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Comparision of sequential use of in tracervical foley's catheter and misoprostol versus misoprostol alone for induction of labour in primigravida

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Abstract

Introduction: Induction of labor is a commonly practiced intervention in modern obstetrics. The present study aims to evaluate comparative outcome of induced labour by intracervical Foley's catheter and misoprostol versus misoprostol alone. The objective of the study is to assess the induction-delivery interval, mode of delivery, caesarean section rate, maternal and neonatal outcome.

Materials and Methods: The study included 60 women with singleton full term pregnancy, with cephalic presentation and intact membranes, bishop score <6, reactive NST prior to induction and no obstetric complications. The participants were randomly divided into 2 groups of 30 each. A detailed history was taken. Complete general, systemic and per abdominal examination was performed. Per speculum and per vaginal examination was done. Cervix was assessed using modified Bishop score. Those in group1 were induced sequentially with intracervical Foley's catheter and misoprostol. Those in Group2, were induced with intracervical 50mcg misoprostol alone under aseptic precautions. Modified bishop score was assessed after 4hours and if required reinsertion of 25mcg misoprostol was done for a maximum of 3 doses every 4hours.

Results: The mean induction-delivery interval was shorter in group1 compared to group2 by 3hours. Higher percentage of patients in group1 had spontaneous vaginal delivery. Caesarean section rate, ventouse delivery rate, incidence of fetal distress and rate of NICU admission was more in group2. There was no much difference in APGAR scores and birth weight in between the two groups.

Conclusion: The outcome of combination of intracervical Foley's catheter and misoprostol is superior over misoprostol alone for labor induction, without affecting maternal or perinatal outcome.

Keywords: induction of labour, primigravida, induction- delivery interval, mode of delivery, maternal and neonatal outcome, modified bishop score

1. Introduction

In the recent decades induction of labour by using mechanical or pharmacologic methods in order to generate progressive cervical dilatation and subsequent delivery became a common practice [1, 2]. Induction of labour designates the sequence of artificial cervical ripening and exciting uterine contractions followed by active labor with the aim of completing a vaginal delivery [3]. Labour induction is not without risk but usually done when the risks of continuation of pregnancy outweigh the hazards of labour induction [4, 5].

Incidence of induction varies from setting to setting ranging from 5% to 22% of all labour room admissions and depends upon the institutional protocol [6, 7, 8, 9]. Although labour is usually induced for maternal or fetal indications, inductions without maternal or fetal indication, or elective inductions, recently have been on the rise [10, 11, 12]. Currently, the most frequently used mechanical method is Foley's catheter balloon, which has a dual mechanism of action by causing mechanical dilatation of the cervix and release of endogenous prostaglandins. Misoprostol is a synthetic analogue of prostaglandin E 1 that was formerly used for the treatment of gastric ulcers. Subsequently, its action on cervical ripening and myometrial contractility was recognized. The combination of mechanical and pharmacological methods for labour induction has been evaluated, and the results were promising [4].

In the present study, 60 women fulfilling the inclusion criteria were included and divided into 2 groups (30 each). Group 1 were induced with intracervical Foley's catheter and misoprostol sequentially. Group 2 were induced with intracervical misoprostol alone. The women were followed up till delivery.

This study was undertaken to compare the sequential use of intracervical Foley's catheter and misoprostol versus misoprostol alone for the induction of labour.

2. Aims and Objectives of the study

- The present study aims to evaluate comparative outcome of induced labour by intracervical Foley's catheter and misoprostol versus misoprostol alone.
- The objective of the study is to assess the induction-delivery interval, mode of delivery, caesarean section rate, maternal and neonatal outcome.

3. Materials and Methods

This is a prospective, randomized study conducted at our institution. The study is done on 60 patients attending Obstetrics and Gynaecology OPD satisfying the inclusion and exclusion criteria.

