Comparison of Intravaginal Misoprostol Tablet (Prostaglandin E1) and Intracervical Dinoprostone (Prostaglandin E2) Gel in Induction of Labour

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Abstract— *Cervical ripening is an essential factor for initiation of normal labour for vaginal delivery. Prior to onset of spontaneous labour the cervix undergoes a gradual process of ripening. But in certain cases it does not occur spontaneously at term and sometimes induction of labour is required. Then cervical ripening means high bishop score in essential for successful induction of labour. This comparative study was conducted at Bikaner to compare induction of labour by vaginal prostaglandin E1 tablet (tablet Misoprostol 25 µg 4 hourly) and Intra cervical Dinoprostone gel 0.5 mg. For this purpose 100 clients were given vaginal prostaglandin E1 tablet (tablet Misoprostol 25 µg 4 hourly) and 100 clients were given Intra cervical Dinoprostone gel 0.5 mg. It was observed in this study that Dinoprostone gel is more efficacious for cervical ripening and labour induction in cases of nulliparous & primiparous at term with unfavourable cervix with intact membranes, as compared to misoprostol in terms of shorter total duration of labour, shorter mean induction delivery interval, more spontaneous vaginal deliveries, and reduced incidence of LSCS as well as instrumental deliveries*.

Keywords— Cervical Ripening, Induction of Labour, Intracervical Dinoprostone Gel, Intravaginal MisoprostolTablets.

I. INTRODUCTION

Labour is a process through which the fetus moves from Intra-uterine to the extra-uterine environment. It is a clinical diagnosis defined as initiation and perpetuation of uterine contractions with the goal of producing progressive cervical effacement and dilatation, resulting in expulsion of the fetus into the outside world when the labour would not begin spontaneously at term.

A spectrum of medical and obstetrical complications has lead to the evolution of the concept of Induction of labour. Induction of labour refers to the process whereby uterine contractions are initiated by medical or surgical means before the onset of spontaneous labour.

Cervical ripening is an essential factor for initiation of normal labour for vaginal delivery. Prior to onset of spontaneous labour the cervix undergoes a gradual process of ripening. When cervix is not favorable or ripe, labour often fails leading to an overall increase in incidence of caesarean section. But in certain cases it does not occur spontaneously at term and sometimes induction of labour is required. Then cervical ripening means high bishop score in essential for successful induction of labour.

Various studies have been conducted worldwide and in our country to find out most efficacious drug for induction of labour but results are inconsistent and non uniform. Only few studies have been conducted in Rajasthan to compare prostaglandins with conventional cerviprime but final guide are still awaited.

Therefore, the present study was an attempt to draw observations to compare induction of labour by vaginal prostaglandin E1 tablet (tablet Misoprostol 25 µg 4 hourly) and Intra cervical Dinoprostone gel 0.5 mg for population in western Rajasthan.

II. METHODOLOGY

The present study was carried out in 200 clients who came for delivery in the department of obstetrics & gynecology at Prince Bijay singh Memorial hospital Bikaner from October 2010 to Oct. 2011. For eligibility of the clients, pregnant women aged 18-35 years who has completed 37 weeks or more of pregnancy without evidence of CPD on history and excluding women those having previous caesarean, multiparous, Foetal Malpresentation, Placenta Previa, Preecalampcia, IUGR, Post maturity, Bishop score <3& >7, Uterine construction >3 in 10 minutes, Cervical dilatation >3 Cm, Non-reactive foetal heart rate on monitor tracing. Client with known gynecological diseases and pregnancy induced hypertention were also excluded from study.

Out of these eligible 200 clients, 100 were randomly given vaginal prostaglandin E1 tablet (tablet Misoprostol 25 µg 4 hourly) and 100 were given Intra cervical Dinoprostone gel 0.5 mg through alternate allocation.

Detailed history was taken and general & specific examination was done and recorded on a pre-designed Performa. Progress of labour was closely monitored by investigator as per partogram and recorded.

Successful induction: it was defined by onset of active labor with 8 hours of induction. And F**ailed**

Induction: if no active labor was established after trial period of 8 hours and if induction was stopped because of side effects of drugs.

Data analysis: Data thus generated was entered in excel sheet and was subjected for statistical analysis. Continuous variables were summarized as mean & standard deviations whereas nominal /categorical variables as proportions (%). Unpaired 't' test was used to compare continuous variables while chi-square test was used for nominal/categorical data analysis. 'p' value<0.05 was taken as significant. SPSS trial version software was used for all statistical calculations.

