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Original Research Article

Comparing the Efficacy of Inducing Labor with 25 Micrograms of Vaginal Misoprostol Against Cerviprime Gel in Term Pregnancies

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Abstract

Background: This comparison research was carried out to assess the efficacy of 25 micrograms of intravaginal misoprostol with that of intracervical cerviprime gel in terms of the efficacy of the medicine, the foeto-maternal result, the side effects, and the complications of the pharmaceuticals.

Methods: This research comprised a total of 150 first-time mothers who were full-term and had been admitted to the hospital for labor induction. They were given either misoprostol administered intravaginally or cerviprime gel administered intracervically based on a random drawing. In Group A, 75 women were given 25 micrograms of misoprostol intravaginally every six hours for a maximum of five doses. In Group B, 75 women were given 0.5 milligrams (2.5 milliliters) of intracervical cerviprime gel for a maximum of three doses. A comparison was made between the two groups' neonatal outcomes, as well as the amount of time it took for induction to lead to birth, the average amount of time it took for labor to start, the APGAR score at 1 and 5 minutes, and how quickly labor started.

Results: In the group that was given misoprostol, the average length of time it took for labor to begin was significantly less than in the group that was given cerviprime (P=0.49). In a similar manner, the period from induction to delivery was shorter with misoprostol (P>0.05) as compared to cerviprime gel. In the misoprostol group, the need for augmentation with oxytocin was lower (16%) as compared to the cerviprime group (46%), and this difference was statistically significant. The misoprostol group had a rate of cesarean sections that was 2% greater than the control group. Both groups had favorable outcomes for the newborns, with favorable maternal and neonatal complication rates. The cost of induction was significantly reduced for those who used misoprostol.

Conclusions: In comparison to cerviprime gel, misoprostol is a medicine that is safe, effective, relatively inexpensive, and well tolerated by both the mother and the fetus. It was discovered to be a better inducing agent, has a short induction to delivery interval, which results in a shorter length of labor, and has a safety profile that is comparable for both the mother and the unborn child.

Keywords: Misoprostol, Cerviprime gel, Induction of labour.

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Introduction

An induction of labor is a medical procedure that involves the artificial initiation of uterine contractions. These contractions cause the cervix to become progressively dilated and effaced, and ultimately result in the delivery of the fetus before the labor would have started on its own.[1,2] Somewhere in the range of five to twenty-five percent of pregnancies reach a point at which the birth of the baby and/or the mother would be beneficial to the progression of the pregnancy. An analogue of prostaglandin has recently been developed for use in the inducement of labor. Prostaglandins change the extracellular ground material of the cervix, ripen the cervix, and enhance the activity of collagenase in the cervix all at the same time. In addition to this, they make it possible for the calcium levels within the cells to rise, which results in the contraction of the myometrial muscle.[3,4] In April of 2002, the FDA made a change to the labeling for misoprostol, changing the phrase "contraindicated in pregnancy" to "contraindicated in pregnancy for the treatment and prevention of NSAID-induced ulcers."[5] Misoprostol and Cerviprime gel are the two prostaglandin analogs that are currently on the market for the aim of cervical ripening. PGE1 is also known as prostaglandin. The first synthetic prostaglandin analogue to be made accessible for the treatment of peptic ulcer was misoprostol, also known as 15-deoxy-16-hydroxy-16 methyl-PGE1. Sanchez Ramos employed it in 1993 for the therapy of numerous different obstetric problems, and he was impressed by the stimulating effects it had on the uterus. Tablets of 25, 50, 100, and 200 micrograms are all possible strengths for this medication. Cerviprime, also known as PGE2, is a synthetic formulation of prostaglandin E2, which occurs naturally in the body. PGE 2 gel is offered in a syringe with a capacity of 2.5 milliliters, and it may be used to administer 0.5 milligrams of cerviprime intracervically.[6] However, the American College of Obstetrics and Gynecology's recommendations were produced in the lack of substantial well-designed clinical trials, despite the fact that they suggest the use of 25 micrograms of misoprostol for the induction of labor. In the WHO model list of necessary drugs for labor induction at term, misoprostol is advised to be taken in a low dosage (25-50 microgram) in order to induce labor. This clinical trial was carried out to evaluate the effectiveness and safety of intravaginal 25 microgram misoprostol with that of cerviprime gel containing 0.5 mg PGE2 in cervical ripening and labor induction at term.

Methods

This comparative research was carried out between feb 2022 to feb 2023, in the department of obstetrics and gynecology at Vilasrao Deshmukh government medical college Latur. A sample of 150 women who were hospitalized to our hospital for an induction of labor were chosen at random for the research.

