ORIGINAL ARTICLE

A Randomised Controlled Study on the Effectiveness of Oral versus Rectal Misoprostol as Adjunct for Prevention of Primary Postpartum Haemorrhage at the University of Maiduguri Teaching Hospital, Maiduguri, Nigeria

Mba PC,[1] Katagum DA,[2] Mandara MU,[3] Bako B[3]

ABSTRACT

Background: Misoprostol is administered either orally or rectally as an adjunct to oxytocin in the active management of the third stage of labour in high-risk patients to prevent primary postpartum haemorrhage (PPH). **Objectives:** The objective of this study was to evaluate the effectiveness, safety and participants' satisfaction of oral versus rectal misoprostol administration during the third stage of labour for the prevention of primary PPH at the University of Maiduguri Teaching Hospital. **Methods:** A randomised controlled trial was conducted amongst 206 consenting participants in the active phase of labour at UMTH. After delivery of the baby, active management of the third stage of labour (AMTSL) was initiated with intramuscular oxytocin and misoprostol. Participants in group I received 600 micrograms of misoprostol orally while participants in group II received 600 micrograms of misoprostol rectally. Blood loss was measured and analysed using IBM SPSS version 25. Variables were presented as median ± IQR, proportions and percentages. Chi-square and Mann-Whitney U- test were used as appropriate. A p-value <0.05 was considered statistically significant. **Results:** Median blood losses were similar in both groups. The median blood loss in group I was 247(172-368) ml and that in group II was 253(192-354) ml. There was no statistically significant difference in both groups with respect to median blood losses (P=0.431). The incidence of primary PPH was 5.3% in group I and 9.4% in group II (P=0.285). Shivering occurred in 54.3% of the participants in group I and in 28.1%of participants in group II. Also, fever was detected in 28.7% of participants in group I and in 15.6% of participants in group II. There were statistically significant differences between the participants in both groups in terms of the occurrence of shivering and fever. Only 1% of the participants experienced allergic reactions. The majority of the participants (79.8% in group I and 88.5% in group II) expressed satisfaction with the route of administration of misoprostol received during the study, with p-value =0.098. Similarly, most of the participants in both groups expressed willingness to choose the same route of administration for future deliveries (91.5% for the oral route and 92.7% for the rectal route; p-value=0.755). **Conclusion:** Adjunct misoprostol use in the third stage of labour to prevent PPH is effective and safe, with tolerable side effects and significant patient satisfaction. Both routes of administration were acceptable to the patients; there was no preference for one route over the other. We recommend that women be given the options and asked to choose their preferred route of administration of misoprostol as an adjunct for AMTSL

Key words: Adjunct misoprostol, Maiduguri, Oral routes, Prevention, Primary postpartum haemorrhage, rectal route.

[1] Department of Obstetrics & Gynaecology, University of Maiduguri Teaching Hospital
[2]. Department of Obstetrics & Gynaecology, Federal University of Health Sciences Teaching Hospital Azare, Bauchi State
[3]. Department of Obstetrics & Gynaecology, College of Medical Sciences University of Maiduguri Borno State, Nigeria

Corresponding Author:
babaganabako@gmail.com, Department of Obstetrics & Gynaecology, University of Maiduguri Teaching Hospital

Date Received: 13th June 2025
Date Accepted: 27th August 2025
Date Published: 31st December 2025

Introduction

Postpartum haemorrhage (PPH) is unequivocally the leading cause of maternal mortality worldwide, accounting for approximately 25% of maternal deaths.(1) The condition is more prevalent in middle- and low-income countries, underscoring the necessity

Access this article online
QuickResponse Code
website:www.bornomedicaljournal.com
DOI: 10.31173/bomj.bomj_2521_22

for continuous search for effective interventions to address this critical health challenge.[2] In 2023, nearly 75,000 maternal deaths were recorded in Nigeria, which translates 28.7% of the global maternal mortality.[3] More than two-thirds of PPH are caused by uterine atony, which can often be prevented with prophylactic oxytocic administration.[4]

The active management of the third stage of labour (AMTSL) is a proven approach to decrease primary PPH.[5] This involves administering a prophylactic uterotonic, employing controlled cord traction, and performing uterine massage. The World Health Organization (WHO) recommends oxytocin as the preferred uterotonic because of its enhanced efficacy and better safety profile.[1] However, oxytocin requires syringes and refrigeration at 2–8°C.[6] Unfortunately, the incessant power outage in our environment would compromise its potency, and to overcome that, the International Federation of Gynaecology and Obstetrics (FIGO) has recommended a single dose of misoprostol as an adjunct to AMSTL in settings where the oxytocin cold chain cannot be guaranteed.[7] The department of Obstetrics and Gynaecology of the UMTH has adopted that approach, especially in high-risk patients.

