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Original Research Article.

Comparison of the Efficacy and Safety of Misoprostol with That of Dinoprostone as a Cervical Ripening and Inducing Agent

Nidhi Rani[1], Neha Dubey[2]

[1]MBBS, DNB (OBG), Assistant Professor, Rama Medical College and Hospital, Hapur, Uttar Pradesh, India.
[2]MBBS, DNB (OBG), Medical Officer, Civil Hospital, Jind, Haryana, India.

ABSTRACT

Background: Induction of labour is defined as the stimulation of uterine contractions using medical or surgical means prior to spontaneous labor in order to achieve vaginal delivery. Dinoprostone gel has been widely used as cervical ripening and inducing agent. There has been a growing interest in using misoprostol, a prostaglandin E1 analogue, as an alternative agent for inducing labor. Hence; the present study was conducted for comparing the efficacy and safety of misoprostol with that of dinoprostone as a cervical ripening and inducing agent.

Materials & Methods: A total of 60 eligible women who required induction of labour were admitted. After taking a well-informed consent; detailed history, general examination and obstetric examination was conducted. Patients who fulfilled the above criteria were divided in two groups either to receive misoprostol tablet 25µg every 4 hourly intravaginally upto a maximum of 5 doses or dinoprostone gel 0.5mg intracervically every 6 hourly upto a maximum of 3 doses. Intravenous Oxytocin was administered as and when required in either group. A Performa was filled for each patient and at the end of study data collected from these Performa's was tabulated in a master chart. Statistical analysis was done using SPSS software.

Results: Initial Bishops score in the misoprostol and dinoprostone group was 3.85±1.26 and 3.89±0.97 respectively. Change in the Bishops score after single dose of misoprostol and dinoprostone was 5.48±1.89 and 5.0±2.05 respectively. This result was statistically not significant. 66.67% of patients in the dinoprostone group where as 60% of patients in the misoprostol group required oxytocin. This difference was not statistically significant. Only 5 subjects required 3 doses of dinoprostone whereas 14 subjects needed 2 doses and 11 subjects needed only 1 dose of dinoprostone. There were 5 cases of failure of induction in the dinoprostone group as compared to only 3 cases in the misoprostol group. The result was not statistically significant.

Conclusion: Both dinoprostone and misoprostol are equally safe and efficacious in cervical ripening and labor induction.

Keywords: Misoprostol, Dinoprostone, Cervical Ripening.

***Correspondence to:**

Dr. Neha Dubey,
MBBS, DNB (OBG),
Medical Officer,
Civil Hospital, Jind, Haryana, India.

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INTRODUCTION

Induction of labour is defined as the stimulation of uterine contractions using medical or surgical means prior to spontaneous labor in order to achieve vaginal delivery. Induction of labour is indicated in those cases where the benefits of early delivery are greater than the risks of continuing pregnancy.[1-3]

For these reasons extensive research has been directed towards the development of agents for efficient cervical ripening. Various prostaglandins used for this purpose are PGE1 and PGE2. PGE2 or dinoprostone gel has been widely used as cervical ripening and inducing agent but due to its cost and storage requirements the need for an effective, safe, easily stored and affordable labor inducing agent has been strongly felt by obstetricians worldwide.

There has been a growing interest in using misoprostol, a prostaglandin E1 analogue, as an alternative agent for inducing labor since the first reported use of it in 1988; however there has been a general fear and concern regarding the safety, efficacy and optimum dose required. The economic advantage due to its low cost and convenient storage conditions makes misoprostol a more affordable alternative as compared to dinoprostone.[4, 5]

Cervical ripening is the process of making cervix soft and pliable by a series of complex biochemical changes mediated by hormones. As term approaches there is a certain amount of softening, shortening and opening of cervix. The uterus and cervix start getting ready for labour and consequently there is an

increased recruitment of oxytocin and prostaglandin receptors in the myometrium. With the use of prostaglandins, the cervical smooth muscles and matrix change from 'sol' to 'gel' state, with opening of muscle fibres and increased accumulation of hyaluronic acid and glycosaminoglycans. These changes make the cervix softer and more pliable, thus rendering cervix favourable for induction.[6,7]

Hence; the present study was conducted for comparing the efficacy and safety of misoprostol with that of dinoprostone as a cervical ripening and inducing agent.

MATERIALS & METHODS

The present study was conducted with the aim of comparing the efficacy and safety of misoprostol with that of dinoprostone as a cervical ripening and inducing agent. A total of 60 eligible women who required induction of labour were admitted in the department of Obstetrics and Gynaecology, Rama Medical College and Hospital, Hapur, Uttar Pradesh, India. The inclusion and exclusion criteria of the study were as follows:

Inclusion Criteria

- Singleton Gestation
- Live Intrauterine Fetus
- Intact Membranes
- Cephalic Presentation
- Bishop's score of Five or Less.

