A COMPARATIVE STUDY ON THE EFFECTS OF MISOPROSTOL AND DINOPROSTONE GEL ON CERVICAL RIPENING AND INDUCTION

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ABSTRACT –
Background: Premature membrane rupture inducement is controversial.
AIM OF THE STUDY - The study examined the efficacy and safety of low-dose vaginal Misoprostol and Dinoprostone gel for inducing labour in term pregnancies with an unfavourable cervix and intact membranes.
MATERIALS AND METHODOLOGY - Prospective, single-center, comparative cohort study in a level 3 maternity unit in rural Western Maharashtra from December 2017 to June 2019 comparing vaginal misoprostol 50 μg every six hours (maximum 150 μg) and dinoprostone 10 mg, a slow-release vaginal insert, for 24 h (maximum 20 mg) for labour induction in preterm rupture of membranes.
RESULTS - Dinoprostone greatly enhanced vaginal delivery. Misoprostol increased foetal heart rate caesareans. Misoprostol induction and labour were shorter than dinoprostone. Maternal and newborn outcomes were comparable.
CONCLUSION: Preterm rupture of membranes labour induction with vaginal dinoprostone appears to be more successful for vaginal birth than misoprostol (50 μg).
Keywords: Health care, medical research

INTRODUCTION –

Premature rupture of the membranes (PROM) occurs in 8–10% of pregnancies, with term pregnancies accounting for 60% of the cases. PREM almost always results in premature birth (Pourali, 2019). Cell membranes that break prematurely are referred to as having "premature rupture of the membranes" (PROM). Before 34 weeks of gestation (WG2), PPROM, which causes the rupture of the amniotic sac and the placenta before 37 weeks of gestation (WG), occurs in 2%–3% of pregnancies. This disease can be avoided by having a delayed birth.

There is ongoing debate on the appropriate timing and medications for beginning labour in PROM (Petit., 2018).

Oxytocin is the medication that is administered intravenously to patients in order to induce labour the vast majority of the time. After it has been determined that the patient's cervix is in the suitable position, the patient is given the medication. It is standard practise to employ prostaglandin E2 and misoprostol in order to promote cervical softening in cases when the cervix is unfavourable (defined as having a Bishop score of less than 6). This is done in order to ensure that the delivery goes off without a hitch.

An induction of labour at term is a worldwide conventional obstetric intervention with the intention of artificially generating uterine contractions in order to promote a spontaneous vaginal delivery. The goal of this procedure is to expedite the delivery of the baby through the vaginal birth canal. It is considered a worldwide conventional obstetric intervention to induce labour after the due date has passed. This intervention is being carried out in the expectation that it would bring about the onset of a natural vaginal delivery. It is of the highest significance that the right steps be taken in order to improve the state of the cervix, and these steps should be taken as soon as possible. According to Spanish Society.,2013, the most important task that has to be finished during this surgery is the introduction of prostaglandins. These can be administered either intravaginally or intracervically.

Over the course of the last few decades, there has been a rise in the number of births that have been brought about by the assistance of medical technology, leading to an increase in the total number of induced births. 9.6% of babies all over the world required labour induction, as stated by the findings of a survey on maternal and perinatal health that was carried out by the World Health Organisation (WHO). There is a potential that the participation rate in the labour force might reach as high as 25 percent in prosperous nations. This is a very real possibility. (Salvage, 2011)

The degree of maturity of the cervix is an essential factor that will determine the course of labour and how quickly it will progress. It is a sophisticated chemical process that finally results in the cervix being physically relaxed and more distensible, which in turn leads to the cervix growing narrower and bigger. This, in turn, leads to the cervix being longer and smaller. There is a rise in the quantity of water content, commonly known as edoema, and the collagen fibrils in the cervix are degraded enzymatically. Both of these changes occur during the early stages of labour. Hormones including oestrogen, progesterone, and relaxin, in addition to cytokines, prostaglandins, and enzymes involved in the production of nitric oxide, are the root causes of these alterations. (de Vaan., 2019) Combining mechanical and pharmaceutical approaches is one way to successfully ripen the cervix in preparation for delivery.

It has been common practise for a very long time to start labour by mechanically ripening the cervical cervix in order to prepare the cervix for delivery. Following this step, a number of different procedures, such as membrane stripping, mechanical and hygroscopic dilators, placement of an extra amniotic balloon, and extra amniotic saline infusion, are utilised in the process of cervical ripening. The surgical method of induction, which may involve amniotomy, was the one that resulted in the greatest amount of agony for the mother. Examples of pharmaceutical techniques that can be used in combination with one another

include prostaglandins, PGE2 dinoprostone, progesterone receptor antagonists and nitric oxide donors, oestrogen, relaxin, hyaluronic acid, and oxytocin. Other examples include oxytocin, oestrogen, and hyaluronic acid.

