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COMPARATIVE EFFICACY OF SUBLINGUAL MISOPROSTOL VERSUS INTRAMUSCULAR OXYTOCIN IN TERM OF PREVENTION OF PRIMARY POSTPARTUM HEMORRHAGE

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Abstract

Background: *Numerous randomized trials have compared the use of uterotonic agents with placebo or other uterotonics. However, limited data exist regarding the relative efficacy of injectable oxytocin versus sublingual misoprostol in preventing postpartum hemorrhage. Furthermore, local studies comparing these two agents have yielded inconsistent findings.*

Objective: *To compare the efficacy of sublingual misoprostol and injectable oxytocin for the prophylaxis of primary postpartum hemorrhage.*

Material and Methods: *This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, Maula Bukhsh Teaching Hospital, Sargodha, Pakistan, over a period of six months following synopsis approval (February to August 2024). A total of 120 patients meeting the inclusion criteria were enrolled after approval from the institutional Ethical Review Board. Participants were randomly divided into two equal groups (n=60 each) using a computer-generated random number table. Group A received 600 µg of sublingual misoprostol, while Group B received 10 IU of intramuscular oxytocin. All patients were managed according to WHO guidelines, including controlled cord traction, fundal massage, and 24-hour postpartum monitoring. Blood loss was assessed using the gravimetric method with pre-weighed materials. Data were collected on a standardized proforma.*

Results: *The mean age was slightly higher in Group B (32.55 ± 7.45 years) compared to Group A (32.08 ± 7.29 years). The mean gestational age was comparable between Group A (38.57 ± 1.19 weeks) and Group B (38.52 ± 1.17 weeks). Among women in Group A, 33.3% had given birth once compared to 30% in Group B, while 41.7% in Group A and 33.3% in Group B had given birth twice. Group A had a higher percentage of participants with no history of abortion or stillbirth. With regard to efficacy, 90% of participants in the misoprostol group (Group A) achieved effective prophylaxis compared to 75% in the oxytocin group (Group B), demonstrating a statistically significant difference (p = 0.031). Stratified analysis further indicated that efficacy remained consistently higher in Group A across multiple subgroups, including older age categories, higher parity, and participants without a history of abortion or stillbirth.*

Conclusion: *This research indicates that sublingual misoprostol is often more efficacious than injectable oxytocin for the prevention of primary postpartum hemorrhage. With 90% of participants in the misoprostol group reporting positive outcomes compared to 75% in the oxytocin group, the findings suggest that misoprostol may be a preferable alternative for postpartum hemorrhage prophylaxis, particularly in resource-limited settings.*

Keywords: *Efficacy, Hemorrhage, Injectable, Misoprostol, Oxytocin, Prophylaxis, Postpartum, Primary, Sublingual*

INTRODUCTION

Approximately 287,000 women worldwide lose their lives each year during pregnancy, childbirth, or the first six weeks after delivery (the postpartum period) (1). About 85% of maternal fatalities occur in low- or middle-income countries, resulting from postpartum hemorrhage (PPH), post-delivery infections,

unsafe abortions, obstructed labor, and hypertensive disorders of pregnancy (2). PPH is the leading cause of maternal mortality and morbidity globally, accounting for nearly 25% of annual deaths (3).

The third stage of labor is often carefully monitored with the use of uterotonic drugs (4). An intramuscular injection of oxytocin, a hormone that promotes uterine contractions and reduces uterine bleeding, may be administered to the mother as soon as possible after birth to help prevent PPH (5). Multiple clinical trials have validated oxytocin formulations as key preventive agents for PPH (6). However, most oxytocin formulations are delivered by injection, necessitating sterile conditions and precise dosing (7). It was also previously thought that only trained personnel could administer intramuscular injections, and oxytocin requires cold storage, which limits its use in low- and middle-income countries. Consequently, misoprostol, a synthetic prostaglandin analog, has been promoted as an alternative strategy to prevent PPH in resource-limited settings (8).

Misoprostol is a methyl derivative of prostaglandin E1 that is extensively used as a uterotonic agent (9). It is available in tablet form for oral, rectal, vaginal, or sublingual administration. It offers several advantages over oxytocin, including oral administration and a prolonged shelf life at room temperature (10). When administered sublingually, misoprostol bypasses first-pass metabolism, resulting in a faster onset of action and increased bioavailability (11). Despite these advantages, most recommending organizations endorse sublingual misoprostol as a second-line option to injectable uterotonics due to insufficient or conflicting evidence regarding its effectiveness in the active management of the third stage of labor (12).

