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Original Research Article

Maternal and Neonatal Outcome after the Use of Low-Dose Sublingual 25 µg Misoprostol for Labor Induction in Women with Term Pregnancy

Preetha Solomon[1], Vijaya Lakshmi Nambula[2], Deepana S. N.[3]

[1]Assistant Professor, Department of Obstetrics and Gynecology, Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu, India

[2]Assistant Professor, Department of Obstetrics and Gynecology, Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu, India

[3]Assistant Professor, Department of Obstetrics and Gynecology, Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu, India

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Corresponding author: Dr. Deepana S. N.

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Abstract:

Background: Labor induction is a common obstetric intervention employed to manage pregnancies at or beyond term. Misoprostol, a prostaglandin analog, has been widely used for this purpose. This study aims to investigate the maternal and neonatal outcomes following the administration of a low-dose sublingual 25 µg misoprostol regimen for labor induction in women with term pregnancies.

Materials and Methods: A prospective observational study was conducted over a one-year duration, from October 2022 to September 2023, at Karpagam Medical College Hospital in Othakkalmandapam, Coimbatore, Tamil Nadu. Eligible participants included women with term pregnancies (≥37 weeks) who required labor induction for medical or obstetric indications. Sublingual misoprostol, at a dose of 25 µg, was administered, and maternal and neonatal outcomes were assessed. Data on maternal age, gestational age, parity, indications for induction, labor duration, mode of delivery, neonatal birth weight, Apgar scores, and maternal and neonatal complications were collected and analyzed.

Results: A total of 250 women with term pregnancies were included in the study. The average maternal age was 28.5 years, and the mean gestational age at induction was 39 weeks. The most common indications for labor induction were post-term pregnancy (45%) and maternal medical conditions (30%). The majority of women (72%) achieved successful vaginal deliveries, with an average duration of labor of 8 hours. Neonatal birth weight averaged 3.2 kg, and Apgar scores at 1 and 5 minutes were 8.5 and 9.3, respectively. Maternal complications were observed in 10% of cases, including uterine hyperstimulation and postpartum hemorrhage, while neonatal complications occurred in 8% of cases, predominantly related to transient tachypnea.

Conclusion: Low-dose sublingual 25 µg misoprostol for labor induction in women with term pregnancies appears to be a safe and effective method, associated with favorable maternal and neonatal outcomes. This regimen can be considered as an option for labor induction in this population.

Keywords: Labor induction, misoprostol, term pregnancy, maternal outcome, neonatal outcome, sublingual administration.

Introduction

Labor induction is a common obstetric practice employed to initiate or accelerate labor in women with various medical or obstetric indications, particularly in pregnancies at or beyond term (≥37 weeks). Misoprostol, a synthetic prostaglandin E1 analog, has gained widespread acceptance as an effective agent for labor induction due to its uterotonic properties [1]. Its use has been extensively studied and documented in various regimens and routes of administration.

In recent years, there has been increasing interest in optimizing misoprostol protocols to achieve safer and more efficient labor induction while minimizing potential maternal and neonatal complications [2]. Sublingual administration of misoprostol has emerged as a promising alternative to traditional routes, such as oral or vaginal administration, offering rapid onset and better bioavailability [3].

Despite the growing body of evidence supporting the efficacy and safety of sublingual misoprostol for labor induction, there remains a need for further research in diverse clinical settings to better understand its maternal and neonatal outcomes.

This study was conducted at Karpagam Medical College Hospital in Othakkalmandapam, Coimbatore, Tamil Nadu, with the aim of assessing the maternal and neonatal outcomes following the administration of a low-dose sublingual 25 µg misoprostol regimen in women with term pregnancies. The outcomes of interest include maternal complications, such as uterine hyperstimulation and postpartum hemorrhage, as well as neonatal outcomes, such as birth weight and Apgar scores. By investigating the impact of this specific misoprostol protocol on maternal and neonatal health, this study contributes valuable insights to the ongoing efforts to refine labor induction practices.

Materials and Methods

Study Design and Setting

This prospective observational study was conducted at Karpagam Medical College Hospital in Othakkalmandapam, Coimbatore, Tamil Nadu, India, over a one-year period from October 2022 to September 2023. The study received ethical approval from the hospital's Institutional Review Board. Study includes subjects with primi or multiple gravida with term pregnancy, Single live fetus with cephalic presentation, uncomplicated pregnancy and the subjects with previous Iscs Induction before 37 weeks and patients with contraindications for normal delivery presentation other than cephalic were excluded.

Study Population

The study included women with term pregnancies (≥37 weeks gestation) who required labor induction for medical or obstetric indications. Participants were recruited from the labor and delivery unit of the hospital. Informed consent was obtained from all eligible participants prior to enrollment.

Labor Induction Protocol

All participants received sublingual misoprostol (25 µg) for labor induction. The misoprostol tablets were placed sublingually every 4 hours, as per the hospital's standard protocol, until adequate uterine contractions were achieved, or a maximum of three doses was administered.

Data Collection

Data were collected using a standardized data collection form. The following variables were recorded for each participant:

Maternal demographics: Age, parity, and gestational age at the time of induction.

Indication for labor induction: Indications were categorized as post-term pregnancy, maternal medical conditions, fetal indications, and other obstetric indications.

Maternal outcomes: These included the mode of delivery (vaginal or cesarean section), duration of labor (from induction to delivery), and any maternal complications such as uterine hyperstimulation and postpartum hemorrhage.

Neonatal outcomes: Neonatal outcomes included birth weight, Apgar scores at 1 and 5 minutes, and any neonatal complications, such as transient tachypnea, respiratory distress syndrome, or neonatal intensive care unit (NICU) admission.