Misoprostol is a water-soluble analogue of prostaglandin E1 with strong uterotonic properties. It was primarily used as an effective anti-ulcer drug because it protects the stomach lining from gastric acid.[8] Its uterotonic property arises from its ability to increase the amplitude and frequency of uterine contractions during pregnancy by selectively binding to the EP-2/EP-3 prostanoid receptors.[9,10]

The pharmacokinetics of misoprostol indicate that the oral route has the advantage of a rapid onset of action, while the rectal route offers greater bioavailability and prolonged activity. The increased bioavailability of non-oral routes is thought to be a result of the avoidance of the first-pass metabolism. The total bioavailability for the rectal route, it is 1.5 times that of the oral route.[11] As clearance of the drug is likely to be rapid irrespective of the route of administration, the prolonged activity of the rectal route is presumably due to continued absorption over an extended period. The time of absorption is likely to correlate with the retention of the tablet in the respective site over time.[12]

The ease of administration has prompted the majority of accouchers to administer the drug rectally following the delivery of the fetus. Understandably, the accoucher is gloved and can easily insert the drug into the rectum after delivery. However, the oral route may be easier and more convenient for the patient, given that it is less invasive.

Misoprostol is a very handy and versatile drug, being a stable tablet that can be administered orally, rectally, vaginally, and sublingually. A systematic review has shown that the misoprostol plus oxytocin combination may have some additional desirable effects compared with the current standard of oxytocin in preventing primary PPH.[5] Nevertheless, there exists limited data regarding the optimal route of administration that balances clinical effectiveness and patients' preferences.[10] Consequently, it is essential to investigate the use of misoprostol further, both orally and rectally, to safeguard women from primary PPH and to enhance the evidence required to support its widespread application in our hospitals. Furthermore, the accoucheur should be guided by clinical evidence, including the best and the women's preferred route of administration of misoprostol to prevent or treat primary PPH. This will enable them to counsel the women on the various routes of administration and empower them to make an informed decision.

Methods

Study design

This was a randomised controlled study that compared oral and rectal routes of misoprostol administration for the prevention of primary postpartum haemorrhage.

Study setting

The study was conducted in UMTH Maiduguri, Borno State. UMTH is a 1200 bed tertiary health institution and one of the principal referral Centres in the North Eastern Nigeria. The study was carried out in the labour ward of the department of Obstetrics and Gynaecology of UMTH. The parturients have been attended to by doctors and midwives, and following delivery, the routine practice of AMSTL with 10iu oxytocin was given intramuscularly and 40 iu in 1L of normal saline for high-risk patients to continue flowing for 4 hours. The placenta was removed via controlled cord traction. Any episiotomy was repaired immediately. The annual birth rate from the labour records is approximately 3000, with cases of PPH about 1.9%.[13]

Sample size calculation

The sample size was calculated to be 206 with 103 for each arm of the study based on the formula for quantitative variable.[14]

Inclusion and exclusion criteria

The inclusion criteria included all consenting booked pregnant women (at term) in the labour ward of the hospital without contraindication for vaginal delivery. The exclusion criteria were hypersensitivity to prostaglandins, packed cell volume of <27%, or HB <of 9g/dl.

Women with malpresentations, PPH following trauma, patients undergoing caesarean section, pregnancy-induced hypertension, coagulation abnormalities, previous history of PPH, or other medical disorders were also excluded.

Randomisation and study group allocation methods

A statistician provided 206 computer-generated three-digit' random numbers (Between 100 and 999), these numbers were divided into 2 rolls of 103 random numbers each. Two spreadsheets containing these 206 random numbers arranged in two rolls of 103 numbers each were printed. Each number on the spreadsheet of 206 random numbers was cut into a piece of 5cm x 5cm paper, and sealed up in an unlabelled, opaque, small brown envelope, which was identical for all the random numbers. All 206 envelopes were then placed into a single large opaque container and kept in the labour ward. The statistician then assigned a roll (103 random numbers) each to the two groups of the study. i.e. the oral and rectal routes. The allocation group (generated by the statistician) was written against each roll on the spreadsheet kept by a midwife (who was not involved in the study).