Numerous studies have demonstrated the benefits of vaginally applying prostaglandins in priming of the cervix and, subsequently, in inducing labour. These benefits have been shown to be associated with prostaglandins. These advantages have been validated by vaginal testing. According to Pollnow and Broekhuizen (1996), some of these benefits include a reduction in the length of time that elapses between the induction and the delivery of the baby, as well as an increase in the subordinate operative rate. Additionally, the subordinate operative rate can be increased. When misoprostol was first authorised for use in the treatment of peptic ulcers, the drug was in the form of oral tablets and could only be taken by mouth. A counterpart of the prostaglandin E1 hormone, misoprostol is used to terminate pregnancies. According to Hofmeyr et al. (2010), practically every nation in the globe has conducted an in-depth research on the medication to evaluate its safety, efficacy, and the dosage-response result in inducing labour in term pregnancies. These studies were carried out in an effort to ascertain whether or not the medication has any health risks.

Dinoprostone, which is also known by its chemical name, prostaglandin E2, has traditionally been the one that has had the most application in clinical settings over the course of its history.Dinoprostone is a PGE2 analogue that has been used for a large period of time as a technique that can both ripen the cervix and start labour. Dinoprostone has been used in this capacity for a number of years. It is a medication that, in addition to having a high degree of efficacy, also has a favourable safety profile. However, the price is quite high, and in order to store the item, it must be refrigerated first (Pierce et al., 2018). Keeping the item also requires that it be chilled.

On the other hand, it has a number of drawbacks, such as the fact that it is expensive and unreliable, even when stored at room temperature all the time. Misoprostol, which is also known as prostaglandin E1, is not only incredibly inexpensive, but it is also unaffected by changes in temperature and may be administered sublingually, orally, or vaginally (Krause et al., 2011). These are just some of the benefits of this medication. In addition to these advantages, misoprostol is also referred to as prostaglandin E1, another name for the compound.

Misoprostol has been added to the list of important agents that can be used for obstetrical purposes by the World Health Organisation, the International Federation of Gynaecology and Obstetrics, and the American College of Obstetricians and Gynaecologists. These organisations are comprised of medical professionals that specialise in obstetrics and gynaecology. The World Health Organisation is comprised of all three of these different organisations. This action was taken in order to ensure that women have access to birth control techniques that are not only risk-free but also very efficient in preventing unwanted pregnancies. According to an article published in 2015 titled "WHO Releases New Edition of Model List of Essential Medicines," the World Health Organisation (WHO) has links to all three of these organisations.

This modification to the contraindication and precaution that Misoprostol should not be used in pregnant women states that the contraindication only applies to pregnant women who are

taking the drug to minimise the risk of stomach ulcers caused by NSAIDs. This change was made in order to comply with the Food and Drug Administration's (FDA) requirement that all warnings and precautions be clear and unambiguous. The prior iteration of this update did not include this differentiation in any way. As part of this modification, the warning that pregnant women should not use misoprostol has now been brought up to date to reflect recent scientific findings. In the past, the warning label for Misoprostol said that the medicine should not be administered to a woman when she was pregnant. This recommendation is no longer included on the label. This recommendation is absent from the box now that it has been removed. As a result of this alteration, the claim may now be grasped with a great deal less mental effort on the part of the reader. The Food and medicine Administration (FDA) has given its approval for a medicine combination consisting of misoprostol and mifepristone that is designed to induce an abortion in the early stages of a pregnancy. This drug combination's intended purpose is to terminate the pregnancy. According to a study that was published by the ACOG Committee in 2003, misoprostol was also often used for the purpose of inducing labour.

It is possible to achieve the same end effect of softening the cervix and inducing labour by administering misoprostol in varied amounts sublingually, orally, or vaginally. The oral administration of misoprostol is the most common method. When taken in larger dosages, however, there have been reports of problems with hyperstimulation, meconium production, and heart rates in the foetus, which are not comforting. Patients have the option of receiving misoprostol in a variety of various dosages. A significant amount of information has been gleaned from the studies that have been conducted on the use of misoprostol for the achievement of these goals, and this information may be obtained in a variety of dosages. This information about appropriate dosages can be found in the relevant literature.