Statistical Analysis

Data were analyzed using appropriate statistical software (e.g., SPSS, R). Descriptive statistics were used to summarize participant demographics, indications for induction, and outcomes. Continuous variables were reported as means with standard deviations, while categorical variables were presented as frequencies and percentages. Results were considered statistically significant at a p-value of less than 0.05. Associations between variables were assessed using chi-square tests for categorical data and t-tests for continuous data, as appropriate.

Sample Size Calculation

The sample size was determined based on an estimated prevalence of maternal complications following sublingual misoprostol induction, with a desired level of precision and confidence. A sample size of 250 participants was targeted to ensure adequate power for the study.

Ethical Considerations

This study adhered to ethical principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants, and confidentiality of patient data was maintained throughout the study.

Results

A total of 250 women with term pregnancies who underwent labor induction with sublingual 25 µg misoprostol were included in the study. The results of this study are presented in tables below:

Table 1: Maternal Characteristics

Variable	Mean (±SD) or n (%)
Maternal Age (years)	28.5 ± 3.2
Gestational Age at Induction (weeks)	39.1 ± 1.0
Parity (nulliparous/multiparous)	115 (46%) / 135 (54%)

Table 2: Indications for Labor Induction

Indication	Number of Cases (%)
Post-term Pregnancy	113 (45.2%)
Maternal Medical Conditions	75 (30.0%)
Fetal Indications	37 (14.8%)
Other Obstetric Indications	25 (10.0%)

Table 3: Labor and Delivery Outcomes

Outcome	Value (Mean ± SD or n (%))
Mode of Delivery (Vaginal/Cesarean Section)	180 (72%) / 70 (28%)
Duration of Labor (hours)	8.2 ± 2.1
Maternal Complications (Yes/No)	25 (10%) / 225 (90%)

Table 4: Neonatal Outcomes

Outcome	Value (Mean ± SD or n (%))
Birth Weight (kg)	3.2 ± 0.4
Apgar Score at 1 Minute	8.5 ± 1.2
Apgar Score at 5 Minutes	9.3 ± 1.0
Neonatal Complications (Yes/No)	20 (8%) / 230 (92%)
Neonatal Admission to NICU (Yes/No)	15 (6%) / 235 (94%)

Table 1 provides an overview of maternal characteristics. The mean maternal age was 28.5 years, with an average gestational age at induction of 39.1 weeks. Approximately 46% of the participants were nulliparous.
Table 2 displays the indications for labor induction. The most common indication was post-term pregnancy (45.2%), followed by maternal medical conditions (30.0%).

Table 3 presents labor and delivery outcomes. Vaginal delivery was achieved in 72% of cases, with an average duration of labor of 8.2 hours. Maternal complications were observed in 10% of cases, including uterine hyperstimulation and postpartum hemorrhage.

Table 4 outlines neonatal outcomes. The average birth weight of neonates was 3.2 kg, and Apgar scores at 1 and 5 minutes were reassuring (8.5 ± 1.2 and 9.3±1.0, respectively). Neonatal complications were reported in 8% of cases, primarily related to transient tachypnea. Neonatal intensive care unit (NICU) admission was required for 6% of neonates.

Discussion

The present study aimed to evaluate the maternal and neonatal outcomes following labor induction using a low-dose sublingual 25 µg misoprostol regimen in women with term pregnancies. The findings of this study suggest that this approach is associated with favorable outcomes for both mothers and neonates.

The maternal characteristics in this study, including maternal age and gestational age at induction, were consistent with the demographics of term pregnancies undergoing induction reported in previous studies [1]. The most common indication for labor induction was post-term pregnancy (45.2%), which aligns with the clinical practice of inducing labor when pregnancies extend beyond 41 weeks to reduce the risk of adverse perinatal outcomes [2].

The mode of delivery in our study favored vaginal delivery (72%), and the average duration of labor was 8.2 hours. These results are consistent with studies that have demonstrated the efficacy of misoprostol in achieving successful vaginal deliveries with a relatively short duration of labor [3]. The low cesarean section rate in our study is encouraging, as avoiding unnecessary cesarean sections is a key goal in obstetric care [4].

Maternal complications were observed in 10% of cases, which is in line with the reported rates of maternal complications associated with misoprostol induction in the literature [5]. Uterine hyperstimulation and postpartum hemorrhage were among the complications noted, emphasizing the importance of close monitoring during induction with misoprostol.

Neonatal outcomes in our study were generally favorable, with an average birth weight of 3.2 kg and reassuring Apgar scores at 1 and 5 minutes. The rate of neonatal complications (8%) was consistent with other studies investigating misoprostol for labor induction [6]. The majority of neonatal complications were related to transient tachypnea, which is known to occur more frequently in infants born after labor induction [7]. It is important to note that the low-dose sublingual 25 µg misoprostol regimen used in this study appears to be a safe and effective option for labor induction in term pregnancies, with outcomes comparable to or better than those reported in the existing literature [8].

Limitations of this study include its observational design, which may introduce selection bias, and its

single-center nature, which may limit generalizability to broader populations. Additionally, the sample size may have limited the ability to detect less common complications.

Conclusion

In conclusion, the findings of this study support the use of low-dose sublingual 25 µg misoprostol for labor induction in women with term pregnancies as an effective and safe option. This regimen was associated with favorable maternal and neonatal outcomes, including a high rate of successful vaginal deliveries and reassuring neonatal outcomes. Further research, including randomized controlled trials, is warranted to confirm these findings and provide additional evidence for the use of sublingual misoprostol in labor induction.

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