Original Research Article

Comparative study of labour outcome in foley bulb and vaginal misoprostol versus vaginal misoprostol for induction of labour at a teaching hospital

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Abstract

Background: Labour induction is one of the most common procedures performed in obstetrics, reaching 10 - 20% of deliveries worldwide, common indications are post-term pregnancy, gestational hypertension, preeclampsia, maternal diabetes mellitus, fetal compromise and for logistic reasons. In present study we compared the labour outcome after induction of labor with extra amniotic Foleys catheter with vaginal misoprostol versus vaginal misoprostol alone at a teaching hospital. **Material and Methods:** Present study was single-center, prospective, comparative, parallel-group, randomized, interventional study, conducted in pregnant women with term singleton, live pregnancy, cephalic presentation, intact membranes and unfavourable cervix (Bishop score < 6), planned for induction of labour. 200 pregnant women who meet the inclusion criteria were randomly divided into two groups as patients induced with catheter and misoprostol (Group A) and patients induced with misoprostol (Group B). **Results:** Mean preinduction Bishop score was 2.48± 0.78 in group A and 2.37±0.8 in Group B and difference was statistically insignificant. (p=0.246). A statistically significant difference was noted for mean Bishop score after induction of labour and mean change in Bishop score between group A and B. Favorable changes in Bishops score was noted in group B. Mean duration of induction to active phase of labour and induction to delivery interval was less in group A and difference was statistically significant (p=<.0001). The number of patients delivered vaginally were 87% in Group A and 89% in Group B. 13% patients had undergone lower segment caesarian section in group A and 11% in Group B. The results were found to be statistically insignificant (p=0.663). No intrapartum or postpartum complications were noted in both groups. All newborns were live at the time of delivery with APGAR score of >7. NICU admissions were 8% in Group A and 9% in Group B and difference was statistically insignificant (p=0.800). **Conclusion:** Foley's catheter with vaginal misoprostol is effective in shortening of induction to delivery interval and requires minimum number of doses of misoprostol.

Keywords: induction of labour, primigravida, intracervical foley catheter, intravaginal misoprostol

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INTRODUCTION

Induction of labour is defined as the artificial induction of labour, before its spontaneous onset for the purpose of delivery of the fetoplacental unit.[1] Labour induction is one of the most common procedures performed in Obstetrics, reaching 10 - 20% of deliveries worldwide, but its success depends largely on the condition of the cervix.[2] The common indications are post-term pregnancy, gestational hypertension, preeclampsia, maternal diabetes mellitus, fetal compromise and for logistic reasons.[1] Induction of

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labour includes natural, mechanical, surgical and pharmacological methods. Use of Foley's Catheter as a mechanical method of induction of labour had its advantages of simplicity, cost effectiveness, reversibility and minimal side effects.[3] Foley's catheter balloon causes mechanical dilatation of cervix and stimulates endogenous release of prostaglandins by stripping the fetal membranes and release of lysosomes from decidual cells.[4] Misoprostol has been extensively investigated for use in cervical ripening and labour induction. It has several potential advantages such as stable at room temperature, relatively inexpensive, and can be administered by several routes (oral, vaginal, sublingual, and buccal).[5] The purpose of this study was to compare the labour outcome after induction of labor with extra amniotic Foleys catheter with vaginal misoprostol versus vaginal misoprostol alone at a teaching hospital

MATERIAL AND METHODS

Present study was single-center, prospective, comparative, parallel-group, randomized, interventional study, conducted in Post Graduate Department of Obstetrics and Gynaecology, S.M.G.S. Hospital, Jammu, India. Study duration was of 1 year (November 2018 to October 2019). Study was approved by institutional ethical committee.

INCLUSION CRITERIA:

- Pregnant women with term singleton, live pregnancy, cephalic presentation, intact membranes and unfavourable cervix (Bishop score < 6), willing to participate.

EXCLUSION CRITERIA:

- Pregnant women with previous LSCS, placenta previa, chorioamnionitis, previous uterine surgeries like myomectomy, fetal malpresentation, multifetal gestation.
- Fetal demise, Fetal growth restriction.
- Contraindication to prostaglandins.
- Pregnant women not willing to participate.

