

Comparison of the Effectiveness of Rectal Misoprostol with I/V Oxytocin in Prevention of Postpartum Hemorrhage

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Abstract

Objective: Prevention of Postpartum Hemorrhage (PPH) was evaluated by comparing the efficacy of rectal misoprostol with intravenous oxytocin in a tertiary-care obstetric setting.

Methodology: This prospective, randomized controlled trial (RCT) was conducted at Obstetrics and Gynecology Department of Jinnah Postgraduate Medical Center, Karachi, from June 2025 to December 2025. Pregnant women aged 15 to 40 years, gestational age > 37 weeks, with singleton live pregnancy and duration of labour of 24 hours, parity of less than 5 kids, who were scheduled for normal vaginal deliveries with induced labour, spontaneous labour or augmented labour, without clinical evidence of active antepartum hemorrhage and preoperative hemoglobin level of ≥ 10 g/dL were included. Patients were subsequently allocated equally into the two treatment groups (A& B). Patients of group A received rectal misoprostol 600 μ g and the patients of group B received intravenous oxytocin 10 IU only. Total blood loss was assessed immediately after delivery using a calibrated collection container and by weighing blood-soaked pads/gauze. Subsequently women were monitored for 24 hours for further evidence of postpartum bleeding, and a volume of >500 mL of blood loss was considered as PPH. SPSS version 26 was used for data analysis.

Results: All the enrolled patients (50 misoprostol, 41 oxytocin) showed comparable baseline demographic and obstetric characteristics between groups ($p > 0.05$). The misoprostol group found with significantly reduced PPH incidence (2.0% vs. 14.6%) and mean blood loss (299.9 ± 80.4 mL vs. 408.6 ± 125.4 mL) compared to oxytocin group ($p < 0.05$), with less mechanical procedures need and transfusions rate (2.0% and 9.8%). Conversely the misoprostol administration was linked to a higher rate of non-significant side effects including fever, shivering and the gastrointestinal side effects ($p > 0.05$). The mean blood loss was differed significantly according to age groups ($p = 0.038$), being highest in the 25–35 years, while incidence of PPH incidence and hemoglobin levels showed insignificant age-related association ($p > 0.05$).

Conclusion: Rectal administration of misoprostol showed more hemostatic efficacy in the prevention of postpartum bleeding, whereas oxytocin appears to carry a more favorable short-term tolerability profile.

Keywords: Misoprostol; Oxytocin; PPH; Vaginal delivery, Prevention.

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Introduction

The maternal mortality remains particularly high in the developing and limited resources counties, where majority of maternal deaths occurred, mostly because of poor access to timely and quality maternal

healthcare. The PPH remains as the leading cause of maternal death and morbidity throughout the world, contributing to over a quarter of all maternal deaths per year.¹ Based on the WHO data, PPH accounts for

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around 60% of maternal deaths in the developing nations, resultant in more than 100,000 maternal deaths annually throughout the world.^{1,2} It is defined as the blood loss exceeding 500 mL after vaginal delivery, or more than 1000 mL following the cesarean delivery and alternatively, it can be defined as any degree of postpartum bleeding per vaginal sufficient to cause imbalance in vital signs or the hemoglobin drop of 10% or more from the baseline.¹ Based on mode of delivery it is a significant complication of labour and delivery, with estimated incidence around 2–4% following the vaginal delivery and approximately 6% following the cesarean delivery.³

During physiological alterations during pregnancy including increased uterine blood flow of up to 700 mL/min along with postpartum hemostatic mechanisms such as myometrial contraction and local decidual factors, can lead to significant bleeding and PPH if these mechanisms fail, particularly in women with the above-mentioned risk factors.⁴ In Pakistan, according to a comparative analysis of national surveys of 2007 and 2019, reported PPH continued to be the leading contributor to maternal mortality, approximately for 41% of deaths.⁴ Moreover worldwide the PPH claims as causative factors for around 70,000 maternal death annually corresponding to one maternal death from PPH occurring roughly every eight minutes.⁵

Based on this persistent burden, active management of the 3rd stage of labor with a uterotonic agent is suggested as the cornerstone prevention of PPH. During 2023, the WHO and other organizations launched the Roadmap to Combat Postpartum Hemorrhage (2023–2030), as a unifying global strategy to enhance the progress in research of PPH, clinical guidance, and the implementation.^{7,8} Although the intravenous oxytocin remains the standard first-line uterotonic in most health facilities, due to its proven efficacy, safety, and cost-effectiveness; however, its heat sensitivity limits its use in low-resource settings that lack cold-chain infrastructure.⁹ However the misoprostol, a prostaglandin E1 analogue, serves as an alternative that is heat-stable and easier to administer, but it is associated with side effects including fever, shivering, and gastrointestinal symptoms.¹⁰

