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Original research article

Sublingual Misoprostol for the Prevention of Postpartum Haemorrhage – A Randomised Control Trial

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Abstract

Aim – The aim of the study was to study the effect of sublingual misoprostol for prevention of PPH.

Materials and Methods: This was a prospective, randomized, double blind, placebo controlled study. Inclusion criteria were women aged 20-40 years with 38-40 weeks of gestation who underwent elective caesarean section. Exclusion criteria were women have risk factors for post-partum haemorrhage, active thromboembolic disease and intrinsic risk for thrombosis. Participants were randomly assigned to misoprostol group or group A (n=50) and placebo group or group B(n=50). Group A received 400µg of sublingual misoprostol after delivery of the baby, group B received placebo tablet at the same time. Primary outcome measures were blood loss from delivery of the placenta to the end of the caesarean section to 2 hours postpartum, haemoglobin estimation was done in all patients pre operatively and 24 hours post operatively and the change in concentration was noted. Secondary outcome measures were need for additional uterotonics, use of additional surgical interventions to control post-partum haemorrhage.

Result: Blood loss from both placental delivery to the end of caesarean section and from end of caesarean section to 2 hours postpartum were significantly lower in the study group. ($p<0.0001$). Change in haemoglobin concentration in study group was also significantly less than in the control group. ($p<0.0001$). Total amount of Oxytocin required was significantly less in the study group ($p=0.01$). The number of women requiring other oxytocics (inj. Methyl ergometrine, inj. Carboprost) was significantly less in study group ($p=0.0078$). Conclusion – Sublingual misoprostol has been found to be effective in preventing PPH.

Introduction

About 10.5% of all live births results in severe post-partum haemorrhage (PPH) which amounts to almost 14 million[1]. The caesarean delivery frequency is rising gradually and caesarean delivery results in almost double blood loss when compared to vaginal delivery[2]. Although many obstetric units use intravenous bolus or infusion of oxytocin to prevent uterine atony during and after caesarean delivery, 10%-40% of women receiving oxytocin require additional uterotonic agents[3,4].

Misoprostol is a synthetic prostaglandin analog which is cheap, stable at room temperature, orally active, and has few adverse effects. It was used initially for prophylaxis of peptic ulcer and subsequently as a cervical priming agent for induction of labor, medical termination of pregnancy and for preventing and treating postpartum haemorrhage[5].

The aim of the present study was to study the effect of sublingual misoprostol for prevention of PPH.

MATERIALS AND METHODS

This was a prospective, randomized, double blind, placebo-controlled study conducted in the department of Gynaecology and Obstetrics, Patna Medical College and Hospital from March 2017 to February 2018. Inclusion criteria were women aged 20-40 years with 38-40 weeks of gestation who underwent elective caesarean section, Exclusion criteria were. Women having risk factors for post-partum haemorrhage, such as, multiple pregnancy, polyhydramnios, fetal macrosomia, antepartum haemorrhage, obstructed labor, haemoglobin <8gm%, severe pre eclampsia and coagulopathy; previous history of caesarean delivery or intra abdominal surgery; active thromboembolic disease, eg., deep vein thrombosis, pulmonary embolism, cerebral thrombosis; history of thrombosis or thromboembolism; intrinsic risk for thrombosis, eg., thrombogenic valvular disease, thrombogenic cardiac rhythm disease, hypercoagulopathy, thrombophilia; cardiovascular, renal or liver disorders.

Participants were randomly assigned to misoprostol group or group A (n=50) and placebo group or group B (n=50) Randomization was done by residents using computer generated random numbers. Allocation concealment was done by sequentially numbered opaque sealed envelope (SNOSE). Group A received 400µg of sublingual misoprostol after delivery of the baby, group B received placebo tablet at the same time. Both the patients and the investigators remained blinded to the group assignment. All patients also received 20 units of oxytocin during the first 8 hours post operatively. Additional uterotonics in the form of oxytocin infusion. Inj methyl Ergometrine, Inj. Carboprost were given as and when needed.

Primary outcome measures were –

1. Blood loss from delivery of the placenta to the end of the caesarean section which was measured by adding the volume of the contents of the suction bottle which was changed after delivery of placenta to avoid being mixed with amniotic fluid and blood from parities and the difference in weight (in grams) between the dry and the soaked operation sheets, gauze pieces and mops (1gram is equivalent to 1ml.).
2. Blood loss from the end of caesarean section to 2 hours post-postpartum which was measured by weighing the soaked pads (in grams) and subtracting the weight of dry pads (in grams) from it (1gram is equivalent to 1ml).
3. Hemoglobin estimation was done in all patients pre-operatively and 24 hours post operatively and the change in concentration was noted. **Secondary outcome measures were –**

1. Need for additional uterotonics.
2. Use of additional surgical interventions to control post-partum haemorrhage.
3. Need for blood transfusion.

Table 1:

Variables	Study group (mean±SD)n=45	Placebo group (mean±SD) n=45	P
Blood loss from placental delivery to the end of CS (ml)	370.8± 36.66	622.8±95.2	<0.0001t test
Blood loss from end of CS to 2 hours post-partum (ml)	47.16±8.245	76.23±6.211	<0.0001t test
Change in Hb% (gm/dl)	1.13±0.411	1.53±0.472	<0.0001t test
Oxytocin administered (units)	40±0.411	1.53±0.472	<0.0001t test
Number of patients requiring other uterotonics	12	26	0.0078 Fisher's test

RESULT

Initially 100 women were enrolled for the study. Eight did not meet the inclusion criteria and two refused to participate. Ninety women were randomized into study and placebo group. Analysis was by intention to treat.

Blood loss from both placental delivery to the end of caesarean section and from end of caesarean section to 2 hours postpartum were significantly lower in the study group. ($p<0.0001$). Change in haemoglobin concentration in study group was also significantly less than in the control group. ($p<0.0001$). Total amount of Oxytocin required was significantly less in the study group ($p=0.01$). Also the number of women requiring other oxytocics (Inj. Methyl ergometrine, Inj. Carboprost) was significantly less in study group ($p=0.0078$).

Neither group required any additional surgical intervention to control PPH.

DISCUSSION

A number of studies have been performed to find out the effect of sublingual misoprostol to prevent post-partum haemorrhage in caesarean section. Othman EF et al[6] have found mean blood loss to be significantly lower in the misoprostol group compared to the oxytocin group. However, changes in haematocrit level (pre and postpartum) was comparable between both groups. Vimala N et al[7] have found sublingual misoprostol to be equally effective as oxytocin infusion in preventing PPH. However they found minor side effects in the misoprostol group.

CONCLUSION

Sublingual misoprostol has been found to be effective in preventing PPH. More studies are required to establish this role of misoprostol.

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