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Original Research Article

A study of vaginal misoprostol tablet versus intra cervical dinoprostone gel for the induction of labour

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ABSTRACT

Background: This was a comparative study conducted to compare the effectiveness of 25 microgram of intravaginal misoprostol with intracervical dinoprostone gel in terms of efficacy of drug, fetal-maternal outcome, side effects and complications of drugs.

Methods: 400 nulliparas at term, admitted for induction of labor were included in this study. They were randomly selected to receive either intravaginal misoprostol or intracervical dinoprostone gel. Group A (200 women) received tablet misoprostol 25 micrograms vaginally 4 hourly to a maximum of 3 doses and Group B (200 women) received dinoprostone gel 0.5mg intracervically 6 hourly to a maximum of 3 doses. Comparison was done in terms of Induction to delivery interval, need for augmentation, LSCS and instrumentation rate, need for NICU admissions and cost effectiveness.

Results: The mean induction to delivery interval was less in the misoprostol group than dinoprostone group (12.5 hrs vs. 20 hrs). 78% patients delivered in the first 24 hrs in misoprostol group compared to 52% patients in dinoprostone group. Group A had a higher success rate (81% vs. 76%) and also required less augmentation of labor (30% vs. 60%) compared to group B. Need for LSCS was also lower in misoprostol group (11% vs. 16%). 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

INTRODUCTION

Induction of labor at term with an intention of achieving a vaginal delivery is a common accepted obstetric intervention when continuation of pregnancy is deleterious to mother or fetus or both. It is an intervention that artificially stimulates uterine contractions leading to progressive dilation and effacement of cervix and expulsion of fetus prior to onset

of spontaneous labor.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 Advent of prostaglandins has revolutionized induction of labor.

Many studies have shown the advantages of using vaginal prostaglandins in cervical priming and labor induction in terms of reduced induction-delivery interval and lower operative rate compared to oxytocin alone.^{3,4}

Prostaglandins alter the extracellular ground substance of the cervix, ripen the cervix and also increase the activity of collagenase in the cervix. They also allow for an increase in intracellular calcium levels, causing 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, two prostaglandin analogs, PGE1 (misoprostol) and PGE2 (dinoprostone gel) are available for cervical ripening.

Dinoprostone is the drug of choice and is accepted for labor induction at term. Although safe and effective, it is expensive and requires refrigeration for storage. Misoprostol (15-deoxy-16-hydroxy-16 methyl-PGE1) was the first synthetic prostaglandin analogue to be made available for the treatment of peptic ulcer. It has been shown to be effective in cervical priming and labor induction. It is inexpensive, can be stored at room temperature and has few systemic side effects.^{8,9} Misoprostol is proposed for induction in WHO model list of essential medicines for labor induction at term to be used in low dose (25-50 microgram). Several studies have shown that misoprostol used vaginally, orally or sublingually is effective in labor induction and reduces the induction-delivery interval and oxytocin requirement. At the same time concerns were expressed about the increased 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 by comparing their:

- Induction to delivery interval
- Need for augmentation
- Success rate
- LSCS rate
- Need for instrumentation
- Fetal complications- fetal distress, need for NICU admissions
- Side effects
- Cost effectiveness

METHODS

This was a prospective observational 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 Smt. Kashibai Navale Medical College and General Hospital, Pune. Duration of study is 18 months from 1st November 2014 to 30th April 2016. Sample size was 400 nulliparas.

Patients fulfilling the inclusion criteria were randomly allocated to

- Group A: receiving tablet misoprostol 25 microgram vaginally 4 hourly to a maximum of 3 doses.
- Group B: 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 of the patient.

Inclusion criteria

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

Exclusion criteria

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

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).

RESULTS

In present study, 400 cases were included. 200 cases were induced with misoprostol 25µgm vaginally and 200 cases with intra cervical dinoprostone gel.

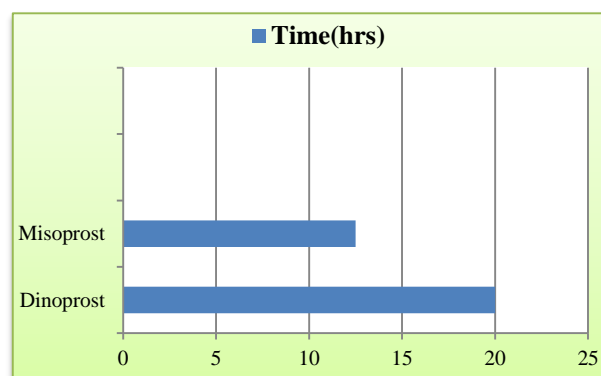


Figure 1: Induction to delivery interval.

The desired outcomes were compared and results were analyzed. The mean induction to delivery interval was less in the misoprostol group than dinoprostone group (12.5 hrs vs. 20 hrs) (Figure 1). 78% patients delivered in the first 24 hrs in misoprostol group compared to 52% patients in dinoprostone group (Figure 2).

