International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Agrawal M et al. Int J Reprod Contracept Obstet Gynecol. 2017 Apr;6(4):1283-1287
www.ijrcog.org

pISSN 2320-1770 | eISSN 2320-1789

DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20171008

Original Research Article

Comparative study of vaginal misoprostol and intra cervical Foley's catheter for pre-induction cervical ripening at term

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Received: 20 February 2017
Accepted: 07 March 2017

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ABSTRACT

Background: At times of unfavorable cervix induction of labor with cervical ripening agents were necessary. The present study was done to compare the efficacy and outcome of vaginal misoprostol and Foleys catheter in pregnant women for induction of labor.
Methods: This randomized clinical trial was performed on 10o pregnant women during a time period of December 2014 to November 2016. These women were randomly divided into two groups: Misoprostol (50 patients) and Foley catheter (50 patients). For the first group, 25 mcg vaginal misoprostol was administered every 4 h up to maximum of 3 doses for a period of 12 hours. For the second group, Foley catheter 18 F, was placed through the internal os of the cervix. Data was analyzed using SPSS software 20. $p < 0.05$ was considered statistically significant.
Results: The mean age of the patients in Group 1 was 24.72±2.93 years and Group 2 was 24.12±2.88 years. Pre-induction & post-induction modified Bishop score was significantly higher in Group 1 (Misoprostol) as compared to Group 2 (Foley's catheter) in primigravida and multigravida patients. The difference in the birth weight and Apgar score at 1 min and 5 min between the two groups was statistically not significant ($p>0.05$). The rate of vaginal delivery was significantly more in Misoprostol group as compared to Foley's catheter group ($p<0.05$). The caesarean section rate was more in Foley's catheter group as compared to Misoprostol group and the results were statistically significant ($p<0.05$).
Conclusions: It was concluded that misoprostol decrease the delivery time and increases the vaginal delivery compared to Foleys catheter.

Keywords: Cervical ripening, Foleys catheter, Labor induction, Vaginal misoprostol

INTRODUCTION

In the recent decades induction of labor by using mechanical or pharmacologic methods in order to generate progressive cervical dilatation and subsequent delivery became a common practice.[1] Many studies have shown that pre-induction cervical ripening improves the success of induction of labor. Spontaneous labor is preceded by a stage of pre-labor & ripening of cervix is an important component of pre-labor.[2-4]

Labor induction is generally performed when there are risks of continuing a pregnancy than the benefits of delivery. Common indications for induction of labor include severe preeclampsia or ruptured membranes with chorioamnionitis. The other indications include gestational hypertension, postdated pregnancy,

intrauterine growth restriction, nonreassuring fetal status, chronic hypertension and diabetes.[5]

There are number of techniques available for cervical ripening & induction of labor such as prostaglandins, oxytocin, transcervical catheter, extra amniotic saline infusion, hygroscopic cervical dilators &membranes stripping etc. The most common methods of labour induction when the status of cervix is unfavourable in case of first delivery was intravaginal use of misoprostol. However its use is limited in women who have previously undergone a caesarean section. As it leads to increased risk for uterine rupture in connection with vaginal delivery. The other method adopted was transcervical application of Foleys catheter with different balloon volumes. It induces labor through direct mechanical dilation of the cervix and by stimulating the endogenous release of prostaglandins.[4]

In developing countries like India, a method, which is effective, safe, easily storable and cheaper, is always welcome. Hence the present study was aimed to compare the two methods intravaginal misoprostol and intracervical Foley's catheter for pre-induction cervical ripening and to compare maternal and fetal outcome in both the groups.

METHODS

This randomized controlled study was conducted on 100 pregnant women admitted to the labour ward for induction of labor. The study was conducted at Lata Mangeshkar Hospital, Nagpur during a time period of December 2014 to November 2016 after obtaining permission from Institutional Ethics Committee.

The included criteria were pregnancy with gestational age 37-42 weeks, Singleton live pregnancy, cephalic presentation, Bishop score 6 or less, intact membranes with no uterine contractions, and indications like postdates, pre eclampsia, chronic hypertension, diabetes. Women were excluded from the study if they are having previous uterine surgery, Non reassuring Fetal heart rate tracing, oligohydraminos (amniotic fluid less than 5), placenta praevia, antepartum hemorrhage, multifetal pregnancy, fetal malpresentation, cord prolapse, any evidence of chorioamnionitis, active herpes, estimated fetal weight >4 kg, renal or heart disease, hypersensitivity to prostaglandins, asthma, history of asthma, glaucoma or raised intraocular pressure and intrauterine fetal demise. They were randomly divided into two groups: 50 cases in misoprostol group (group 1) and 50 cases in Foley catheter group (group 2). A written consent form was taken from the participants after complete explanation of the study.

A detailed history was taken including obstetric, menstrual, family and past history. Antenatal records of patients and investigations done in the antenatal period was noted. USG was done in each case to rule out Placenta praevia. 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.

