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Comparative study of combined Foley Bulb and Vaginal Misoprostol with Vaginal Misoprostol alone for cervical ripening and Induction of Labour

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ABSTRACT

To study efficacy of combination of foley bulb and vaginal misoprostol in comparison to vaginal misoprostol alone for cervical ripening and induction of labour. A prospective randomized study was conducted on 150 patients with term singleton pregnancy admitted for induction of labour. Seventy five patients were induced with both foley bulb and vaginal misoprostol and another 75 were given vaginal misoprostol alone for induction of labour. Both groups were then compared with respect to change in bishop score, induction to active phase of labour interval, induction delivery interval, duration of labour, maternal complications and neonatal outcomes. Data was analyzed using chi square test and student t test.: Of two groups, change in bishop score after 4 hours of induction of labour was more in combination group. Induction delivery interval was shorter in combination group;11.76±5.89 hours than misoprostol group; 14.54±7.32hours;p=0.018. Total duration of labour was less in combination group(6.08±2.88 hours) than misoprostol group(8.20±3.62 hours);p=0.000. The results were more significant in nulliparous women. Change in bishop score is more and duration of labour and induction delivery interval becomes shorter when induction is done with combination of foley bulb and vaginal misoprostol instead of vaginal misoprostol alone. So, all nulliparous women with poor bishop should be offered induction with combination of foley bulb and vaginal misoprostol.

Keywords: Foley, Misoprostol, Combination, Induction

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INTRODUCTION

Labour is a sequence of uterine contractions that results in effacement and dilatation of cervix and voluntary bearing down efforts leading to expulsion per vaginum of the products of conception[1]. Induction of labour is a common procedure in obstetrics. It is defined as initiation of labour by artificial means prior to spontaneous onset at viable gestational age with aim of achieving vaginal delivery in pregnant women. In developed countries, rate of induction of labour has doubled and it accounts for 25% of all deliveries[2]. In developing countries the rates vary; lower in some regions and high in some areas. Induction of labour is indicated in patients where benefits of induction to either the mother or the fetus outweighs the risk of continuing pregnancy[3]. Benefits of labour induction must be outweighed against the potential maternal and fetal risk associated with the procedure. Methods of inducing labour include pharmacological, mechanical and physical approaches. Mechanical methods are among the oldest and most important approach used for induction of labour[4]. Mechanical methods exert local pressure on cervix, overstretching the lower uterine segment and indirectly stimulating the secretion of prostaglandins[5]. There is no direct effect on uterus. Pharmacological agents include prostaglandins E_2, prostaglandin E_1, relaxin, nitic oxide donors and mifepristone. Misoprostol is a prostaglandin E1 analogue[6]. It was initially approved by FDA for prevention and treatment of gastric ulcer. It has been extensively used in obstetrical practice for induction of labour, intrauterine death, evacuation of uterus, abortion and prevention and treatment of postpartum haemorrhage. Both of these methods acts through different mechanism ultimately leading to cervical dilatation, effacement and initiation of labour. So, it can be assumed that the combination of these two methods will result in early initiation of labour, start of active phase of labour and delivery. With this assumption in mind many studies were carried out in different parts of the world. But all came with different results. The present study was conducted on 150 patients to compare the efficacy of combination of foley bulb and vaginal misoprostol with vaginal misoprostol alone for cervical ripening and induction of labour.

MATERIALS AND METHOD

The present study was a prospective clinical trial conducted over 150 patients admitted to the labour room for induction of labour in the Department of Obstetrics and Gynaecology, Pt. B.D. Sharma Postgraduate Institute of Medical Sciences, Rohtak. The women with term singleton pregnancy, cephalic presentation, viable gestation, intact membranes and unfavourable cervix i.e. bishop score less than 6 were included in the study. The women with previous LSCS, placenta previa, chorioamnionitis, previous uterine surgeries like myomectomy, fetal mal presentation, multifetal gestation, fetal growth restriction, fetal