For the research, only first-time mothers who had completed at least 37 weeks of their pregnancies but were not yet in labor were considered eligible for participation. They have been induced for reasons related to either the mother's or the obstetrician's health.

Inclusion criteria: multiple pregnancies, aberrant presentation, prior caesarean section, cardiopulmonary illness, unexplained vaginal hemorrhage during pregnancy, intrauterine mortality, and allergy to prostaglandin.

Exclusion criteria: multiple pregnancies, atypical presentation, previous caesarean section.

After informing the subjects of the study about the potential outcomes, a signed informed permission was collected from everyone who took part in the research. The patient population was split into two groups, respectively: Patients who were given vaginal misoprostol containing 25 microgram for the purpose of inducing labor constituted Group A (the study group). It is put in the posterior fornix and repeated once every six hours for a maximum of five doses, or until the patient went into active labor, enough uterine contractions were reached, i.e. three per ten minutes, or fetal distress arose, whichever occurred sooner.Patients who got cerviprime gel 0.5 mg PGE2 in a 2.5 ml syringe and had it administered intracervically immediately below the internal os in order to induce labor were considered to be part of Group B, which served as the control group. This process is continued up to a maximum of three dosages every six hours or until induction is accomplished, whichever comes first. Misoprostol was administered intravaginally to 75 women, and intracervical cerviprime gel was injected into another 75 women at a dosage of 0.5 milligrams each. The process of labor was controlled in accordance with the protocol of the labor ward. In the course of the abdominal and vaginal examination, it was possible to monitor and record the progression of labor. Uterine contractions were timed and recorded every 10 minutes, noting their frequency and length. A sufficient number of contractions was determined to be three every ten minutes, with each one lasting for 45 seconds. It was observed that the patient had tachysystole, hypertonus, and hyperstimulation. When the patient's cervical dilatation reached at least 3–4 centimeters, it was determined that they were in the active phase. Women who were in the process of labor received treatment that was in line with standard obstetric procedures. When they reached the active part of their cycle, syntocinon was administered in order to amplify the pattern of uterine contractility that had been seen. In the event that a woman did not enter active phase within twenty-four hours after having an induction, a caesarean section was performed as a failed induction procedure. When the frequency of uterine contractions reached three times every ten minutes, augmentation was not performed. The time from induction of labor to the start of labor, the time from induction of labor to delivery, as well as maternal and fetal problems were the key outcome measures. The successful completion of the induction process was determined to be transitioning into the active phase of the cycle within twenty-four hours after the first administration of the medication. The necessity for syntocinon augmentation, the style of birth, the need for a cesarean section, and side effects were the other factors that were investigated. The Apgar score served as the metric for determining the outcome of the neonatal period. The data were reported using the mean value as well as the standard deviation. In order to determine the statistical significance, the Student t test and the Chi square test were used. The qualitative factors were reported as a percentage of the total.

Results

The patient population was split into two groups: group A (the study group), which consisted of 75 patients who were given 25 micrograms of misoprostol vaginally, and group B (the control group), which included 75 patients who were given 0.5 milligrams of cerviprime gel intracervically. The majority of the patients in both groups were somewhere between the ages of 20 and 30. (Table 2) There was no statistically significant difference in the mean age between the two groups. In none of the two

