Original Article

Effect of Preoperative use of Misoprostol on Mean Change in Hemoglobin in Patients Undergoing Caesarean Section

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ABSTRACT

Background: Blood loss during caesarean section is a common complication and adversely affects the perinatal outcome. Measures to reduce blood loss and subsequent need for transfusion have always gained attraction in clinical practice. Misoprostol, known for its role in managing obstetric bleeding, is reported to be more effective when administered pre-operatively. This study was conducted to evaluate the effect of preoperative per rectal misoprostol on mean change in hemoglobin concentration in patients undergoing caesarean section.

Methods: A Randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Sir Ganga Ram Hospital, Lahore from 3rd October 2020 to 2nd April 2021. Women undergoing caesarean section (CS) were either given 800µg per-rectal misoprostol preoperatively or no misoprostol at all in addition to IV Oxytocin infusion in all patients. Pre-operative and postoperative hemoglobin and hematocrit levels along with their difference levels were measured and data was analyzed using SPSS version 20.0.

Results: A total of 62 patients were randomized into two groups of 31 patients each. Group A and B had similar mean ages (27.55 ± 3.92 vs. 26.00 ± 3.93 years) and gestational ages (38.97 ± 1.05 vs. 39.16 ± 1.04 weeks). The most common indication of CS was failed induction (45.2%) followed by breech presentation (30.6%). The mean change in hemoglobin was significantly lower in misoprostol group as compared to the group which did not receive misoprostol at all (0.65 ± 0.30 vs. 1.13 ± 0.37 g/dL; $p < 0.05$). The mean change of hematocrit was significantly lower in misoprostol group as compared to group which did not receive misoprostol at all (1.56 ± 0.96% vs. 1.56 ± 0.85%; $p = 0.978$)

Conclusion: Pre-operative per-rectal misoprostol resulted in significantly lesser change in hemoglobin, which suggests optimal control of blood loss during surgery with pre-operative misoprostol. Therefore, preoperative use of per-rectal misoprostol may be recommended in future practice as prophylactic uterotonic in clinical practice for reducing PPH and transfusion related complications.

Keywords: Caesarean Section; Obstetric blood loss, pre-operative misoprostol; Hemoglobin

INTRODUCTION

Caesarean section (CS) is one of the most common obstetric procedures performed in women of reproductive age. The global rate of CS has increased significantly, often surpassing the WHO's recommended rate of 10 to 15%.[1] The reported frequency of CS in Pakistan is 31.26%, which is a huge economic burden on a developing country like Pakistan.[2] This raised frequency of CS is often associated with potential intraoperative complications like excessive hemorrhage, utero-cervical laceration, injury to adjacent organs, and emergency hysterectomy due to bleeding.[3] One of the most encountered complications of CS is postpartum hemorrhage (PPH) which may be potentially fatal. Generally, PPH is defined as an estimated blood loss of more than 500 mL in normal vaginal delivery and more than 1000 ml in cesarean section.[4] PPH accounts for 25% of maternal mortality and 12% of survivors develop severe anemia. The majority of maternal deaths associated with hemorrhage could be preventable.[5] The single most common cause is uterine atony which is responsible for 70-80% of the cases.[6] Oxytocin commonly used drug for prevention of PPH, however it requires specific storage temperature and being parentally administered, requires a skilled person during its administration.[7] In the local study by Shah et al., the mean blood loss in the rectal misoprostol group was less as compared IV oxytocin group (776 ± 285.7 mL 817 ± 1318 mL, $p = 0.043$).[8] Misoprostol, synthetic prostaglandin E1 analogue, is extensively utilized in obstetrics and gynecology for induction of labor, miscarriage management, cervical ripening as well as prophylaxis and treatment of postpartum hemorrhage.[9,10] Previous study demonstrated

