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Transcervical foley catheter and vaginal misoprostol compared with vaginal misoprostol alone for induction of labor

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Abstract
Objectives: To compare the proportion of women delivering within 24 hours of concurrent transcervical Foley catheter and vaginal misoprostol versus vaginal misoprostol alone for induction of labor.
Methods: Two hundred and forty-two women (34 to 41 weeks of gestation, singleton live fetus in cephalic presentation, modified Bishops score ≤6 and intact membranes) were randomized into two groups of 121 each. Transcervical Foley catheter inflated with 50 cc saline (kept for maximum of 12 hours) was used along with 25 µg of misoprostol in combined group. Second group received misoprostol alone. Both groups received 25 µg of misoprostol per vaginum every 4 hours (maximum 5 doses). Women not in active labor after 5 doses of misoprostol were considered as failed induction and further management was done according to hospital protocol.
Results: Induction to delivery time was shorter by 1.75 hours in combined group. There was 9% increase in rate of delivery in 24 hours with concurrent Foley and misoprostol. The first stage and active stage of labor was shorter by 2 hours and fewer doses of misoprostol were required in concurrent group. Maternal and neonatal complications were comparable in the two groups.
Conclusions: The concurrent method (mechanical + pharmacological) conferred significant benefits like shorter time to enter active labor, shorter duration of first stage of labor and induction to delivery interval, resulting in an average of two hours shorter stay for a woman in labor without affecting maternal and neonatal outcomes.

Keywords: foley, misoprostol, induction of labor, induction to delivery time, rate of delivery, caesarean, vaginal delivery, oxytocin

Introduction

Over the past several decades, the incidence of labor induction has been on the rise in developed and developing countries. In the United States, incidence has more than doubled (9.5% in 1991 to 23.2% in 2011) [1]. The incidence of induction of labor (IOL) in India varies in different settings ranging from 5% to 22% [2, 3, 4] and in the present scenario, the burden of labor rooms has increased tremendously. Therefore, the researches are looking for a better method of induction which can result in fast patient turnover from crowded labor rooms without increasing maternal or neonatal morbidities.

In FORMOMI trial 2017, when different methods (pharmacological and mechanical) were combined for IOL, it resulted in women spending at least 3.5 million fewer hours in labor [5].

This evidence can be used to the advantage of developing countries, where the health centers have to cater to a large population with limited facilities. It will not only result in large scale reduction in the duration of stay of women in the labor rooms but will also reduce doses and amount of pharmacological agents needed and their associated side effects.

However, more elaborate and convincing studies are required to approve the combined methods of IOL into standard practice of care. This study was performed with an *aim* to evaluate whether the concurrent use of Transcervical Foley catheter with vaginal misoprostol for labor induction will increase the rate of delivery within 24 hours as compared to vaginal misoprostol alone and the *objectives* were to measure and compare the proportion of women delivering within 24 hours of combined method versus vaginal misoprostol alone for induction of labor, Induction to delivery time (IDI)**,** time to Foley's expulsion and time to active labor, rate of delivery within 24 hours and within 12 hours, total dose and duration of misoprostol, change in Bishop's score**,** rate of caesarean delivery and maternal and neonatal outcomes as there is limited Indian literature in this field [6, 7, 8].

