

## Assessing Rectal Misoprostol versus Intravenous Oxytocin in Reducing Intra and Postoperative Bleeding during Elective Cesarean Section: A Comparative Clinical Study

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### Abstract

**Aim:** The aim of the present study was to compare the efficacy and safety of 400mcg misoprostol per rectum preoperatively versus intravenous oxytocin in reducing intra operative and post-operative bleeding in elective caesarean section.

**Methods:** The present study included 200 women and take place in the Department of Obstetrics & Gynaecology, Government Medical College Bettiah, West Champaran, Bihar, India who were elective cases for cesarean section. Detailed history of all the patients were taken according to the performa and complete examination and all necessary investigations was done. After having met all the inclusion and exclusion criteria and obtaining written consent.

**Results:** The mean age of misoprostol and Oxytocin Group was 23.87 and 21.95 years respectively. We found no significant difference as the p value was 0.854. Multiparous and primiparous women were 55% and 45% respectively in Misoprostol group; 65% and 35% in Oxytocin group. In Misoprostol group the most common side effect was shivering accounts for 23% patients followed by fever accounts for 7% patients. In Oxytocin group nausea and vomiting were the commonest side effect account for 6% patients each. While analyzing we found statistically insignificant difference for side effects in both groups as the p value was <0.001. Mean blood loss level for Misoprostol and Oxytocin group was 187.12 and 181.09 ml respectively. The difference in blood loss was statistically insignificant between the two groups as the p value was 0.316. The difference in mean Hb level before and after 24 hrs of delivery was insignificant as the p value was >0.05.

**Conclusion:** The present study indicated that in the context of active management of 3rd grade labour, Misoprostol has comparable effectiveness to oxytocin (10IU IV in 500ml RL) in the prevention of early postpartum haemorrhage However, misoprostol was associated with higher incidence of shivering and pyrexia but no other serious adverse effects occurred.

**Keywords:** misoprostol, intravenous oxytocin, intra operative, post-operative bleeding, elective caesarean section

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### Introduction

Postpartum hemorrhage (PPH) is a serious condition and is considered the main contributor to death in nations that are both developing and developed. [1] PPH is characterized as a blood loss of more than 500 mL during 24 h after a normal vaginal birth or more than 1000 mL following a cesarean section. [2] PPH can complicate up to 5% of births in both developed and developing nations. [3] The World Health Organization (WHO) has reported 100,000 deaths yearly due to PPH.

Cesarean section (CS) is the most frequent major surgical operation done on women in the United States; around one million CS are performed each year, and 15% of births worldwide occur by CS. [4] The rising rate of CS is concerning because blood loss throughout CS is nearly double that of vaginal delivery, and the necessity of blood transfusion, with all its risks, is also greater after CS than after vaginal births. [5] Uterine Atony is the cause of up to 80% of PPH leading to postnatal anemia, and hemorrhagic shock so a rapid transfusion and

surgical interventions are needed [6]. Oxytocin is considered as the first line of treatment for PPH [7]. Despite being effective and safe, oxytocin has certain drawbacks: 10-40% of the women who received it were found to require supplementary uterotonics. The use of oxytocin has been linked to tachycardia, hypotension, and antidiuresis. [8]

Misoprostol is an analog of prostaglandin E1 that is used to prevent and treat PPH because of its uterotonic effect. Misoprostol is readily accessible, inexpensive, and stable at room temperature. It is easy to administer via multiple routes (oral, sublingual, vaginal, rectal, and intrauterine), has minimal adverse effects and has few contraindications for use. According to certain research, oxytocin and misoprostol both work well to prevent intra and postoperative bleeding. [8,9] Misoprostol may be given orally, or sublingual. Due to the difficulty in use oral or sublingual misoprostol in general or spinal anesthesia and based on pharmacological studies proving that the blood level of rectal misoprostol is the same of oral misoprostol [10], therefore rectal misoprostol is a suitable alternative to oxytocin.

