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KEY WORDS: Induction, misoprostol, sublingual, cervical ripening, induction of labour

STUDY ON COMPARISION OF EFFICACY AND SAFETY OF TWO DIFFERENT ROUTES OF REGIMEN OF MISOPROSTOL FOR CERVICAL RIPENING AND INDUCTION OF LABOUR.

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ABSTRACT

BACKGROUND: Induction of labour (IOL) is the process of initiating contractions in pregnant persons who are currently not in labour, to help them achieve vaginal delivery within 24 to 48 hours. Cervical ripening is one of the methods used for labour induction; it is "the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery. **OBJECTIVE OF THE STUDY:** The objective of the study is to compare the efficacy and safety of two different routes of regimen of misoprostol for cervical ripening and induction of labour. **MATERIALS & METHODS:** This prospective comparative study, was conducted in the Department of Obstetrics and Gynaecology at R.C.S.M Govt. Medical College, Kolhapur, for a period from may 2012 to June 2013. Overall 60 patients were enrolled in the study, which were randomly divided into two groups of 30 each i.e Group A (Tab misoprostol 25 µg given sublingually) and Group b (Tab misoprostol 25 µg given vaginally). **RESULTS & CONCLUSIONS:** In our study, we found that there were no statistically significant differences in demographis, Bishops Score after induction, number of doses required, complications (foetal distress, meconium stained liquor and hyper stimulation), maternal side effects and neonatal Apgar Scores between the two groups. There were statistically highly significant differences in the need for oxytocin augmentation between the two groups. Oxytocin augmentation was more in group B i.e. in 76.7% patients as compared to 30.0% patients in group B (p = 0.00).

INTRODUCTION:

Induction of labour (IOL) is the process of initiating contractions in pregnant persons who are currently not in labour, to help them achieve vaginal delivery within 24 to 48 hours. Cervical ripening is one of the methods used for labour induction; it is "the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.[1] Induction of labour is the artificial initiation of uterine contractions before its spontaneous onset for the purpose of delivery of the fetoplacental unit using mechanical or pharmacological methods.[2] The success of labour induction largely depends on the cervical status or Bishop's score at the time of induction. It is generally predicted that the patients with a poor Bishop's score at the initiation of induction have higher chances of failure of induction.[3] Prostaglandin E2 has been the agent of choice for pre- induction cervical ripening for several decades and is one of the pharmacologic agents approved by the United States Food and Drug Administration for this indication. However, it has several disadvantages: it is expensive, requires intracervical application, and continuous refrigeration.[4,5] Induction of labour with oxytocin is unlikely to lead to vaginal delivery in an unripe cervix.[6] Misoprostol (a prostaglandin E1 analogue) is a comparatively new agent for pre-induction cervical ripening and labour induction. It has excellent cervical ripening and uterotonic properties.[7] Although, misoprostol currently is approved by U.S. FDA for the prevention and healing of peptic ulcers induced by NSAIDs, in 2002, the U.S Food and Drug Administration approved a new label on the use of misoprostol during pregnancy for cervical ripening and for induction of labour.[8,9] It is economical, stable at room temperature, with very few side effects and can be easily administered through oral, sublingual, vaginal , buccal or rectal routes.[10] Most clinical trials have used doses ranging from 25µg to 100µg, inserted intra-vaginally into the posterior fornix.[11-15] The most common vaginal dose used has been 50µg, inserted once or administered every four to six hours; inserting 25µg every six hours intra-vaginally has been associated with the fewest side effects.[16]

OBJECTIVE OF THE STUDY:

The objective of the study is to compare the efficacy and safety of two different routes of regimen of misoprostol for cervical ripening and induction of labour.

MATERIALS AND METHODS: This prospective comparative study, was conducted in the Department of Obstetrics and Gynaecology at **R.C.S.M Govt. Medical College, Kolhapur**, for a period from may 2012 to June 2013. Overall 60 patients were enrolled in the study, which were randomly divided into two groups of 30 each i.e Group A (Tab misoprostol 25 µg given sublingually) and Group b (Tab misoprostol 25 µg given vaginally).

Comparison between the two groups was done in terms of:

1. Effect on uterine activity mild/ moderate/ hyper stimulation
2. Need for Oxytocin augmentation
3. Fetal heart rate pattern regular/ irregular – bradycardia / tachycardia
4. Incidence of Meconium stained liquor
5. Mode of delivery (normal vaginal/ assisted instrumental delivery/ caesarean section)
6. Apgar score at one minute and five minutes
7. Induction to vaginal delivery interval

STATISTICAL ANALYSIS:

The collected data were entered SPSS. Statistical analysis was performed by chi-square test and partial correlation coefficient. The level of statistical significance was set at $P < 0.05$.

RESULTS AND DISCUSSION:

In our study, we included 60 patients aged 20-34 years, who were randomly divided into two groups of 30 each i.e Group A (Tab misoprostol 25 µg given sublingually) and Group b (Tab misoprostol 25 µg given vaginally). Maximum numbers of patients i.e.18 (60.0%) in the group A are in the age group of 20-24 years and also the same no of patients i.e.18 (60.0%) in the group taking 25 µg group B fall in the age group of 20-24 years. Age difference between the two groups was found to be statistically not significant (P=1.00).