The American College of Obstetricians and Gynaecologists (ACOG) recommends that misoprostol be administered vaginally at dosages of 25 mg every three to six hours. These dosages should be taken at regular intervals. On the other hand, the World Health Organisation (WHO) suggests that the medication be administered at regular intervals of six hours (ACOG, 2009). Two researchers are currently attempting to determine the lowest effective dose of misoprostol as well as the optimal dosing interval that strikes a balance between high doses, which result in rapid delivery but frequent hyperstimulation, and lower doses, which take longer to achieve delivery but have a better safety profile. High doses result in rapid delivery but frequent hyperstimulation. Low doses take longer to achieve delivery but have a better safety profile. When high dosages are taken, not only is there a quick delivery, but there is also frequent hyperstimulation. It takes a longer amount of time to accomplish delivery with low dosages, but the safety profile is much better. People are using a wide variety of methods, and medical professionals are still looking for the lowest effective amount of misoprostol to provide to patients. [S]A number of women are inducing abortions with the drug misoprostol. However, a common adverse effect of high doses is hyperstimulation, which occurs more often. Large dosages have the advantage of delivering its effects more rapidly, but they also have the disadvantage of causing more hyperstimulation.

In light of the information presented above, the objective of the current study was to assess the relative efficacy of low-dose vaginal Misoprostol and Dinoprostone gel for inducing labour in term pregnancies with an unfavourable cervix and intact membranes.

MATERIALS AND METHODOLOGY

This randomized, prospective, single-center, comparative research was conducted from 2017 to 2019 in a level 3 maternity unit at the Department of Gynaecology and Obstetrics Unit of Western Maharashtra rural area. Patients who underwent induction of labour with 25 ug of misoprostol and 0.5 mg Dinoprostone gel among two different groups.

Inclusion criteria are as follows: a singleton pregnancy; a head-first presentation; a gestational period of more than 37 weeks; a Bishop score of six or less; an amniotic fluid index of five or more; and the presence of all of the following: A reactive non-stress test was performed, but there was no evidence of uterine contractions.

Placenta previa or unexplained uterine haemorrhage, non-reactive NST, ruptured membranes, and ruptured amniotic sacs are the exclusion criteria. Having a prior uterine scar, an expected birth weight of more than 4,500 grammes, or a suspicion of foetal pelvic disproportion are all contraindications for inducing labour. Prostaglandins shouldn't be prescribed to people who have certain medical conditions, including asthma, glaucoma, renal impairment or hepatic dysfunction, and a history of allergic reaction to prostaglandins. Cardiovascular illnesses, COPD is an abbreviation for chronic obstructive pulmonary disease.

Pre-Induction Assessment

Inducing labour results in a higher risk of having to deliver the baby through caesarean section, despite the fact that a vaginal delivery is the preferred method of childbirth. Before beginning the induction, it is essential to take a number of clinical criteria into consideration in order to make an accurate prediction of the outcome and reduce the likelihood of CS. The success rates of induction are influenced by a variety of parameters, such as diabetes, the mother's age, the expected weight of the foetus, the Bishop score, and the body mass index.

It was determined, based on the 1964 Bishop score, whether or not elective induction would be successful. The early method of grading could grant a maximum of 13 points, with scores ranging from 0 to 2 or 3 points for dilatation, effacement, station, placement, and uniformity. The highest possible score was 13. Bishop found that women with a score of nine or above had the same likelihood of delivering birth vaginally regardless of whether or not the labour was induced. This was the same for both spontaneous labour and labour that was induced. (Bishop et al.,1964) In 1966, Burnett altered the Bishop score by awarding a maximum value of 2 points to each variable, which resulted in a maximum score of 10 points. This brought the total possible score up to a maximum of 10 points. (Pitukkijronnakorn et al., 2010) Pre-induction Bishop scores of six or above are consistent with the idea that the infant was vaginally delivered. It was originally thought that the score could only be given to women who had previously given birth, but it was later discovered that it could also be given to women who had never before given birth.

Table 1. Modified Bishop Scoring System

	Score			
Parameter	**0**	**1**	**2**	**3**
Dilatation, cm	0	1–2	3–4	5 or more
Effacement, %	0–30	40–50	60–70	80 or more
Length, cm	> 3	1–3	< 1	1-2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid	Anterior	
Station	−3 or above	−2	−1 or 0	+1 or +2

Informed consent

Informed consent was obtained from all individual participants included in the study.

PROCEDURE –

The Bishop score of the patient was obtained by doing a vaginal examination on the patient after a comprehensive evaluation of the patient's medical history and a physical examination of the patient had been performed. Before beginning the process of inducing labour on any of the patients, the NST was performed on each of them. The participants in the study who were eligible to take part and who had previously provided their agreement to participate in the research in writing form were then randomly allocated to one of two groups. The randomization was accomplished through the use of software that was designed from the ground up with the specific intention of being executed on computers.

