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Comparative Cross-Sectional Study Evaluating the Efficacy and Safety of Sublingual Misoprostol versus Intravaginal Dinoprostone for Labor Induction

Gulafshana Hafeez Khan, Syeda Wajeeha Ojala Shah, Iqra Nadeem, Saima Iqbal, Rabia Saleem, Zaeema Khalid

ABSTRACT

Objective: The investigation aimed to evaluate the effectiveness and safety of sublingual misoprostol compared with intravaginal dinoprostone for labor induction at Maroof International Hospital.

Study Design and Setting: A comparative cross-sectional study was carried out in the Obstetrics Department, Maroof International Hospital from 1 August 2023 to 30 September 2024, including 219 pregnant women aged between 18 and 40 years and gestation periods ranging from 37 to 42 weeks.

Methodology: Participants were randomly allocated to receive either sublingual misoprostol (50 mcg every 4 hours, up to 6 doses) or intravaginal dinoprostone (3 mg every 6 hours). The study assessed the interval between induction and delivery, delivery method, induction failure, and adverse consequences including gastrointestinal problems and fetal distress. Data analysis was conducted utilizing SPSS, with a significance threshold established at $p < 0.05$.

Results: Misoprostol markedly decreased the induction-to-delivery interval (8.4 vs. 10.2 hours, $p < 0.05$). Nonetheless, it was linked to an increased incidence of cesarean sections (12.5% compared to 5%), predominantly attributable to fetal discomfort. Misoprostol also elevated the occurrence of nausea and vomiting in comparison to dinoprostone.

Conclusion: Sublingual misoprostol reduced induction-to-delivery time but increased adverse effects and cesarean sections. Misoprostol for labor induction requires careful monitoring to balance efficacy and safety.

Keywords: Cesarean Section, Dinoprostone, Fetal Distress, Labor Induction, Misoprostol, Pregnancy

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Gulafshana Hafeez Khan
Head of Department Obstetrics and Gynecology
Maroof International Hospital, Islamabad
Email: gulafshanahafeez@hotmail.com

Syeda Wajeeha Ojala Shah
Senior Registrar, Department of Obstetrics and Gynecology
Shifa College of Medicine, Islamabad
Email: wajeehaojala42@gmail.com

Iqra Nadeem
Assistant Consultant, Department Obstetrics and Gynecology
Maroof International Hospital, Islamabad
Email: iqranadeem313@gmail.com

Saima Iqbal
Assistant Consultant, Department Obstetrics and Gynecology
Maroof International Hospital, Islamabad
Email:dr.saimaiqbal@yahoo.com

Rabia Saleem
Senior Registrar, Department of Obstetrics and Gynecology
Shifa College of Medicine, Islamabad
Email: rabiasaleem100@yahoo.com

Zaeema Khalid
Assistant Consultant, Department Obstetrics and Gynecology
Maroof International Hospital, Islamabad
Email: zaeemakhalid@gmail.com

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INTRODUCTION

Labor induction, a procedure originating in the time of Hippocrates, has seen considerable evolution throughout the years. Initially, techniques like as breast stimulation and mechanical cervical ripening were employed.[1] Advancements in medicine and obstetrics have refined the methods of labor induction, customizing them to enhance results for both women and newborns. The escalation in labor induction rates is mostly ascribed to the growth in advanced mother age and the growing incidence of maternal comorbidities, including hypertension and diabetes.[2] Various pharmacological and mechanical techniques are employed to induce and enhance uterine contractions and facilitate cervical ripening, aiming to optimize outcomes for both the mother and the fetus.[3] The increasing accessibility of antenatal surveillance and monitoring has resulted in a diminished threshold for labor induction, as its safety has been extensively validated, notably through studies such as the ARRIVE trial (2018), which compared induction to expectant management in low-risk pregnancies and revealed advantageous outcomes for induction.[4] Consequently, the practice of labor induction has grown prevalent in contemporary obstetric treatment. Labor induction techniques are designed to induce and enhance uterine contractions, as well as promote cervical

softening to enable a successful vaginal birth.[5] Intravaginal dinoprostone and sublingual misoprostol are the most often utilized medicines, each with distinct advantages and limits. Misoprostol, a synthetic derivative of prostaglandin E1, is esteemed for its efficacy in producing uterine contractions and facilitating cervical ripening. Misoprostol has gained favor in labor induction procedures due to its quick beginning of action and convenience of administration, especially in its sublingual form.[6]

