



Comparative Study of Intracervical Dinoprostone Gel Versus vaginal Misoprostol for Cervical Ripening and Induction of Labour

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ABSTRACT

Background and objective: The induction of labour is nonspontaneous initiation of uterine contractions before their spontaneous onset leading to progressive effacement and dilatation of cervix and delivery of the baby. Overall rate of induction of labour has increased over last decade. PGE₂ has been used for more than a decade for cervical ripening and induction of labour. It has been evidenced in literature that misoprostol a PGE₁ analogue is extensively evaluated for cervical ripening and induction of labour. We aim to compare between the efficacy of intracervical dinoprostone gel versus vaginal misoprostol tablets for the cervical ripening and induction of labour.

Method: This was a prospective study. 100 women which were admitted and who fulfilled the criteria, 100 cases were randomized equally in two groups, 50 patients underwent induction with dinoprostone gel 0.5mg intracervically every 6 hourly till maximum 3 doses and in another group of 50 pts, labour was induced by 25 mcg of misoprostol in posterior fornix of vagina every 4 hourly for maximum 5 doses.

Result: In 72% pts in misoprostol group the Bishop score was 2-3, in 90% of pts 25-75mcg of misoprostol was required for successful induction of labour when compared to 66% of cases in dinoprostone group by single application. Induction delivery interval was between 5-18 hours in 84% of cases in the misoprostol group, whereas in only 68% cases, in dinoprostone group induction delivery interval was 7-18 hours. Incidence of LSCS was also less around 6% in misoprostol group when compared to 16% in dinoprostone group, cost of misoprostol is cheaper 70/- when compared to 250/- in dinoprostone group. Meconium staining of liquor was found to 8% with misoprostol and 4% in with dinoprostone group.

Key Words: vaginal misoprostol tablet, intracervical Dinoprostone gel



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INTRODUCTION

One of the most important role of obstetrician is to deliver a patient when required. It is done by induction of labour or caesarian section. Timely induction of labour has importance in antenatal management of many obstetric problems.

Induction of labour is the spontaneous initiation of uterine contraction, prior to their spontaneous onset leading to progressive dilatation and effacement of cervix and delivery of the baby.[1]

The aim of successful induction is to attain vaginal delivery and to reduce caesarian section. The baby should be delivered in good conditions within an acceptable time frame and with minimum side effects to mother.[1]

The overall rates of induction of labour have increased significantly over last decade and so are the options available. It has become clear that prostaglandins have the advantage over oxytocin both by acting locally and secondarily by inducing endogenous oxytocin release.[2]

PGE₂ dinoprostone gel has been used for many years for induction of labour and cervical ripening and also approved by FDA.[3]

Recently a prostaglandin analogue of PGE₁ misoprostol has received attention as highly effective cervical ripening agent, it has advantage of being cheaper and easy to store and stable at room temperature.[4]

Successful outcome of spontaneous or induced labour is well co-ordinated interplay between contracting and dominant upper segment and passive and dilating lower segment, prostaglandins are found to achieve this goal.



Materials and Method

This was a prospective study. With consent 100 women which were admitted and who fulfilled the criteria, 100 cases were randomized equally in two groups, 50 patients underwent induction with dinoprostone gel 0.5mg intracervically every 6 hourly till maximum 3 doses and in another group of 50 pts, labour was induced by 25 mcg of misoprostol in posterior fornix of vagina every 4 hourly for maximum 5 doses.

Inclusion criteria:

Patient should not be in labour and the membranes should be intact.

- 1) Singleton pregnancy, cephalic presentation.
- 2) Completed 37weeks, fetal maturity confirmed by dates, clinical examination.
- 3) Bishop score less than or equal to 4.
- 4) No contraindication for vaginal delivery like CPD, contracted pelvis, or abnormal presentation.
- 5) No contraindication for prostaglandin use.
- 6) No lower genital infections.

Exclusion criteria:

- 1) Non reassuring fetal heart pattern.
- 2) Malpresentation, multiple pregnancy, CPD cephalopelvic disproportion, antepartum haemorrhages, grand multipara, allergy to prostaglandins, history of previous caesarian section or any uterine scar.

Statistical analysis:

The data was entered in Microsoft excel sheets and analysed using SPSS version 26 and EPI info version 7.2. Comparison of categorical variables was done by using counts and percentage and chi-square test for significance. The student t-test was used to compare the means of independent variables and data. A p value <0.05 was considered to be significant.

Results

100 pts were followed in this study. Among them 50 were induced with misoprostol vaginally and 50 with intracervical dinoprostobegel. The parity ranged from primi to gravida III.

Table 1: Parity

Parity	Misoprostol		Dinoprostone	
	No. of cases	Percentage	No. of cases	percentage
Primi (G1)	36	72	30	60
Gravida 2	12	24	16	32
Gravida 3	02	04	04	08

Table 2: Age

Almost all women were in 18-35 age group, the most fertile period of any woman's life.

