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Research Article

An analytical study comparing Misoprostol and Oxytocin to prevent postpartum haemorrhage

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Abstract

Introduction : The present study was carried out with objectives to see the efficacy of rectal misoprostol in comparison to intramuscular oxytocin in prevention of postpartum haemorrhage in low risk patient. Methods: Data of 400 randomly selected obstetric patients who seeked care for delivery at the Obstetrical Units were retrospectively identified. Divided into two groups of A (Rectal Misoprostol & B of Oxytocin I.M. Results: No statistical difference among baseline variables , mean duration of labour. The difference in mean blood loss between rectal misoprostol group and oxytocin group is statistically significant. Blood loss during third stage is found to be more in misoprostol group than oxytocin group.

Conclusion : It is observed that the misoprostol rectally is less effective than intramuscular oxytocin when used as prophylactic uterotonic during the active management of third stage of labour. Third stage blood loss found to be significantly more with misoprostol.

Keywords: Misoprostol , Oxytocin , PPH , Labour

1 | INTRODUCTION

Postpartum haemorrhage (PPH) is the most common cause of maternal death worldwide. Most cases of morbidity and mortality due to PPH are in the first 24 hours following delivery and these are regarded as primary PPH whereas any abnormal or excessive bleeding from the birth canal occurring between 24 hours and 12 weeks postnatally is regarded as secondary PPH [1, 2]. Although medical advances have dramatically reduced the dangers of childbirth, death from haemorrhage still remains a leading cause of maternal mortality in both developed and developing countries. Uterine atony or diminished myometrial contractility, accounts for 80% of PPH.

Certain factors are associated with developing PPH, such as prolonged third stage of labour; pregnancy induced hypertension; previous PPH; twins or previous multiple pregnancies early detachment of placenta from the uterus; soft tissue laceration; instrumental delivery; infection and obesity [3].

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However, most of cases of PPH take place in women with no known risk factors. That is why all women must have access to prevention during pregnancy and to emergency treatment at the time of delivery for severe blood loss. There are several different types of uterotonic drugs (oxytocin, ergometrine, prostaglandins) that play a critical role in both prevention and treatment of PPH. The relative advantages and disadvantages of these different drugs and potential side effects have been an important topic of research for prevention and treatment of PPH. For centuries, the uterotonic agent of choice has been oxytocin with or without supplemental ergot preparations. Both oxytocin and ergometrine are unstable at room temperature and thus require special temperature and light storage conditions to remain effective. These storage requirements are a major hurdle to the widespread use of oxytocin in the developing countries. Misoprostol is a prostaglandin E1 (PGE1) analogous which stimulates pregnant uterus through prostanoid EP2 and EP3 receptors [4]. It is an active uterotonic agent and allows the uterus to contract within few minutes. It is stable at room temperature, inexpensive and rapidly absorbed into the circulation after administration. In addition it can be administered by various routes eg. orally, sublingually, vaginally or rectally. For this reason, misoprostol has attracted considerable attention as an alternative to oxytocin for prevention of PPH in resource poor settings [5, 6, 7]. The present study was carried out with objectives to see the efficacy of rectal misoprostol in comparison to intramuscular oxytocin in prevention of postpartum haemorrhage in low risk patient.

2 | METHEDOLOGY

This Retrospective Analytical study involved Prior Consent from Hospital Authorities / Medical Superintendents of the Local Randomly selected Secondary & Tertiary care hospitals having Full Facility Obstetrical Unit / Department / Labour room & Paediatric Unit , to see the records of the patients from Medical Records Department (MRD).The study was conducted within ethical standards. The Obstetrical Patients who were admitted in randomly selected tertiary care hospitals including Our Teaching Hospital in the city were selected for the study . Randomization was done using computer tables in selecting data. It was observed in the records that the obstetric patients who seek care for delivery at the medical centers were admitted to the obstetrics department for delivery after initial evaluation. All Patients underwent standard clinical examinations, routine biochemical and haematological investigations, Ultrasonography of whole abdomen and received treatment . Medical record numbers were used to generate the data for analysis.

For the purpose of the present study, data of 400 of the randomly selected obstetric patients (candidates / study subjects) who seeked care for delivery at the Obstetrical Units were retrospectively identified.

