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Study of Labour Induction with Foley's Catheter and Misoprostol in Comparison with Misoprostol Alone and Its Effect on Fetal and Maternal Outcome

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Abstract
Background: Induction of labor is an obstetric procedure in which termination of pregnancy is done at or after the age of viability by medical, surgical or combined method, with the purpose of initiation of labour and vaginal delivery. The objective of this study was to compare the efficacy of vaginal misoprostol in combination with Foleys catheter with vaginal misoprostol alone for labor induction.
Materials and Methods: This was a hospital based comparative study done in pregnant women with a medical or obstetrical indication for induction of labor between the age group of 20-35 years. Total of 200 patients were included. Subjects were randomly assigned into two groups Group A (Foleys + Misoprostol) and Group B (Misoprostol alone). Primary and secondary outcomes were analyzed and statistical analysis performed.
Results: The induction to delivery time was shorter in Foleys with misoprostol group as compared to misoprostol group alone by 3.67 hours. There was no significant difference in the mode of delivery and maternal and fetal complications between the two groups.
Conclusion: The addition of Foleys catheterization to vaginal misoprostol has a synergistic effect and results in early cervical ripening and delivery.

Keywords: Labour induction, bishop score, misoprostol, foleys

Introduction
Induction of labour is an obstetric procedure in which termination of pregnancy is done at or after the viable age of gestation by the use of some interventional method (Medical, Surgical or combined), with the purpose of initiation of labour and vaginal delivery and such intervention is done to serve the interest of either the mother or baby or both [1]. Induction of labour designates the sequence of artificial cervical ripening and causing excitation of uterine contractions followed by active labour with the aim of completing a vaginal delivery [2]. The different methods of induction of labor are non-mechanical, mechanical and pharmacological methods. Mechanical dilatation of cervix with Foley's catheter to induce labour was first described by Krause in 1833 [3]. Foley's catheter is one of the cheapest, safest and effective mechanical methods of induction verified in various studies [4, 5]. The pharmacological methods include oxytocin and prostaglandin analogues like PGE1 and PGE2. Benefits of misoprostol [PGE1] include low cost, its stability at room temperature, rapid onset of action, multiple potential routes of administration (oral, buccal, sublingual, vaginal, rectal). These potential benefits make it an attractive alternative to PGE2. Numerous reports in the recent Cochrane 2009 studies, including a meta-analysis by Sanchez Rames *et al*., (1997), has found that misoprostol, a synthetic PGE_1 analogue, safely and effectively ripens the cervix and induces labour in patients with unfavorable cervices [6]. The present study was carried to compare the efficacy of vaginal misoprostol in combination with Foleys catheter with vaginal misoprostol alone for labor induction.

Materials and Methods
This was a hospital based comparative study done in pregnant women with a medical or obstetrical indication for induction of labor between the age group of 20-35 years. Total of 200 patients with a singleton pregnancy, fetal cephalic presentation, intact membranes and unfavorable cervix beyond the age of viability were taken from the said age group after admitting the patient to the labor room and ruling out any contraindication for induction of

labour. Detailed history of patient was taken and complete examination was done to rule out any medical contraindication of prostaglandin use, history of uterine scar, check presentation, rule out any cephalopelvic disproportion and rule out any other contraindication for induction as described in introduction.

- Sonography was done in all patients to confirm lie and presentation, for placental position, amniotic fluid index, estimated fetal birth weight and to rule out multiple pregnancies. Subjects were randomly assigned into two groups

1. In Group A patients a Foley catheter was inserted through internal cervical os under all aseptic precautions and filled with 60 ml of normal saline. Catheter was then pulled against os and taped to inner side of the thigh. Simultaneously they received 25 micrograms of misoprostol per vaginum for every four hours to a maximum of 6 doses. Catheter was removed after 12 hrs. If spontaneous expulsion did not occur or earlier if patient went in active labour, developed bleeding per vaginum, fetal distress or artificial rupture of membranes (ARM) was to be done.
2. Group B received 25 mcg of misoprostol per vaginum every 4 hours to a maximum of 6 doses till cervix became favorable or patient was in active labour.