200 pregnant women who meet the inclusion criteria, admitted in labour ward of S.M.G.S Hospital, Jammu were selected randomly divided into two groups:

1. Patients induced with catheter and misoprostol (Group A)
2. Patients induced with misoprostol (Group B).

An informed and written consent was taken from each patient for inclusion into the study. Demographic data such as age, parity, height, weight was recorded. All study patients underwent detailed history taking, general physical, systemic and obstetric examination including per-vaginal examination for assessment of Bishop Score. Routine antenatal investigations were carried out. Partogram was maintained throughout the labour.

1. Group A - in 100 patients, under all aseptic precaution 16F foley catheter was inserted through internal cervical ostium. Foley's catheter then inflated with 50 ml of normal saline. Catheter was then pulled against os and taped to inner side of the thigh. Simultaneously 25µg of misoprostol was kept per vaginum every four hourly for a maximum of 6 doses. Catheter was removed after 12 hrs or earlier if patient went in active labour.
2. Group B - In 100 patients, 25 µg of misoprostol was kept per vaginum in the posterior fornix every four hourly for a maximum of 6 doses, till cervix became favourable or patient went in active labour, when required intravenous oxytocin was started 4 hrs after the last dose of misoprostol at a rate of 2 milliunits per minute and subsequently increased by 2 milliunits every 30 minutes.

Both groups received prophylactic antibiotic i.e., single dose of Injection cefotaxime 1 gm iv. Induction to delivery interval time, number of patients who required oxytocin augmentation, mode of delivery, indication for LSCS were noted. Fetal outcome such as passage of meconium and NICU admission were recorded. The participants and their neonates were followed until early neonatal period. The data was analyzed with SPSS version 23. Statistically significant differences were evaluated using t- test and Chi square test. P value of <0.05 was considered as statistically significant.

RESULTS

In present study 70% patients in Group A and 82% percent of patients in Group B were from age group of 21-30 years. Both the groups were comparable in terms of maternal age, mean gestational age and distribution of multigravida and primigravidae and difference between them was statistically insignificant ($p < 0.05$).

Table 1: General characteristics

Characteristics	Group A	Group B	Total	P value
Age (years)				0.142
≤20	16 (16.00%)	9 (9.00%)	25 (12.50%)	
21-25	46 (46.00%)	46 (46.00%)	92 (46.00%)	
26-30	24 (24.00%)	36 (36.00%)	60 (30.00%)	

>30	14 (14.00%)	9 (9.00%)	23 (11.50%)	
Mean Gestational age	39.09 ± 1.03	39.11 ± 0.9		0.878
Obstetrical history				0.149
Primigravidae	77 (77.00%)	85 (85.00%)	162 (81.%)	
Multigravida	23 (23.00%)	15 (15.00%)	38 (19.00%)	
Indication of induction of labour				0.701
Postdated Pregnancy	22 (22.00%)	21 (21.00%)	43 (21.50%)	
Hypertensive disorders of pregnancy	19 (19.00%)	18 (18.00%)	37 (18.50%)	
Term on maternal request	15 (15.00%)	15 (15.00%)	30 (15.00%)	
Oligohydramnios	10 (10.00%)	15 (15.00%)	25 (12.50%)	
Term With Gest. HTN	7 (7.00%)	11 (11.00%)	18 (9.00%)	
Rh Negative Pregnancy	16 (16.00%)	10 (10.00%)	26 (13.00%)	
GDM	5 (5.00%)	6 (4.00%)	11 (5.50%)	
Previous Stillbirth	6 (6.00%)	4 (4.00%)	10 (5.00%)	

Mean preinduction Bishop score was 2.48± 0.78 in group A and 2.37±0.8 in Group B and difference was statistically insignificant. (p=0.246). A statistically significant difference was noted for mean Bishop score after induction of labour and mean change in Bishop score between group A and B. Favorable changes in Bishops score was noted in group B.

Table 2: Bishop score

Mean ± SD	Group A	Group B	p value
Bishops score at admission	2.48 ± 0.78	2.37 ± 0.8	0.246
Bishop score after induction of labour	6.15 ± 1.1	6.49 ± 0.92	0.04
Change in bishop score	3.67 ± 1.25	4.12 ± 1.02	0.006

Mean duration of induction to active phase of labour and induction to delivery interval was less in group A and difference was statistically significant (p=<.0001).