Table 1: Modified Bishops score.

Cervical factor	Scores			
	0	**1**	**2**	**3**
Dilatation	< 1 cm	1 – 2 cm	2 – 4 cm	>4 cm
Cervical length	4 cm	2 – 4 cm	1 -2 cm	< 1 cm
Position	Posterior	Midposed/Anterior		
Consistency	Firm	Medium	Soft	
Fetal head station	-3	-2	-1/0	+1/+2

For the first group, under all aseptic precautions while patient in lithotomy position, tablet Misoprostol 25 mcg was inserted vaginally in the posterior fornix. Attention was given to insert the tablet after diluting it with normal saline or distilled water so that proper dissolution occurs rather than intact tablet falling. The first per vaginal examination was done after 4 hours 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 labor or not. If patient was in labor and getting good contractions then labor was allowed to progress and augmentation of labor if required was done. But if patient was not in labor then reinstallation of tablet Misoprostol was done and modified Bishop score was reassessed after 4 hours. Maximum 3 doses were allowed for a period of 12 hours.

For the second group Foley's self-retaining catheter no 18 with 30cc capacity of balloon was inserted in the extra amniotic space trans cervically by taking all aseptic precautions. The vaginal portion of the uterine cervix was exposed with a sterile speculum and cleaned thoroughly with antiseptic solution. Under direct vision, catheter was inserted through the external cervical os till the tip of catheter was 3-4 cm beyond the internal os. The balloon was inflated with 30 cc of distilled water or normal saline

and then a gentle tug was given to the catheter so that bulb was placed just beyond the internal os. The external end of the catheter was taped to the thigh without traction. Maternal monitoring was done by one hourly pulse, blood pressure record. Fetal monitoring was done by half hourly fetal heart monitoring by stethoscope. 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 12 hours. The time required for spontaneous expulsion of Foley's catheter was noted. Modified Bishop score was assessed immediately after spontaneous expulsion of Foley's catheter. If spontaneous expulsion of Foley's catheter did not occur till 12 hours then catheter was deflated and removed at the end of 12 hours and modified Bishop score was assessed.

Post-delivery care

Vaginal delivery patients were monitored for 2 hours in labor room and LSCS patients were monitored for 6 hours. After this patient was shifted to postnatal ward. Patients were given routine postpartum care with normal diet and adequate analgesia and patients were discharged from hospital after 5 days and LSCS patient after 8 days.

Statistical analysis

Statistical analysis was performed using SPSS software (Version 20). Quantitative data was presented with the help of Mean and Standard deviation. Comparison among the study group was done with the help of unpaired 't' test as per results of normalcy test. Qualitative data was presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher's test, Student 't'test and Chi square test. 'p' value less than 0.05 is taken significant.

RESULTS

In this study, a total 100 pregnant women with indication for partituration were evaluated. They were randomly divided into groups consisting of 50 each. Maternal baseline characteristics were similar between the two groups in terms of age, residence, booking status, parity, gestational age and indications for induction as shown in Table 2.

As shown in Table 3 statistically significant improvement in modified Bishop score for pre-induction and post induction labour was observed in both the groups in primigravida and multigravidia cases.

Table 2: Demographic profile and indication for induction.

Parameters	Group 1	Group 2	P value
Mean age	24.72±2.93	24.12±2.88	P >0.05
Residence			
Rural	32 (64%)	39 (78%)	P >0.05
Urban	18 (36%)	11 (22%)	
Parity			
Primigravida	25 (50%)	35 (70%)	P >0.05
Multigravida	25 (50%)	15 (30%)	
Booking status			
Un-booked	25 (50%)	35 (70%)	P >0.05
Booked	25 (50%)	15 (30%)	
Duration of gestation			
37-39w+6d	26 (52%)	27 (54%)	P >0.05
40-42 weeks	24 (48%)	23 (46%)	
Indications			
PIH	21 (42%)	21 (42%)	P >0.05
PIH, Postdate	7 (14%)	4 (8%)	P >0.05
Postdate	16 (32%)	20 (40%)	P >0.05
PIH, GDM	0	1 (2%)	P >0.05
GDM	4 (8%)	2 (4%)	P >0.05
Oligohydramnios	1 (2%)	1 (2%)	P >0.05
Decreased fetal movement with NST reactive	1 (2%)	1 (2%)	P >0.05

The mode of delivery in both the groups were compared and found statistically significant with each other as given in Table 4. The rate of vaginal delivery was significantly more in Misoprostol group as compared to Foley's catheter group (P<0.05). The caesarean section rate was more in Foley's catheter group as compared to Misoprostol group and the results were statistically significant (p<0.05).

Table 3: Comparison of Modified Bishop score in primigravida and multigravida patients at different times of induction.

Modified bishop score	Group 1	Group 2	P Value
Primigravida			
Pre-induction	3.58±1.3	2.53±1.59	**P <0.05**
Post-induction	6.21±1.69	4.62±1.77	
Multigravida			
Pre-induction	4.28±1.52	3.54±1.12	**P <0.05**
Post-induction	8.01±1.45	5.01±1.48	

Table 4: Comparison of mode of delivery.

