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Original Article

Comparison of Intrauterine versus Per-Rectal Misoprostol in Prevention of Postpartum Hemorrhage in Women undergoing Caesarean Section: A Quasi-Experimental Study

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ABSTRACT

Objective: to compare the efficacy of the intrauterine vs. Rectal Misoprostol in preventing PPH among women undergoing caesarean section.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Gynecology and Obstetrics, Avicenna Hospital, Lahore Pakistan, from May to Oct 2023.

Methodology: Participants were allocated into two groups: Group A received 800 µg intrauterine misoprostol, while Group B received 800 µg rectal misoprostol immediately after delivery. The primary outcome was the occurrence of PPH. Secondary outcomes included approximate blood loss, hospital stay, maternal complications, adverse effects, and additional uterotonic requirement.

Results: The intrauterine group showed significantly lower mean blood loss (370.94±120.14 mL) compared to the rectal group (500.32±140.86 mL, p<0.001). The PPH incident was clearly reduced (13.1% vs. 52.0%, p<0.001). The stay in the hospital was reduced in the intrauterine group (2.23(0.63) days vs. 3.14(0.85) days, p<0.001). Fewer women require additional uterotonic (10.7% vs. 39.8%, p<0.001). The adverse effects were less frequent in the intrauterine group.

Conclusions: The intrauterine misoprostol is better than rectal misoprostol during the Caesarean section with low complications

Keywords: Caesarean Section, Misoprostol, Postpartum Hemorrhage, Uterotonic.

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INTRODUCTION

PPH continues to pose the major global challenge in maternal health, ranking among the foremost causes of morbidity, maternal and mortality. It is clinically defined as loss of blood >500 mL after a normal vaginal birth or more than 1,000 mL following a cesarean section.[1] This risk is even more pronounced after cesarean procedures, where surgical intervention can impair the availability of clotting factors, underscoring the importance of effective prophylactic strategies to prevent surgical-site infection and hemorrhage.[2]

In recent years, a number of interventions have been assessed to prevent or treat PPH, and uterotonics remain the mainstay. In particular, misoprostol, a synthetic prostaglandin E1 analogue, is prescribed more often than others due to its strong and potent uterotonic effects, low cost, and lack of refrigeration requirements.[3] Developed in the 1980s to prevent gastric ulcer complications, misoprostol is now commonly used off-label in obstetric practice for labor induction, cervical ripening, and management of PPH.[4] All routes (oral, sublingual, rectal, or intrauterine) can achieve peak plasma levels quickly after administration (8–11 minutes), but oral and sublingual administration have a higher risk of causing systemic side effects.[5] Research studies demonstrate that intrauterine misoprostol plus oxytocin for uterine atony leads to less blood loss than sublingual administration, while misoprostol administered rectally has also been shown to improve control while having fewer side effects.[6]

Despite these promising consequences, the optimal route for misoprostol administration during the Caesarean section remains under debate, with limited high-quality studies directly comparing intrauterine vs. per-rectal misoprostol within strong quasi-experimental frameworks. The purpose of this quasi-experimental study is to compare the efficacy and safety of the intrauterine vs. Rectal Misoprostol for PPH prevention in women undergoing Caesarean section. By monitoring the intraoperative blood loss, changes in hemoglobin, and closely monitoring the side effect profiles, the study will provide valuable

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insight into how the administration can adapt the clinical results and inform guidelines for the use of the uterus during CS.

METHODOLOGY

This quasi-experimental study was conducted at Avicenna Hospital, Lahore Pakistan, in a period of six months from May 2023 to October 2023. The primary objective was that they were to compare the efficacy of the intrauterine vs. rectal administration of Misoprostol in preventing women as well as postpartum hemorrhage (PPH).

Inclusion Criteria: Women aged 18 to 45 were eligible to include women who were prescribed for elective or emergency Caesarean section and who had given written informed consent.