Gravida status of Study Subjects: Maximum number of patient in both the groups are gravida one that is 15(50%) and 12(40%) respectively. These differences are not statistically significant (P = 0.34).

Parity status of study subjects: 17 Patients (56.7%) in the group B where as 18 patients (60%) in the group A were primipara. 13 patients (43.3%) were multipara in group B as compared to 12 patients (40%) in group A. These differences were statistically not significant (P = 1.00).

Gestational age status of study subjects: Maximum patients

that is 9 (30%) in the group B were in the range of 37-38 weeks of gestation. In group A maximum patients that is 10(33.3%) also fall in the range of 37-38 weeks gestation. This difference was found to be statistically not significant (P = 1.00).

The indications for Induction of labour included, PIH, Mild Oligohydromnias, Mild IUGR, Post-dated and PROM. Out of these indications, the most common indication for induction of labor was PIH in both the groups. 12 patients (40%) in the group B required induction of labour for pregnancy induced hypertension where 13 patients (43.33%) in group A. In some cases, more than one indication for induction of labour was present.

Table 1: Shows the Number of Doses Wise Distribution of The Two Groups

No. of Doses	Vaginal 25µg Misoprostol		Sublingual 25µg Misoprostol	
	No.	%	No.	%
1	6	20.0	5	16.7
2	14	46.7	13	43.3
3	8	26.7	9	30.0
4	1	3.3	1	3.3
5	1	3.3	2	6.7

The number of doses required to achieve a favourable change in cervix after induction was comparable between the groups. In group A, one and two doses resulted in favourable change in cervix in 5 patients (16.7%) and 13 patients (43.3%) respectively as compared to 6 patients (20.0%) and 14 patient (46.7%) in group B after one and two dose respectively. By favourable, we mean Bishop's score ≥ 6. The difference in the number of doses required in both the groups to produce effect on cervical ripening and dilatation was statistically not significant (p=0.97).

Both groups showed unfavourable change in Bishop's score at the time of induction i.e. 22 patients (73.3%) in group A & 23 patients (76.7%) group B but the difference was statistically not significant (p=1.00). Both groups showed favourable change in Bishop's score at the end of induction i.e. 28 patients (93.33%) in 25□g l group & 25 patients A (83.3%) in the group B. The difference was also statistically not significant (p=0.42).

Table 2: Need for Augmentation between the two Groups

Need for Augmentation	Vaginal 25µg Misoprostol		Sublingual 25µg Misoprostol	
	No.	%	No.	%
Needed	23	76.7	9	30.0
Not needed	7	23.3	21	70.0
TOTAL	**30**	**100.00**	**30**	**100.00**

23 patients (70%) needed augmentation by oxytocin in 25µg Misoprostol vaginal group as compared to 9 patients (30%) in 25µg Misoprostol sublingual group. The difference in both the groups for requirement of augmentation was statistically significant (p = 0.00). The patients included in both the groups were those who achieved full cervical dilatation following induction and augmentation of labour as well as those who underwent lower segment caesarean section.

Table 3: Uterine activity-wise comparison between the groups

Uterine Activity	Vaginal 25µg Misoprostol		Sublingual 25µg Misoprostol	
	No.	%	No.	%
Regular	27	90.0	27	90.0
Hyperstimulation	3	10.0	3	10.0
TOTAL	**30**	**100.00**	**30**	**100.00**

3 patients (10%) in the group taking 25□g Misoprostol vaginally had uterine hyperstimulation as compared to 3 patients (10%) in the group taking 25□g sublingually. The difference in between the groups is statistically not significant (p = 1.00).

Table 4: Induction Delivery Time Wise Comparison Between the Groups

Time (Minutes)	Vaginal 25µg Misoprostol	Sublingual 25µg Misoprostol
Minimum Time	450	410
Maximum Time	900	860
Mean Time	663.60	642.47
Std. deviation (sd)	104.70	105.78

In patient of group taking 25µg Misoprostol vaginally mean induction to delivery time was 663.60±104.70 minutes versus 624.47±105.78 minutes in 25µg Misoprostol sublingual group. There was highly significant statistical difference in the induction delivery interval between the groups with (p= 0.44).

Table 5: Apgar Score Wise Comparison Between the Groups:

Apgar Score	Vaginal 25µg Misoprostol	Sublingual 25µg Misoprostol	"t" value	"P" value
At 1 Min.	7.2 ± 0.92	7.37 ± 1.00	0.68	0.49
At 5 Min.	8.6 ± 0.50	8.3 ± 0.65	2.00	0.05

The neonatal outcome at 1 and 5 minutes was comparable in both the groups. The mean Apgar value at 1 and 5 minutes were similar in both group. Also, no major maternal complications were seen in terms of fever, vomiting, diarrhea or bronchospasm in both the groups.

CONCLUSION:

In our study, we found that there were no statistically significant differences in demographis, Bishops Score after induction, number of doses required, complications (foetal distress, meconium stained liquor and hyper stimulation), maternal side effects and neonatal Apgar Scores between the two groups. There were statistically highly significant differences in the need for oxytocin augmentation between the two groups. Oxytocin augmentation was more in group B i.e. in 76.7% patients as compared to 30.0% patients in group A (p = 0.00).

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