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Research Article

Comparative study to assess the safety of misoprostol and dinoprostone for cervical ripening and induction of labour

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ABSTRACT

Background: To compare safety of induction of labour with dinoprostone and misoprostol with respect to maternal complications like fever, diarrhoea, vomiting, hyperstimulation, tachysystole; and Neonatal outcomes like APGAR score of baby, meconium aspiration, birth asphyxia, hyperbilirubinemia and NICU admission.
Methods: 200 Patients admitted to labour ward of Sree Gokulam Medical College and Research Foundation with an indication of induction of labour and unfavourable cervices were randomly assigned to receive either intravaginal misoprostol or intracervical dinoprostone between December 2012 and May 2014.
Results: There was no significant difference in maternal or neonatal complications between the two groups. Apgar at 1 minute was significantly higher for Misoprostol group while at 5 minutes Apgar was comparable between the two groups.
Conclusions: Misoprostol is as safe as dinoprostone for the induction of labour.

Keywords: Misoprostol, Dinoprostone, Induction of labour, PPH, Hyperstimulation, Meconium staining

INTRODUCTION

Induction of labour is the non-spontaneous initiation of uterine contractions, prior to their spontaneous onset leading to progressive effacement and dilation of cervix with descent of the presenting part to achieve vaginal delivery, when the continuation of pregnancy presents a threat to the life or wellbeing of the mother or her unborn fetus[1]. The aim of successful induction is to achieve vaginal delivery and to reduce caesearean section. The infant should be delivered in a good condition within an acceptable time frame and a minimum of maternal side effects or discomfort.

In this study, cervical ripening with end cervical prostaglandin E2 gel, and intravaginal prostaglandin E1 tablet is compared with regard to safety.

METHODS

Total of 200 patients (100 in each group) admitted to the labour room with an indication of induction of labour were selected for the study. Out of total sample, 100 patients were induced with Misoprostol and rest 100 was induced with Dinoprostone. The study was conducted from December 2012 to May 2014. Primi gravid women with singleton fetuses in cephalic presentation at or above 37 weeks of gestation with Bishops score <6 and reactive fetal heart rate pattern were selected. Excluded were women with previous caesarean section, malpresentation, multiparity, placenta previa, previous uterine surgery and abnormal fetal heart rate patterns.

The informed consent was taken from those patients admitted in labour room in proforma approved by institutional ethical committee. The patients were randomly divided into 2 groups. 100 patients with an

indication for induction received 25µg misoprostol intravaginally and same dose repeated after 6hrs if no progress seen. Alternately 100 patients with an indication for labour received 0.5mg intracervical dinoprostone gel and same dose repeated after 6 hrs if no progress seen.

Patients were evaluated by Modified Bishop's score and admission test for fetal well-being. Patients with score less than 6 and positive admission test are induced. After drug insertion, patients were monitored for signs of labour, maternal vitals, fetal heart rate and progress of labour. A partogram was maintained in all patients induced. Oxytocin was started depending on the Modified Bishops's score and in the absence of adequate uterine contraction or in case of arrest of dilatation. Membranes were ruptured when cervix was completely effaced with a dilatation of more than 3 cm or at the onset of active stage of labour.

At the end of the study period, the safety of Misoprostol and Dinoprostone was compared with respect to the variables like occurrence of fever, gastrointestinal symptoms, hyperstimulation and postpartum haemorrhage. Fetal criteria including presence of thick meconium in the amniotic fluid, fetal distress as defined by abnormal cardiotocography prompting emergency delivery, APGAR scores at one and five minutes, meconium aspiration, transfer to NICU were also assessed.

Statistical analysis

Data was entered into MS Excel software and results analysed using chi square and t test.

RESULTS

Table 1: Association between method of induction and maternal complication.

Maternal complication	Misoprostol		Dinoprostone		χ	P
	Count	Percentage	Count	Percentage		
Nil	69	69.0	62	62.0	1.78	0.938
Fever	4	4.0	5	5.0		
Diarrhoea	3	3.0	5	5.0		
Vomiting	10	10.0	12	12.0		
Hyperstimulation	4	4.0	3	3.0		
Tachysystole	2	2.0	2	2.0		
Postpartum Hemorrhage	8	8.0	11	11.0		

Table 2: Association between method of induction and foetal complication.

Foetal complication	Misoprostol		Dinoprostone		χ^2	p
	Count	Percentage	Count	Percentage		
Nil	89	89.0	88	88.0	0.15	0.928
Meconium Stained Aminotic Fluid	8	8.0	8	8.0		
Fetal Distress	3	3.0	4	4.0		

Table 3: Comparison of Apgar at 1 minute based on method of induction.

Method of Induction	Mean	SD	N	t	p
Misoprostol	7.6	1.2	100	2.66**	0.009
Dinoprostone	7.2	1.1	100		

*Significant at 0.01 level.

Table 4: Comparison of Apgar At 5 minute based on method of induction.

Method of Induction	Mean	SD	N	t	p
Misoprostol	8.8	0.8	100	1.76	0.079
Dinoprostone	8.6	0.8	100		

Both groups were comparable with respect to gestational age, number of doses received and MBS before induction.