Exclusion Criteria: Patients with a contraindication known for misoprostol, such as hypersensitivity to prostaglandins, were kept out to ensure participants and to reduce bleeding disorders and confounding.

Using the Rao soft sample size calculator, a sample size was calculated based on a confidence level of 95%, a margin of error of 5%, and an estimated prevalence of postpartum hemorrhage (PPH) of approximately 52% among women treated with rectal misoprostol.[7] The total sample size was calculated to be 245.

All enrolled women were allocated to two intervention groups. Group A received the intrauterine Misoprostol, where four tablets of 200 µg (total 800 µg) were placed directly into the uterine cavity, immediately after delivery of the newborn and before the closure. Group B received the Rectal Misoprostol, which was administered as a total dose of 800 µg per rectum at the end of the Caesarean process (Figure).

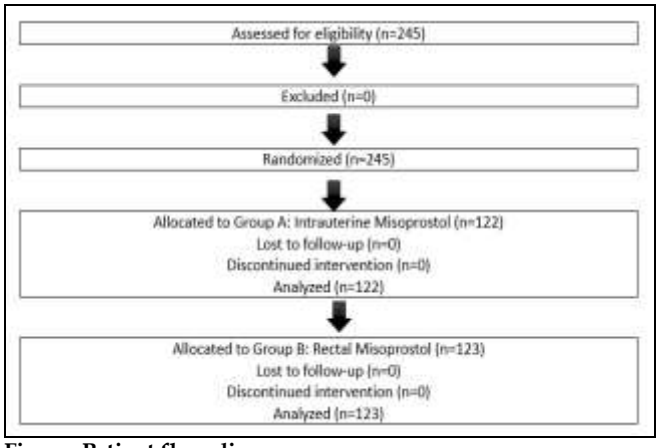

Figure: Patient flow diagram

Before surgery, baseline demographic details, maternity history, and relevant clinical characteristics were documented for each participant. The primary result was the occurrence of PPH, which is more than 500 mL of blood loss within the first 24 hours after delivery. Blood loss was measured intraoperatively by a gynecologist with a minimum experience of 6 years using a calibrated suction device, in which gravimetric methods, as well as pre-weighed gauge pads and linen, were positively re-weighed, which had a difference in the form of blood. These combined methods ensured more accurate estimates of blood loss. Secondary results included intra-and postoperative complications, additional uterotonics requirement, and adverse effects related to misoprostol administration. For any adverse incidents, participants were monitored to stay in their hospitals, which were systematically documented.

Particular criteria for both inclusion and exclusion were used to guarantee participant homogeneity and reduce subjective bias. Instead of depending solely on visual estimation, blood loss during the procedure was measured objectively using techniques such as gravimetric evaluation of gauze and linens and calibrated suction devices. There was less interpretive variance because outcomes like postpartum hemorrhage, hospitalization, and adverse effects had been predefined with distinct thresholds. Standardized statistical analyses were employed to ensure objective interpretation of the results, and both groups were treated in comparable surgical settings.

Data analysis was done using the Statistical Package for Social Sciences version 27.0. Normality was examined by the Shapiro-Wilk test; only age (p=0.116) and estimated blood loss (p=0.091) fulfilled normality assumptions (p>0.05), while the other variables such as gravida, para, length of hospital stay, group type, type and indication of cesarean, history of cesarean section, route of misoprostol, postpartum hemorrhage (PPH), use of additional uterotonics, adverse effects, maternal complications, and condition on discharge, were determined to be non-normally distributed (p<0.05).

Mean±SD was calculated for continuous, normally distributed variables (age, estimated blood loss); frequencies (n) and percentages (%) were used for categorical variables and non-normal variables, such as gravida, para, and other variables. Median and interquartile range were reported for continuous, non-normal variables such as the length of stay at the

hospital. An Independent samples t-test was performed for the mean estimated blood loss, and a Mann-Whitney U test for the mean length of stay between the intrauterine misoprostol and rectal misoprostol groups, for inferential analysis. A Chi-square test examined associations between the route of misoprostol (rectal, intrauterine) and categorical outcomes (PPH, type of cesarean, maternal complications, adverse effects, and need for additional uterotonics). The *p*-value <0.05 was recognized as statistically significant.