Age	Misoprostol		Dinoprosone	
	No. of cases	percentage	No. of cases	Percentage
18-20	22	44	26	52
21-25	20	40	22	44
26-30	06	12	02	04
31-35	02	04	00	00

Table 3: Socioeconomic status

Majority of women belongs to low socioeconomic class.

	Misoprostol		Dinoprostone	
Socioeconomic class	No. of cases	percentage	No. of cases	percentage
Low	34	68	30	60
Middle	11	22	12	24
high	05	10	08	16

Table 4: gestational age

The major (52%) pts were of 41weeks -42weeks, 32% were 37-38weeks because of risk factors like PIH, oligohydramnios, polyhydramnios etc.

Gestational age (weeks)	Misoprostol		Dinoprostone	
	No of cases	Percentage	No of cases	percentage
37-38	16	32	12	24
39-40	8	16	8	16
41-42	26	52	30	60

Table 5: Bishop score

Pre induction Bishop score	Misoprostol		Dinoprostone	
	No of cases	percentage	No of cases	percentage
0-1	10	20	26	52
2-3	36	72	23	46
4	04	08	01	02

In 72% cases of misoprostol group the bishop score was 2-3 and in 52 % of cases in dinoprostone group the Bishop score was 0-1.

Table 6: indication for induction

Indication	Misoprostol		Dinoprostone	
	No of cases	percentage	No of cases	percentage
Post datism	24	48	28	56
PIH	16	32	14	28
oligohydramnios	6	12	8	16
polyhydramnios	2	4	0	0

Major indication was post datism followed by PIH pregnancy induced hypertension.

Table 7: dosage of drug required for induction to delivery.

Misoprostol

Dose of drug (mcg)	No of cases	percentage
25	6	12
50	28	56
75	10	20
100	6	12
125	0	0

56% cases in this study needed 50 mcg dose for induction, whereas 20% required 75mcg, 12% required 25mcg misoprostol.

Dinoprostone gel

Dose of drug	Supplementation	
Single application(0.5mg)	Two applications(1mg)	Oxytocin
33(66%)	2(4%)	12(24%)
		3(6%)

66% of cases needed single dose of 0.5mg dinoprostone ,4% cases given second application of dinoprostone , 30% pts were supplemented with oxytocin and misoprostol.

Table 8: induction delivery interval

Time (hours)	Misoprostol		Dinoprostone	
	No of cases	percentage	No of cases	Percentage
<6	6	12	0	0
7-12	16	32	22	44
13-18	20	40	12	24
19-24	8	16	10	20
>24	0	0	6	12

84% of pts in misoprostol group delivered within 18 hours of induction. 12 % pts in dinoprostone group took >24 hrs for delivery after induction.

Shortest induction delivery interval was 5 hrs in misoprostol group and 8hrs in dinoprostone group. longest delivery interval was 20 hrs in misoprostol group and 30 hrs in dinoprostone group.

Table 9: relation between parity and induction delivery interval

parity	Average induction delivery interval (hrs)	
	Misoprostol	Dinoprostone
Primi	14.58	18.2
Gravida 2	9.11	12
Gravida 3	6	14

Induction delivery interval in primi was 14.58 hrs in misoprostol group, 18.2hrs in dinoprostone group, in multi it was 9.12 in misoprostol group and 12.2 in dinoprostone group.

Table 10: relation between gestational age and induction delivery interval

Gestational age (weeks)	Average induction delivery interval (hrs)	
	Misoprostol	Dinoprostone
37-38	11.05	17.33
39-40	9.2	17
41-42	13.28	15.62

In all the three gestational age average induction delivery interval is lesser in misoprostol group than dinoprostone.

Table 11: bishop score and induction delivery interval

Bishop score	Misoprostol		Dinoprostone	
	No of cases	percentage	No of cases	percentage
0-1	10	13.72	26	18.62
2-3	36	11.75	23	13.73
4	4	9.66	1	10.24

In pts with bishop score 4 induction delivery interval was less.

Table 12: Outcome of induction

	Misoprostol	Dinoprostone
Normal vaginal delivery	45 (90%)	41 (82%)
Emergency LSCS	3 (6%)	8 (16%)
Outlet forcep	2 (4%)	1 (2%)

94% cases with misoprostol and 84 % with dinoprostone delivered normally. Only 4% with misoprostol and 2% with dinoprostone needed outlet forcep for the delay of delivery of head. 6% with misoprostol and 16 % with dinoprostone needed termination by emergency LSCS for various reasons like fetal distress associated with PIH and oligohydramnios. In some cases termination due to severe PIH and imminent eclampsia. Moderate meconium staining of liquor was observed but no baby developed meconium aspiration syndrome.

Table 13: neonatal outcome

Misoprostol			Dinoprostone		
No of cases	APGAR Score		No of cases	APGAR Score	
	At 1 minute	At 5 minute		At 1 minute	At 5 minute
45(normal)	8-10	10	41(normal)	8-10	10
3(LSCS)	8-10	10	8(LSCS)	8-10	10

In our study neonatal outcome was good even though a few cases had moderate meconium staining, but no babies developed meconium aspiration syndrome, indicating that drug had no adverse effects on the babies outcome.

