Comparative Study between Tablet Misoprostol (Prostaglandin $E_{_{\! 1}}$) and Dinoprostone GEL (Prostaglandin $E_{_{\! 2}}$) for the Induction of Labor

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OBJECTIVES -To investigate the safety and efficacy of misoprostol in the induction of labor by comparing it with commonly used dinoprostone gel. METHODS - A prospective observational case control study was carried out on 100 women undergoing induction of labor who were alternately allotted to one of the two groups. In group Lot 50 subjects, labor was induced by intravaginal 50 µg misoprostol tablet repeated every 4-6 hours, whereas in group II of 50 subjects, intracervical dinoprostone gel was repeated every 6-12 hours to induce labor. The success and failure rate, complication rate, induction delivery interval and cost effectiveness were compared. RESULTS - The mean induction-delivery interval was 14.4 hours in misoprostol group and 19.2 hours in the dinoprostone group. This difference is statistically significant (p=0.0001). Misoprostol was more cost effective than dinoprostone. The apgar score was normal in both the groups though slightly higher but statistically insignificant maternal and fetal side effects were found in misoprostol group. CONCLUSION - Misoprostol can be considered as a more cost effective alternative to dinoprostone gel for induction of labor, especially for non-fetal indications.

Key words: misoprostol, dinoprostone, induction of labor

Introduction

The term induction of labor implies artificial initiation of regular uterine contractions, after 28 weeks of gestation before their spontaneous onset, with an aim to secure natural delivery.

Among the various methods available for induction of labor, prostaglandins (especially PGE₁) because of their short induction-delivery interval, easy availability, low cost, easy storage, low maternal and fetal complications and low failure rate are especially useful.

Prostaglandins stimulate both the tone and amplitude of uterine contractions by increasing the calcium influx and modulation of c-AMP. They play a role in cervical ripening in pregnant uterus near term by inducing or increasing the synthesis of collagen which in turn leads to collagen breakdown in cervical tissue and by altering glycosaminoglycans and proteoglycans composition of the ground substances of cervical tissue, which then causes dispersal of collagen fibers.

The present study was undertaken to analyse and compare the efficacy and safety of PGE₁ (misoprostol) and PGE₂ (dinoprostone) for induction of labor.

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Material and Methods

This is a prospective, case-control study of 100 women undergoing induction of labor from 2nd May 2002 to 14th December 2003.

Nulliparous women of 20 to 30 years age having singleton pregnancy at 34 weeks gestation and having Bishop score of < 5 were included in the study. Women with placenta previa, vasa previa, abnormal fetal lie, cord presentation, cephalopelvic disproportion and bronchial asthma were excluded from the study. The women were alternately allotted to one of the two groups. Group I consisted of 50 subjects who were induced with tablet misoprostol 50 μ g placed in the posterior fornix every 4-6 hours. Group II consisted of 50 women in whom dinoprostone gel was instilled intracervically every 6-12 hours.

The women received either of the drugs at scheduled intervals till the onset of adequate uterine contractions, cervical dilatation > 3 cm with effacement > 60%, rupture of membranes, or signs of maternal or fetal distress resulted.

Indication for induction, drug used and its dosage, induction-delivery interval, mode of delivery, side effects of the drug, maternal and fetal condition were noted. The data were statistically analysed by paired 't' test and chi-square test.

Results

The mean induction-delivery interval was 14.4 hours

in PGE_1 (misoprostol) group and 19.2 hours in PGE_2 (dinoprostone) group. This difference is statistically highly significant (P < 0.001).

The success rate in achieving a vaginal delivery with a healthy mother and a healthy baby was 80% (40/50) in Group I and 76% (38/40) in Group II. This difference however, was not statistically significant. The most common indication for cesarean delivery in misoprostol group was fetal distress and that in dinoprostone group was failed induction. In the misoprostol group, 80% (40/50) delivered within 24 hours as against 60% (30/50) in the dinoprostone group. This difference is significant

(p=0.03). In the misoprostol group 32% (16/50) required oxytocin augmentation as against 56% (28/50) in the dinoprostone group. This difference is highly significant (p=0.014).

Table I gives maternal side effects and Table II fetal side effects in the two groups. The differences between the two groups are not statistically significant.

The average cost of induction of labor with misoprostol is Rs. 9.25 and that with dinoprostone gel Rs. 352.80. The difference is statistically highly significant (P = 0.001). Misoprostol is an efficient cost effective alternative to dinoprostol gel for induction of labor.

Table I. Maternal Side Effects

	Misoprostol group N= 50	Dinoprostone group N=50
Vomiting (more than twice)	5	3
Diarrhea (more than twice)	3	2
Shivering	1	1
Fever (more than 100-F)	1	-
Postpartum hemorrhage	1	-
Uterine hyperstimulation	2	1

Table II. Fetal Side Effects

Side Effects	Misoprostol Group	Dinoprostone Group
Meconium staining of ligor	4	2
Bradycardia	3	2
Total	7	4

Discussion

Padnis et al¹ in their randomized control trial, concluded that induction of labor by misoprostol as compared to that by dinoprostone gel was associated with a significantly shorter median induction to delivery interval time, higher incidence of vaginal delivery within 24 hours of induction and a reduced need for pitocin augmentation during labor. These results were quite consistent with our study. However, they used cervical length determined by transvaginal sonography for their pre-induction scoring as against Bishop's preinduction scoring used in our study. The studies conducted by Belfrage et al², Neiger R et al³, Rozenberg et al⁴ and Nunes et al⁵, reported results similar to those reported in our study.

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