



A STUDY OF VAGINAL MISOPROSTOL TABLET VERSUS INTRACERVICAL DINOPROSTONE FOR INDUCTION OF LABOUR

Obstetrics & Gynaecology

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ABSTRACT

Background: Induction of labour is the process of initiating the labour by artificial means post 24 weeks of gestation. This study was undertaken to compare the efficacy and safety of vaginal Misoprostol [25-50ug] with intracervical Dinoprostone gel (0.5mg) for induction of labour at term in terms of efficacy of drug, foeto-maternal outcome, side effects and complications of drugs.

Methods: 400 nulliparas at term admitted in the OBG ward were included in this study. They were randomly allocated to two groups A & B. Group A (200 women) received tablet Misoprostol 25 micrograms vaginally 4 hrly to a maximum of 3 doses and Group B (200 women) received Dinoprostone gel 0.5mg intracervically 6 hrly to a maximum of 3 doses. Comparison was done in terms of induction to delivery interval, rates of instrumental and LSCS delivery, need for NICU care and cost-effectiveness. ADRs, if any were documented and proper care taken.

Results: The mean induction to delivery interval was less in the Misoprostol group than Dinoprostone group (12 hrs vs. 22 hrs). 82% patients delivered in the first 24 hrs in Misoprostol group compared to 54 % patients in Dinoprostone group. Group A had a higher success rate (80% vs. 75%) and also required less augmentation of labor (35% vs. 65%) compared to group B. Need for LSCS was also lower in Misoprostol group (13% vs. 18%). Need for instrumentation and incidence of NICU admission was similar in both groups. Misoprostol was more cost effective compared to Dinoprostone.

Conclusions: The Misoprostol group had a shorter induction to delivery interval, more number of deliveries in the first 24 hrs of induction and a reduced need of augmentation of labor with oxytocin. There was no significant difference in the rate of caesarean section, hyper-stimulation syndrome, neonatal and maternal morbidity between the two groups. Thus, Misoprostol appears to be safer, cheaper and more efficacious alternative for induction of labor especially for non-fetal indications as compared to Dinoprostone gel.

KEYWORDS

Dinoprostone gel, Induction of labour, Vaginal Misoprostol, PGE1, PGE2

INTRODUCTION

Induction of labor at term for achieving a vaginal delivery has become a common and accepted practice when continuation of pregnancy is harmful to mother or fetus or both. Induction is an intervention performed prior to onset of spontaneous labor which stimulates uterine contractions leading to progressive dilation and effacement of cervix and expulsion of fetus.¹ In some 5-25% of pregnancies, there comes a time when the fetus and/or mother would be better off if the delivery was conducted.² Introduction of prostaglandins has revolutionized induction of labor. Many studies have shown the superiority of vaginal prostaglandins compared to oxytocin alone in cervical priming and labor induction in terms of reduced induction-delivery interval and lower operative rate.^{3,4} Prostaglandins change the extracellular matrix of the cervix, ripen the cervix and also enhance the collagenase activity in the cervix. They increase the intracellular calcium levels and causes contraction of myometrial muscle.^{5,6} The FDA revised its labelling of Misoprostol in April 2002 from contraindicated in pregnancy to contraindicated in pregnancy for the treatment and prevention of NSAID induced ulcers.⁷ Currently, the prostaglandin analogs that are used for cervical ripening are PGE1 (Misoprostol) and PGE2 (Dinoprostone gel). Among the two, Dinoprostone is considered the drug of choice and is accepted for labor induction at term. Although safe and effective, it is expensive and needs to be refrigerated for storage purposes. Misoprostol (15-deoxy- 16-hydroxy-16 methyl-PGE1) was the first synthetic analogue to be made available for the treatment of peptic ulcer. It has shown efficacy in cervical priming and labor induction. In contrast to Dinoprostone, it is inexpensive, can be stored at room temperature and has few systemic side effects.^{8,9} Misoprostol has been listed in the WHO model list of essential medicines for labor induction at term, in low dose (25-50 microgram). Results from several studies state that Misoprostol used vaginally, orally or sublingually is effective in labor induction and reduces the induction-delivery interval and oxytocin requirement; but can increase the incidences of hyper-stimulation and cesarean for fetal distress.¹⁰⁻¹² This study was undertaken to compare the efficacy and safety of vaginal Misoprostol with intracervical Dinoprostone gel for induction of labour at term. Objective of present study is to compare the safety and efficacy of vaginal Misoprostol 25 µgm with intracervical instillation of Dinoprostone gel 0.5 mg in terms of

