ORIGINAL ARTICLE

Foley's Catheter and Vaginal Misoprostol vs Vaginal Misoprostol Alone for Labor Induction

Shikha Manohar Toshniwal[1], Saunitra Inamdar[2], Sakshi Rajesh Sharma[3]

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Abstract

Objectives: To compare the efficacy of transcervical Foley's catheter and vaginal misoprostol vs vaginal misoprostol alone in the induction of labor at or after 39 weeks of gestation.

Methods: This randomized comparative study included 110 women with a singleton gestation, vertex presentation, gestation>39 weeks, Bishop's score <6, and no contraindication for normal vaginal delivery. General examination, systemic examination, obstetric examination, and pelvic examination were done to note the Bishop's score and adequacy of pelvis, and the patients were grouped in two categories: Group A: Tablet Misoprostol 25 µg and Group B: Tablet Misoprostol 25 µg plus Foley's catheter (No. 16).

Results: Mean ± SD of induction to delivery interval (hours) in group B (14.6 ± 2.26) was significantly lesser as compared to group A (17.9 ± 2.82) (*p* value 0.05). The intrapartum complications were comparable between groups A and B (fever, diarrhea, tachysystole, hypertonic contraction, hyperstimulation syndrome, $p = 0.495$). The postpartum complications were comparable between groups A and B (atonic PPH, traumatic PPH: $p > 0.05$). The abnormal heart rate (bradycardia: 3.64% vs 5.45%, $p = 1$ and persistent tachycardia: 3.64% vs 1.82%, $p = 1$) and presence of meconium-stained liquor (7.27% vs 5.45%, $p = 1$) were comparable between groups A and B. Group A and B had comparable neonatal outcomes [NICU admission, reason for NICU admission, early neonatal death, mean Apgar at 1 minute (7.8 vs 7.85, $p = 0.524$), and Apgar at 5 minutes (8.85 vs 8.95, $p = 0.242$)].

Conclusion: To conclude, the combination of Foley's catheter + vaginal misoprostol resulted in significant improvement in Bishop score and shorter induction to delivery interval than vaginal misoprostol alone. Thus, it is more preferable to use a combination of vaginal misoprostol and Foley's catheter for induction of labor. However, both techniques were equally effective in terms of mode of delivery, indication for cesarean section, intrapartum and postpartum complications, abnormal heart rate, meconium-stained liquor, and neonatal outcomes.

Keywords: Bishop's score, Foleys catheter, Labor induction misoprostol.

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Introduction

The aim of ideal antenatal care is to have a healthy infant and a healthy mother. Mostly, at or near term, labor starts spontaneously, and that leads to vaginal delivery. The same method that is used for vaginal delivery, in which pregnancy terminates artificially, any time after fetal viability, is called "induction of labor".[1,2]

Indication of labor induction is when it outweighs risks associated with pregnancy continuation. Commonly mentioned indicators for labor induction are premature rupture of membrane (PROM), post-dated pregnancy, gestational hypertension, oligohydramnios, intrauterine death, Rh isoimmunization, fetal growth restriction, abruption placenta, chorioamnionitis, and many other maternal conditions like intrahepatic cholestasis and gestational diabetes of pregnancy.[3] At 39 weeks, in low-risk women, labor induction causes lesser occurrence of cesarean deliveries without significantly affecting the perinatal outcomes.[4]

Induction success is mostly dependent on cervical ripeness.[5] It encompasses a string of compound biochemical processes, which results in a plentitude of variations, which consists of realignment and rearrangement of collagen fibril, alteration in composition of glycosaminoglycan, increase in production of cytokine, and infiltration of WBC.[6]

As the induction failure and lengthened induction-to-delivery time are related to the anxiety of parents, adverse outcomes, and high hospitalization cost, it is important to have a successful induction.[7]

Modified Bishop scoring is a method used for cervical assessment during labor. A score of six or higher is considered favorable for labor induction.[5,8] However, a score less than six demands methods of cervical ripening.[9]

Misoprostol, fabricated analog of "prostaglandin E1",[10] was developed in form of gastrocytoprotective agent. Routes are sublingual, vaginal, oral, buccal, and rectal. Cervical ripening and rate of vaginal delivery significantly improves within 24 hours via the vaginal route.[11] It is used widely for labor induction, abortion, prevention, and treatment of postpartum hemorrhage.