groups' bishop scores did they significantly vary from one another. As can be shown in Table 1, the signs of induction were not significantly different between the two groups. Induction of labor was performed on the majority of patients because they had post-dated pregnancies. In addition to this, pregnancy-related hypertension and intrauterine growth restriction were among the most prevalent diagnoses. The group receiving misoprostol requires a much greater number of doses than the group receiving cerviprime. In contrast, one pill of misoprostol costs just 5 Indian rupees, but one application of cerviprime gel costs 215 rupees. On the other hand, misoprostol does not need to be refrigerated and there is a reduced need for syntocinon augmentation. In the group that was given misoprostol, the average length of time it took for labor to begin was considerably less ($P<0.05$): 6.5 hours as opposed to 8 hours. In comparison to the cerviprime, the use of misoprostol results in an earlier onset of labor and, thus, an earlier delivery. It is clear that 17.3 percent of patients in the misoprostol group delivered within 12 hours, but only 14.8 percent of patients in the cerviprime group did so. In the misoprostol group, the time required from induction to delivery was marginally shorter, but this difference was not statistically significant ($P>0.05$). The difference in the mean length of labor between the two groups was not statistically significant ($P>0.05$).In the misoprostol group, an augmentation with syntocinon was necessary for 16% of patients, but in the cerviprime group, an augmentation was necessary for 46% of instances. It seems from the results that the need for oxytocin was much lower in instances that were brought on by misoprost ($P <0.001$). Normal deliveries occurred for 92% of women receiving misoprost and 94% of those receiving cerviprime.(Table 3) There were more cesarean deliveries in group A (8%), but the difference was not statistically significant ($P = 0.695$). There were only 6% of births in group B that were performed through cesarean section. In both sets of patients, a caesarean section was performed because of fetal discomfort. Because of fetal distress, caesarean section was performed on 3 (6%) of the patients in group B and 4 (8%) of the patients in group A. It was not noted that the labor was not progressing or that the induction attempt was unsuccessful. 97% of patients in group A and 98% of patients in group B delivered without suffering any notable complications or adverse effects throughout the process. There were only two cases of hyperstimulation out of fifty patients in group A, which is not statistically significant. In group B, there was only one case out of two patients. Only one woman in group A had a perineal laceration and a tear of the second degree, and only one woman in group B had a cervical tear. No statistically significant differences were seen between the two groups in terms of the average birth weight of the neonates. It was also discovered that the mean APGAR score at 1 minute and 5 minute intervals was comparable in both groups.

Table 1

Onset of labour in hours	Group A		GroupB	
	No.	%	No.	%
1-6	37.5	50	25	33.3
7-12	37.5	50	25	33.3
13-18	0	0	10	12
19-24	0	0	15	20
>24	0	0	0	0

Total	75	100	75	100
Median (range)	6.23 (1-11) Hours		7.33 (1-20) hours	

P=0.033 (Significant)

Table 2: Distribution according baseline data

	Group A Mean±SD	Group B Mean±SD	P value
Age group (years)	22.34±1.11	21.78±2.13	>0.05(NS)
Status of membrane			
Present	75%	70%	>0.05(NS)
Absent	25%	30%	

Table 3: Distribution according to mode of delivery.

Mode ofdelivery	GroupA	GroupB
	%	%
Normal	92	94
Forceps	0	-
LSCS	8	6
Total	100	100

Discussion

The introduction of prostaglandins into clinical practice, in particular their local application for cervical ripening, has resulted in a significant reduction in the primary challenges associated with labor induction. Since prostaglandins were first used, there has been a significant reduction in the length of time between induction and delivery. Along the same lines, it also reduced the related complications of amnionitis and fetalinfection. For both the softening of the cervix and the inducement of labor, this medication is exceedingly efficient and cost-effective. Induction of labor is necessary when the health of either the mother or the fetus is in peril. In our analysis, postdatism was the most prevalent rationale for induction, occurring in 40% of patients in group A and 36% of patients in group B correspondingly. PIH was the second most common indication for induction, occurring in 28% of patients in group A and 26% of patients in group B. According to the findings of the research conducted by Greagsons *et al*.[7], 95% of patients receiving misoprostol and 94% of patients receiving cervigel required induction of labor for postdatism. In a similar vein, C. N. Sheela *et al*.[8] revealed that the most prevalent indications in both groups were postdatism (36% and 32% respectively) and PIH (22% and 26% respectively). It has been discovered that misoprostol is more effective for bringing on labor at an earlier stage. In the group that was given misoprost, the average amount of time it took for labor to start was much less (6.5 hours) than the amount of time it took in the cerviprime group (8.0 hours).There is also a shorter amount of time between the induction and the delivery. In the group that received misoprost, the time between induction and delivery was significantly shorter (20.088.24hours vs 23.199.59hours on average). In the research conducted by Murthy Bhaskar Krishnamurthy[11] in 2006, the induction delivery interval was shown to

be shorter in the group that received misoprostol. Additionally, the same result was seen in other studies[12,13] that were published. Because of this, misoprostol shortens the average length of labor, which in turn minimizes the amount of time a patient spends in pain while laboring. It also expedites delivery, which is essential in situations including preterm rupture of membranes, eclampsia, and fetal distress. In the misoprostol group, an augmentation with syntocinon was necessary for 16% of patients, but in the cerviprime group, an augmentation was necessary for 46% of instances.

It seems from the results that the need for oxytocin was much lower in instances that were brought on by misoprost (P 0.001).In comparison to cerviprime, the use of misoprostol was associated with a significantly lower incidence of cesarean sections (6%). In the misoprost group, 92% of women delivered vaginally, whereas in the cerviprime group, 94% of patients delivered vaginally. Despite the fact that there were slightly more cesarean births performed in group A (8%) than in group B (6%), the difference was not statistically significant (P = 0.695).