Exclusion Criteria

- Multiple Pregnancy
- Malpresentation
- Abnormal Fetal Heart Rate
- Cephalopelvic Disproportion
- Ruptured membranes
- Previous Cesarean Section
- A scar on uterus
- Parity More Than Five
- A History of Hypersensitivity to Prostaglandin

After taking a well-informed consent; detailed history, general examination and obstetric examination was conducted. Patients who fulfilled the above criteria were divided in two groups either to receive misoprostol tablet 25µg every 4 hourly intravaginally upto a maximum of 5 doses or dinoprostone gel 0.5mg intracervically every 6 hourly upto a maximum of 3 doses. Intravenous Oxytocin was administered as and when required in either group.

Failure of Induction: If a woman failed to enter the active phase of labour after 24 hours of starting induction, it was taken as a case of failure of induction. Active phase of labor was defined as either cervical dilatation of equal to or more than 3 cms or 3 or more than 3 uterine contractions lasting for 45 seconds in a period of 10 minutes.

Table 1: The Bishop's scoring system[8]

	Score			
Factor	**0**	**1**	**2**	**3**
Dilatation (cms)	0	1-2	3-4	>4
Effacement	0-30	40-50	60-70	80
Station	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	
Position	Posterior	Middle	Anterior	

Statistical Analysis

A Performa was filled for each patient and at the end of study data collected from these Performa's was tabulated in a master chart. Statistical analysis was done using SPSS software and p value calculated using Fishers exact test and chi square test.

Table 1: Pre induction bishop score in the two groups.

Bishop Score	Dinoprostone		Misoprostol	
	N	**(%)**	**N**	**(%)**
0-2	5	16.67	3	10
3-4	20	66.67	18	60
>4	5	16.67	9	30
TOTAL	30	100	30	100

Table 2: Change in the Bishops score after single dose of either dinoprostone or misoprostol.

Bishops Score	Misoprostol	Dinoprostone	p value
Initial Bishops score	3.85±1.26 (n=30)	3.89±0.97(n=30)	0.89
After 1 dose	5.48±1.89(n=21)	5.0±2.05(n=19)	0.45

Table 3: Oxytocin requirement in two groups

Oxytocin requirement	Dinoprostone		Misoprostol	
	N	**%**	**n**	**%**
Required	20	66.67	18	60
Not required	10	33.33	12	40
p- value		0.79		

Table 4: Indications for caesarean section in two groups

Indication of caesarean section	Dinoprostone	Misoprostol
Fetal Distress	3	5
Non progress of labour	2	1
DTA	1	0
Failed induction	5	3
Total	11	9

Table 5: Correlation of outcome of induction with the parity status

Outcome of Induction	Parity Status		Total
	Primi	Multi	
Failed	7	1	8
Successful	27	13	40

p value = 0.41

RESULTS

Mean age in the dinoprostone group was 25.43 years while that in the misoprostol group was 24.8 years. 50% of subjects in the dinoprostone group and 63.33% of subjects in the misoprostol group had gestational age of 37 to 40 weeks. 46.66% in dinoprostone group and 36.66% in the misoprostol group were in between 40 to 41 weeks of gestational age and only 1 subject in the dinoprostone group had more than 41 weeks of gestation. 16.67% of study subjects in the Dinoprostone group and 10% of subjects in the misoprostol group had pre induction bishops score of 0-2. 66.67% of subjects in the Dinoprostone group and 60% of subjects in the Misoprostol group had pre induction Bishops score of 3-4 where as 16.67% of subjects in the Dinoprostone group and 30% of subjects in the Misoprostol group had pre induction Bishops score of 5.

Initial Bishops score in the misoprostol and dinoprostone group was 3.85±1.26 and 3.89±0.97 respectively. Change in the Bishops score after single dose of misoprostol and dinoprostone was 5.48±1.89 and 5.0±2.05 respectively. This result was statistically not significant. 66.67% of patients in the dinoprostone group where as 60% of patients in the misoprostol group required oxytocin. This difference was not statistically significant. 60% of subjects in the dinoprostone group had normal vaginal delivery as compared to 63.33% in the misoprostol group. The rate of caesarean section in the Dinoprostone group was 36.67% while in the Misoprostol group was 30%. The results were statistically not significant.

