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Research Article

A comparative study between PGE₁ and PGE₂ for induction of labour in premature rupture of membrane at term

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ABSTRACT

Background: Premature rupture of membranes at term can be managed expectantly with good results. However, low bishop score may lead to undue latency. It can lead to complications if no intervention done. So, timely intervention by labour induction in selected cases can improve maternal and fetal outcome. Prostaglandins has very vital role for induction of labour. This study is to compare the effectiveness between the two molecules of prostaglandins PGE₁ and PGE₂ for induction of labour in term premature rupture of membrane (PROM).

Methods: It is a prospective interventional study performed at a tertiary hospital attached to a medical college. It was conducted upon randomly selected 100 women of term PROM from April 2011 to April 2015. They were divided into two comparable groups each containing 50 women. Both the groups were comparable in age, parity and bishop score. One group was induced with PGE₁ (Tab Misoprostol) and the other with PGE₂ (Dinoprostone gel).

Results: Among 100 women, a good number of women were primigravida (76%). Majority of women were induced in between 6 to 12 hours after PROM (69%). Vaginal deliveries were 68% in tab. Misoprostol group while 80% in dinoprostone gel group which are comparable in both the groups. The significant difference observed was average induction delivery interval, which was 11.26 hours in tab. misoprostol group and 14.72 hours in dinoprostone gel group (P=0.004). The other women (26%) underwent cesarean section. Among them 46.15% were done for fetal distress and 43.84% for induction failure.

Conclusions: Both the molecules of prostaglandins are efficient for labour induction in term PROM. Though, PGE₁ (tab. Misoprostol) is faster acting as compare to PGE₂ (dinoprostone gel) even with low bishop score. But it can lead to complications like hyperstimulation, fetal distress and postpartum hemorrhage if not used properly. So, tab misoprostol is not a safe drug where continuous monitoring of women is not available.

Keywords: Term PROM, Tab Misoprostol, PGE₁, Dinoprostone gel, PGE₂, Induction of labour

INTRODUCTION

Premature rupture of membranes (PROM) remains a problem of great relevance and interest to obstetricians. PROM can occur before 37 weeks of pregnancy called preterm PROM. While term PROM denotes as rupture of the membranes prior to the onset of labour at or beyond 37 weeks of gestation. The incidence of term PROM is

8%. Spontaneous labour follows term PROM at 24, 48 and 96 hours in 70%, 85% and 95% of women, respectively.¹ Thus, an important proportion of women have significant latency from PROM to delivery if managed expectantly, particularly nulliparous women. In majority of cases the cause of PROM is not known but some of the causes are increased friability and decreased tensile strength of the membrane, multiple pregnancy,

polyhydroamnios, cervical incompetence and infections. It can lead to maternal complications like chorioamnionitis and endometritis and fetal complications like cord prolapse, cord compression, neonatal infection.²

As the etiology of PROM remains obscure and prevention is difficult, so one should concentrate on its management. Thus, delivery should be within the reasonable period of time to avoid complications.³Hence, timely interventions can reduce the complications and improve maternal and fetal outcome.

Misoprostol is a newer synthetic PGE₁, acts on myometrium. It can be given through oral, sublingual, intravaginal and rectal route. It is cheaper as compare to PGE₂ (Dinoprostone gel) and requires no refrigeration. It has side effects like hyperstimulation, tachysystole of uterus.

Dinoprostone gel contains PGE₂. It acts by softening of cervix. It can be used intracervically. The gel is costly and requires refrigeration for storage purpose.

The aim of this study is to compare the effectiveness of two methods of induction of labour, Tab Misoprostol and Dinoprostone gel.

METHODS

This is a prospective interventional study conducted in labour room of a tertiary hospital attached to a medical college from April 2011 to April 2015. This study shows observations of 100 women of term PROM selected randomly. The inclusion criteria included term PROM, singleton pregnancy with cephalic presentation, reactive fetal heart rate, no contraindication to vaginal birth, bishop score <6, gravida <5. After admission, through clinical examination and ultrasound were done to confirm the maturity. Injectable antibiotics were given to all women. After all routine investigations available, decision for induction of labour was taken. Written and informed consent was taken from all women and their relatives. The women were randomly placed into two statistically comparable groups. Each group had 50 women.

