

Comparative Study of Induction of Labour with Dinoprostone Gel and Tab. Misoprostol



Medical Science

KEYWORDS : Induction of labour, Misoprostol tablet, Dinoprostone gel.

DR.NEHA N. LIMBANI	3RD YEAR RESIDENT, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE
DR.PRIYANKA J. PARMAR	3RD YEAR RESIDENT, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE
DR.SANTVAN B. MEHTA	MS GYNEC, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE
DR.RIDDHI B. SHAH	MS GYNEC, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE
DR.MUNJAL J. PANDYA	ASSISTANT PROFESSOR, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE
DR.JANKI M. PANDYA	ASSISTANT PROFESSOR, OBSTETRICS AND GYNECOLOGY DEPARTMENT SMT. N H L MUNICIPAL MEDICAL COLLEGE

ABSTRACT

Objective : To compare the safety and efficacy of intravaginal misoprostol (PGE1) with intra cervical dinoprostone gel (PGE2) for induction of labour, To study the maternal & fetal outcome, To measure an average induction to delivery interval time, To assess the need of oxytocin augmentation. **Methods :** This is a prospective study conducted at labour rooms of V.S. Municipal hospital, S.C.L. Municipal hospital, L.G Hospital attached to Smt. N.H.L. Municipal medical college, Ahmedabad from June 2012 to December 2013. This study was performed with 100 randomly selected patients with an indication for induction of labour. Among them 50 patients were induced with Dinoprostone gel and 50 patients with Tab. Misoprostol. **Results :** The change in the Bishop's score after 6 hours was markedly high in the Tab. Misoprostol group as compared to the Dinoprostone Gel group, 11% Patient in the Tab. Misoprostol group required oxytocin augmentation as compared to 19% in the Dinoprostone Gel group, Induction-Delivery interval was significantly shorter in the Tab. Misoprostol group, Maternal and fetal side effects were low and comparable in both groups. **Conclusion :** Induction of labour confers benefits in various maternal and fetal conditions, it must be done in the set up where trained staff for continuous monitoring of the patients are available.

INTRODUCTION

Induction of labour is an obstetric procedure, in which pregnancy is terminated artificially, any time after fetal viability is attained, by a method to secure vaginal delivery⁽¹⁾. In modern obstetrics, 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.⁽²⁾ In this study, our traditional methods of cervical ripening with endocervical prostaglandin E2 gel, and the new one intravaginal prostaglandin E1 tablet are compared with regard to efficacy and safety.

METHOD OF INDUCTION

Tab. Misoprostol GROUP:

- 50 patients were induced with Tab. Misoprostol 25µgm through intravaginal route and repeated 4-6 hourly as needed.
- 25 µgm Tab. Misoprostol inserted in the posterior vaginal fornix, under aseptic precautions.
- Further doses withheld if patient entered active labour.
- Patient was advised for recumbent position for one hour after drug insertion.

Dinoprostone Gel GROUP:

- 50 Patient were induced with 0.5mg Dinoprostone gel intracervical route and repeated at duration of 12 hours as per needed, maximum 2 doses.
- 0.5 mg Dinoprostone gel available in 2.5ml syringe with an applicator was introduced intra-cervically under aseptic precautions.
- Further doses withheld if patient entered active labour.
- Patient was advised for recumbent position for four hours after drug insertion.

After induction of labour patients were monitored for:

- Signs of labour
- Maternal and fetal wellbeing

- Progress of labour
- Bishop's score after 6 hours.
- Fetal heart rate was monitored with intermittent auscultation.
- Artificial rupture of membrane done when there was well effaced cervix with 4-5 cm cervical dilatation reached.
- If contractions were not adequate with improved bishop's score, oxytocin was started to accelerate labour in selected patients with 2.5IU in 500ml of Ringer's lactate with 6 drops per minutes and 2 drops were increased on every 30 minutes till adequate uterine contraction established without fetal bradycardia in between uterine relaxation.

RESULTS

In our study total 100 patients, requiring induction of labour were studied. These patients were having low Bishop Score and they were randomly divided in two groups, one group of 50 patients were induced with 0.5mg Dinoprostone Gel (Intra-Cervical) and other group of 50 patients were induced with 25µgm Tab. Misoprostol (Intra-Vaginal).

