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Original Research Article

Efficacy of misoprostol over Foley's catheter as a cervical ripening agent: a comparative study

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ABSTRACT

Background: Timely induction of labour could reduce maternal mortality and morbidity as well as assure a delivery of healthy baby. Objective of present study was to evaluate the efficacy of Misoprostol as a cervical ripening agent and its comparison with Foley's catheter in terms of success rate, safety, side effects and patient compliance.
Methods: A total of 250 pregnant women requiring induction of labor were recruited. Out of 250 cases, 150 were induced with 50 microgram Misoprostol and in 100 cases Foley catheter 18 F, was placed through the internal os of the cervix during September 2014 to August 2017 at the department of Obstetrics and Gynecology, GMERS Medical College, Dharpur-Patan. Written and informed consent was taken from the patients. Outcome measures, such as change in Bishop's score, need of augmentation, induction delivery interval; complications like hyperstimulation, fever and meconium passage were compared between two groups. Statistical analysis was performed by Epi Info 7.
Results: Age range of the patients was 21 to 35 years. 72.4 % of the patients were in 21-25 years age groups. 54.4% patients were multigravida. 59.2% patients had more than 37 weeks of pregnancy. 46.4% of the patients had premature rupture of membrane as indication of labour. The mean Bishop's score for induction was 3.21 in Misoprostol group. 81.3% patients in Misoprostol group and 88% of patients in Foley's catheter group were delivered by vaginal delivery. 60 % patients delivered within 6 hours in Misoprostol group. (Misoprostol: 60%, Foley's catheter: 9%, $p<0.001$) Incidence of thin meconium was 11.3% in Misoprostol group, 9 % in Foley's catheter group. In Misoprostol group 3.3 women had fever after induction while it was 6% in Foley's catheter group.
Conclusions: The results of the present study confirm that vaginal misoprostol is more effective than Foleys catheter in pre-induction cervical ripening.

Keywords: Bishop's score, Cervical ripening, Foley's catheter, Induction of labour, Misoprostol

INTRODUCTION

Induction of labour is a well established obstetric concept since ancient times. Induction is warranted when the benefits to either the mother or foetus outweigh those of continuing pregnancy. Induction of labour is defined as iatrogenic stimulation of uterine contraction to accomplish delivery prior to the onset of spontaneous labour aimed at delivery by vaginal route. A delicate balance between uterine activity, cervical dilatation rate and response of the foetus should be sought to achieve successful induction of labour. Timely induction could reduce maternal mortality and morbidity as well as assure a delivery of healthy baby. Induction of labour involves a complete interaction between oxytocin and prostaglandins and success of labour depends on cervical condition like dilatation, effacement, consistency and position in the pelvis.[1,2]

Prostaglandins as pharmacological agents have always fascinated the obstetrician for induction of labour as well as cervical ripening agent. Up till now, 2 types of prostaglandins PGE2and PGF2 were used in obstetrics. 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.[3]

Present study is to evaluate the efficacy of Misoprostol as a cervical ripening agent and its comparison against Foley's catheter in terms of success rate, safety, side effects and patient compliance.

METHODS

This prospective study was carried out in 250 cases with gestational age equal to or greater than 28 weeks, no uterine activity at the time of induction, Cervical dilatation should be less than 3 cm and effacement should be less than 50% , positive non stress test without having history of antepartum hemorrhage, cesarean section and allergy to prostaglandins selected by purposive sampling method during September 2014 to August, 2017 at the department of Obstetrics and Gynecology, GMERS Medical College, Dharpur-Patan. The procedure, possible complications and chances of failure of the procedure were explained to each patient in detail. Written and informed consent was taken from the patient. Before conducting the study, approval was obtained from institutional ethical committee for human research. Data safety and confidentiality was also given due consideration. The file containing identity related details was kept password protected and the filled Performa were kept in lock with key accessible only to researcher.

Out of 250 cases, 150 were induced with 50 microgram Misoprostol and in 100 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. 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 Bishop score was assessed.[3] Patients with cardiovascular disease, bronchial asthma, renal or hepatic disorders. Cephalopelvic disproportion, low lying placenta, acute local cervical lesion and previous lower segment caesarean section or any scar over the uterus were excluded from study.