Mechanical devices cause physical cervical dilatation while softening and effacing of the cervix are achieved by PG agents. So,

[1]Department of Obstetrics and Gynecology, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India

[2]Department of Obstetrics and Gynecology, Acharya Vinoba Bhave Rural Hospital, Wardha, Maharashtra, India

[3]Department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Wardha, Maharashtra, India

Corresponding Author: Shikha Manohar Toshniwal, Department of Obstetrics and Gynecology, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India, Phone: +91 8905669695, e-mail: shikhatoshniwal802@gmail.com

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mechanical methods in addition to prostaglandins is considered to be useful method for cervical ripening for the unripe cervix.[12]

Combination of methods can take care of various adversities together and lead to better outcomes in labor induction. Research continues to determine if the combination is better than the individual method alone.

There is insufficient number of previous studies on the comparative evaluation of the combination methods vs single method; leading to sparse evidence of the superiority of the combination. Thus, this study was conducted to further build-up the evidence about the usage of combination methods in induction of labor (intracervical Foley's catheter and vaginal misoprostol) over a single method (vaginal misoprostol).

Materials and Methods

The study followed 110 women (with singleton gestation, vertex presentation, gestation>39 weeks, Bishop's score <6, and no contraindication for normal vaginal delivery) who attended Obstetrics and Gynecology, JNMC, AVBRH, DMIMS, Wardha from September 2019 to September 2021.

The study population was divided into two groups:

Group A (n = 55): Vaginal tablet misoprostol
Group B (n = 55): Vaginal tablet misoprostol plus Intracervical Foley's catheter (No. 16).

Inclusion Criteria

- Singleton gestation
- Vertex presentation
- Gestation >39 weeks
- Bishop's score <6
- No contraindication for normal vaginal delivery
- Post-term pregnancy
- Low-risk pregnancy

Exclusion Criteria

- High-risk pregnancy example hypertensive disorders of pregnancy, gestational diabetes mellitus, etc.
- Placenta previa
- Known allergy to misoprostol
- Severe intrauterine growth restriction
- Previous uterine scar
- Severe oligohydramnios
- CPD
- Prolonged PROM (>12 hours)
- Abnormal non-stressed test (NST) and Doppler findings on admission.

Methodology

A total of 110 subjects who fulfilled the inclusion and exclusion criteria were admitted and monitored in the prelabor room. The detailed information regarding age, booked/unbooked, gravidity, and gestational age were collected from all women, based on the predesigned data sheet. A detailed history was taken to exclude any contraindications for induction of labor. General examination, systemic examination, and a thorough obstetric examination were done. Pelvic examination was done to note the Bishop's score and adequacy of pelvis.

A baseline NST was done for at least 10 minutes to rule out the already existing compromised state of the fetus-*in-utero*. Routine investigations and an obstetric ultrasound and Doppler were done to check for fetal wellbeing in addition to other parameters like gestational age, placental site including grading and liquor volume.

The patients were grouped in two categories according to randomization no. —

Group A (n = 55): Vaginal tablet misoprostol
Group B (n = 55): Vaginal tablet misoprostol plus intracervical Foley's catheter (No. 16).

For subjects assigned to group A, the tablet misoprostol 25 μg was placed intravaginally in the posterior fornix of vagina every 4 hours for a maximum of four doses.

For subjects assigned to group B, the first Foley's catheter 16F was inserted intracervically with visualization of the cervix by sterile speculum examination and avoiding contact of catheter with the vagina or ectocervix and performing the procedure with sterile technique. After proper placement was ensured, the catheter balloon was inflated with 30 cc of sterile normal saline solution. Traction was applied to the catheter until the balloon was taut against the internal cervical os. The catheter was then taped with traction to the inner thigh of the patient until spontaneous expulsion or for maximum of 12 hours.

