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RESEARCH ARTICLE
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ROLE OF DINOPROSTONE AND MISOPROSTOL FOR LABOR INDUCTION IN PATIENTS OF PROM

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ABSTRACT

Background: Some studies found that Misoprostol took 10.75 hours and prostaglandin 9.37 hours to induce labour. The groups had similar caesarean section rates (7.61% vs. 15.30%), while other indicate 50% of misoprostol-treated women and 33.3% of Dinoprostone treated women had births within 12 hours. The purpose of this research was to determine if vaginal prostaglandin E1 or prostaglandin E2 pills were more effective in inducing labor in women who presented with prelabour rupture of fetal membranes.

Materials and Methods: The current retrospective and comparative research design was conducted in Department of obstetrics & Gynaecology, HMC Peshawar. The sample of 150 was divided in 2 groups i.e., vaginal administration of misoprostol 25µg (Group A) and administration of dinoprostone 3mg (Group B). The research included all pregnant women who were 15–45 years old, whose gestational age was between 34 and 41 weeks as determined by LMP, regardless of parity, and who presented with PROM within 72 hours. SPSS version 20.0 was used for data collection and analysis.

Results: The results indicated that both Dinoprostone and Misoprostol are effective for labor induction in patients with prelabor rupture of membranes (PROM). However, Misoprostol demonstrated a significantly shorter interval from induction to the onset of labor and a reduced labor duration compared to Dinoprostone. The results indicated a significant difference in the time taken from the induction to the onset of labor, with Misoprostol having a shorter interval (450.2 minutes) compared to Dinoprostone (720.5 minutes), while the duration of labor was also significantly shorter in the Misoprostol group (330.7 minutes) compared to the Dinoprostone group (380.4 minutes).

Conclusion: The study condluded that a more rapid and effective method of labour induction might be provided by misoprostol. Regarding patient demographics and manner of delivery, both approaches had comparable results. More research is advised to verify these conclusions and investigate long-term effects.

Keywords: Misoprostol, Dinoprostone, Prostaglandin, Gynaecology, PROM

INTRODUCTION

Premature rupture of membranes (PROM) affects between 8 and 10 percent of pregnancies, with term pregnancies accounting for roughly 60% of these occurrences.[1] PPROM occurs in roughly 2%–3% of pregnancies before 34 weeks of the gestation (WG) and occurs before the 37th week of pregnancy.[2] Still up for debate are the best ways to induce labour in the case of PROM, both in terms of when to do it and which medications to utilise. The drug most often used to induce labour is the oxytocin, which is given intravenously if cervix is deemed favourable. In cases when the cervix is not favourable (Bishop score6), it is common practice to promote cervical softening using prostaglandin E2 and misoprostol.[3]

Within the next four days, around two-thirds of women with PROM give birth, while the other patients give birth within a week.[4] The duration between the rupture of membranes and the beginning of labour might range from a few hours to many days. Research done between 1960 and 1980 found that there was a higher risk of maternal and perinatal illness and mortality when the period between membrane rupture and delivery was prolonged. This was the primary rationale for implementing a strategy of prompt induction of labour after PROM at term. [5] The risks of complications such as induced labour, surgical delivery, foetal distress, newborn infections, and maternal infection rise sharply as the period between PROM and delivery increases.Among the most challenging and contentious issues in obstetrics over the last few decades has been the treatment of a case of PROM.[6,7]

Induction of labor is suggested by many worldwide recommendations for a range of medical reasons, counting pregnancy-related high blood pressure, diabetes, intrauterine growth restriction, preterm rupture of membranes beyond 34 weeks, and other difficultie. [8] In order to shorten the labour time and increase the likelihood of a vaginal birth, pharmacological drugs such prostaglandins (dinoprostone and misoprostol) are often employed. These agents stimulate the artificial cervical ripening and enhance cervical dilatation.[9]