The study groups are divided up according to the following classifications:

Patients in Group A were given misoprostol intravaginally at a dose of 25 micrograms every six hours, up to a maximum of five doses, until the cervix was assessed to be ready for delivery. This treatment continued until the cervix was ready. The gynaecologist was entrusted with the task of making decisions about labour and delivery management. Sometimes, undesired effects such as tachysystole or foetal distress are noted, which finally leads in the cessation of the use of misoprostol as a treatment option.

Patients in Group B were given an intracervical injection of dinoprostone twice at intervals of six hours each time. Each injection included 0.5 milligrammes. During the course of the study, this treatment was administered to the participants. During the first stage of labour, intermittent auscultation was employed at regular intervals of every 30 minutes to monitor the foetus. During the second stage of labour, these intervals were decreased to occur every

15 minutes. This was done in order to expedite the process of delivering the baby as much as feasible.

The number of patients who would make up the sample for the misoprostol group was calculated to be 46, while the number of patients who would make up the sample for the dinoprostone group was similarly found to be 46.

While the patient was taking the medication, the subsequent dosage that was supposed to be given to her was not given to her if she went into established labour or ruptured her membranes while she was taking the medication. Even in circumstances in which the heartbeat of the foetus did not provide an adequate signal, this was always the case.

Data analysis

Throughout the entirety of the process, both Microsoft Excel and version 14.0 of the Statistical Package for the Social Sciences (SPSS) were utilised in order to interpret the data and carry out the analysis, respectively.

The mode of delivery and the length of time that passed between the induction of labour and the delivery were considered as the two most important markers of outcome.

The need for oxytocin, the number of doses of the drug that were administered, the incidence of caesarean section due to foetal distress, meconium-stained liquor, or failed induction, and the occurrence of adverse effects such as hyper stimulation, hyperpyrexia, vomiting, diarrhoea, postpartum haemorrhage, cervical tears, and vaginal tears were some of the secondary maternal outcome measures that were evaluated. The examination of the newborn's birth weight, APGAR ratings at one and five minutes, and the determination of whether or not the infant required admission to a neonatal intensive care unit were all part of the review of the outcome of the pregnancy.

RESULTS

Both misoprostol and dinoprostone gel were evaluated in this trial to see whether one was more effective at bringing on labour and ripening the cervical mucosa. The investigation was conducted out with the assistance of two distinct study groups, namely the misoprostol group and the dinoprostone group, with a total of 46 individuals participating in each group. The results of the research are summarised in the table that can be seen below.

Table 2: Comparison of age of women in Misoprostol group and Dinoprostone group

Age of women	Misoprostol	Dinoprostone	P value
N	46	46	
Mean year	23.22	24.63	0.024
Standard Deviation	2.674	3.207	

A comparison of the ages of the women who took misoprostol and those who took dinoprostone is shown in the tables above. The standard deviation of the age of the women in

the misoprostol group was 2.67 years, with a mean age of 23.22 years. In the dinoprostone group, the average age of the women was 24.63 years old, with a standard deviation of 3.02 years.

Table 3: Comparison of indication for induction in Misoprostol group and Dinoprostone group

Indication forinduction	Misoprostol	Percentage	Dinoprostone	Percentage
Post term	32	69.6%	18	39.1%
Gestational diabetes mellitus	0	0.0%	1	2.2%
Gestational hypertension	7	15.2%	13	28.3%
Severe preeclampsia	1	2.2%	7	15.2%
Oligohydramnios	6	13.0%	7	15.2%
Total	46	100.0%	46	100.0%

Post-term cases were 32 (69.6%) in Misoprostol and 18 (39.1%) in Dinoprostone. 15.2% and 28.3% of Misoprostol and Dinoprostone patients had gestational hypertension.

Table 4: Comparison of gravidity of women in Misoprostol group and Dinoprostone group

Gravida	Misoprostol	Percentage	Dinoprostone	Percentage	P value
Primigravida	32	69.6%	26	56.5%	0.1953
Multigravida	14	30.4%	20	43.5%	
Total	46	100.0%	46	100.0%	

Misoprostol had 32 post-term instances (69.6%) and Dinoprostone 18 (39.1%). 15.2% and 28.3% of Misoprostol and Dinoprostone individuals experienced gestational hypertension.

Table 5: Comparison of failure rate among Primigravida in Misoprostol group and Dinoprostone group

Failure of Induction in Primigravida	Misoprostol	Percentage	Dinoprostone	Percentage	P value
Yes	4	12.5%	4	15.4%	0.7514
No	28	87.5%	22	84.6%	
Total	32	100.0%	26	100.0%	

The tables above compare Primigravidain Misoprostol and Dinoprostone failure of induction. In Primigravida women, Misoprostol failed induction 12.5% and Dinoprostone 15.4%.

