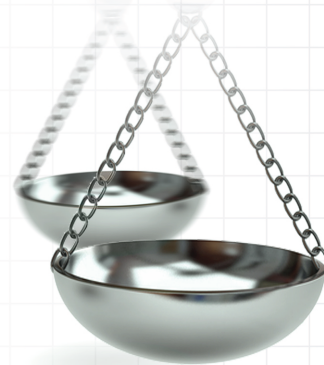




Comparative outcome of induced labor by intracervical Foley catheter with misoprostol versus misoprostol alone

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Aim: To evaluate the comparative outcome of induced labor by intracervical Foley catheter with misoprostol versus misoprostol alone. **Materials & methods:** A total of 1306 women were enrolled over 4 years, induced with either intracervical Foley with misoprostol or misoprostol alone and compared in terms of induction-delivery interval, mode of delivery, the presence of uterine tachysystole, postpartum hemorrhage and perinatal outcome. **Results:** Induction to delivery interval, the duration between induction to active labor was significantly reduced, deliveries within 24 h were significantly higher and the number of misoprostol doses used was significantly less in Foley with misoprostol group. **Conclusion:** The outcome of combination of intracervical Foley catheter and misoprostol is superior for labor induction, without affecting maternal or perinatal outcome.

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Induction of labor may be defined as artificial initiation of uterine contractions before spontaneous onset in order to accomplish the delivery of fetus [1]. Induction of labor is vindicated when the risks of continuing the pregnancy are high and termination of pregnancy is validated for maternal and fetal benefits.

Based on electronic data for Six United States Health Plans, induction prevalence rose from 28% in 2001 to 32% in 2005 and then declined to 29% in 2007 [2]. WHO states that in developed countries 25% of all deliveries at term undergo induction of labor [3].

Currently, several methods of induction are available including prostaglandin E1, prostaglandin E2, oxytocin, amniotomy, membrane stripping, Foley catheter, hygroscopic dilators, saline injections, which may be used solely or in combination [4].

Several randomized trials have been conducted which have compared the efficacy of various mechanical and pharmacological agents used for induction of labor. Their results are antithetical in terms of time taken from starting of induction till delivery and labor complications [5–8].

There is still no established guidance on the most efficacious agent for induction of labor. It can be hypothesized that the addition of a mechanical agent like the Foley bulb to a pharmacological agent like misoprostol will result in a better outcome of induced labor, by ensuring greater cervical ripening and effacement by mechanical stretching.

The objective of this study was to evaluate the comparative outcome of combination of the Foley bulb and misoprostol with misoprostol alone for induction of labor.

Materials & methods

This was a randomized controlled trial conducted in the Department of Obstetrics and Gynecology, King George's Medical University, Lucknow, India, over a time period of 4 years. Ethical clearance from the institutional committee was taken (Trial Registration number – ECR/262/Inst/UP/2013 and Ethical Clearance number – 68th ECM I-B-ii/P3).

Women with a single, live fetus (34 weeks and above), vertex presentation, intact membranes and an unfavorable cervix (Bishop's score 6 or less) coming to our department, at term or with indications of induction, and willing to participate in the study, were included.

Exclusion criteria were: women already in labor at admission, multiple pregnancy, malpresentation, previous cesarean delivery or any other uterine surgeries, contraindications to prostaglandins and malformed or dead fetus. During random allocation, methods were placed consecutively in opaque envelopes and sealed. After informed written consent, each woman was assigned to receive intracervical Foley catheter with misoprostol or misoprostol alone as a method of induction.

In Group A, Foley catheter was introduced into the cervical canal just beyond the internal OS with fingers or by direct visualization with the help of a sterile speculum. During insertion, any contact of the catheter tip with the perineum, vaginal wall or ectocervix was avoided. After insertion and ensuring proper placement, the catheter balloon was inflated with 30 ml 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 aspect of thigh of the patient until spontaneous expulsion. If not expelled spontaneously, the catheter was removed after 24 h. It was followed by tablet misoprostol 25 µg intravaginally after 4 h of catheter insertion and then 4 h up to a maximum of eight (200 µg) or until onset of active phase of labor (cervical dilatation 4 cm).

In Group B, 25 µg of misoprostol was inserted per vaginally every 4 h. Once, the patient was in active labor (cervical dilatation 4 cm), misoprostol administration was discontinued. If contractions were not initiated, maximum eight (200 µg) doses of misoprostol were used.