The following observations were made:-

Table – 1 Distribution of cases according to Indications for Induction :

Indications	Misoprost Group No. (%)	Dinoprostone Group No. (%)	Total No. (%)
Postdatism	15 (15%)	15 (15%)	30 (15%)
PROM	12 (12%)	12 (12%)	24 (12%)
IUD	6 (6%)	6 (6%)	12 (6%)
Oligohydroamnios	7 (7%)	6 (6%)	13 (6.5%)
Pre Eclampsia	9 (9%)	7 (7%)	16 (8%)
Eclampsia	1 (1%)	4 (4%)	5 (2.5%)
Total	50	50	100 (50%)

- Postdatism(15%) was commonest indication for the both the groups. Postdatism was defined by calculating the maturity of the fetus, taking into consideration Last Menstrual Period(LMP) and 2nd trimester sonography.
- In cases of Premature Rupture of Membranes(PROM), Patients were observed for establishment of labour spontaneously for about 12 hours and if the Bishop Score remained the same, then only patients were induced with either of the drugs.

- Table – 2 Mean Bishop Score :

Mean Bishop Score	Misoprost Group	Dinoprostone Group
Initial	2.78	2.68
After 6 hours	6.64	5.79
Mean Rise in Bishop score	3.88	3.11

- Bishop Score was calculated in both the groups after 6 hours of induction. Mean rise in Bishop score was significantly higher in both the groups, however the mean rise in Bishop score was significantly higher in the Tab.Misoprostol group than Dinoprostone gel Group(P<0.05).

Table – 3 Mode of Delivery:

Mode of Delivery	Misoprost Group No. (%)	Dinoprostone Group No. (%)	Total No. (%)
Vaginal Delivery	39 (39%)	37 (37%)	76 (38%)
Caesarean Section	11 (11%)	13 (13%)	24 (12%)
Total	50	50	100 (50%)

Good number of patients were delivered vaginally in both the groups.37% of patients induced with Dinoprostone gel, while 39% of those induced with Tablet Misoprostol delivered vaginally. Thus mode of delivery in both the group is comparable. (P>0.05)

Table – 4 Requirement of Oxytocin Augmentation :

Oxytocin Augmentation	Misoprost Group No. (%)	Dinoprostone Group No. (%)	Total No. (%)
Required	11 (11%)	19 (19%)	30 (15%)
Not Required	39 (39%)	31 (31%)	70 (35%)
Total	50	50	100 (50%)

19% of patients induced with Dinoprostone gel required Oxytocin augmentation , while only 11% of those induced with Tablet Misoprostol required Oxytocin augmentation. Thus Oxytocin augmentation was required more in Dinoprostone Group.(P<0.05)

Table – 5 Indication for Caesarean Section :

Indication	Misoprost Group No. (%)	Dinoprostone Group No. (%)
Fetal distress	5 (45.45%)	5 (38.46%)
Induction Failure	5 (45.45%)	8 (61.53%)
Obstructed Labour	1 (9.09%)	-
Total	11 (11%)	13 (13%)

Indications for C.S. in Misoprostol group were Fetal distress and Induction failure, while for Dinoprostone group, Induction failure was more commoner (61.5%) indication than fetal distress.

Fetal distress - It was identified either clinically by meconium stained liquor or by auscultating fetal bradycardia(Heart rate<110/min.)

Induction failure was assigned to those cases in whom cervical Bishop score was unfavourable even after 24 hours of induction.

Table – 6 Neonatal Outcome :

Neonatal Complications	Misoprostol Group No.	Dinoprostone Group No.
Meconium Present	7	5
NICU Admission - Prematurity - Hyperbillirubinemia	4 2 2	5 3 2
Perinatal Mortality	1	2
Total Live Births	49	48

- Thus this table shows that neonatal complications were similar in both the groups, no statically significant difference was noted (P>0.05).