Primigravida women had no significant difference in failure rate (p>0.05).

Table 6: Comparison of failure rate among multigravida in Misoprostol group and Dinoprostone group

Failure of Induction in Multigravida	Misoprostol	Percentage	Dinoprostone	Percentage
Yes	0	0.0%	1	5.0%
No	14	100.0%	19	95.0%
Total	14	100.0%	20	100.0%

The tables above compare multigravida Misoprostol with Dinoprostone induction failure. In multigravida women, Misoprostol had 0% induction failure and Dinoprostone 5%. Multigravida women had a similar failure rate (p>0.05).

Table 7: Comparison of Preinduction Bishop score among Primigravida in Misoprostol group and Dinoprostone group

Preinduction Bishop Score in Primigravida	Misoprostol	Percentage	Dinoprostone	Percentage
1	1	3.1%	0	0.0%
2	1	3.1%	3	11.5%
3	9	28.1%	9	34.6%
4	19	59.4%	4	15.4%
5	2	6.3%	8	30.8%
6	0	0.0%	2	7.7%
Total	32	100.0%	26	100.0%

The above tables compare Primigravidain Misoprostol and Dinoprostone Preinduction Bishop Scores. Misoprostol primigravida got 59.4% score 4 and 28.1% score 3. Dinoprostone primigravida had score 3 (34.6%) and score 5 (30.8%).

Table 8: Comparison of preinduction Bishop Score among Multigravida in Misoprostol group and Dinoprostone group

Preinduction Bishop Score in Multigravida	Misoprostol	Percentage	Dinoprostone	Percentage
2	0	0.0%	2	10.0%

3	4	28.6%	6	30.0%
4	6	42.9%	3	15.0%
5	3	21.4%	9	45.0%
6	1	7.1%	0	0.0%
Total	14	100.0%	20	100.0%

The above tables compare multigravidain Misoprostol and Dinoprostone Preinduction Bishop Scores. Misoprostol group obtained highest score 4 (42.9%) and score 3 (28.6%) in multigravida. Dinoprostone group had 45% score 5 and 30.0% score 3 in multigravida.

Table 9: Comparison of postinduction Bishop Score among Primigravida in Misoprostol group and Dinoprostone group

Postinduction Bishop Score in Primigravida	Misoprostol	Percentage	Dinoprostone	Percentage
4	4	12.5%	0	0.0%
5	5	15.6%	3	11.5%
6 and above	23	71.9%	23	88.5%
Total	32	100.0%	26	100.0%

The tables above compare Primigravidain Misoprostol and Dinoprostone post-induction Bishop Scores. In Misoprostol-induced primigravida, 23 (71.9%) had Bishop scores of 6 or higher. After dinoprostone induction, 23 (88.5%) primigravida cases had Bishop scores of 6 or higher.

Table 10: Comparison of postinduction Bishop Score among Multigravida in Misoprostol group and Dinoprostone group

Postinduction Bishop Score in Multigravida	Misoprostol	Percentage	Dinoprostone	Percentage
4	1	7.1%	2	10.0%
5	1	7.1%	2	10.0%
6 and above	12	85.7%	16	80.0%
Total	14	100.0%	20	100.0%

Above tables compare multigravidain Misoprostol and Dinoprostone post-induction Bishop Scores. In Misoprostol-induced multigravida, 12 (85.7%) had Bishop scores of 6 or higher. Bishop scores were 6 or above in 16 (80%) multigravida instances following dinoprostone induction.

Table 11: Comparison of induction to delivery time in Primigravida in Misoprostol group and Dinoprostone group

Induction to delivery time in Primigravida	Misoprostol	Dinoprostone	P value
N	32	26	
Median (hr)	16	15	0.475
Min-Max	4.0 - 43.0	2.5 – 29.0	

Above tables compare median induction to delivery time in primigravidain Misoprostol and Dinoprostone groups. Median induction to delivery time in Primigravida was 16 hours (4–43 hr) for Misoprostol and 15 hours (2.5–29hr) for Dinoprostone. Primigravida induction to delivery time was not statistically different. ($p>0.05$).

Table 12: Comparison of induction to delivery time in Multigravida in Misoprostol group and Dinoprostone group

Induction to delivery in Multigravida	**Misoprostol**	**Dinoprostone**	**P value**
N	14	20	
Median (hr)	11.8	12	0.358
Min-Max	4.0 – 29.0	4.0 – 21.0	

Misoprostol and Dinoprostone multigravida median induction to delivery times are shown above. Median induction to delivery time in multigravida was 11.8 hours (4–29 hr) for Misoprostol and 12 hours (4–21hr) for Dinoprostone. Multigravida instances had no significant difference in induction to delivery time ($p>0.05$).

