Original Research Article

To compare the efficacy of intravaginal misoprostol with intracervical dinoprostone gel in induction of labour at term

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Abstract

Introduction: There are various mechanical and pharmacological methods currently in use for induction of labour, however no single method or agent has been found suitable for all clinical conditions. **Aims:** To compare efficacy of induction of labour with Dinoprostone gel and Misoprostol with respect to induction delivery interval, type of delivery.To study the maternal and fetal outcome of both groups. **Materials and methods:** This randomized prospective study was conducted in 100 low risk singleton pregnant women who consented for the study and in whom cervical ripening and labour induction was indicated were studied. 50 women received Misoprostol-25µg in the posterior vaginal fornix and other 50 patients received intracervical Dinoprostone-0.5mg gel. **Results**: In the Dinoprostone group the mean induction delivery interval was 17.0±3.10hrs. In the Misoprostol group the mean induction delivery interval was 12.0±2.23 hrs.80% cases had a vaginal delivery and 20% had caesarean section in Dinoprostone group. In the Misoprostol group 10% cases were failed inductions, the major cause being fetal distress. There was 38% incidence of side effects of Dinoprostone of which vomiting 4% and PPH 22% were seen commonly. In Misoprostol group tachysystole 4% and hyperstimulation 6% formed the major side effects out of an incidence of 30%.There was a 6% incidence of thick meconium stained liquor in Misoprostol group, compared 2% incidence in Dinoprostone group. There was 10% incidence of NICU admission in both groups. Meconium aspiration syndrome and birth asphyxia were the major indications with an incidence of 6% and 4% Misoprostol group. Hyperbiluribinemia was the major cause of NICU admission in Dinoprostone group with an incidence of 6%. **Conclusion:** Misoprostol is apparently safe, efficient and a cost-effective drug for induction of labour.

Keywords: Dinoprostone, Misoprostol, Meconium stained liquor.

Introduction

Labour is a stress factor for the fetus. During active labour the integrity of the uteroplacental circulation and the frequency and intensity of uterine activity influence the acid base status of the fetus which is reflected in the fetal heart tracings on cardiotocograph. Fetal heart rate monitoring is sensitive to diagnose fetal asphyxia before permanent brain damage occurs. Labour induction is indicated when the benefits of delivery to the mother are fetus out weights the potential risk of continuing the pregnancy[1].

Induction of labour is an obstetric procedure, designed to pre-attempt the natural process of labour by initiating its onset artificially, before this occurs spontaneously. The aim of successful induction is to achieve vaginal delivery when continuation of pregnancy presents a threat to the life or well being of the mother or her unborn child. The infant should be delivered in a good condition in an acceptable time frame and with minimum maternal discomfort or side effects. In order to be successful, induction of labour must fulfill three criteria. First, it should result in labour namely adequate uterine contractions and progressive dilation of the cervix. Second, this labour should result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section.

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Third, in viable pregnancies these aims must be achieved with minimal risk to both mother and fetus. When induction of labour is done with an unripe cervix there is high rate of failure of induction, Arulkumaran[2].The human cervix is an organ of diverse properties. Ripening of the cervix takes place during prelabour phase, resulting in increased softening, effacement and early dilation. Pharmacologically and physiologically prostaglandins have two direct actions associated with labour ripening of the cervix and a direct oxytocic effect. Labour was one or the first indications for the use of prostaglandins in obstetrics.The method of administration that has been explored thoroughly is endocervical Dinoprostone or prostaglandin E_2. Though this is widely used, it is expensive and required refrigeration for storage with warming before use. It was only a matter of time before a comparably cheap, safe and effective vaginally administered Prostaglandin with limited side effects would be available and Misoprostol or PGE_1 tablet fitted those criteria admirably.Of late, a number of recently published clinical trials abroad and in India have shown that intravaginal Misoprostol is an effective agent for induction of labour and cervical ripening at term, when compared to other methods of labour induction. In present study, our traditional methods of cervical ripening with endocervical prostaglandin E2 gel, and the new one intravaginal prostaglandin El tablet are compared with regard to efficacy and safety.

