Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-8, Issue-5 | September-October 2022
DOI: 10.53339/aimdr.2022.8.5.17
Page no- 127-133 | Section- Research Article (Gynecology and Obstetrics)

Study of Effectiveness of Medical Method for Induction of Labor and its Outcome

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Received: 06 May 2022
Revised: 28 July 2022
Accepted: 06 August 2022
Published: 22 August 2022

Abstract

Background: Modern obstetrics has a tremendous issue in inducing full-term labor in women with a viable fetus. When the hazards of prolonging pregnancy outweigh the advantages of birth, induction is undertaken. This study's objective was to evaluate the efficacy of misoprostol 50µg administered sublingually, orally and vaginally in the process of inducing labor.

Material & Methods: Between June 2021 and July 2022, 120 pregnant women admitted in Department of Gynecology and Obstetrics, Shaheed Ziaur Rahman Medical College and Hospital, Bogura in Bangladesh were recruited randomly for a randomized control trial as per inclusion criteria. Misoprostol was administered either orally or sublingually to each patient. A maximum of three doses might be administered if necessary. A previous cesarean birth was an exclusion criterion. The number of women who had a vaginal birth during 24 hours of induction was our major metric for success. SPSS 26 was used to analyze the data.

Results: The induction to delivery intervals were considerably shorter in the sublingual group (18 hours versus 25.5 hours; mean difference was 6.2 hours; 95 percent confidence interval, 1.5 to 14.6). In the sublingual group, there was just 2% occurrence of uterine hyperstimulation. The two groups did not vary significantly in terms of delivery method, fetal distress, or newborn outcomes. A total of 80% percent and 82.60 percent of patients were satisfied with the oral and sublingual groups, respectively, and only 10% percent believed the sublingual tablets didn't entirely dissolve.

Conclusion: Sublingual misoprostol seems to be a successful method of delivery, although further clinical studies are needed to demonstrate the safety and effectiveness of the sublingual mode.

Keywords:- Induction of labor, Misoprostol 50µg, Vaginal delivery (VD), Premature Rupture of Membrane (PROM)

INTRODUCTION

Pregnancy may be hastened by a variety of ways, including mechanical osmotic dilatation with dilators and balloon catheters,[1,2] and biochemical ripening with prostaglandins,[3] antiprogestins.[4] There is currently no consensus on the optimal strategy for inducing labor in women with an unripe cervix among the several acceptable methods of cervical

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ripening. It is common practice to utilize Misoprostol (PGE1) for "induction of labor" and cervical ripening, two purposes for which prostaglandins are often employed.[5,6] Prostaglandin E2 receptors are activated during cervical ripening.[7] Equivalent dosages of vaginal misoprostol have been demonstrated to be more effective than oral misoprostol.[8] However, there has been a concern for extreme uterine contractions with vaginal dosages of 50µg or more.[8,9,10] Even though the duration between induction to vaginal delivery was shorter using 50µg of oral misoprostol and 50µg of a vaginal misoprostol given four hours apart, our experience showed that the vaginal course resulted in higher rates of uterine hyperstimulation and consequently more initiatives for fetal distress.[11] Patients also preferred the oral method. This may be due to the fact that the drug's pharmacokinetics are better suited to the vaginal route. According to Zeiman et al,[12] vaginally administered misoprostol has a systemic bioavailability that is three times greater than oral misoprostol. Vaginal delivery takes longer to reach its maximum concentrations, but once there, the drug remains in the body for longer due to the pre systemic hepatic or gastrointestinal processing that happens when taken orally. Increased uterine contractility might be the result of an influence on the cervix that triggers the physiologic mechanisms that lead to an increase in efficacy.[13] Sublingual misoprostol delivery was examined in part due to patient preference concerns. As far as we know, no one else has tried this method of delivery. Due to its less direct contact with the uterus and cervix, we hypothesized that sublingual misoprostol may achieve the greater efficacy of vaginal misoprostol while also being less toxic to the gastrointestinal and liver systems. This study aimed to compare the effectiveness of a 50µg sublingual dose given every 8 hours with an oral dose regimen of equal strength. In addition, we hoped to compare the two methods of administration in terms of their safety and acceptance by patients.