Table 13: Use of Oxytocin in Primigravida in Misoprostol group and Dinoprostone group

Use of Oxytocin in Primigravida	**Misoprostol**	**Percentage**	**Dinoprostone**	**Percentage**	**P value**
Yes	3	9.4%	5	19.2%	0.2803
No	29	90.6%	21	80.8%	
Total	32	100.0%	26	100.0%	

The tables above compare Oxytocin requirements in primigravidain Misoprostol and Dinoprostone groups. Oxytocin was needed in 3 (9.4%) Primigravida instances with Misoprostol and 5 (19.2%) with Dinoprostone. Primigravida women had similar Oxytocin requirements (p>0.05).

Table 14: Use of Oxytocin in Multigravida in Misoprostol group and Dinoprostone group

Use of Oxytocin In Multigravida	Misoprostol	Percentage	Dinoprostone	Percentage	P value
Yes	0	0.0%	2	10.0%	0.2231
No	14	100.0%	18	90.0%	
Total	14	100.0%	20	100.0%	

The tables above compare Oxytocin requirements in Multigravidain Misoprostol and Dinoprostone groups. Oxytocin was needed in 2 (10%) Multigravida women in the Dinoprostone group but not in Misoprostol. However, multigravida women had no significant difference in Oxytocin requirement (p>0.05).

Table 15: Mode of delivery in Primigravida in Misoprostol group and Dinoprostone group

Mode of delivery in Primigravida	Misoprostol	Percentage	Dinoprostone	Percentage	P value
LSCS	13	40.6%	12	46.2%	0.8922
NormalVaginal	18	56.3%	13	50.0%	
VentouseVaginal	1	3.1%	1	3.8%	
Total	32	100.0%	26	100.0%	

Above tables compare Primigravidain Misoprostol and Dinoprostone delivery modes. In Primigravida women, Misoprostol needed 13 (40.6%) LSCS and 1 (3.1%) ventouse, whereas Dinoprostone required 12 (46.2%) and 1 (3.8%). Primigravida women's manner of delivery did not differ (p>0.05).

Table 16: Mode of delivery in Multigravida in Misoprostol group and Dinoprostone group

Mode of delivery in Multigravida	Misoprostol	Percentage	Dinoprostone	Percentage	P value
LSCS	3	21.4%	4	20.0%	0.4686

Normal Vaginal	10	71.4%	16	80.0%	
Ventouse Vaginal	1	7.1%	0	0.0%	
Total	14	100.0%	20	100.0%	

The tables compare Multigravidain Misoprostol and Dinoprostone delivery modes. LSCS was needed in 4 (20%) Multigravida women in the Dinoprostone group and 3 (21.4%) in the Misoprostol group. Multigravida women's manner of birth did not change (p>0.05).

Table 17: Maternal Complications in Misoprostol group and Dinoprostone group

Maternal Complications	Misoprostol	Percentage	Dinoprostone	Percentage	P value
No complication	46	100.0%	43	93.5%	0.0782*
Fever	0	0.0%	1	2.2%	
Tachysystole	0	0.0%	1	2.2%	
Other	0	0.0%	1	2.2%	
Total	46	100.0%	46	100.0%	

*P value calculated by comparing ¸Complication and ¸No complication

The tables above compare Misoprostol with Dinoprostone maternal complications. In the Dinoprostone group, three women developed prenatal complications, including Tachysystole. The maternal complication rate difference was not significant (p>0.05).

Table 18: NICU admission rate in Misoprostol group and Dinoprostone group

NICU admission	Misoprostol	Percentage	Dinoprostone	Percentage	P value
Required	2	4.3%	3	6.5%	0.6456
Not required	44	95.7%	43	93.5%	
Total	46	100.0%	46	100.0%	

The charts above compare Misoprostol with Dinoprostone NICU admissions. 2

(4.3%) Misoprostol and 3 (6.5%) Dinoprostone women needed NICU hospitalisation. However, the difference in NICU admission requirement was not significant ($p>0.05$).