The aim of the present study was to compare the efficacy and safety of 400mcg misoprostol per rectum preoperatively versus intravenous oxytocin in reducing intra operative and post-operative bleeding in elective caesarean section.

### Materials and Methods

The present study included 200 women and take place in the Department of Obstetrics & Gynaecology, Government Medical College Bettiah, West Champaran, Bihar, India who were elective cases for caesarean section. Detailed history of all the patients were taken according to the performa and complete examination and all necessary investigations was done. After having met all the inclusion and exclusion criteria and obtaining written consent.

After calculation, total 300 women of high risk pregnancy were included undergoing caesarean section in whom Post-Partum Hemorrhage (PPH) was anticipated. Women were counselled about their participation in the study. Written informed consent was obtained before caesarean section.

### Inclusion Criteria:

- Singleton term pregnancy (37 -40) wks undergoing elective LSC.

### Exclusion Criteria:

- Previous rupture uterus
- Coagulopathy
- Fetal Distress

- Presence of Comorbid diseases like Cardiac, Respiratory, Renal or Hepatic disease.

The study included two groups.

### Group (A) MISOPROSTOL Group-100:

In group A, preoperatively tablet misoprostol 400 microgram per rectum was kept after spinal anesthesia before painting and draping was done in women who under went elective LSCS .

### Group (B) –OXYTOCIN Group -100

In group B, women were given intravenous oxytocin 10 IU in 500ml RL after the baby was extracted in cesarean section.

Hemoglobin level was measured before and after 24 hours of the operation. Side effects like shivering, nausea and vomiting along the operation and up to 2 hours after the operation was recorded. Temperature was monitored routinely and noted in the data sheet when greater than 37.5°C.

The amount of blood loss during caesarean section and 2 hours postoperatively was assessed. Total blood loss during caesarean delivery was measured by adding the volume of the suction bottle with the blood soaked sponges (know dry weight). Blood loss 2 hours after caesarean delivery was also measured by using blood collection drape. The whole blood loss was estimated by adding the blood in the suction bottle, blood-soaked sponges and blood collection drapes.

Haematocrit values were noted before and 24 hours following surgery. Vital signs were observed continuously intraoperative and every 30 minutes after that.

### Study Outcomes:

The primary outcome of this study was estimation of blood loss during and after CS following administration of rectal misoprostol or intravenous oxytocin. The secondary outcome measures included the need for any additional oxytocic drugs or changes in hematocrit value after deliver and incidence of side effects.

### Statistical Analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and data was analyzed by Chi square test for association, comparison of means using t test, ANOVA and diagrammatic presentation.

### Results

**Table 1: Mean age between study groups**

Parameters	Misoprostol		Oxytocin		P value
	Mean	SD	Mean	SD	
Age in years	23.87	2.68	21.95	2.86	0.854

The mean age of misoprostol and Oxytocin Group was 23.87 and 21.95 years respectively. We found no significant difference as the p value was 0.854.

**Table 2: Distribution of parity and side effects between study groups**

Parity	Misoprostol		Oxytocin		P value
	N	%	N	%	
Mutli	55	55	65	65	0.112
Primi	45	45	35	35	
Total	100	100	100	100	
Side effects					
Fever	7	7	0	0	<0.001
Nausea	0	0	6	6	
Shivering	23	23	0	0	
Vomiting	0	0	6	6	

Multiparous and primiparous women were 55% and 45% respectively in Misoprostol group; 65% and 35% in Oxytocin group. In Misoprostol group the most common side effect was shivering accounts for 23% patients followed by fever accounts for 7%

patients. In Oxytocin group nausea and vomiting were the commonest side effect account for 6% patients each. While analyzing we found statistically insignificant difference for side effects in both groups as the p value was <0.001.

**Table 3: Mean blood loss between study Groups**

Parameters	Misoprostol		Oxytocin		P value
	Mean	SD	Mean	SD	
Blood loss	187.12	48.64	181.09	54.52	0.316

Mean blood loss level for Misoprostol and Oxytocin group was 187.12 and 181.09 ml respectively. The difference in blood loss was statistically insignificant between the two groups as the p value was 0.316.

