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"A COMPARATIVE STUDY OF USE OF MISOPROSTOL & DINOPROSTONE IN PREINDUCTION CERVICAL RIPENING & INDUCTION OF LABOUR"

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ABSTRACT

Objective(s)- To compare the safety ,efficacy & efficacy of intravaginal misoprost (PgE1) with intracervical dinoprostone(PgE2) for preinduction cervical ripening & Induction of labour. **Methods-** 100 women with indications of induction of labour were randomly allocated to misoprostol & dinoprostone group in 1:1 ratio. They were randomized to receive either .5 mg. of intracervical dinoprostone for a maximum of 3 doses at 6 hrs interval or 25 µg of vaginal misoprostol every 4 hrly upto maximum of 8 doses. Oxytocin infusion is given in titrated doses if required. **Results-** Rate of successful induction was not statistically significant in misoprostol group as compared to dinoprostone group(p=1.00). Caesarean rate was not significantly different in both groups(p=0.773). Oxytocin augmentation was needed more in dinoprostone group than misoprostol group which is statistically significant (p=0.0273). **Conclusion-** Vaginal misoprostol is as effective as dinoprostone in induction of labour at term pregnancy. But it is cost effective & decreases the requirement of oxytocin for augmentation of labour in comparision to dinoprostone.

KEYWORDS: Induction of labour, cervical ripening, vaginal misoprostol, intracervical dinoprostone.

INTRODUCTION

Labour induction is an intervention that artificially initiate uterine contraction leading to progressive dilatation, effacement of the cervix & birth of the baby. It is required in 10-20% of women near term. Medication that will ripen the cervix in a short period of time play an important role in modern obstetrics. The commonly available methods for preinduction cervical ripening & induction of labour are ARM or use of drugs like oxytocin, dinoprostone gel & misoprostol.

Oxytocin takes a reasonable period of time for labour induction in unripe cervix. Dinoprostone gel (PgE2) needs an intracervical application, requires refrigeration & is expensive. Misoprostol (PgE1) has better user acceptability, does not require cold chain for storage & is cost effective. In our study a maximum of 3 doses of misoprostol was used as compared with standard protocol of dinoprostone(PgE2) gel.

MATERIAL AND METHODS

100 women, admitted for induction of labor with Bishop's score ≤6 in labor room of E.S.I.Hospital, Basaidarapur, New Delhi, from Jan2005 to Dec2005 were included in the study after approval from the local ethical committee. The inclusion criteria were, women with age group ≥18yrs, primigravida & multigravida(upto 3 pregnancy), term singlet pregnancy, cephalic presentation, reactive FHR, & no contraindication for vaginal delivery. Those cases with malpresentation, previous H/O LSCS, preterm pregnancy, major uterine surgery, placenta previa, grand multigravida, H/O glaucoma & cardiac disease were excluded from the study. After informed & written consent, the pregnant women were randomly allocated to either misoprostol or dinoprostone group in ratio of 1:1. Women in study group either received 0.5mg of intracervical dinoprostone gel 6 hrly for a maximum of 3 doses or vaginal misoprostol 25µgm(by cutting 100µgm tablet available commercially) which was kept in posterior fornix of vagina after moistening, at 4hr interval(upto maximum of 8 doses).Cardiotocographic monitoring was done for 30min. each at insertion of 1st dose & onset of active labor. When pregnant women were entered in active phase, augmentation of labor was donewith ARM & oxytocin. No augmentation was done if uterine contraction were adequate. If at the end of 24hrs the patients was not in active labor, failure of induction was labelled & caesarean was done for them
The whole data was fed in SPSS version of 10.00. The means of continuous variables between groups were analysed using student 't' test. The differences in

proportion between the groups were analysed using **chi-square** or **fischer's exact** test.

OBSERVATIONS AND RESULTS

The baseline data of the study population included maternal age, parity & gestational age.They were comparable in both groups. The median preinduction score did not differ between the two groups(Table-1). Indications for induction were also similar & non-significant in both the groups. Postdated pregnancy and pregnancy induced hypertension were the commonest indications in both groups(Table-2).

In dinoprostone group, 4 patients delivered after 24 hrs. However the mean duration of induction delivery interval in misoprostol group is less than the dinoprostone group but found statistically insignificant(p value-0.160) (Table-3)

In misoprostol group only 34% women required oxytocin augmentation & in dinoprostone group 58% women needed oxytocin augmentation& this difference was found statistically significant. There was no significant difference in rate of caesarian & instrumental delivery. In misoprostol group 16% cases delivered by caesarian & 12% in dinoprostone group.In both the groups, main indications of caesarian section were meconium stained liquor & failed induction. These data were found statistically insignificant (Table-4).

The incidence of meconium stained liquor was high in misoprostol group(8%) in comparision to dinoprostone(6%) but data were found statistically insignificant. There were only one case of hypersystole & one case of dystocia in misoprostol group.No complication in form of fever, diarroea or vomiting was noted in either group.