Methods

- It was an experimental study conducted from November 2017 to April 2019. Sample size was calculated by using "Power and Sample Size Calculations: A Review and Computer Program". We needed to study 121 subjects in each group to be able to reject the null hypothesis so that the exposure rates were equal for both groups (power 80%). The type I error probability associated with this test was 0.05. Uncorrected chi-square statistic was used to evaluate the null hypothesis.
- 242 pregnant women (34 to 41 weeks period of gestation, singleton live fetus, cephalic presentation, modified Bishops score ≤6 and intact membranes) were randomized into two groups of 121 each. We excluded the following: age <18 years, any contraindication for vaginal delivery, prior caesarean section or other significant uterine surgery, women having HIV/ active genital infection, severe anemia, contraindication to misoprostol use, fetal anomaly, fetal growth restriction, oligohydramnios, non-reassuring fetal heart rate and those unwilling to participate.
- After detailed history, physical and obstetrical examination, patients were allocated into group by lottery method.
- In combined group, 16F Foley catheter (capacity 30-50 ml) was inserted through the cervical canal till it reached beyond internal os, was filled with approximately 50 ml of normal saline and then pulled snugly against the internal os. The external end of catheter was taped to the woman's medial aspect of thigh under gentle traction and tablet misoprostol 25ug was kept in posterior fornix. Pervaginal assessment was done every 4 hours to note progress of labor to decide further dosing of misoprostol (maximum 5 doses). In vaginal misoprostol alone group, tablet misoprostol 25ug was kept in posterior fornix (maximum 5 doses) and were given at 4 hourly intervals till they entered active stage of labor.
- Microsoft Excel (version 2010) and statistical software SSPS for windows (version 20.0) was used for data presentation and statistical analysis. P value <0.05 was considered as significant. Following tests were applied:
- Unpaired Student's t-test: Socio-demographic characteristics and obstetric profile, maternal outcomes and birth weight of neonate.
- Pearson Chi-square test: Socio-demographic characteristics and obstetric profile, maternal and neonatal complications and mode of delivery.
- Fisher's exact test: Clinical outcome.
- Non parametric Mann-Whitney test: Duration of stages of labor and Apgar scores
- Induction to delivery time was also analyzed using Kaplan-Meier survival analysis.

Results and Observations

The two groups were well matched for socio-demographic characteristics, general physical examination and obstetric parameters. Almost half of the women in each group were primigravidae (50% vs 54%). Most of the women in both the groups had received some antenatal care and the commonest indication for IOL was postdated pregnancy in the both groups. The mean POG at recruitment was 39 weeks and mean pre-induction Bishop Score was 3 (Table 1).

Table 1: Comparison of obstetrical parameters in two study groups

Parameter	(Foley + Misoprostol) n=121 Number (%)	(Misoprostol alone) n=121 Number (%)	p value
Parity			
Nulligravida	61(50)	65(54)	0.607
Multigravida	60(50)	56(46)	
Antenatal care			
Yes	119(98)	119(98)	1.000
No	2(2)	2(2)	
Indication for IOL			
Postdatism	77(64)	73(60)	0.678
PIH (gestational hypertension and pre-eclampsia)	19(16)	27(22)	
Diabetes	8(6.3)	7(6)	
IHCP	7(5.8)	5(4.5)	
Decreased fetal movements	8(6.3)	8(6.7)	
Others	2(1.6)	1(0.8)	
	Mean±SD	Mean±SD	
Period of gestation at induction(weeks)	39.47±1.517	39.52±1.421	0.793
Pre induction Bishop score	3.02±1.56	2.87±1.591	0.463

*p value <0.05 is considered significant

Relatively larger proportion of women delivered within 24 hours (88% vs 79%) in concurrent/combined method of IOL (Table 2). Time to reach active labor (shorter by almost 2 hours), first stage of labor (shorter by 1.6 hours), induction delivery interval (less by 1.75 hours), dose and duration of misoprostol exposure were significantly less in combined (Foley + Misoprostol) group than misoprostol group alone (Table 2). Mean time to Foley expulsion was 6.37±3.055 hours. Rate of sequential improvement in Bishop score, requirement and duration of oxytocin use and mode of delivery were not significantly different in the two groups (Table 2).

Table 2: Comparison of maternal outcomes in the study groups

Maternal Outcome	(Foley + Misoprostol) n=121	(Misoprostol alone) n=121	p value
	Number (%)	Number (%)	
Delivery in 24 hours	106(88)	96(79)	0.083
Delivery in 12 hours	43(35)	32(26)	0.126
Rate of caesarean	11(9)	20(17)	0.113
	Mean±SD	Mean±SD	
Time to Foley expulsion (hours)	6.37±3.055	-	-
Time to active labor (hours)	8.44±3.318	10.21±4.064	*<0.001*
Change in Bishop score			
4 hours	5.21±2.501	5.05±1.927	0.565
8 hours	8.41±2.483	7.79±2.601	0.074
12 hours	10.06±2.469	9.35±2.310	0.081
Stages of labor			
1st stage (hours)	12.59±5.14	14.20±4.88	*0.008*
2nd stage (hours)	0.76±0.73	0.99±1.30	0.140
3rd stage (minutes)	3.09±2.07	3.42±2.14	0.231
Induction to delivery time (hours)	13.80±5.83	15.55±5.81	*0.020*
Dose of misoprostol(µg)	54.34±22.285	65.70±25.847	*<0.001*
Duration of misoprostol (hours)	8.63±3.615	10.54±4.129	*<0.001*
Duration of oxytocin(hours)	4.45±3.633	5.30±2.818	0.068
	Number (%)	Number (%)	
Need for additional oxytocin	104(86)	99(82)	0.382
Mode of delivery			
Vaginal	110(91)	101(83)	0.083
Caesarean	11(9)	20(17)	
Final outcome			
Successful			
1. Vaginal	110(91)	101(83)	0.684
2. Caesarean	9(7)	16(13)	
Failed	2(2)	4(4)	