Materials and methods

This randomized prospective study was conducted in the department of obstetrics and Gynaecology in100 Patients admitted to labour ward of OBG Dept of Kamineni Institute of Medical Sciences with an indication for induction of labour from Jan 2013 to Aug 2014.

Indications for Induction in present Study were mild pre eclampsia, severe pre eclampsia,postdated pregnancy, mild polyhydramnios, mild oligohydramnios, gestational diabetes mellitus, chronic hypertension and Rh negative Pregnancy

Inclusion Criteria

Singleton fetus with cephalic presentation, Over 37 weeks of gestationwith reactive fetal heart pattern, Unfavourable cervix Bishop score < 4

Exclusion Criteria

Previous LS.C.S or any uterine surgery, Mal presentation, Grand Multiparity, abnormal fetal heart rate pattern and allergy to Prostaglandins

Method of Induction

50 patients with an indication for labour induction received with 25µg of intravaginal misoprostol and repeated for a maximum of 6 doses every 4 hours as needed. 50 patients with an indication for induction of labour received 0.5 mg intracervical dinoprostone gel and repeated for a maximum of 3 doses every 6 hours as needed. After informed written consent had been obtained, the patients selected for the study were evaluated initially by modified Bishop's score and admission test for fetalwell being. Patients with a modified bishops score ≤ 4 and a positive admission test were induced. After drug insertion, patients were monitored for signs of labour maternal vital signs, fetal heart rate and progress of labour. The fetal heart rate was monitored by either intermittent auscultation or continuous fetal heart rate monitoring. A partogram was strictly maintained in all patients induced. Oxytocin was started depending on the modified Bishop's score and in the absence of adequate uterine contractions after 6 hrs of the last dose, or for augmentation of labour in case of an arrest of dilation. Oxytocin was started at the dose of 2 mu / min with increments of 2mu/min every 30 minutes.Membranes were ruptured, when the cervix was completely effaced with a cervical dilatation of more than 3 cms or at onset of active stage of labour.

The data collection included indication for indication, booked / unbooked case, maternal age, parity, gestational age on entry into the study, modified Bishop's Score at time induction, induction - delivery interval, oxytocin augmentation, type of delivery, Apgar score of the baby, maternal and neonatal complications. The results observed were subjected to statistical analysis by students 't' test, odds ratio chi-square test and a p value of < 0.05 was considered as significant.

Modified Bishop's Score (Calder et al)[2].

	0	1	2	3
Dilatation (cms)	Less than 1	1-2	3-4	>4
Length (cms)	More than 4	2-4	1-2	<1
Consistency	Firm	Medium	Soft	
Position	Posterior	Midline	anterior	
Station of head	-3	-2	-1; 0	+1, +2

Total Score -13

Procedure for dinoprostone gel instillation was as patient was taken on the edge of table, Cleaning painting &draping were done. Cervix was visualized with Sims speculum. Anterior lip of cervix was caught with the sponge holder. Canula of dinoprostone gel was applied to the syringe. 1/3 of gel was inserted at the internal os. 1/3 of the gel was inserted into cervical canal. 1/3 of gel was inserted into posterior fornix. Patient was asked not to get up from the bed for an hour.

Procedure for Misoprostol Tablet insertion was as patient was taken on the edge of table **.** Cleaning, painting & draping were done. Tablet. Misoprostol 25 microgram inserted in the posterior fornix. Patient was asked not to get up from the bed for an hour.

Results

Total number of patients studied was 100. 50 patients were induced with 25 µg intravaginal Misoprostol tablets and the other 50 patients induced with 0.5mg intracervical Dinoprostone gel. The result observed were subjected to statistical analysis by students 't' test, Odd's ratio and Chi-square test.