Certain recent comparative evidence remains controversial, as few trials reported that the misoprostol reduces the incidence of significant bleeding rate more effectively compared to the oxytocin,⁹ whereas others find comparable effectiveness between these two

agents, with misoprostol linked to a higher rate of side effects including shivering and pyrexia.^{11,12} However, these adverse effects, such as shivering, fever, and gastrointestinal side effects, are typically mild, self-limiting, and do not require specialized personnel for drug administration. Moreover, many studies have shown that oxytocin is a preferred uterotonic¹³, and according to a national study, the rectal misoprostol is more effective than oxytocin.¹⁴ Based on this inconsistency across the studies and dosing protocols, along with very limited comparative data from local/regional obstetric populations, emphasizes a gap in context-specific evidence required to guide the routine practice. Therefore, this study was conducted to compare the effectiveness of rectal misoprostol with intravenous oxytocin in preventing PPH among women undergoing normal vaginal delivery, with aimed to generating a more relevant evidence to the local clinical protocols and contribution in the broader global efforts to reduce preventable PPH-associated maternal morbidity and mortality.

Methodology

This was a prospective, randomized controlled trial (RCT) conducted at Obstetrics and Gynecology Department of Jinnah Postgraduate Medical Center (JPMC). Study was conducted after IRB approval from Jinnah Postgraduate Medical Center Karachi (F.2-81/2025-GENL/329/JPMC), with duration of six months from June 2025 and December 2025. All the pregnant women aged 15 to 40 years, gestational age ≥ 37 weeks, with singleton live pregnancy and duration of labour of 24 hours, parity of less than 5 kids, who were scheduled for normal vaginal deliveries with induced labour, spontaneous labour or augmented labour, without clinical evidence of active antepartum hemorrhage and preoperative hemoglobin level of ≥ 10 g/dL were included. On the other hand pregnant women who underwent instrumental delivery or cesarean section, secondary PPH with cardiac disease or on anticoagulant therapy, and bleeding disorders with uterine anomalies or fibroids distorting the uterine cavity were excluded from the study. A convenience sampling technique was employed. A written informed consent was obtained from each participant prior to their enrollment in the study, after explaining the purpose of study and procedure of study. Participants were informed that they are voluntary and they could withdraw at any time without any effect on their management care. Patients were randomly allocated in

two groups using randomization method like sealed envelope. Unfortunately, few patients of oxytocin group could not be followed up for the full 24 hours post-delivery, and some declined participation at the time of the data collection, therefore the 41 evaluable cases in the oxytocin group compared to 50 patients in the misoprostol group. Women of group A received 400–600 µg of rectal misoprostol immediately after delivery of the baby, whereas the women of group B given 10 IU of intravenous oxytocin as part of standard active management of the third stage of labor, with the uterotonic agent being the only variable differing between groups. Instantly following the delivery, blood loss was measured using a calibrated collection container placed to directly capture the blood loss, supplemented by weighing the blood-soaked pads and gauze, and the total volume of the blood loss was documented in milliliters for each patient.

Consequently, all the women were monitored for 24 hours following the delivery for any further evidence of postpartum bleeding, and a total blood loss exceeding 500 mL within the period was considered as PPH. Additionally the hemoglobin and hematocrit levels were measured before the deliveries in all women and after delivery repeated after 24 hours postpartum to confirm the estimated blood loss and to assess the clinical impact. The secondary outcomes were recorded in terms of requirement of additional uterotonic agents, need of blood transfusions and any drug-related side effects including shivering, fever and gastrointestinal side effects. All the relevant data were recorded by study proforma. Afterward the data were entered and analyzed using SPSS version 24. The quantitative variables were reported as median (IQR), while the qualitative data were presented as frequencies and percentages. The Chi-square test was applied to evaluate the efficacy between categorical variables of two groups, taking a p-value <0.05 as statistically significant.

Results

Overall 91 patients were comparatively enrolled after adjusting the sample size, with almost similar median parity (1 versus 3) and median gestational (38 versus 39 weeks), without significant difference ($p>0.05$). The age groups of the patients were also comparable across the groups falling in the 18–25 or 25–35 year range, without significant difference ($p=0.25$). The spontaneous labor being the most common in both misoprostol (84%) and oxytocin (78%) patients, followed by induced and augmented labor, also did not showed the significant difference across the groups ($p=0.78$), as presented in table I.

The blood loss (>500 mL) following the vaginal deliveries was significantly lower in misoprostol groups (only in one patient (2% out of 50), compared to oxytocin group, in around 06 (14.6%) patients ($p=0.02$). Additionally, the requirement of mechanical procedure and blood transfusion were markedly higher in patients of oxytocin group compared to misoprostol (12.2% and 9.8%) and (4.0% and 2.0%) respectively, while the difference was statistically insignificant ($p>0.05$).

