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Original Research Article

Rectal Misoprostol versus Intramuscular Oxytocin: A Comparative Study to Prevent Postpartum Haemorrhage

Kumari Snehalata[1], Nirmala Kumari[2], Abha Rani Sinha[3]

[1]Senior Resident, Department of Obstetrics and Gynaecology, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar.

[2]Senior Resident, Department of Obstetrics and Gynaecology, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar.

[3]Professor and Head of Department, Department of Obstetrics and Gynaecology, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar.

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Corresponding author: Dr. Nirmala Kumari

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Abstract

Background: Worldwide, postpartum haemorrhage (PPH) is the most frequent reason for maternal mortality. The majority of PPH-related morbidity and death instances occur in the first 24 hours after delivery and are classified as primary PPH, whereas any abnormal or excessive birth canal bleeding that takes place between 24 hours and 12 weeks after birth is classified as secondary PPH. The study's objectives are to evaluate the safety of both medicines and compare the effectiveness of 800 mcg of rectal misoprostol and 10U of intramuscular oxytocin in preventing postpartum haemorrhage.

Methods: A prospective, double-blind study was conducted from January 2022 to June 2022 at Department of Obstetrics and Gynaecology, SKMCH, Muzaffarpur, Bihar. For the study, 120 cases were collected, and each group of 60 cases received either Group B (800 mg of misoprostol rectally administered immediately after delivery of the infant) or Group A (10 IU of oxytocin given intramuscularly soon after delivery). The chosen cases' personal information and medical information were gathered using a standardised proforma.

Results: Mean blood loss for Groups A and B was 219.5 ml and 230.93 ml, respectively, with a statistically insignificant difference (p=0.138). Although the mean blood loss in the Oxytocin injection group was less than that in the Misoprostol tablet group, the difference was not statistically significant. In Group A, the incidence of PPH was 6.66%, whereas in Group B, it was 10.0%. Statistics did not support the difference. When compared to the oxytocin group, the incidence of shivering and pyrexia was higher in the misoprostol group (13.33 versus 6.67% and 8.3 versus 3.33%, respectively). The statistical analysis was carried out with SPSS 19.0.

Conclusion: When administered during the active management of the third stage of labour for the prevention of postpartum haemorrhage, it has been found that misoprostol 800g rectally is just as effective as injectable oxytocin 10 IU.

Keywords: Haemorrhage, misoprostol versus, IU oxytocin.

Introduction

The most dangerous consequence in obstetric practise is postpartum haemorrhage. The majority of maternal haemorrhage deaths are caused by PPH, which is mostly a preventable illness. PPH is described by the WHO as blood loss of 500 ml or more in the first 24 hours after delivery.[1] Evaluation of postpartum blood loss is challenging, particularly in impoverished nations like India where the majority of women have low haemoglobin reserves and anaemia, diseases that are made worse by increased demand during pregnancy and blood loss during the third stage of labour.[2] With an estimated mortality rate of 1,40,000 per year, or one maternal death every four minutes, PPH is the greatest cause of maternal death globally.[3-5] PPH occurs in 5% of deliveries and contributes significantly to maternal mortality. The bulk of these fatalities occur within 4 hours of birth, which suggests that the third stage of labour is to blame.Nonfatal PPH causes further interventions, iron deficiency anaemia, pituitary infarction (Sheehan's syndrome) with poor lactation as a result, exposure to blood products, coagulopathy, and organ destruction with accompanying hypotension and shock.[6-8] The incidence of severe postpartum haemorrhage and postpartum blood loss have both been decreased through a number of measures. It has been advantageous to actively manage the third stage of labour, including early cord clamping, controlled cord traction, and the use of uterotonic medications like oxytocin, [9-11] with or without ergometrine. The incidence of PPH is reduced by 70% during active care as opposed to expectant management.[12] The uterotonic medications available today are far from ideal, especially for routine usage in underdeveloped nations. Affordable medications with straightforward administration methods and lengthy shelf lives are required because many deliveries take place outside of hospitals or other medical facilities and are only attended by birth attendants. The majority of uterotonics require parenteral administration and cold chain maintenance, which are essential for their efficacy, but are occasionally impractical in some peripheral locations due to a lack of clean needles, syringes, or refrigeration equipment.[12] Misoprostol, a synthetic prostaglandin E1 counterpart, is frequently used for peptic ulcer disease prophylaxis and treatment.[13] After oral administration, it is quickly absorbed, cheap, stable at room temperature, and has few negative effects. It induces labour at term and has been used to induce uterine contractions and end pregnancies in the first and second trimesters. Its usage during the third stage of labour has also been studied when either orally or intravenously. India needs uterotonics that are just as effective and safe as currently available uterotonics because it is a developing nation without storage facilities in distant places.[14] The current study compares the safety and effectiveness of intramuscular oxytocin and rectal misoprostol in preventing postpartum haemorrhage.

