

Comparative study of combination of Foley's bulb and vaginal misoprostol versus vaginal misoprostol alone for cervical ripening and induction of labour at a tertiary hospital

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Abstract

Background: A variety of methods have been used for cervical ripening or induction of labour. Such as mechanical methods (membrane stripping, mechanical dilators, hygroscopic dilators, laminaria tents and foleys balloon catheter), medical methods (oxytocin, dinoprostone, misoprostol, mifepristone, nitric oxide donors, estrogen) and surgical method (amniotomy). Present study was aimed to evaluate combination of foley bulb with intravaginal misoprostol versus intravaginal misoprostol alone in cervical ripening and induction of labour at a tertiary hospital. **Material and Methods:** Present interventional, randomized prospective study was conducted in pregnant women with term singleton pregnancy, cephalic presentation, viable gestation, intact membranes and unfavorable cervix i.e. bishop score less than 6, planned for induction of labour. 200 patients were randomly divided into 2 groups as patients induced with catheter and misoprostol (Group A) and patients induced with misoprostol (Group B). **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. ($p < 0.05$). 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. ($p=0.246$). Mean Bishop score after induction of labour was 6.15 and 6.49 in Group A and B respectively and the difference was statistically significant ($p=0.04$). Mean change in Bishop score was 3.67 ± 1.25 in Group A and 4.12 ± 1.02 in Group B. Both the groups were compared statistically ($p=0.006$). Mean duration of induction to active phase of labour was 10.65 ± 0.95 and 12.31 ± 1.81 in Group A and B respectively and difference was statistically significant ($p=0.001$). 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 ($p=0.663$). **Conclusion:** Combination of catheter and vaginal misoprostol seems to be faster and better method than vaginal misoprostol alone for induction of labor, effective in shortening 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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Labour is the process by which the fetus, after the period of viability is expelled from the genital tract to the outer world.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 Common indications of labor induction are hypertensive disorders of pregnancy, post-dated pregnancy, premature rupture of membranes, intrauterine growth restriction, fetal complications (isoimmunization, oligohydramnios, non-reassuring fetal

heart status, intrauterine fetal death) and maternal medical complications (diabetes mellitus, renal disease, chronic pulmonary disease).^{1,3} Cervical ripening refers to the process of preparing the cervix for labor induction by promoting dilatation and effacement. A variety of methods have been used for cervical ripening or induction of labour. Such as mechanical methods (membrane stripping, mechanical dilators, hygroscopic dilators, laminaria tents and foleys balloon catheter), medical methods (oxytocin, dinoprostone, misoprostol, mifepristone, nitric oxide donors, estrogen) and surgical method (amniotomy).⁴ The present study was aimed to evaluate combination of foley bulb with intravaginal misoprostol versus intravaginal misoprostol alone in cervical ripening and induction of labour at a tertiary hospital.

MATERIAL AND METHODS

Present study was conducted in Post Graduate Department of Obstetrics and Gynaecology, S.M.G.S. Hospital, Jammu over a period of one year from November 2018 to October 2019, after approval from Hospital Ethical Committee. Present study design was interventional, randomized prospective study

INCLUSION CRITERIA: Pregnant women with term singleton pregnancy, cephalic presentation, viable gestation, intact membranes and unfavourable cervix i.e. bishop score less than 6, planned for induction of labour, willing to participate in the study.

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
An informed and written consent was taken from each patient for inclusion into the study. 200 patients were

randomly divided into 2 groups as patients induced with catheter and misoprostol (Group A) and patients induced with misoprostol (Group B).

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.

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. Partogram was maintained throughout the labour.

The two groups were then compared with respect to change in bishop score, total duration of labour, induction to active phase of labour, induction to delivery interval, intrapartum complications (tachysystole, chorioamnionitis), mode of delivery, fetal outcome at birth, APGAR score and postpartum complications. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Quantitative variables were compared using Mann-Whitney Test between the two groups. Qualitative variables were correlated using Chi-Square test. A p value of <0.05 was considered 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. (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%)	

Most common indication of induction was postdatism in both groups (22% patients in Group A and 21% patients in Group B). 15% of the patients among each group were induced at term gestation on maternal request. 16% and 13% of the patients were induced for preeclampsia in Group A and B respectively.

Table 2: Indication of induction of labour.

