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Comparison of efficacy of sublingual vs rectal misoprostol in the prevention of primary postpartum hemorrhage

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ABSTRACT

Objective: To determine the efficacy of sublingual vs rectal misoprostol in the prevention of primary postpartum hemorrhage

Methods: Prospective randomized clinical trial was conducted on 200 female pregnant patients, reported in gynecology department of CMH Multan. Divided into A and B two groups by lottery method with 100 respondents in each group. This study was conducted during Feb 2022- July 2023. Misoprostol was given at the end of SVD or caesarean. Group A received 4 tablets in 200mcg Misoprostol in sublingual form, while group B received 4 tablets 200 mcg Misoprostol in rectal form. Total blood loss was recorded at the end of surgery with the help of soaked pads. Data was collected, entered and analyzed in SPSS version 26.0

Results: Mean age of respondents in group A was 25.4 ± 4.3 years with gestational age 37.2 ± 0.90 weeks and in group B it was 26.2 ± 4.6 years with gestational age 37.9 ± 1.0 weeks. Mean blood loss in Group was 541 ± 123 ml in relation to Group B where mean blood loss was 401 ± 96 ml. In group A 30 (30%) while in group B 15(15%) participants suffered from postpartum hemorrhage. Postpartum hemorrhage was considerably lower in Group-B compared to Group-A women and found statistically significant (p-value<0.001).

Conclusion: Misoprostol is effective in reducing bleeding though rectal misoprostol was found better than the sublingual technique for hemorrhage control.

Keywords: Labor induction, postpartum hemorrhage, pregnancy, rectal misoprostol, sublingual misoprostol

1. INTRODUCTION

One of the top five causes of maternal mortality, especially in underdeveloped countries, is postpartum haemorrhage¹. Caesarean section surgery (C-Section) is the most prevalent women's surgery worldwide for child birth². Overall worldwide incidence of C-Section is 20-30%³. Prevalence of C-Section in Pakistan increased from 3.2% (1990) to 20% (2018)⁴. One of the main causes of maternal death, especially in developing countries, is postpartum haemorrhage. Blood loss of at least 500 millilitres after a normal birth and at least 1000 millilitres after a caesarean section is referred to as "postpartum haemorrhage"⁵. It accounts for roughly 25% of all maternal deaths globally⁶. The overall prevalence of postpartum hemorrhage in Pakistan is 34%⁷. In between 75 and 90 percent of cases, uterine atony is the most common cause of PPH. Additional reasons encompass preeclampsia, uterine inversion, accreta, laceration of the lower genital tract, and ruptured uterus.⁸.

In Pakistan, traditional birth attendants (TBAS) perform roughly 90–95% of deliveries. They offer some antenatal and intra-natal care but little to no postpartum care. Therefore, the mothers are taken to the hospital in a moribund state when they experience certain postpartum difficulties. Different studies have proved Proper use of therapeutic protocols to regulate PPH in addition to preventing uterine atony and improving the conditions of preeclampsia in women, also helps avoid potentially fatal complications like hysterectomy⁹. The two facets of managing PPH kev are resuscitation, diagnosing and treating the underlying cause. PPH can be treated by pharmacological medicines like Misoprostol from PGE1. oxytocin, syntometrine, ergometrine, PGF2 alpha, they are used as uterotonics⁷. Synthetic Misoprostol derived

from PGE1 analog has been found to be effective in controlling PPH¹⁰. According to a study on the prophylactic use of misoprostol, mixing oxytocin with misoprostol have been found to reduce bleeding more effectively than using just oxytocin alone¹¹.

The prophylactic use of Misoprostol before C-section has been found to have a positive and considerable impact on PPH prevention¹². Many studies have proved the effectiveness of Misoprostol in prevention of PPH, but its route of usage sublingual vs rectal is least studied in present literature. Therefore, the purpose of this study was to compare the effectiveness of rectal versus sublingual misoprostol in preventing primary postpartum haemorrhage.

2. METHODOLOGY

was Clinical randomized study conducted in gynecology department of CMH Multan on 200 pregnant female patients from Nov, 2022 - May, 2023 divided into 2 groups 100 respondents in each group. Ethical permission was taken from ethical review committee of CMH Multan and granted ethical permission (ERC No. 88/2023). Inclusion criteria included patients with age between 18 to 30 years, Hb>9g/dL, emergency C-section, singlefetus pregnancy of 37 weeks gestation, and who gave informed consent. Exclusion criteria included previous history of postpartum hemorrhage, co-morbidities like hypertension, anemia, CKD, previous history of coagulopathy, allergy to prostaglandin.

