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RESEARCH ARTICLE

WHAT IS NEW ABOUT INDUCTION OF LABOUR WITH ORAL MIFEPRISTONE VERSUS ORAL MISOPROSTOL AT TERM

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ABSTRACT

Introduction: Induction of labour implies the artificial initiation of uterine contraction in a quiescent uterus by any method like medical, surgical or combined prior to their spontaneous onset.one of the most common indication for labour induction is prolonged pregnancy, which is associated with many of the fetal complications. present study compares effectiveness and safety of induction of labour with mifepristone and with misoprostol. ***Aim and objective****:* To compare the safety and efficacy of oral mifepristone with that of oral misoprostol in induction of labour at term. ***Materials and methods****:* This was a comperative study involving 100 women with term gestation, women were divided alternatively into two groups with 50 in each group(group 1 mifepristone 200mg given ,group 2 misoprostol 25mcg was given) .The primary outcome measures were successful vaginal delivery ,induction to delivery interval and secondary outcome measures were failed induction ,mode of delivery, birth weight, meconium stained liquor ,fetal distress ,NICU admission ,primary post partum haemorrhage ***Results****:* The mean age of women in group 1 and group 2 was 23.16 and 22.72 years respectively .The mean BMI in both the group was similar (22.63kg/m2 and 22.27 kg/m2) The mean induction to delivery was 31.86 hours in group 1 and in group 2 16.11 hours .this is statistically significant in both groups with favourable and unfavourable cervix(p=.00001) ***Conclusion****:* we concluded that oral mifepristone seems as effective as oral misoprostol for induction of labour at term, misoprostol was responsible for meconium stained liquor in most of the cases, which was less with mifepristone, so better neonatal outcomes when compared to misoprostol.

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INTRODUCTION

Induction of labour is mainly attempted when continuation of pregnancy may harm either mother or foetus or both. Prolonged pregnancy is associated with significantly increased risk of postpartum hemorrhage, oligohydramnios, fetal birth injury, fetal distress in labour, increased rates of cesarean delivery. Different methods of labour induction in full term pregnancy are widely practiced to prevent these complications. Previous studies have shown that prevention of progestogenic effect by mifepristone promotes cervical ripening owing to action of estrogens such as increase in cervical collagenase and prostaglandin synthetase activity. There are studies on comparing effectiveness of oral versus vaginal misoprostol in induction of labour, misoprostol versus combination of mifepristone and misoprostol in induction of labour but there are not enough studies on comparison of mifepristone and misoprostol in induction of labour in full term pregnancy. The present study compared the effectiveness and safety of induction of labour with mifepristone and with misoprostol.

MATERIAL AND METHODS

A hospital based, comparative study on hundred pregnant women admitted with term gestation at JLNMCH, Bhagalpur was carried out from MARCH 2021 to May 2022.

Women presenting to outpatient department/Labour room with term gestation were interviewed & examined clinically. Gestational age at presentation was determined preferably by first trimester scan. If first trimester scan was not available, then menstrual dating and/or a second trimester scan was considered. Complete blood picture, random blood sugar, blood grouping & typing, complete urine examination, viral screening, serum TSH were done as part of antenatal profile. Dating scan, anomaly scan and growth scan were done routinely. Women of 18 to 35 years age, gestational age 40 weeks and above, singleton, live pregnancy with cephalic presentation with intact membranes were included in the study. Parity greater than 3, women with obstetric complications like hypertension/preeclampsia, prior caesarean deliveries, gestational diabetes mellitus, overt DM, fetal malformations, any medical indications for caesarean section were excluded from the study. Eligible women were informed regarding details of the study protocol, alternative methods, and the adverse effects of the drugs. Written informed consent was taken from willing participants. A total of 100 pregnant women with term gestation were included in the study. Women were divided alternatively into 2 groups with 50 in each group (group 1 mifepristone was given & in group 2 misoprostol was given). Group I (Mifepristone): Women received 200 mg mifepristone orally followed by mifepristone 2nd dose when required after 24 hrs. If induction of labour was not achieved with 2 doses of mifepristone, such cases were labelled as failed induction and in these cases cerviprime or misoprostol was used.

Group II (Misoprostol): Misoprostol 25micrograms orally 6 hourly for maximum of 4 doses. Assessment of cervix was based on Bishop scoring. Induction was considered failed with misoprostol, when vaginal delivery was not achieved with 4 doses of misoprostol. Subsequent to induction of labour, vital signs and progress of labor were recorded in modified World Health Organization (WHO) partographs. Active management of third stage of labor was performed. Oxytocin was used for augmentation of labour in active labour if required. Successful treatment was defined as delivery within 48 hours of 1st misoprostol / mifepristone dose in both the groups. The primary outcome measures were successful vaginal delivery, induction to delivery interval (first dose of misoprostol / mifepristone to complete delivery of fetus and placenta) and secondary outcome measures were failed induction, mode of delivery, birth weight, meconium stained liquor, fetal distress, NICU admission, primary postpartum haemorrhage.

RESULTS

In the present observational study, 100 pregnant women with term gestation were divided alternatively into two groups of 50 each. Group 1 patients received tablet mifepristone and Group 2 patients received only tablet misoprostol. The age of the women ranged from 18 to 35 years. The mean age of women in group 1 was 23.1 years and 22.7 years in group 2. Ninetyfive percent of women belonged to low socioeconomic status. Majority of women were booked in both the groups (92% and 88% respectively).

