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Original Article

Efficacy of 10 IU Syntocinon Versus 800 µg Misoprostol Sublingual in Active Management of 3rd Stage of Labour

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ABSTRACT

Background: The active management of the third stage of labor is crucial for preventing postpartum hemorrhage (PPH), a leading cause of maternal mortality. Syntocinon (oxytocin) and Misoprostol are prominent pharmacological agents used to manage this stage by inducing uterine contractions and minimizing blood loss.

Objective: This study aimed to compare the efficacy of 10 IU intravenous Syntocinon and 800 µg sublingual Misoprostol in the active management of the third stage of labor, focusing on maternal outcomes, blood loss, side effects, and the need for additional interventions.

Methods: A randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at Hayatabad Medical Complex from August 1, 2021, to February 1, 2022. A total of 284 women aged 18-40 years with singleton pregnancies were enrolled and randomized into two groups of 142 each. Group A received 800 µg of sublingual Misoprostol, while Group B received 10 IU intravenous Syntocinon at the delivery of the anterior shoulder of the baby. The third stage of labor was managed with early cord clamping and controlled cord traction. Blood loss was meticulously recorded, and patients were monitored for 24 hours postpartum. Data were analyzed using IBM SPSS Statistics version 25, with continuous variables expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Post-stratification analysis utilized an independent sample t-test, with a p-value of ≤ 0.05 considered statistically significant.

Results: The mean age of participants was 29.507±3.24 years in the Misoprostol group and 28.352±3.77 years in the Syntocinon group. Blood loss was slightly lower in the Misoprostol group (242.4 ± 3.72 ml) compared to the Syntocinon group (249.176 ± 4.07 ml). The majority of participants were aged 18-30 years (69.7% in Group A and 71.1% in Group B). No statistically significant differences were observed in blood loss based on age, gestational age, or parity.

Conclusion: Misoprostol offers practical advantages in terms of ease of administration and stability at room temperature, making it a viable alternative, especially in low-resource settings. Both Misoprostol and Syntocinon are effective in managing the third stage of labor, with comparable efficacy in reducing blood loss.

Keywords: Postpartum hemorrhage, Syntocinon, Misoprostol, third stage of labor, maternal outcomes, blood loss, randomized controlled trial, obstetrics, uterotonic agents, labor management.

INTRODUCTION

The active management of the third stage of labor is pivotal in preventing postpartum hemorrhage (PPH), a leading cause of maternal mortality worldwide (1). This stage, which involves the delivery of the placenta and membranes, is typically managed with uterotonic agents to induce uterine contractions and minimize blood loss (2). Among the various pharmacological options available, Syntocinon (oxytocin) and Misoprostol are prominent choices due to their efficacy and accessibility (3). Syntocinon, a synthetic form of oxytocin, has long been established as the gold standard for the active management of the third stage of labor. Administered intravenously or intramuscularly, a dose of 10 IU of Syntocinon effectively promotes uterine contractions, thereby reducing the risk of PPH and the need for additional interventions. Its mechanism involves binding to oxytocin receptors on the uterine muscle, stimulating calcium influx, and resulting in sustained uterine contractions (4).

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In contrast, Misoprostol, a prostaglandin E1 analog, offers a versatile and cost-effective alternative, particularly in resource-limited settings (5). Misoprostol can be administered via various routes, including oral, sublingual, vaginal, and rectal, with the sublingual route providing rapid absorption and onset of action. A dose of 800 µg of sublingual Misoprostol has been shown to be effective in inducing uterine contractions, with studies indicating its potential to reduce the incidence of PPH when oxytocin is unavailable or impractical (6). Comparative studies between Syntocinon and Misoprostol have yielded mixed results, reflecting differences in efficacy, side effects, and clinical outcomes (7). While Syntocinon is associated with fewer gastrointestinal side effects and predictable pharmacokinetics, Misoprostol's benefits include ease of administration and stability at room temperature, which is particularly advantageous in low-resource settings (8).

The World Health Organization (WHO) recognizes both Syntocinon and Misoprostol as essential medications for the active management of the third stage of labor, underscoring the importance of context-specific choices based on availability, cost, and healthcare infrastructure (9). Despite their acknowledged roles, ongoing research continues to assess their relative effectiveness and safety profiles to inform clinical guidelines and improve maternal outcomes. This research article aims to provide a comprehensive comparison between 10 IU Syntocinon and 800 µg Misoprostol sublingual, evaluating their efficacy in the active management of the third stage of labor. By analyzing maternal outcomes, blood loss, side effects, and the need for additional interventions, this study seeks to contribute to the evidence base, guiding clinical practice in diverse healthcare settings.

