Original Article

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# Comparative Study of Intra-Cervical Foley Catheter and Vaginal Misoprostol for Pre-Induction Cervical Ripening

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## Abstract

**Background:** Physical and chemical changes in the uterine cervix and the lower uterine segment, which normally precede the onset of labor are referred to as ripening and seem to be essential to normal labor and delivery.

**Objective:** The aim of this study was to compare the efficacy of intracervical Foley catheter and 50 mcg vaginal misoprostol in pre-induction cervical ripening.

**Study Design:** A randomized, prospective study was conducted in the Department of Obstetrics and Gynecology, Government Medical College, Srinagar from March 2012 to August 2013. 200 patients at term with a Bishop's score ≤3 with various indications for induction were randomly allocated to receive intracervical Foley catheter (100 pts) or 50 mcg vaginal misoprostol (100 pts). After 6 h post-induction bishop's score was noted and labor was augmented if required. Statistical analysis was done using Chi-square test and *t*-test.

**Result:** The groups were comparable with respect to maternal age, gestational age, indication of induction, and initial bishop's score. Both groups showed significant change in the Bishop's score, 3.8 ± 1.1 and 3.6 ± 1.1 for Foley catheter and misoprostol, respectively, $P < 0.001$; however there was no significant difference between the two groups. 14 cesarean sections (14%) were performed in Group A and 19 (19%) were performed in Group B (not significant).The induction to the delivery interval was 18.1 ± 3.6 h in Group A and 17.7 ± 4.1 h in Group B ($P = 0.408$). Apgar score, birth weights, neonatal intensive care unit admissions, and maternal side effects showed no difference between the two groups.

**Conclusion:** This study shows that both Foley catheter and vaginal misoprostol are equally effective in pre-induction cervical ripening.

**Key words:** Cervical ripening, Foley catheter, Misoprostol

## INTRODUCTION

The success of induction of labor depends on the cervical status at the time of induction. It is predicted that the patient with a poor Bishop's score ≤3 have unacceptably higher failure rates.[1,2] Studies have shown that a low Bishop's score is associated with increased rates of cesarean sections, maternal fever, and fetal asphyxia.[2,3] To decrease the induction failure, cervical ripening by any method is the answer. The ripening agents include mechanical dilation and prostaglandin administration. Mechanical dilation was first described with laminaria tents; more recently, the use of a transcervical balloon catheter (Foley catheter) has also been used successfully.[4,5] The Foley catheter is inserted in order to act primarily as a cervical ripening agent, and may have limited effect on uterine contractions due to the release of prostaglandins. Regarding prostaglandin administration, prostaglandin $E_2$ (dinoprostone) was given vaginally or intracervically has been shown to be an effective ripening agent.[6] In addition, prostaglandin $E_1$ (misoprostol) has been shown to be effective for cervical ripening.[7]

The purpose of this study was to compare the efficacy of intracervical Foley catheter with vaginal misoprostol for

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pre-induction cervical ripening. Various parameters such as induction delivery interval, maternal and fetal outcome, and the need for augmentation of labor were compared between the two groups.

## MATERIALS AND METHODS

This prospective comparative study was carried out in the Department of Obstetrics and Gynecology, Government Medical College, Srinagar from March 2012 to August 2013. Institutional ethical clearance was taken. A sample size of 200 cases was divided by simple randomization into two groups, with each group comprising 100 patients. Group A (100 patients) underwent induction by intracervical Foley catheter and Group B (100 patients) by vaginal misoprostol. Patients at term with various indications for induction of labor were included in the study after a written, valid consent was given by the patients.

### Inclusion Criteria

1. Primigravida
2. ≥37 weeks of gestation
3. Singleton pregnancy
4. Cephalic presentation
5. Bishop's score ≤3
6. Intact membranes.

### Exclusion Criteria

1. Multiple pregnancy
2. Mal-presentation
3. Absent membranes
4. Antepartum hemorrhage
5. Medical disease e.g. heart disease and renal disease.

Demographic profile, gestation age, last menstrual period was ascertained and correlated clinically. Detailed history and examination was done in each patient. The baseline investigations were done including complete blood count, blood group, kidney, and liver function tests. The pre-induction bishop's score was determined and after 6 h of induction the post-induction bishop score was assessed.

Improvement of bishop's score, induction delivery interval, mode of delivery, and the fetomaternal outcome were noted. Need of augmentation of labor was assessed and implemented by other methods such as rupture of membranes and oxytocin administration. Failure of induction was declared if the patient failed to go in the active phase of labor within 24 h of labor induction.

Student's *t*-test and Chi-square test were used to statistically compare the two groups. Differences with a $P < 0.05$ were considered statistically significant with a confidence limit of 95%.

## RESULTS

Group A and Group B had 100 randomized patients each. Both the groups were comparable with respect to the maternal age, gestation age, indication for induction, and pre-induction bishop's score (Table 1).

No statistically significant difference was demonstrated between the two groups.

In this study, improvement in the bishop's score in Group A was 3.8 ± 1.1 ($P < 0.001$) and in Group B it was 3.6 ± 1.1 ($P < 0.001$); however, no significant difference in the mean changes in the two groups could be established (Table 2).

The need for further augmentation of labor was noted in the study. In Foley catheter group, the need for augmentation was required in 67 patients and in misoprostol group it was required in 61 patients. There was no significant difference in the need for augmentation of labor in both the groups (Table 3).