Nonetheless, although it is efficacious, it is concomitantly linked to adverse effects, such as gastrointestinal disorders, uterine hyperstimulation, and fetal distress, which raise concerns over its application.[7] Conversely, dinoprostone, a naturally occurring prostaglandin E2, has historically been the agent of choice for cervical ripening and labor induction owing to its demonstrated safety and effectiveness.[8] Dinoprostone is typically administered intravaginally, and though it is generally regarded as safe, it too has potential side effects, including uterine hyperstimulation and fever.[9] Notwithstanding these apprehensions, dinoprostone continues to be extensively utilized in clinical practice, especially for individuals deemed at elevated risk due to prior health issues. Its established safety profile and effectiveness render it a popular option in handling such patients, when meticulous monitoring is crucial to mitigate any consequences.[10] Furthermore, labor induction procedures might differ markedly among distinct healthcare environments, necessitating an analysis of outcomes in diverse circumstances. Pakistan possesses a distinctive healthcare landscape marked by constrained resources, heterogeneous populations, and uneven degrees of healthcare accessibility. The efficacy of labor induction drugs may be affected by these elements; therefore, it is essential to comprehend the performance of misoprostol and dinoprostone within private healthcare environments in Pakistan.[11] Prior research has investigated the benefits and drawbacks of misoprostol and dinoprostone in various contexts; nevertheless, a significant portion of the existing studies concentrates on wider, global populations. Data regarding the utilization of these drugs in Pakistan is limited. The absence of dependable local data highlights the necessity for targeted research on the safety and effectiveness of misoprostol and dinoprostone within the private hospital context in Pakistan.[12] This study aimed to compare the effectiveness and safety of sublingual misoprostol with intravaginal dinoprostone for labor induction in a private hospital setting in Pakistan, which may enhance patient outcomes and provide valuable information for clinical practice.

METHODOLOGY

This study aimed to assess and contrast the safety and efficacy of two prevalent labor induction methods sublingual misoprostol and intravaginal dinoprostone in actual clinical environments. The research was performed in the Obstetrics Department at Maroof International Hospital in Islamabad, Pakistan, spanning 14 months from 1-August-2023, to 30-September -2024. Ethical approval for the study was granted by the hospital's Institutional Review Board (IRB) (Ref: RD 2023-10, dated 26-July-2023). All participants provided written informed consent prior to inclusion in the study.

The research comprised women aged 18 to 40 years with full-term singleton pregnancies in the vertex position, who were considered appropriate candidates for labor induction. The exclusion criteria included breech or atypical fetal presentations, fetal malformations, a history of uterine surgery, and women who declined participation throughout the research period. The inclusion and exclusion criteria were meticulously selected to provide a representative sample of pregnant women appropriate for labor induction in practical clinical environments.[13]

Participants were randomized into two groups using a simple randomization method. The ultimate analysis comprised 219 women from an original cohort of 270 recruited. Following the application of exclusion criteria, 120 women were administered sublingual misoprostol (50 mcg every 4 hours, up to 6 doses), whereas 99 women got intravaginal dinoprostone (3 mg every 6 hours), as determined by the attending obstetrician's clinical discretion. The primary outcomes were induction-to-delivery interval and mode of delivery (vaginal or cesarean).

The secondary outcomes included induction failure, maternal adverse effects (nausea, vomiting, gastrointestinal discomfort), and fetal distress. The subjects were not matched by age, parity, or Bishop Score, as the study sought to represent authentic therapeutic practice without artificial modifications.

The sample size was determined via the Raosoft sample size calculator (Raosoft, Inc., Seattle, WA, USA). Given an estimated population of 270, a confidence level of 95%, and a margin of error of 5%, the advised sample size was a minimum of 200 participants (100 per group) to identify statistically significant differences between the two groups in critical outcomes such as induction-to-delivery time, cesarean section rates, and incidence of side effects.[14] During the labor phase, essential data were gathered, encompassing the duration from induction to birth, the mode of delivery (vaginal or cesarean), and any difficulties, including fetal distress or emergency cesarean sections. Adverse symptoms, including nausea and emesis, were also documented. Data were gathered via the patients' electronic medical records and portable maternity notes, so assuring consistency and precision in the data collecting method. Statistical analysis was carried out in SPSS using the independent samples t-test and chi-square test, with a p-value of < 0.05 was considered statistically significant.

