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Original Research Article

Safety and effectiveness of Oral Misoprostol for Induction of Labour

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Abstract

Background: In low-resource areas, oral misoprostol is replacing dinoprostone and oxytocin as the drug of choice for inducing labour since it is less expensive, more stable at room temperature, and less complicated to administer. The study's goal was to quantify the proportion of pregnant women who gave birth within the first 24 hours after ingesting misoprostol orally. Successful vaginal delivery, induction-delivery delay, induction failure ending in caesarean section, retained placenta requiring manual removal, uterine hyperstimulation, and uterine rupture were the noted maternal outcomes.

Methods: This six-month retrospective observational study was conducted in a tertiary care teaching hospital. 50 patients who met induction requirements according to induction guidelines received 50 mcg oral misoprostol after bimanual pelvic examination for estimating modified bishops score and reactive CTG. The patient was monitored for six hours. If the cervix is still unfavourable, a second oral dosage of 50 mcg misoprostol may be repeated every 4-6 hrs up to three times. Patients who delivered birth within 24 hours were noted.

Results: Mean (SD) of their age was 27.78 (2.98) years. 45 patients gave birth vaginally within the first 24 hours of pregnancy. The modified Bishop's score of the 5 women, who did not undergo delivery within 24 hours was less than 3, with the majority of them (80%) having a score of 0. The mean (SD) gestational age was 39.74 weeks (1.44). The median amount of time that passed between the induction of labour and the delivery of the baby was 13.38 (4.84) hours.

Conclusion: Oral misoprostol is a safe, effective and easily available, low cost drug leading to more number of vaginal deliveries within 24 hours of induction with less maternal and perinatal complications. This can be delivered easily in low resource situations.

Keywords: Dinoprostone, Induction Delivery, Bishop's Score, Misoprostol

Introduction

In many developing nations around the world, lowering the rate of maternal death continues to be a serious public health concern. Since the Millennium Development Goals (MDG) were announced in the year 2000, the implementation of MDG 5, which aims to reduce maternal mortality by three-quarters by the year 2015, has been a major undertaking in the majority of developing countries [1,2].

Significant progress has been made in some countries, but not all of them. In spite of recent attention brought to the issue by the Sustainable Development Goals (SDG3), the rate of maternal mortality in underdeveloped nations is still 14 times greater than in rich ones. As a direct result of this, complications like prolonged labour pose a significant risk of death to both the mother and her child [3].

Induction of labour (also known as IOL) is an essential life-saving strategy that lowers the risk of poor outcomes [4]. It has been demonstrated that the procedures that are currently in use, which involve the intravenous administration of oxytocin, oral and vaginal route prostaglandins are successful in inducing labour. Dinoprostone ad is a prostaglandin E2 agent that is widely used in developed countries and is approved by the Food and Drug Administration (FDA) [5]. However, randomised trials have failed to show that it reduces rates of caesarean sections despite its benefit as a cervical ripening agent. Dinoprostone is widely used in developed countries and is approved by the FDA [6]. In addition, the fact that it is unstable at room temperature and has a high price, restricts its usage as a cost-effective agent, which is especially problematic in contexts where resources are in short supply [7].

In recent years, the use of misoprostol, which is a prostaglandin E1 analogue, has become widespread as an induction of labour (IOL) agent [8] Misoprostol was initially manufactured and marketed in the United States in the 1980s with the primary purpose of preventing peptic ulcer disease caused by the use of non-steroidal anti-inflammatory drugs [9]. There has been a lot of interest in the use of misoprostol in obstetrics since it was discovered by accident that it can cause uterine contractions in the early stages of pregnancy.

In April of 2002, the Food and Drug Administration (FDA) completed a labelling revision for misoprostol and gave its approval for usage during pregnancy. When compared to other prostaglandins, misoprostol offers a number of possible benefits that set it apart from the others. It is affordable, does not degrade when exposed to room temperature, and can be administered in a variety of ways (oral, vaginal, sublingual and buccal) [10].

In spite of this, there are still insufficient evidence about the safety, efficacy, and practicability of providing oral misoprostol in normal clinical practise in resource-limited countries, where the burden of obstetric and perinatal problems remains high. The purpose of this research is to determine the percentage of pregnant women who give birth within the first 24 hours after taking oral misoprostol. To evaluate the maternal outcome based on factors such as successful vaginal delivery, length of time between induction of labour and delivery, failure of induction of labour resulting in a caesarean section, retained placenta needing manual removal, uterine hyperstimulation, and uterine rupture.