Table 1: Demographic details in study

	Dinoprostone		Misoprostol	
	(N = 50)	%	(N = 50)	%
Booked	32	64	30	60
Unbooked	18	36	20	40
Total	50	100	50	100
Age in years				
19-23	10	20	8	15
24-28	30	60	37	75
29-33	10	20	5	10
Parity				
Primigravida	30	60	32	64
Multigravida	20	40	18	36
Gestational age				
≤ 40 WEEKS	36	72	36	72
40 weeks 1 day - 41weeks 6 days	14	28	14	28

There is no staistical difference between the groups.

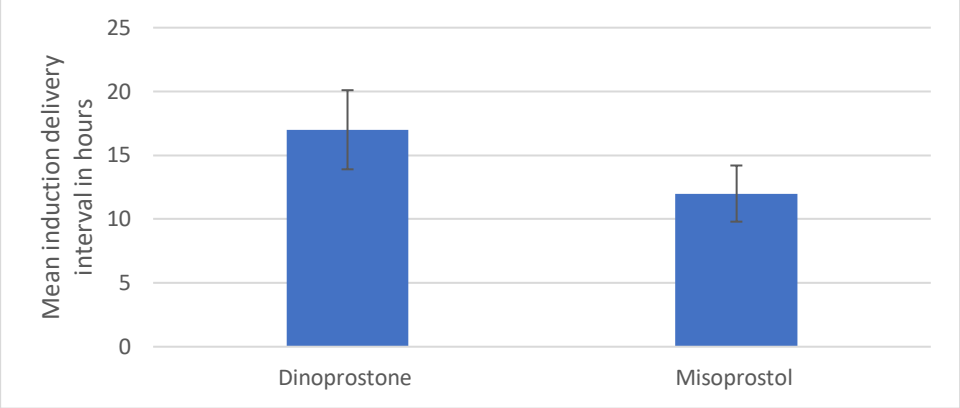

Fig 1: Induction delivery interval in hours

The mean induction delivery interval in dinoprostone is 17.0 ± 3. 109. The mean induction delivery interval in misoprostol is 12.0 ± 2.234. Mean induction delivery interval subjected to student's test. This had statistical significance

Table 2: Induction to delivery interval in hours

Interval in Hrs	Dinoprostone		Misoprostol	
	(N = 40)	%	(N = 45)	%
<6 Hrs	4	8	5	10
>6-12hrs	8	16	8	16
>12-18hrs	20	40	22	44
>18-24hrs	6	12	7	14
>24hrs	2	4	3	6
Total	40	80	45	90

Table 6 shows in dinoprostone, out of 40 women who delivered vaginally, 4 delivered within 6hours , 8 delivered within 12hours, 20 delivered within 18hours, 6 delivered within 24hours, 2 required more than 24hours. In misoprostol out of 45 women who delivered vaginally, 5 delivered within 6hours, 8 delivered within 12hours, 22 delivered within 18hours, 7 delivered within 24hours, 3 required more than 24hours.

Table 3: Indications for induction

Primigravida	Dinoprostone		Misoprostol	
	(n = 30)	%	(n = 32)	%
Mild preeclampsia	4	8.0%	6	12.0%
severe preeclampsia	4	8.0%	4	8.0%
post-dated pregnancy	6	12.0%	6	12.0%
mild polyhydramnios	6	12.0%	6	12.0%
mild oligohydramnios	4	8.0%	4	8.0%
gestational diabetes	4	8.0%	4	8.0%
chronic hypertension	1	2.0%	1	2.0%
rh -ve pregnancy	1	2.0%	1	2.0%
Multigravida				

Mild preeclampsia	3	6.0%	3	6.0%
severe preeclampsia	3	6.0%	3	6.0%
post-dated pregnancy	6	12.0%	5	10.0%
mild polyhydramnios	3	6.0%	3	6.0%
mild oligohydramnios	2	4.0%	1	2.0%
gestational diabetes	1	2.0%	1	2.0%
chronic hypertension	1	2.0%	1	2.0%

The largest group for induction in primigravida in Dinoprostone group are Mild Preeclampsia, Severe Preeclampsia, Post dated pregnancy which are of 12% each. In Misoprostol group, post-dated pregnancy, Mild polyhydramnios, Mild oligohydramnios which are of 12 % each. The largest group for induction in multigravida is post dated pregnancy which is of 12%, 10% in dinoprostone group, misoprostol group respectively.