Table 1. Demographic details of women from both groups

Age in years	Group 1 (n=50)	Group 2 (n=50)	P value
<20	8(16%)	17(34%)	
21-29	40(80%)	33(66%)	
>-30	2(4%)	-	
Mean +- SD	23.16 +- 3.44	22.72+-2.82	0.2
BOOKING STATUS			
Booked	46(92%)	44(88%)	
BMI(kg/m2)			
<18.5	9(18%)	8(16%)	
18.5-22.9	17(35%)	23(46%)	
23-24.9	12(24%)	7(14%)	
25 29.9	10(20%)	9(18%)	
>=30	2(4%)	3(6%)	
Mean +- SD	22.63+-3.41	22.27+-3.93	0.3
Gravida status			
Primigravida	30(60%)	28(56%)	0.4
multigravida	20(40%)	22(44%)	

Table 2. Labour characteristics of women from both groups

LABOUR CHARACTERISTIC OF WOMEN FROM BOTH GROUPS

Bishop score	Group 1	group 2	P value
<4	11(22%)	6(12%)	
4-6	32(64%)	35(70%)	
>6	7(14%)	9(18%)	
Mean +-SD	4.68+-1.72	5.26+-1.81	0.08
Induction to delivery interval in hours			
1-8	11	7	
9-16	8	23	
17-24	8	12	
25-32	1	6	
33-40	6	1	
41-48	2	1	
49-56	3		
>56	11		
Mean +-SD	31.86+-22.93	16.11+-8.34	0.00001

Table 3. Delivery and neonatal outcomes of women from both groups

Induction to delivery interval in relation to Bishop score	In hours Group 1	In hours Group 2	P value
1-2	80	36	
3-4	35.96	18.97	
5-6	24.7	14.43	
7-8	35.1	15.42	

The mean BMI in both the groups was similar (group 1 – 22.63kg/m2 and 22.27kg/m2 respectively). Primigravida constituted 60% in group 1 and 56% in group 2.

sex of baby	group 1	Group 2	p value
Female	25(50%)	27(24%)	
male	25(50%)	23(46%)	
Birthweight(kg)			
<2.5	5(10%)	5(2%)	
2.5-3	23(46%)	15(30%)	
3 3.5	20(40%)	23(46%)	
3.5-4	2(2%)	11(22%)	
Mean+SD	2.94+-0.03	3.13+-0.39	0.06
Mode of delivery			
Vaginal delivery	37(74%)	33(66%)	0.6
Instrumental delivery	3(6%)	5(10%)	
Emergency lscs	10(20%)	12(24%)	
APGAR SCORE AT 1 MIN			
<7		5(10%)	
>7	50(100%)	45(90%)	
NICU ADMISSIONS			0.15
YES	2(4%)	4(8%)	
NO	48(96%)	46(92%)	

Bishop score was 4-6 in 64% and 70% in group 1 and 2 respectively. The mean induction to delivery interval in women who received mifepristone was 31.3 hours and only 16.11 hours in women who received misoprost. In mifepristone group, 3 out of 50 women needed misoprostol and one women needed cerviprime gel after failed induction with mifepristone. The mean induction to delivery interval was statistically significant in both women with favourable and unfavourable cervix (p= 0.00001). In group 1, 60% of women required only one dose of oral mifepristone. A second dose of oral mifepristone was needed in 40 % of women. In group 2, 32% of women delivered after induction with one dose of misoprostol and 20% of women needed 3 doses of misoprostol. With respect to mode of delivery, 74% and 66% in group 1 and 2 delivered vaginally. Instrumental delivery was required in 6% and 10% of women in group 1 and 2 respectively. Emergency caesarean section was done in 20% and 24% of women in group 1 and 2 respectively for reasons like non progress of labor and fetal distress. APGAR scores did not vary much in both the groups. NICU admissions were required for 4 % of babies in women who received mifepristone and 8% of babies in women induced with misoprostol. However, this was not statistically significant. There were no cases of uterine tachysystole, hypertonicity primary postpartum haemorrhage observed in both the groups. However, fever was the only side effect noticed in women induced with misoprostol.

DISCUSSION

The present study was conducted in JLNMCH BHAGALPUR majority of women belonged to low socio economic status & usually get married around the age of 20 years and conceive soon. Hence the mean maternal age in the present study was 23.16 years in group 1 & 22.72 years in group 2, How close a woman to the onset of spontaneous labour will influence the likelihood that induction of labour will be successful. This is assessed by vaginal examination and cervical status measured using the bishop's score. The five characteristics of Bishops score cervical dilatation, length, consistency, position, and fetal station were assessed. The score was commonly used to predict labour induction outcome. Bishop score of 6 or less identifies an unfavourable cervix and may be an indication for cervical ripening. Bishop score of more than 6 is considered as favourable cervix. Eighty percent of women in group 1 and eighty two percent in group 2 had unfavourable cervix prior to induction. In the present study, group 1 patients had favourable bishop score when compared with group 1 though the difference was statistically not significant (p=0.08. In the present study, the mean induction to delivery interval in group 1 was 31.86 hours and in group 2 was 16.11 hours which was statistically significant (p=0.00001). In group 2, the caesarean section rate was 24% of the cases, reasons being fetal distress was seen in 60% of the cases, meconium stained liquor was seen in 30% of the cases, non progress of labour was seen in 20% of the cases birth weight was higher in group 2 than in group 1 which was not statistically significant (p=0.06), as in group 1, 40% of the women were multigravidae. The babies tend to weigh heavier as parity increases. NICU admissions were needed in 4% in group1.

Fetal distress was seen in 66%, meconium stained liquor was seen in 33% of the neonates in group 2. 8 percent of neonates required NICU admissions and all babies had meconium stained liquor.

CONCLUSION

Women induced with mifepristone had higher rates of successful vaginal delivery, and better neonatal outcomes when compared to misoprostol.

Disclosure of interest -none declared.

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