III. RESULTS

Maximum clients in both group were of 20 to 25 Years age i.e. and 78% in misoprostol group and 70% in dinoprostons gel group. Mean age in misoprostol group was 23.12±1.82 years whereas in dinoprostone gel group it was 24.6±2.10. The youngest patient was 18 years and oldest clients were 33 years in study group. The difference in mean age in two groups was statistically non significant. So both groups were comparable. (Table1)

There was no significant difference in two groups as per parity. (Figure 1)

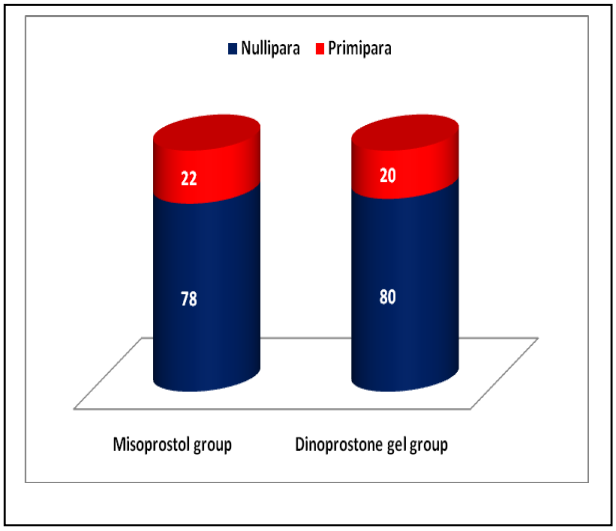
Bishop Score that all the clients in present study had initial bishop Score in the range of 1 to 4 with mean induction bishop scores of 3.25 ± 0.44 and 3.14±0.68 for dioprostone gel and misoprostol group respectively. (Table2)

Table 1:
Comparison of maternal age in both groups

Age (in years)	Misoprostol group (N=100)		Dinoprostone group (N=100)	
	No.	%	No.	%
s<20	8	8	10	10
20-25	78	78	70	70
26-30	12	12	18	18
>30	2	2	2	2
Mean age ± SD (yrs)	23.12±1.82		24.6±2.10	

Chi-square Test= 1.85 at 3DF, p= 0.60 LS=NS

Figure 1:
Comparison of Parity in both groups



Chi-square Test= 0.85 at 1DF, p= 0.35 LS=NS

Table 2
Comparison of pre-induction Bishop score in both groups

Initial Bishop score	Misoprostol group		Dinoprostone gel group	
	N=100	%	N=100	%
1	4	4	6	6
2	18	18	14	14
3	58	58	60	60
4	20	20	20	20
Mean±SD	**3.14±0.68**		**3.25±0.44**	

unpaired 't' Test= 1.35, p= 0.178 LS= NS

Mean interval between induction and delivery in 82 cases of misoprostol group was 16.84±2.01 hrs whereas in 88 cases of dinoprostone gel group, it was 11.48±1.55 hrs.

The distribution of cases in misoprostol group reveals that majority of cases (38%) had interval between induction and delivery as >16 hrs closely followed by 12-16 hrs in 32% cases. In dinoprostone Gel group the maximum number of cases having interval between Induction and delivery period as 8-12 hrs (46%) closely followed by 12-16 hrs in 36% cases. The difference in the mean interval between indication and delivery was **significantly different** in two groups

Table 3
Interval Between induction and delivery in clients delivered vaginally

Interval between Induction and delivery (hrs)	**Misoprostol group**		**Dinoprostone gel group**	
	N=100	%	N=100	%
0-4	0	0	0	0
4-8	2	2	2	2
8-12	10	10	46	46
12-16	32	32	36	36
>16	38	38	4	4
Mean±SD (hrs)	**16.84±2.01**		**11.48±1.55**	

unpaired 't' Test= 21.11, p<0.001 LS= S

It was also reveals that clients showed varied side effects of the drug. In misoprostol group, diarrhea was found to predominate as reported in 4% cases, followed by shivering in 2% and pyrexia in 2% cases. Dinoprostone gel group showed only one case each of nausea & vomiting and diarrhea.

Table 4
Distribution of cases according to side effects in both the groups

Side effect	**Misoprostol group**		**Dinoprostone gel group**	
	N=100	%	N=100	%
Nausea, vomiting	-	-	01	1.0
Diarrhoea	4	4.0	1	1.0
Shivering	2	2.0	-	-
Pyrexia	2	2.0	-	-
Hyperstimulation	-	-	-	-
Tachysystole	-	-	-	-
PPH	-	-	-	-

In this study neonatal complications were 4% v/s 5% in Dinoprostone and misoprostol group respectively. There were no neonatal complications in 96% cases in dinoprostone group and 95% cases in misoprostol group.