The definition of postpartum haemorrhage for the present study was any amount of bleeding after delivery of baby that makes the patient symptomatic (eg. Light headness, vertigo, syncope) and/or results in signs of hypovolemia (eg. Hypotension, tachycardia, or oliguria) and quantitatively blood loss more than 500 ml in vaginal delivery. Women who were admitted into the labour room (booked or unbooked) had been taken for the study with the following inclusion criteria: 1. Patients who could give the proper history of time of onset of regular pain and general, systemic and pelvic examination demonstrated a term, live, singleton pregnancy with cephalic presentation and with an effaced cervix with 4cm or more dilation. 2. Patients belonging to age group in the range of 18-36 years and up to third gravida with history of regular menstrual cycle. Exclusion criteria: 1. Caesarean section or instrumental delivery, 2. Haemoglobin less than 8 gm%, 3. History of antepartum haemorrhage, 4. Severe pregnancy induced hypertension, 5.Pre-eclampsia or eclampsia, 6. Prolonged labour or precipitate labour, 7. Foetal weight >3.5kg, 8. Polyhydramnios, and 9. Medical disorders (cardiovascular disease, diabetes mellitus, thyroid disorders and other coagulation abnormality etc.).

Informed written consent was obtained from the patient after proper counselling on admission to the labour room. The personal information and medical data of the selected cases were collected in structured proforma. A total number of 400 cases we took for the study, which were divided randomly into two groups containing 200 cases each. ie. Group A and Group B. Group A patients were given 600 µgm misoprostol rectally immediately following delivery of baby. Group B patients were given 10 IU of oxytocin intramuscularly immediately after delivery. It was seen that The third stage of labour was managed actively with delivery of placenta by controlled cord traction. Any blood clot which expressed from the uterus was measured in the calibrated glass container. After delivery, the general condition was assessed at regular interval up to 2 hours. Maternal haemoglobin concentration was measured before delivery and repeated 24 hours after delivery. Comparison of quantitative variables between the study groups was done using 't' test for independent sample. $P < 0.05$ was considered statistically significant. Statistical analysis was done using SPSS version 15.0.

Continuous data were expressed as mean ± standard deviation (SD) . The data were analyzed by IBM SPSS Statistics 23 . Overall, < 0.05 was proposed to represent statistical significance after correction.

3 | RESULTS

The baseline variables like antenatal registration, age, gravida, parity, gestational age, duration of labour, duration of third stage of labour, progress of labour and number of episiotomy of both study and control group where no significant statistical difference was observed between these two groups . The mean third stage blood loss was 180 ±74.65 ml and 166±18.37ml in group A and group B respectively with p-value being 0.023 suggested that there was significant difference (p less than 0.05).

Incidence of PPH was 4 % and 3% in group A and group B respectively and found to be 3.5% in whole study population. There was no significant difference in the incidence of PPH in both groups where the $p>0.05$ was not significant.

Blood transfusion was given to the patient who had blood loss >500ml and/or who developed signs and symptoms of shock. In misoprostol group out of 200 women only 6 patients and in oxytocin only 5 patients got blood transfusion. Side effects were found to be more in study group A than the control group B. The incidence of shivering was significantly higher in the study group A than the control group B . The degree of shivering was mild to moderate and subsided spontaneously within 4-5 hours without any treatment. Similarly, incidence of fever was significantly higher in group A than group B . Pyrexia was transient and did not require treatment, subsided spontaneously within 6- 8 hours after delivery. Overall there was no significant difference found in the incidence of side effects between study and control group, except in the incidence of shivering and pyrexia which was found to be more in misoprostol group. (Table 1)

Table 1 showing side effects of drugs.

Side Effects	A (n=200)	B (n=200)
1. Headache	6 (3%)	4 (2%)
2. Nausea	20 (10%)	8 (4%)
3. Vomiting	5 (2.5%)	3 (1.5%)
4. Shivering	44 (22%)	6 (3%)
5. Diarrhoea	12 (6%)	7 (3.5%)
6. Pain Abdomen	3 (1.5%)	1 (0.5%)
7. Fever	18 (9%)	1 (0.5%)

4 | DISCUSSION

The number of unbooked cases was more in both study and control groups compared to booked cases. The maximum number of patients in both the study and control group was primigravida .. Due to difference in randomized selection of the patients by exclusion criteria, there was minimum difference in percentage. The mean age was 22.89±2.93SD and 23.48±3.76SD in Group

A and Group B respectively with p-value being P=0.15 (P>0.05) which suggest there was no significant difference in the mean age between two groups. The commonest age group involved in the study and control group was 21-25 years . The mean age group taken for the study was quite comparable to some other studies like Shrestha et al (2010) [8], Steven et al (2006) [9], Masoumeh et al (2009) [10] and Ibrahim et al (2003) [11].