3.1 Inclusion criteria

1. Primigravida
2. Singleton full term pregnancy
3. Cephalic presentation
4. Intact membranes
5. Bishop score <6
6. A reactive non-stress test prior to induction.

3.2 Exclusion criteria

1. Women with any obstetric complications prior to induction
2. Women satisfying the inclusion criteria but in labour.

3.3 Methodology

A detailed history was taken including obstetric, menstrual, family and past history. Antenatal records of patients and investigations done in the antenatal period were recorded. Complete general examination, systemic examination and per abdominal examination was performed. Per speculum and per vaginal examination was done. Cervix was assessed using modified Bishop score as given in Table 1.

The participants were divided into 2 groups by computer generated random allocation. Those in group 1 were induced sequentially with intracervical Foley's catheter and misoprostol. The vaginal portion of the uterine cervix was exposed with a sterile speculum and cleaned thoroughly with antiseptic solution. Under direct vision, 14 F Foley's catheter was inserted through the external cervical os till the tip of catheter is 3-4 cm beyond the internal os. The balloon was inflated with 40 cc of distilled water and then a gentle tug was given to the catheter so that bulb was placed just beyond the internal os. The catheter was taped to the inner thigh to maintain traction. Under aseptic precautions, misoprostol 50mcg was kept intracervically once the Foley's bulb was out. Those in group 2, were induced with intracervical 50mcg misoprostol alone under aseptic precautions.

Maternal monitoring was done by one hourly pulse, blood pressure record. Fetal monitoring was done by half hourly fetal heart monitoring by fetal doppler. Per abdominal examination was done every half an hour to note the onset of uterine contractions. Symptoms such as pain in abdomen, leaking and bleeding per vagina, loss of fetal movements and excessive fetal movements were noted. After insertion of Foley's catheter patients were monitored for spontaneous expulsion upto 12h. Modified Bishop score was assessed immediately after spontaneous expulsion of Foley's catheter. If spontaneous expulsion of Foley's catheter did not occur till 12h then catheter was deflated and removed at the end of 12h and modified Bishop score was assessed. Foley's catheter is kept in situ till one of the followings happened: (1) spontaneous expulsion, (2) spontaneous rupture of membranes, or (3) maximum period of 12h was reached, and then 25 mcg misoprostol tablet was inserted intracervically immediately after removal of Foley's catheter and every 4h up to a maximum of three doses.

The first per vaginal examination was done after 4h and modified Bishop score was noted. The cervix was graded as a favorable cervix when the modified Bishop score was greater than or equal to six. If modified Bishop score was less than six at reassessment then it was assessed whether patient was in true labour or not. If patient was in labour and getting good contractions then labour was allowed to progress and augmentation of labour if required was done. But if patient was not in labour then reinsertion of tablet misoprostol was done and modified Bishop score was reassessed after 4h. Maximum 3 doses were allowed for a period of 12h.

3.4 Study period

October 1st 2019 till November 15th 2019.

3.5 Sample size

Sixty primigravida fulfilling the inclusion criteria, attending Department of Obstetrics and Gynaecology labour room during the study period.

3.6 Follow up: Till delivery.

3.7 Statistical analysis: Proportion, Chi-square test, P value.

4. Results

In the present study, 60 patients satisfying the inclusion and exclusion criteria were included. They were divided into 2 groups by computer generated random allocation. Those in group 1 were induced sequentially with Foley's and misoprostol. Those in group 2 were induced with misoprostol alone as shown in figure 1.

In the present study, 56.25% of patients in group 1 and 57.14% of patients in group 2 were ≤25years; 35.71% of patients in group 1 and 37.5% of patients in group 2 were in between 26-30years; 6.25% of patients in group 1 and 7.14% of patients in group 2 were in between 31-35years as shown in table 2.

The mean Bishop score of patients in group 1 was 2.8 and those in group 2 was 2.4 as shown in table 3.

The mean induction delivery interval among those in group 1 was 8.6h and among those in group 2 was 11.5h as shown in table 4.