Uterine contractions were monitored manually in terms of frequency per 10 min and duration of one contraction. During induction, if the woman developed tachysystole (> five uterine contractions per 10 min), the next dose of misoprostol was withheld. A per-vaginal examination was done every 4 h to assess changes in Bishop score. Labor was monitored using a partograph.

Data recorded included duration between induction to onset of active labor, time elapsed between starting of induction and delivery, mode of delivery, presence of uterine tachysystole, postpartum hemorrhage (defined as estimated blood loss >500 ml for vaginal delivery or >1000 ml for cesarean delivery), non-reassuring fetal heart rate abnormalities (i.e., persistent fetal tachycardia [>160 beats/min], fetal bradycardia [<110 beats/min] and variable or late decelerations) and perinatal outcome (i.e., Apgar score, need for neonatal unit admission). Successful induction defined as women who progressed to have regular uterine contractions or Bishop score > 6.

Continuous variables were analyzed using Analysis of Variance and Kruskal–Wallis tests and Fisher exact test were used for categorical data. All tests were two-sided. Statistical analysis was done using SPSS 11.0 (SPSS Inc., IL, USA). A probability value of less than 0.05 was considered as statistically significant.

Results

A total of 1306 women were enrolled in the study, divided into two groups to have one of the methods of induction, either intracervical Foley with misoprostol or misoprostol alone. Both the groups were similar with regard to demographic parameters and indications for induction of labor (Table 1). The most common indication for induction of labor was preeclampsia.

Induction to delivery interval was significantly reduced in Group A than Group B (19.65 ± 9.21 vs 24.99 ± 12.76) and the difference was statistically significant ($p = 0.002$; Table 2). Duration was significantly reduced in primigravida (17.71 ± 8.90 vs 22.99 ± 9.45 ; $p = 0.003$). Mean duration between induction to active labor was significantly reduced when Foley catheter used along with misoprostol (11.40 ± 5.91) than misoprostol alone (20.00 ± 6.60) and the difference was statistically significant ($p\text{-value} < 0.001$). More subjects had successful induction in Group A (84%) as compared with Group B (60%) and the result was statistically significant ($p = 0.003$). Deliveries within 24 h were significantly higher in Foleys with misoprostol group (91.90%) as compared with 62% with misoprostol alone ($p = 0.001$). More subjects had vaginal delivery in Foley with misoprostol group (76%) as compared with misoprostol alone (56.8%) and cesarean rate was less in Group A but the result was not statistically significant ($p = 0.20$). In the present study, the number of misoprostol doses used was significantly less in Group A (2.70 ± 2.36) as compared with Group B (4.85 ± 2.38 ; $p = 0.001$).

Both groups were comparable in terms of neonatal Apgar score at 1 and 5 min. NNU admissions were less in Group A (11%) as compared with Group B (15%), but no statistically significant difference was found ($p = 0.67$; Table 3).

Table 1. Baseline demographics.

Characteristics		Group A	Group B	p-value
Age		25.1 ± 2.8	25.6 ± 4.1	t' = 1.89 p = 0.54
Parity (Nullipara)		55%	59%	X ² = 0.326 p = 0.568
Gestational age		320 ± 30.78	290 ± 28.81	t' = -0.28 p = 0.995
Indications of induction	Decreased fetal movement	125	145	X ² = 8.29 p = 0.451
	Postdated pregnancy	147	94	
	Preeclampsia	315	304	
	Cholestasis	43	81	
	IUGR	20	26	
Preinduction Bishop score	0–2	225	276	X ² = 6.42 p = 0.099
	3–4	380	301	
	5–6	45	73	

IUGR: Intra uterine growth restriction.

Table 2. Maternal outcome.

Characteristics		Group A	Group B	t-value	p-value
Induction delivery interval	Total	19.65 ± 9.21	24.99 ± 12.76	-3.92	0.002
	Primigravida	17.71 ± 8.90	22.99 ± 9.45	-2.99	0.003
	Multigravida	20.21 ± 9.02	25.02 ± 13.21	-1.98	0.09
Induction-active phase interval		11.40 ± 5.91	20.00 ± 6.60	-4.948	<0.001
Successful induction		84.00	60.00	8.341	0.003
Delivery within 24 h		91.90	62.00	13.876	0.001
Vaginal deliveries		76.00	56.8	4.910	0.20
Cesarean deliveries		23.00	43.2		
Misoprostol doses		2.70 ± 2.36	4.85 ± 2.38	-6.416	<0.001

Table 3. Fetal outcome.