After taking informed consent, patient personal, family and gynecologicalhistory and information was noted. General physical and obstetric examination was performed. All respondents went through ultrasonography (USG) abdomen and pelvis to confirm gestational age. All baseline laboratory tests were done. Patients were anaesthetized using spinal anesthesia, following a C-section delivery, right after the umbilicus has been clamped, 4 tablets 200ug of Misoprostol sublingual was given to Group A and other group B received same dose via rectal route. The amount of blood loss in each case after surgery was evaluated using the amount of blood absorbed by each gauze. Long gauzes were weighted before and after surgery.

Data analysis was conducted using version 20 of the Statistical Package for Social Sciences (SPSS). Measurements included mean and standard deviation. To assess the significance between these two groups, the chi square test was used. A Pvalue of less than 0.05 was deemed statistically significant.

3. RESULTS

Mean age of respondents and gestational age in group A and B was 25.4 ± 4.3 years and 37.2 ± 0.9 weeks and 26.2 ± 4.6 years and weeks 37.9 ± 1.0 weeks respectively. Demographic characteristics and clinical details of patients are shown in Table 1.

Furthermore, total blood loss in Group A where Misoprostol sublingually was given was found to be 541 ± 123 ml in relation to Group B of Rectal Misoprostol of 401 ± 96 ml. When statistical significance was seen between the groups using Chi-Square test, group B (rectal misoprostol) was found better than the group A (sublingual misoprostol) with p-value <0.001.

Table 1: Demographic and clinical details of participants (n=200)

or participation (in 2000)				
Serial No	Group A n=100	Group B n=100	P-value	
Age (Years)	25.4±4.3	26.2±4.6		
Gestational Age (Weeks)	37.2±0.90	37.9±1.0	N/A	
Previous Pregnancies	1.23±0.92	1.31±0.76		
Diabetes Mellitus	29	23		

Blood Loss (ml)	541±12	401±96	< 0.001

The present study's findings demonstrated that group A experienced a greater overall blood loss than group B, indicating that rectal Misoprostol use is beneficial for PPH prevention and management.

Minor complications were observed in both cases, only 6 respondents from group A had complication which include vomiting and shivering. The 3 respondents of group B face complications of mild shivering only.

4. DICSCUSSION

This prospective study was conducted on 200 individual divided into two groups 100 respondents each, group A was given misoprostol in sublingual form against group B in which misoprostol through rectal route for prevention of PPH. Present study used Misoprostol for prevention and control of PPH. In multiple researches, the impact of misoprostol in reducing blood loss due to PPH has been proved¹³⁻¹⁵. Our study proved that use of Misoprostol via rectal route is effective for prevention for PPH is in accordance to a research carried out by Mansooreh Samimi et al. where they proved that Misoprostol is more effective in prevention and control of PPH¹⁶.A research by Wafa Najeeb et al. in Peshawar Pakistan favors our study proved that rectal Misoprostol was effective in prevention of PPH then oxytocin but they were unable to determine the total amount of drug required for prevention¹⁷. Present study used 4 tablets200ug of drug for Group B, similar to study carried out by Sweed MS et al. where they gave 200ugmisoprostol, but they gave only 1 tablet. The outcome in their proved that uterine treatment was recommended where 200ug of Misoprostol was used¹⁸. Another study used 800ug of rectal Misoprostol that favors our study. They found that 800ug was effective in prevention of PPH and minor complications like

shivering was observed in less no of cases¹⁹. Mohamed S Sweed et al. performed a double blinded RCT and they proved that Misoprostol was effective in sublingual route only when they are given with combination with oxytocin, hence this will increase the cost for the patients¹⁸. Another study conducted by Beigi et al. confirmed that blood loss was slightly higher in Tranxemic acid group as compared to that those where rectal Misoprostol was administered in series²⁰. Similar to study conducted by Ahmed Nasr et al. where less harmful effects were scene in Misoprostol group as compared to intravenous Oxytocin because they administered 800ug of Misoprostol in 4 tablets 200ug^{21} .

Small sample size, exclusion of patients with normal results, no control group, and no correlation with risk factors were studied. More study in view of above limitations can be made in future.

5. CONCLUSION

Misoprostol administered rectally was found more effective when compared against its sublingual use and was found safer.

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