Original Article

The Effectiveness of Vaginal Misoprostol and Intracervical Catheterization in Inducing Labour in cases of Intrauterine Fetal Mortality

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Abstract

Objective: To compare the efficacy of intracervical catheterization and vaginal misoprostol in the induction of labour in intra-uterine fetal death.

Methodology: This is a randomized controlled trial study was conducted from 10th January 2021 to 10th July 2021. The sample was gathered via non-probability consecutive sampling. The study comprised sixty pregnant mothers who had experienced intrauterine fetal mortality. There are two groups of patients: one for intracervical catheterization and the other for vaginal misoprostol. Both groups' vaginal deliveries occurred within 24 hours of vaginal misoprostol administration and 12 hours of intracervical catheterization, demonstrating their efficacy.

Results: A statistical analysis program (IBM-SPSS version 22) was used to analyze the data. The efficacy in both groups was compared using Chi-square test, with $p \leq 0.05$ being considered significant. The study's age range was 18 to 40 years, with Group A's mean age of 27.866±2.66 years and Group B's mean age of 28.166±2.69 years. 26 (86.7%) patients in group A and 18 (60%) patients in group B showed efficacy (P= 0.019).

Conclusion: In conclusion, intracervical catheterization proved to be more successful in inducing labour in cases of intrauterine fetal mortality than vaginal misoprostol in this regard.

Keywords: Intrauterine fetal death, Intracervical catheterization, Vaginal misoprostol.

Cite this article as: Munir H, Bibi N, Khan AB, Khan F. The Effectiveness of Vaginal Misoprostol and Intracervical Catheterization in Inducing Labour in cases of Intrauterine Fetal Mortality. J Soc Obstet Gynaecol Pak. 2024; 14(2):63-67.

Introduction

In as many as 30% of pregnancies, induction of labour (IOL) is a common technique in obstetrics. Mechanical or pharmacological induction of labour techniques are available.[1] The best cervical ripening technique should be economical, safe for the mother and fetus, and not require constant observation. Embrey was the first to describe the transcervical Foley catheter for cervical ripening. The cervical canal is mechanically stretched by the catheter, which releases prostaglandin and produces cervical alterations.[2] While some studies[3–8] did not provide any strain to the Foley catheter, others[2, 9–14] detailed how to apply tension by taping the transcervical catheter to the patient's inner thigh. Gibson[15] subsequently conducted a randomized control trial (RCT) on 197 women to compare transcervical catheters with and without traction. The purpose of the study was to evaluate the efficacy of traction with a 500 ml weighted bag against inner thigh tape. Without influencing the delivery time, traction did reduce the time until spontaneous catheter ejection ($p < 0.001$), but there was no difference in the groups' changes in Bishop and pain scores. A 500 ml weighted bag of fluid was hung at the patient's bed end in the prior trial to provide traction, which limited the patient's range of motion. We attempted to solve this problem by

Authorship Contribution:[1,3]Substantial contributions to the conception or design of the work or the acquisition, Final approval of the version to be published. [2,4,5,6]Drafting the work or revising it critically for important intellectual content,

Funding Source: none
Conflict of Interest: none

Received: Dec 12, 2023
Accepted: April 26, 2024

developing a novel method. Finding the perfect pulling force for the Foley catheter presents another issue with tension.[15] The amount of traction required during induction for optimal cervical ripening results is yet unknown. Misoprostol is a synthetic prostaglandin E1 analogue that acts on the smooth muscle of the uterus and the cervix to promote uterine contractions and cervical dilatation. Misoprostol was initially given vaginally in 1991 to induce delivery in a fetus that was still alive.[16] Since then, other investigations with progressively lower dosages and varied dosage schedules have been carried out. Furthermore, some investigations have contrasted misoprostol with alternative labour induction techniques, while other studies have contrasted various administration routes.