demise and contraindication to prostaglandins were excluded from the study. The study was conducted over a total of 150 patients with 75 patients in each group. Alternate women were assigned in two groups. An informed and written consent was taken from each patient for inclusion into the study. In Group A patients a 16F foley catheter was inserted through internal cervical os under all aseptic precautions and filled with 50 ml of normal saline. Catheter was then pulled against os and taped to inner side of the thigh. Simultaneously they received 25 micrograms of misoprostol per vaginum for every four hours for a maximum of 6 doses. Catheter was removed after 12 hrs or earlier if patient went in active labour. Group B patients received 25 micrograms of misoprostol per vaginum in the posterior fornix for every four hour for a maximum of 6 doses, till cervix became favourable or patient went in active labour. If required iv oxytocin was started 4 hrs after the last dose of misoprostol at a rate of 2 milliunits per minute increased by 2 milliunits every 30 minutes. Partogram was maintained throughout the labour. Women with failure of induction were offered cesarean section.The two groups were then compared with respect to change in bishop score, total duration of labour,induction to active phase of labour, induction to delivery interval, tachysystole, mode of delivery, chorioamnionitis, fetal outcome, apgar score and postpartum complications.

Statistical analysis

At the end of the study, the data was collected and analyzed by using Student t-test and Chi-square test. A p value of < 0.05 was considered significant.

RESULTS AND DISCUSSION

Of the total 150 patients studied, 75 patients were assigned to each group. Both group were comparable with respect to maternal age, period of gestation at time of induction, indication of induction of labour and bishop score at time of admission.

Table 1: Patients characteristic in both groups

Variable	Group A	Group B	Statistical significance (p value)
Age(years)	23.82±3.14	23.98±3.06	0.752
Period of gestation(weeks)	39.77±1.25	39.38±1.37	0.074
Bishop score on start of induction	2.50±1.35	3.01±1.89	0.056

In both the groups nulliparous women were more than parous women. In combination group 44(58.66%) and in misoprostol group 43(57.33%0) patients were nulliparous. Preeclampsia and postdated pregnancy were the leading indications for induction of labour. Number of doses of misoprostol used was 2.53±1.44 in combination group and 2.77±1.50 in misoprostol group (p=0.155).

Change in bishop score, induction to active phase of interval, induction to delivery interval, duration of labour was noted for both groups and compared.

Table 2: Descriptive analysis of study outcome in both groups

	Group A	Group B	P value	CI
Change in bishop score	2.99±1.72	2.17±1.48	0.001	-0.1978 to 0.8378).
Induction to active phase of labour interval (hours)	9.63±5.71	10.65±6.62	0.250	-3.1396 to 1.0996
Induction delivery interval(hours)	11.76±5.89	14.54±7.32	0.018;S	-5.1042 to -0.4558
Total duration of labour(hours)	6.08±2.88	8.20±3.62	0.000;S	-3.1765 to -1.0645

These outcomes when analyzed separately for nulliparous and multiparous women, the result was found to be more significant in nulliparous women.

Table 3: Descriptive analysis of study outcome in nulliparous women

	Group A	Group B	P value	CI
Induction to active phase of labour interval(hours)	11.40±5.91	14.20±6.60	0.05	-4.9483 to -0.6551
Induction delivery interval(hours)	13.64±5.75	18.40±7.09	0.002	1.0465 to 14.7335

Both groups were comparable with respect to vaginal delivery rate, caesarean section rate, use of augmentation, delivery within 24 hours, tachysystole, chorioamnionitis, baby weight and NICU admission

Table 4: Maternal and neonatal outcomes

	Group A	Group B	P value
Rate of vaginal delivery	64(85.33%)	64(85.33%)	1
Use of augmentation	39(52%)	34(45.33%)	0.414
Delivery within 24 hours	69(92%)	64(85.33%)	0.179
Fetal apgar score at 1 min.	6.62±0.80	6.60±0.94	0.852
Fetal apgar score at 5 min.	8.53±0.64	8.56±0.62	0.796
Baby weight(kg)	2.79±0.38	2.79±0.34	0.955
NICU admission	7(9.33%)	10(13.33%)	0.439
Rate of Tachsystole	0	1(1.33%)	0.315
Chorioamnionitis	0	0	

DISCUSSION

Induction of labour is a commonly practiced intervention in obstetrics designed to artificially initiate cervical effacement, dilatation, uterine contractions and delivery of baby. Induction of labour with unfavourable cervix results in prolonged labour and increased rate of cesarean section, more so in nulliparous females. With time various methods of induction of labour came into practice. Each method has certain advantages and disadvantages inherent to it. So no single method of labour induction can be called superior to the other. In an effort to find a better way to induce labour, various studies have been conducted all over the world. In the present study, bishop score of the patients were comparable at time of admission and after 4 hours of labour induction. Change in bishop score was noted and compared. It was 2.99±1.72 in combination group and 2.17±1.48 in misoprostol group, with significant difference on statistical analysis (p=0.001, 95% CI -0.1978 to 0.8378). This signifies that induction with combination of foley bulb and vaginal misoprostol results in greater change in bishop score

than vaginal misoprostol alone. Eleven patients (14.66%) in each group had cesarean section. Most common indication for cesarean section in both groups was fetal distress. In combination group ten (13.33%) and in misoprostol group nine (12%) cesarean sections were due to fetal distress (p=0.806). One (1.33%) cesarean section in combination group and two (2.66%) in misoprostol group were for failed induction (p=0.559). Hussein et al more caesarean for failed induction in misoprostol group[7].