One study reported that PPH occurred within 24 hours in 26.6% of cases receiving misoprostol and 30.5% of those receiving oxytocin, with no significant difference between the groups ($p = 0.449$) (13). Numerous randomized trials have compared the use of uterotonics with placebo or other uterotonic drugs. Nevertheless, there is limited information on the relative effectiveness of injectable oxytocin and sublingual misoprostol for preventing postpartum bleeding. Furthermore, local studies comparing these two agents have yielded conflicting results. Therefore, comparing the efficacy of injectable oxytocin and sublingual misoprostol for primary PPH prevention is the motivation behind the present investigation. This research aims to compare the effectiveness of injectable oxytocin with sublingual misoprostol for primary postpartum hemorrhage prevention.

MATERIALS AND METHODS

This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, Maula Bukhsh Teaching Hospital, Sargodha, Pakistan. The investigation was carried out over a period of six months after the acceptance of the summary. The sample size of 120 (60 each group) is calculated based on 80% statistical power, a 5% significance level, and an assumed prevalence of postpartum hemorrhage (PPH) of 15.7% in the misoprostol group and 38.6% in the oxytocin group[1]. Sample selection was conducted using non-probability, sequential sampling. The operational definition said that inclusion criteria for female patients to have a full-term gestation (more than 37 weeks), and be aged between 18 and 45 years. The subsequent patients were excluded: individuals undergoing drug-induced or instrumentally assisted vaginal delivery; those with a history of previous cesarean sections; patients with bleeding disorders; individuals with uterine malformations; patients with polyhydramnios; individuals with intrauterine fetal demise; and those with medical conditions including pre-eclampsia, diabetes, or cardiopulmonary disorders. The postpartum hemorrhage was defined as a loss of blood > 500ml during first 24-hours of childbirth. Efficacy of treatment was labelled if the blood with in the first 24-hours after the <500ml i.e., absence of postpartum hemorrhage without need for additional Uterotonic.

After receiving written informed permission from each patient and receiving clearance from the institution's Ethical Review Board, a total of 120 patients who met the inclusion criteria were included to the research. By employing a computer-generated random number table, each female volunteer was assigned at random to one of two groups of equal size. 600 µg of sublingual misoprostol was given to Group A, whereas 10 IU of intramuscular oxytocin was given to Group B. The patients were treated in accordance with the World Health Organization (WHO) recommendations, namely by cutting and clamping the umbilical cord 1-3 minutes post-delivery. Controlled cord traction was used until the expulsion and delivery of the

placenta. A minimum of fifteen seconds was dedicated to bimanually rubbing the uterine fundus. The third stage of labor was quantified by total duration. The placenta was manually removed if it was not expelled within thirty minutes post-delivery. Blood loss was assessed with gravimetric method using pre-weighed sanitary pads and Swabs. Following the severance and clamping of the cord and the full evacuation of the amniotic fluid, the assessment of blood loss commenced. Blood loss estimation was conducted for one hour, with vigilant monitoring for further bleeding maintained until 24 hours post-delivery. When the ensuing hemorrhage was considered excessive, further oxytocin were provided. The blood gathered on the sanitary towel, and the volume was evaluated according to the operational criteria. All swabs used in the third stage had their dry weight assessed and recorded. An intravenous infusion of 80 IU oxytocin in 1000 ml saline solution was administered over 4 hours to any patient, irrespective of the assigned trial group, if the uterus was not fully contracted or if there was substantial vaginal bleeding following fetal delivery (initial supplemental Uterotonic treatment). If bleeding continued after oxytocin infusion or an atonic uterus was detected, an intramuscular dose of Methylergometrine maleate 0.2 mg was given as a second supplemental Uterotonic.

DATA ANALYSIS

SPSS version 25.0 was used for the analysis of the data. Quantitative information such as age, gestational age, parity, the number of abortions, and stillbirths were provided using the mean and standard deviation. Frequency and percentages were used to present qualitative data, including the intervention's success. The Chi-Square test was used to compare the effectiveness of two groups. The data was categorized by age, gestational age, parity, number of abortions, and stillbirths. A post-stratification chi-square test was conducted, with a significance threshold set at a p-value of ≤0.05.