Table 4: Variables compared in two gorups

Doses	**Dinoprostone**		**Misoprostol**	
	(N = 40)	**%**	**(N = 45)**	**%**
Dose 1	7	14.0%	12	24.0%
Dose 2	25	50.0%	32	64.0%
Dose 3	8	16.0%	1	2.0%
According to Bishop's				
0 – 2	35	70%	32	64%
3 – 4	15	30%	18	36%
Mode of delivery				
VAGINAL	40	80.0%	45	90.0%
LSCS	10	20.0%	5	10.0%

Out of 40 women delivered vaginally, 7 required single dose, 25 required two doses and remaining 8 required 3 doses. in misoprostol group, Out of 45 women delivered vaginally , 12 required single dose, 32 required two doses and 1 required 3 doses.35 have Bishops score less than 2, 15 have Bishop's score less than 4. In misoprostol group, Out of 50 women, 32 have Bishops score less than 2, 18 have Bishop's score less than 4. In the Dinoprostone group 80% patients delivered vaginally and 20% patients underwent caesarean delivery.In the Misoprostol group 90% patients delivered vaginally and 10% patients underwent caesarean delivery.

Table 5: Reasons for failed induction

Indications	**Dinoprostone**		**Misoprostol**	
	No. of Patients	**%**	**No. of Patients**	**%**
Fetal Distress	2	4%	4	8%
Deep Transverse arrest	2	4%	0	0%
Secondary arrest of dilation	6	12%	1	2%
Total	10	20%	5	10%

In the Dinoprostone group the total number of failed induction were 10 out of 50 patients giving an incidence of 20%. The majority of failed inductions were due to secondary arrest of dilation - 6 cases. 2 patients had fetal distress and 2 patients had deep transverse arrest.

In the Misoprostol group the total numbers of failed inductions were 5 out of 50 patients giving an incidence of 10%. The majority of failed inductions were due to fetal distress — 4 cases. It was seen that fetal distress was associated with uterine hyperstimulation in 3 out of 4 cases. 1 patient had secondary arrest of dilation.

Table 6: Effects on the mother and foetus

Complications	Dinoprostone		Misoprostol	
	No. of Patients	%	No. of Patients	%
Tachysystole	0	0	2	4
Hyperstimulation	1	2	3	6
Fever	1	2	3	6
Vomiting	2	4	2	4
Diarrhoea	4	8	2	4
Postpartum haemorrhage	11	22	3	6
Total	19	38	15	30
NICU Admission				
< 6 days	4	8	2	4
> 6 days	1	2	3	6
TOTAL	5	10	5	10
Indications of admission				
Meconium aspiration syndrome (MAS)	1	2.0%	3	6.0%
Birth asphyxia	1	2.0%	2	4.0%
Hyperbiluribinemia	3	6.0%	0	0.0%
TOTAL	5	10.0%	5	10.0%

There was a 38% incidence of side effects in the Dinoprostone group and 30% incidence of side effects in the Misoprostol group. In the Dinoprostone group there was 4% incidence of vomiting and 4% in the Misoprostol group. There was 22% incidence of postpartum haemorrhage. In the Misoprostol group, the present study says there is an increased incidence of tachysystole 4% and hyperstimulation 6%. Hyperstimulation was associated with fetal distress in three patients for which caesarean delivery was done. 6% patients had postpartum haemorrhage of traumatic type.

In the Dinoprostone group 4 babies were kept in NICU for less than 6 days and 1 baby was admitted for more than 6 days.In the Misoprostol group out of 5 babies 2 babies were admitted for less than 6days.

It was seen in the Dinoprostone group the main indication for NICU admission was hyperbiluribinemia - 3 babies (6%) and in the Misoprostol group the major indication for NICU admission was meconium aspiration syndrome - 3 babies (6%).