The study groups were booked women at term, who were identified earlier during the ANC. They were counselled during the ANC without administering a consent form. Those who indicated interest were encouraged to present early in labour. When participants arrived at the labour ward, written informed consent was obtained from each patient. The participants were handed a large envelope containing sealed numbers and asked to select one, which could not be replaced. The envelope was then opened, and the random number chosen by the participant was verified. The corresponding number and labell on the spreadsheet were checked to determine the group by the same midwife who randomised the patient. Each participant was allowed to select only one envelope, and no changes to group allocations were permitted afterwards.

The brand name of misoprostol used in this study was Cytotec, produced by Pfizer and supplied by Premium Medical Equipment and Pharmacy Ltd. The misoprostol was provided and the participants folder clearly marked with the group based on the number she picked and the corresponding labell into group I (oral) or group II (rectal) misoprostol after delivery.

Study procedure

In the labour ward, the baseline haemoglobin (HB) was checked before delivery. After delivery of the baby (within 1 minute of cord clamping and cutting), all patients had routine active management of the third stage of labour with intramuscular 10 IU of oxytocin. In addition, Group I (103) patients received 600µg oral misoprostol with a full glass of water and Group II (103) patients received 600µg rectal of misoprostol inserted into the rectum before delivery of the placenta. Blood loss during the third stage of labour was estimated by collecting the blood in a receptacle, a fixable, non-calibrated Brass-V-drape produced by an Excellent ISO 13485 certified company. The drape was weighed using an Essae weighing scale, BS-250, and the difference in weight in grams of the drape before and after blood collection was noted and converted to the volume of blood loss in mLs. Also, the number and weight of soaked pads (volume in mLs = weight in grams) were determined. After delivery of the placenta, the zero hour was set. A pre-weighed perineal pad was used, and the patient was instructed to keep the pad in-situ without replacing it or adding any other pad to it. After 1 hour, the pad was removed and weighed to determine the blood loss at 1 hour postpartum. Another pre-weighed pad was then inserted and removed at 2 hours from the zero hour. The estimated blood loss for each patient is the sum of blood collected via the drape and the weighted perineal pads.

A venous blood sample was collected in a micropipette from the parturient at any moment before delivery and 24 hours after delivery. This was placed on a micro-haematocrit centrifuge, Hawsley, England. It was spun at 5 minutes in the labour ward haematocrit centrifuge and read with the aid of Hawksley Micro-Haematocrit reader for PCV (3% PCV equals 1 gram HB)[15]

Outcomes of the study

The primary outcome measured was the median vaginal blood loss in millilitres during stages 3 and 4 of labour among participants receiving oral versus rectal misoprostol. Secondary outcomes included; The incidence of primary postpartum haemorrhage (PPH) in both groups, the mean difference in pre- and post-delivery Haemoglobin concentration (g/dl) recorded

24 hours after delivery, the need for additional agents to control vaginal bleeding, maternal side effects such as nausea, vomiting, fever, shivering, headache, and diarrhoea, in both groups and patient satisfaction rates regarding the oral and rectal routes of misoprostol administration. The side effects developed by the participants were treated as appropriate with intravenous fluid, antipyretics, antimotility and analgesics.

Before assessing their satisfaction, mothers were informed about the existence of both oral and rectal routes for administering misoprostol. This ensured they understood the available options prior to providing feedback on their experience with the method they received. Their satisfaction with the route used to administer the adjunct misoprostol was assessed using a 5-point Likert scale (1 = highly dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, 5 = highly satisfied).[16] Participants who gave a rating of 4 or 5 were considered satisfied with the method of administration, whereas those who rated it between 1 and 3 were considered dissatisfied. Additionally, the participants were asked to indicate whether they would recommend the same route of administration they had used for their siblings and friends, or whether they would prefer to recommend an alternative route.

