

ORIGINAL RESEARCH

Efficacy of intravaginal misoprostol v/s dinoprostone vaginal insert in induction of labour- A comparative open label randomised study

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ABSTRACT

Background: Induction of labour being a routine obstetric practice warrants the need to conduct more and more studies for the advancement of the techniques which aid it. Prostaglandins are a common method of induction of labor. In our study, we compare cervical ripening with intravaginal prostaglandin E1 analogue and the comparatively newer intravaginal prostaglandin E2 pessary with regard to induction delivery interval, mode of delivery, efficacy, safety, along with maternal outcomes of induction. **Materials and methods:** 100 Patients admitted in OBG Department of ASCOMS Hospita jammu with an indication for induction of labour from October 2021 to October 2022 who fulfilled the inclusion and exclusion criteria were included in the study. 50 patients were induced with 25µg of intravaginal misoprostol. Rest 50 patients were administered 10 mg intravaginal dinoprostone pessary (insert). the efficacy was compared with respect to induction delivery interval, Oxytocin Augmentation, Type of delivery, Cost effectiveness and maternal outcome. **Results:** Misoprostol is more cost-effective and stable at room temperature and has lesser Induction delivery interval and requirement of Oxytocin augmentation than dinoprostone. However with dinoprostone the vaginal delivery rate is high, need for caesarean section is less, uterine tachysystole and hyperstimulation rate is lesser than with misoprostol. **Conclusion:** Dinoprostone pessary, is a safe, efficient and a reliable induction agent which may become the method and drug of choice, for induction of labour in the coming years.

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INTRODUCTION

Induction of labor has become a common obstetric practice referring to the process of non-spontaneous initiation of uterine contractions which results in progressive dilatation with effacement of cervix and descent of presenting part of fetus, culminating in safe vaginal delivery of the baby after 28 weeks of gestation, with a good outcome. **De Ribes, (1988)**. Over the years, the techniques for inducing labor have also changed from dietary delicacies and physical stimulation by cervical stretching and amniotomy to sophisticated pharmacological manipulation using oxytocin and prostaglandins. In **1968, Karim et al.**, were the first to report the use of prostaglandins for labor induction. Since then, the use of prostaglandins, in different varieties and forms of administration, has become a common method of labor induction. Of late, a number of recently published clinical trials abroad and in India have shown that

intravaginal Dinoprostone (prostaglandin PGE₂) is an effective agent for induction of labour and cervical ripening at term, when compared to other methods of labour induction. In this study, our traditional methods of cervical ripening with intravaginal prostaglandin E1 analogue and the comparatively newer intravaginal prostaglandin E2 pessary are compared with regard to induction delivery interval, mode of delivery, efficacy, safety, along with maternal outcomes of induction.

AIMS and OBJECTIVES

1. To compare the efficacy of induction of labour with Dinoprostone vaginal insert (pessary) and Misoprostol with respect to:
 - Induction delivery interval
 - Oxytocin Augmentation
 - Type of delivery
 - Cost effectiveness.

2. To study the maternal outcome of both groups.

MATERIAL AND METHODS

100 Patients admitted in Obstetrics and Gynaecology Department of Acharya Shri Chander College of Medical Sciences and Hospital with an indication for induction of labour from October 2021 to October 2022 who fulfilled the inclusion and exclusion criteria were included in the study. Written and informed consent for participation in the study was taken from them. 50 patients were induced with 25µg of intravaginal misoprostol and repeated for a maximum of 6 doses every 4 hours as needed. Rest 50 patients were administered 10 mg intravaginal dinoprostone pessary (insert). The maternal vital signs, fetal heart rate and progress of labour were strictly monitored in all patients. 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 in case of misoprostol and after 30 minutes in case of dinoprostone pessary, or for augmentation of

labour in case of an arrest of dilation. 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 results observed were subjected to statistical analysis by Odd's ratio and Chi-square test.

INCLUSION CRITERIA

- Singleton fetus with cephalic presentation.
- Over 37 weeks of gestation.
- Reactive fetal heart pattern
- Unfavorable cervix Bishop score < 4
- No contraindication to vaginal delivery

EXCLUSION CRITERIA

- Previous L.S.C.S or any uterine surgery
- Mal presentation
- Grand Multiparity
- Abnormal fetal heart rate pattern
- Allergy to Prostaglandins

RESULTS

TABLE 1 - PARITY

PARITY	DINOPROSTONE		MISOPROSTOL	
	NO.OF PATIENTS	%AGE OF PATIENTS	NO. OF PATIENTS	%AGE OF PATIENTS
PRIMIGRAVIDA	31	62	25	50
MULTIGRAVIDA	19	38	25	50
TOTAL	50	100	50	100

P<0.05, Significant (S); Odds Ratio: 0.196

Primigravida were found to be the largest group in the study, 62% and 50% in dinoprostone and misoprostol group respectively. Multigravida in dinoprostone and misoprostol group were 38% and 50% respectively.