Characteristics		Group A	Group B	t-value	p-value
Apgar score at 1 min	<6	50.00	55.00	0.55	0.367
	≥6	600.00	595.00		
Apgar score at 5 min	<6	10.00	20.00	0.39	0.521
	≥6	640.00	630.00		
NNU admission		11.00	15.00	0.93	0.67

NNU: Neonatal unit.

Table 4. Labor complications.

Characteristics	Group A	Group B	t-value	p-value
Traumatic PPH	4.00	5.00	1.989	0.891
Atonic PPH	8.00	10.00		
Tachysystole	6.00	12.00		

PPH: Post-partum hemorrhage.

The incidence of PPH was 12% in Group A as compared with 15% in Group B. Tachysystole occurred in 6% women in Group A as compared with 12% in Group B. Thus, the complications like PPH and tachysystole were slightly less in Group A, but no statistically significant difference was found (p = 0.891; Table 4).

Discussion

Our study concluded that the synergistic use of the Foley bulb and vaginal misoprostol for induction of labor decreased the time elapsed between starting of induction and delivery as compared with vaginal misoprostol alone, also resulting in a greater number of deliveries within 24 h. The incidence of adverse perinatal and maternal outcomes and labor complications were similar in both groups. Two other significant randomized controlled trials have compared vaginal misoprostol alone with combination of Foley bulb plus vaginal misoprostol [8,9]. Whereas Aduloju *et al.* found the combination to be faster in terms of cervical ripening time, induction-delivery time and cervical ripening-delivery time ($p = 0.001$) [9], Lanka *et al.* did not find any statistically significant benefit in reducing the induction to delivery time ($p = 0.9$). However, according to this study, the incidence of uterine hyperstimulation and meconium stained liquor was significantly reduced by the addition of Foley catheter to misoprostol [8]. In a meta-analysis done by Chen *et al.*, the combined use of Foley catheter and misoprostol resulted in reduced time to delivery ($p = 0.007$) and reduced frequency of tachysystole ($p = 0.02$) [10]. Ande *et al.* concluded that the sequential use of intracervical Foley catheter and misoprostol resulted in more vaginal deliveries occurring within 12 h ($p = 0.001$) than misoprostol alone [11]. In a study done by Ercan *et al.* on second-trimester pregnancy termination, the combination reduced the total dosage of misoprostol ($p = 0.001$) and the time ($p = 0.03$) required for termination, thereby increasing patient's comfort [12].

Conclusion

The combinatorial approach of using intracervical Foley catheter and vaginal misoprostol results in a decreased induction to delivery time, reduced misoprostol doses and a greater number of deliveries occurring within 24 h without increasing labor complications. More studies are needed to evaluate significant labor complications, adverse perinatal and maternal outcomes to draw comprehensive and definitive conclusions.

Future perspective

The combinatorial approach of using misoprostol with Foley bulb and the statistically significant favorable results with no adverse maternal and neonatal outcomes will result in more women opting for vaginal delivery and reduced cesarean delivery on maternal request rates, hence curbing the exorbitantly rising rates of cesarean section and maternal morbidity associated with it.

Summary points

- Induction of labor may be defined as artificial initiation of uterine contractions before spontaneous onset in order to accomplish the delivery of fetus. Several methods of induction are currently available; the best method is still uncertain.
- This study was a randomized controlled trial comparing efficacy of Foley catheter and misoprostol with misoprostol alone for induction of labor, 1306 women were enrolled.
- Maximum dose of misoprostol used was 200 µg (eight doses of 25 µg each) in both the groups.
- Induction to delivery interval, duration between induction to active labor was significantly reduced, deliveries within 24 h were significantly higher and the number of misoprostol doses used was significantly less in Foleys with misoprostol group with more patients delivering vaginally.
- The differences in perinatal outcome, rates of tachysystole and postpartum hemorrhage were not significant.
- The combinatorial approach of using intracervical Foley catheter and vaginal misoprostol results in a decreased induction to delivery time, reduced misoprostol doses and a greater number of deliveries occurring within 24 h without increasing labor complications or affecting perinatal outcome.

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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