Table 3: Duration from induction to active phase of labor and delivery

Mean ± SD	Group A	Group B	p value
Induction to active phase of labour	10.65 ± 0.95	12.31 ± 1.81	<.0001
Induction to delivery interval	18.52 ± 1.1	21.99 ± 2	<.0001

Duration from induction to active phase of labor in Group A was observed to be 8-10 hours in 44.33% of the patients, 11-13 hours in 55.67% of the patients. In Group B, 31.63% patients had induction to active phase interval between 8-10 hours, 29.59% had this duration of 11-13 hours, 38.78% patients were found to had this duration of >13 hours. Maximum patients went in labor in 11-13 hours in Group A and >13 hours in Group B. Both groups were compared and found to be statistically significant (p=0.0001).

Table 4: Duration of labour from induction to active phase

Duration in hours	Group A	Group B	Total	P value
8-10	43 (44.33%)	31 (31.63%)	74 (37.95%)	
11-13	54 (55.67%)	29 (29.59%)	83 (42.56%)	
>13	0 (0.00%)	38 (38.78%)	38 (19.49%)	
Total	**97 (100.00%)**	**98 (100.00%)**	**195 (100.00%)**	<.0001

Total number of misoprostol used in Group A was 223 and Group B was 300. On an average 2.23 number of misoprostol was used per patient in Group A and 3.00 in Group B. While 46% of the patients in Group A went into labor with two doses of misoprostol, 41% of the patients in Group B went in labor with three doses of misoprostol. Both the groups were compared and result found to be statistically significant (p=0.0001).

Table 5: Comparison of no. of misoprostol used in both groups.

No. of misoprostol used	Group A	Group B	Total	P value
1.00	19 (19.00%)	4 (4.00%)	23 (11.50%)	
2.00	46 (46.00%)	25 (25.00%)	71 (35.50%)	
3.00	32 (32.00%)	41 (41.00%)	73 (36.50%)	<.0001
4.00	0 (0.00%)	28 (28.00%)	28 (14.00%)	
5.00	2 (2.00%)	1 (1.00%)	3 (1.50%)	
6.00	1 (1.00%)	1 (1.00%)	2 (1.00%)	
Total no. of misoprostol	223	300	523	

The number of patients delivered vaginally were 87% in Group A and 89% in Group B. 13% patients had undergone lower segment caesarian section in group A and 11% in Group B. The results were found to be statistically insignificant (p=0.663). Maximum no. of caesarian deliveries (62.50%) were performed due to meconium induced fetal distress in both the groups. On comparing both the groups, the results were found to be statistically insignificant (p=0.951). No intrapartum or postpartum complications were noted in both groups. All newborns were live at the time of delivery with APGAR score of >7. NICU admissions were 8% in Group A and 9% in Group B and difference was statistically insignificant (p=0.800).

Table 6: Labour outcome

Labour outcome	Group A	Group B	Total	P value
Mode of delivery				
FTVD	87 (87.00%)	89 (89.00%)	176 (88.00%)	0.663
LSCS	13 (13.00%)	11 (11.00%)	24 (12.00%)	
Indication for LSCS				0.951
AFD bradycardia	2 (15.38%)	2 (18.18%)	4 (16.67%)	
AFD meconium	8 (61.54%)	7 (63.64%)	15 (62.50%)	
Failed induction	3 (23.08%)	2 (18.18%)	5 (20.83%)	
neonatal outcome				
NICU admission	8 (8.00%)	9 (9.00%)	17 (8.50%)	0.800
Apgar score	8 ± 0.55	8 ± 0.55	200 (100.00%)	1