Material and Methods

During the six-month period from January 2022 to June 2022, a prospective, double-blind study was conducted in the Obstetrics & Gynaecology department of Sri Krishna Medical College and Hospital in Muzaffarpur, Bihar. In this study, patients between the ages of 18 and 35 with gestational ages of 37 weeks or more, singleton pregnancies with live foetuses, and spontaneous and assisted vaginal births with or without episiotomies were included. This study excluded participants with known hypersensitivity to administration of prostaglandins, patients undergoing caesarean sections, pregnancy-related illnesses, coagulation problems, and patients with a history of caesarean section.

A total of 120 instances were collected for the study, and these cases were split up into two groups of 60 cases each at random. Specifically, Groups A and B. Following delivery, group A patients received 10 IU of oxytocin intramuscularly. Following birth, group B patients received 800 mmg of misoprostol rectally. Active management of the third stage of labour resulted in the controlled cord traction delivery of the placenta. Any uterine blood clot that manifested was quantified in the calibrated glass container. The general state was evaluated up to two hours after delivery at regular intervals.

The amount of maternal haemoglobin was measured before delivery and again 24 hours later.

Using a 't' test for an independent sample, quantitative variables between research groups were compared. Statistics were deemed significant at $P < 0.05$. The statistical analysis was carried out with SPSS 19.0.

Results

The chosen cases' personal information and medical information were gathered using a standardised proforma. The statistical analysis was carried out with SPSS 19.0.

Table 1: Age Distribution of both groups

Age in Years	No. of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No.	%
< 20	3	5.0%	3	5.0%
20 – 24	33	55.0%	30	50.0%
25 – 29	17	28.33%	24	40.0%
30 & above	7	11.67%	3	5.0%
Total	60	100	60	100
p-value	0.759 (Not Significant)			

A majority of the patients were between the ages of 20 and 29 in both groups, with 90% (54/60) in Group B and 83.33% (40/60) in Group A, respectively. A minority of the population is made up of people aged 30 and older, with 11.67% (7/60) in Group A and 5% (3/60) in Group B. The percentage of those under 20 years old (3/60) is the same in both groups at 5%. The mean age of the cases in the two groups is not significantly different.

Table 2: Antenatal care of both groups

Antenatal care	No of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No.	Percentage
Booked	41	68.33%	43	71.67%
Unbooked	19	31.67%	17	28.33%
Total	60	100	60	100
p-value	0.8385 (Not Significant)			

In Group A, 68.33% (41/60) of the seats were reserved, while 31.67% (19/60) were not. In Group B, 71.67% (43/60) of the seats were reserved, while 28.33% (17/60) were not. The antenatal care that the two groups got did not differ statistically significantly.

Table 3: Type of Labour in both groups

	No. of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No	Percentage
Spontaneous	48	80.00%	51	85.00%
Induced	12	20.00%	9	15.00%
Total	60	100	60	100
p-value	0.0659 (Not Significant)			

Both groups labour types were contrasted. The majority of the patients in the groups started their labours on their own. (Group B: 85% (51/60) vs. Group A: 80% (48/60). 20% (12/60) of women in Group A and 15% (9/60) of women in Group B had labour inductions. The two groups types of labour do not considerably differ from one another.

Table 4: Method of Delivery in both groups

Method of Delivery	No. of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No.	Percentage
Normal vaginal delivery	60	100	60	100

Comparing the delivery methods in the two groups, Groups A and B both had all of the patients deliver vaginally.

Table 5: Duration of III stage of labour of both groups

Duration of III stage of labour (in minutes)	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No.	Percentage
< 2 minutes	-	-	-	-
3-5 minutes	18	30.00%	15	25.00%
5-7 minutes	23	38.33%	24	40.00%
7-9 minutes	19	31.67%	21	35.00%
>9 minutees	-	-	-	-
Total	60	100	60	100
p-value	0.268			

Third stage labour in group A lasted 5-7 minutes for 38.33%, 7-9 minutes for 31.67%, and 3-5 minutes for 30% of the women. In group B, third stage of labour lasted for 5-7 minutes in 40%,7-9 minutes in 35% and 3-5 minutes in 25% women.

The average length of the third stage of labour is shorter in the Oxytocin injection group than in the Misoprostol tablet group.

Table 6: Blood loss in both groups

Blood loss (in ml.)	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	Percentage	No.	Percentage
101-150	24	40.00%	22	36.67%
151-200	15	25.00%	14	23.33%
201-250	7	11.67%	7	11.67%
251-300	9	15.00%	11	18.33%
301-350	-			

351-400	-			
401-450	-		2	3.33%
451-500	2	3.33%	-	
More than 500 ml	3	5.00%	4	6.67%
Mean	219.5		230.93	
S.D.	218.8			
p-value	0.138 In Significant			

Although the mean blood loss in the Oxytocin injection group was lower than that in the Misoprostol tablet group, the difference was not statistically significant.

Table 7(a): Post-partum complication - Injection Oxytocin group

PPH	Inj. Oxytocin group	
	No.	Percentage
> 1000 ml	1	1.66%
500-1000 ml	3	5.00%
Nil	56	93.33%

Table 7(b): Post-partum complication - Tablet Misoprostol group

PPH	T. Misoprostol Group	
	No.	Percentage
> 1000 ml	2	3.33%
500-1000 ml	4	6.67%
Nil	54	90.00%

In Group A, the incidence of PPH is 6.66%, whereas in Group B, it is 10.0%. Statistics do not support the difference.