*p value <0.05 is considered significant

Also, maternal and neonatal complications were not found to be statistically different between the two groups (Table 3).

Table 3: Comparison of maternal and neonatal complications in the two study groups

Maternal complication	(Foley+ Misoprostol) n=121 Number (%)	(Misoprostol alone) n=121 Number (%)	p value
Tachysystole			
No	115(95)	116(96)	0.758
Yes	6(5)	5(4)	
Chorioamnionitis	0(0)	0(0)	
Postpartum hemorrhage			
No	112(93)	114(94)	0.605
Yes(Mild atonic PPH)	9(7)	7(6)	
Uterine rupture	0(0)	0(0)	
ICU admission	0(0)	0(0)	
Mortality	0(0)	0(0)	
Neonatal complication	(Foley + Misoprostol) n=121 Number (%)	(Misoprostol alone) n=121 Number (%)	p value
NICU admission			
No	92(76)	94(78)	0.760
Yes	29(24)	27(22)	
Meconium stained liquor	19(16)	16(13)	0.583
Neonatal mortality	0(0)	0(0)	

*p value <0.05 is considered significant

Survival Analysis

The difference in survival times (probability of women left undelivered at the end of 24 hours) was significantly different in the two methods of induction of labor (p= 0.020). The proportion of women left undelivered at the end of each hour (depicted as log rank) was significantly fewer in the combined method of induction of labor as compared to individual method inferring thereby that combined method (Foley + misoprostol) can be offered as a significantly superior alternative to individual method (vaginal misoprostol alone) for induction of labor (Figure 1).