DISCUSSION

Induction of labour is an integral component of all maternity practices and is important as patients spend more than 24 hours in this process. A variety of methods have been used for cervical ripening or induction of labour. Such as mechanical methods (membrane striping, mechanical dilators, hygroscopic dilators, laminaria tents and foleys balloon catheter), medical methods (oxytocin, dinoprostone, misoprostol, mifepristone, nitric oxide donors, estrogen) and surgical method (amniotomy).[1] The American College of Obstetricians and Gynecologists describe the Foley catheter as an acceptable induction agent because it has demonstrated high efficacy and safety across several studies.[6] Foley's catheter cause mechanical dilatation of cervix and also causes release of prostaglandins F2α from the decidua or prostaglandins E2 from cervix. Advantages over pharmaceutical ripening agents (e.g. prostaglandins) include low cost, stability at room temperature and reduced risk of uterine tachysystole with or without fetal heart rate changes. Misoprostol is effective as an agent for cervical ripening and induction of labour. It is inexpensive, easy to store, and stable at room temperature. The efficacy of misoprostol as a cervical ripening and labour inducing agents with 85% and 95% for 25 µg and 50 µg respectively achieving vaginal deliveries.[7] A total of 200 pregnant patients with term gestation were randomly divided into two groups. The patients were assessed in labour and the outcome of the study was observed. Santosh *et al.*,[8] noted that the mean Bishop score in Group A and Group B was 3.07 ± 0.76 and 3.56 ± 0.68 respectively, difference was statistically insignificant (p value 0.124). Bhatiyani *et al.*,[9] noted that mean Bishop score was more in misoprostol group as compared to combination group but, there was no significant difference in the improvement in Bishop score between the two groups. Similar findings were noted in present study. In study by Ten Eikelder MLG *et al.*,[10] caesarean delivery rates did not differ significantly (25% Foley vs. 17% misoprostol group). Maternal and neonatal outcomes were comparable. Time from induction to birth was longer in the Foley catheter group (36h vs. 25h; p<0.001). Meta-analysis showed no difference in caesarean delivery rate, and reduced vaginal instrumental deliveries and hyper-stimulation in the Foley catheter group. Charaya E *et al.*,[11] induction delivery interval was shorter in combination group (11.76±5.89 hours) than misoprostol group (14.54±7.32hours) (p=0.018). Total duration of labour was less in combination group (6.08±2.88 hours) than misoprostol group (8.20±3.62 hours) . they concluded that nulliparous women with poor Bishop should be offered induction with combination of foley bulb and vaginal misoprostol. Aduloju OP *et al.*,[12] noted that pregnant women in the combined group (Foley's catheter and vaginal misoprostol) had significantly higher postcervical ripening Bishop's score than the women in the other two groups (p=0.001).Women in combined group had less cervical ripening time, induction to delivery interval, significantly lesser oxytocin augmentation required than the other two group. The combination group acts by additive action of mechanical as well as pharmacological ripening of cervix and leads to faster dilatation of cervix. Combination group had less induction to active phase interval than misoprostol only group. The combination group leads to 1.66 hours shorter induction to active phase interval when compared with misoprostol only group. Therefore, use of combination of catheter with vaginal misoprostol is better than vaginal misoprostol only for

induction of labour. We found that mean induction to delivery interval was 18.52±1.1 in Group A and 21.99±2 in Group B. The median interval of induction to delivery interval was 19 hours and 23 hours in Group A and Group B respectively. The mean induction to delivery interval was shorter in combination group by a mean of 3.47 hours when compared with those induced with misoprostol group, the difference being statistically significant. Thus, combination of foley's catheter with misoprostol seems to better and faster method for induction of labour. The results were consistent with the other studies.[8,11,12] On the contrary Kashanian M *et al.*,[13] Bhatiyani BR *et al.*,[9] found that the duration of induction to delivery interval was faster with vaginal misoprostol alone compared to the combination group. In addition Chung *et al.*,[14] Rust OA *et al.*,[15] reported no difference in induction to delivery interval between the two groups. They also reported that the addition of mechanical ripening with the trans-cervical foley balloon to intravaginal misoprostol did not improve the efficiency of preinduction cervical ripening . Mechanical and pharmacological cervical ripening agents appear to act independently rather than synergistically. Combination group had more no. of cesarean deliveries but the difference was statistically insignificant (p=0.663). Similar findings were noted in other studies.[8,11,12] Santosh *et al.*,[8] noted hypertonic uterine action in 6.12% of the cases in Group A and 5.05% of the cases in Group B, there was no differences in labor complications in both the groups. Carbone JF *et al.*,[16] noted that there were no differences in risk of chorioamnionitis, endometritis and postpartum hemorrhage in both the groups. In the present study no intrapartum or postpartum complications were observed in both the groups. Cochrane review[17] compared induction of labour with a balloon with vaginal misoprostol and showed a balloon probably reduces the risk of uterine hyperstimulation with an abnormal heart rate of the baby, but may increase the risk of a caesarean section. When compared to low-dose vaginal misoprostol, a balloon catheter may be less effective, but probably has a better safety profile for the baby.

Limitations of present study were small sample size, lack of a placebo group and lack of blinding after randomization. Multicentric studies with larger number of women are needed to achieve a statistical power sufficient to compare the occurrence of infrequent events

CONCLUSION

Intracervical Foley's catheter and vaginal misoprostol is better option for induction of labour compared to vaginal misoprostol alone. Foley's catheter with vaginal misoprostol is effective in shortening of induction to delivery interval and requires minimum number of doses of misoprostol. There was no statistically significant difference in the maternal and neonatal outcome when these two methods were used for induction of labour.

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