Fetal distress was the indication for caesarean section in 3 cases in the Dinoprostone group and in 5 cases in Misoprostol group. There were two cases of non-progress of labor in Dinoprostone group whereas one case of non-progress of labor in the misoprostol group. There was only 1 case of hyperstimulation in the misoprostol group whereas no case of hyperstimulation was seen in the dinoprostone group. Only 5 subjects required 3 doses of dinoprostone whereas 14 subjects needed 2 doses and 11 subjects needed only 1 dose of dinoprostone. There were 5 cases of failure of induction in the dinoprostone group as compared to only 3 cases in the misoprostol group. The result was not statistically significant. Out of 8 cases of failure of induction 7 were primi and 1 was multi. Out of the 40 vaginal deliveries 27 were primi and 13 were multi.

DISCUSSION

Labour induction is one of the most frequent procedures in pregnant women and its incidence is increasing day by day due to the improvement in antenatal care and thus increased recognition of the various indications. There is always a felt need of a labor inducing agent that reduces the induction to delivery interval and is safe for both the mother and baby. Amongst the various methods of labor induction prostaglandins hold a very important therapeutic role. Both PGE1 (misoprostol) and PGE2 (dinoprostone) are currently being used as cervical ripening and inducing agents. Although dinoprostone gel is a widely used method of labor induction it is relatively expensive and also requires refrigeration for storage. Misoprostol carries the advantage of being much cheaper and stable at room temperature but according to certain studies uterine contraction abnormalities and fetal heart rate irregularities were found to be more common with the use of misoprostol.[9, 10] Hence; the present study was conducted for comparing the efficacy and safety of misoprostol with that of dinoprostone as a cervical ripening and inducing agent. In the present study, the ultimate aim of induction of labor is to achieve normal vaginal delivery. 60% of women in the dinoprostone group and 63.3% of women in the misoprostol group delivered vaginally. This difference was statistically not significant. Thus, the vaginal delivery rates in both the groups were found to be comparable. There was 1 case of forceps delivery in the dinoprostone group and 2 cases of forceps delivery in the misoprostol group.

The indication for applying forceps in all the 3 cases was to expedite delivery due to fetal bradycardia observed in the second stage of labor. From our study the rates of caesarean section in the Dinoprostone and Misoprostol group were 36.67% and 30% respectively. According to Chaudhari S[11] et al the caesarean section rates in both the groups were comparable but misoprostol was associated with a higher rate of instrumental delivery. According to studies by Ayaz A[12] et al and Papinkolaou[13] et al. misoprostol was associated with significantly lower caesarean rate as compared to dinoprostone. But according to us, there was no statistically significant difference in the mode of delivery in the two groups. The difference in the rate of caesarean section occurring due to fetal distress in either group was statistically insignificant in both the groups. This result was found

in accordance with the studies conducted by Saxena P[14] et al, Ozkan S[15] et al and Krithika KS et al.[16] However according to Denguezli W et al.[17] caesarean delivery rate due to fetal distress was higher in the dinoprostone group as compared to the misoprostol group. In our study, a greater number of primi had failure of induction as compared to multipara. Our studies were found in accordance with the earlier studies conducted by Crane JM et al.[18] who concluded the primi had lesser chances of successful labor induction as compared to multi.

According to our study pre induction Bishops score was an important predictor of the success of labor induction as 87.5% of the subjects with failure of induction had a pre induction Bishops score of less than 3. This result was found to be in accordance with the earlier studies by Rishkin et al.[19] and Williams MC et al.[20]

Denguezli W et al compared the efficacy and safety of intravaginal misoprostol with dinoprostone cervical gel for cervical ripening and labour induction. They observed that the proportion of vaginal delivery within 24 hours was significantly higher in the misoprostol group (75%) than in the dinoprostone group (53.8%). There was no significant difference between the mean interval to delivery time in the misoprostol group as compared to the dinoprostone group. The Bishop score was found to be significantly higher in the misoprostol group 6 hours after the initiation of the induction. The caesarean delivery rate for fetal distress was higher in the dinoprostone group (21 vs. 10.8%, P = 0.15). The tachysystole (misoprostol 6.1% vs. dinoprostone 4.6%, relative risk 1.15, 95%) and hyperstimulation syndrome rates (misoprostol 7.6% vs. dinoprostone 4.6%, relative risk 1.26, 95%) were slightly increased in the misoprostol group than in the dinoprostone group but this was not statistically significant. They concluded that misoprostol is more effective than cervical dinoprostone gel in the cervical ripening and labour induction however there is a tendency for an increase in the rate of tachysystole and hyperstimulation syndrome.[17]

CONCLUSION

To conclude, both dinoprostone and misoprostol are equally safe and efficacious in cervical ripening and labor induction. The vaginal delivery rates at 12 hours were statistically higher in the Misoprostol group as compared to the Dinoprostone group. No significant difference was found in the mode of delivery, mean induction to delivery interval and rate of caesarean section in the two groups.

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