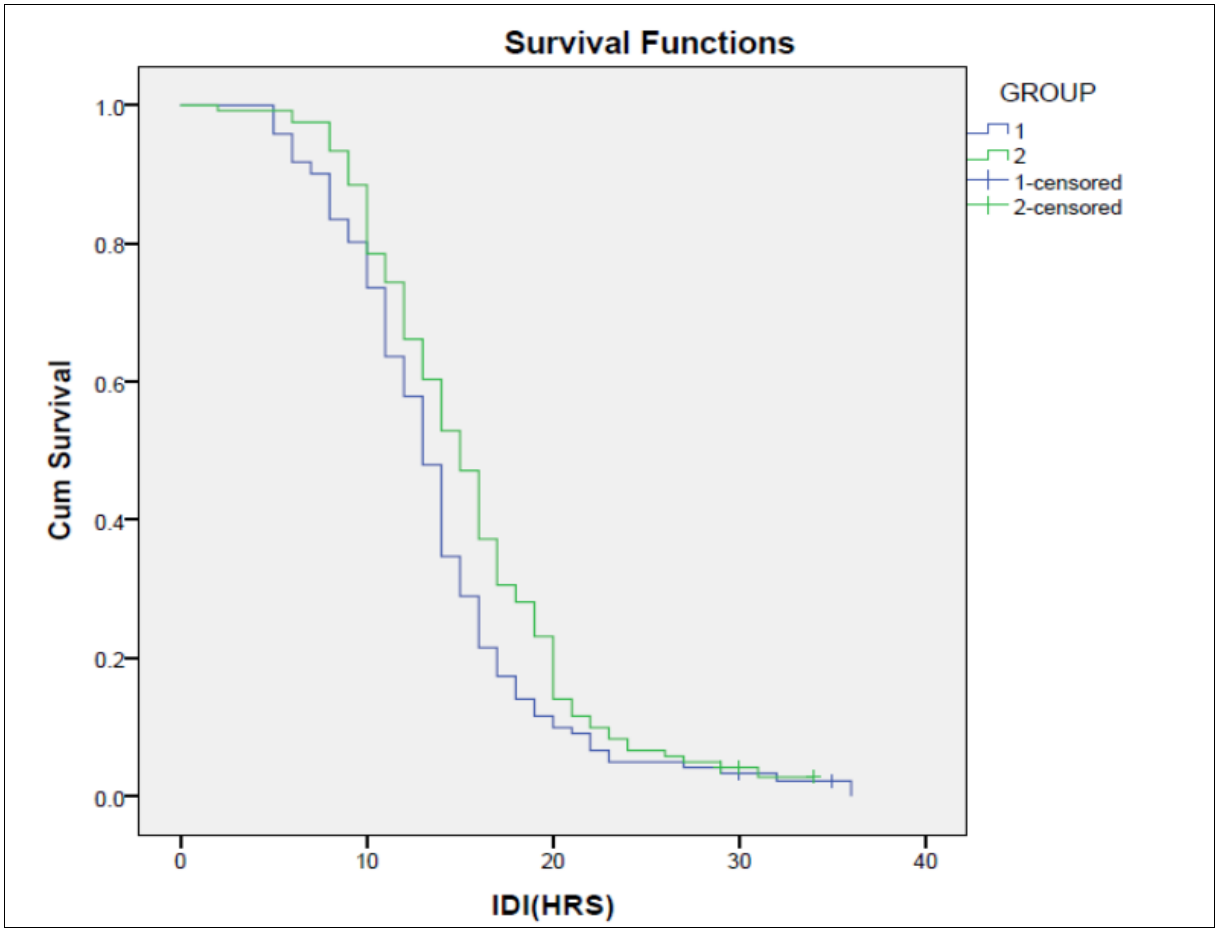

Fig 1: Kaplan-Meier curve using log rank test for induction to delivery interval survival analysis (with successful induction as end point) between the two study groups

Discussion

With time, various methods of induction of labor came into practice. Each method has certain advantages and disadvantages inherent to it. In a search for an ideal method of induction of labor, various studies have been conducted and new studies are being planned all over the world.

With an increase in the incidence of induction of labor, the rate of caesarean section is also on the rise. Major concern in current obstetric practice is to have a better and faster method of induction of labor; but also the one which has better vaginal delivery rates without compromising the maternal and neonatal outcomes. WHO global survey on patterns and outcomes of induction of labor in 2013 showed that African countries have lower rates of IOL (lowest: Niger, 1.4%) compared with Asian and Latin American countries (highest: Sri Lanka, 35.5%), while in India 12.8% deliveries were induced out of which 8.5% were medically indicated and 3.6% were elective inductions [9].

This study compares two methods (combined transcervical foley catheter and vaginal misoprostol versus vaginal misoprostol alone) with objective to measure and compare the proportion of women delivering within 24 hours of the two groups for induction of labor. Benefits gained may be large scale reduction in the duration of stay of subjects in the labor rooms, reduce dosages and amounts of pharmacological agents needed and their associated side-effects, reduce number of per vaginal examinations during labor thereby reducing the incidence of infections and improving the standard of care for individual subjects.

The demographic profile of study population was quite similar to that reported in other Indian studies; 21-26 years of age in study by Charaya and Dahiya and 21-25 years in Bhatiyani study [7, 8]. The mean age reported in trials from abroad was slightly higher which can be attributed to late marriage and child bearing in western counterparts [5, 10]. The mean period of gestation at the time of recruitment was 39 weeks which is similar to most of the earlier reported studies eg: by *Levine et al.* in FORMOMI trial (39 weeks), Carbone *et al.* (39 weeks), Charaya *et al.* (39 weeks), Bhatiyani *et al.* (39 weeks) and Sreelakshmi *et al.* (39 weeks) [5, 10, 7, 8, 6].

Although a higher delivery rate in combined group in the present study, the difference was not statistically significant. The more recent studies have shown a significant improvement in rate of delivery in 24 hours with combined method [5, 11] (Table 4). Chung *et al.* and Sreelakshmi *et al.* found no difference but recent studies by Hill *et al.* and Carbone *et al.* have demonstrated superiority of combined methods [12, 6, 11, 10] (Table 4).