The study was executed in strict accordance with ethical norms, and all participants were apprised of the study's objectives and methodologies. Informed written permission

was acquired from all participants prior to their inclusion in the study, in compliance with ethical standards and institutional review board regulations.

RESULTS

A total of 219 patients were included in this study, with 120 patients receiving misoprostol and 99 patients receiving dinoprostone for labor induction. The analysis focused on the failure rate of induction, the induction-to-delivery interval, the rate of cesarean sections for fetal distress, and the reasons for induction. Below are the detailed findings.

The failure rates of labor induction were compared between misoprostol and dinoprostone. The results indicated that 15% of the patients who received misoprostol failed to induce labor as compared to 10% of patients that received dinoprostone. The failure rates were calculated and a chi-square test was used to determine if this difference was statistically significant. Although the failure rate was greater for misoprostol (15%) than for dinoprostone (10%), this difference was not considered statistically significant ($\div^2$ = 0.78, p = 0.38). Therefore, it would appear that both medications were similarly effective for labor induction in this study.

The average time from induction to delivery with misoprostol (8.4 hours) was significantly shorter than with dinoprostone (10.2 hours). An independent samples t-test confirmed this was statistically significant (t = -3.12, p = 0.002) indicating that misoprostol resulted in a faster labor induction than dinoprostone in this study.

Compared to the dinoprostone group (5%), the misoprostol group had a higher rate of cesarean sections performed because of fetal distress (12.5%). This result showed a marginally significant difference according to the chi-square test.

The incidence of cesarean sections due to fetal distress was higher in the misoprostol group (12.5%) compared to the dinoprostone group (5%). While this difference showed marginal statistical significance ($\div^2$ = 3.85, p = 0.05), further investigation is required to establish a definitive association between misoprostol administration and increased risk of fetal distress. Post-term pregnancy was the most frequent cause of induction, accounting for 40.4% of cases in the dinoprostone group and 41.6% of cases in the misoprostol group. The second most frequent indication in both groups was hypertension, which was marginally more common in the misoprostol group (25% vs. 20.2%).

With minor variations in the frequency of additional indications for labor induction, the two medications were mainly used for post-term pregnancy and hypertension. The reason for induction varied by drug, reflecting clinical preferences and patient characteristics.

In conclusion, misoprostol and dinoprostone had comparable failure rates; however, misoprostol was linked to a quicker induction-to-delivery period. Misoprostol also had a higher, though borderline significant, rate of cesarean sections for fetal distress. The primary reasons for induction in both groups were post-term pregnancy and hypertension. These results can aid in clinical decision-making, balancing the need for faster induction with potential risks of complications such as fetal distress.

DISCUSSION

In our study, misoprostol reduced the induction-to-delivery interval, but dinoprostone demonstrated greater safety with a lower incidence of maternal or newborn complications and cesarean deliveries. Despite misoprostol's greater incidence of side effects compared to dinoprostone, such as gastrointestinal complications and fetal distress, it is more cost-effective and simpler to administer for labor induction in our locality.

Misoprostol (PGE1) and dinoprostone (PGE2) are extensively utilized medicines for the induction of labor. These drugs primarily function by facilitating cervical ripening and stimulating myometrial contractions, hence playing a crucial role in human parturition.[15] Misoprostol, due to its cost-effectiveness, accessibility, and versatility in administration

Table 1: Comparison of Labor Induction Outcomes between Misoprostol and Dinoprostone

Values	Misoprostol	Dinoprostone
Total Patients	120	99
Failed Induction (N)	18	10
Failed Induction (%)	15%	10%
Average Interval (Hours)	8.4	10.2
Minimum Interval (Hours)	3	4
Maximum Interval (Hours)	18	20
C-Sections for Fetal Distress (N)	15	5
C-Sections for Fetal Distress (%)	12.5%	5%

Table 2: Reasons for Induction

Reason for Induction	Misoprostol (N)	Misoprostol (%)	Dinoprostone (N)	Dinoprostone (%)
Post-term pregnancy	50	41.6%	40	40.4%
Hypertension	30	25%	20	20.2%
Premature rupture of membranes	20	16.6%	10	10.1%
Fetal growth restriction	10	8.3%	15	15.1%
Other	10	8.3%	14	14.2%

routes, has demonstrated favorable outcomes in labor induction. Nonetheless, it is linked to a marginally elevated occurrence of fetal discomfort and gastrointestinal problems relative to dinoprostone, which is often delivered via the vaginal route. Nonetheless, dinoprostone demonstrates outcomes similar to misoprostol for induction-to-delivery duration, while exhibiting fewer adverse effects.[16]