However, the side effects showed a different pattern as the dizziness rate was higher in oxytocin groups (9.8% vs. 2.0%, $p=0.106$), whereas the fever, shivering, and gastrointestinal side effects were all more frequent in the misoprostol group (14.0% vs. 4.9%, 22.0% vs. 9.8%, and 20.0% vs. 7.3%) correspondingly, while the difference was statistically insignificant across the groups ($p>0.05$). Table II.

The blood loss outcomes did not significantly vary across the different age groups for PPH incidence ($p=0.270$), pre-Hb ($p=0.140$), or post-Hb ($p=0.248$). Nevertheless, the mean blood loss was significantly different across age groups ($p=0.038$), being raised in the 25–35 years' group (376.03 ± 122.7 mL) compared to the women aged >35 years of age (242.54 ± 59.3 mL). Table III

Table I: Comparative analysis between groups for demographic and obstetric Characteristics. (n=91)

Patient Characteristics		Misoprostol n=50	Oxytocin n=41	P-value
Parity		1 (0-3)	3 (1-4)	0.1***
Gestational age		38 (37-39)	39 (38-40)	0.2***
Age groups	18-25 years	31 (62)	19 (46.3)	0.25*
	25-35 years	16 (32)	20 (48.8)	
	>35 years	3 (6)	2 (4.9)	
Labor type	Spontaneous	42 (84)	32 (78)	0.78*
	Induced	5 (10)	6 (14.6)	
	Augmented	3 (6)	3 (7.3)	

***Mann-Whitney U Test, *Fisher's Exact Test

Table II: Comparative analysis for clinical and outcome characteristics. (n=91)

Patient Characteristics		Misoprostol (n=50)	Oxytocin (n=41)	P-value
Mechanical Procedure	Yes	2 (4.0%)	5 (12.2%)	0.144**
	No	48 (96.0%)	36 (87.8%)	
Blood Transfusion	Yes	1 (2.0%)	4 (9.8%)	0.106**
	No	49 (98.0%)	37 (90.2%)	
Side Effect	Dizziness	Yes	4 (9.8%)	0.106**
		No	37 (90.2%)	
	Fever	Yes	2 (4.9%)	0.147**
		No	39 (95.1%)	
	Shivering	Yes	4 (9.8%)	0.117**
		No	37 (90.2%)	
	Gastrointestinal side effects	Yes	3 (7.3%)	0.058**
		No	38 (92.7%)	
Blood loss	<500ml	49 (98)	35 (85.4)	0.02**
	≥500ml	01 (2.0)	06 (14.6)	
Mean pre-Hb level		11.17±0.77	11.25±0.84	0.001*
Mean post-Hb level		10.43±1.06	9.91±0.82	0.661*
Mean blood loss (ml) (mean ±SD)		299.9±80.37	408.6±125.44	0.010*

**Chi-Square Test, *independent, t-test

Table III: Blood loss outcomes according to different age groups. (n=91)

Variables		Age groups				p-value
		18-25	25-35	35-45	Total	
Blood loss category	≥500 ml	02	04	01	07	0.270
		4.0%	11.1%	20.0%	7.7%	
	<500 ml	48	32	04	84	
		96.0%	88.9%	80.0%	92.3%	
Mean pre-Hb level		11.14 ± 0.78	11.37 ± 0.80	10.70 ± 0.96	11.21 ± 0.80	0.140
Mean post-Hb level		10.18 ± 0.81	10.32 ± 1.11	9.54 ± 1.32	10.20 ± 0.97	0.248
Mean blood loss (ml) (mean +SD)		340.01±109.22	376.03±122.7	242.54 ± 59.3	348.90 ± 116.0	0.038

Table IV: Blood loss outcomes according to types of labour. (n=91)

Variables		LABOR TYPES				p-value
		Spontaneous	Induced	Augmented	Total	
Blood loss category	≥500 ml	02	04	01	07	0.670
		4.0%	11.1%	20.0%	7.7%	
	<500 ml	48	32	04	84	
		96.0%	88.9%	80.0%	92.3%	
Mean pre-Hb level		11.18 ± 0.81	11.04 ± 0.82	11.85 ± 0.51	11.21 ± 0.80	0.109
Mean post-Hb level		10.13 ± 0.98	10.25 ± 0.99	10.93 ± 0.40	10.20 ± 0.97	0.145
Mean blood loss (ml) (mean +SD)		354.02 ± 117.77	331.25±97.01	318.13 ±137.78	348.90 ±116.0	0.668

Moreover, the blood loss outcomes did not significantly different across the types of labour ($p>0.05$) as presented in table IV.

Discussion

The PPH possess a major threat to the maternal health, making the choice of an effective and practical uterotonic agent a critical clinical decision, specifically in limited resource health settings. This study compares the blood loss prevention and adverse effects among women administered misoprostol (group 1) or oxytocin (group 2).