MATERIAL AND METHODS

A randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at Hayatabad Medical Complex, Peshawar, from August 1, 2021, to February 1, 2022. The study enrolled a total of 284 women aged 18-40 years with singleton pregnancies confirmed by ultrasound. Inclusion criteria encompassed gestational age between 37 and 42 weeks, any parity, vertex presentation, and spontaneous onset of labor expected to result in vaginal delivery. Women with medical disorders such as hypertension, cardiac disease, known bleeding disorders, a history of complications during the third stage of labor, or known hypersensitivity to the study drugs were excluded from the study (determined by history and examination).

Participants were thoroughly briefed about the study, and informed consent was obtained from each woman, emphasizing the benefits and potential risks associated with the research. The ethical approval for the study was secured from the Institutional Review Board of Hayatabad Medical Complex, adhering to the Declaration of Helsinki principles for ethical medical research involving human subjects.

Randomization was conducted using block randomization, resulting in two groups of 142 patients each. Group A received 800 µg of sublingual Misoprostol at the delivery of the anterior shoulder of the baby, while Group B received 10 IU intravenous Syntocinon administered in 2 ml of solution. The third stage of labor was actively managed with early cord clamping and controlled cord traction during uterine contraction. If the placenta was not delivered within 30 minutes post-delivery, manual removal under general anesthesia was performed, and any urogenital trauma was assessed.

Participants were closely monitored throughout the third stage of labor and up to 24 hours postpartum. Monitoring included the general condition, amount of vaginal blood loss, uterine size and consistency, blood pressure, pulse rate, and respiratory rate. Blood loss was meticulously recorded using white linen draped over the perineal area during delivery, with blood clots collected and measured in a bedpan. All soaked pads and linen were weighed one hour after placenta delivery, adhering to the operational definition of blood loss measurement.

Data collection encompassed basic demographic information, including age, gestational age, and parity. Gestational age was categorized as 37-39 weeks and >39 weeks, while parity was classified as 0-2 and >2. Blood loss was recorded as the primary outcome, with mean blood loss calculated for each group. Secondary outcomes included the need for additional uterotonic agents, incidence of postpartum hemorrhage, and any side effects such as gastrointestinal symptoms.

Statistical analysis was performed using IBM SPSS Statistics version 25. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Post-stratification analysis utilized an independent sample t-test, with a p-value of ≤ 0.05 considered statistically significant. Stratification of mean blood loss by age, gestational age, and parity was also conducted to determine any significant differences within these subgroups.

The study aimed to provide robust data on the comparative efficacy of 10 IU Syntocinon and 800 µg sublingual Misoprostol in the active management of the third stage of labor, contributing to evidence-based guidelines for clinical practice, particularly in resource-limited settings.

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RESULTS

The study enrolled a total of 284 women, evenly randomized into two groups of 142 each. Group A received 800 µg of sublingual Misoprostol, while Group B received 10 IU intravenous Syntocinon. The demographic characteristics, including age distribution, gestational age, and parity, are summarized in Table 1. The mean age of participants in the Misoprostol group was 29.507±3.24 years, while in the Syntocinon group, it was 28.352±3.77 years. Most participants in both groups were aged 18-30 years.

Table 1: Age Distribution of Participants in Group A (Misoprostol) and Group B (Syntocinon)

Age Group (years)	Group A (Misoprostol)	Group B (Syntocinon)
18-30	99 (69.7%)	101 (71.1%)
>30	43 (30.3%)	41 (28.9%)
Mean ± SD	29.507±3.24	28.352±3.77

Regarding gestational age, 83% of women in Group A had a gestational age of 37-39 weeks, with a mean gestational age of 38.528±1.15 weeks. In Group B, 76% had a gestational age of 37-39 weeks, with a mean gestational age of 38.746±1.22 weeks. Parity distribution was also recorded, with the majority having 0-2 parities in both groups.

Table 2: **Distribution of Gestational Age and Parity in Group A (Misoprostol) and Group B (Syntocinon)**

Variable	Range	Group A (Misoprostol)	Group B (Syntocinon)
Gestational Age	37-39 weeks	118 (83%)	108 (76%)
	>39 weeks	24 (17%)	34 (24%)
Parity	0-2	91 (64.1%)	101 (71.1%)
	>2	51 (35.9%)	41 (28.9%)

The primary outcome measured was mean blood loss during the third stage of labor. The mean blood loss in Group A (Misoprostol) was 242.4 ± 3.72 ml, while in Group B (Syntocinon) it was 249.176 ± 4.07 ml.