In the present study, 80% in group 1 and 66.66% in group 2 had spontaneous vaginal delivery. None of them in both the groups had forceps assisted vaginal delivery. None of them in group 1 had ventouse assisted vaginal delivery while 6.66% of patients in group 2 had ventouse assisted vaginal delivery. 20% in group 1 and 26.66% in group 2 had caesarean section as shown in table 5.

Maternal side effects like nausea and vomiting were seen among 13.33% in group 1 and 10% in group 2. Fetal distress was present among 3.33% of patients in group 1 and 6.66% of patients in group 2. None of the patients in both the groups had complications like uterine hyperstimulation, rupture of the uterus and chorioamnionitis as shown in table 6.

In the present study, among those in group 1, APGAR of newborns at 1 min was 8.5 and in group 2 was 8; APGAR at 5min in group 1 was 9 and in group 2 was 8.5. 6.66% of newborns in group 1 had NICU admission (3.33% for transient tachypnea of newborn and 3.33% for hypoglycemia) and 10% in group 2 had NICU admission (6.66% for transient tachypnea of newborn and 3.33% for meconium aspiration syndrome). No still births and neonatal deaths were reported in the present study. The mean birth

weight of neonates in group 1 was 2.8kg and in group 2 was 2.9kg as shown in table 7.

5. Discussion

In the present study, 60 patients were selected by simple randomization, 30 in Foley's with misoprostol group and 30 in only misoprostol group. The Foley's catheter was acceptable to the patients as misoprostol tablet. There was no accidental rupture of membrane while inserting the catheter. No antepartum or postpartum pyrexia was noted after insertion of Foley's catheter or misoprostol tablet.

In the present study, there is no significant difference in the distribution of patients according to age among the two groups.

The mean pre-induction Bishop score was similar between the two groups (2.8 in the sequential group and 2.4 in the misoprostol alone group).

The induction to delivery time was shorter in the sequential group when compared to misoprostol alone group by a mean of 2.9 hours which was statistically significant, with a P value of 0.0001.The results of our study were similar to study done by Carbone *et al*., which showed that the mean time from induction to complete cervical dilatation was shorter by 3.5h when both Foley's and misoprostol were used for induction than misoprostol alone [13]. Study done by Priyadarshini *et al*., showed that induction to delivery interval, the duration between induction to active labour was significantly reduced, deliveries within 24h were significantly higher and the number of misoprostol doses used was significantly less in Foley's with misoprostol group [14]. The results of our study were contrary to the study done by Bhatiyani *et al*., which showed that the induction to delivery time was shorter in misoprostol group as compared to Foley's with misoprostol by 3h [15].

In the present study, higher rate of vaginal delivery was noted in sequential group (80%) as compared to misoprostol alone group (73.32%). The results of the present study were similar to study done by Husain S *et al*., which showed that the number of women who delivered vaginally in the combination group was significantly higher than misoprostol alone group (91% vs 79%, P = 0.001) [16].

Higher rate of caesarean section was noted in misoprostol only group (26.66%) than sequential group for fetal distress (20%). The results of our study were contrary to the study done by Bhatiyani *et al*., which showed higher rate of cesarean section for fetal distress in the combination group than in the misoprostol only group (53% vs 44%) [15]. Study done by Carbone *et al*., showed that the rate of cesarean section was comparable between the two groups [13].

Our study had shown a higher incidence of maternal side effects like nausea and vomiting in the sequential group (13.33%) than misoprostol alone group (10%). Incidence of fetal distress was more in misoprostol alone group (6.66%) than sequential group (3.33%). The results of our study showed no significant difference in maternal outcome among the two groups. The results of our study were similar to study done by Osoti *et al*., which showed a higher incidence of maternal complications in misoprostol alone group (8.9%) compared to combined group (4.4%) [17]. However, the complications were not statistically different between the two groups.