TABLE 2 - GESTATIONAL AGE

GESTATIONAL AGE	DINOPROSTONE		MISOPROSTOL	
	NO. OF PATIENTS	PERCENTAGE	NO.OF PATIENTS	PERCENTAGE
≤ 40 Weeks	41	82.0	41	82.0
40 Weeks 1 day – 41 Weeks 6 days	9	18.0	9	18.0
TOTAL	50	100.0	50	100.0

P>0.05, Not Significant (NS)

When gestational age was compared, it was seen that there were equal number of patients in both the groups with similar gestational age who underwent induction. The highest number in both the groups being below 40 weeks which were 82% and 82% in Dinoprostone and Misoprostol groups respectively.

TABLE 3 – MEAN INDUCTION DELIVERY INTERVAL

DRUG	Mean Induction Delivery Interval In hours
Dinoprostone	10.11 ± 3.83
Misoprostol	9.98 ± 3.32

P<0.05, Significant (S)

The mean induction delivery interval in Dinoprostone group (10.11±3.83) was noted to be more than in Misoprostol (9.98±3.32).

TABLE 4 – MODE OF DELIVERY

MODE OF DELIVERY	DINOPROSTONE		MISOPROSTOL	
	NO. OF PATIENTS	PERCENTAGE	NO.OF PATIENTS	PERCENTAGE
Vaginal Delivery	41	82.0	36	72.0
Caesarean Delivery	9	18.0	14	28.0
TOTAL	50	100.0	50	100.0

P<0.05, Significant (S)

In the Dinoprostone group 82% patients delivered vaginally and 18% patients underwent caesarean delivery. In the Misoprostol group, 72% patients delivered vaginally and 28% underwent caesarean section.

TABLE 5-INDICATION OF FAILED INDUCTION

INDICATIONS	DINOPROSTONE		MISOPROSTOL	
	NO. OF PATIENTS	PERCENTAGE	NO.OF PATIENTS	PERCENTAGE
FETAL DISTRESS	3	6	8	16
DEEP TRANSVERSE ARREST	0	-	1	2
SECONDARY ARREST OF DILATATION	6	12	5	10
TOTAL	9	18	14	28

Failed inductions were considered as those cases which did not culminate in normal vaginal delivery. Thus all caesarean deliveries were considered as 'failed inductions'. In the Dinoprostone group the incidence of failed inductions was 18%. The majority of failed inductions were due to secondary arrest of dilatation – 6 cases, 3 patients had fetal distress. In the

Misoprostol group the incidence of failed induction was 28%. The majority were due to fetal distress – 8 cases out of which 4 cases were associated with hyperstimulation of the uterus alone. 5 patients had secondary arrest of dilatation and 1 patient had deep transverse arrest.

TABLE 6 – MODIFIED BISHOP'S SCORE PRIOR TO INDUCTION

Drug	Parity	1-3		4-6		7-10	
		No.of patients	Percentage	No.of patients	Percentage	No.of patients	Percentage
DINOPROSTONE	Primi	26	83.9	5	16.1	0	-
	Multi	8	42.1	11	57.9	0	-
MISOPROSTOL	Primi	18	72	7	28	0	-
	Multi	10	40	15	60	0	-

In Dinoprostone group, 83.9% primigravidas had a score between 1-3 and 16.1% primigravidas had a score between 4-6 where as 42.1% multigravidas in the same group had a score between 1-3 and 57.9% had a score between 4-6. In the Misoprostol group,

72% primigravidas had a score between 1-3 and 28% primigravidas had a score between 4-6 where as 40% multigravidas in the same group had a score between 1-3 and 60% had a score between 4-6.

TABLE 7 – MODIFIED BISHOP'S SCORE AT 6 HRS

Drug	Parity	1-3		4-6		7-10	
		No.of patients	Percentage	No.of patients	Percentage	No.of patients	Percentage
DINOPROSTONE	Primi	2	6.3	26	84	3	9.7
	Multi	1	5.3	9	47.4	9	47.4
MISOPROSTOL	Primi	11	44	14	56	0	-
	Multi	9	36	11	44	5	20

It was seen that in the present study, the overall modified Bishop's score at 6 hrs in primigravida and multigravida in the Dinoprostone group was more than the Misoprostol group.