- Success rate
- LSCS rate
- Need for instrumentation
- Fetal complications- fetal distress, need for NICU admissions
- Side effects
- Cost effectiveness

METHODS

This was a prospective study conducted on nulliparous females in the age group of 20-30 years with gestational age more than 37 weeks. The study was conducted in the Department of Obstetrics and Gynecology at Government Medical College And General Hospital, Anantapur. Institutional Ethical Committee approval was obtained prior to the study. Written informed consent also was obtained from all the participants. Duration of study was 18 months from 1st November 2017 to 30th April 2019. Sample size was 400 nulliparas. Patients fulfilling inclusion and exclusion criteria were randomly allocated to two groups

Group A Receiving Misoprostol 25ug vaginally 4 hourly to a maximum of 3 doses.

GroupB Receiving Dinoprostone gel 0.5mg intracervically 6 hourly to a maximum of 3 doses.

Patients were monitored by intermittent electronic fetal monitoring for development of fetal complications. The entire drug profile including its side effects, success rate and failure rate were explained to the patient and her attendants in detail. It was explained that refusal to participate in the study will not affect the management.

Inclusion Criteria

- Singleton pregnancy
- Cephalic presentation
- Gestational age more than 37 weeks
- Pre-induction cervical score less than 5 by Bishop scoring system.

Exclusion Criteria

- Multiparas
- Previous LSCS
- Placenta/vasa previa
- Abnormal fetal lie
- Cord presentation etc.

- Induction to delivery interval
- Need for augmentation

Statistical Analysis

The data was collected, tabulated and analyzed for various parameters and were compared. The statistical significance among all parameters was derived by the student t test (unpaired t test) and presented using Student version of Statistical Package for Social Sciences (SPSS) software in 21.0 versions and MS Excel.

RESULTS

In present study, 400 individuals satisfying the inclusion and exclusion criteria were randomly allocated to groups A and B. Group A of 200 participants were induced with Misoprostol 25µgm vaginally and group B of 200 participants with intra cervical Dinoprostone.

The desired outcomes were compared and results were analyzed. The mean induction to delivery interval was less in the Misoprostol group than Dinoprostone group (12 hrs vs. 22 hrs). 82% patients delivered in the first 24 hrs in Misoprostol group compared to 54% patients in Dinoprostone group. Group A had a higher success rate (80% vs. 75%) and also required less augmentation of labor (35% vs. 65%) compared to group B.

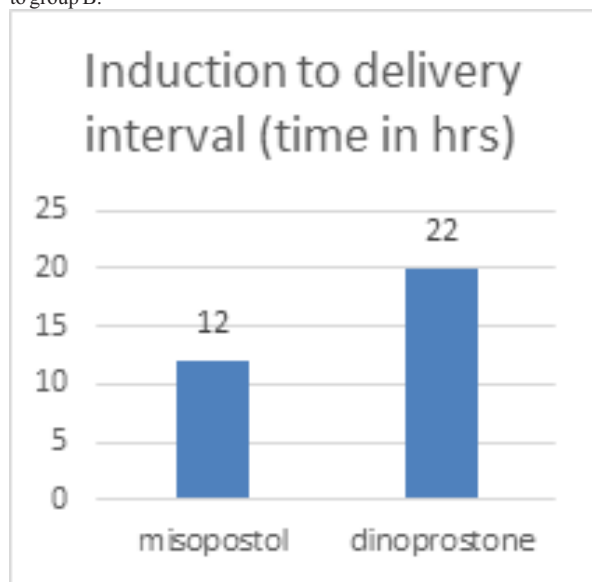


Fig. Showing the mean induction to delivery interval between Misoprostol and Dinoprostone groups