Table 8: Patient requiring additional oxytocics in each group

	Group A		Group B	
	No.	%	No.	Percentage
Use of additional oxytocis	6	10.0%	8	13.33%

A total of 14 individuals out of 120 in the current trial needed extra oxytocin to reduce third stage blood loss. Six (10.0%) of the 14 patients were from group A, while eight (13.33%) were from group B.

Table 9: Patient requiring blood transfusion

	Group A		Group B	
	No.	Percentage	No.	Percentage
Need For Blood Transfusion	4	6.66%	5	8.33%

The need for blood transfusion was 6.66% in oxytocin groupand 8.33% in misoprostol group.

Table 10: Maternal Side effects

	Group A		Group B	
	No.	Percentage	No.	Percentage
Nausea	3	5.00%	4	6.67%
Vomiting	1	1.66%	3	5.00%
Shivering	4	6.67%	8	13.33%
Diarrhea	1	1.66%	1	1.66%
Headache	5	8.33%	3	5.00%
Fever	2	3.33%	5	8.33%
Hypotension	2	3.33%	0	-

Side effects like nausea occurred in 5.00% in group A and 6.67% ingroup B.

In group A there were 1.66% cases of vomiting and 5.00% in group B. In group A, 6.67% report shivering, compared to 13.33% in group B. Both group A (1.66%) and group B (1.66%) experienced diarrhoea.

In group A, 8.33%, and in group B, 5.00%, headache complaints are made. Fever rates in groups A and B were respectively 8.33% and 3.33%. Only group A showed hyptension, which was found to be 3.33%.

Table 11: Change in Hb of both groups

Hb.	Inj. OxytocinGroup		Tab. MisoprostolGroup		'p'
	Mean	S. D.	Mean	S. D.	
At admission	9.1	0.90	8.98	0.93	0.9363 (Not Significant)
After delivery	8.81	0.99	8.86	0.78	0.3771 (Not Significant)

Both groups haemoglobin levels at admission and those following delivery are contrasted. In terms of statistics, there was no discernible difference between the two groups haemoglobin changes.

Discussion

Worldwide, postpartum haemorrhage (PPH) is the most frequent reason for maternal mortality. The majority of PPH-related morbidity and death cases occur in the first 24 hours after delivery and are classified as primary PPH, whereas any abnormal or excessive birth canal bleeding that takes place between 24 hours and 12 weeks after birth is classified as secondary PPH[15,16]. The risks associated with childbirth have significantly decreased with to medical advancements, yet in wealthy nations, haemorrhage death continues to be the largest cause of mother mortality. 80% of PPH is caused by uterine atony or decreased myometrial contractility. Some conditions, such as protracted third stage of labour, pregnancy-induced hypertension, prior PPH, twins or prior multiple pregnancies, early placental separation from the uterus, soft tissue laceration, instrumental delivery, infection, and obesity are linked to developing PPH.

However, women with no recognised risk factors experience the majority of PPH occurrences. Because of this, all pregnant women must have access to both prenatal preventive and postpartum emergency care for substantial blood loss.

The use of uterotonic medications, such as oxytocin, ergometrine, and prostaglandins, is essential for both the prevention and treatment of PPH. The standard treatment for PPH prophylaxis during the third stage of labour is oxytocin [17]. However, the use of

oxytocin in low-income nations has historically been constrained by a variety of variables, such as the perception that it must be administered by trained staff, be kept in a cold chain, and require the use of sterile syringes and needles [18,19]. Recent research has started to question these restrictions, as shown by the successful use of oxytocin by lay community health professionals during home deliveries [20].

Prostaglandin E1 (PGE1) analogue misoprostol stimulates the uterus during pregnancy by binding to prostanoid EP2 and EP3 receptors [21]. The uterus can contract with this active uterotonic drug in just a few minutes. It is reasonably priced, stable at room temperature, and quickly absorbed into the bloodstream after ingestion. Additionally, it can be given orally, sublingually, vaginally, or rectally, among other ways. Because of this, misoprostol has received a lot of interest as an oxytocin substitute for PPH prophylaxis in situations with limited resources [22-24].

Conclusion

When used to actively control the third stage of labour in women with an uncomplicated delivery, misoprostol 800 microgram is equivalent to 10 units of oxytocin given intramuscularly. Misoprostol can be used widely in low resource situations due to how straightforward and simple it is to administer. Misoprostol can be especially helpful in outlying healthcare facilities where a skilled delivery attendant is not available to administer an injection due to its temporary and self-resolving side effects, effectiveness, and ease of administration when compared to injectable oxytocin.

Misoprostol is therefore a very important medication in the arsenal of doctors in rural settings and especially midwives who work in the periphery of developing countries where parenteral drugs could not be stored at the desired temperature and where parenteral drugs are impractical to administer or simply not available.

As a result, it can be said that misoprostol is a potent uterotonic and a straightforward therapeutic choice for healthcare professionals in underdeveloped nations to use in the fight against obstetric haemorrhage.

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