Methods

Study design and settings

This was a retrospective observational study that was carried out over the course of a

period of six months at a tertiary care teaching hospital after getting institutional ethical committee clearance. 50 term antenatal patients coming to OPD satisfying inclusion and exclusion criteria were selected.

Study inclusion and exclusion criteria

Women who have an indication for inducing labour, such as post-dated, pre-labour rupture of membranes, pre-eclampsia, gestational or overt diabetes, suspected foetal compromise, such as IUGR with normal doppler were selected. Cephalic presentation was confirmed, and informed written consent was obtained.

Women who had multiple pregnancies, preterm labour with rupture of membranes, a history of caesarean delivery, malpresentation, or a history of hypersensitivity to misoprostol or prostaglandins analogue were not allowed to participate in the study.

Intervention

The size of the sample was determined to be 50. After estimating the modified bishop score of the study population and verifying CTG to be reactive, the patients who met the inclusion criteria for induction were administered oral misoprostol of 50 mcg. The patient was then followed for a period of six hours.

The outcomes and measures

The cervix has been reevaluated at this time. If the cervix was good and the patient was experiencing heavy contractions, the patient was transferred to the labour and delivery ward for an ARM and delivery. If the cervix is unfavourable, a second dose of misoprostol containing 50 mcg will be administered orally, and this process may be repeated up to three times every 4-6 hours. This study estimated the number of women who gave birth within 24 hours of using oral misoprostol.

Analysis of maternal outcome included factors such as successful vaginal birth, length of time between induction of labour and delivery, failure of induction of labour resulting in a caesarean section, retained placenta that required manual removal, uterine hyperstimulation, and uterine rupture.

Statistical analysis

The statistical analysis was carried out with IBM SPSS Statistics for Windows, Version 26.0, which was developed by IBM Corporation and is based in Chicago, Illinois. Descriptive statistics were used to conduct research on the demographic data. For continuous variables, descriptive statistics were supplied as the mean together with the standard deviation, and for categorical variables, frequencies along with percentages were given.

Results

Demographic baseline characteristics

The screening process was carried out on a total of fifty patients over the course of the research study; of these, fifty individuals met the requirements to be included in the research and were consequently enrolled. The standard deviation of their age was 2.98 years, making their mean age 27.78 years. 45 out of the ladies gave birth vaginally within the first 24 hours of pregnancy. The modified Bishop's score of the 5 women who had failed induction of labour was less than 3, with the majority of them (80%) having a score of 0. The mean (standard deviation) gestational age was 39.74 weeks (1.44).

The median amount of time that passed between the induction of labour and the delivery of the baby was 13.38 (4.84) hours. Other demographic and clinical variables at the beginning of the study are presented in Table 1.

Table 1: Demographic data.

S No	Variable	Mean	SD
1	Age	27.78	2.98492813
2	Parity	1.02	0.86873119
3	Indication for induction		
4	Abnormal GTT	5	10%
5	Hypertension	6	12%
6	IUGR	3	6%
7	Post dated	27	54%
8	Preeclampsia	4	8%
9	PROM	5	10%
10	Initial bishops score	2.4	1.83
11	0-3	34	68%
12	3-6	16	32%
13	Gestational age	39.74	1.44009637
14	Height	155.22	4.45517356
15	Weight	63.02	10.2628516
16	BMI	26.2193044	4.54969265
17	SBP	109.76	5.86431616
18	DBP	69.96	6.39502358

Indications for induction of labour

The majority of the ladies (54%) followed through with the IOL procedure for post-dates. Five of the patients (10%) had premature rupture of membranes (PROM), four of the patients (8%) had pre-eclampsia, five of the patients (10%) had abnormal glucose tolerance test results, six of the patients (12%) had hypertension, and three of the patients (6%) had intrauterine growth restriction.

Maternal outcomes

Compared to the 10% of women (five out of fifty) whose IOL was unsuccessful and required caesarean section, 90% of women were able to successfully deliver their babies vaginally. One hundred percent of the women who had a successful vaginal delivery gave birth within twenty-four hours, and there was no significant difference between the various diagnostic categories in this regard. The majority of deliveries (88%) had a positive outcome, which was beneficial for the mothers as well as the babies. The failure of IOL and/or extended labour were the key factors for cesarean sections.

When compared to those who delivered after the second course of oral misoprostol, the majority of women gave birth following the first course of treatment with the medication (91.1% [41/45] versus 8.9% [4/45]). Eight women, or 17.78% of the total, needed to have their labour augmented with intravenous oxytocin because their contractions were not strong enough to move the labour along.

Maternal complications

There was evidence of maternal problems in 6 out of 50women (12%). One of them needed to have the placenta manually removed since it had been retained. There were five women who experienced postpartum hemorrhage, but this was not significantly associated with any diagnostic category or the method of delivery (vaginal versus caesarean).