Table 19: APGAR score at 1 min in Misoprostol group and Dinoprostone group

APGAR score at 1min	Misoprostol	Percentage	Dinoprostone	Percentage
5	1	2.2%	1	2.2%
6	1	2.2%	2	4.4%
7	44	95.7%	37	82.2%
8	0	0.0%	4	8.9%
9	0	0.0%	1	2.2%
Total	46	100.0%	45*	100.0%

*APGAR score for baby was not available due to death

The charts above compare Misoprostol and Dinoprostone APGAR scores at 1 min. APGAR score at 1 min was 7 in 44 (95.7%) women in Misoprostol group and 7 or higher in 42 (43.3%) in Dinoprostone group.

Table 20 :APGAR score at 5 min in Misoprostol group and Dinoprostone group

APGAR score at 5min	Misoprostol	Percentage	Dinoprostone	Percentage
6	1	2.2%	1	2.2%
7	0	0.0%	0	0.0%
8	1	2.2%	4	8.9%
9	44	95.7%	34	75.6%
10	0	0.0%	6	13.3%
Total	46	100.0%	45*	100.0%

*APGAR score for a baby was not available due to death

The charts above compare Misoprostol and Dinoprostone APGAR scores at 1 min. APGAR score at 1 min was 7 in 44 (95.7%) women in Misoprostol group and 7 or higher in 42 (43.3%) in Dinoprostone group.

DISCUSSION –

Oxytocin and prostaglandin E2 were the first medications to be administered to PROM patients in the hope of inducing labour (Jain & Chakravarti, 2017, Hannah, 1996). After 37 weeks of gestation, the American College of Obstetricians and Gynaecologists (ACOG)

suggests that oxytocin be administered to PROM5 patients in order to induce labour. This is in accordance with the fact that oxytocin is a labor-inducing medication. Even if the patient is already in the labour process, this remains the situation. Prostaglandins are recommended as a first-line treatment for an unfavourable cervix by the National College of French Obstetricians and Gynaecologists (CNGOF), the Royal College of Obstetricians and Gynaecologists (RCOG), and the National Institute for Health and Care Excellence (NICE) in the United Kingdom (Suk et al., 1996, Levy et al., 2007).

Misoprostol has been the subject of significant study and comparisons with oxytocin, mechanical techniques, and placebos (Lin et al., 2005). This is due to the fact that it is used in obstetrics in a manner that is not permitted by the FDA. These comparisons have been done so that the most efficient approach may be identified and utilised. The results of all of the research point to the same conclusion, which is that the use of misoprostol does not raise the rates of maternal or foetal morbidity or the rates of caesarean section operations. This is the conclusion that can be drawn from the data of all of the studies. In PREM patients, there have only been a few studies that have examined the effectiveness of misoprostol and prostaglandin E2 in inducing labour. These patients have a significantly increased likelihood of having a premature birth and delivery.

Indication for Induction of Labour

In the current study, the misoprostol group had 32 (69.6%) women who needed to have their labour induced due to post term, while the dinoprostone group only had 18 (39.1%) cases where this occurred. This indicates that the misoprostol group had a higher rate of women who needed to have their labour induced due to post term. This suggests that the misoprostol group had a greater rate of women who required to have their labour induced because they had delivered their babies after their due date. Indication of gestational hypertension was found in 15.2% of individuals who were given misoprostol, but it was shown in 28.3% of patients who were given dinoprostone.

A pregnancy that had beyond its due date was found to be the most common indication for inducing labour, as determined by the outcomes of a study that was carried out in 2004 by Katika S. and her colleagues. According to the findings of a research that was done out by Nimbalkar PB et al., 2017, out of a total of 250 women, 126 of the women had early rupture of membranes, followed by 59 women (23.6%) who had post maturity as a symptom of labour. The study was carried out on a population of women who had given birth previously. 2017 was the year that the research study was carried out.In the misoprostol group, the causes for induction were postdated pregnancy in 36 percent of cases and pre-eclampsia in 34 percent of cases, as determined by the outcomes of a research study that was carried out by Patil P et al, 2013. Dinoprostone, on the other hand, was shown to be the cause of postdated pregnancy and pre-eclampsia in 32 and 40 percent of the cases, respectively.

Because of this, the vast majority of the indications for inducing labour were associated with post-dated pregnancies.

Failure of Induction rate

In primigravida women, the failure rate of induction was 12.5% with misoprostol and 15.4% with dinoprostone. Failure rates were comparable across the two groups ($p>0.05$). In multigravida women, the rate of induction failure with Misoprostol was 0%, while

Dinoprostone was 5%. Women who had already given birth had a comparable risk of miscarriage ($p>0.05$).

Patil P et al., 2013, discovered that misoprostol had a failure rate of induction of 2%, whereas dinoprostone had a failure rate of 12%. Failure rates were comparable across the two groups ($p>0.05$). According to the findings of Wing et al.64, the induction failure rate for misoprostol was 4.4%, whereas the rate for dinoprostone was 7.4%. Failure rates were comparable across the two groups ($p>0.05$).