Objectives

General objective

- To compare the effectiveness of a Misoprostol 50µg sublingual, oral and vaginal route in first 24 hours.

Specific objectives

- To assess the labor outcomes
- To identify the neonatal outcome

MATERIAL AND METHODS

To conduct this research, we conducted a randomized controlled trial. After 37 weeks of gestation, 120 women were brought to Department of Gynecology and Obstetrics, Shaheed Ziaur Rahman Medical College and Hospital, Bogura, Bangladesh for induction of birth due to a medical or obstetric reason during June 2021 and July of 2022. Criteria included a low Bishop's score of 8 or more, as well as an uncomplicated heartbeat for the fetus. In addition, they had to be open to participating in the research. Women who have previously had cesarean sections were not included in this research. In addition, multiple pregnancies, or a presentation other than cephalic were excluded, as were known limitations for using prostaglandins and serious maternal or fetal issues necessitating induction under close observation. Investigators administered

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sublingual or oral misoprostol after the participants had given their complete informed permission, and they were not engaged in their clinical care. Sequentially numbered envelopes were opened one by one to reveal cards that stated the method of administration. Using a computer produced table, these cards were created. An at least 30-minute fetal cardiotocography and a vaginal examination were done before each dosage to ensure proper development of the fetus and to determine the cervical score. The fetal heart rate was monitored for an additional 30 minutes one hour after the misoprostol was administered. During labor, the patient was transported to the labor ward for an AROM and oxytocin infusion if the cervical Bishop's score reached 8 or greater. The management of labor was carried out in accordance with standard procedures in the labor ward. As soon as the patient was admitted to the labor ward, a fetal heart rate monitor was placed. A failed induction was regarded if the cervical ripening was not sufficient to allow for AROM and there was no substantial uterine contraction. After the final dosage of misoprostol, the lady was offered the choice of cesarean birth. The number of women who gave birth vaginally within 24 hours of the induction was the most important metric for us. Additionally, the length of time between induction and birth, the number of misoprostol doses given, and the number of failure inductions were other markers of effectiveness. Prevalence of meconium, cesarean births due to uterine hyperstimulation, fetal concerns, pyrexia and gastrointestinal side effects were all documented. Among the newborn outcomes were the pH of the umbilical cord and admissions to the neonatal unit. Pregnant women with hyperstimulation were described as having an excessive uterine reaction (tachysystole or protracted contractions) that necessitated the use of albuterol or the birth of the baby. Aside from these demographics, we also compared the induction status of patients based on the age of the patient (age at induction, reason for induction, gestational age at induction, and cervical score before induction). After evaluating and rechecking the data, SPSS version 26 was used to perform statistical analyses.

RESULTS

The research included a total of 120 participants. None of the participants opted out of the research once recruitment began, and there were no breaches of the protocol. Neither the demographics nor the reasons for induction differed substantially between the two groups [Table 1 & Figure 1]. Compared to the oral group, the sublingual group had more vaginal deliveries within 24 hours (74 percent versus 44.3%; relative risk, 1.2; 95 percent confidence interval, 1.0 to 2.1), and the mean time from initiation of labor until delivery was shorter (18 hours as opposed to 25.5 hours; mean difference, 6.2; 95 percent confidence interval, 1.5 to 14.3). [Table 2]. This group had more patients who entered active labor after a single sublingual dosage, however there was no difference between the two groups in terms of active labor duration or oxytocin administration. Neither mode of birth nor cesarean deliveries for fetal concerns differed between the two groups. Except for the 5% of women in the oral group who required an emergency cesarean birth due to a suspected second-stage placental abruption, fetal blood sample was done in patients who had undergone cesarean delivery due to fetal

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distress. In the four hours after the initial dosage of misoprostol, 2% of the primiparous women from sublingual group had uterine hyperstimulation, necessitating a cesarean birth for reasons of fetal safety [Table 3]. Neonatal outcomes did not vary across the groups [Table 4]. The newborn in the misoprostol oral administration group was born with a cord pH, <7.0 and needed emergency resuscitation following placental abruption. After resuscitation, the newborn was found to be healthy. In the oral and sublingual groups, 80 percent and 82.60 percent of patients were satisfied, respectively. 10% believed that the sublingual pills had not fully dissolved when they were administered. Sublingually, 11% and orally, 6% believed the pills had an undesirable taste, respectively [Figure 2].