Data collection and statistical analysis

Data was obtained from the participants using a pretested proforma. Information pertaining to sociodemographic characteristics (including age, parity, and education), management, and outcome was extracted and transferred to the computer using IBM SPSS version 25 software in 2017. Simple frequency tables were generated. Normally distributed data were expressed as means ± standard deviation (SD), and skewed data were expressed as medians or interquartile ranges. The chi-square test or Fisher's exact test, as appropriate, was used to analyze the categorical variables. The Mann-Whitney U test was used to compare independent variables. A p-value <0.05 was considered significant.

Ethical consideration

Ethical approval for this work was obtained from the Research and Ethics Committee of the University of Maiduguri Teaching Hospital. All the participants were counselled about the study, and informed consent was obtained from each patient. An ethical consideration in this study was based on the general ethical principles as applicable to human subjects. These are respect for persons, beneficence, non-maleficence and justice.

Definition of Terms

a. Primary PPH is defined as blood loss in excess of 500 millitres or 10% drop in haemoglobin from admission to the time the patient is discharge(24 hours after delivery).

b. Social class by Olusanya et al classification into high (class I & II), medium (class III) and low (class IV & V) based on husband profession and the woman's education status.[17]

c. Maternal satisfaction: Is maternal reported outcome or getting fulfillment from her expectations. Maternal satisfaction was assessed using the 5-point Likert scale (1- highly dissatisfied, 2- dissatisfied, 3- neutral, 4- satisfied, 5-highly satisfied)(16). Participants who gave a rating of 4 or 5 were considered satisfied with the method of administration, whereas those who rated it between 1 and 3 were deemed dissatisfied.

d. Adjunct misoprostol: Misoprostol added after oxytocin, used as the primary drug for preventing primary PPH at AMTL

Results

A total of two hundred and six consenting participants who presented to the labour ward in the active phase of labour were recruited for this study. The participants were randomised into two arms: group I (oral misoprostol) and group II (rectal misoprostol), and analysis was done as per protocol. In group I, out of the 103 that were randomised, 9 were excluded because of incomplete information and loss of follow-up (4 did not receive treatment intervention, and five did not complete the study). Ninety-four participants were finally analysed in group I of the study. In group II, seven out of 103 randomised participants were excluded due to incomplete information, allowing for 96 of the participants to be analysed.

Table 1 depicts the basic characteristics of participants in both groups of the studied adjunct misoprostol for the prevention of primary postpartum haemorrhage. The median age in Group I was 27 years (IQR: 24–31) compared to 27 years (IQR: 23–32) in Group II, $p = 0.982$. The median gestational age at delivery was also comparable, 39 weeks (IQR: 38–40) in both groups ($p = 0.301$). Parity distribution, educational status, employment, and social class were similarly matched

across both groups. While grand multiparity appeared slightly more prevalent in group II (18.8%) than group I (10.6%), the difference did not reach statistical significance (p = 0.071). Educational attainment and employment status were also comparable (p = 0.289 and p = 0.134, respectively), as was the distribution of social class (p = 0.869). These findings suggest that the two groups were matched demographically and obstetrically at baseline.

Table 1: Basic Characteristics of participants

Demographic characteristics	Group I (oral)	Group II (rectal)	χ^2	p-value
Median age in years (IQR)	27 (24 – 31)	27 (23 – 32)	4503.5	0.982[α]
Median period of gestation in weeks (IQR)	39 (38 – 40)	39 (38 – 40)	4127.5	0.301[α]
Parity distribution				
Nullipara	21 (22.3)	29 (30.2)	5.295	0.071
Para 1-4	63 (67.1)	49 (51.0)		
Para ≥ 5	10 (10.6)	18 (18.8)		
Educational level				
Non formal education	3 (3.2)	9 (9.4)	3.802	0.289*
Primary	5 (5.3)	5 (5.2)		
Secondary	28 (29.8)	32 (33.3)		
Tertiary	58 (61.7)	50 (52.1)		
Employment				
Employed	24 (25.5)	16 (16.7)	2.246	0.134
Non employed	70 (74.5)	80 (83.3)		
Social class				
High	1 (1.1)	0 (0.0)	1.014	0.869*
Medium	70 (74.5)	71 (74.0)		
Low	23 (24.4)	25 (26.0)		

χ^2: chi-square, *Fisher's exact, [α]U-test (Mann-Whitney), IQR: Interquartile range

Table 2 shows the primary and secondary outcomes related to blood loss. The estimated blood loss (EBL), was not significantly different between the two groups. Median EBL was 247 ml (IQR: 172–368) in the oral group and 253 ml (IQR: 192–354) in the rectal group (p = 0.431). The median drop in haemoglobin was similar in both groups at 2 g/dL (IQR: 1–3), with no significant difference (p = 0.981). A small proportion of participants in both groups required additional uterotonics, 2.1% in the oral group versus 1.0% in the rectal group (p = 0.619). Interestingly, a higher number of participants in the rectal group required blood transfusion (11.5%) compared to the oral group (4.3%), although this difference approached but did not reach statistical significance (p = 0.066).