RESULTS

Patients in groups A (sublingual misoprostol) and B (intramuscular oxytocin) had respective mean ages of 32.55±7.45 and 32.08±7.29 years respectively. Women in Groups A and B had mean gestational ages of 38.57±1.19 and 38.52±1.17 months respectively. In Group-A, 20 (33.3%) have given birth once, compared to 18 women (30%) in Group-B. This results in a combined total of 38 women (31.7%) who have given birth once across both groups. For women who have given birth twice, Group-A has 25 women (41.7%), while Group-B has 20 women (33.3%); together, they account for 45 women (37.5%) in the study. When looking at women who have given birth three times, Group-A includes 10 women (16.7%), whereas Group-B includes 19 women (31.7%); the combined total for this parity status is 29 women (24.2%). Lastly, for women who have given birth four times, Group-A has 5 women (8.3%) and Group-B has 3 women (5.0%), making a total of 8 women (6.7%) with this parity status.

Table I. Baseline demographic and obstetric characteristics of study participants in group A and group B

Parameter	Group-A (sublingual misoprostol)	Group-B (intramuscular oxytocin)
Mean age of patient	32.55±7.45 Years	32.08±7.29 Years
Mean gestational ages	38.57±1.19 Months	38.52±1.17 Months
Primigravida	20 women (33.3%)	18 women (30%)
Second pregnancy	25 women (41.7%)	20 women (33.3%)
Third pregnancy	10 women (16.7%)	19 women (31.7%)
Fourth pregnancy	5 women (8.3%)	3 women (5.0%)

Table II gives the stratified comparison of efficacy between sublingual misoprostol and intramuscular oxytocin across different patient parameters. With respect to age, both groups showed comparable efficacy in the 18–30 years category (84.6% vs. 84%, p=0.952) and in patients older than 40 years (85.7% vs. 80%, p=0.761), indicating no statistically significant difference. However, in the 31–40 years age group, sublingual misoprostol demonstrated significantly better efficacy (96.3%) compared to oxytocin (64%) with a statistically significant value (p=0.003).

Considering the gestational age, efficacy was higher with misoprostol in both categories. Although the difference was not statistically significant at 37–38 weeks (p=0.275), a significant difference was observed

at 39–40 weeks, where misoprostol showed superior efficacy (p=0.018). In terms of history of abortions, among patients with no prior abortions, misoprostol showed significantly higher efficacy (92% vs. 75%, p=0.023). However, in patients with one previous abortion, the difference between the two groups was not statistically significant (p=0.78). For history of stillbirth, although misoprostol consistently showed higher efficacy in both categories (no history and one stillbirth), the differences were not statistically significant (p=0.070 and p=0.154, respectively).

Overall, sublingual misoprostol demonstrated consistently higher efficacy across most subgroups, with statistically significant superiority in selected categories, particularly in patients aged 31–40 years, gestational age 39–40 weeks, and those with no history of abortion.

Table II. Stratified Analysis of Efficacy of According to Patient Characteristics in Group A and Group B

	Efficacy	Group-A Sublingual misoprostol	Group-B Intramuscular oxytocin	p-value
		60	60	
Age				
18-30 Years	Yes	20(84.6%)	21(84%)	0.952
	No	4(15.4%)	4(16%)	
31-40 Years	Yes	26(96.3%)	16(64%)	0.003
	No	1(3.7%)	9(36%)	
>40 Years	Yes	6(85.7)	8(80%)	0.761
	No	1(14.3)	2(20%)	
Gestational age				
37-38 Weeks	Yes	23(%)	20(%)	0.275
	No	6(%)	10(%)	
39-40 Weeks	Yes	31(%)	25(%)	0.018
	No	0(%)	5(%)	
Abortions				
None	Yes	46(92%)	36(75%)	0.023
	No	4(8%)	12(25%)	
1	Yes	8(80%)	9(75%)	0.78
	No	2(20%)	3(25%)	
Still birth				
None	Yes	49(89.1%)	41(75.9%)	0.070
	No	6(10.9%)	13(24.1%)	
1	Yes	5(100%)	4(66.7%)	0.154
	No	0(0%)	2(33.3%)	

DISCUSSION

When traditional uterotonics are unavailable or unsuitable, misoprostol is recommended by the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization (WHO) as a useful agent for managing postpartum bleeding (14). Our research demonstrated substantial evidence for the effectiveness of sublingual misoprostol, showing a significantly lower incidence of PPH compared to intramuscular oxytocin (p = 0.031). The findings of our study demonstrate that sublingual misoprostol is more effective than intramuscular oxytocin in the prevention of primary postpartum hemorrhage. Overall efficacy was significantly higher in the misoprostol group compared to the oxytocin group (90% vs. 75%, p=0.031). Stratified analysis further revealed that this superiority was particularly evident among women aged 31–40 years and those with a gestational age of 39–40 weeks, where statistically significant differences were observed.