Table 4 shows no significant statistical difference in spontaneous vaginal delivery in both the groups. Group A had 82% spontaneous deliveries whereas Group B had 78%

**Table 1: Demographic profile**

| Variable | *n*=100 | | *P* |
|---|---|---|---|
| | Group A | Group B | |
| Maternal age | 26.1±2.8 | 26.2±3.3 | 0.645 |
| Indication for induction | | | |
| Elective | 37 | 36 | 0.873 |
| Postdatism | 39 | 38 | |
| Oligohydramnios | 6 | 7 | |
| IUGR | 7 | 8 | |
| Gestational diabetes mellitus | 5 | 4 | |

IUGR: Intrauterine growth restriction

**Table 2: Change in Bishop score**

| Bishop score | Group A | Group B |
|---|---|---|
| Mean pre-induction bishop score | 2.9±0.7 | 3.0±0.8 |
| Mean post-induction bishop score | 6.7±0.8 | 6.6±0.8 |
| Mean change in score | 3.8±1.1 | 3.6±1.1 |
| | *P*=0.000 | *P*=0.000 |

**Table 3: Need for augmentation**

| Need for augmentation | Group A (%) | Group B (%) | *P* value |
|---|---|---|---|
| Spontaneous | 33 (33) | 39 (39) | |
| ARM | 6 (6) | 30 (30) | 0.378 |
| Oxytocin | 28 (28) | 24 (24) | |
| ARM+Oxytocin | 33 (33) | 100 | |
| Total | 100 | 100 | |

ARM: Artificial rupture of membranes

spontaneous deliveries. The induction delivery interval in Group A was 18.1 ± 3.6 h and 17.7 ± 4.1 in Group B. However, the difference was not statistically significant.

The need for operative intervention was also not statistically significant in both the groups. Cesarean section for fetal distress was done in 8 cases (Group A) and 10 cases (Group B). The other indications for Cesarean section being the failure of the progress of labor (five each) and failure of induction (1 and 4, respectively).

Table 5 shows that 1 min and 5 min Apgar score were similar in both the groups. The neonatal birth weights were also comparable in both the groups (2.77 ± 0.51 in Group A and 2.73 ± 0.24 in Group B). 8% of babies in Group A and 11% of babies in Group B got admitted in the neonatal intensive care unit (NICU) (Table 5). However, the morbidity in both the groups were not statistically significant.

## DISCUSSION

The result of this study confirms that both Foley catheter and vaginal misoprostol are equally effective in pre-induction cervical ripening. The mean change in bishop's score with Foley catheter 3.8 ± 1.1 ($P < 0.001$) and misoprostol 3.6 ± 1.1 ($P < 0.001$) were highly significant, however, there was no statistically significant advantage of one over the other. Similar observations were made by Oliveira *et al.*[8]

The need for augmentation of labor was 67% in Group A and 61% in Group B. The induction delivery interval showed no significant difference in the two groups. The mean I-D interval was 18.1 ± 3.6 in Foley group and 17.7 ± 4.1 in the misoprostol group. Similar were the observations made by Goonawardane *et al.*[9] and Tuuli *et al.*[10]

The rate of cesarean section in Group A was 14% and 19% in Group B ($P = 0.52$, NS). The most common indication for cesarean section in both the groups was fetal distress. Group A had 8 cases of fetal distress and Group B had 10 cases of fetal distress. Jindal *et al.*[11] in their study found no difference of lower segment cesarean section (LSCS) rate between the two groups. The rate of LSCS in our study is agreeable.[2,4]

Fetal outcome data showed no significant difference between Group A and Group B with respect to birth weight ($P = 0.529$), 1 and 5 min Apgar score ($P = 0.263$), and NICU admission rate (8 and 11, respectively). Thus, the present study showed that the fetal outcome results were also comparable in both Group A and Group B. Similar observations were made by Kashanian *et al.*[12]

**Table 4: Mode of delivery and induction delivery interval**

| Variable | Group A *n*=100 (%) | Group B *n*=100 | *P* value |
|---|---|---|---|
| Spontaneous | 82 (82) | 78% | *P*=0.52 |
| Instrumental | 4 (4) | 3% | |
| LSCS | 14 (14) | 19% | |
| Total | 100 | 100 | |
| Induction-delivery interval | 18.1±3.6 | 17.7±4.1 | *P*=0.408 |

LSCS: Lower segment cesarean section

**Table 5: Neonatal outcome**

| Variable | Group A | Group B | *P* value |
|---|---|---|---|
| 1 min Apgar score | 7.8±0.5 | 7.8±0.6 | 0.632 |
| 5 min Apgar score | 9.7±0.6 | 9.8±0.5 | 0.263 |
| Mean birth weight (kg) | 2.7±0.51 | 2.7±0.24 | 0.529 |
| Admission to NICU | 8% | 11% | 0.47 |
| Fetal distress | 9% | 12% | 0.49 |

NICU: Neonatal intensive care unit

## CONCLUSION

This study shows that for cervical ripening there is no difference in efficacy between intracervical Foley catheter and vaginal misoprostol. Furthermore, other factors such as induction delivery interval, maternal and fetal outcome, and the need for further augmentation were similar in both the groups.

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