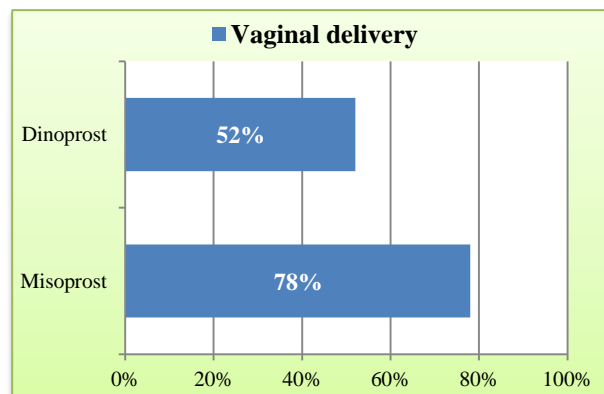


Figure 2: Delivery in 1st 24hrs.

Group A had a higher success rate (81% vs. 76%) and also required less augmentation of labor (30% vs. 60%) (Figure 3, 4a and 4b) compared to group B.

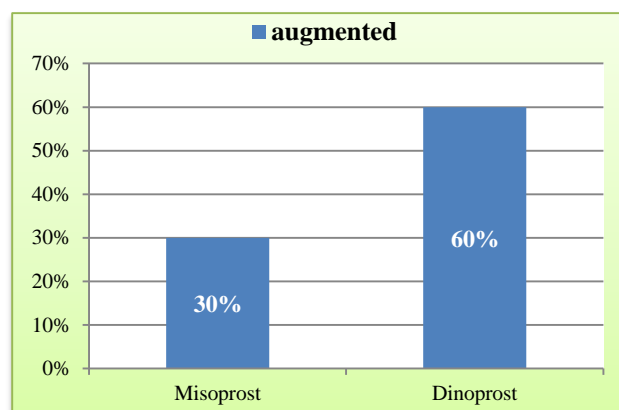


Figure 3: Augmentation of labour.

Need for LSCS was also lower in misoprostol group (11% vs. 16%) (Figure 5). The maximum LSCS (19%) in the dinoprostone group were done for failure of induction of labour (Table 1). Need for instrumentation (Figure 6) and incidence of NICU admission was similar in both groups (Figure 7, 8). Misoprostol was more cost effective compared to dinoprostone. Average cost of induction of labor was Rs. 17.5 with misoprostol and that with dinoprostone gel was Rs. 345. Thus misoprostol tablet was more cost effective than dinoprostone gel. The side effects of drugs used like nausea, vomiting, diarrhoea, pain, hyper-stimulation were more (28%) in the misoprostol group (Figure 9).

DISCUSSION

The mean induction to delivery interval was less in the misoprostol group than dinoprostone group (12.5 hrs vs. 20 hrs) (Figure 1). 78% patients delivered in the first 24 hrs in misoprostol group compared to 52% patients in dinoprostone group (Figure 2) 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 (11% vs. 16%) (Figure 5). This was consistent with the study of Sahu latika et al and also with the study of Patil kamal et al¹⁵ and Murthy Bhaskar et al.^{13,14}

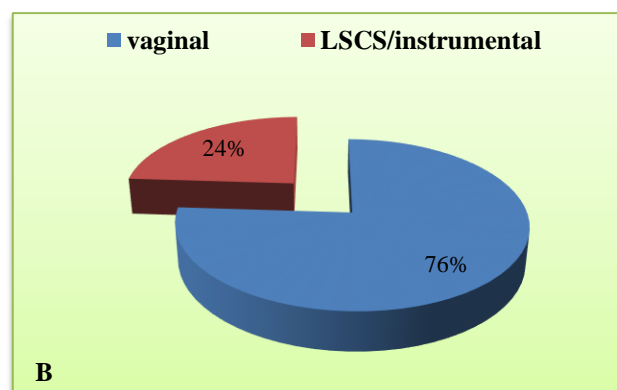
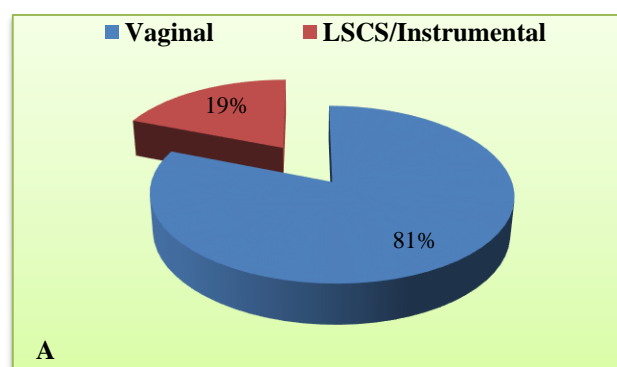


Figure 4A and 4B: Healthy mother and baby with no need of instrumentation.