TABLE 8– EFFECTS ON THE MOTHER

COMPLICATIONS	DINOPROSTONE		MISOPROSTOL	
	No. of Patients	Percentage	No. of Patients	Percentage
Forceps	2	4	1	2
Postpartum Haemorrhage	5	10	3	6
Hyperstimulation	4	8	10	20
Fever	1	2	4	8
Tachysystole	4	8	8	16
Ventose	1	2	1	2
Postpartum Ecclampsia	1	2	0	0
Tear	0	0	3	6
Total	15	30	22	44

P<0.05 Significant (S)

There was a 30% incidence of side effects in Dinoprostone group and 44% incidence of side effects in the Misoprostol group. In the Dinoprostone group, there was increased incidence of instrumental delivery which included 4% incidence of forceps when compared to 2% in the Misoprostol group. The incidence of ventouse application was equal i.e. 2% in both the groups. There was a 10% incidence of postpartum hemorrhage, out of which 6% were due to traumatic postpartum hemorrhage and 4% were due to atonic post-partum hemorrhage. In the Misoprostol group, there was an increased incidence of hyperstimulation 20% as compared to 8% in Dinoprostone group and an increased incidence of tachysystole 16% as compared to 8% in Dinoprostone group.

Hyperstimulation was associated with fetal distress in 5 patients for which caesarean was done. Incidence of postpartum hemorrhage was 6%.

DISCUSSION

In our study, the rate of vaginal delivery in the Dinoprostone group was found to be 82% which is consistent with the studies of **Pitale et al.** (85%), (2017) and **Mamatha et al.** (85%), (2021). The vaginal delivery rate with Misoprostol in our study was 72% which is consistent with the studies of **Tabasi et al.** (72.7%), (2007) and **Hokkila et al.**, (2019) (79.9%). In the present study, the mean Bishop's score at 6hrs in the Dinoprostone group was 5.2 and 6.1 in primigravidae and multigravidae respectively, which is consistent with studies of **Tempe et al** who also observed mean Bishop's score at 6hrs was 5.22 ± 1.58 . In the present study it was seen that the induction delivery interval was longer in the Dinoprostone group as compared to the Misoprostol group 10.11 ± 3.83 and 9.98 ± 3.32 respectively. In the present study the Induction-delivery interval in the Dinoprostone group is comparable to the studies of **Yan et al.** (2022)- 10.71 ± 7.60 . Our present study uses 25µg Misoprostol every 4 hourly with an induction delivery interval of 9.98 ± 3.32 hrs which is comparable to the studies of **Bharathi et al.**, (2013) who has used 50µg Misoprostol 3 hourly to a maximum of 300µg with an

induction delivery interval of 9.45 hrs and **Ramya and Jaju (2017)** who used 50µg Misoprostol 6 hourly to a maximum of 150µg with an induction delivery interval of 7.83 ± 5.63 hrs. In our study the caesarean section rate with Dinoprostone was 18%, which is consistent with the studies of **Gaudineau et al.**, (2021)-19.9%. In Misoprostol group of the present study, the caesarean section rate was 28% which is consistent with the observation of **Chaudhari et al.**, (2021) 22% and **Gaudineau et al.**, (2021) 22.1%. In the present study the requirement for oxytocin augmentation was more in the Dinoprostone group – 48% than in the Misoprostol group – 28%, this was statistically significant. These observations are consistent with that of **Danelien et al.**, (1999) where it was 47% in the dinoprostone group and 21% in the misoprostol group. In the Dinoprostone group the major side effect was PPH 10% of which traumatic –6% and 4% atonic. The major side effects observed in the Misoprostol group was tachysystole 16% and hyperstimulation 20%. Our observations are nearly consistent with the studies of **Sanchez Ramos et al.**, - 34.4% and 10.9%. (1993) and **Wing et al.**, (1995b).-17.4% and 5.8%.

CONCLUSION

Dinoprostone and Misoprostol are safe and effective for cervical ripening and labour induction. Misoprostol is more cost-effective and stable at room temperature than dinoprostone which needs refrigeration. It has lesser Induction delivery interval and requirement of Oxytocin augmentation than dinoprostone. However with dinoprostone the vaginal delivery rate is high, need for caesarean section is less, uterine tachysystole and hyperstimulation rate is lesser than with misoprostol. In conclusion, we believe that Dinoprostone pessary, is a safe, efficient and a reliable induction agent which may become the method and drug of choice, for induction of labour in the coming years.

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