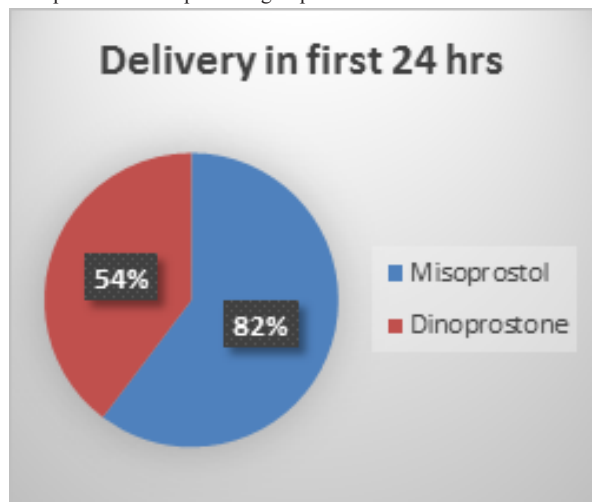


Fig. Showing the % of individuals delivered in first 24 hrs following induction with Misoprostol and Dinoprostone groups

Need for LSCS was also lower in Misoprostol group (13% vs. 18%). The maximum LSCS (18%) in the Dinoprostone group were done for failure of induction of labour. Need for instrumentation and need for NICU admissions was similar in both groups. The average cost of Misoprostol for 3 doses is Rs.18/- compared to intracervical Dinoprostone gel which costs around Rs.235/-. The side effects of

drugs used like nausea, vomiting, diarrhoea, pain, hyper-stimulation were more with Misoprostol group (28%) compared to Dinoprostone group (16%).

Table: Comparisons Between Misoprostol And Dinoprostone

	Misoprostol	Dinoprostone
Vaginal delivery	80%	75%
LSCS/instrumental	20%	25%
LSCS	13%	18%
Augmentation of labour	35%	65%
Instrumentation	7%	7%
Need of NICU admission	8%	8%
ADRs	28%	16%
Cost	RS.18/-	Rs.235/-

DISCUSSION

The mean induction to delivery interval was less in the Misoprostol group than Dinoprostone group (12 hrs vs. 22 hrs). 82% patients delivered in the first 24 hrs in Misoprostol group compared to 54 % patients in Dinoprostone group in our study which was comparable to similar studies. In the study of Murthy Bhaskar Krishnamurthy in 2006, induction to delivery interval was shorter in the Misoprostol group.¹³ Need for LSCS was also lower in Misoprostol group (13% vs. 18%). This was consistent with the study of Sahu latika et al¹⁴ and also with the study of Patil kamal et al¹⁵ and Murthy Bhaskar et al.¹³ Frank Chuck and Huffaker have compared 50 microgram vaginal PGE1 with in intracervical PGE2 gel every 4 hours for labor induction and have reported similar results.¹⁶

Agarwal et al have studied vaginal PGE1 50mg 6 hourly vs intracervical PGE2 gel, and have concluded that vaginal Misoprostol is more effective and safe for labor induction at term.¹⁷ Garry et al and Le Roux et al have reported an increased incidence of cesarean for fetal distress and tachysystole with 50 microgram of vaginal PGE1 when compared to vaginal Dinoprostone.^{11,18} Van Gemund et al in their study comparing 25 microgram vaginal Misoprostol with Dinoprostone, with adverse neonatal outcome as the primary outcome measure, concluded that this lower dose of Misoprostol is safer with less admissions.¹⁹

Maydanli et al have concluded that 25 microgram vaginal Misoprostol could be as effective as 50 microgram for cervical ripening and labor induction.²⁰

Hence Misoprostol 25 microgram as used in our study appears to be both effective and safe and could be the dosage that can be adopted in clinical practice for labor induction at term in primigravidas with unfavourable cervixes. The safety in grand multiparas and in women with previous uterine scar cannot be commented upon as these women have been excluded from our study.

CONCLUSION

In this prospective study where 200 cases were induced with 25µgm Misoprostol vaginally and 200 cases were induced with 0.5 mg of Dinoprostone gel intracervically-The Misoprostol group (group A) was associated with a shorter induction to delivery interval, more number of deliveries in the first 24 hrs of induction and a reduced need of augmentation of labor with oxytocin. Need for LSCS was more with Dinoprostone group. There was also no significant difference in neonatal and maternal morbidity between the two groups. Thus, in conclusion, Misoprostol appears to be safer, cheaper and more efficacious alternative for induction of labor especially for non fetal indications as compared to Dinoprostone gel.

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