TO COMPARE THE EFFICACY OF PGE2 GEL AND 25MG OF INTRAVAGINAL MISOPROSTOL FOR INDUCTION OF LABOR IN TERM PROM

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Abstract

Background: Induction of labour is one of the most common obstetric interventions worldwide. The study was conducted to compare the efficacy and safety of 25µg (low dose) vaginal Misoprostol with intracervical Dinoprostone for cervical ripening and induction of labour in term pregnancy.

Methods: For the purpose of this study, 100 term pregnancy patients (only primigravidae and second gravidae) were included who had spontaneous rupture of membrane before onset of labor. Data was collected from cases admitted in labor room at Pannadhy Mahila Chikitsalaya associated with RNT Medical College, Udaipur between July 2014 to July 2015.

Results: Requirement of Oxytocin for augmentation of labor between group A and group B. It is evident from the table that oxytocin was required in only 16% of patients in group A, while 46% in group B. This indicates that requirement of oxytocin was significantly less in misoprostol group ($P < 0.001$).

Conclusion: This study was designed to assess efficacy of a 25 µg misoprostol vaginal tablet, Finding confirms that vaginal misoprostol tablet is as effective as dinoprostone in cervical ripening and labour induction with dinoprostone.

Keywords: Cervical ripening, Dinoprostone, Labour induction, Low- dose misoprostol.

Introduction

Passage through birth canal is the shortest but probably the most hazardous journey made by any individual in his or her life. Modern Obstetrics aims at culmination of every pregnancy in a healthy baby and healthy mother. Prevention is the foundation stone of successful obstetrics. Induction of labour is the intentional initiation of labour for the purpose of delivery of the fetoplacental unit. It is carried out in 20% deliveries.¹ Oxytocin and prostaglandins are the main stay for labour induction. Cervical favorability is the prime determinant of success of labour induction and vaginal delivery. The incidence of failed induction in unripe cervixes is up to 50%.² Oxytocin does not promote cervical ripening. Prostaglandins, on the other hand, stimulate myometrial contractions as well as facilitate cervical ripening. Two prostaglandin analogues are available commercially. Dinoprostone (PGE₂) gel is a licensed, time tested preparation and is recommended widely as the preferred agent for labour induction. Misoprostol is a PGE₁ analogue used through oral or vaginal route. It is used widely off label as an abortifacient and for labour induction. As compared to Dinoprostone, Misoprostol has certain decided advantages. It is stable at room temperature, does not require special storage, is inexpensive, less invasive to use, has no bronchoconstrictor action and can be administered through several routes. There has been concern about

uterine hyper stimulation with the use of higher doses of Misoprostol. Recent published studies have, however, established that lower dosages of Misoprostol give similar or better results than PGE₂, but with similar safety profile.³

Material & Methods

For the purpose of this study, 100 term pregnancy patients (only primigravidae and second gravidae) were included who had spontaneous rupture of membrane before onset of labor. Data was collected from cases admitted in labor room at Pannadhy Mahila Chikitsalaya associated with RNT Medical College, Udaipur between July 2014 to July 2015.

Inclusion criteria:

1. Only primigravidae and second gravidae
2. PROM at term (>37 wk = gestational age)
3. Singleton pregnancy
4. Cephalic presentation
5. Not in labor

Exclusion Criteria:

1. Acute sepsis
2. Patient in active labor with cervical dilatation >3 cm
3. Complicated pregnancy (obstetric or medical)
4. PROM > 12 hours
5. Foetal distress and meconium stained amniotic fluid
6. Allergic reaction

Study Groups:

Group I – (study group) in this group misoprostol 25µg vaginal tablet inserted in posterior fornix in patients with term PROM.

Group II – (control group) Dinoprostone gel available as 2.5ml ready to use sterile syringe that contains 0.5mg PGE₂.

Detailed history was taken. Diagnosis of PROM was confirmed by sterile speculum examination to demonstrate the presence of amniotic fluid in posterior fornix and positive ferning or absence of membranes on per vaginal examination.

Detailed history and examination was done as per proforma attached. Written informed consent was taken after proper counseling.

Observation and Discussion

This prospective study was conducted in Department of Obstetrics and Gynecology, Pannadhy Mahila Chikitsalaya, RNT

Medical College, Udaipur over a period of July 2014 to July 2015.

Group A (study group) - vaginal misoprostol group included 100 cases.

Group B (control group) – Dinoprostone gel included 100 cases.

Most of the patients in both groups were between 20-30 years of age group. Mean age was 23.32 ± 2.91 and 23.68 ± 3.11 in group A and group B respectively which is statistically insignificant ($p > 0.05$).

Table 1: Distribution According to Pre-induction Bishop Score

Bishop Score	Group-A	Group-B
0-2	50(50.00%)	44(44.00%)
3-4	50(50.00%)	54(54.00%)
5-6	-	2(2.00%)
Total	100	100

In present study 50% of patients of group A and 44% patients of group B had Pre-induction Bishop score 0-2. The Pre-induction Bishop score of group A & group B was ranges from 0-4 with median 2 and 3 in group A & B respectively hence the difference was statistically insignificant ($P > 0.05$).

Present study is correlating with the studies done by Sheela et al (2007) and Neiger, Greaves et al (2001).

Table 2: Requirement of augmentation by Oxytocin

	Group-A	Group-B
Oxytocin required	16(16.00%)	46(46.00%)
Not required	84(84.00%)	54(54.00%)
Total	100	100

Above table compared the requirement of Oxytocin for augmentation of labor between group A and group B. It is

evident from the table that oxytocin was required in only 16% of patients in group A, while 46% in group B. This indicates that requirement of oxytocin was significantly less in misoprostol group ($P < 0.001$).

Present study is correlating with the study done by Sheela et al(2007).

Table 3: Induction Delivery Interval

Induction Delivery Interval	Group-A	Group-B
0-6	2(2.00%)	2(2.00%)
7-12	28(28.00%)	38(38.00%)
13-24	56(56.00%)	46(46.00%)
>24	6(6.00%)	10(10.00%)
Total	92	96

Above table shows comparison in relation to total duration required from induction to vaginal delivery between misoprostol and dinoprostone gel group.

It is evident from table that 30% of women in misoprostol group achieved vaginal delivery within 12 hrs compared with 40% of patients in dinoprostone group. It indicates that in misoprostol group/induction delivery interval was slightly less than dinoprostone group but when compared using a student t test ($t = 1.74$, $P > 0.05$) showed that difference was not statistically significant.

Conclusion

This study was designed to assess efficacy of a 25 µg misoprostol vaginal tablet, Finding confirms that vaginal misoprostol tablet is as effective as dinoprostone in cervical ripening and labour induction with dinoprostone. Use of misoprostol is also cost effective then dinoprostone. Therefore, 25 µg vaginal misoprostol tablet provide an effective and well tolerated option for cervical ripening and labour induction in developing countries.

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