Table 2. Primary and secondary outcome measures indicative of blood loss among the women studied

Variable measured	Group I (oral)	Group II (rectal)	Statistics	p-value
1. Median (IQR) blood loss in mls	247 (172 – 368)	253 (192 – 354)	4213.5	0.431[α]
2. Median (IQR) Change in Hb level in g/dl	2 (1 -3)	2 (1 – 3)	4503.5	0.981[α]
3. Need for additional uterotonics	2 (2.1%)	1 (1.0%)	0.360	0.619*
4. Need for blood transfusion	4 (4.3%)	11 (11.5%)	3.389	0.066*

*Fisher's exact test, [α]U- test (Mann-Whitney), IQR: Interquartile range, mls: millilitre.

The incidence of primary postpartum haemorrhage was higher in the rectal group (9.4% with 95% CI = 4.4 – 17.1) than in the oral group (5.3% with 95% CI = 1.7 – 12). However, this difference was not statistically significant ($\chi^2 = 1.145$, p = 0.285). The relative risk (RR) was 1.045 (95% CI: 0.964–1.132), indicating no significant risk increase between the two misoprostol administration routes.

Side effects associated with misoprostol use are shown in Table 3. Shivering and fever were the most common side effects and were significantly more frequent in the oral group. Shivering occurred in 54.3% of the oral group compared to 28.1% in the rectal group (p = 0.001, RR = 1.9), while fever was reported in 28.7% of the oral group compared to 15.6% of the rectal group (p = 0.03, RR = 1.8). Nausea and vomiting occurred in 3.2% of the oral group and 5.2% of the rectal group, with no significant difference (p = 0.721). Diarrhoea was observed in 4.3% of the oral group but was absent in the rectal group (p = 0.479), and allergic reactions were similar between groups (1.1% vs. 1.0%, p = 1.000).

Table 3. Medication side effects in two groups of parturient studied

Side effect	Group I (oral) Frequency (%)	Group II (rectal) Frequency (%)	χ^2	RR	p-value
Fever	27 (28.7)	15 (15.6)	4.7	1.8 (1.1 – 3.2)	0.03
Shivering	51 (54.3)	27 (28.1)	13.4	1.9 (1.3 – 2.8)	0.001
Nausea & Vomiting	3 (3.2)	5 (5.2)	0.5	-	0.721*
Diarrhea	4 (4.3)	0 (0.0)	4.0	-	0.479*
Allergic reaction	1 (1.1)	1 (1.0)	0.0	-	1.000*

***Fisher's exact test. RR: Relative risk**

Table 4 presents participants satisfaction with the route of misoprostol administration. While a higher percentage of participants in the rectal group (88.5%) reported satisfaction compared to the oral group (79.8%), the difference was not statistically significant (p = 0.098, RR = 1.4(0.9-1.9). Both groups were willing to utilize the same route for future deliveries and recommend it to others. In Group I, 91.5% indicated a readiness to reuse the oral route, however, 8 (8.5%) of the participants would prefer to have the drug via the rectal route. Similarly, 89 (92.7%) of the participants in the rectal group will use the same route in future deliveries but, 7 (7.3%) will prefer the oral route in future deliveries. Additionally, 90.4% of the participants in Group I were inclined to recommend the same route for others, and in Group II, 93.6% would also recommend the same route for others. The statistical analysis revealed no significant differences between the groups (p = 0.755 and p = 0.73, respectively).