The effectiveness of vaginal misoprostol in inducing labour in cases of intrauterine fetal mortality was shown to be 86% in research conducted by Tharihalli C, et al [17] According to research by Das SR et al., the effectiveness of vaginal misoprostol in causing intrauterine fetal mortality was 53.3%.[18] The effectiveness of vaginal misoprostol was shown to be 81.3% in a study by Nimbalkar PB, et al., but intrauterine fetal death occurred in 88% of cases when intracervical catheterization was used to induce labour.[19] When cervix status is not suitable for inducing labour, the most common way of induction of labour is intravaginal misoprostol usage. Its application is restricted to women who have had prior cesarean sections, though. because it raises the risk of uterine rupture during vaginal birth. A third approach that may be used is the transcervical insertion of a Foleys catheter with varying balloon volumes. By directly mechanically dilatation of the cervix and by inducing the release of prostaglandins endogenously, it promotes labour. Since no prior research of this kind has been conducted in our general population, my objective is to compare the effectiveness of vaginal misoprostol and intracervical catheterization in inducing labour in cases of intrauterine fetal death. My study's findings will be useful in choosing the best intervention for the broader public.

Methodology

This is a randomized controlled trial. The study was conducted at Dera Ismail Khan's Zanana Hospital's Department of Obstetrics and Gynecology, DHQ. The time frame for this study was 10 January 2021–10 July 2021. The sample was gathered via non-probability consecutive sampling.

A total of 60 samples were used, with an estimated 30 samples in each group. Thirty sample size for Group A, intracervical catheterization, and thirty sample size for Group B, vaginal misoprostol. Misoprostol 50 mcg was administered vaginally into the posterior fornix of group A patients while they were in the lithotomy posture and all aseptic measures were followed.

To ensure correct dissolution rather than the intact tablet falling, care was taken to inject the pill after diluting it with regular saline or distilled water. After four hours, the first vaginal examination was performed, and the Bishop score was updated. When the modified Bishop score was six or higher, the cervix was classified as a favourable cervix. The presence of uterine contractions with a frequency of two or more every ten minutes, lasting thirty seconds, and an intensity that causes progressive effacement and dilation of the cervix greater than three centimetres was considered to indicate whether the patient was in true labour if the modified Bishop score was less than six at the time of reassessment.

A patient's labour was permitted to proceed and, if necessary, augmentation of labour was carried out if they were experiencing strong contractions (two or more every ten minutes). However, if the patient was not in labour, the Misoprostol tablet was reinstalled, and four hours later, the modified Bishop score was reevaluated. A maximum of three dosages were permitted during twelve hours. Using strict aseptic measures, the Foley self-retaining catheter no. 18, which has a balloon capacity of 30 cc, was transcervically placed into the excess amniotic space in group B. Using a sterile speculum, the vaginal part of the uterine cervix was exposed and thoroughly cleaned with an antiseptic solution.

The catheter was introduced through the external cervical os under direct eyesight, stopping 3–4 cm beyond the internal os. After gently pulling the catheter to position the bulb just past the internal os, the balloon was inflated using 30 cc of distilled water or regular saline. Without using any traction, the catheter's external end was taped to the thigh. The mother was observed using a single blood pressure and pulse record per hour. Fetal cardiac monitoring using a stethoscope was carried out every 30 minutes. Every 30 minutes, an abdominal exam was performed to record the beginning of uterine contractions. The efficacy was reported from both groups considering the fact that vaginal delivery occurs within 24 hours of

vaginal misoprostol administration and within 12 hours after intracervical catheterization.

A statistical analysis program (IBM-SPSS version 22) was used to analyze the data. For qualitative variables including parity, intrauterine fetal death in a prior pregnancy, and efficacy, frequency and percentage were calculated. For quantitative factors including weight, gestational age, and age, standard deviation was provided. The efficacy in both groups was compared using the Chi-square test, with $p \leq 0.05$ being considered significant. To determine the impact of these variables on efficacy, stratification was carried out based on age, gestational age, parity, intrauterine fetal death in prior pregnancy, and weight. After using the chi-square test for stratification in both groups, a p-value of less than 0.05 was deemed statistically significant.

Results

The study's age range was 18 to 40 years. As indicated in Table I, the mean age in Group A was 27.866±2.66 years, the mean gestational age was 33.800±3.84 weeks, and the mean weight was 67.100±4.67 kg. In Group B, the mean age was 28.166±2.69 years, the mean gestational age was 34.733±2.92 weeks, and the mean weight was 69.366±3.51 kg.

Table I: Demographics of patients according to age, gestational age and weight.

Demographics	Group A (n=30)	Group B (n=30)
Age (years)	27.866±2.66	28.166±2.69
Gestational age (weeks)	33.800±3.84	34.733±2.92
Weight (Kg)	67.100±4.67	69.366±3.51

The frequency and percentage of parity in previous pregnancies in both groups are shown in Table II. As demonstrated in Table III, Efficacy was seen in 26 (86.7%) patients in group A compared to 18 (60%) individuals in group B (P= 0.019).