Mean Induction – Delivery Interval :

- The mean induction and delivery interval for tab. Misoprostol was 12.04 hours and for dinoprostone gel was 15.84 hours. In both the groups mean induction-delivery interval was less than 24 hours, But it was significantly shorter in the Tab.Misoprostol Group.(P<0.05, significant)

- Total no. of doses required :

- 42% of patients induced with Dinoprostone gel required only a single a dose and only 8% of patients required 2 doses, while 16% of those induced with Tablet Misoprostol required 2 doses and 22% of patients required only a single dose.
- Thus the induction and so the delivery with the Tab.Misoprostol is quite better than Dinoprostone Gel.

DISCUSSION

- The synthetic PGE1 analogue, Misoprostol has been compared with PGE2 gel, Dinoprostone Gel with respect to outcome of induction in terms of change in BISHOP'S Score, need for oxytocin augmentation, induction delivery interval, mode of delivery, maternal and neonatal complications. The comparative study between these two inducing agents has been carried out by many investigators since 1990s. The present study has been compared with some of such studies of Indian as well as Western background.

1. MEAN BISHOP'S SCORE AT 6 HOURS:

Mean Bishop score was higher in patients of Tab. Misoprostol group compared to that of Dinoprostone group. While other studies showed similar increase in Bishop score.

STUDY	Tab. Misoprostol	Dinoprostone Gel
Present Study	6.64	5.79
G. Shivarudraiah et al 2011	5.22	5.37
A.K. Anand 2012	5.24	5.32

2. OXYTOCIN AUGMENTATION:

In this study significantly lesser percentage of patients in the Tab. Misoprostol group needed oxytocin augmentation as compared to the patients in the Dinoprostone Gel group. These findings were observed in other studies also.

STUDY	Tab. Misoprostol	Dinoprostone Gel
Present Study	11%	19%
G. Shivarudraiah et al 2011	34%	35.4%
A.K. Anand 2012 ^[10 1]	28%	48%

3. INDUCTION DELIVERY INTERVAL:

In this study, induction delivery interval was significantly short-

er in the Tab. Misoprostol group as compared to Dinoprostone Gel group, same was observed in following other studies.

STUDY	Tab. Misoprostol (Hours)	Dinoprostone Gel (Hours)
Present Study	12.04	15.84
S. Kulshreshtha et al 2007	6.92	12.54
P.Danielian et al 1999	14.4	22.9

4. LABOUR OUTCOME:

In the present study, among 100 patients who were induced with either Tab. Misoprostol or Dinoprostone Gel, 12 % required cesarean section , which is comparable to other studies.

STUDY	No of Cases	Vaginal	Cesarean Section
Present Study	100	38%	12%
S. Kulshreshtha et al 2007	40	90%	10%
G. Shivarudraiah et al 2011	320	74.37%	25.63%

CONCLUSION

Induction of labour with Prostaglandins has improved outcome in women with low Bishop Score. When compared, the two drugs, Tab. Misoprostol and Dinoprostne Gel, has some differences, Dinoprostone Gel is an established and widely used drug for cervical ripening and labour induction. However dinoprostone gel is expensive and need refrigeration for storage. While Tab.Misoprostol, a recently introduced drug, is cheap and easy to store with no special storage requirement. When introduced vaginally Tab. Misoprostol is faster in improving Bishop Score and Induction-Delivery interval shorter than Dinoprostone gel. It required less Oxytocin augmentation. Dinoprostone Gel is slower in action with longer labour duration and requires Oxytocin augmentation more often. Rate of vaginal delivery is same in both the groups. However judicious use with the proper dosage and frequency of administration is must for safer inductions in Tab.Misoprostol, as it may lead to complications. Thus both drugs have their pros and cons.

REFERENCE

1. Ian Donald's Practical Obstetric Problems. 6th Edition.488-503. | | 2. Frank J, Chuck B, Joyce H. Labour induction with intra vaginal misoprostol versus intra cervical prostaglandins E2 (Prepidil gel) Randomize comparison. Am J Obst & Gynae 1995; 175(4): 1137-1142. | 3. Fletcher HM, Mitchell S, Simeon FJ. Intravaginal misoprostol as a cervical ripening agent. Brit J Obst & Gynae 1993; 100: 641-644. | | 4. Munro Kerr's Operative Obstetrics. 11th edition. 69-79. | | 5. William's Obstetrics. 23rd edition.138-150. |