Table 4. Maternal satisfaction and willingness to use of oral or rectal misoprostol

Variable	Group I (oral) Frequency (%)	Group II (rectal)	χ^2	RR (Confidence Interval)	P value
Maternal satisfaction with the route of administration					
Yes	75(79.8)	85 (88.5)	2.7	1.4(0.9-1.9)	0.098
No	19 (20.2)	11 (11.5)			
Willingness to use the same route in future deliveries					
Yes	86 (91.5)	89 (92.7)	0.1	1.2 (0.4-3.1)	0.755
No	8 (8.5)	7 (7.3)			
Willingness to recommend the same route to others					
Yes	85 (90.4)	91 (94.8)	3.2	1.1 (0.9-1.1)	0.73
No	9 (9.6)	5 (5.2)			

NB: RR: Relative risk, χ^2: chi-square

Discussion

Our study showed that administering adjunct misoprostol either orally or rectally during the third stage of labour is equally effective in preventing primary postpartum haemorrhage. It is safe, with tolerable maternal side effects, and consistently results in high patient satisfaction, regardless of the route of administration.

We found a comparable postpartum blood loss between the participants who received oral adjunct misoprostol and those who received it via the rectal route. Our finding was similar to the finding of Hofmeyr et al[12] whose blood loss estimation for the oral misoprostol was 264mls. Ratna et al[18] and Awoleke et al[19] reported a higher mean blood loss. Ratna et al.[18] reported a mean blood loss estimation of 356 mL ± 102.79 mL for the oral group and 398.20 mL ± 119.2 mL for the rectal group. Awoleke et al.[19] reported an average blood loss of 322 mls after four hours of delivery for the rectal route. However, unlike the other authors, we estimated blood loss over two hours following delivery, which could explain the lower blood loss recorded in our study. Our finding is in contrast with the findings of Parveen et al,[20] Mansouri et al[21] and Bajwa et al,[22] who recorded a significantly higher blood loss in the oral group compared to the rectal group. The cause of this disparity could be that blood loss estimation in our study was measured more objectively with a receptacle-type, non-calibrated Brass-V-drape from an Excellent ISO 13485 certified company. Bajwa et al employed a kidney-shaped bowl and administered a lower dose of misoprostol.[22]

Another notable finding from this study was the decrease in the incidence of primary PPH, which was 5.3% in the oral misoprostol group compared to 9.4% in the rectal misoprostol group.

Despite the difference not being significant, it suggests the likely advantage of oral administration over rectal administration that may warrant further investigation with a larger cohort.

Our finding compares to those of Ratna et al, who recorded a low incidence of PPH in the oral misoprostol group of 6%,[19] but contrasts with that of Bajwa et al, who also recorded a high PPH of 16% in the oral group.[22] A high incidence of PPH was reported by Awoleke et al (15.7%)[19] and Ratna et al (16%).[18] The long latency period with rectal misoprostol may explain the higher incidence of PPH in group II. Studies by Tang et al showed that the rectal misoprostol has a longer time to peak concentration compared to the oral route of misoprostol administration.[9]

This is a notable disadvantage of rectal misoprostol in the prevention and management of primary PPH, where prompt action is essential. An additional consideration is the need to evacuate the rectum of faecal matter before administering rectal misoprostol when necessary, which may pose a significant practical limitation to this route of administration.

Another important indicator of blood loss is the change in haemoglobin levels. In this study, the mean difference in pre- and post-delivery haemoglobin concentration was identical in both the oral and rectal misoprostol groups, averaging 2 g/dl. This observation differs from the findings of Parveen et al[20] and Mansouri et al,[21] who reported varying degrees of haemoglobin change between the two routes of administration. The consistency in haemoglobin drop across both groups in our study further supports the comparable efficacy of oral and rectal misoprostol in managing postpartum blood loss. Our finding aligns with that of Rani et al.[23] In their study, the mean haemoglobin changes before and after delivery were 0.69 g/dL ± 0.68 for the oral group and 0.59 g/dL ± 0.81 for the rectal group, closely mirroring the results observed in our study.

Intramuscular ergometrine was employed as an additional uterotonic in only 3.1% of cases in this study. This rate is substantially lower than the 19.6% and 30% reported by Awoleke et al.[19] and Mansour et al.[21] respectively. The reduced reliance on additional uterotonics in our cohort may reflect the efficacy of misoprostol regimens utilised. While ergometrine remains a potent agent for controlling uterine atony, its regular application is limited by the potential for significant adverse effects. This underscores the importance of exploring safer and equally effective alternatives for the prevention of primary PPH.

The need for postpartum blood transfusion did not differ significantly between the oral and rectal misoprostol groups. This finding further reinforces the comparable effectiveness of both administration routes in preventing primary PPH. The parity in transfusion rates serves as an additional indicator that both oral and rectal misoprostol regimens are reliable options for clinical management in this context.