Dose was repeated every four hours to a maximum of 150 micrograms (6 doses) for those who did not get adequate uterine contractions (3 in 10 min).
Strict monitoring of fetal heart rate and uterine contractions was done.
Primary outcome was assessed in terms of vaginal delivery within 24 hours, Bishops score at 12 and 24 hours, Induction delivery time and Neonatal outcome
Secondary outcome was assessed in terms of caesarean delivery, oxytocin use for augmentation, number of doses required, hyper stimulation syndrome, meconium and tachysystole.

Statistical Analysis: The standard statistical test like student's independent T-test was used to analyze the data. For the analysis of the data, the statistical software SPSS V20 and Microsoft Excel was used.

Observations and Results

Age distribution was similar between two groups. Maximum patients were in age group of 26-30 years in both groups with 72% in group A and group B respectively. 20% in group A and 18% in group B were between 20-25 years and 8% in group A and 10% in group B were between 31-35 years of age.
Gestational age was similar in two groups with maximum patients between 37-40 weeks, 80% in group A and 79% in group B respectively. Rest of the patients were greater than 40weeks in both groups.
Gravidity distribution was statistically similar between two groups with 56% primi gravida and 44% multigravida in group A and 50% primi gravida and 50% multi gravida in group B with p-value 0.231.
Difference in pre-induction Bishop Score was statistically insignificant in two groups with p-value of 0.580. [Table 1]

Table 1: Pre Induction Bishop Score

Pre Induction bishop Score	Group A Number (%)	Group B Number (%)	P-Value
1	6	7	0.580
2	26	27	
3	53	50	
4	15	16	
Total	100	100	

Post induction Bishop's score at 12 hours shows statistically significant difference with p-value of <0.001. [Table 2]

Table 2: Post induction Bishops score at 12 hours

Bishops Score at 12 Hours	Group A Number (%)	Group B Number (%)	P-Value
<6	23	33	<0.001
>6	64	56	
Total			

80% of patients in group A and 80% of patients in group B required oxytocin augmentation whereas 20% in group A and 20% in group B did not require any augmentation.
This difference is statistically insignificant 90% of patients in group A and 73% in group B delivered within 24 hrs. Whereas 10% in group A and 27% in group B took more than 24 hrs. To deliver respectively. This difference was statistically significant with p-value <0.001.
Mean induction to delivery time was significantly shorter in group A (15.47_+5.59 hours) than in group B(19.13_+4.62 hours) with mean difference of 3.66 hours and p value 0.002 which was statistically significant.
Mode of delivery in terms of vaginal and LSCS was similar in two groups with p-value of 0.740.
10(10%) of patients in group A and 12(12%) in group had LSCS for failed induction .12 (12%) in each group had LSCS for fetal distress. This difference was statistically insignificant with p value of 0.756.
Average APGAR score at 1 min in group A was 7.02 - +1.092 and in group B was 6.95_+1.009. This difference was statistically insignificant with p value of 0.402.
Average APGAR score at 5 min in group A was 9.32_+1.072 and in group B was 9.27_+0.983.This difference was statistically insignificant with p value of 0.353.
7(7%) of neonates in group A and 8(8%) of neonates in group B were admitted in NICU. This difference was statistically insignificant with p value of 0.593.
There was no statistically significant difference in incidence of maternal complications between two groups. [Table 3]

Table 3: Maternal Complication

Maternal Complications	Group A Number (%)	Group B Number (%)	P-Value
Tachysytole	0	0	0.208
Hypertonus	0	0	
Hyperstimulation	0	0	
Uterine Rupture	0	0	
Nausea/Vomiting	5	6	
Diarrhea	2	3	
Postpartum hemorrhage	4	5	

Discussion

In our study, mean maternal age in group A was 27.61+_2.41 (in years) while in group B it was 27.50+_2.53 (in years). Maximum numbers of patients were in age group of 26-30 years with 72% in group A and group B respectively. In a study by Charaya *et al*. (2016) [7] mean age in combined group was 23.82+_3.14 (in years) while in misoprostol group mean maternal age was 23.98+_3.06 (in years) with p-value of 0.752.