Antibiotic coverage was given to avoid any infection. Along with it, tablet misoprostol 25 μg was placed intravaginally in the posterior fornix of the vagina every 4 hours for a maximum of four doses. After the establishment of a contraction pattern of >3 contractions in 10 minutes, they did not receive further dose of misoprostol and a repeat Bishop score was assigned by the same initial examiner and if the Bishop score was 8, the patient was transferred to the labor unit. Resident physicians supervised intra-partum care and continuous external electronic fetal heart rate (FHR), and tocodynamic monitoring were used routinely beginning immediately after the patients transfer to the labor unit until delivery. Artificial rupture of membranes was performed for all patients when the fetal head was engaged, and the Bishop score was found to be 8. Progress of labor was monitored. Complaints of patients, vital signs, uterine contractions, and fetal heart rate patterns were monitored. If the cervical score was still unfavorable/unchanged (Bishop score <6, cervical dilatation <3 cm) at the 24th hour after the first dose, the procedure was considered unsuccessful and labeled "failure of induction".[11]

The decision to perform an emergency cesarean delivery was made immediately whenever a non-reassuring FHR tracing was obtained. All women undergoing cesarean delivery with the indication of non-reassuring FHR tracings gave birth within 30 minutes following the decision to undertake cesarean delivery.

Induction to delivery interval was noted. Soon after delivery, Apgar scores at 1 and 5 minutes birth weight, meconium aspiration, sepsis, and other associated complications were recorded. In presence of complications, the opinion of neonatologist was sought. All neonates with signs and symptoms of probable sepsis were admitted to NICU. Neonatal morbidity and mortality were noted. Both mother and the baby were followed up till they stayed in the hospital.

Parameters such as Bishop score, improvement in Bishop score, mode of delivery, induction to delivery interval, indication

Table 1: Comparison of Bishop score between groups A and B

Bishop score	*Group A*	*Group B*	*Total*	*p value*
At 0 hour				
Mean ± SD	3.98 ± 0.68	3.75 ± 0.75	3.86 ± 0.72	
Median (25th–75th percentile)	4 (4–4)	4 (3–4)	4 (3–4)	0.086*
Range	3–5	2–5	2–5	
At 4 hours				
Mean ± SD	5.15 ± 0.89	6.13 ± 1.33	5.64 ± 1.23	
Median (25th–75th percentile)	5 (5–6)	6 (6–7)	6 (5–6)	<0.0001*
Range	3–8	3–9	3–9	
At 8 hours				
Mean ± SD	7.02 ± 1.47	8.23 ± 1.86	7.61 ± 1.78	
Median (25th–75th percentile)	7 (6–8)	8 (7–9)	8 (6–9)	0.0003*
Range	4–11	4–12	4–12	
At 12 hours				
Mean ± SD	9.07 ± 2.44	9.84 ± 2.13	9.43 ± 2.32	
Median (25th–75th percentile)	9 (8–11)	11 (9–11)	9 (8–11)	0.144*
Range	4–12	4–12	4–12	

*Independent *t* test

Table 2: Comparison of improvement in Bishop's score between groups A and B

Improvement in Bishop score	*Group A*	*Group B*	*Total*	*p value*
At 4 hours				
Mean ± SD	1.16 ± 0.74	2.38 ± 1.08	1.77 ± 1.11	
Median (25th–75th percentile)	1 (1–2)	3 (2–3)	2 (1–3)	<0.0001*
Range	0–3	0–4	0–4	
At 8 hours				
Mean ± SD	3.06 ± 1.39	4.52 ± 1.7	3.77 ± 1.71	
Median (25th–75th percentile)	3 (2–4)	5 (3.75–5.25)	4 (2–5)	<0.0001*
Range	1–6	1–8	1–8	
At 12 hours				
Mean ± SD	5.1 ± 2.32	6.35 ± 2.06	5.68 ± 2.28	
Median (25th–75th percentile)	5 (4–7)	7 (5–8)	6 (4.5–7.5)	0.014*
Range	1–9	1–9	1–9	

*Independent *t*-test

for cesarean section, intrapartum complications, postpartum complications, abnormal heart rate, meconium-stained liquor, and neonatal outcomes were compared between groups.