Table II: Frequency and percentage of parity in both groups.

	Parity	Group A n=30	Group B n= 30
1	0-2	26 (86.7%)	23 (76.7%)
2	3-4	4 (13.3%)	7 (23.3%)
	Total	30 (100%)	30 (100%)

Discussion

The loss of a viable foetus causes anxiety for both the obstetrician and the family. Pregnancy waste continues to occur at an unacceptable high incidence even with advancements in medical research, diagnostics, and treatment techniques. Fetal deaths continue to be high even if perinatal mortality has decreased over the past few decades.[20] In this study, we examined misoprostol and intracervical catheterization as two strategies for inducing labour in patients with IUFD. Compared to 18 (60%) patients in the misoprostol group, 26 (86.7%) patients in the intracervical catheterization group showed efficacy (P= 0.019). According to research by Tharihalli C. et al., 86% of vaginal misoprostol cases resulted in intrauterine fetal death during labour induction.[17]

An intrauterine fetal death study by Das SR et al. found that the effectiveness of vaginal misoprostol in inducing labour was 53.3%.[18] According to a study by Nimbalkar PB, et al., the effectiveness of intrauterine fetal death-inducing labour with vaginal misoprostol was 81.3%, compared to 88% with intracervical catheterization.[19] The previously accessible ethacridine lactate would have been a great choice in the second trimester, but there are no recent reports of its usage in IUFD in the literature.

Table III: Comparison of efficacy in both groups

	Efficacy	Group A n=30	Group B (n=30)	P Value
1	Yes	26 (86.7%)	18 (60%)	0.019
2	No	4 (13.3%)	12 (40%)	
	Total	30 (100%)	30 (100%)	

In contrast to our study, a Chinese study conducted on 276 women between 16 and 27 weeks of gestation compared the effectiveness of mifepristone and ethacridine lactate with ethacridine lactate alone for pregnancy termination. This study is the sole recent publication on the subject. Mei[21] discovered that the misoprostol plus ethacridine lactate group performed considerably better than the ethacridine group. To streamline IUFD management and prevention procedures, Singh[22] identified risk variables. But in 33.44% of their 296 cases, no aetiological causes could be found; this was comparable to our analysis, in which 26% of cases had no aetiological explanation.

In prospective research conducted by Biswas[23], 40 women with IUFD after 28 weeks of gestation were compared for their efficacy, safety, and tolerance when misoprostol and dinoprostone gel were used to induce labour. They came to the conclusion that while both misoprostol and dinoprostone gel is safe, misoprostol works better at shortening the time between induction and delivery and requires a lower dose. In a Brazilian teaching hospital, Nascimento[24] examined the use of

intravenous oxytocin for induction/augmentation and/or vaginal misoprostol in the second and third trimesters for 171 women with IUFD. The average time from induction to delivery was 15.4 hours.

Using a Cook cervical ripening balloon or a Foley catheter, 200 women with stillbirths, unfavourable cervixes, and scarred uteri received cervical ripening in randomized controlled research conducted in Egypt by Rab et al.[25] The Foley group experienced a considerably shorter duration from balloon insertion to expulsion and from insertion to delivery. The authors concluded that, whereas Foley is more affordable and has a shorter induction delivery interval, both techniques are equivalent in situations involving scarred uterine.

When comparing women who used misoprostol to those who used catheters, anomalies in uterine contractility were more likely. The discovery that using a catheter doesn't increase the risk of hyperstimulation could be especially helpful for women who have had previous cesarean sections and are more likely to rupture their uterus when initiating labor. Hyperstimulation was observed more frequently in the misoprostol group.[26] In another study, it was discovered that hyperstimulation happened in 11.1% of women receiving a catheter and 33.3% of women receiving misoprostol.[27] Contractile irregularities are seen more common in the misoprostol group than in the catheter group.[28]

Conclusion

In modern obstetric practice, IUFD management is extremely important. In conclusion, intracervical catheterization and misoprostol can both be utilized to induce labour in third-trimester IUFD. Based on the study's findings, pregnant women with IUFD can induce labor more successfully with intracervical catheterization than with vaginal misoprostol.

ACKNOWLEDGEMENT: The authors would like to acknowledge the Medical Affairs department of Getz Pharma for their technical support and assistance in the publication process

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