RESULTS

In this research, postpartum hemorrhage (PPH >500 mL) occurrence was designated as the primary outcome, the main measure of comparison between intrauterine and rectal misoprostol effectiveness. The secondary outcomes were quantified blood loss, length of stay, need for further doses of uterotonics, maternal morbidity (including atony, infection, or transfusion), adverse effects (fever, chills, nausea, diarrhea, or abdominal pain), and disposition at the time of discharge. Thus, a total of one primary outcome and six secondary outcomes were assessed throughout the study.

The average participant age was 29.20±4.06 years for the intrauterine group and 29.63±5.44 years for the rectal group. This resulted in an overall mean age of 29.41±4.80 years for the entire study cohort. With a total mean of 435.89±145.88 mL, the estimated blood loss was significantly lower in the intrauterine group (370.94±120.14 mL) than in the rectal group (500.32±140.86 mL). In a similar vein, the intrauterine group's median hospital stay was significantly shorter (2.23(0.63) days) than the rectal group's (3.14(0.85) days), with an overall mean hospital stay of 2.69(0.87) days.

Table-I: Comparison of Baseline Characteristics and Perioperative Outcomes between Intrauterine and Rectal Groups (n=245)

Variable	Groups	Mean±SD	n
Age (years)	Intrauterine	29.20±4.06	122
	Rectal	29.63±5.44	123
	Total	29.41±4.80	245
Estimated Blood Loss (mL)	Intrauterine	370.94±120.14	122
	Rectal	500.32±140.86	123
	Total	435.89±145.88	245
Hospital Stay (days)(median(IQR)	Intrauterine	2.23(0.63)	122
	Rectal	3.14(0.85)	123
	Total	2.69(0.87)	245

The incidence of postpartum hemorrhage (PPH) over 500 mL was significantly lower in the intrauterine group (13.1%) than in the rectal group (52.0%). 69.9% of the women in the rectal group and 62.3% of the women in the intrauterine group were primiparous. In the intrauterine and rectal groups, placenta previa (minor) (20.5% vs. 16.3%) and maternal request (18.9% vs. 15.4%) were the most common reasons for caesarean section, but fetal discomfort and prior caesarean sections were similar. Compared to 36.6% of rectal cases, 31.1% of intrauterine patients had a history of prior caesarean sections. In both categories, emergency caesarean sections were more common than elective ones (rectal: 64.2%; intrauterine: 60.7%). Although the intrauterine group experienced fewer problems (6.6% vs. 11.4%), the majority of patients were released in stable condition.

Table-II: Distribution of Categorical Variables among Intrauterine and Rectal Groups (n=245)

Variables	Categories	Intrauterine (n=122)	Rectal (n=123)
PPH (>500 mL)	Yes	16(13.1%)	64(52.0%)
	No	106(86.9%)	59(48.0%)
Para	0	76(62.3%)	86(69.9%)
	1	36(29.5%)	24(19.5%)
	2	8(6.6%)	12(9.8%)
	3	2(1.6%)	1(0.8%)
Indication for Caesarean Section	Previous Caesarean section	20(16.4%)	21(17.1%)
	Fetal Distress	17(13.9%)	18(14.6%)
	Malpresentation	17(13.9%)	27(22.0%)
	Maternal Request	23(18.9%)	19(15.4%)
	Non-progress of Labor	20(16.4%)	18(14.6%)
	Placenta Previa (minor)	25(20.5%)	20(16.3%)
Previous C-section	Yes	38(31.1%)	45(36.6%)
	No	84(68.9%)	78(63.4%)
Type of Cesarean	Elective	48(39.3%)	44(35.8%)
	Emergency	74(60.7%)	79(64.2%)
Condition at Discharge	Stable	114(93.4%)	109(88.6%)
	Complicated	8(6.6%)	14(11.4%)
Gravida	1	37(30.3%)	36(29.3%)
	2	39(32.0%)	40(32.5%)
	3	22(18.0%)	26(21.1%)
	4	18(14.8%)	11(8.9%)
	5	6(4.9%)	10(8.1%)
Maternal Complications	None	114(93.4%)	109(88.6%)
	Atony	1(0.8%)	6(4.9%)
	Infection	4(3.3%)	3(2.4%)
	Transfusion	3(2.5%)	5(4.1%)
Adverse Effects	None	105(86.1%)	100(81.3%)
	Shivering	5(4.1%)	3(2.4%)
	Fever	3(2.5%)	8(6.5%)
	Nausea	6(4.9%)	7(5.7%)
	Diarrhea	1(0.8%)	2(1.6%)
	Abdominal Pain	2(1.6%)	3(2.4%)
Additional Uterotonics	Yes	13(10.7%)	49(39.8%)
	No	109(89.3%)	74(60.2%)