Results

Table 1 shows the significant difference seen in Bishop's score at 4 hours and at 8 hours between groups A and B (p value <0.05). Mean ± SD of Bishop's score at 4 hours and at 8 hours in group B was 6.13 ± 1.33 and 8.23 ± 1.86, respectively, which was significantly higher as compared to group A [5.15 ± 0.89 (p value <0.0001), 7.02 ± 1.47 (p value = 0.0003)], respectively.

No significant difference was seen in Bishop's score at 0 hour (p value = 0.086) and at 12 hours (p value = 0.144) between groups A and B. Mean ± SD of Bishop's score at 0 hour and at 12 hours in group A was 3.98 ± 0.68 and 9.07 ± 2.44, respectively, and in group B was 3.75 ± 0.75 and 9.84 ± 2.13, respectively, with no significant difference between them.

A significant difference was seen in improvement in Bishop's score at 4 hours, at 8 hours, and at 12 hours between groups A and B (p value <0.05). Mean ± SD of improvement in Bishop's score at 4 hours, at 8 hours, and at 12 hours in group B was 2.38 ± 1.08, 4.52 ± 1.7, and 6.35 ± 2.06, respectively, which was significantly higher as compared to group A [1.16 ± 0.74 (p value <0.0001), 3.06 ± 1.39 (p value <0.0001), and 5.1 ± 2.32 (p value = 0.014)], respectively (Table 2).

Table 3 depicts that the distribution of mode of delivery was comparable between groups A and B (LSCS: 27.27% vs 21.82%, respectively, vaginal delivery: 72.73% vs 78.18%, respectively) (p value = 0.506).

Table 3: Comparison of mode of delivery between groups A and B

Mode of delivery	*Group A (n = 55)*	*Group B (n = 55)*	*Total*	*p value*
LSCS	15 (27.27%)	12 (21.82%)	27 (24.55%)	
Vaginal delivery	40 (72.73%)	43 (78.18%)	83 (75.45%)	0.506*
Total	55 (100%)	55 (100%)	110 (100%)	

*Chi-square test

Table 4: Comparison of induction to delivery interval (hours) between groups A and B in vaginal delivery

Induction to delivery interval (hours)	*Group A (n = 40)*	*Group B (n = 43)*	*Total*	*p value*
Mean ± SD	17.9 ± 2.82	14.6 ± 2.26	16.19 ± 3.02	
Median (25th–75th percentile)	18.5 (16.75–20)	14 (13–16)	16 (13–19)	<0.0001*
Range	12–22	11–20	11–22	

*Independent *t*-test

Table 5: Comparison of intrapartum complication between groups A and B

Intrapartum complication	*Group A (n = 55)*	*Group B (n = 55)*	*Total*	*p value*
Fever	5 (9.09%)	3 (5.45%)	8 (7.27%)	0.716*
Diarrhoea	2 (3.64%)	2 (3.64%)	4 (3.64%)	1*
Tachysystole	2 (3.64%)	2 (3.64%)	4 (3.64%)	1*
Hypertonic contraction	1 (1.82%)	1 (1.82%)	2 (1.82%)	1*

*Fisher's exact test

Table 6: Comparison of postpartum complication between groups A and B

Postpartum complication	*Group A (n = 55)*	*Group B (n = 55)*	*Total*	*p value*
Atonic PPH	4 (7.27%)	2 (3.64%)	6 (5.45%)	0.679*
Traumatic PPH	3 (5.45%)	4 (7.27%)	7 (6.36%)	1*
Rupture of uterus	0 (0%)	0 (0%)	0 (0%)	No *p* value

*Fisher's exact test

Mean ± SD of induction to delivery interval (hours) in group A was 17.9 ± 2.82 which was significantly higher as compared to group B (14.6 ± 2.26) (*p* value <0.0001) (Table 4).

Table 5 shows that the distribution of intrapartum complication was comparable between groups A and B [Fever: 9.09% vs 5.45%, respectively (*p* value = 0.716), Diarrhoea: 3.64% vs 3.64% respectively (*p* value = 1), Tachysystole: 3.64% vs 3.64% respectively (*p* value = 1), Hypertonic contraction: 1.82% vs 1.82% respectively (*p* value = 1)].