In this study the rectal administration of misoprostol significantly reduced PPH incidence (2.0% vs. 14.6%), $p=0.02$, and mean blood loss (299.9 ± 80.4 mL vs.

408.6 ± 125.4 mL), $p=0.010$, compared to oxytocin I/V administration, with less need of mechanical procedures and transfusions needed ($p>0.05$). A study by Lashin et al¹⁵ contradicted our study, reporting that the blood loss in the oxytocin-administered group was less in the oxytocin group and higher in the misoprostol group (457.4 ± 4.1 mL vs. 511.9 ± 6.2 mL). While other studies reported similar results, Abdelaleem et al¹⁶ reported reductions in blood loss with intrauterine misoprostol compared with intravenous oxytocin. The same study reported that both groups experienced a statistically significant postoperative decline in hematological measurements. The hemoglobin related findings of this study were further supported by a recent trial, where postoperative hemoglobin and hematocrit levels at different follow up times were significantly

higher in the misoprostol-supplemented groups compared with oxytocin alone ($p=0.001$).¹⁷

Consistently, a study on women with pre-eclampsia undergoing C-cesareans, reported a hemoglobin levels at 6 hours following the delivery were significantly lower in the group of oxytocin (10.39 g/dL) inconstant to the rectal misoprostol group (10.92 g/dL), along with significantly higher need of blood transfusion in the oxytocin group, compared to misoprostol group with avoiding transfusion rate around (65.1% vs 90.5%) respectively,¹⁸ as observed in this study. Consistent with the findings of this study, an Iranian double-blind RCT of 400 vaginal delivery women reported the rate of bleeding >500 cc significantly higher in the oxytocin group compared to the misoprostol group (33% vs. 19%), ($p=0.005$), subsequently with greater hematocrit decline in the oxytocin arm, a direction of effect that matches to this study.¹⁹ On the other hand a similar trend was observed by a RCT which similarly reported that blood loss quantity was raised in the oxytocin group compared to misoprostol, while in that trial the variations of hemoglobin/hematocrit decline between groups were statistically insignificant.²⁰

Additionally, in this study, women administered misoprostol had significantly higher adverse effects as compared to the group treated with oxytocin. The majority of the women in the group treated with misoprostol had experienced shivering, fever, dizziness, and gastrointestinal symptoms. Similarly, previous studies have linked the misoprostol group with side effects. A study reported that the majority of the women with misoprostol had symptoms of shivering, as compared to the oxytocin group (23.6% vs. 13.1%). The symptoms of shivering and fever in the misoprostol group are associated with the dose of the drug, and these symptoms were observed in 30–70% of cases. In the oxytocin group, the symptoms of headache and vomiting were frequent.¹⁶

In our study, the misoprostol was more effective than oxytocin, as results showed the patients in the misoprostol group had minimal blood loss. While the side effects were less common in the patients administered oxytocin, the results showed that patients were more tolerable to oxytocin as compared to the other group. In earlier studies, the adverse effects were observed in patients who were administered misoprostol and oxytocin in combination. A significant relative risk ratio of 2 was reported, demonstrating that patients administered with both misoprostol and

oxytocin in combination had twice the likelihood of experiencing side effects as compared with pregnant women administered with only oxytocin ($p < 0.001$; $RR = 2.000$). As fever and shivering are not recognized as adverse effects of oxytocin by the WHO and UNICEF, these findings are attributable to misoprostol. Similar observations have been reported in other studies, which also noted dose-dependent increases in shivering and pyrexia with misoprostol.²¹

Collectively the misoprostol appears effective in the PPH prevention among women undergoing vaginal – sections with some higher rate of temporary side effects compared to oxytocin, across the reviewed studies. Some the significance of overall findings varied across the studies, likely due to variations in dosage of misoprostol, its route of administration, and a significant different in sample size of studies, as this study, being carried out on a relatively limited sample size, along with other limitations including lack of dose comparison and route-of-administration comparison. Consequently, further large-scale, multi-center trials with standardized dosing and administration protocols are endorsed specifically at local level to confirm and strengthen the evidence.

Conclusion

Rectal misoprostol administration observed to be more effective compared to intravenous oxytocin in reducing the incidence of PPH and mean blood loss after normal vaginal delivery, with less mechanical procedures need and transfusions rate. However, it showed some higher but statistically non-significant rate of temporary side effects including fever, shivering, and gastrointestinal side effects. Moreover, based on low cost, heat stability, and easy to administration, the misoprostol represents as an effective alternative to oxytocin specifically in resource-limited health settings sustaining its wide use in prevention of PPH prevention. However, based on certain study limitations, further larger multi-center trials are recommended to validate the findings and to create the more robust local evidence, regarding PPH prevention.

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