Tab Misoprostol group In this group 50 women were induced with tab misoprostol 25µg through intravaginal route under aseptic precaution and repeated at 4 to 6 hours if needed for maximum 5 doses.

Dinoprostone gel group In this group 50 women were induced with 0.5 mg dinoprostone gel intracervical route under aseptic precaution and repeated at 12 hours if needed for maximum 2 doses.

After induction, women were monitored for fetal and maternal wellbeing and progress of labour. The results observed were subjected to statistical analysis by 't' test

and a 'p' value of <0.05 was considered statistically significant.

RESULTS

Total number of patients in this study was 100. Among them 76% were primigravida and others were multigravida (Table 1). There were 2 groups; one was induced by tab misoprostol and the other by dinoprostone gel. Each group contain 50 patients. Majority of the patients (69%) were induced between 6 to 12 hours after PROM (Table 2). Study showed in misoprostol group 68% delivered vaginally and 32% undergone cesarean section while in dinoprostone group 80% delivered vaginally and 20% by cesarean section. Good number of patients delivered vaginally in both the groups so this mode of delivery in both the group is comparable (Table 3). Further evaluation suggested 33% of total delivered patients delivered within 12 hours of induction, out of which 57.57% belonged to misoprostol group, while 42.43% belonged to dinoprostone group. The average induction-delivery interval in tab misoprostol group was 11.26 hours while in dinoprostone gel, it was 14.72 hours. Thus, misoprostol had faster effect as compare to dinoprostone as an inducing agent (p=0.004, p<0.05%) (Table 5). While indication of cesarean section was mainly fetal distress in misoprostol group (56.25%) and induction failure in dinoprostone group (70%) and fetal distress was identified by fetal brady/tachycardia, meconium stained liquor, irregular fetal heart rate pattern and induction failure was assigned to those cases in whom cervical bishop score was unfavourable (<6) even after 24 hours of induction (Table 4).

Table 1: Parity wise distribution.

Parity	Tab Misoprostol	Dinoprostone gel	Total
Primi	37 (74%)	39(78%)	76(76%)
Multi	13 (26%)	11(22%)	24(24%)
Total	50	50	100

Table 2: Prom induction interval.

Time (hours)	Tab Misoprostol	Dinoprostone gel	Total
<6	12 (24%)	9 (18%)	21
6 to 12	32 (64%)	37 (74%)	69
>12	6 (12%)	4 (8%)	10
Total	50	50	100

Table 3: Mode of delivery.

Mode Of Delivery	Tab Misoprostol	Dinoprostone gel	Total
Vaginal birth	34 (68%)	40 (80%)	74 (74%)
Cesarean section	16 (32%)	10 (20%)	26 (26%)
Total	50	50	100

Table 4 : Indication for cesarean section.

Indication	Tab Misoprostol	Dinoprostone gel	Total
Fetal distress	9 (56.25%)	3 (30%)	12(46.15%)
Induction failure	7 (43.75%)	7 (70%)	14(53.84%)
Total	16 (32%)	10 (20%)	26

Table 5: Induction delivery interval.

Time (hours)	Tab Misoprostol	Dinoprostone gel	Total
<12	19 (57.57%)	14 (42.43%)	33 (33%)
12-24	13 (38.23%)	21 (61.76%)	34 (34%)
>24	2 (28.57%)	5 (71.42%)	7 (7%)
Average time	11.26	14.72	
Vaginal	34 (45.94%)	40 (54.05%)	74

DISCUSSION

The synthetic analogue of PGE₁, Tab Misoprostol has been compared with PGE₂ Dinoprostone gel with respect to outcome of induction in terms of parity, induction delivery interval, maternal and fetal complications in term PROM. A comparative study between these two inducing agents has been carried out since 1990s to find out the optimum dosing, shortening of labour duration, reducing operative delivery, and minimizing side effects to mother and fetus. Previous studies have shown that oxytocin is more useful for augmentation when bishop score is favourable (>6), while 25µg of vaginal misoprostol (PGE₁) are useful when cervix is unfavourable (<6) and it improves bishop's score, reduces induction delivery interval, reduces cesarean section rates and does not affect fetal outcome.^{1,4}