Indication of induction of labour	Group A	Group B	Total	P Value
Postdated Pregnancy	22 (22.00%)	21 (21.00%)	43 (21.50%)	0.701
Term on maternal request	15 (15.00%)	15 (15.00%)	30 (15.00%)	
Preeclampsia	16 (16.00%)	13 (13.00%)	29 (14.50%)	
Oligohydramnios	10 (10.00%)	15 (15.00%)	25 (12.50%)	
Term With Gest. HTN	7 (7.00%)	11 (11.00%)	18 (9.00%)	
Cholestasis Of Pregnancy	10 (10.00%)	6 (6.00%)	16 (8.00%)	
Previous Stillbirth	6 (6.00%)	4 (4.00%)	10 (5.00%)	
Rh Negative Pregnancy	6 (6.00%)	4 (4.00%)	10 (5.00%)	
Term With GDM	5 (5.00%)	4 (4.00%)	9 (4.50%)	
Term With Chronic HTN	3 (3.00%)	3 (3.00%)	6 (3.00%)	
Severe Gest. HTN	0 (0.00%)	2 (2.00%)	2 (1.00%)	
Term with Type 2 DM	0 (0.00%)	2 (2.00%)	2 (1.00%)	

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. ($p=0.246$). Mean Bishop score after induction of labour was 6.15 and 6.49 in Group A and B respectively and the difference was statistically significant ($p=0.04$). Mean change in Bishop score was 3.67 ± 1.25 in Group A and 4.12 ± 1.02 in Group B. Both the groups were compared statistically ($p=0.006$).

Table 3: Bishop score

Mean \pm 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 was 10.65 ± 0.95 and 12.31 ± 1.81 in Group A and B respectively and difference was statistically significant ($p=0.001$). Induction to delivery interval was found to be 19-21 hours in maximum (51.14%) no. of the patients in Group A. Whereas, the interval was >21 hours in maximum (59.55%) no. of patients in Group B. The mean duration was 18.52 ± 1.1 in Group A and 21.99 ± 2 in Group B. Both the groups were compared and found to be statistically significant ($p < .0001$).

Table 4: Duration from induction to active phase of labor and delivery

Mean \pm 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	$<.0001$

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 ($p=0.663$).

Table 5: Mode of delivery

Mode of delivery	Group A	Group B	Total	P value
FTVD	87 (87.00%)	89 (89.00%)	176 (88.00%)	0.663
LSCS	13 (13.00%)	11 (11.00%)	24 (12.00%)	

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 ($p=0.951$).

Table 6: Indications for LSCS

Indication for LSCS	Group A	Group B	Total	P value
AFD bradycardia	2 (15.38%)	2 (18.18%)	4 (16.67%)	0.951
AFD meconium	8 (61.54%)	7 (63.64%)	15 (62.50%)	
Failed induction	3 (23.08%)	2 (18.18%)	5 (20.83%)	

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 7: Comparison of NICU admission in both groups

	Group A	Group B	Total	P value
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. Therefore, in this study we compared the efficacy and safety of vaginal misoprostol in combination with transcervical foley's catheter versus vaginal misoprostol alone. The mean age of patients in Group A was 24.81 ± 4.24 . However it was observed to be 25.46 ± 4.05 in Group B, difference was statistically insignificant. In the study done by Santosh *et al.*,⁵ it was found that the mean age in Group A and Group B was 24.32 ± 3.35 yrs. and 24.35 ± 3.30 respectively. It was analysed and found to be statistically insignificant. Carbone JF *et al.*,⁶ found that the mean age of patients in Group A and Group B was 25.7 ± 7.2 and 24.2 ± 5.5 respectively and 67% patients in Group A and 65% in Group B were nulliparous patients. The mean gestational age was 39.09 ± 1.03 in Group A and 39.11 ± 0.9 in Group B and difference was statistically insignificant. Santosh *et al.*,⁵ observed that the mean gestational age in Group A and Group B was 39.069 ± 1.596 and 39.166 ± 1.602 respectively and difference was statistically insignificant. In study done by Santosh *et al.*,⁵ noted that postdatism, antepartum eclampsia and antepartum haemorrhage were the leading indications for induction of labour. Similar findings were noted in present study. In the present Bishop score was better in misoprostol group after induction when compared combination group (foley's with misoprostol). But misoprostol took more time to change this Bishop score. However in combination group there were two mechanisms working simultaneously to cause cervical dilatation and effacement in inducing labour. Our results were consistent with the studies done by Bhatiyani *et al.*,⁷ who found 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. Kashanian M *et al.*,⁸ noted that mean change in bishop score was more in misoprostol group as compared to combination group (catheter with misoprostol). Similar findings were noted in present study. 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. Our results were consistent with the studies done by Hussein M *et al.*⁹ We found that 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. The results were consistent with the other studies.^{5,6,9} On the contrary Kashanian M *et al.*,⁷ Bhatiyani BR *et al.*,⁸ 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.*,¹⁰ Rust OA *et al.*,¹¹ 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. In the present study no intrapartum or postpartum complication was observed in both the groups. Our results were consistent with the finding of Santosh *et al.*,⁵ who found 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. Santosh *et al.*,⁵ concluded that the neonatal complications in the form of mild asphyxia were seen in 9.18% of the neonates in Group A and 12.12% of the neonates in group B. Neonatal jaundice was observed in 4.08% of the newborn in Group A and 4.08% in Group B. Around 2% of neonates had hypoglycaemia in both groups. Statistically, there was no difference in adverse neonatal outcome in both the groups. Similar findings were noted in present study.

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

Combination of catheter and vaginal misoprostol seems to be faster and better method than vaginal misoprostol alone for induction of labor, effective in shortening 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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