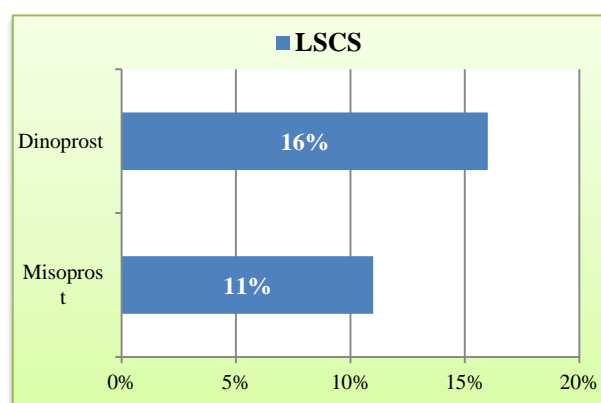


Figure 5: Need for LSCS.

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 lesser neonatal admissions.¹⁹

Table 1: Indication for LSCS.

Indication for LSCS	Misoprostol	Dinoprostone
Failure of induction	03	19
Meconium stained liquor	10	09
Fetal distress	09	04
Total	22	32

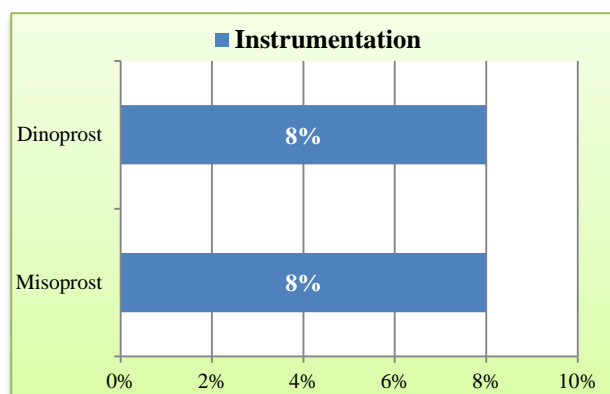


Figure 6: Need for instrumentation.

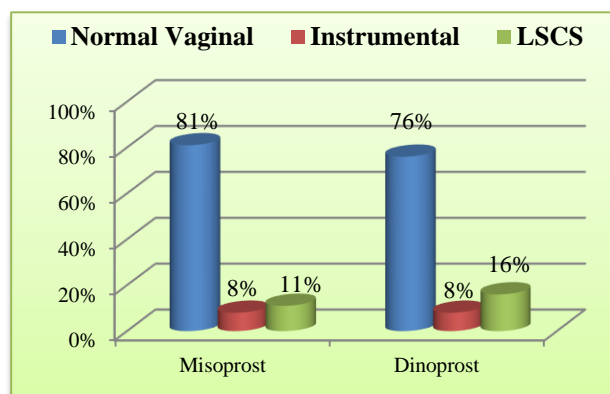


Figure 7: Combined overview.

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

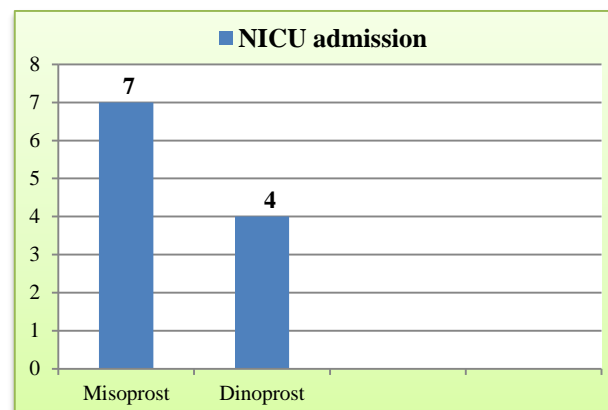


Figure 8: NICU admissions.

Hence 25 microgram as used in our study appears to combine efficacy with safety and could be the dosage that can be adopted in clinical practice for labor induction at term in primigravidas and multigravidas with unfavourable cervixes.

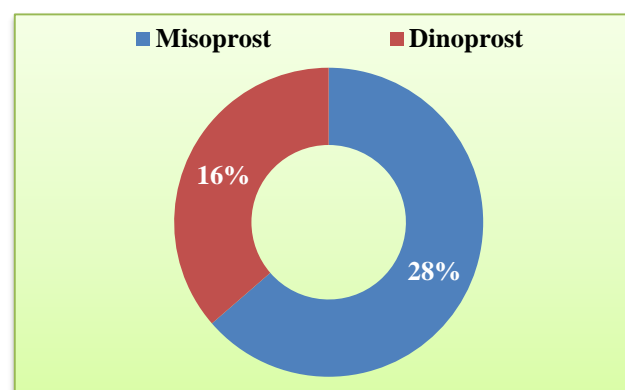


Figure 7: Side effects of the drugs used.

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. There was no significant difference in the rate of caesarean section and hyper-stimulation syndrome.

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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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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