Table 1: Maternal characteristics (n=120).

	Oral misoprostol	**Sublingual misoprostol**	**Vaginal misoprostol**
Age in years*	28 (7.7)	27 (7.4)	26(5.4)
Height in cm*	155.8 (5.5)	153.6 (5.9)	154.3(5.7)
Weight in kg*	75 (12.7)	70 (14.3)	72(13.5)
Primipara†	60%	52%	55%
Gestation‡	41 week, 4 d	41 week, 2 d	41 week, 2 d
	(range, 37-42 week)	(range, 38-42 week)	(range, 38-42 week)
Cervical score*	3.4 (1.55)	3.1 (1.68)	3.3 (1.60)

*Data given as mean values, with SD given in parentheses. ‡Data given as median values

Table 2: Labor outcome in those delivering vaginally (n=120)

	Sublingual misoprostol	**Oral misoprostol**	**Vaginal misoprostol**	**Mean difference 95% CI**	**RR 95% CI**
deliveries within 24 hours of the induction†	74%	44.3%	40.0%	-	1.2 (1.0 to 2.1)
Interval between Induction and delivery (h)*	18 (12.3)	25.5 (12.4)	20.2 (12.5)	6.2 (1.5 to 14.6)	-
No needing more than one dose†	25%	60%	30%		0.6 (0.1 to 0.7)
Duration in the induction ward (h)*	14 (13.5)	21 (14.7)	15 (14.2)	7.1 (0.6 to 12.1)	-
Duration in the labor ward (h)*	3.5 (2.5)	5.6 (4.7)	4.9 (4.2)	1.1 (0.5 to 2.1)	-

RR, Relative risk; 95% CI, 95% confidence interval. *Data given as mean values, with SD given in parentheses.

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Table 3: Labor outcome (n=120)

	Sublingual misoprostol	**Oral misoprostol**	**Vaginal misoprostol**	**RR**	**95% CI**
No of oxytocin given	35%	47%	40%	0.70	0.6 to 1.1
Doses of misoprostol*	1.5 (1.3)	2.5 (1.4)	2.0 (1.2)	1	0.7 to 1.3
Modes of delivery					
Spontaneous VD	61%	52%	55%	1.2	0.5 to 1.1
Instrumental VD	24%	12%	15%	1.4	0.9 to 2.9
Cesarean delivery	15%	28%	20%	1.7	0.8 to 3.5
Cesarean deliveries for fetal concerns	4%	5%	3%	1.1	0.5 to 3.7
Uterine hyperstimulation	2%	1%	1%	2.7	0.3 to 9.0
Gastrointestinal side effects					
Vomiting	10%	11%	7%	1.2	0.8 to 3.9

**Data given as mean values, with SD given in parentheses.*

Table 4: Neonatal outcomes (n=120)

	Sublingual misoprostol	**Oral misoprostol**	**Vaginal misoprostol**	**Mean difference 95% CI**	**RR 95% CI**
Birth weight in gm*	3770 (445.3)	3800 (12.3)	3700 (18.5)	-	11 (180 to –212)
Apgar scores < 7 at 5 minutes	0	0	0	-	-
Cord pH*	7.50 (0.21)	7.51 (0.20)	7.50 (0.21)		0.03 (–0.05 to 0.07)
Base deficit*	–5.1 (2.76)	–5.95 (3.0)	-5.1 (2.76)		0.41 (1.4 to –1.3)
Neonatal admission†	8%	10%	7%	0.95 (0.4 to 2.8)	-