Distribution of postpartum complication was comparable between groups A and B [Atonic PPH:7.27% vs 3.64%, respectively (*p* value = 0.679), Traumatic PPH: 5.45% vs 7.27%, respectively (*p* value = 1), Rupture of uterus: 0% vs 0% respectively] (Table 6).

Distribution of NICU admission was comparable between groups A and B (16.36% vs 10.91%, respectively) (*p* value = 0.405).

Distribution of reason for NICU admission was comparable between groups A and B (Meconium aspiration syndrome: 33.33% vs 66.67%, respectively, Respiratory distress syndrome: 66.67% vs 33.33%, respectively) (*p* value = 0.315).

Distribution of early neonatal death was comparable between groups A and B (1.82% vs 1.82%, respectively) (*p* value = 1) (Table 7).

No significant difference was seen in Apgar at 1 minute (*p* value = 0.524) and Apgar at 5 minutes (*p* value = 0.242) between groups A and B. Mean ± SD of Apgar at 1 minute and Apgar at 5 minutes in group A was 7.8 ± 0.49 and 8.85 ± 0.52, respectively, and in group B was 7.85 ± 0.4 and 8.95 ± 0.23, respectively, with no significant difference between them.

Discussion

The combination of intracervical Foley's catheter and vaginal misoprostol was found to show superiority over vaginal misoprostol alone in fastening up the process of labor as determined by induction delivery interval values (14.6 ± 2.26 vs 17.9 ± 2.82, *p* value <0.0001).

Similar results were reported by Davalagi et al.,[13] who found that significantly more number women delivered within 12 hours in Misoprostol + Foley's catheter group than misoprostol alone group (87.33% vs 76.67%, *p* = 0.0093), which means misoprostol plus Foley's catheter combination resulted in faster delivery.

Even similar results to present study were found by Carbone et al.,[14] where the use of Foley catheter + vaginal misoprostol decreased induction-to-delivery time by a mean of 3 hours in comparison to vaginal misoprostol alone (15.3 vs 18.3, *p* <0.05).

Similarly, Santosh et al.[15] reported that the mean induction delivery interval (IDI) in Group Foley catheter + vaginal misoprostol was faster (14.58 hours), while in Group misoprostol, it was slower (19.11 hours, *p* <0.05).

Table 7: Comparison of neonatal outcome between groups A and B

Neonatal outcome	*Group A*	*Group B*	*Total*	*p value*
Apgar at 1 minute				
Mean ± SD	7.8 ± 0.49	7.85 ± 0.4	7.83 ± 0.45	0.524*
Median (25th–75th percentile)	8 (8–8)	8 (8–8)	8 (8–8)	
Range	6–8	6–8	6–8	
Apgar at 5 minutes				
Mean ± SD	8.85 ± 0.52	8.95 ± 0.23	8.9 ± 0.41	0.242*
Median(25th–75th percentile)	9 (9–9)	9 (9–9)	9 (9–9)	
Range	07–10	08–9	07–10	
NICU admission				
No	46 (83.64%)	49 (89.09%)	95 (86.36%)	0.405*
Yes	9 (16.36%)	6 (10.91%)	15 (13.64%)	
Reason for NICU admission				
Meconium aspiration syndrome	3 (33.33%)	4 (66.67%)	7 (46.67%)	0.315†
Respiratory distress syndrome	6 (66.67%)	2 (33.33%)	8 (53.33%)	
Early neonatal death				
No	54 (98.18%)	54 (98.18%)	108 (98.18%)	1†
Yes	1 (1.82%)	1 (1.82%)	2 (1.82%)	

*Independent *t*-test, †Fisher's exact test, *Chi-square test

Even, Hill et al.[16] found that the time from initiation of ripening to vaginal delivery was significantly less in the Foley and misoprostol group than vaginal misoprostol group (12.9 vs 17.8 hours, $p < 0.001$).

Contrary results were reported by Chung et al.,[17] who reported that no significant difference was found in induction-to-delivery time between the patients who received vaginal misoprostol alone, misoprostol + Foley catheter or Foley catheter alone.

