: Confidence interval, CPD: Cephalo-pelvic disproportion.

Table 4: Distribution of Apgar scores amongst the study population.

Apgar scores		Group A women (n=31) N (%)	Group B women (n=33) N (%)	RR	95% CI	P-value
1st min	<7	1 (3.2)	11 (33.3)	0.10	0.01-0.71	0.002
	7-8	24 (77.4)	19 (57.6)	1.34	0.95-1.91	0.077
	9-10	6 (19.4)	3 (9.1)	2.13	0.58-7.78	0.206
5th min	<7	0 (0)	6 (18.2)	-	-	0.015
	7-8	1 (3.2)	15 (45.4)	0.07	0.01-0.51	0.0000
	9-10	30 (96.8)	12 (36.4)	2.66	1.67-4.20	0.0000

RR: Relative risk, CI: Confidence interval.

CSs were significantly less frequent in women of group A. The indications for CS in group B women were mainly acute fetal distress and cervical dystocia (Table 3).

First and 5th minutes Apgar scores were significantly higher in women of group A (Table 4). We observed no increased risk of maternal endometritis or neonatal infection in women of group A (Tables 1 & 2).

Discussion

Our survey showed that prior insertion of an inflated transcervical Foley catheter at the moment of induction of labor with vaginal misoprostol was associated with less labor augmentation, less uterine overstimulation, shorter labor duration, reduced cesarean section risk, best 5th minute Apgar score and less neonatal asphyxia.

Success rate of labor induction depends on numerous factors such as induction method, parity, birth weight, pelvic capacity and especially Bishop score [11,15]. Poor Bishop score has been associated with a rate of failed induction ranging between 20.9% and 29.6% [7,16]. The rate of failed induction, defined in our series as the inability for the cervix to dilate up to 4 cm or to have good uterine contractions after a period of six hours [17], was 20.9% in our series when misoprostol was used alone, as observed in Ethiopia [7].

Poor Bishop score has also been associated with high rate of CS when misoprostol was used alone, as in our study where CS rate was 75.8% when misoprostol was used alone. When Foley catheter was associated with misoprostol, there was a significant reduction of the CS rate to 35.5% (P=0.001), as also noticed in Brazil [12]. In this combined method, we also had shorter labor time and less frequent need for a third dose of misoprostol, as already observed [12]. This can be explained by the synergistic effect of both methods. Inflated Foley catheter distends mechanically the cervix by rupturing collagen fibers [18]. Indeed, the proteolytic effects of matrix metalloproteinases (MMPs) contribute to softening of the cervix by degradating extracellular matrix components. Moreover, hyaluronic acid of the extracellular matrix favor cervical ripening [19]. Foley catheter also enhances the production of small quantity of endogenous prostaglandins [19]. The higher the amount of liquid inflated the higher the success rate [20,21]. Finally, with the taping of the catheter to the inner thigh, a mild Ferguson reflex was stimulated leading to oxytocin released by the posterior pituitary gland [22]. The different effects of transcervical Foley catheter can explain why a third dose of misoprostol or labor augmentation with oxytocin were rarely used when the two methods were associated.

Time to active phase of labor (latent phase) was significantly shorter in women of group A attributed to endogenous prostaglandins liberated and to mechanical cervical dilatation induced by the Foley catheter [18]. Indeed, when the Foley catheter was spontaneously expelled averagely 4 hours after insertion, the cervical dilatation was already at 3 or 4 cm.

Also, active phase duration was shortened in women of group A, attributed to cervical changes induced by Foley catheter, production of endogenous prostaglandins and oxytocin liberation as well when the Ferguson reflex was stimulated [22]. Labor duration was therefore shortened in women of group A because of shorter latent and active phases.

Uterine overstimulation was less observed in women of group A attributed to the fact that less misoprostol was needed for labor induction. Also, labor augmentation was less practiced.

Favorable neonatal outcome in group A, as noticed in a meta-analysis [15], was attributed to less misoprostol needed for induction, less labor augmentation, less uterine overstimulation and shorter labor duration as well.

We observed no significant difference in both groups as concerns neonatal infection or postpartum endometritis attributed to the fact that Foley catheters were inserted with aseptic measures.

The limitations of our study are the small sample size, given that some obstetricians preferred to perform CS than to carry out an induction of labor when the Bishop score was poor. Furthermore, cases of premature rupture of membranes were excluded from this survey because we assumed that Foley catheter being a foreign body could favor maternal or neonatal infections.

Conclusion

The association of Foley catheter with misoprostol for labor induction significantly reduces labor duration and the risk of cesarean section and also improves neonatal outcomes. Therefore, both methods should be associated for labor induction in women with poor Bishop scores.

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