An affordable synthetic prostaglandin, misoprostol is an analogue of prostaglandin E1. [10] According to research, women with an unfavourable Bishops score (i.e., less than 6), may benefit from using a vaginal prostaglandin E1 analogue to induce labour and ripen the cervical mucosa. Most importantly, misoprostol does not need cold chain storage, is effective at low dosages, is inexpensive, and is easy to administer with minimal gastrointestinal distress. [11] The use of preparations containing prostaglandin E2 (PGE2) to pharmacologically induce labour has become widely accepted. In 1995, the vaginal insert (dinoprostone 10 mg) containing prostaglandin E2 was approved by the US Food and Drug Administration. In addition, they employ a controlled-release hydrogel pessary that contains 10 mg of prostaglandin E2 for cervical softening prior to induction.[12]

Different investigations indicated that the time it took for the prostaglandin group to give birth was 9.37 hours and the misoprostol group 10.75 hours, while there was no statistically significant difference in the caesarean section rate (7.61% vs. 15.30%). Thirty-three percent of women induced with dinoprostone and fifty percent of women induced with misoprostol had a delivery interval of less than twelve hours, according to another study.[13] These inconsistent results shows a gap in the literature regarding the comparison and effectiveness of dinoprostone and misoprostol for the labor induction in the patients of PROM. To fill this research gap, the current study was conducted for comparing efficacy of the vaginal prostaglandin E1 and the prostaglandin E2 tablets in terms of the induction of the labor among the women with prelabour rupture of fetal membranes. Premature rupture of the membranes before labour begins is widespread in our community; thus, it is critical to address this condition as soon as possible by inducing labour.

MATERIALS AND METHODS

The current study adopted retrospective and comparative research design . The current study was conducted May 2023 in Department of the obstetrics and Gynecology, Hayatabad Medical Complex Peshawar. The sample from the population divided into 2 groups i.e., vaginal administration of misoprostol25µg (Group A) and administration of dinoprostone 3mg (Group B) for the labor induction in preterm rupture of membranes (PROM) was considered in this study.The sample size was determined through below formula;

$$n_0=Z^2p(1-p)/e^2$$

n_0 stands for Sample size
Z stands for Z-value i.e., 1.96
p value is 0.5 for maximum variability
e is margin error i.e., 0.05

$$n_0 = (1.96)^2 x\ 0.5\ x\ (1-0.5)/\ (0.05)^2$$
$$n_0 = 384.16$$

Given the limited population, the formula for finite population adjustment was used as below;

$$n = n_0/1+ n_{0/N}$$

where the anticipated population is 250 and N is the size of the population;

$$n = 384.16/1+ 384.16/250 = 151$$
$$n = 151$$

To get an equal distribution between the both groups the sample size of 150 was considered with 75 individuals in each Group A and Group B.

Both clinical examination and the Insulin-like Growth Factor-Binding Protein-1 (IGFBP-1) test (Actim PROM or Amniodiag) were used to confirm the diagnosis of PROM. In women who had a vaginal swab (VS) test after the 35th week of gestation and found a positive result for Streptococcus B, the induction of labor was started within six hours of rupture; in cases where the VS result was uncertain, the same protocol as for patients with a positive result was followed: induction of labor was started within twelve hours of rupture. Labor fetal heart rate monitors were on constant vigil throughout the process. The International Federation of Gynecology and Obstetrics (FIGO) has defined what constitutes a suspicious or pathological anomaly in the fetal heart rate. Participating women had to be between the ages of 15 and 45, have a gestational age between 34 and 41 weeks (as measured by LMP), and present with PROM within 72 hours, regardless of parity. Excluded from the study were women who had a history of twin pregnancies, cardiac issues, oxytocin infusion or misoprostol use, or a failed induction attempt. Expert obstetricians oversaw all observations and therapeutic procedures. Details such as name, age, the gravidity, the parity, induction to delivery time, gestational age and method of delivery were meticulously documented in a predesigned proforma. Information gathered and examined using SPSS 20.0. Quantitative factors such as the age of the mother, the gestational age, and the duration from induction to delivery were measured using means and standard deviations. For categorical variables such as parity, gravidity, method of delivery, and effectiveness, percentages and frequencies were computed. Statistical significance was established when the p-value for the chi-square test was less than 0.05, which was used to compare the two groups' efficacy.