**Table 4: Hb Parameters between Study Groups**

Parameters	Misoprostol		Oxytocin		P Value
	Mean	SD	Mean	SD	
Before Delivery Hb	9.96	0.82	9.86	0.86	0.325
After delivery Hb (24Hrs )	9.36	0.88	9.36	0.72	0.644

The difference in mean Hb level before and after 24 hrs of delivery was insignificant as the p value was >0.05.

### Discussion

Cesarean delivery in the most common surgical procedure performed on women worldwide and its rates continues to rise steadily in both developed and developing countries. [11] Post partum haemorrhage (PPH) is a major cause of maternal mortality, especially in under-resourced Countries, accounting for nearly one-quarter of all maternal deaths world wide. The most common cause of PPH is the failure of the uterus to contract adequately which is responsible for approximately 70% of primary PPH with the increasing incidence of Caesarean section.PPH. May be more common because the average blood loss

during a Caesarean section is twice that during vaginal delivery. [12]

Post partum haemorrhage (PPH) is defined as a blood loss of more than 1000ml is the first 24hr. following cesarean section. PPH is the leading cause of maternal mortality world wide and the number. Of maternal deaths due to post parting haemorrhage is estimated to exceed 100,000 maternal death each year. [13] Although most obstetric units use intravenous oxytocin, given as either a bolus or an infusion as a first line agent to prevent uterine atony and reduce blood loss during cesarean section, 10 –42% of women receiving oxytocin were found to require additional oxytocic agents, such as ergot alkaloids and prostaglandine. [14] The mean age of misoprostol and Oxytocin Group was 23.87 and 21.95 years respectively. We found no significant

difference as the p value was 0.854. Nialm S et al [15] in a similar study also found the mean age of Misoprostol and Oxytocin group was  $23.3 \pm 3.57$  and  $24.28 \pm 4.49$  respectively which is quite consistent with our study. Multiparous and primiparous women were 55% and 45% respectively in Misoprostol group; 65% and 35% in Oxytocin group. Rahim AYHA et al [16] also found similar observation where primiparous and multiparous women were 28.6% and 71.4% respectively in their study. In Misoprostol group the most common side effect was shivering accounts for 23% patients followed by fever accounts for 7% patients. In Oxytocin group nausea and vomiting were the commonest side effect account for 6% patients each. While analyzing we found statistically insignificant difference for side effects in both groups as the p value was  $<0.001$ . Shivering was significantly higher with per rectal Misoprostol which was similar with study done by Kundodyiwa et al. [17]

Othman et al [18], in their study showed shivering and metallic taste were reported in the misoprostol group more than in the oxytocin group. In the present study the mean blood loss level for Misoprostol group (185.13) was higher while compared to Oxytocin group (180.07). While analyzing in terms of mean blood loss level in both groups we found no statistically significant difference. Mean blood loss level for Misoprostol and Oxytocin group was 187.12 and 181.09 ml respectively. The difference in blood loss was statistically insignificant between the two groups as the p value was 0.316. The difference in mean Hb level before and after 24 hrs of delivery was insignificant as the p value was  $>0.05$ . However, Villar [19] in a systematic review that focused on the use of misoprostol in preventing early postpartum haemorrhage indicated the greater effectiveness of other conventional uterotonic (oxytocin, methylergometrine) for the reduction of blood loss during delivery compared to misoprostol. We noted no statistically significant difference between the two groups based on the average hemoglobin levels before and after delivery.

### Conclusion

The present study indicated that in the context of active management of 3rd grade labour, Misoprostol has comparable effectiveness to oxytocin (10IU IV in 500ml RL) in the prevention of early postpartum haemorrhage. However, misoprostol was associated with higher incidence of shivering and pyrexia but no other serious adverse effects occurred. Hence, per rectal misoprostol can be safely used in low risk caesarean deliveries as an alternative to 10 IU oxytocin in AMTSL. It should be included as an alternative in delivery protocols and also added to the list of essential drugs for affordable access.

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