The occurrence of side effects is another significant observation from this study. Fever and shivering were

more common among the participants in the oral misoprostol group compared to those in the rectal administration group. This trend is consistent with findings reported by Hofmeyr et al,[12] Ratna et al,[18] and Mansouri et al,[21] and may be attributable to the greater systemic bioavailability of misoprostol when administered orally. Such differences in the side-effect profile highlight the necessity for clinicians to thoughtfully evaluate patient tolerance and safety when selecting the appropriate route of administration of adjunct misoprostol for primary PPH prophylaxis.

The majority of participants across both groups reported high levels of satisfaction and indicated a willingness to recommend their assigned route of misoprostol administration to others. The patient satisfaction appeared marginally higher among those in the rectal group, a trend that may be attributed to the lower frequency of side effects—particularly fever and shivering—reported in this cohort. This finding aligns with that of Awoleke et al,[19] who observed a comparably elevated satisfaction rate of 72.5% in the rectal administration group. One of the strengths of this study was the use of an objective and dependable instrument for quantifying blood loss, thereby enhancing the precision and validity of our recorded blood loss estimates. However, a possible limitation pertained to the inadvertent inclusion of urine or faecal matter in the collected blood, which might skew volume estimations. To address this concern, participants were advised to void their bladders before delivery or were provided with intermittent bladder drainage assistance as deemed appropriate. Furthermore, any faecal matter encountered during the collection process was meticulously removed and segregated from the measured blood loss prior to weighing. These precautions were implemented to minimise methodological bias and uphold the integrity of the data generated. In conclusion, this study demonstrates that the adjunct use of both oral and rectal misoprostol during the third stage of labour is effective and safe for preventing primary PPH. Both routes were associated with minimal and manageable side effects, as well as high patient satisfaction levels. Both methods of administration of adjunct misoprostol similarly reduced blood loss and the need for additional interventions for treatment of primary PPH. Given these findings, we recommend the routine use of either oral or rectal misoprostol as adjunct prophylaxis for women at high risk of primary PPH. The choice of route of administration should be made in collaboration with the patient, taking into account both clinical evidence and patient preference. Further research in a larger and more diverse populations is warranted to confirm these results and to optimise protocols for misoprostol use in postpartum care.

Conflict of interest

We declare that there was no conflict of interest.

References

1. World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage [Internet]. 2012. Available from: www.who.int/maternal_child_adolescent
2. Bláha J, Bartošová T. Epidemiology and definition of PPH worldwide. Best Pract Res Clin Anaesthesiol [Internet]. 2022 Dec 1 [cited 2025 Jun 24];36(3–4):325–39. Available from: https://www.sciencedirect.com/science/article/abs/pii/S1521689622000520
3. Trends in maternal mortality estimates 2000 to 2023: estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division. World Health Organization, Geneva. 2025;
4. Yunas I, Islam MA, Sindhu KN, Devall AJ, Podesek M, Alam SS, et al. Causes of and risk factors for postpartum haemorrhage: a systematic review and meta-analysis. Lancet [Internet]. 2025 Apr 26;405(10488):1468–80. Available from: http://www.ncbi.nlm.nih.gov/pubmed/40188841
5. Gallos ID, Papadopoulou A, Man R, Athanasopoulos N, Tobias A, Price MJ, et al. Uterotonic agents for preventing postpartum haemorrhage: A network meta-analysis. Vol. 2018, Cochrane Database of Systematic Reviews. John Wiley and Sons Ltd; 2018.
6. World Health Organization. A Roadmap to combat postpartum haemorrhage between 2023 and 2030. World Health Organization, Geneva. 2023;
7. Escobar MF, Nassar AH, Theron G, Barnea ER, Nicholson W, Ramasauskaite D, et al. FIGO recommendations on the management of postpartum hemorrhage 2022. International Journal of Gynecology and Obstetrics. 2022 Mar 1;157(S1):3–50.