RESULTS

Table 1: Demographic Characteristics

Variable	Dinoprostone (Group B) (n=75)	Misoprostol (Group A) (n=75)	p-value
Age (Mean ± SD)	29.8 ± 4.5	30.1 ± 4.8	0.724
Parity (Mean ± SD)	1.7 ± 0.6	1.6 ± 0.5	0.624
Primiparity (%)	50 (66.7%)	53 (70.7%)	0.614
Multiparity (%)	25 (33.3%)	22 (29.3%)	0.614
Body Mass Index (BMI)	24.5 ± 1.8	24.3 ± 1.7	0.752

Table 1 shows that the mean age of participants in both groups was similar (29.8 ± 4.5 years for Dinoprostone and 30.1 ± 4.8 years for Misoprostol), with no statistically significant difference (p=0.724).
Both groups showed comparable parity levels, with mean parity slightly higher in the Dinoprostone group (1.7 ± 0.6) compared to the Misoprostol group (1.6 ± 0.5), but the difference was not significant (p=0.624).
The proportion of primiparous participants was slightly higher in the Misoprostol group (70.7%) compared to Dinoprostone (66.7%), but this was not statistically significant (p=0.614). Both groups had similar mean BMI, with no significant difference (24.5 ± 1.8 for Dinoprostone vs. 24.3 ± 1.7 for Misoprostol, p=0.752).

Table2: Patients Distribution According to Mode of Delivery

Mode of Delivery	Dinoprostone (n=75)	Misoprostol (n=75)	p-value
Cesarean (%)	12 (16.0)	15 (20.0)	0.521
Vaginal (%)	63 (84.0)	60 (80.0)	0.521
Vaginal Delivery Type			
Normal (%)	52 (69.3)	45 (60.0)	0.291
Instrumental (%)	11 (14.7)	15 (20.0)	0.389

Tabl2 shows that both groups showed a higher proportion of vaginal deliveries compared to cesarean sections. The slight variation in cesarean rates (16.0% in the Dinoprostone group vs. 20.0% in the Misoprostol group) was not statistically significant.
Similarly, Normal vaginal deliveries were more frequent in the Dinoprostone group (69.3%) compared to the Misoprostol group (60.0%). However, the difference was not statistically significant.

Table 3: Duration and Labor Induction Outcomes

Outcome	Dinoprostone (n=75)	Misoprostol (n=75)	p-value
Interval from Induction to Onset of Labor (Mean ± SD)	720.5 ± 35.6	450.2 ± 22.1	<0.001
Labor Duration (Mean ± SD)	380.4 ± 19.2	330.7 ± 16.8	0.004

Table 3 shows that there is a significant difference in the time taken from the induction to the onset of labor, with Misoprostol having a shorter interval (450.2 minutes) compared to Dinoprostone (720.5 minutes). This suggests that Misoprostol may be more effective in initiating labor faster.
Similarly, the duration of labor was also significantly shorter in the Misoprostol group (330.7 minutes) compared to the Dinoprostone group (380.4 minutes), thus supporting the idea that Misoprostal may lead to quicker labor process. This further supports the idea that Misoprostol might lead to a quicker labor process.
The above analyses indicate that Misoprostol offer a more efficient approach to labor induction compared to Dinoprostone in the context of prelabor rupture of membranes (PROM).

