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Original Research Article

A study comparing vaginal misoprostol alone with vaginal misoprostol in combination with Foley catheter for cervical ripening and labour induction

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ABSTRACT

Background: Induction of labor is a commonly practised intervention in modern obstetrics. The objective of this study was to compare the efficacy of vaginal misoprostol alone with vaginal misoprostol in combination with Foley catheter for labour induction. It aims to assess the induction delivery interval, the outcome of labour, the incidence of instrumental delivery and Cesarean section. The neonatal outcomes and maternal complications would also be assessed.
Methods: 105 women with singleton viable pregnancies of 28 weeks or more gestation with cephalic presentation, intact membranes and an unfavorable cervix (Bishops score less than 6) were randomly assigned to induction of labor using vaginal misoprostol or Foley catheter in combination with vaginal misoprostol. Women in the misoprostol only group received 25 micrograms of misoprostol per vagina every 4 hours for a maximum of six doses. Whereas women in the combination group received vaginal misoprostol and in addition Foley catheter was introduced through the cervix for 12 hours. Interruption of the trial was done in case of failure to enter the active phase of labour after 24 hours of induction, fetal distress, hyperstimulation, hypersensitivity to drugs.
Results: The induction to delivery time was shorter in misoprostol group as compared to the Foley with misoprostol group by 3 hours. There was no significant change in Bishops score after induction with Foley in combination with misoprostol as compared to misoprostol alone. There was no increase in the maternal and fetal complications in the misoprostol group as compared to Foley with misoprostol.
Conclusions: Misoprostol alone was more efficacious for ripening and inducing agent as compared to Foley in combination with misoprostol.

Keywords: Cervical ripening, Foley catheter, Labour induction, Misoprostol

INTRODUCTION

A study comparing vaginal misoprostol alone with vaginal misoprostol in combination with Foley catheter for cervical ripening and labour induction Induction of labour can be 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 goal of induction of labor is to achieve vaginal delivery in a safe and timely manner. Thus although the best agent and method for induction of labor remains uncertain, it is biologically plausible that a combination of a mechanical device (Foley bulb) and chemical agent (synthetic prostaglandin) may have an additive effect, resulting in a greater degree of cervical ripening and shorter induction to delivery time. The addition of a

synthetic prostaglandin to the Foley bulb may also overcome the scenario of frequent dilatation with the Foley bulb without significant effacement.

METHODS

This was a randomized clinical trial comparing the efficacy of vaginal misoprostol alone with vaginal misoprostol in combination with Foley catheter.

The study was approved by the hospital ethics committee. All women with a singleton, viable gestation 28 weeks or greater, cephalic presentation, intact membranes and an unfavourable cervix (Bishops score 6 or less) presenting for labour induction from January 2013 to November 2014 were evaluated for participation.

Women were excluded if any of the following criteria were encountered fetal malpresentation, multifetal gestation, spontaneous labour, more than 5 uterine contractions in 10 minutes, contraindication to prostaglandins, fetal demise, anomalous fetus, fetal heart tracings showing decelerations, tachycardia or bradycardia or previous Cesarean delivery or other uterine surgery e.g. myomectomy, cornual wedge resection. Eligible patients were approached for consent to participate in the study if inclusion criteria had been met.

Women in the misoprostol only group received 25 micrograms of misoprostol per vagina every 4 hours for a maximum of six doses. Once the cervix became favourable (Bishops score more than 6) or the patient was in active labour, misoprostol was discontinued. Further management of labour was with expectant management, amniotomy or intravenous oxytocin as per unit protocol. If indicated oxytocin was started as per standard protocol 4 hours from the last misoprostol dose. Oxytocin was administered per standard protocol starting at 2 milliunits/min increasing by 2 milliunits/min every half an hour. Interruption of the trial was done in case of failure to enter the active phase of labour after 24 hours of induction, fetal distress, hyperstimulation, hypersensitivity to drugs.

Women in the combination group received vaginal misoprostol as per standard protocol at 25 micrograms every 4 hours for a maximum of six doses. In addition, a Foley catheter was inserted digitally or by direct visual examination with the aid of a sterile speculum. The Foley was inserted through the internal os, filled with 40 ml of normal saline, and then pulled snugly against the internal os. The catheter was taped to patient's inner thigh under gentle traction. The Foley was removed after 12 hours if it was not spontaneously expelled. When the Foley bulb was expelled, further management of labour was either expectant, amniotomy or IV oxytocin. Other aspects of labour management was similar in both groups including continuous electronic fetal monitoring. The primary outcome measure was induction to delivery interval.

Secondary outcome measures were mode of delivery, tachysystole (defined as greater than five uterine contractions in 5 minutes), PPH defined as estimated blood loss greater than 500 ml for vaginal delivery or greater than 1000 ml for Cesarean delivery, neonatal Apgar scores and neonatal intensive care admissions.

RESULTS

A total of 105 women were enrolled for the study from January 2013 to November 2014. Of these 51 women were assigned to vaginal misoprostol and 54 with Foley with misoprostol. The two groups were comparable with regards to baseline characteristics including the indications for induction of labor. The distribution of patients according to parity was also statistically not significant, Tables 1-3.

