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Maternal and Neonatal Outcomes with Combined Foley Catheter and Vaginal Misoprostol versus Vaginal Misoprostol Alone for Induction of Labour at 40 Weeks

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Abstract: ***Background: In addition to shortening induction, the choice of cervical-ripening method may influence labour progression, mode of delivery, maternal complications and neonatal outcomes. This study compared selected secondary outcomes after combined transcervical Foley catheter and vaginal misoprostol versus vaginal misoprostol alone. Methods: This prospective, two-arm randomised controlled trial included 76 women at 40 weeks of gestation, allocated equally to transcervical Foley catheter (60 mL saline balloon) plus vaginal misoprostol (25 µg every four hours, maximum five doses) or vaginal misoprostol alone. Secondary outcomes included duration of labour, misoprostol dose requirement, oxytocin use, mode of delivery, meconium-stained liquor, neonatal Apgar scores, NICU admission and recorded maternal complications. Results: Mean duration of labour was 349.06±58.80 minutes in the combined group and 450.07±56.09 minutes in the misoprostol-only group (reported $p<0.001$). One misoprostol dose was required by 50.0% versus 18.4%, respectively (overall distribution $\chi^2=10.617$, $p=0.031$). Oxytocin was used in 5.3% versus 18.4% ($p=0.076$). Caesarean delivery occurred in 13.2% versus 23.7% (overall mode-of-delivery comparison $p=0.387$). Meconium-stained liquor, Apgar scores, NICU admission and recorded maternal complications did not differ significantly. Conclusions: The combined method was associated with shorter labour duration and lower misoprostol dose requirement. Differences in oxytocin use and mode of delivery were not statistically significant.***

Keywords: Foley catheter; misoprostol; labour induction; mode of delivery; Apgar score; neonatal intensive care unit

1. Introduction

Cervical ripening and induction of labour can be achieved using pharmacological agents, mechanical methods or a combination of both. There is increasing evidence now that using a Transcervical Foley's Catheter or cervical ripening balloon is an effective way of inducing labour, with lower rates of hyperstimulation than prostaglandin[1]. The use of Foley's Catheter for cervical ripening is supported by WHO, ACOG, and NICE guidelines[2]. No maternal or neonatal infectious morbidity increase has been associated with FC cervical ripening[3,4,5]

Misoprostol uterotonic effects arise from prostaglandin binding to uterine smooth muscle cells, enabling it to induce labour and promote cervical ripening primarily by collagen breakdown in the cervical stroma. These properties also help reduce postpartum bleeding[6,7,8].

The transcervical Foley catheter provides mechanical cervical dilatation, while vaginal misoprostol promotes cervical ripening and uterine contractions. In addition to delivery time, clinically relevant outcomes include the number of prostaglandin doses, need for oxytocin augmentation, mode of delivery, intrapartum events, maternal morbidity, and neonatal condition at birth.

In this study, we recorded outcomes in a randomised comparison of the combined approach of transcervical Foley catheter with vaginal misoprostol versus vaginal misoprostol alone in women at 40 weeks of gestation.

2. Materials and methods

This study was a prospective, two-arm randomised controlled trial conducted at Dr. Radhakrishnan Government Medical College and Hospital, Hamirpur, Himachal Pradesh, India. The study period was from August 2025 through February 2026.

The inclusion Criteria were singleton live cephalic pregnancy at 40 weeks and Maternal age (18-40 years) and the exclusion criteria were Modified Bishop score ≥6, All contraindications to vaginal delivery (e.g. carcinoma cervix, structural pelvic abnormalities e.g. rachitic pelvis, Cephalopelvic disproportion.), Foetal malpresentations, Previous uterine surgery (CS/ hysterotomy/ myomectomy/metroplasty), Multifetal gestation, Antepartum haemorrhage, Intrauterine Fetal demise, Intrauterine Growth Restriction, Hypertension, Diabetes, Placenta or vasa previa or cord presentation, Latex Allergy, Active genital herpes and Contraindications to prostaglandins (e.g. Asthma, cardiac disease, known bleeding disorder, concurrent anticoagulant therapy, pelvic infection, hypersensitivity).

A total of 76 pregnant women were randomized into two groups, 38 in each group, by computer-generated random table numbers. The allocation was concealed by placement in

sequentially numbered, opaque, sealed envelopes that were drawn in a consecutive order stratified by group.
Group 1: Transcervical foley's catheter with vaginal misoprostol
Group 2: Vaginal misoprostol alone

Group 1 received a transcervical Foley catheter with a 60-mL normal-saline balloon plus vaginal misoprostol 25 µg every four hours, up to five doses or until uterine contractions/active labour (cervical dilatation ≥4 cm), whichever occurred first.

Group 2 received vaginal misoprostol 25 µg at the same interval and maximum dose. Labour management and augmentation were undertaken according to the unit protocol.

The duration of labour; number of misoprostol doses; requirement for oxytocin; mode of delivery; indication for caesarean section; meconium-stained liquor; birth weight; Apgar scores at one and five minutes; NICU admission; and recorded postpartum haemorrhage, genital injury and maternal mortality were noted.

3. Statistical Analyses

The thesis reports analysis using IBM SPSS version 22. Continuous variables were summarised as mean and standard deviation and categorical variables as frequencies and percentages. The stated tests were the unpaired Student's t-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables. A p value <0.05 was considered statistically significant.