Atony (0.8% vs. 4.9%) and the requirement for transfusion (2.5% vs. 4.1%) were more common in the rectal group, but maternal problems were rare. Shivering and fever were less common in the intrauterine group (4.1% vs. 2.4% and 2.5% vs. 6.5%,

respectively), and other side effects were generally mild. Crucially, the intrauterine group's requirement for extra uterotonics was significantly lower (10.7%) than that of the rectal group (39.8%), demonstrating the clinical efficacy of the procedure.

Table-III: Comparison of means of key Clinical Outcomes between Intrauterine and Rectal Groups (n=245)

Parameters	Study Groups		*p*-value
	Group A-Intrauterine (n=122)	Group B-Rectal (n=123)	
Blood loss(mL)	370.94±120.14	500.32±140.86	<0.001

When compared to the rectal group, the intrauterine group showed a considerably lower estimated blood loss (mean difference = –129.37 mL, p<0.001). Likewise, the intrauterine group's hospital stay lasted less time (mean difference = –0.91 days, p<0.001).

Table-IV: Comparison of means of key Clinical Outcomes between Intrauterine and Rectal Groups (n=245)

Parameters	Study Groups		*p*-value
	Group A-Intrauterine (n=122)	Group B-Rectal (n=123)	
Hospital Stay (days)(median(IQR)	2.23(0.63)	3.14(0.85)	<0.001

Table-V: Comparison of key Categorical Clinical Outcomes between Intrauterine and Rectal Groups (n=245)

Parameters	Study Groups		*p*-value
	Group A-Intrauterine (n=122)	Group B-Rectal (n=123)	
Postpartum Hemorrhage (>500 mL) 80(32.6%)			
Yes	16(13.1%)	64(52.0%)	<0.001
No	106(86.9%)	59(48.0%)	
Additional Uterotonics Required 62(25.3%)			
Yes	13(10.7%)	49(39.8%)	<0.001
No	109(89.3%)	74(60.2%)	

The incidence of postpartum hemorrhage (PPH) (>500 mL) was significantly lower for the intrauterine group (13.1%) when compared with the rectal group (52.0%) (p<0.001). Similarly, fewer women needed additional uterotonics in the intrauterine group (10.7%) when compared with the rectal group (39.8%) (p<0.001).

DISCUSSION

The findings of the current study display the significantly low estimated blood loss (meaning difference = -129.37 mL) and shorter hospital stay in the intrauterine misoprostol group compared to the rectal group. It aligns with recent evidence that supports the better efficacy of the intrauterine misoprostol in controlling the intrauterine bleeding. For example, a randomized controlled trial did not reveal any statistically significant difference in blood loss between intrauterine and rectal misoprostol, but referred to better newborn results and practical benefits with intrauterine administration during Caesarean delivery.[8] Similarly, a study in Pakistan highlighted that the intrauterine Misoprostol reduced the loss of intraoperative blood and underlined its clinical efficacy, with less decline in hemoglobin compared to per-rectal passage.[9]