Discussion

It has been determined that misoprostol is effective in the treatment of peptic ulcers. Initial research demonstrated that misoprostol's utero tonic properties and intra vaginal administration were effective in terminating first and second trimester pregnancies [11]. These findings also demonstrated that the medication was safe to administer [12] South American researchers were the ones who pioneered the use of misoprostol for cervical ripening and induction in the first studies of their kind [13]. According to the research that has been conducted, the recommended time gap between administrations of misoprostol ranges from every three to six hours. On the other hand, numerous research had centred the use of a 4-6 hour gap as the primary focus of their protocols due to the possibility of tachysystole [14].

Oral misoprostol was found to be effective as a cervical priming agent for patients who presented with pre-labor rupture of membranes at term, according to the findings of an investigation conducted by Ngai *et al* [15]. These researchers concluded that oral misoprostol was an effective agent for this group of patients. Similar findings were reported by Sanchez-Ramos *et al* [16] and Shetty *et al*., who observed that active management with oral misoprostol resulted in more women going into labour and delivering within 24 hours of the prelabor rupture of membranes, without an increase in the number of women who experienced maternal or neonatal complications. This was the case even though the number of women who experienced prelabor rupture of membranes increased, positive ttitudes were more prevalent among women about the active management of prelabor rupture of membranes. Misoprostol taken orally is a potential choice for patients who desire active therapy of their condition [17].

In our research, ninety percent of patients went on to have healthy vaginal births after being induced. Our findings are corroborated by a comprehensive study that discovered low-dose oral misoprostol (less than 25 mcg) to be just as effective and safe as vaginal dinoprostone, with significantly fewer women requiring caesarean delivery as a result of its use [18]. When compared to the vaginal route of administration, it is clear that the oral method of administering misoprostol is associated with a lower risk of serious side events such as hyperstimulation of the uterine muscle and rupture of the uterine wall [19].

Because misoprostol has a longer half-life and a direct effect on the cervix, induction regimens that use vaginal misoprostol have been linked to concerns of hyperstimulation and alterations in foetal heart rate. It is obvious that the duration of treatment and the amount of time that passes between doses play a vital influence in the efficacy and safety of oral misoprostol in the induction of labour. This is true regardless of the method of administration or the dosage that is used [20]. Nevertheless, there is still a high prevalence of heterogenicity between studies that compare the vaginal and oral routes of misoprostol administration. This is the case despite the fact that a large number of research of this type have been carried out in the past and examined in systemic reviews. On the other hand, there is a dearth of data and there is still a need for intervention trials to compare alternative oral misoprostol dose regimens. Particular focus should be placed on dosage, the amount of time that passes in between doses, and the length of time that medication is administered [21]. In many developing nations, the use of oral misoprostol to induce labour is a relatively new approach. In addition, authoritative advice to do IOL, which frequently results in 20–30% of induced deliveries in affluent nations, are frequently not realistic in settings

with low resources due to the presence of a variety of variables. It is possible for patients to be severely delayed in their presentation at the hospital due to pre-hospital variables such as poverty, illiteracy, and cultural viewpoints, as well as geographic remoteness, constraints in logistics and infrastructure, and so on. In addition, the healthcare system is often ignored in settings that have little resources, and in-hospital variables, such as a slow turnaround time for emergency caesarean sections due to a lack of personnel, laboratory, and blood bank services, are prevalent factors that compound the problem. This highlights the significance of IOL as a crucial tool, as well as the requirement for the development of IOL procedures that are both safer and more applicable in settings with limited resources [22].

The present study has a limited sample size, which is a limitation to the study; also, the absence of a control group makes the study less robust than it could have been. Before we could move on to comparing this regimen with other regimens, the primary purpose of the study was to determine the safety and effectiveness of this regimen when it was used in ordinary clinical practise. This was accomplished through the use of an observational research design. To ensure that appropriate safety and efficacy are maintained without increasing the risk of misoprostol-induced adverse events, further intervention trials comparing the current regimen to other oral misoprostol regimens will be required. These trials will be required in the near future.

Conclusion

Our research indicates that oral misoprostol is not only safe and effective but also reduces the risk of maternal and perinatal mortality, and it may be conveniently administered in settings with limited access to resources. Oral misoprostol is not only less expensive and more stable at room temperature when compared to dinoprostone and oxytocin, but its widespread use and ease of administration also make it more likely that it will improve Induction of labour rates in developing countries. This, in turn, will lead to a reduction in the high maternal and perinatal mortality rates that are seen in these locations.

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