

Fetomaternal outcome of 25µg vaginal Misoprostol v/s Dinoprostone Gel for IOL at Term PROM

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Abstract

Background: Premature rupture of membranes (PROM) is one of the most confusing and controversial obstetric dilemma. It is defined as spontaneous rupture of membranes with release of amniotic fluid with a latent period before the onset of labor. Rupture before 37 completed weeks of gestation is known as preterm PROM. When it occurs after 37 completed weeks it is called term PROM. 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 Pannadhay Mahila Chikitsalaya associated with RNT Medical College,Udaipur between July 2014 to July 2015.

Results: 97% women of misoprostol group and 98% women of dinoprostone group achieved delivery smoothly without any significant maternal complication. Only 4 out of 100 women in group A and 2 women in group B had uterine hyperstimulation. 4 women in misoprostol group had meconium stained liquor. These babies admitted in NICU transiently for

observation. 8 women out of 100 in misoprostol group had fetal heart rate abnormalities for which they were delivered by CS.

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: Fetomaternal outcome, Dinoprostone, Labour induction, Low- dose misoprostol.

Introduction

Situations arise in obstetrics where it becomes necessary to interrupt a pregnancy in the interest of mother or baby or both. Recently, elective inductions of labor at term have increased dramatically. Although dinoprostone gel is considered as the preferred method for labor induction, it is relatively expensive drug. The average maximum retail price is 230.50 per 0.5 mg dose of the endocervical gel. Dinoprostone gel also requires refrigeration for storage which can cause significant problems for maternity units. There is a growing interest on misoprostol, a prostaglandin E1 analogue for labor induction which is much cheaper

and stable at room temperature. A single 100 tablet costs 8.60, thus a low dose of 25 µg dose costs approximately 2.15 Replacing dinoprostone with misoprostol would allow considerable cost savings. A large body of data exists on misoprostol for use in cervical ripening and labor induction. Vaginal application of misoprostol has been reported in over 9000 women worldwide and seems to have safety profile similar to that of dinoprostone.^{1, 2} The initial trials have used much higher dose of drug. But the American College of Obstetricians and Gynecologists (ACOG) recommends the use of low dose of 25 µg vaginal misoprostol every 3 to 6 hours.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 Pannadhay 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, Pannadhay 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

Various aspects were studied statistical analysis was done by student T test and CHI square test. The data obtained by the study were analyzed and tabulated the observations are as follows:

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 No. 1: Maternal Complications

Maternal Complications	Group-A	Group-B
Uterine hyperstimulation	4(4.00%)	2(2.00%)
Cervical tear	0(0.00%)	2(2.00%)
Perineal tear	2(2.00%)	0(0.00%)

Above table shows relation of complication experienced by women of misoprostol and dinoprostone group.

It can be seen from the table that 97% women of misoprostol group and 98% women of dinoprostone group achieved delivery smoothly without any significant maternal complication. Only 4 out of 100 women in group A and 2 women in group B had uterine hyperstimulation. The difference was not statistically significant. One

women of group A developed perineal laceration and second degree tear. One women in group B suffered cervical tear.

Similar study was done by Gregson (2005), incidence of hyperstimulation was 1% in misoprostol and 3% in dinoprostone group.

There was no maternal mortality or significant morbidity experienced by women in either group.

Table No. 2.FETAL Complications

Maternal Complications	Group-A	Group-B
Meconium in amniotic fluid	4(4.00%)	2(2.00%)
Fetal heart rate abnormalities	8(8.00%)	6(6.00%)
Transient NICU admission	4(4.00%)	0(0.00%)
Neonatal jaundice	2(2.00%)	4(4.00%)

The above table shows relation of neonatal complication with misoprostol and PGE2 gel for induction of labor at term PROM.

It can be seen from table that 4 women in misoprostol group had meconium stained liquor. These babies admitted in NICU transiently for observation. 8 women out of 100 in misoprostol group had fetal heart rate abnormalities for which they were delivered by CS,

They delivered healthy baby with Apgar more than 6. In PGE2 two women had meconium stained liquor but baby was recovered after resuscitation.

Six women developed fetal heart rate abnormalities, for same they were delivered by CS.

All the newborns had apgar >6 at five minute in both groups.

There was no NICU admission in either group.

The difference of neonatal complication between both groups didn't reach statistical significance.

No gross congenital anomaly was seen in neonates of both groups.

None of the baby experienced birth trauma in any group.

The difference between two groups was found statistically insignificant ($P>0.05$).

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 and demonstrate a similar fetal and maternal safety profile 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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