Discussion

In the present study 100 patients were studied with indications for induction of labour of which 50 patients received intracervical Dinoprostone gel containing 0.5mg and 50 patients received intravaginal Misoprostol tablet 25µg.An ideal method must encompass its efficacy and safety for the mother and fetus, short induction delivery interval minimum side effects. It was that majority of patients in both groups were booked cases at our institution, who had regular antenatal checkups at our institution or elsewhere. The other patient's characteristics like gravidity, gestational age and Bishops score prior to induction had no major differences in both groups. The rate of vaginal deliveries was 80% in the Dinoprostone group and 90% in the Misoprostol group.

Table 7: Vaginal Delivery Rate and Induction delivery interval

Authors and Year	Vaginal Delivery Rate
Dinoprostone	
Surg Cdr Sushil Kumar et al (2001)[3]	77.0%
Murthy B Krishnamurthy et al (2006)[4]	62.5%
Present Study	80.0%
Misoprostol	
Surg Cdr Sushil Kumar et al (2001)[3]	82.0%
Murthy B Krishnamurthy et al (2006)[4]	62.5%
Walid denguezil et al (2007)[5]	75.0%
Present Study	90.0%
Dinoprostone	**Induction delivery interval**

Agarwal N et al (2003)[6]	18.53 ± 8.5
Murthy B Krishnamurthy et al (2006)[7]	14.27 ± 5.51
Present Study	17.0 ± 3.10
Misoprostol	
Agarwal N et al(2003)[6]	12.8 ± 6.5
Murthy B Krishnamurthy et al (2006)[4]	10.2 ± 3.5
Present Study	12.0 ± 2.23

In my study, the rate of vaginal delivery in the Dinoprostone group is consistent with the studies of Murthy B Krishnamurthy et al (2006) and Surg Cdr Sushil Kumar et al (2001). The vaginal delivery rate with Misoprostol in my study is consistent with the studies of Surg Cdr Sushil Kumar et al (2001), Murthy B Krishnamurthy et al (2006) and Walid denguizil et al (2007)[3,4,5].

In the present study it was seen that the induction delivery interval was shorter in the Misoprostol group compared to Dinoprostone group 12 ± 2.23 hrs and 17 ± 3.10 hrs respectively. This was statistically significant (P<0.05). In the present study the induction — delivery interval of Dinoprostone is comparable to the studies of Agarwal N et al (2003), Murthy B Krishnamurthy et al (2006)[3,6]. In the Misoprostol group it was shown that by various dosages of Misoprostol used the induction - delivery interval also varies. Our present study uses 25µg Misoprostol every 4th hourly with an induction delivery interval or 12.0 ± 2.23hrs which is comparable to the studies of Agarwal N et al(2003)[6] who has used 50µg Misoprostol 6th hourly to a maximum of 200µg with an induction delivery interval of 12.8hrs and Murthy B Krishnamurthy et al (2006) who used 25µg Misoprostol 4th hourly to a maximum of 200µg with an induction delivery interval of 10.2 ± 3.5hrs.

Table 8: Induction to vaginal delivery interval

Authors and year	Dinoprostone (Dosage)	Misoprostol (Dosage)
Varaklis et al (1995)[7]	22.4 ± 10.9 (0.5mg 6hrs)	16.0 ± 7.7 (25µg 2hrs)
Wing Da et al (1995)[8]	23.5 ± 14.5 (0.5mg 6hrs)	15.1 ± 8.0 (50µg 3hrs)
Walid Denguezli et al[5](2007)	15.8	14.9
Present Study	17.0 ± 3.10 (0.5mg 8hrs)	12.0 ± 2.23 (25µg 4hrs)