This study reports low events of PPH more than 500 mL in the intrauterine group (13.1%), which also resonates conclusions compared to the rectal group (52.0%) by a systematic review concluded that Misoprostol is administered through different routes effectively reduces the PPH after the Caesarean section, but it was suggested that the intrauterine administration may offer an enhanced hemostatic control.[10,11] In addition, the low requirement for the additional uterotonic in the intrauterine group (10.7% vs. 39.8%) corresponds to the reports of recent clinical trials, which found that the intrauterine misoprostol was found to be more powerful in obtaining sufficient uterine tone, which reduced the need for supplementary pharmacological intervention.[12,13]

The side effect profiles reported in this study were reduced shivering and fever in the intrauterine group, comparable with other recent literature. The shivering is a well-written side effect of Misoprostol and is more pronounced with systemic routes such as rectal or sublingual administration. A study reported less adverse maternal effects in intrauterine groups, emphasizing a favorable security profile without compromising efficacy.[14,15] It is clinically relevant that maternal comfort and fewer complications contribute to shorter hospital stays, as seen in the current Cohort.

It is important to pinpoint these conclusions within the widespread context of rising cesarean section rates and the affiliated burden of PPH globally. The recent guidelines of the World Health Organization support the use of uterine agents, including Misoprostol, especially in settings where oxytocin availability or administration is challenging.[16] While intravenous oxytocin remains the gold standard, thermal stability and numerous administration routes of misoprostol make it an attractive option, especially in low-resource settings.[17,18] In this regard, studies comparing rectal misoprostol with intravenous oxytocin found rectal misoprostol equally impressive in preventing PPH after alternative caesarean classes.[19] However, the intrauterine misoprostol can provide additional

benefits by direct local uterine action during the Caesarean section, as the current study indicates better hemostatic results and is confirmed by the literature.

Another notable aspect is the similar maternal base characteristics and signs for cesarean classes among groups, such as primiparity rates and placenta previa phenomena, which strengthen the results and strengthen the internal validity. In addition, the high ratio of emergency cesarean classes in both groups reflects the real-world clinical practice, increasing the external validity of these findings.

Comparative studies have suggested that the time of misoprostol administration also affects the results. The preoperative Rectal Misoprostol vs. intrauterine misoprostol administration was found the intrauterine placement during surgery, more practical, possibly connected with a better newborn Apgar score, a benefit that is exclusively provided for the overall maternal-neonatal outcomes. These ideas are important for making clinical decisions during Caesarean operations.[11]

In terms of functioning, this study's quasi-experimental design of this study provides practical insight, but also requires alert interpretation due to the possible confounders contained in non-randomized studies. However, significant associations, especially with strong *p*-values in relation to blood loss and uterotonic requirements, clinically highlight meaningful differences that warrant further randomized trials to confirm these findings.

Future research may detect a combination of intrauterine misoprostol with other uterotonic or assess various doses and times to adapt to efficacy and safety. Additionally, patient-centered consequences such as postoperative recovery, breastfeeding initiation, and long-term sickness will provide wide evidence in tailoring PPH prevention strategies.

CONCLUSION

This study contributes to the growing evidence on the intrauterine misoprostol over the rectal route for the prevention of postpartum hemorrhage during the Caesarean section by demonstrating significant decrease in the duration of the hospital stay, and significant decrease in the additional uterotonic, and contributes to the growing evidence on the side of the intrauterine route, and additional uterotonic needs, coupled with low side effects. These findings align with recent high-quality observations and randomized studies that emphasize the clinical benefits and safety profiles of the intrauterine administration. Such evidence supports the inclusion of intrauterine misoprostol as a valuable intervention in the PPH Prophylaxis protocol, especially in settings where rapid and effective uterine contraction is mandatory.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

ZG & GW: Data acquisition, data analysis, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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