The present study shows vaginal deliveries were 68% versus 80% in misoprostol and dinoprostone group respectively. Both the groups are comparable similar to Anjali, Sunita et al (78% versus 88%) and Chaudhary et al (92.39% versus 84.70%) without any significant.^{5,6}

In present study, cesarean section were 32% versus 20% is similar to Anjali, Sunita et al (22% versus 12%) but

contrary to Chaudhary et al (7.61% versus 15.30%).^{5,6} Main indications for cesarean section are fetal distress and induction failure in present study.

In the present study, mean induction to delivery interval was statistically significant in two groups (p=0.004). The results are contrary to Anjali, Sunita et al (11.18 ± 6.02 versus 10.51 ± 5.48 hours in PGE₁ and PGE₂ respectively) and Chaudhary et al (10.75 ± 6.69 versus 9.37 ± 5.48 hours).^{5,6} But similar to that of Frohn et al (16.4 ± 10.2 versus 22.0 ± 12.9 hours) and Abraham et al (13.5 versus 21.5 hours), as the induction to delivery time was significantly less in misoprostol group as compared to dinoprostone group.^{7,8}

In present study, women delivered vaginally within 24 hours of induction of labour were comparable in both the groups and is similar to Frohn et al (81% versus 71%) and Abraham et al (88.4% versus 58%).^{7,8}

Induction of labour with prostaglandins has improves outcome in women with low bishop score. When compared with the two drugs tab misoprostol and dinoprostone gel, had some differences. Dinoprostone is an established and widely used drug for cervical ripening and labour induction in PROM. However, drawbacks of dinoprostone gel are that it is expensive and needs refrigeration for storage while tab misoprostol, a recently introducing drug, is cheap and easy to store with no special storage requirement. When introduced vaginally, tab misoprostol is faster in improving bishop score and induction –delivery time is shorter than dinoprostone gel. Dinoprostone gel is slower in action with longer labour duration. The average repeat dose of Tab Misoprostol was 2.3 at 6 hour interval while in Dinoprostone gel, no such repeat dose were required in this study. 26 cesarean section was done, out of which fetal distress was indicated in 12 cases (out of 12, 2 babies sent for NICU admission for delayed cry) and induction failure in the other 14 cases (with no NICU admission). However, judicious use with the proper dosage and frequency of administration is must for safer inductions in tab misoprostol, to prevent complications as it can lead to hyperstimulation, fetal distress and postpartum hemorrhage. Total 100 live babies delivered out of which 2 where NICU admission for delayed cry. Women who are given aggressive management have less chances of chorioamnionitis, neonatal infection and morbidity and thus less hospital stay.^{3,9}

Table 6: Various comparison of misoprostol and dinoprostone with present study and previous reported studies.

	Vaginal deliveries		Cesarean section		Induction-delivery interval	
	Misoprostol	Dinoprostone	Misoprostol	Dinoprostone	Misoprostol	Dinoprostone
Present Study	68%	80%	32%	20%	11.26 hours	14.72 hours
Anjali, Sunita et al ⁵	78%	88%	22%	12%	11.18 hours	10.51 hours
Chaudhary et al ⁶	92.39%	84.70%	7.61%	15.30%	10.75 hours	9.37 hours

CONCLUSION

There is no doubt that induction of labour confers benefits in various maternal and fetal conditions in term PROM rather than spontaneous deliveries. Prostaglandins have significant role as inducing agent I term PROM. However, both the drugs have their pros and cons. As tab misoprostol is associated with fetal distress more than dinoprostone gel, one should only use tab misoprostol in a set up where close fetal monitoring is possible where close monitoring of foetus is not available. Misoprostol is not a safe drug. Dinoprostone gel is a relatively slower than tab misoprostol but its steady progress of labour makes it a safer option. It must be done in set up with trained staff for close continuous monitoring of the patients. With judicious use with proper dosage and frequency of tab misoprostol, complications like hyperstimulation, fetal distress and postpartum hemorrhage can be prevented.

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