8. Krugh M, Patel P, Maani C V. Misoprostol. xPharm: The Comprehensive Pharmacology Reference [Internet]. 2024 Dec 11 [cited 2025 Jun 24];1–5. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539873/
9. Tanga OS, GDKHPC. Misoprostol Pharmacokinetic profiles, effects on the [Internet]. [cited 2025 Jun 24]. Available from: https://studylib.net/doc/8427194/tang-et-al.-misoprostol-pharmacokinetic-profiles--effects.
10. Mousa HA, Blum J, Abou El Senoun G, Shakur H, Alfirevic Z. Treatment for primary postpartum haemorrhage. Cochrane Database of Systematic Reviews [Internet]. 2014 Feb 12 [cited 2025 Jun 24];2017(9). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003249.pub3/full
11. Parsons SM, Walley RL, Crane JMG, Matthews K, Hutchens D. Rectal Misoprostol Versus Oxytocin in the Management of the Third Stage of Labour. Journal of Obstetrics and Gynaecology Canada [Internet]. 2007 [cited 2025 Jun 24];29(9):711–8. Available from: https://pubmed.ncbi.nlm.nih.gov/17825135/
12. Hofmeyr GJ, Walraven G, Gülmezoglu AM, Maholwana B, Alfirevic Z, Villar J. Misoprostol to treat postpartum haemorrhage: A systematic review. BJOG [Internet]. 2005 May [cited 2025 Jun 25];112(5):547–53. Available from: https://pubmed.ncbi.nlm.nih.gov/15842275/
13. Bukar M. Department of Obtestrics and Gynaecoloy, 2019 and 2020 annual reports, University of Maiduguri Teaching Hospital. Bukar M, editor. 2020. 13–14 p.
14. Das S, Mitra K, Mandal M. Sample size calculation: Basic principles. Vol. 60, Indian Journal of Anaesthesia. Indian Society of Anaesthetists; 2016. p. 652–6.
15. Turkson PK, Ganyo EY. Relationship between haemoglobin concentration and packed cell volume in cattle blood samples. Onderstepoort Journal of Veterinary Research [Internet]. 2015 [cited 2025 Jun 26];82(1):5. Available from: http://www.ojvr.org
16. Likert R. A Technique for the Measurement of Attitudes. . Archives of Psychology. 1932;140:1–55.
17. Olusanya O, Okpere E, Ezimokhal M. The importance of social class in voluntary fertility control in a developing country. West Afr J Med. 1985;4:200–11.
18. Bulusu R, Ray P, Rani A, Handa P. Comparison of Side Effects of Misoprostol by Oral and Rectal Routes in Active Management of Third Stage of Labour. Journal of Evidence Based Medicine and Healthcare. 2017 Jan 9;4(3):146–9.
19. Awoleke JO, Adeyanju BT, Adeniyi A, Aduloju OP, Olofinbiyi BA. Randomised Controlled Trial of Sublingual and Rectal Misoprostol in the Prevention of Primary Postpartum Haemorrhage in a Resource-Limited Community. Journal of Obstetrics and Gynecology of India. 2020 Dec 1;70(6):462–70.
20. Parveen DS. Per Rectal use of Misoprostol give the better result than oral route among the female of Bangladesh. Journal of Medical Science And clinical Research [Internet]. 2019 Jul 30;7(7). Available from: http://jmscr.igmpublication.org/v7-i7/144%20jmscr.pdf
21. Mansouri HA, Alsahly N. Rectal versus oral misoprostol for active management of third stage of labor: A randomized controlled trial. Arch Gynecol Obstet. 2011 May;283(5):935–9.
22. Bajwa S, Bajwa SJ, Kaur H, Goraya SPS, Singh A, KaurIshar H. Management of third stage of labor with misoprostol: A comparison of three routes of administration. Perspect Clin Res. 2012;3(3):102.
23. Rani BU, Kumari K, Kumari A. Efficacy of 600mcg of Misoprostol Orally versus per Rectal in the Active Management of 3rd Stage of Labour to Prevent 3rd Stage PPH & Its Complications. Journal of Evidence-Based Medicine and Healthcare. 2015 Oct 24;2(43):7717–23.

Cite this Article as: Mba PC, Katagum DA, Mandara MU, Bako B. A Randomised Controlled Study on the Effectiveness of Oral versus Rectal Misoprostol as Adjunct for Prevention of Primary Postpartum Haemorrhage at the University of Maiduguri Teaching Hospital, Maiduguri, Nigeria **Bo Med** J 2025; 22 (2):142-150 **Source of Support:** Nil, **Conflict of Interest:** None declared