Bhatiyani et al.[10] also found contrast findings, as the vaginal misoprostol group had significantly shorter mean induction delivery interval than Foley bulb + misoprostol (8.15 vs 10.75 hours, $p = 0.005$).

Similarly, Kashanian et al.[18] found that combination of Foley catheter + vaginal misoprostol did not increase the effectiveness, and no synergistic effect was found on induction-to-delivery time, because the vaginal misoprostol group had significantly shorter induction delivery interval than Foley catheter + vaginal misoprostol group (10.5 vs 11.7, $p < 0.001$).

Bishop's Score

In the present study, there was comparable baseline (at 0 hour) Bishop score between group A and group B (3.98 ± 0.68 vs 3.75 ± 0.75, $p = 0.086$). However, subsequently, group B showed significantly higher Bishop's score at 4 hours (6.13 ± 1.33 vs 5.15 ± 0.89, p value<0.0001) and at 8 hours (8.23 ± 1.86 vs 7.02 ± 1.47, p value = 0.0003), respectively, leading to a significant improvement in Bishop's score at 4 hours, 8 hours, and 12 hours (p value <0.05). Mean ± SD of improvement in Bishop score at 4 hours, at 8 hours, and at 12 hours in group B was 2.38 ± 1.08, 4.52 ± 1.7, and 6.35 ± 2.06, respectively, which was significantly higher as compared to group A [1.16 ± 0.74 (p value <0.0001), 3.06 ± 1.39 (p value <0.0001), and 5.1 ± 2.32 (p value = 0.014)], respectively. When we compared the findings of the present study with previous published studies, we found that though the absolute values of Bishop score were higher in the group using Foley catheter + vaginal misoprostol (as compared to group using only vaginal misoprostol), statistically, it failed to cross the boundaries of significance. This was observed in the study by Bhatiyani et al.,[10] where Bishop score in vaginal misoprostol group and Foley catheter + vaginal misoprostol group at 0 hour was 3 vs 1.63, 4 hours was 7 vs 5, 8 hours was 8 vs 7, and 12 hours was 10 vs 8 ($p > 0.05$); in the study by[2] Hill et al.[16] also found the similar mean Bishop score (2 vs 3, $p = 0.053$). Literature falls short in assessing and reporting the progress of Bishop score among the two groups. Most of the previous other studies such as by Kashanian et al.,[18] Santosh et al.[15] (3.0700 vs 3.5600, $p > 0.05$), Carbone et al.,[14] Davalagi et al.,[13] [Bishop score of 4–5: (67.33% vs 49.34%, $p > 0.05$)] and Osoti et al.[19] ["Pre-induction mean (SD) Bishop's score was 2.1 (1.5) vs 2.8 (1.1), $p > 0.05$]; only report comparable baseline similar Bishop's score between vaginal misoprostol group and Foley catheter + vaginal misoprostol group. In this aspect, the present study holds importance as it showed that the use of combined methods of induction had better improvement in the Bishop's score. Since Bishop's score rates the readiness of the cervix for induction of labor, the study results matched with the shortened induction to delivery interval in group B, which was even shown in various other studies as a primary outcome.

Conclusion

- The mean induction to delivery interval can be significantly decreased by using combination method of intracervical Foley's catheter and vaginal misoprostol for induction of labor.
- At 4, 8, and 12 hour assessment, significant improvement in Bishop's score was observed in women induced with combination of intracervical Foley's catheter and vaginal misoprostol.
- Rate of LSCS did not increase with combination of intracervical Foley's catheter and vaginal misoprostol for induction.

- Combining intracervical Foley's catheter with misoprostol for labor induction did not increase any of the adverse maternal and neonatal outcomes.

It can be concluded that the use of combination of Foley's catheter and vaginal misoprostol for induction of labor is more preferable than vaginal misoprostol alone as it significantly decreases the induction to delivery interval without any increase in maternal and neonatal adverse outcomes.

Orcid

Shikha Manohar Toshniwal https://orcid.org/0000-0001-7987-1180

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