69.0% of the Misoprostol group and 62.0% of the Dinoprostone group had no maternal complication ($p>0.05$) (Table1).

89.0% of Misoprostol group and 88.0% Dinoprostone group had no foetal complication (P>0.05) (Table 2).

Average Apgar at 1 minute among Misoprostol group was 7.6±1.2 and that of dinoprostone group was 7.2±1.1. Misoprostol group had statistically significant higher Apgar level than the Dinoprostone group (p 0.009) (Table 3).

Average Apgar at 5 minute among Misoprostol group was 8.8±0.8 and that of dinoprostone group was 8.6±0.8. There was no significant difference in Apgar level at 5 minutes between the two groups (P>0.05) (Table 4).

Table 5: Distribution according to neonatal complication.

Neonatal complication	Misoprostol		Dinoprostone	
	Count	Percent	Count	Percent
Meconium Aspiration Syndrome	6	42.9	5	38.5
Birth Asphyxia	2	14.3	3	23.1
Hyperbilirubinemia	6	42.9	5	38.5

Table 6: Association between method of induction and NICU > 24hrs.

NICU > 24 hrs	Misoprostol		Dinoprostone		χ^2	P
	Count	Percent	Count	Percent		
Yes	16	16.0	16	16.0	0.00	1.000
No	84	84.0	84	84.0		

42.9% of Misoprostol group and 38.5% of Dinoprostone group had hyperbilirubinemia. 42.9 % of Misoprostol group and 38.5% of Dinoprostone group had Meconium Aspiration Syndrome (Table 5). 16.0% of both groups had NICU admission >24 hours (Table 6).

DISCUSSION

In this study maternal complications were minimal and similar in both the groups. 69.0% of the Misoprostol group and 62.0% of the Dinoprostone group had no maternal complication (p>0.05).The maternal side effects observed were tachysystole, hyperstimulation, vomiting, diarrhea, fever and PPH. In the misoprostol group, only 4% had uterine hyperstimulation and in the dinoprostone group, 3% had uterine hyperstimulation 2% in both group had tachysystole. This difference was not statistically significant. In a study by Denguezli W, the tachysystole and hyperstimulation syndrome rates were slightly increased in the misoprostol group than in the dinoprostone group without reaching the level of statistical significance.[2] In misoprostol group the major side effects were vomiting - 10% and PPH 8% of which was traumatic - 5% and 3% atonic. In the Dinoprostone group the major side effects were vomiting - 12% and PPH 11% of which was traumatic - 5% and 6% atonic. None of the PPH in both groups required any blood transfusion. Calder AA demonstrated a similar maternal safety profile in both groups.

89.0% of Misoprostol group and 88.0% Dinoprostone group had no foetal complication (P>0.05).The main foetal complications were meconium stained amniotic fluid (8% in both groups) and foetal Distress (3% with misoprostol and 4% with dinoprostone). This difference was not statistically significant.

Calder AA, Prager M and Chitrakar NS demonstrated a similar fetal safety profile in both groups.[3-5] Average Apgar at 1 minute among misoprostol; group was 7.6±1.2 and that of dinoprostone group was 7.2±1.1. Misoprostol group had significantly higher Apgar level than the Dinoprostone group (statistically significant) Average Apgar at 5 minute among Misoprostol group was 8.8±0.8 and that of dinoprostone group was 8.6±0.8. There was no significant difference in Apgar level at 5 minutes between the two groups.

The major neonatal complications wer hyperbilirubinemia, meconium aspiration syndrome and birth asphyxia. 6% of Misoprostol group and 5% of dinoprostone group had hyperbilirubinemia.6% of Misoprostol group and 5% dinoprostone group had meconium aspiration syndrome. 2% of Misoprostol group and 3% of dinoprostone group had birth asphyxia (not statistically significant). Neiger R. Greaves, Lapaire, Prager M and Sifakis S and Oliveira TA et al demonstrated similar neonatal outcome in both the groups.[6-9]

16.0% of both group had NICU admission >24 hours (not statistically significant). Neonatal outcome was equally good both the groups. The indications for NICU admission were meconium aspiration syndrome, birth asphyxia and hyperbilirubinemia.

Patrick. S. Ramsey reported a slightly higher rate of NICU admission in dinoprostone group than misoprostol group. Prager M ,Sanchez-Ramos L et al, Gaudineau A et al reported no significant differences in NICU admission between both the groups.[10-12]

CONCLUSION

The use of prostaglandins provide an effective method for achieving the induction of labour. There was clearly a superior neonatal outcome in terms of 1 min Apgar score in misoprostol group but maternal and perinatal outcome in both groups were similar. One disadvantage with Misoprostol is uterine tachystole and hyperstimulation with fetal distress. This is reduced by using 25 micrograms misoprostol and the duration of application was increased to 6 hrs. Misoprostol is cost-effective when compared to Dinoprostone. Misoprostol is stable at room temperature and does not need refrigeration whereas Dinoprostone requires refrigeration.

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