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that pre-operative misoprostol significantly reduced intraoperative and postoperative blood loss as reflected by mean change in hemoglobin concentration (10.4 ± 0.67 vs. 10.8 ± 0.45 g/dL; p < 0.001).[9] Despite global research data regarding timing, dosage, and route of preoperative misoprostol administration remains controversial. Misoprostol is more effective preoperatively in order to reduce blood loss but conflicting results have been also stated in literature regarding its dose and route.[11,12] Misoprostol has strong uterotonic properties, is cheaper than oxytocin ,shows more heat stability, clinical efficacy and can be given through oral, rectal or vaginal route.[13] A randomized controlled trial conducted by Afkham et al. showed that both rectal and sublingual misoprostol were superior to oxytocin in preventing PPH (p < 0.005) and difference in bleeding between two routes of misoprostol was insignificant.[14] Many studies have evaluated the role of rectal misoprostol as a preventive measure for PPH.[15,16] Administration of rectal misoprostol in CS prior to incision is safe, more effective than postoperative administration for decreasing intraoperative blood loss and as prophylactic uterotonic drug.[17] Misoprostol is not widely used for the prophylactic management of PPH in our setup. Availability of local evidence will serve to formulate guidelines for the routine use of misoprostol. This study was thus designed to compare average change in hemoglobin with and without use of per rectal misoprostol preoperatively in patients undergoing cesarean section.

PATIENTS AND METHODS

This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Sir Ganga Ram Hospital, Lahore from 3rd October 2020 to 2nd April 2021 after getting approval from Ethical Review Committee, Fatima Jinnah Medical University (No. 50-Synop-Gynaecology-FJ/ERC dated 12th September,2020). RCT was conducted to check the effectiveness of preoperative and pre-rectal misoprostol in reduction of blood loss undergoing caesarean section. Informed consent was taken from women undergoing C-section. Selection criteria included women who were at term (37 completed weeks and beyond as per LMP / dating scan), aged between 18-35 years, with previous unscarred uterus, having normal fetal heart tracing and undergoing C-section due to the Failed induction (inability to attain the active phase of labor (≤4 cm) after one cycle of induction), breech presentation, transverse/oblique lie and maternal request. Patients were excluded from study who were hypertensive (systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg), diabetic (fasting blood sugar levels > 110 mg/dL), multiple gestations, polyhydroamnios, failed progress of labour, placenta previa, preoperative Hb < 9 g/dL, coagulation disorder (INR ≥ 1.5), medical disorders (cardiac disease, renal disease, hepatic disease) or known allergy with misoprostol. A simple random sampling technique was used and a sample size of 62 (31 in each group) was calculated with 80% power of test and 95% confidence interval while taking magnitude of mean change in hemoglobin concentration to be 10.4 ± 0.67 g/L with preoperative misoprostol and 10.8 ± 0.45 g/L without misoprostol in patients undergoing elective caesarean section.[7] Patient's demographic details and gravidity, parity, gestational age were noted along with CS indication. Clinical evaluation and detailed sonographic examination were performed. Patients were divided into two equal groups by computer generated table of numbers method. The patients in intervention group (group A) received single dose of 800 µg of Misoprostol preoperatively and per-rectally after administration of spinal anesthesia and before painting and draping. while non-intervention group (group B) did not receive misoprostol at all. Hemoglobin and hematocrit levels were the main parameters which was studied. The mean change of hemoglobin concentration was measured in g per dl and has been presented as change = preoperative hemoglobin – postoperative hemoglobin for which three milliliters of venous blood was sampled on operation theater table before surgery and 24 hours after surgery. Samples were sent to same laboratory (hematological lab SGRH emergency) to eliminate bias and hemoglobin concentration and hematocrit were measured by automated machine. All caesarean deliveries were performed by researcher herself and resident of equivalent experience who was allowed by supervisor under supervision of consultant gynaecologist to minimize bias. All caesarean deliveries were performed under spinal anesthesia through Pfannenstiel incision and lower segment uterine incision. Time interval between drug administration and delivery of fetus was noted. Total time duration of cesarean was also noted. Placenta was removed after spontaneous separation. Uterus was repaired with a continuous unlocked suture in two layers using a Polyglactin 910 No.1 suture, peritoneum was left unsutured, rectus sheath was closed using Polyglactin 910 No.1 and the skin was closed by simple interrupted suturing technique with Polypropylene 2/0. All patients received the same regime of management including 5 units oxytocin intravenous after delivery of fetus, same antibiotics (ceftriaxone (1 gram) / metronidazole (500 mg) intravenous for 48 hours and same analgesia (diclofenac sodium 75 mg) intramuscular TDS for first 24 hours. Oxytocin infusion (40 IU in 500 mL isotonic crystalloid at 125 mL/hour) was started in participants of both the groups after the delivery of baby. The need for additional uterotonics, tranexamic acid and need for blood transfusion was recorded for all patients. Postoperative monitoring was done by recording BP, pulse, fundal height measure-