Mode of delivery	Group 1	Group 2	P Value
Forceps	0	1 (2%)	P >0.05
LSCS	14 (28%)	40 (80%)	
Vaginal	36 (72%)	9 (18%)	

Indication of LSCS were compared for both the groups and presented in Table 5. As per Fishers test 'p' value for Fetal distress and Prolonged latent phase was <0.05 which was statistically significant. And for remaining indications prolonged second stage, arrest of descent and arrest of dilatation, 'p' value was >0.05 which was not statistically significant. There was no maternal mortality in both the groups.

Table 5: Comparison of indication of LSCS.

Indication of LSCS	Group 1	Group 2	P Value
Fetal distress	10 (20%)	30 (60%)	P <0.05*
Prolonged latent phase	0	6 (12%)	P <0.05*
Prolonged second stage	2 (4%)	2 (4%)	P >0.05
Arrest of descent	0	2 (4%)	P >0.05
Arrest of dilation	2 (4%)	0	P >0.05

The mean birth weight in group 1was 2.71±0.394 kgs. The mean birth weight in group 2 was 2.67±0.321 kgs. The difference in the birth weight between the two groups was statistically not significant (p>0.05) as depicted in Figure 1. In both the groups, fetal Apgar score ranged from 8 to 10 at 1 minutes and 10 at 5 minutes. No neonatal mortality was observed in both the groups.

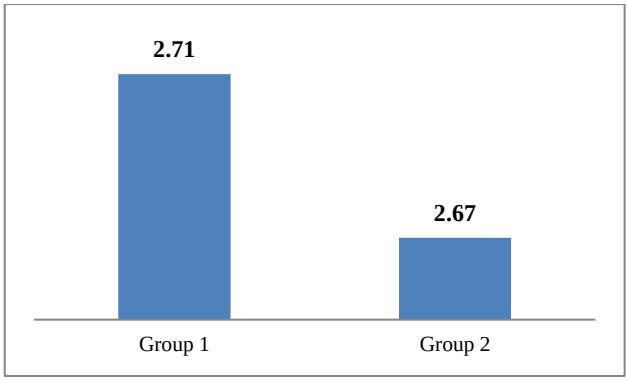

Figure 1: Comparison of neonatal outcomes in terms of birth weight.

DISCUSSION

Induction of labour in case of unfavourable cervix is necessary to shorten the labour time and for easy delivery thereby avoiding the incidence of caesarean section. Hence the use of cervical ripening agents gaining more importance prior to conventional methods. Hence this study was conducted with the objective to compare two methods of cervical ripening and labor induction with vaginal misoprostol and Foley catheter.

In the present study the mean age group of the participants was 24.72 and 24.12 in group 1 and group 2 respectively and the difference was found to be statistically insignificant. This was similar with the previous studies of Noor et al.[4]

52% patients in Group 1 presented between 37 - 39 weeks of gestation while 48% patients were at 40 - 42 weeks of gestation.54% patients in Group 2 presented between 37 - 39 weeks of gestation while 46% patients were at 40 - 42 weeks of gestation. The commonest indication for induction in both groups was pregnancy induced hypertension. This is similar to the study of Jagielska et al.[6]

In our present, study the pre-induction and post-induction Bishop score was significantly higher in Group 1 as compared to Group 2 in primigravida and multigravida patients. It was also observed in both groups that there was significant improvement in post-induction Bishop's score. Similar observations were made by Fareed et al and Oliveira et al.[7,8]

Our study had the rate of vaginal delivery was 72% and 18% while 28% and 80% delivered through caesarean section in Group 1 and Group 2 respectively. The rate of vaginal delivery was significantly more in Misoprostol group as compared to Foley's catheter group (p<0.05) and vice versa in case of the caesarean section rate and the results were statistically significant (p<0.05). Fetal distress and prolonged latent phase indications in Group 2 was significantly more as compared to Group 1. This is

similar to the studies of Roudsari et al, Noor et al and Chavakula et al.[2,4,9]

The birth weight was 2.71±0.394 kgs and 2.67±0.321 kgs in Group 1 and Group 2 respectively. The difference in the birth weight between the two groups was statistically not significant (p>0.05) and is in accordance with the findings of Fareed et al.[7] The Apgar score in our study was 8/10 at 1 minute & 10/10 at 5 minutes. Similar findings were made by Filho et al.[10]

CONCLUSION

The results of the present study confirm that vaginal misoprostol is more effective than Foleys catheter in pre-induction cervical ripening. However, more studies with higher sample size can be led to justify these results.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Agarwal M, Kose V. Comparative study of vaginal misoprostol and intra cervical Foley's catheter for pre-induction cervical ripening at term. Int J Reprod Contracept Obstet Gynecol 2017;6:1283-7.