4. Results

Seventy-six participants were reported, with 38 in each group. The combined-method group had a shorter reported mean duration of labour and a greater proportion requiring only one dose of misoprostol. Oxytocin use was numerically lower in the combined group, but the difference was not statistically significant. (Table 1)

Table 1: Comparison of duration of labour, Misoprostol doses and requirement of oxytocin between the two study groups

Outcome	Foley + misoprostol (n=38)	Misoprostol alone (n=38)	Reported p value
Duration of labour (minutes), Mean ± SD	349.06 ± 58.80	450.07 ± 56.09	<0.001*
One misoprostol dose, n (%)	19 (50.0)	7 (18.4)	0.031
Oxytocin required, n (%)	2 (5.3)	7 (18.4)	0.076

The overall distribution of mode of delivery did not differ significantly between groups. Meconium-stained liquor, birth weight, Apgar scores and NICU admission were also reported as comparable. No postpartum haemorrhage, genital injury or maternal mortality was recorded in either group. (Table 2)

Table 2: Comparison of mode of delivery, neonatal outcomes and maternal complications between two groups

Outcome	Foley + misoprostol (n=38)	Misoprostol alone (n=38)	Reported p value
Vaginal delivery, n (%)	32 (84.2)	27 (71.1)	0.387
Instrumental delivery, n (%)	1 (2.6)	2 (5.3)	
Caesarean section, n (%)	5 (13.2)	9 (23.7)	
Meconium-stained liquor, n (%)	3 (7.9)	2 (5.3)	1.000
Birth weight (g), Mean ± SD	2701.32 ± 246.73	2721.05 ± 249.50	0.730
Apgar at 1 minute, Mean ± SD	7.89 ± 0.31	7.87 ± 0.34	0.727
Apgar at 5 minutes, Mean ± SD	8.87 ± 0.34	8.84 ± 0.37	0.748
NICU admission, n (%)	1 (2.6)	2 (5.3)	1.000
Postpartum haemorrhage, genital injury or maternal mortality	0 reported	0 reported	Not calculable

5. Discussion

The findings suggest that the combined method was associated with a shorter duration of labour and a lower requirement for repeated misoprostol doses. Half of the participants in the combined group required one dose, compared with fewer than one-fifth in the misoprostol-only group. This is biologically plausible because mechanical cervical dilatation may complement the cervical-ripening effects of misoprostol.

However, there was no statistical difference with respect to mode of delivery (p value=0.387), oxytocin use (p value=0.076), maternal & fetal or neonatal complications. The proportion requiring oxytocin was lower in the combined group (5.3% versus 18.4%), although the reported p value was 0.076 and did not meet the prespecified threshold for statistical significance. Similarly, caesarean delivery was numerically less frequent in the combined group (13.2% versus 23.7%), but the overall mode-of-delivery comparison was not statistically significant.

Neonatal outcomes were broadly similar in the two groups. Mean Apgar scores at one and five minutes and mean birth weight did not differ significantly. NICU admission was uncommon in both groups. No postpartum haemorrhage, genital injury or maternal mortality was recorded.

Similar results were also found in the study conducted by Elpo et al., there was a lower need for misoprostol use for overall cervical ripening (p<0.001) and a lower relative risk of needing a second, third, or fourth misoprostol tablet in the "combined" group (risk ratio [RR] 0.80, 95% confidence interval [CI] 0.71–0.91; RR 0.41; 95%CI 0.31–0.56; and RR 0.29, 95%CI 0.17–0.52, respectively) (p<0.001). No statistically significant difference was found in induction failure rate, caesarean section rate, or perinatal outcomes[9].

In the study by Priyadarshini et al., they found that the number of misoprostol doses used was significantly lower in the combined group (2.70 ± 2.36) compared with the misoprostol-alone group (4.85 ± 2.38; p = 0.001). Both the groups were similar with regard to demographic parameters and indications for induction of labour. The differences in perinatal outcome, rates of tachysystole and postpartum haemorrhage were not significant[10].

A study by Lanka et al., compared the efficacy of combined intracervical Foley catheter and low-dose vaginal misoprostol with low-dose vaginal misoprostol alone for induction of labour. The mean induction-to-delivery interval and rate of vaginal deliveries were not significantly different between the groups (26.52 h in the combination group and 27.64 h in the misoprostol group, P = 0.65; 65.07% and 65.07%, respectively, P = 0.9). Uterine hyperstimulation and meconium-stained liquor were significantly more prevalent in the misoprostol group (P = 0.001). Neonatal outcomes did not differ significantly between the groups. The addition of foley's catheter to misoprostol did not cause any statistically significant benefit in reducing the induction-to-delivery time. However, it reduced the incidence of uterine hyperstimulation and meconium-stained liquor[11].

The study by Viteri et al., showed the rate of Caesarean delivery was similar between the groups (45 vs. 43%, p = 0.84). There was no difference in the occurrence of tachysystole that resulted in fetal heart rate abnormalities between the groups (8.8 vs. 16.2%, p = 0.09, RR: 0.54, 95% CI: 0.27-1.11)[12].

In a study by Aduloju et al., they compared the efficacy of combined Foley's catheter and vaginal misoprostol with Foley's catheter or low-dose vaginal misoprostol alone for cervical ripening Cervical ripening time, induction–delivery time were significantly shorter in the combined group compared to the other two groups; P = 0.001. There was no difference in Apgar scores at 1 or 5 minutes or in special baby care unit admission among the groups[13].

Given the small sample size and low event frequencies, absence of a statistically significant difference should not be interpreted as proof of equivalence or as definitive evidence that rare harms are absent. Important limitations include the single-centre design, small sample size and limited power for uncommon maternal and neonatal outcomes

6. Conclusion

In this trial, concurrent transcervical Foley catheter and vaginal misoprostol was associated with shorter labour duration and fewer misoprostol doses. Oxytocin requirement and caesarean delivery were numerically lower but not statistically significantly different. Neonatal outcomes and recorded maternal complications were similar in the two groups. Larger studies are needed to evaluate uncommon safety outcomes and clinically important differences in mode of delivery.

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Declaration
This author takes full responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation

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