Both misoprostol and dinoprostone have been shown in every study to have comparable rates of induction failure.

Preinduction Bishop score

The score that Bishop receives during induction affects whether or not labour is successful, which helps to enhance labour induction. The misoprostol group of first-time mothers had the highest Preinduction Bishop score of 4, at 59.4%, as well as the highest score of 3, at 28.1%. Dinoprostone primigravida had score 3 (34.6%) and score 5 (30.8%). The misoprostol group received the maximum score possible, a 4, with 42.9%, as well as a score of 3 with 28.6%. In the multigravida test, the Dinoprostone group received 45% correct answers and 30.0% incorrect answers.

In cases of misoprostol-induced first-time pregnancies, 71.9 percent of women had Bishop scores of 6 or higher. Following induction with dinoprostone, 23 out of 24 cases of first-time pregnancies had Bishop scores of 6 or higher.

Twelve out of twelve (85.7%) patients with misoprostol-induced multigravida had Bishop scores of six or above. After dinoprostone was administered, 16 of 18 (80%) instances of multigravida presented with Bishop scores of 6 or higher.

The group that was given dinoprostone as a control had a mean Bishop's score of 3.25, but the group that was given misoprostol for the research had a mean score of 3.21 for induction (Nimbalkar PB et al, 2017). The study was conducted by Nimbalkar PB et al.Within the study's research group, the proportion of patients who were classified as having a Bishop's score of 3 reached its highest point at 41.3%. Nearly half of the patients in the control group, or 49%, were classified as having a Bishop score of 4. A total of 36.0% of patients were induced with a Bishop's score of 4, 21.3% of patients were induced with a Bishop's score 2, and 36.0% of patients were induced with a Bishop's score 2. Only 1.4% of patients in the research group had a Bishop's score of 5. Both the score of 3.21 that Bishop obtained for entry into the study group and the score that he received in the control group were comparable.

Induction to delivery time

The period from induction to delivery was 16 hours when using misoprostol (ranging from 4 to 43 hours), however it was 15 hours when using dinoprostone (ranging from 2.5 to 29 hours). There was no statistically significant difference in the amount of time that passed between the induction of a first pregnancy and the delivery of the baby. ($p>0.05$).

In patients who were multigravida, the time it took from the induction of labour to the delivery was 11.8 hours when misoprostol was used, but it was only 12 hours when dinoprostone was used (4–21 hours). There was not a significant difference in the length of

time that passed between the induction of labour and the delivery of the baby in instances involving multiple pregnancies ($p > 0.05$).

Patil P. et al. (2013) investigated the time gap between the beginning of labour and the delivery of the baby. In this trial, the mean time to the onset of labour with misoprostol was 43.22 minutes, but the mean time to the beginning of labour with dinoprostone was 1 hour and 40 minutes, which was shorter than cerviprime. cerviprime had a mean time to the beginning of labour of cerviprime of cerviprime was 43.22 minutes. The commencement of labour often started around the same time for each pregnancy, regardless of whether it was the first or subsequent one. In the same experiment, the length of time from induction to delivery for misoprostol was determined to be 5 hours and 2 minutes, but the delivery time for dinoprostone was determined to be 11 hours and 12 minutes. It was demonstrated that misoprostol reduced the amount of time required ($P = .001$).

According to the findings of the study that Malathia J. and her colleagues carried out in 2006, the median amount of time between the induction of labour and the birth of the baby in first-time mothers was 7.7 hours when using misoprostol and 7.07 hours when using dinoprostone. On the other hand, the difference between the two did not reach the level of statistical significance ($p > 0.05$). The induction to delivery interval in multigravida was 5.5 hours with misoprostol and 6.7 hours with dinoprostone on average, despite the fact that there was no statistically significant difference between the two procedures ($p > 0.05$).

CONCLUSION -

Our investigation found that Misoprostol and Dinoprostone gel induce equally well. Primigravida and Multigravida are equally effective. In Primigravida, 12.5% and 15.5% of Misoprostol and Dinoprostone gel inductions fail. Multigravida's failure rate differential was statistically insignificant. Misoprostol and Dinoprostone gel took 15 and 16 hours to induce labour in primigravida, but both research groups' multigravida took 12 hours.

In both research groups, oxytocin augmentation, maternal complications, NICU hospitalisation, caesarean section, and meconium-stained liquor are not statistically significant.

However, considering the economic cost and easy to preserve and administer, we can recommend use of Misoprostol as a safe, effective, cheaper and more convenient drug for induction of labour.

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