In our study, mean gestational age in weeks in group A was 38.98 and 39.05 in group B respectively. These results were consistent with Charaya E *et al*. (2016) [7] where mean gestational age in combination group was 39.77+_1.25 (weeks) and in misoprostol group it was 39.38+_1.37 (weeks) with p-value of 0.07.

Pre induction Bishops score were similar in two groups with p-value of 0.580. In the present study, Bishop's score calculated for pregnant women with unfavourable cervices requiring cervical ripening has showed statistically significant difference with p-value<0.001 at 12-hour interval. In group A, post induction Bishop's score of <6 was found in 23% patients and >6 in 64% of patients. In group B, post induction Bishop's score of <6 was found in 33% of patients and >6 in 56% of patients. This was statistically significant with p-value of <0.001. In a similar study conducted by Aduloju OP *et al*. (2016) [8], women in the combined group has statistically higher post cervical ripening Bishop's score than women in other two groups.

In our study, 80% of group A and B required oxytocin augmentation and 20% in both groups did not require oxytocin augmentation. This difference was statistically insignificant with p-value of 1. This result was consistent with Binti R Bhayini *et al*. (2016) [9] who found no significant difference in oxytocin augmentation in the two groups.

In present study, mean induction delivery interval was significantly shorter in group A (15.47_+4.47 hours) than in group B (19.135_+4.62 hours) with mean difference of 3.66 hours and p-value of 0.002. These results were consistent with Carbone JF, *et al*. (2013) [10] where average induction delivery time was 3.1 hours shorter in combined group than in misoprostol alone group with mean induction delivery interval of 15.3+_6.5 hours in combined group and 18.3+_8.7 hours in vaginal misoprostol alone. (P-value=0.03). Similarly in a study conducted by Hussain Mustafa *et al*. (2012) [11], there was significant shortening of the interval from induction to establishment of active phase (p-0.003) with significant reduction of induction to delivery time interval in the combination group more than in the misoprostol alone group (p-0.006 and 0.001 respectively).In contrast in a study conducted by Lanka *et al*. (2014) [12] there was not any significant difference in mean induction to delivery interval between two groups.

In the present study, 78% in group A and 76% in group B had normal vaginal delivery while as 22% and 24% underwent LSCS in group A and group B respectively. Mode of delivery was not statistically significant in the two groups with p-value of 0.740. These results were consistent with Charaya *et al*. (2016) [7] where 85.3% in combined group and 85.3% in vaginal misoprostol group had normal vaginal delivery.

In the present study, average Apgar score at 1 minute in group A was 7.02+_1.092 and in group B was 6.95+_1.009. Mean APGAR score at 5 minute in group A 9.32+_1.072 and 9.27+_0.983 in group B. Similar results were found by Charaya *et al*. (2016) [7] where mean APGAR score at 1 minute in combined group was 6.62+-0.80 and in vaginal misoprostol group was 6.60+_0.94 with p-value of 0.852. Also mean APGAR score at 5 minute in combination group was 8.53_+0.64 and in misoprostol group was 8.56_+0.62 with p value of 0.796.

Among maternal complications, in our study, 5% in group A and 6% in group B had nausea and vomiting. 2% in group A and 3% in group B had diarrhoea. 4% in group A and 5% in group B had postpartum haemorrhage respectively. None of the patients had tachysystole, hypertonus, hyperstimulation and uterine rupture. These results were consistent with Binti R Bhatiyani (2016) [9] where 7.4% in combination group and 5.9 %in misoprostol group had nausea and vomiting respectively.

Conclusion

From the present study, it was concluded that addition of Foley catheterization to vaginal misoprostol have synergistic effect and results in early cervical ripening and delivery.

- The results of this comparative study showed that the use of Foley's catheter with misoprostol results in a shorter induction to delivery time compared with misoprostol alone.
- These results also suggest that the combination of Foley's catheter with misoprostol may be useful to achieve timely and safe delivery in the presence of unripe cervix.
- There was no significant difference in the mode of delivery between the two groups.
- There was no significant difference in APGAR score in both the groups.
- There was no increase in maternal and fetal complications of misoprostol as compared to Foley's catheter with misoprostol.

As our study and other literature evidence shows, it is recommended that Foleys catheterization with misoprostol can be used as a safe and effective method for the induction of labour in the indicated set of patients who would benefit from the procedure.

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