Various authors in their studies have compared the efficacy of Misoprostol and Dinoprostone in relation to induction - delivery interval. In the present study the outcome of induction delivery interval is much shorter than the various studies and almost comparable to the studies of Walid Denguezli et al (2007)[5].Failed inductions were those causes which did not fulfill the criteria for the definition of "induction of labour". Thus all caesarean deliveries were considered failed induction irrespective of the cause of the same.Caesarean delivery rates in the present study are 20% in the Dinoprostone group and 10% in the Misoprostol group. The various indications were fetal distress. Failure to progress due to deep transverse arrest or secondary arrest of dilation. In the Dinoprostone group secondary arrest or dilation formed the major indication for caesarean delivery and in the Misoprostol group fetal distress formed the major indication for caesarean delivery. In the Misoprostol group it was seen that three cases which had fetal distress also had hyperstimulation and in all cases oxytocin augmentation was done and preoperatively it was found the presence of thick meconium stained liquor, in all cases. In our study the caesarean section rate with Dinoprostone was 20%, which is consistent with the studies of Trufatter et al (1985)[9]. In Misoprostol group the caesarean section rate was 10% which is consistent with the observation of Sanchez Ramos and associated in a recent meta analysis (1997), in which they found on analysis of all published studies (controlled and uncontrolled) that 108 of 1708 (9.8%) women delivered by caesarean section[10].The incidence of thick meconium stained liquor was 2% and 6% in Dinoprostone and Misoprostol groups respectively. 2 out of 3 patients in the Misoprostol group were induced for postdatism and found to have thick meconium stained liquor. It was not known whether the thick meconium was due to the drug or due to the indication for induction which was postdatism. The maternal side effects observed were tachysystole, hyperstimulation, vomiting, diarrhoea, fever and PPH. In the Dinoprostone group the major side effects were vomiting - 4% and PPH of 22%. Vomiting was noticed in patients who had rapid dilation of the cervix and could have been a cause of the same. The major side effects observed in the Misoprostol group was tachysystole 6% and hyperstimulation 4%. A concern with Misoprostol induction has been excessive uterine activity namely tachysystole and hyperstimulation, 3 cases of hyperstimulation were seen with fetal distress for which caesarean delivery had to be done. Our observations are nearly consistent with the studies of Fletcher et al (1994)[11]. The difference in the incidence of tachysystole and hyperstimulation by different authors could probably be attributed to the different dosing regimens. Other side effects in the Misoprostol group were fever, vomiting and diarrhea which were minimal. Misoprostol had 3 patients with traumatic PPH all were cervical tears and did not require any blood transfusion.

Table 9: Incidence of side effects with Misoprostol

Author and Year	Dosage	Tachysystole	Hyperstimulation
Fletcher et al (1994)[11]	100µg single dose	4%	3%
Wing et al (1995b)[13]	25µg q 3hrs	17%	6%
Bugalho et al(1996)[13]	25µg q 3hrs	15%	6%
Present Study	25µg 4hrs	6%	4%

The mean birth weight and mean apgar scores in both groups did not show any major difference.The incidence of NICU admission was 10% in both groups. The indications for NICU admission were meconium aspiration syndrome. Birth asphyxia and hyperbilirubin-emia. There was an increased incidence of meconium aspiration syndrome and birth asphyxia in the Misoprostol group and was associated with uterine hyperstimulation. Mundle and Young (1996) evaluated the effect of Misoprostol for labour induction on neonatal outcome[14]. They found that neonatal outcome was similar in both the groups (PGE1 and PGI groups). Cord blood acid base analysis did not differ between both the groups. No neonate met the ACOG criteria for birth asphyxia in their study. Sanchez Ramos et al[10], 1998 their meta analysis found no differences in incidence of low 5minutes apgar score and admission to NICU between Misoprostol and control groups.

Conclusion

Misoprostol and Dinoprostone are safe and effective for cervical ripening and labour induction. Misoprostol is cost-effective when compared to Dinoprostone. Misoprostol is stable at room temperature and does not need refrigeration whereas Dinoprostone requires refrigeration. Induction delivery interval is less in Misoprostol group when compared to Dinoprostone. Vaginal delivery rate is high in misoprostol group when compared to Dinoprostone.

One disadvantage with Misoprostol is uterine tachysystole and hyperstimulation with further fetal distress. In conclusion, we believe that Misoprostol is apparently safe, efficient and a cost-effective drug for induction of labour.

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