Table 1: Age distribution of patients in the study.

Age in years	Inducing agent	
	Misoprostol	**Foley with misoprostol**
Up to 25 years	30 (58.8%)	34 (63.0%)
26 to 30 years	16 (31.4%)	10 (18.5%)
31 to 35 years	5 (9.8%)	10 (18.5%)
Total	**51**	**54**
Mean	**25.49**	**25.80**

Table 2: Distribution of patients according to parity.

Parity	Inducing agent	
	Misoprostol	**Foley with misoprostol**
Nulliparous	20 (39.2%)	27 (50%)
Multiparous	31 (60.8%)	27 (50%)

Table 3: Distribution of patients according to indications for induction of labour.

Inducing agent		
	Misoprostol	Foley plus misoprostol
Postdatism	25 (49%)	22 (40.7%)
PIH	14 (27.5%)	24 (44.4%)
IUGR	5 (9.8%)	6 (11.1%)
Oligohydramnios	7 (13.7%)	2 (3.7%)

Table 4: Mean Bishops scores after induction.

Hours	Bishops score	
	Misoprostol	**Foley with misoprostol**
0	3	1.63
4	7	5
8	8	7
12	10	8

Most of the patients were term. The most common indication for induction was postdatism. The mean Bishops score was similar in the two groups. In the

course of the study, it was noted that there was no significant difference in the improvement in Bishops score between the two groups 12 hours after induction. Table 4.

Table 5: Mean Induction delivery interval.

Misoprostol	Foley with misoprostol	p value
8.15 hours	10.75 hours	0.005

It was noted that the mean induction delivery interval was shorter in misoprostol group by a mean of 3 hours when compared with those induced with Foley bulb in combination with misoprostol (mean 8.15±3.23) compared with (mean 10.75±3.82 hours), the difference being statistically significant (p = 0.005) Table 5.

In present study, there was a higher rate of vaginal delivery in misoprostol group (64.7%) as compared to the combination group (50%). However, this was not statistically significant. There were no differences in oxytocin augmentation in the two groups. Labor characteristics and complications are shown in Tables 6 and 7. Although the various indications for Cesarean were statistically not significant, higher rate of Cesarean section was done for fetal distress in the combination group tha in the misoprostol only group (53.%) vs (44.%)

Table 6: Distribution of patients according to the mode of delivery.

Mode of Delivery	Inducing Agent	
	Misoprostol	*Foley with misoprostol*
Spontaneous vaginal	33(64.7%)	28 (50.0%)
Forceps	nil	nil
Ventouse	nil	nil
Caesarean Section	18 (35.3%)	26 (46.3%)

Table 7: Complications and side effects.

Complications and side effects	Inducing Agent	
	Misoprostol	**Foley with misoprostol**
Hyper stimulation	nil	nil
Nausea and vomiting	3 (5.9%)	4 (7.4%)
Fever	5 (9.8)	6 (11.1)
Fetal Distress	8 (44.44%)	14 (53.84%)
Rupture uterus	None	None
Chorioamnionitis	none	none

There was no difference in the incidence of tachysystole, use of terbutaline, or meconium passage in the two groups. The risks of chorioamnionitis, endometritis, and PPH were also not significantly different in the two groups. The neonatal outcomes are shown in Table 8. There were no differences in birth weight, Apgar scores in the two groups. Though there was a higher rate of NICU admission in misoprostol as compared to Foley plus misoprostol group, this was statistically not significant (p = 1.38).

Table 8: Neonatal outcome.

Neonatal Outcomes	Inducing Agent	
	Misoprostol	**Foley with misoprostol**
APGAR at 1 min	8.24	8.52
APGAR at 5min	8.84	9.04
NICU admission	11	7
Stillbirths	Nil	Nil
Neonatal deaths	Nil	Nil
Mean birth wt in kgs	2.72	2.68

DISCUSSION

We found that the induction to delivery interval was shorter by 3 hours in the misoprostol only group. No differences were observed in labour complications or adverse neonatal and maternal outcomes. In the randomized study conducted by Carbone et al, where 123 women were enrolled, the use of Foley bulb and vaginal misoprostol shortened induction to delivery time by an average of 3 hours compared with vaginal misoprostol alone.[3] Whereas in another randomized trial by Kashanian et al, combination of the two methods did not increase their effectiveness and there seemed to be no synergistic effects.[4] Also the induction delivery interval was shorter in the vaginal misoprostol alone than in the combination of Foley bulb and vaginal misoprostol. Chung et al reported no difference in induction to delivery time between the three arms comparing vaginal misoprostol alone, misoprostol in combination with Foley bulb or with Foley bulb alone.[5] Contrary to present study their study, reported a statistically significant increase in tachysystole, terbutaline use and chorioamnionitis with misoprostol alone when compared with the combination group.

CONCLUSION

Induction to delivery time was shorter in misoprostol group as compared to Foley in combination with misoprostol by three hours. There were no increased maternal and fetal complications of misoprostol as compared to Foley with misoprostol. There were no differences in oxytocin augmentation in the two groups. There was no significant difference in the improvement in Bishops score between the two groups 12 hours after induction .There was no statistically significant difference in the mode of delivery between the two groups.

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