This was similar with the research that was done by Sahu Latika and her colleagues9 (8% vs. 20%), as well as the studies that were done by Patil Kamal and her colleagues [10] and Murthy Bhaskar and her colleagues.[11] Fetal distress was the most often cited reason for an emergency cesarean section. Because of complications with the pregnancy, caesarean sections were performed on 3 (6%) of the patients in group B and 4 (8%) of the patients in group A.

It was not noted that the labor was not progressing or that the induction attempt was unsuccessful. In the study group, there was a greater presence of the liquour with the meconium stain. In none of the groups did the mothers experience a significant amount of discomfort. Patients in group A had a smooth delivery without any severe complications 97% of the time, whereas patients in group B had the same experience 98% of the time. Patients using misoprost were more likely to have fever with chills (16%), nausea (8%) and vomiting (2%) than those taking the placebo. There were only two cases of hyperstimulation out of fifty patients in group A, which is not statistically significant. In group B, there was only one case out of two patients. In group A, just one woman had a perineal laceration and a tear of the second degree, while in group B, only one woman had a cervical tear. One contraction that lasted more than two minutes was considered to be hypertonic, but tachysystole was described as having more than six contractions in ten minutes during the course of two consecutive 10-minute intervals.6Uterine hyperstimulation occurs when any of these conditions (hypertonus or tachysystole) leads to an unsettling pattern of fetal heart rate. [7]

Uterine hyperstimulation may also occur when the fetal heart rate is irregular.[6] As a result of the high incidence of tachysystole that is associated with the vaginal administration of misoprostol, some studies are examining the efficacy of the oral and sublingual/buccal routes in an effort to discover whether or not the effectiveness can be maintained while simultaneously reducing the incidence of tachysystole.[14,15] In the year 2000, G.D. Scarle & company informed medical professionals that misoprostol is not authorized for use in the inducement of labor or termination of pregnancies.

Despite this, the American College of Obstetricians and Gynecologists (2000) swiftly reiterated its recommendation for the use of the medicine due to the drug's demonstrated safety and effectiveness.[6] There was found to be no statistically significant difference in the mean birth

weight of neonates between the two groups. In addition to this, it was discovered that the mean APGAR score at 1 minute and 5 minutes was comparable in both groups. In the cerviprime group, Sahu Latika *et al*.[9] likewise found that 12% of neonates had an APGAR score of 7 at one minute, which is in line with the findings of our research. Since misoprostol does not need to be refrigerated, its affordability and availability in the peripheral areas is greater than that of cerviprime gel, which needs to be refrigerated. In comparison, the mean overall induction cost in the misoprostol group was significantly lower than that of the cerviprime gel group.

Conclusion

According to the findings of our research, misoprostol is a superior inducing agent than cerviprime gel. This is due to the fact that misoprostol has shorter induction-to-delivery intervals, resulting in a shorter length of labor. Additionally, misoprostol offers the benefit of quick labor, which is advantageous in situations when pre-eclampsia and eclampsia are present. In comparison to cerviprime, the use of misoprostol resulted in a greater number of women delivering their babies vaginally, and there is less of a need for oxytocin augmentation with its use.

As a result, the use of misoprostol lowers the probability of cesarean sections and also decreases the likelihood of an unsuccessful induction. Despite the fact that hyperstimulation and meconium-stained liquor were more common in the misoprostol group, the neonatal outcome was not affected in any way by these side effects. In addition to this, misoprostol does not have to be stored in a cold chain and is less expensive.

As a result, misoprostol may be regarded as a medicine that induces labor that is not only safe but also effective, relatively inexpensive, and kind to both the mother and the unborn. The purpose of this research was to evaluate the effectiveness of a specially produced vaginal tablet containing 25 milligrams of misoprostol in the treatment of premature labor. According to the findings, it is just as efficient as cerviprime gel for both the ripening of the cervix and the inducement of labor. It was discovered to have a safety profile that was comparable for both mothers and their unborn children. It was discovered that the use of misoprostol was more cost effective than the use of cerviprime gel. This medication was well tolerated by the patients. Because of this, the usage of it is suggested for softening the cervix and inducing labor in underdeveloped nations. money: There are no other sources of money. Declared there to be no conflicts of interest. Approval on an ethical level: The institutional ethics committee gave its stamp of approval to the research project.

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