**Data given as mean values, with SD given in parentheses*

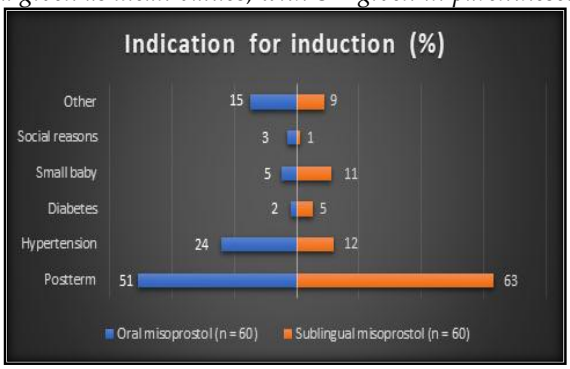

Figure 1: Case distribution according to indication for induction (n=120). Data given as median values.

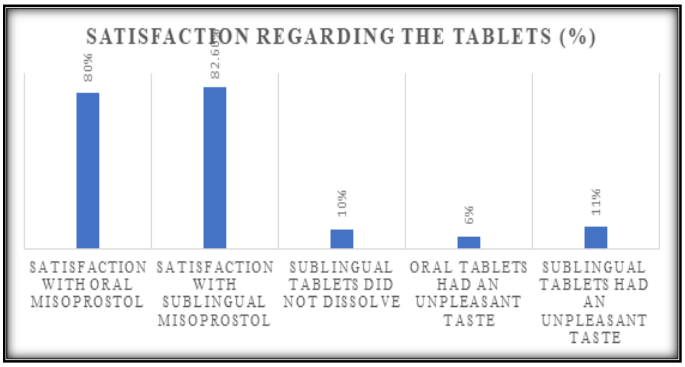

Figure 2: Satisfaction regarding the tablets (n=120).

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DISCUSSION

The study findings suggest that sublingual misoprostol was more effective than oral misoprostol, resulting in a quicker time between induction and delivery, with more birth within 24 hours of induction. The rates of surgical delivery, and the outcomes for newborns in the two groups did not differ. In the sublingual group, there was a 2% incidence of hyperstimulation. When Danielsson et al.[13] evaluated the contraction of uterus after both vaginal and oral treatment, they hypothesized that a different reason for the long-lasting stimulant impact of the vaginal route might be its direct effects on the cervix, commencing physiological processes. Sublingual administration may not have the same immediate effects, and as a result, hyperstimulation rates may be reduced. More than 80 percent of patients in the group that received an equal amount of oral and vaginal misoprostol gave birth within 24 hours, a research found.[14] The mean duration between induction and delivery was 17.8 hours (Standard Deviation, 13.5 hours). This is in line with the sublingual group's mean induction-to-delivery period of 20 hours, with delivery happening in 24 hours after induction in 73.8% of patients in this research. Uterine hyperstimulation was more common (4.9%) and interventions for fetal interests were more frequent in the vaginal group (13%). Using the sublingual route, we may be able to achieve the vaginal route's better effectiveness while avoiding issues with excessive contractions of the uterus. There was a high degree of patient satisfaction with the use of sublingual misoprostol for induction. This method, like the oral one, may be provided without the need for frequent vaginal inspections, making it more acceptable to patients and especially helpful for those whose membranes have ruptured. It's the first-time misoprostol taken sublingually has been documented for labor induction. According to our findings, the sublingual route is more effective than the oral route in terms of effectiveness as well as safety and acceptability for patients. More research on misoprostol is needed, including pharmacokinetic studies to establish the best effective dose and method of administration, since labor induction is a frequent obstetric intervention.

CONCLUSIONS

Misoprostol taken sublingually indicates that using sublingual misoprostol to induce labor at term is more successful than doing so with oral misoprostol, looks to be appropriate for patients, and should be investigated further.

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Source of Support: Nil, Conflict of Interest: None declared