Caesarean rate was similar in the two groups as in studies by Sreelakshmi *et al.*, Carbone *et al.*, Charaya *et al.* and Bhatiyani *et al.* and FORMOMI trial [6, 10, 7, 8, 5] (Table 4).

In contrast to this study where time to active labor was shorter by 2 hours, Charaya and Dahiya *et al.*, Sreelakshmi *et al.* and Kashanian *et al.* did not find a statistical difference [7, 6, 13] (Table 4).

First stage of labor was shorter by 1.6 hours and Induction to delivery interval by 1.75 hours in combined group. Hill *et al.* reported a significant difference of 5 hours (17.8 hours vs 12 hours; $p<0.001$) [11]. Another study also reported significantly shorter IDI by 3 hours in combined group [8]. Combined group required significantly fewer doses and amount of misoprostol and also for significantly *shorter duration* (Table 4).

Table 4: Comparison of outcomes of present study with previous similar studies

Parameter	Carbone *et al*., 2013	Levine, Formomi trial, 2016	Charaya and Dahiya *et al*., 2016	Bhatiyani *et al*., 2017	Present study, 2017-2019
Number of subjects	**123**	**492**	**150**	**105**	**242**
Groups	Group 1: Foley and vaginal misoprostol 25µg (n=56) Group 2: Vaginal misoprostol only (n=56)	Group A: Foley plus vaginal misoprostol (25µg 3 hourly, 5 doses) Group B: Foley plus oxytocin Group C: Vaginal misoprostol alone (as above) Group D: Foley alone.	Group 1: Foley bulb and vaginal misoprostol 25µg (n=75) Group 2: Vaginal misoprostol alone (n=75)	Group 1: Vaginal misoprostol (25µg) alone (n=51) Group 2: Vaginal misoprostol with Foley catheter (n=56)	Group 1: combination of Foley catheter and vaginal misoprostol 25µg (n=121) Group 2: Vaginal misoprostol alone (n=121)
Rate of delivery within 24 hours	Not significantly high	Significantly high	Similar	-	Not significantly high
Time to active labor	Significantly less in combined group	-	Not significantly less	-	Significantly less
First stage of labor	Significantly shorter	-	-	-	Significantly shorter
Change in Bishop's score	-	-	Similar	Significantly better in combined group	Similar
IDI	Significantly shorter	Significantly shorter	Significantly shorter	Significantly shorter	Significantly shorter
Use of misoprostol	Significant less requirement	-	-	-	Significant less requirement
Need for additional oxytocin	Similar rates	-	Higher in combined group but not significant	-	Similar rates
Mode of delivery	Similar rate of vaginal delivery	-	Similar rate of vaginal delivery	Higher rate in misoprostol alone group	Similar rate of vaginal delivery
Rate of caesarean	Similar rate	Similar rate	Similar rate	Similar rate	Similar rate
Tachysystole	Similar rate	Similar rate	One in misoprostol alone group	No case reported	Similar rate
Postpartum haemorrhage	Similar rate	-	No case reported	-	Similar rate
Apgar score at 1 and 5 minutes	Similar rate (8 vs 9)	Similar	6 vs 8	Similar (8vs 9)	Similar (9 vs 9)
NICU admission	Two in misoprostol group only	Similar rate	Similar rate	Similar rate	Similar rate
MSL	Similar rate	Similar rate	-	Similar rate	Similar rate

Conclusion

The combined method of induction of labor (Foley + misoprostol) conferred significant benefits in terms of shorter time to enter active labor, shorter duration of first stage of labor and induction to delivery interval, resulting in an average of two hours shorter stay for a woman in labor. This indirectly translates into other benefits (reduced infection rate by reducing number of vaginal examinations, reduced exposure to dose and duration and side effects of inducing agents), ensuring better maternal and neonatal outcomes.

To conclude, the combined transcervical Foley and vaginal misoprostol method of induction of labor, by virtue of synergistic action of mechanical and pharmacological agent, offers significantly better outcomes and can be offered as a superior method (faster and safer) while counselling women admitted for induction of labor.

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