DISCUSSION

Using a sample from the Department of Obstetrics and Gynecology at Hayatabad Medical Complex Peshawar, this study aimed to compare the effectiveness of prostaglandin E1 vaginal tablets with prostaglandin E2 tablets in inducing labor among women who presented with PROM, where population was divided into 2 groups i.e., vaginal administration of misoprostol25µg (Group A) and administration of dinoprostone 3mg (Group B). The results indicated that Misoprostol offer a more efficient approach to labor induction compared to Dinoprostone in the context of prelabor rupture of membranes (PROM). There has been a quest for ways to promote cervical ripening since the traditional technique of inducing labour, oxytocin infusion, is rather ineffectual in women with an

unfavourable cervix. [14] When it comes to cervical ripening, there are a few options. Nonetheless, when it comes to cervical ripening and triggering labour, prostaglandins are still the gold standard, guaranteeing both clinical efficacy and patient happiness.[15,16] A number of nations have approved dinoprostone (PGE2) for use in inducing labour. Nevertheless, cold chain maintenance is required, and it is costly. Misoprostol, an equivalent of PGE1, provides several benefits.[6,17] Oral, vaginal, sublingual, and buccal delivery options are available, and it is inexpensive, stable at room temperature, and versatile.[18] When prostaglandin E2 is not accessible, cannot be stored well, or is too costly, misoprostol is an effective drug for inducing labor due to its properties. A total of 38 clinical trials comparing vaginal misoprostol versus placebo or other pharmacologic methods in a group of the women undergoing induction were included in the 2010 Cochrane review. The results showed that there was no influence on the incidence of vaginal deliveries.[5] However, misoprostol was linked to a higher rate of vaginal delivery within 24 hours. When compared to vaginal dinoprostone, misoprostol was related with fewer adverse events, such as oxytocin augmentation and epidural analgesia, but higher uterine tachysystole and amniotic fluid stained with meconium. When administered vaginally, misoprostol successfully induces labour.[9,16] While misoprostol has been the subject of several research in recent years, very few have examined PROM specifically as a method of inducing labour. The evaluation conducted by Kerr et al. in 2021 contained thirteen randomised trials that compared the effectiveness of low-dose oral misoprostol with that of the prostaglandin dinoprostone administered vaginally.[6] Their study found that oral misoprostol reduced the requirement for caesarean sections more effectively than vaginal dinoprostone. Subgroup analysis was made exceedingly difficult by the fact that most trials included women with both intact and ruptured membranes, and the subgroups were very lopsided. Pourali et al.1 compared intravenous oxytocin with 25 µg of sublingual misoprostol every four hours in 270 participants in a randomized experiment that was done in 2018.[5] Abnormal foetal heart during tachysystole or uterine hypertonicity (10%), uterine hypertonicity (4.2%), and tachysystole (14.2%) were the uterine contraction-related adverse effects in the misoprostol group. There were 5.8%, 4.2%, and 8.2% incidences of these adverse effects in the oxytocin group, respectively. The two groups were significantly different from one another (p= 0.023). The two groups had a same rate of caesarean sections. The indication for caesarean section differed significantly (p =0.022) between the two groups; more caesarean sections were performed in the misoprostol group due to abnormal foetal heart rate. Our findings are supported by this outcome. Tachysystole has been documented as a side effect of misoprostol in other research. When compared to other prostaglandins approved for use in assisting with labour induction, treating postpartum haemorrhage, and ending pregnancies, this medication is more affordable.[13] It has few systemic adverse effects and is heat stable, making it easy to keep at room temperature. Despite being designed for oral administration, it may be quickly absorbed when administered sublingually, vaginally, or intrarectally.

CONCLUSION

In conclusion, both Dinoprostone and Misoprostol are effective for labor induction in patients with prelabor rupture of membranes (PROM). When compared to Dinoprostone, Misoprostol showed a shorter labor length and a much shorter time between induction and the start of labor. These results provide evidence that misoprostol could be a faster and more effective method of inducing labor. Both methods showed similar outcomes in terms of mode of delivery and patient demographics. Confirming these results and investigating long-term effects will need more research.

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