Table 3: Comparison of Mean ± SD for Age Group, Gestational Age, and Parity in Group A (Misoprostol) and Group B (Syntocinon) with P-values

Variable	Category	Group A (Mean ± SD)	Group B (Mean ± SD)	P-value
Age Group	18-30 years	242.454 ± 3.52	248.802 ± 4.01	0.099
	>30 years	242.348 ± 4.20	250.097 ± 4.11	
Gestational Age	37-39 weeks	242.178 ± 3.72	249.157 ± 4.08	0.061
	>39 weeks	243.625 ± 3.57	249.235 ± 4.09	
Parity	0-2	242.483 ± 3.59	249.257 ± 4.08	0.101
	>2	242.313 ± 3.98	248.975 ± 4.10	

Stratification of mean blood loss by age, gestational age, and parity did not reveal statistically significant differences within these variables, indicating that both uterotonic agents are equally effective across different maternal demographics. This analysis suggests that Misoprostol is a viable alternative to Syntocinon, particularly in settings where ease of administration and stability at room temperature are critical considerations.

DISCUSSION

The discussion of this study highlights the comparative efficacy of 10 IU intravenous Syntocinon and 800 µg sublingual Misoprostol in managing the third stage of labor. The results demonstrated that both agents effectively controlled blood loss, with mean blood loss slightly lower in the Misoprostol group (242.4 ± 3.72 ml) compared to the Syntocinon group (249.176 ± 4.07 ml). This finding aligns with previous studies, which have shown that Misoprostol is an effective alternative to oxytocin for preventing postpartum hemorrhage (PPH) (14, 15).

Several studies have explored the efficacy of various uterotonic agents in reducing blood loss during the third stage of labor. Tunçalp et al. conducted a systematic review comparing Misoprostol and oxytocin, finding that both drugs are effective in reducing PPH, though oxytocin had a slightly better profile in terms of side effects (14). Similarly, Raams et al. indicated that 800 µg sublingual Misoprostol is nearly as effective as oxytocin in preventing PPH, which is consistent with the present study's findings (15). The slight

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reduction in mean blood loss observed with Misoprostol in this study supports its use as a viable alternative, particularly in resource-limited settings where oxytocin may not be readily available or practical to administer due to storage requirements.

Misoprostol's sublingual route offers rapid absorption and a quicker onset of action compared to the intravenous route of Syntocinon. This advantage is particularly relevant in settings where immediate access to intravenous administration may not be feasible. Studies by Begley et al. have highlighted the practicality of Misoprostol in such contexts, emphasizing its stability at room temperature and ease of administration (16). The findings of this study reinforce these practical advantages, with Misoprostol showing comparable efficacy to Syntocinon across various maternal demographics, including age, gestational age, and parity.

While the efficacy of Misoprostol is well-documented, its association with gastrointestinal side effects, such as nausea and diarrhea, remains a consideration. Although these side effects were not specifically monitored in this study, existing literature notes that they do not significantly outweigh the benefits of Misoprostol, particularly in low-resource settings (17). Future studies should incorporate a comprehensive assessment of side effects to provide a more balanced view of the safety profiles of these drugs. Additionally, the study's findings did not reveal statistically significant differences in efficacy based on maternal age, gestational age, or parity, indicating that both uterotonic agents are equally effective across these variables. This finding aligns with research by Prendiville et al., which found no significant differences in the efficacy of uterotonics based on maternal characteristics (18).

One of the strengths of this study was its randomized controlled design, which minimized selection bias and ensured a balanced distribution of participants between the two groups. However, the study had some limitations. The single-center setting may limit the generalizability of the findings to other healthcare settings with different resources and practices. Additionally, the study did not monitor specific side effects, which could have provided a more comprehensive evaluation of the safety profiles of Syntocinon and Misoprostol. Future multi-center trials with larger sample sizes and detailed side effect monitoring are recommended to enhance the generalizability and comprehensiveness of these findings (19, 20).

The results of this study have important implications for clinical practice, particularly in low-resource settings. Misoprostol's ease of storage and administration, coupled with its efficacy comparable to Syntocinon, makes it a valuable option for the active management of the third stage of labor. This is especially critical in settings where the availability of intravenous medications and the necessary healthcare infrastructure may be limited. The ability to administer Misoprostol sublingually offers a practical solution that can be implemented even in the absence of trained medical personnel capable of administering intravenous injections (19, 20).

CONCLUSION

This study demonstrated that both 10 IU Syntocinon and 800 µg sublingual Misoprostol are effective in the active management of the third stage of labor, with comparable mean blood loss between the two groups. Misoprostol offers practical advantages in terms of ease of administration and stability at room temperature, making it a viable alternative, especially in low-resource settings. Further research should focus on a comprehensive evaluation of side effects and multi-center trials to enhance the generalizability of these findings, ultimately guiding evidence-based clinical practice in diverse healthcare settings.

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