Table 5
Distribution of cases according to neonatal complications in both groups

Neonatal complications	Misoprostol group	Dinoprostone gel group
Mean birth weight ± SD(kg)	2.95±0.65	2.54±0.48
Mean APGAR score at 1 min ±SD	8.68±0.74	8.92±0.83
Mean APGAR score At 5 min ±SD	9.52±1.14	9.82±0.91
Birth asphyxia	Nil	Nil
Jaundice	2 (2%)	3 (3%)
Septicemia	Nil	Nil
Foetal distress	2 (2%)	1 (1%)
Aspiration Pneumonia	1 (1%)	Nil
Neonatal mortality	Nil	Nil
No complication	95 (95%)	96 (96%)

IV. DISCUSSION

Both the groups v.i.z. Misoprostol group and Dinoprostone group were comparable in maternal age, parity and initial Bishop scores[1]. But whey were compared on Interval between Induction and delivery in both the group, it was found that Dinoprostone group have taken significantly less time then the other group.

Dr. Afia Ansar etall (2014)[2] reported Out of 63 patients in the misoprostol group, 43 (67.1%) women had spontaneous vaginal delivery (SVD) while 26 (63.4%) patients out of 41 in dinoprostone group had SVD. The induction to delivery interval was 13.03+3.52 hours in misoprostol group while it was 14.12+3.31 hours in dinoprostone group. With misoprostol, induction of labor started in 18, 33 and 13 women with 1, 2 and 3 doses respectively within 24 hours but in dinoprostone group 16 women were successfully induced with 1 tablet only, while 21 patients required 2 doses for induction.. The need for oxytocin infusion was the same in both the groups. The neonatal weight was 3.54+3.38 kg in misoprostol group as compared to 3.10+0.26 kg in dinoprostone group (p=0.41, t=1.57). Four neonatal deaths were reported in the misoprostol group as compared to two with dinoprostone. Sixteen neonates were admitted to NICU in misoprostol group as compared to five patients in dinoprostone group. Twenty-eight (44.4%) patients in misoprostol group had meconium stained liquor as compared to 14 (34%) patients in dinoprostone group.

GK Pandis etall (2001)[3] concluded from their study that The use of misoprostol is associated with a shorter duration of labor and a higher rate of vaginal delivery within 24 h from induction without an increase in maternal and neonatal morbidity

Evangelos G et all[4] in their study conducted 0n 163 eligible clients reported that the induction-delivery interval was significantly lower in the misoprostol group than in the dinoprostone group (11.9 h vs. 15.5 h, $p < 0.001$). With misoprostol, more women delivered within 12 hours (57.5% vs. 32.5%, $p < 0.01$) and 24 hours (98.7% vs. 91.4%, $p < 0.05$), spontaneous rupture of the membranes occurred more frequently (38.8% vs. 20.5%, $p < 0.05$), there was less need for oxytocin augmentation (65.8% vs. 81.5%, $p < 0.05$) and fewer additional doses were required (7.5% vs. 22%, $p < 0.05$). Although not statistically significant, a lower Caesarean section (CS) rate was observed with misoprostol (7.5% vs. 13.3%, $p > 0.05$) but with the disadvantage of higher abnormal fetal heart rate (FHR) tracings (22.5% vs. 12%, $p > 0.05$). From the misoprostol group more neonates were admitted to the intensive neonatal unit, than from the dinoprostone group (13.5% vs. 4.8%, $p > 0.05$). One woman had an unexplained stillbirth following the administration of one dose of dinoprostone

In this study neonatal complications were 4% v/s 5% in Dinoprostone and misoprostol group respectively. There were no neonatal complications in 96% cases in dinoprostone group and 95% cases in misoprostol group.

In dinoprostone group 4 babies were shifted to neonatal ward, 3 due to jaundice and 1 due to foetal distress whereas in misoprostol Group, 5 babies were shifted to neonatal ward 2 due to jaundice, 2 due to foetal distress and 1 due to aspiration pneumonia. In an identical study papanikolaou et al. (2004) showed that 4.8% Neonates in dinoprostol gel group & 13.5% neonates in misoprostol Group were shifted to neonatal ward. In most of the other studies[5-10] there was no significant difference in neonatal complications in both groups

V. CONCLUSION

Form this comparative study we have concluded that Dinoprostone gel is more efficacious for cervical ripening and labour induction in cases of nulliparous & primiparous at term with unfavourable cervix with intact membranes, as compared to misoprostol in terms of shorter total duration of labour, shorter mean induction delivery interval, more spontaneous vaginal deliveries, and reduced incidence of LSCS as well as instrumental deliveries. Uterine contraction abnormality & foetal heart rate irregularity were slightly less with dinoprostone as compared to misoprostol in our study Maternal and neonatal outcome were similar in both the groups.

Maximum number of clients was delivered spontaneous by vaginal route with single dose of intra cervical dinoprostone gel in the present study. So dinoprostone gel may be considered as a better choice than misoprostol for cervical ripening & labour induction in nulliparous clients with unfavorable cervix.

CONFLICT

None declared till date.

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