ment and vaginal blood loss. Neonatal outcome including Apgar Score and Neonatal ICU admission was assessed. Misoprostol side effects including postoperative fever, shivering, abdominal pain and vomiting were also noted. All the information related to patients was noted on predesigned data collection proforma. Patients at high risk of intraoperative blood loss due to tears and extension of incision were excluded. Patients who received blood transfusion intraoperatively or postoperatively and in which postpartum hemorrhage was observed were excluded from study and managed according to hospital protocol. Confounding variables were controlled by exclusion. Continuous variables such as age, preoperative and postoperative hemoglobin, preoperative and postoperative hematocrit were presented as mean ± standard deviation. Categorical variables such as gravidity, indications for CS, use of oxytocin and tranexamic acid were expressed as frequencies and percentages. Data was entered into Microsoft Excel sheets and analyzed using SPSS version 20.0. Mean change of hemoglobin and mean change of hematocrit was compared in both groups using independent sample t-test. Effect modifiers such as age and gestational age were addressed in both groups through stratification. Post stratification independent sample t-test was applied. A p ≤0.05 was considered statistically significant.

RESULTS

A total of 62 patients were included. Mean ages in Group A and B were 27.55 ± 3.92, and 26.00 ± 3.93 years respectively. Mean gestational age of patients in Group A and B were 38.97 ± 1.05 and 39.16 ± 1.4 weeks respectively. In group A, there were 16 (51.6%) primigravida, 8 (25.8%) were gravida 2, 6 (19.4%) were gravida 3 while 1 (3.2%) was gravida 4. In group B, there were 27 (87.1%) primigravida, while 4 (12.9%) were gravida 3. In group A, most common indication was failed induction 13 (41.9%),. Breech pregnancy was the indication in 9 (29%), while 3 (9.7%) had CS on maternal request. In group B, most common indication was also failed induction observed 15 (48.4%) patients. Breech pregnancy was the indication in 10 (32.3%) while 2 (6.5%) had oblique/transverse lie. In group A, 5 (16.1%) females need additional hemostatic drug (tranexamic acid) as compared to group B, i.e. 16 (51.6%). The difference is significant (p < 0.05). Use of additional oxytocin is insignificant as 19.4% females of group A and 32.3% females of group B need additional oxytocin (Table 1).

In group A, postpartum hemorrhage occurred in 1 (3.2%) case. In group B, 8 (25.8%) females had postpartum hemorrhage (p < 0.05). In group A, blood transfusion was needed in 1 (3.2%) case. In group B, transfusion was needed in 8 (25.8%) patients with significant difference (p < 0.05). In Group A, the mean preoperative hemoglobin level was 11.15 ± 0.69 g/dL. In group B, preoperative mean hemoglobin level was 11.39 ± 0.75 (p > 0.05) In group A, postoperative mean hemoglobin level g/dL was 10.52 ± 0.68, while in group B, mean postoperative Hb was 10.26 ± 0.90 (p > 0.05). Postoperative change in hemoglobin level in group A was 0.65 ± 0.30g/dL and in.

Table 1: Characteristics of patients in both groups (N = 62)

Characteristics	Group A (N = 31)	Group B (N = 31)
Age ([Mean ± SD], years)	27.55 ± 3.92	26.00 ± 3.93
Gestational age ([Mean ± SD], weeks)	38.97 ± 1.05	39.16 ± 1.04
Blood pressure (mmHg)		
Systolic blood pressure [Mean ± SD]	114.84 ± 6.26	115.48 ± 6.24
Diastolic blood pressure [Mean ± SD]	73.55 ± 6.08	74.19 ± 5.02
BSL ([Mean ± SD], mg/dL)	93.13 ± 7.19	92.06 ± 7.01
Gravida		
1	16 (51.6%)	27 (87.1%)
2	8 (25.8%)	0 (0.0%)
3	6 (19.4%)	4 (12.9%)
4	1 (3.2%)	0 (0.0%)
Miscarriage		
Yes	15 (48.4%)	4 (12.9%)
No	16 (51.6%)	27 (87.1%)
Indication of cesarean section		
Breech	9 (29.0%)	10 (32.3%)
Failed induction	13 (41.9%)	15 (48.4%)
Maternal request	3 (9.7%)	4 (12.9%)
Oblique/transverse lie	6 (19.4%)	2 (6.5%)
Additional drugs		
Hemostatic (tranexamic acid)	5 (16.1%)	16 (51.6%)
Oxytocin	6 (19.4%)	10 (32.3%)