However, our findings contrast with several previous studies. Mishra et al. concluded that misoprostol is less effective than oxytocin in managing the third stage of labor (15, 16). Takang et al. reported that the incidence of PPH was 26.6% in the misoprostol group and 30.5% in the oxytocin group, with no statistically significant difference (RR = 0.87, p = 0.449; absolute risk difference 3.9%) (17). Conversely, Bellad *et al.*, 2012 and Rajaei et al. (2014) demonstrated that misoprostol was significantly more effective than oxytocin (18, 19). Additionally, no significant difference was observed in the incidence of severe PPH (hemoglobin change ≥2 g/dL, approximately equivalent to blood loss of ≥1000 mL) between the misoprostol group (1.9%) and the oxytocin group (3.2%), with a relative risk of 0.6 (p = 0.723; absolute risk

difference 1.3%). Similar findings were documented by Mohammad *et al*., 2016 in Nigeria and Atukunda *et al.,* 2014 in Uganda (20, 21).

The inconsistencies between our study and others may be explained by differences in PPH measurement methodologies. Many previous studies relied on birth attendants' visual estimation of blood loss during delivery, which is highly subjective. Another potential explanation is that the majority of our study was conducted at a teaching hospital, which serves as the principal referral institution for the region, potentially introducing selection bias.

Several studies have reported that the misoprostol group experienced a higher incidence of side effects compared to the oxytocin group, including fever and tremors (22,23). However, in our study, at the given dose, none of the aforementioned side effects were observed (24). Mukta and Sahay reported that the misoprostol group had a mean blood loss that was 15.9% higher than that of the oxytocin group, although this difference was not statistically significant (25). In contrast, our study found that sublingual misoprostol was associated with significantly lower mean blood loss compared to injectable oxytocin. Mishra et al. identified statistically significant differences in their results, which is likely attributable to variability in sample size (25, 26).

Furthermore, one study demonstrated an 8% incidence of PPH in the misoprostol cohort compared to 6% in the oxytocin cohort, with a higher proportion of misoprostol recipients requiring additional uterotonic agents (22%) versus the oxytocin group (16%) (27). Although no statistically significant difference was found between the two groups, the misoprostol group had a higher risk of PPH. Conversely, Ghafoor et al. reported that both agents were equally effective in preventing PPH (28).

A Cochrane review evaluating the use of prostaglandins for PPH prevention concluded that misoprostol is not superior to standard injectable uterotonics for managing the third stage of labor, particularly in low-risk women. This analysis included data from 72 studies involving 52,678 women (29). Another study reported that the classic uterotonic regimen (intramuscular oxytocin), which is recommended for active management of the third stage of labor, is significantly more effective than sublingual misoprostol in preventing PPH. Prior studies conducted in low-resource countries such as India, Pakistan, and Nepal have primarily focused on misoprostol's affordability, ease of administration, and convenient storage. These factors have promoted its use in pilot studies; however, misoprostol was shown to be equally as effective as oxytocin (30-34).

Limitations of the study: The findings of this study may be interpreted with caution due to few limitations. The relatively small sample size and single-center study may limit the statistical power and generalizability of the results. Although blood loss was assessed using the gravimetric method, some degree of inaccuracy cannot be excluded.

CONCLUSION

In this study, sublingual misoprostol demonstrated higher efficacy than intramuscular oxytocin in the prevention of primary postpartum hemorrhage. Further large-scale, multicenter randomized trials are required to validate these results and establish the role of misoprostol as a preferred alternative in routine clinical practice.

Conflict of interest:

Authors declared no conflict of interest.

Authors' contribution:

RN Data collection and interpretation; HA Conceptualization, study design, critical review and supervision; AN Data analysis; MQ Statistical analysis; SAM Data analysis and critical review.

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