The patient taken for study were comparable in relation to their mean gestational age in weeks where 38.58±1.79 and 38.22±1.45 was observed in Group A and Group B respectively with p value being P=0.813 (P>0.05). The mean gestational age taken for the study was comparable to some other standard trials [8-10, 12].

Comparing the incidence of spontaneous and augmented or accelerated labour with exclusion of induced labour, this study is found comparable to some other studies [11,12,13]. The mean duration of labour was 5.59±1.29 and 5.65±1.53 in misoprostol group (group A) and oxytocin group (group B) respectively with p-value being P=0.06 considered non significant (P>0.05).

There was no significant difference (P>0.05) in the mean duration of labour between the study and control group. No statistical difference was noted in between two groups in relation to the mean duration of third stage of labour. Similarly, study performed by Karkanis et al in 2002 [14] among 240 women who randomly received 400 µgm rectal misoprostol after delivery of the infants or parentral oxytocin (IM or IV) after delivery of anterior shoulder.

No statistically significant difference found in mean duration of third stage of labour between two groups like that of our study. The difference in mean blood loss between rectal misoprostol group and oxytocin group is statistically significant. Blood loss during third stage is found to be more in misoprostol group than oxytocin group. The results in the present study in relation to the third stage blood loss are similar or comparable to the other studies as shown in table-5 [8,12,15].

The wide range of third stage blood loss in different trails may be due to difference in the estimation of blood loss by subjective visual observation. Considering PPH as a blood loss of ≥500 ml, in the present study, 4% of patients given misoprostol developed PPH as compared to 3% with oxytocin group which is statistically not significant (p>0.05). In some other trails also similar results was found [8,9,11,16]. Blood transfusion was given to the patients who had blood loss ≥ 500ml and developed symptoms of shock. In misoprostol group out of 200 women 6 patients and in oxytocin group 5 patients got blood transfusion. As the blood loss at delivery is a subjective observation rather than an objective measurement, the more reliable estimation of blood loss will be decline in haematocrit or haemoglobin and clinical examination [17,18]. Thus, the difference in mean estimated blood loss between the groups will be better evaluated by difference in haemoglobin between pre-delivery and post-delivery haemoglobin level which is much more objective [19]. There was no significant difference in mean fall in haemoglobin between two groups. In a trial done by Bugalho et al., 663 women with uncomplicated vaginal delivery were randomized to receive 400µg rectal misoprostol or oxytocin 10IU IM after delivery of the infant. No significant differences of haemoglobin level were observed between two groups, before and after delivery [20]. Bamigboye et al. in his search for an effective, easily stored, affordable uterotonic agent to prevent postpartum haemorrhage, conducted a trial where he randomized 491 women to receive either 400µg rectal misoprostol (241 women) or one ample of syntometrine (250 women). His results showed that the incidence of postpartum haemorrhage, duration of third stage of labour and the drop in haemoglobin level were similar [21]. The side effects of misoprostol are gastrointestinal, shivering, pyrexia, pain abdomen etc. In the present study, it was found that the misoprostol was associated with more side effects than the oxytocin.

The incidence of nausea, vomiting, and diarrhoea was more in misoprostol group. The incidence of shivering, pyrexia was found to be more in misoprostol group than oxytocin. Shrestha et al. in their study among 200 cases found that the 16% patients developed shivering in misoprostol group

and 4% developed in oxytocin group [8]. The degree of shivering was mild to moderate and subsided spontaneously within 4-5 hours without any treatment. Pyrexia was transient in nature, subsided spontaneously within 6-8 hours after delivery. Nasr et al. in study among 514 women who are randomly allocated to receive 800µg rectal misoprostol and oxytocin IV found that the incidence of fever was significantly higher in misoprostol group (18.7% verus 0.8%) [22].

5 | CONCLUSION

In our study it is observed that the misoprostol rectally is less effective than intramuscular oxytocin when used as prophylactic uterotonic during the active management of third stage of labour. Third stage blood loss found to be significantly more with misoprostol. But, duration of third stage of labour and mean fall in haemoglobin postpartum was similar. Overall there was no significant difference found in the incidence of side effects between both groups, except in the incidence of shivering and pyrexia which was found more in misoprostol. Most of the side effects were seen in the post delivery period within 2 to 3 hours following administration of drugs and subsided spontaneously within 4-5 hours.

CONCLUSION

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Compliance With Ethical Standards.

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