Table 2: Comparison of outcome in both groups (N = 62)

Variable	Group A (N = 31)	Group B (N = 31)	p-value
Duration of cesarean section ([Mean ± SD], minutes)	38.32 ± 3.34	37.61 ± 1.9	0.307
Time interval between drug administration and Fetus delivery ([Mean ± SD], minutes)	6.55 ± 1.79	6.65 ± 1.89	0.839
APGAR score	7.87 ± 0.92	7.90 ± 1.22	0.117
Preoperative hemoglobin ([Mean ± SD], g/dL)	11.15 ± 0.69	11.39 ± 0.75	0.191
Postoperative hemoglobin ([Mean ± SD], g/dL)	10.52 ± 0.68	10.26 ± 0.90	0.196
Change in hemoglobin ([Mean ± SD], g/dL)	0.65 ± 0.30	1.13 ± 0.37	< 0.001
Preoperative hematocrit ([Mean ± SD], %)	32.18 ± 3.13	33.38 ± 3.52	0.162
Postoperative hematocrit ([Mean ± SD], %)	30.62 ± 2.82	31.82 ± 3.24	0.124
Change in hematocrit ([Mean ± SD], %)	1.56 ± 0.96	1.56 ± 0.85	0.978
Postpartum hemorrhage	1 (3.2%)	8 (25.8%)	0.012
Blood transfusion	1 (3.2%)	8 (25.8%)	0.012
Side Effects of misoprostol	29 (93.5%)	19 (61.3%)	0.002
Abdominal pain	1 (3.2%)	4 (12.9%)	0.162
Shivering	17 (54.8%)	2 (6.5%)	<0.001
Fever	5 (16.1%)	8 (25.8%)	0.349
Nausea and vomiting	9 (29.0%)	7 (22.6%)	0.562

group B, it was 1.13 ± 0.37 g/dL ($p < 0.05$). In group A, preoperative hematocrit level was 32.18 ± 3.13%, while in group B, it was 33.38 ± 3.52% ($p > 0.05$). In group A, post-operative hematocrit level was 30.62 ± 2.82% and in group B, it was 31.82 ± 3. 24% ($p > 0.05$). In group A, post-operative change in hematocrit level was 1.56 ± 0.96%. In group B, postoperative change in hematocrit level was 1.56 ± 0.85% ($p < 0.05$). Various other variables have been summarized in Table 1 and 2.

DISCUSSION

This study was conducted to check the effectiveness of preoperative and per rectal use of misoprostol in reduction of blood loss undergoing cesarean section. Hemoglobin is indirect measure of amount of bleeding in peri-operative period.[18] In our study, both groups were compared according to mean hemoglobin change before and after surgery. The significant change in hemoglobin was lower in patients receiving pre-operative misoprostol than those who did not receive misoprostol. Therefore, these results point towards the effectiveness of rectal misoprostol in reducing the amount of bleeding during cesarean section.

Severe obstetric hemorrhage is one of the serious and potentially life-threatening emergencies during childbirth. About 25% of total maternal deaths are due to postpartum haemorrhage and it is main cause of maternal death in low-income countries.[19] Caesarean section is a major surgery which has various risk factors. Blood loss during C-section is however more important as it adversely affects the perinatal outcome of both the mother and the baby, therefore measures which can reduce the blood loss and subsequent need for transfusion have gained attraction in clinical practice.[5]