Induction to active phase of labour interval was 9.63 ±5.71 hours in combination group and 10.65±6.62 hours in misoprostol group , difference was not statistically significant (p=0.250, 95% CI -3.1396 to 1.0996).) while in Kashanian et al study induction to active phase of interval was shorter in misoprostol group, with statistically insignificant difference[8]. Induction to active phase of labour interval was analyzed separately for nulliparous and parous women. It was 11.4±5.9 hours in nulliparous women of combination group and 14.2±6.6 hours in misoprostol group. Result was statistically significant (p=0.05, 95% CI -4.9483 to -0.6551). In Hussein et al study nulliparous women of combination group had lower induction to active phase of interval than misoprostol group (p=0.003)7.This implies that combination of foley bulb and vaginal misoprostol results in earlier start of active phase of labour in nulliparous women. It was 7.45±4.68 hours in parous women of combination group and 6.70±3.85 hours in misoprostol group; difference was found to be statistically insignificant (p=0.680). Induction to delivery interval was 11.76±5.89 hours in combination group and 14.54±7.32 hours in misoprostol group with difference of 2.78 hours and difference was statistically significant at 95% CI -5.1042 to -0.4558 (p=0.01). In Carbone et al study it was 15.3±6.5 hours in combination group and 18.3±8.7 hours in misoprostol group, difference was of 3.1 hours (p=0.03)[9]. Also in Hussein et al study induction to delivery interval was lower in combination group (p=0.006 and 0.001)[7]. In study by Ande et al this interval was 514±175 min in combination group and 627±268 in misoprostol group (p=0.014)[10].However in Kashanian et al study it was 11.7±2.5 hours in group A and 10.5±3 hours in group B (p=0.001)[8]. This implies that induction to delivery interval is shorter when induction is done with combination of foley catheter and vaginal misoprostol than vaginal misoprostol alone Same data was analyzed separately according to parity and it was observed that induction delivery interval was 13.64±5.75 hours in nulliparous females of combination group and 18.40±7.09 hours in misoprostol group and difference was statistically significant (4.76 hours, p=0.002, 95% CI -1.0465 to 14.7335). In multiparous females it was 9.57±5.35 hours in combination group and 10.19±4.72 hours in misoprostol group with insignificant difference (p=0.636). So it can be implied that combination method for labour induction is

more useful in shortening induction delivery interval in nulliparous females than in parous females.

Total duration of labour of two groups (6.08±2.88 hours in combination group and 8.20±3.62 hours in misoprostol group) difference was found significantly different on comparison (p=0.000, 95% CI -3.1765 to -1.0645). Similarly duration of first stage of labour (5.81±3.20 in combination group and 7.69±3.51 in misoprostol group) was found significant on statistical comparison (p=0.01, 95% CI -2.9638 to -0.7962). Duration of second and third stage of labour were found to be statistically insignificant on comparison. It can be concluded that total duration of labour and duration of first stage of labour becomes shorter on induction with combination of foley bulb and vaginal misoprostol. Maternal and neonatal outcomes were similar in both groups.

CONCLUSION

From the present study it was concluded that addition of foley catheterisation to vaginal misoprostol have synergistic effect and results in early cervical ripening and delivery. Combination of foley bulb and vaginal misoprostol results in significant change in bishop score signifying that it promotes early cervical ripening. Combination of both foley bulb and vaginal misoprostol results in early deliveries which was measured in terms of total duration of labour and induction delivery interval. Effectiveness of combination of foley bulb and vaginal misoprostol was much more in nulliparous female than parous females. However, rate of cesarean section, maternal and fetal outcome and complications were similar with either of these methods. Hence combination of foley bulb and vaginal misoprostol should to be offered to all patients with poor bishop especially nulliparous women undergoing induction of labour.

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