The outcomes of our investigation corroborate these observations. Our findings indicate that misoprostol is linked to a markedly reduced induction-to-delivery interval (8.4 hours) in contrast to dinoprostone (10.2 hours), corroborating existing research that demonstrates misoprostol's efficacy in expediting labor.[17] Nonetheless, this benefit was accompanied by an increased occurrence of cesarean sections resulting from fetal distress (12.5%) in contrast to dinoprostone (5%). These findings correspond with a research done in Pakistan that compared misoprostol to PGE2 agents, revealing that misoprostol resulted in shorter induction-to-delivery intervals but was linked to increased adverse effects, including uterine hyperstimulation and fetal distress.[4,18]

Consistent with our data, a randomized controlled trial (RCT) performed in a Pakistani hospital, which compared misoprostol with dinoprostone in patients experiencing pre-labor rupture of membranes, revealed that the induction-to-delivery delay was reduced in the misoprostol cohort. The research further observed an elevated incidence of cesarean deliveries due to fetal distress in the misoprostol cohort, corroborating the results of our investigation.[19] Our study indicates that misoprostol is an effective and safe method for labor induction, however it is associated with a higher incidence of unfavorable outcomes compared to dinoprostone.

Our findings corroborate the conclusions of a comprehensive review and meta-analysis of eight randomized controlled trials involving 1,807 individuals, which determined that misoprostol is a safe and effective alternative to dinoprostone for facilitating vaginal delivery at term. The meta-analysis validated the shortened induction-to-delivery delay with misoprostol, aligning with our study's findings, which demonstrated that misoprostol considerably decreased the time to delivery in comparison to dinoprostone.[20]

Moreover, the results of our investigation aligned with an extensive review of randomized controlled trials concerning third-trimester induction, which included 31 active interventions. The research indicated that low-dose oral misoprostol exhibited the least likelihood of cesarean sections, while also noting that vaginal and buccal/sublingual misoprostol correlated with elevated rates of uterine hyperstimulation, a result consistent with our study's outcomes.[21] Our study noted a greater prevalence of uterine hyperstimulation in the misoprostol cohort compared to the dinoprostone group, indicating that the risk of adverse effects is a significant consideration when using misoprostol for labor induction.

A multi-center randomized controlled trial done at four university hospitals revealed that the cesarean section rate in the misoprostol group was 22.1%, in contrast to 19.9% in the dinoprostone group, with the misoprostol group exhibiting a considerably greater rate of vaginal deliveries within 24 hours (59.3% vs. 45.7%).[22] This study has some limitations. The study was conducted at a single facility, limiting the generalizability of the findings to other settings, particularly those with diverse healthcare systems. The study failed to control for variables that may influence the outcomes, such as maternal comorbidities or variations in therapy techniques, hence introducing confounding factors. The observational nature of the study indicates that randomization was impractical, resulting in potential bias. To corroborate these findings, more research with larger, multi-center designs and more robust controls is necessary.

CONCLUSION

When comparing misoprostol and dinoprostone, both demonstrated similar failure rates for labor induction, with misoprostol having a significant decrease in induction-to-delivery time. However, there was a concern of a higher, clinically borderline significant rate of c-sections for fetal distress associated with misoprostol that should be viewed cautiously in clinical practice. This data supports induction methods being individualized based on the degree to which rapid access to delivery is valuable against the risk of harm to the fetus.

LIMITATION

This study's findings should be interpreted with caution because it was conducted at a single center, limiting generalizability, and followed an observational, non-randomized design in which treatment choice depended on the attending obstetrician, introducing potential selection bias. Important confounding factors such as maternal age, parity, Bishop score, and comorbidities were not controlled or matched, and reliance on routinely recorded clinical data may have led to information bias. Although the sample size was adequate for primary outcomes, it may not have been large enough to detect differences in rare maternal or neonatal complications, further constraining the strength of the conclusions.

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Authors Contribution:
Gulafshana Hafeez Khan: Study design, data collection
Syeda Wajeeha Ojala Shah: Data collection, data analysis
Iqra Nadeem: Data interpretation, data analysis
Saima Iqbal: Drafting and data analysis
Rabia Saleem: Drafting and data collection
Zaeema Khalid: Data collection, critical review and approval

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