In the present study, a higher incidence of NICU admission was noted in misoprostol alone group (10%) than sequential group (6.66%), which was statistically not significant. There was no significant difference in other neonatal outcome measures like APGAR at 1min and 5min, still births, neonatal deaths and birth weight among the two groups. The results of our study were similar to study done by Osoti *et al*., in which similar proportion of neonates in the combined group and misoprostol alone group were admitted to NICU due to poor APGAR score (7.8% in combined group versus 6.7% in misoprostol alone group) and prematurity (9.8% in combined versus 12.2% in misoprostol alone group) [17].

5.1 Strengths and limitations of the study

The strength of this study is its randomized design.

Among the limitations are its small sample size, which is inadequate to evaluate serious maternal and neonatal morbidities.

Only primigravida with full term pregnancy are included in the study, so the results do not apply to multigravida and to those with lower gestational ages.

6. Conclusion

Use of both Foley's catheter and misoprostol were safe for induction of labour. Foley's with misoprostol had reduced the duration of labour by 2.9hrs. Proportion of vaginal delivery was more in sequential group than misoprostol alone group by 8%. Proportion of Cesarean section was more in misoprostol alone group than combined group by 6.66%.

7. Acknowledgment

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8. Figures and Tables

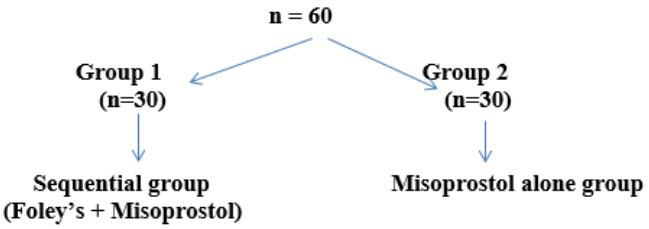

Fig 1: Distribution of patients among the two groups

Table 1: Cervical assessment using modified Bishop score

Cervical Factor	Score			
	0	1	2	3
Dilatation	<1cm	1-2cm	2-4cms	>4cm
Cervical length	4cm	2-4cm	1-2cm	<1cm
Position	Posterior	Midposition/Anterior		
Consistency	Firm	Medium	Soft	
Fetal head station	-3	-2	-1/0	+1/+2

Table 2: Age distribution of patients in the study

Age in years	Inducing agent	
	Foley's with misoprostol	Misoprostol
Upto 25 years	18 (56.25%)	16 (57.14%)
26-30 years	10 (35.71%)	12 (37.5%)
31-35 years	2 (6.25%)	2 (7.14%)
Total	30	30

Table 3: Mean pre-induction Bishop score

Inducing agent	Mean Bishop score
Foley's with misoprostol	2.8
Misoprostol	2.4

Table 4: Mean induction delivery interval

Foley's with Misoprostol group	Misoprostol alone group
8.6h	11.5h

Table 5: Distribution of patients according to the mode of delivery

Mode of delivery	Inducing agent	
	Foley's with misoprostol	Misoprostol
Spontaneous vaginal	24 (80%)	20 (66.66%)
Forceps	Nil	Nil
Ventouse	Nil	2 (6.66%)
Caesarean section	6 (20%)	8 (26.66%)

Table 6: Maternal outcome

Complications and side effects	Inducing agent	
	Foley's with misoprostol	Misoprostol
Nausea and vomiting	4 (13.33%)	3 (10%)
Hyperstimulation	Nil	Nil
Fetal distress	1 (3.33%)	2 (6.66%)
Rupture uterus	Nil	Nil
Chorioamnionitis	Nil	Nil

Table 7: Neonatal outcome

Neonatal outcomes	Inducing agent	
	Foley's with misoprostol	Misoprostol
APGAR at 1 min	8.5	8
APGAR at 5 min	9	8.5
NICU admission	2 (6.66%)	3 (10%)
Stillbirths	Nil	Nil
Neonatal deaths	Nil	Nil
Mean birth weight in kgs	2.8kg	2.9kg

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