Misoprostol is proven alternative to uterotonic agents as easy availability, ease in administration, stability at room temperature and long shelf life are particulars of misoprostol which prefer its use in low resource settings.[9] The spectrum of side effects includes nausea, vomiting, shivering, fever and abdominal pain which are self-limiting and do not require any medical intervention and mostly settle within first 24 hours.[20,21]

In most of previous studies, postoperative misoprostol was given conventionally.[9] Multiple routes of misoprostol administration have been studied but in present trial, the reason behind rectal path of misoprostol administration was to avoid adverse effects on mother and neonate as this route has slow absorption, steady serum rise with lower peak serum concentration and longer half-life. This may account for low side effect profile as compared to oral/sublingual route.[22] The longer half-life of rectal misoprostol has additional benefit of delayed uterine contractions so it was administered just before skin incision which provides enough time for absorption, and it will reduce blood loss during intra and postpartum period without causing any adverse effects on unborn baby. A previous study was conducted on 192 women who did not have any risk factors for postpartum hemorrhage, showed that there was a significant reduction of blood loss in the misoprostol group compared with oxytocin group (144.5 ± 100.1 mL vs. 191.7 ± 117.1 mL; $p < 0.0001$).[23]

In present study, majority of total subjects are primigravida. The mean gestational age of women undergoing C-section was 38.97 ± 1.05 weeks in study group and 39.16 ± 1.04 weeks in control group. Other authors reported similar mean gestational age of 39.20 ± 1.80 weeks and 38.07 ± 2.30 weeks respectively among American women undergoing elective C-section.[24,25] In this study, both groups were compared according to mean hemoglobin change before and after surgery. The significant change in hemoglobin was lower in patients receiving pre-

operative misoprostol with respect to without receiving misoprostol. These results are comparable to a previous study which reported similar significant difference in mean change in hemoglobin with pre-operative versus post-operative misoprostol (10.4 ± 0.67 vs. 10.8 ± 0.45 g/L; p < 0.001) in women undergoing elective cesarean section.[17] This study also defined the significant and confirmed use of misoprostol pre and postoperatively. It can reduce the adverse reactions and effects in terms of blood loss. In present study, both groups were also compared according to haematocrit change. The postoperative haematocrit level change 24 hours after delivery was statistically insignificant. However, the mean change in haematocrit was significantly lower in patients receiving pre-operative misoprostol with respect to without receiving misoprostol. Previous studies reported similar results as mean change in haematocrit was less in preoperative misoprostol group than control group.[17,26]

In this study, the requirement of oxytocin was lesser in group A than in group B (19.4% vs. 32%; p = 0.246) which is similar to that described in a previous study.[26] No harmful effects on fetus were observed in this study as evident through neonatal Apgar score and NICU admission rate in both groups. Observed maternal side effects were shivering, fever, abdominal pain, nausea and vomiting. Total 16% patients developed insignificant transient postpartum fever which is similar to findings described in a previous study.[16] Use of routine prophylactic antibiotic and nonsteroidal analgesic rule out the other causes fever. In present study 54% of participants developed statistically significant shivering. This finding is different from a previous study which reported insignificant result as none of the participants developed shivering.[26] Like the present study, previous authors have demonstrated that pre-operative misoprostol was more efficacious than conventional practice of post-operative misoprostol in terms of lesser mean change in hemoglobin after C-section and advocated pre-operative regimen for future practice.[9]

Finally, the authors acknowledge that the study is not without limitations as it is single centered study as well as estimation of blood loss through assessment of mean change of hemoglobin which is indirect measure of blood loss. Thus the authors, therefore, recommend further larger scale multicentric studies with more reliable method of estimation of blood loss for the estimation of rectally administered misoprostol in order to provide evidence for its use in patients undergoing cesarean section.

CONCLUSION

Preoperative use of per-rectal misoprostol decreases intraoperative and postoperative blood loss in patients undergoing cesarean section. Preoperative use of per-rectal misoprostol may be considered as it is useful modality in minimizing intraoperative and postoperative blood loss as well as incidence of PPH. Further studies are still needed with larger sample size to assess the timing and effectiveness of misoprostol.

Author Contributions

SAB: Conception and design, analysis and interpretation of data, drafting the article, critical revision for important intellectual content, final approval.
HAB: Conception and design, analysis and interpretation of data.
NA: Analysis and interpretation of data, drafting the article.

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