The apgar score were also same in both the groups & these results are found statistically insignificant. 8% babies of misoprostol group & 14% of dinoprostone group requirednursery admission due to reduced apgar score / meconium aspiration. No early neonatal dath were found in our study. (Table-5)

Illustrations

Table-1

Baseline Data

	Misoprostol group (Pg E1) (n=50)	**Dinoprostone Group (Pg E2) (n=50)**	**P value**
Maternal age (Yrs) (Mean ± SD)	25.28 ± 3.22	25.3 ± 3.02	0.975 (NS)
Parity:			
Nulliparous -	25	25	01 (NS)
Multiparous -	25	25	01 (NS)
Gestational age (wks)			
38-40	30	26	
> 40	20	24	
Median	39.4	40	
Mean ± SD	39.183 ± 1.44	39.51 ± 1.44	0.255 (NS)
Initial Bishop's Score			
Median	0.04	04	
Mean ± SD	3.40 ± 1.18	3.60 ± 1.11	0.626 (NS)

Table-2: The distribution of patients according to Indication for Induction of Labour

Indications	**Misoprostol Group (n=50)**	**Dinoprostone Group (n=50)**	**P value**
Post-dated	20	24	0.5455 (NS)
PIH	15	10	0.3556 (NS)
Gestational Diabetes	00	01	1.00 (NS)
Poor Manning score	02	01	1.00 (NS)
IUGR	04	07	0.5226 (NS)
Oligohydramnios	02	03	1.00 (NS)
Premature Rupture of Membranes	07	04	0.5226 (NS)

(Fischer's exact test)

Table-3: The distribution of patients according to Induction & Delivery Interval

I-D Interval (in hrs)	Misoprostol Group (n=42)*	Dinoprostone Group (n=44)*	P value
4-8	05	06	
8-12	15	08	
12-16	11	11	
16-20	05	10	
20-24	06	05	
> 24	00	04	
Median	13	15.25	
Mean	13.631 ± 5.2044	15.8295 ± 6.2608	0.160 (NS)

Chi Square 't' test
* excluding caesarian delivery

Table-4: Distribution of patients according to need of oxytocin augmentation & mode of delivery

	Misoprostol Group (n=50)	Dinoprostone Group (n=50)	P value
Oxytocin Augmentation required	17 (34%)	29 (58%)	1.0273 (S)
Mode of delivery:- Normal vaginal delivery Caesarian Delivery Instrumental Delivery	 40 08 02	 41 06 03	 0.7987 (NS) 0.733 (NS) 1.00 (NS)

Table-5: Neonatal Outcome

Outcome	Misoprostol (n=50)	Dinoprostone (n=50)	P value
Apgar score in 1 min (Mean)	7.96 ± 1.05	8.10 ± 0.93	0.482 (NS)
Apgar Score in 5 min (Mean)	2.06 ± 0.82	8.88 ± 0.63	0.22 (NS)
Birth weight(Kg)- Mean	 2.689 ± 0.369	 2.674 ± 0.439	 0.850 (NS)
Stay in nursery (Days)	4	7	0.525 (NS)

t-test, chi square test, fischer's exact test

DISCUSSION

A number of published controlled trial have shown that misoprostol is more effective agent for cervical ripening & labour induction in patients at term pregnancy than dinoprostone.

The mean age in present study was 25yrs which is comparable with Deborah A Wing et al[1], Neelu Soni[2]. Parity is also comparable with study done by Deborah A Wing et al[1], Howard A Blanchette[3], Sahu Latika[4]. The mean gestation age in present study is 39wks which is comparable with the study of Sahu Latika[4], Howard A Blanchette[3]. The most common indication for induction of labor is postdated pregnancy which corresponds to study of Sahu Latika[4], David Buser et al[5], Howard A Blanchette[3]. The initial median bishop's score(which acts as a major confounding variable) was 4 in present study which is similar to the study of Williams et al[6] & Peter Danielian et al[7]. In present study rate of successful induction in misoprostol & dinoprostone group was statistically insignificant, however David Buser et al[5] found statistically significant difference in both groups.

The mean time from induction to delivery in present study was less in misoprostol group as compared to dinoprostone group but did not achieve statistically significance which is similar to study of Sahu Latika(4)(p=0.1). Oxytocin was used in significantly less number of patients in misoprostol group(34%) as compared to dinoprostone group(58%), comparable to study of David Buser et al[5], K Varaklin etal[6], Aggarwal N et al[7], Papanikolao E G et al[8], Nanda S[9].

The caesarian rate in present study was not significantly different (p=0.7730)in two groups being 16% in misoprostol group & 12% in dinoprostone group which is comparable to study of David Buser et al[5], Shelly Rowland et al[10].

Neonatal outcome were comparable in 2 groups of present study. One neonate in each group had apgar score of <7 in 5 minute. However 7 neonate required nursery admission in dinoprostone group & 4 in misoprostole group. There were similar results in study of David Buser et al[5], William[11].

CONCLUSION

Misoprostol (25µgm by vaginal route ,4 hrly) is as effective as dinoprostone(.5 mg intracervical 6 hrly) in induction of labor at term pregnancy and is cheaper , does not need cold chain storage.Misoprostol decreases the requirement of ox ytocin for augmentation of labor. Last but not the least " Misoprostol has been approved by drug controller of India & in view of its safet, efficacy & cost effectiveness, it will prove to be a wonder drug in year to come."

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