Table 14: Comparison between misoprostol and dinoprostone

	Misoprostol	Dinoprostone
Average incidence of vaginal delivery	94%	84%
Average incidence of LSCS	6%	16%
Average induction delivery interval (hrs)	14.5hrs in primi 9.15hrs in multi	18.2hrs in primi 12.1hrs in multi
Incidence of meconium staining	8%	4%

This result shows that misoprostol induction had 94% of successful vaginal deliveries as compared to 84% in dinoprostone. Incidence of LSCS rate was also less in misoprostol group that's 4% and 16% with dinoprostone. Induction delivery interval of misoprostol group was less than that of dinoprostone group. Meconium staining of liquor was found to 8% with misoprostol and 4% with dinoprostone, but no baby developed meconium aspiration syndrome.

Cost wise misoprostol (70/-) is cheaper than dinoprostone gel (250/-).

DISCUSSION

Induction of labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility[5]. The reports from previous studies showed that vaginal misoprostol was safe and effective method for cervical ripening and induction of labour.[6]

Agarwal et al [7] from AIIMS, New Delhi conducted study with 120 pts in which 60 pts were induced with 50mcg vaginal misoprostol and 50 were induced with 0.5 mg intracervical dinoprostone .73.4% misoprostol cases and 85% cases in dinoprostone group delivered vaginally. The average induction delivery interval with misoprostol was 12.8hrs and 18.5hrs with dinoprostone.

Herabutya et al [8] from Bangkok took 110 pts and 60 pts received 100mcg misoprostol vaginally and 1.5mg of dinoprostone gel with successful delivery of 69% in misoprostol and 68% in dinoprostone group. Average induction delivery interval was 19.14 hrs in misoprostol group whereas 21.3hrs in dinoprostone group. Hyperstimulation was observed only in 1.7% of misoprostol group.

In this study 100 pts were underwent induction of labour, 50 with vaginal misoprostol and 50 pts with intracervical dinoprostone gel. In this study majority of cases the induction was done between 41-42weeks of gestation, in 40 % of cases induction was carried out due to high risk pregnancy. In 72% cases Bishop score was 2-3 in misoprostol group. In 90% cases 25-75mcg misoprostol was required for successful induction of labour.

In dinoprostone group 66% cases required single application and supplementation was required in 30 % cases with Pitocin or misoprostol.

In 84% cases induction delivery interval was between 5-18 hours in misoprostol group only in 68% cases of dinoprostone group induction delivery interval was between 7-18 hours average induction delivery interval was 14.58 hrs in misoprostol group and 18.2hrs in dinoprostone group, in case of primigravida. In multigravida induction delivery interval was between 9.11 hrs and 6hrs in misoprostol group, whereas in case of PGE2 gel it was between 12 and 14 hours.

Induction delivery interval was 14.5 hrs in primi and 9.15hrs in multipara where it was found to be 15hrs by WingDA et al [9] and 9.14 hrs in Herabutya et al [8], 14.4 hrs in Soni Neelu in [10] and 12.8 hrs by Agarwal in misoprostol group.

Success rate of induction with misoprostol was 94% in the present study when compared to 85.3% in Wing DA et al [3] in 1995, 69% by Herabutya et al in [8], 73.4% by Agarwal et al [7] and 80 % by SoniNeelu in [10].

Incidence of caesarian section was only 6% with misoprostol, 14.7% in study of Wing DA et al [9], 31% in Herabutya et al [8], 26.6% in Agarwal et al [7] and 20% by SoniNeelu et al [10].

In the present study 8% cases of misoprostol group, meconium staining liquor was observed ,where as in the study of Wing et al [9] 36.7% cases had tachysystole and 27.9% of meconium stained liquor, in Herabutya et al study hyperstimulation was observed in 1.7% cases, Agarwal et al [7] study found tachysystole in 1.6% cases and meconium stained liquor in 8% cases.

In dinoprostone group labour was induced successfully in 84% of cases when compared to 80.6% by Wing et al [9], 68 % by Herabutya et al [8], 85% by Agarwal et al [7] and 76% by SoniNeelu et al [10].

Induction delivery time interval was 18.2hrs in primi and 12.1 hrs in multi , whereas it was 23.5 hrs in Wing et al [9], 21.3 hrs in Herabutya et al [8], 18.5hrs in Agarwal et al [7], 19.2 hrs in SoniNeelu et al [10].

When comes to side effects 11.9% cases tachysystole and 10.5% had meconium staining liquor in Wing et al [9] study, in our study neonatal outcome was good in both groups , but incidence of thin meconium stained liquor was more in misoprostol group.

CONCLUSION

Hence vaginal misoprostol is much cheaper and safer drug for cervical ripening and induction of labour.

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