Information regarding socio demographic profile, duration of pregnancy, labour pain, leaking per vaginum, foetal movement and any obstetric or medical disorders was collected using predesigned, pretested performa. Patients were examined and evaluated using investigation like haemoglobin, urine albumin and sugar and blood group blood urea, plasma fibrinogen, bleeding time, clotting time. Prophylactic antibiotics were given to all the patients. After induction, patient was monitored for vital signs, uterine activity, fetal heart sound and progress of labour and development of any untoward reaction. 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. Data was collected and analyzed statistically using Epi Info 7.

RESULTS

Age range of the patients was 21 to 35 years. 72.4% of the patients were in 21-25 years age groups (Table 1).

Table 1: Distribution of Patients according to their age groups.

Age group (year)	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
21-25	115 (76.7%)	66 (66%)	181 (72.4%)
26-30	32 (21.3%)	28 (28%)	60 (24.0%)
31-35	03 (2.0)	6 (6%)	9 (3.6%)
Mean age in year	24.38	24.44	24.41

Out of total 250 pregnant women 136 (54.4%) women were multigravida and 148 (59.2%) patients had more than 37 weeks of pregnancy (Table 2).

Table 2: Distribution of Patients according to gravidity and weeks of gestation.

Gravidity	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
Primigravida	73 (48.7%)	41 (41%)	114 (45.6%)
Multigravida	77 (51.3%)	59 (59%)	136 (54.4%)
Weeks of gestation			
<32 weeks	12 (8%)	9 (9%)	21 (8.4%)
32-36 weeks	48 (32%)	33 (33%)	81 (32.4%)
>37 weeks	90 (60%)	58 (58%)	148 (59.2%)

Out of total 250 women 116 (46.4%) of the women had premature rupture of membrane followed by 57 (22.8%) had post maturity as indication of labour (Table 3).

Table 3: Distribution patients according to indication of labour.

Indication	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
Premature rupture of membrane	71 (47.3%)	45 (45%)	116 (46.4%)
Post maturity	34 (22.6%)	23 (23%)	57 (22.8%)
Pre-eclamptic toxemia	18 (12.0%)	18 (18%)	36 (14.4%)
Eclampsia	4 (2.6%)	2 (2 %)	6 (2.4%)
Intra uterine fetal death	6 (4.0%)	5 (5 %)	11 (4.4%)
Intra uterine growth retardation	10 (6.6%)	5(5%)	15 (6%)
Congenital anomalous baby	7 (4.6)	2 (2%)	9 (3.6%)

The mean Bishop's score for induction was 3.21 in study group and 3.20 in control group (Table 4).

Table 4: Distribution of patients according to Bhishop's score at the time of induction.

Bishop's Score	Misoprostol (n=150)	Foley's Catheter (n=100)
2	32 (21.3%)	25 (25%)
3	62 (41.3%)	31 (31%)
4	54 (36.0%)	42 (42%)
5	02 (1.4%)	2 (2%)
Mean Bishop's Score	3.21	3.20

Only 12% of the patients required augmentation in study group while it was 44% in Foley's Catheter group.

Out of total 250 women 122 (81.3%) women in Misoprostol group and 88% of women in Foley's Catheter group were delivered by vaginal delivery (Table 5).

After application of intravaginal Misoprostol 50 µg tablet, 60% patients delivered within 6 hours. The minimum induction delivery interval was 2 hours. In Foley's Catheter group, maximum patients required 6-12 hours for delivery after induction, minimum induction delivery interval was 3 hours 40 min (Table 6).

Table 5: Distribution of patient according to their mode of delivery.

Mode of delivery	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
Vaginal	122 (81.3%)	88 (88%)	210 (84.0%)
Forceps /vacuum	08 (5.3%)	04 (4%)	12 (4.8%)
LSCS	20 (13.3%)	08 (8%)	28 (11.2%)

Table 6: Distribution of patients according to induction delivery interval.

Hours	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
0-6	90 (60.0%)	9 (9%)	99 (39.6%)
6-12	52 (34.6%)	45 (45%)	97 (38.8%)
12-24	08 (5.3%)	33 (33%)	41 (16.4%)
>24	0	13 (13)	13 (5.2%)

Chi square: 86.99 Degree of freedom: 2 $p<0.0001$

11.3% of patients had thin meconium and 15.3% of patients demonstrated thick meconium in study group compared to 9% thin meconium and 10% thick meconium in Foley's Catheter group (Table 7).

Table 7: Distribution of patients according incidence of meconium in each group at the time of delivery.

Hours	Misoprostol (n=150)	Foley's Catheter (n=100)	Total (n=250)
0-6	90 (60.0%)	9 (9%)	99 (39.6%)
6-12	52 (34.6%)	45 (45%)	97 (38.8%)
12-24	08 (5.3%)	33 (33%)	41 (16.4%)
>24	0	13 (13)	13 (5.2%)

In study group 3.3% of the women had fever after induction while 6 % of the women had fever in Foley's Catheter group. There was a single spike of fever of 100°F which responded to oral paracetamoland cold sponging. No patient had diarrhoeaand vomiting. Incidence of cervical tear was comparable in both groups. No case of hyper stimulation was observed in present study (Table 8).

Table 8: Distribution of patients according to their complication.

Complication	Misoprostol (n=150)	Foley's Catheter (n=100)
Fever	05 (3.3%)	6 (6%)
Cervical tear	07 (4.6%)	4 (4%)
Vaginal laceration	02 (1.3%)	0

DISCUSSION

Age definitely influence labour. Pregnancy below 20 years has more complications as mother is also in developing phase. While increasing age increases the resistance of cervix for dilatation and so ripening of cervix will be delayed or failed in case of primigravida women aged more than 35 years.[1]

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.[3]

In present study, no pregnancies were reported below 20 years and above 36 years of age and maximum patients were in age group of 20-30 years. In Jani PS et al age range of the patients was 20-35 years age group with maximum patients was in the age group of 20-30 years.[1] In the present study the mean age group of the participants was 24.38 and 24.44 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]

In present study out of total 250 pregnant women 136 (54.4%) women were multigravida and 148 (59.2%) patients had more than 37 weeks of pregnancy. The commonest indication for induction in both groups was premature rupture of membrane. This is similar to the study of Jani PS et al. and Jagielska et al.[1,5] In present study 23.6% women had post maturity as indication of induction of labour and in Jani PS et al. it was 24%.[1]

Bishop's score at the time of induction is a very important factor determining successful outcome of labour. Increase in the Bishop's score increases the success of outcome of induction of labour. In study group, maximum number of patients 41.3% were induced in Bishop's score of 3.

In control group, maximum patients (42%) were induced in Bishop's score of 4. In study group 36.0% of patients were induced with Bishop's score -4 and 21.3% patients were induced with Bishop's score 2 and only 1.4% of patients had Bishop's score 5. The mean Bishop's score for induction was 3.21 in study group and was similar to that of control group. Similar results were also obtained in Jani PS et al., by Fareed et al and Oliveira et al.[1,6,7]

In present study 60% women delivered within 6 hours in misoprostol group and 9 % patients in Foley's Catheter group. In Jani PS et al 57.4% women delivered within 6 hours in misoprostol group and 8% patients in Foley's Catheter group.[1] In our study no women delivered more than 24 hours after induction while 13 % women in Foley's catheter group were delivered after 24 hours of induction. Similar results were also obtained in Jani PS et al.[1] Present study had the rate of vaginal delivery was 81.3% and 88% while 13.3% and 8% delivered through caesarean section in Group 1 and Group 2 respectively. 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 Noor et al, Roudsari et al and Chavakula et al.[4,8,6]

However, study done in single college of Dharpur-Patan city limits us to generalize the results. There is definitely a need for well-planned, large-scale studies using standardized methodologies to evaluate the efficacy of Misoprostol as a cervical ripening agent and its comparison with Foleys catheter in terms of success rate, safety, side effects and patient compliance.

CONCLUSION

The results of the present study confirm that vaginal misoprostol is more effective than Foley's catheter in pre-induction cervical ripening.

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