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A comparative study on rectal misoprostol versus intramuscular oxytocin to prevent postpartum haemorrhage

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Abstract
Objective: 1. To compare the efficacy of 800 mcg of rectal misoprostol with 10U I.M Oxytocin in prevention of postpartum haemorrhage
2. To assess the safety of both the drugs.
Methodology: A prospective, double-blind study carried out for a period of 1 year. 240 cases had been taken for the study, which were divided randomly into two groups containing 120 cases each *i.e.* Group A were given 10 IU oxytocin intramuscularly immediately after delivery.
Group B were given 800 mcg rectal misoprostol immediately after delivery.
The personal information and medical data of the selected cases were collected in structured proforma. Statistical analysis was done using Epidemiological Information Package (EPI2002).
Results: Mean Blood loss for Group A – 224.4 ml and mean Blood Loss for Group B – 240.4 ml and with insignificant difference (p 0.132). The mean blood loss in the injection Oxytocin group was lower than mean blood loss in the tablet Misoprostol group but the difference was not statistically significant. The incidence of PPH was 5.82% in Group A and 6.6% in Group B. The difference was not statistically significant.
Shivering, pyrexia was found more in misoprostol group than oxytocin with the incidence being 12.5% versus 7% (shivering) and 8.3% versus 2.5% (pyrexia) respectively.
Conclusion: It is observed that the misoprostol 800µg rectally is as effective as intramuscular oxytocin 10 IU when used during the active management of third stage of labour for prevention of postpartum haemorrhage.

Keywords: Haemorrhage, misoprostol versus, IU oxytocin

Introduction
Postpartum hemorrhage (PPH) is a life-threatening obstetric emergency that occurs after caesarean section (CS) or normal vaginal delivery (NVD). It may be defined as ≥500 mL hemorrhage after vaginal delivery or ≥1000 mL hemorrhage after caesarean section.
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 developed 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.
However, most 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. Oxytocin is the standard drug of care for prevention of PPH during the third stage of labor [3]. The use of oxytocin in low-income countries, however, has historically been limited by a number of factors including a perceived requirement for administration by skilled personnel, cold chain storage, and a

requirement for sterile syringes and needles [4, 5]. Recent work has begun to challenge these limitations, as exemplified by effective administration of oxytocin by lay community health workers during home births [6].

Misoprostol is a prostaglandin E_1 (PGE_1) analogous which stimulates pregnant uterus through prostanoid EP2 and EP3 receptors [7]. 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 [8-10]. 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.

Methodology

This was a prospective, double-blind study carried out in the department of 'Obstetrics and Gynaecology' of 'Dr. Sushila Tiwari Government Medical College and Dr. Sushila Tiwari Memorial Government Hospital, Haldwani' for a period of 18 months from January 2019 to September, 2020.

Women who were admitted into the labour room (booked or unbooked) had been taken for the study with the following including criteria.

1. Singleton pregnancy with cephalic presentation
2. Patient with completed 37 weeks of pregnancy
3. Primigravida
4. Patients belonging to age group in the range of 18-35 years

Exclusion criteria: Patient with following risk factors will be excluded from the study.

1. Multigravida
2. Multiple pregnancy
3. Placenta previa (based on ultrasound sonography in the third trimester), placental abruption
4. Previous caesarian section
5. Macrosomia (defined as estimated fetal weight above 4000 gm based on ultrasound sonography)
6. Polyhydramnios (defined as amniotic fluid index more than 24 cm)
7. Heart disease
8. Liver disease
9. Respiratory disease
10. Hemoglobin < 8 gm/dl
11. Disorders of blood coagulation
12. Previous scarred uterus
13. Patient with P.I.H. & eclampsia
14. Epilepsy
15. Patient with I.U.D.
16. Uncontrolled asthma
17. Known hypersensitivity to prostaglandins

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 240 cases had been taken for the study, which were divided randomly into two groups containing 120 cases each. ie. Group A and Group B. Group A patients were given 10 IU of oxytocin intramuscularly immediately after delivery. Group B patients were given 800 µg rectal misoprostol immediately after delivery The third stage of labour was managed actively with delivery of placenta by controlled cord traction.

A blood sample was obtained before delivery and 24 hours after delivery. In addition, the quantity of blood loss was measured by keeping a kidney tray beneath the buttocks during placental separation and weighing all the soaked pads used after delivery of baby. Their dry weight was subtracted from measured weight and this gives the amount of blood loss in ml(weight in gm=volume in cc)

Patient's vitals were monitored for 6 hrs. after delivery (hrly) and any side effects was noted and treated

Results

The personal information and medical data of the selected cases were collected in structured proforma. Statistical analysis was done using Epidemiological Information Package (EPI2002)

Table 1: Age Distribution Profile of cases studied

Age in Years	No of cases in			
	Inj.Oxytocin Group		Tab.Misoprostol Group	
	No	%	No	%
Less than 20	5	4	5	4
20 – 24	67	56	60	50
25 – 29	34	28	48	40
30 & above	14	12	7	6
Total	120	100	120	100
Mean	24.4		23.9	
S.D	4.4		2.9	
'p'	0.742 (Not Significant)			

Comparing the age distribution in both the groups, majority of the patients were between 20-29 years of age 84% (106/120) in Group A and 90%(113/120) in Group B. 30years and more age group contributes to minority of the population (i.e.) 12%(14/120) in Group A 6%(7/120) in Group B. Less than 20 years age group remains the same 4%(5/120) in both the group. There is no significant difference in the mean age of the cases in both the groups.

Table 2: Antenatal care

Antenatal care	No of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No	%	No	%
Booked	82	68	86	72
Unbooked	38	32	34	28
Total	120	100	120	100
'p'	0.8273 (Not Significant)			

In Group A 68% (82/120) were booked and 32% (38/120) were unbooked. In Group B 72% (86/120) were booked and 28% (34/120) were unbooked.

The antenatal care received by the two groups does not exhibit statistically significant difference.

Table 3: Type of Labour

	No. of cases in			
	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No	%	o	
aneous	96	80	01	
duced	24	20	19	
Total	20	100	20	
'p'	0.0647 (Not Significant)			

Type of labour was compared in both the groups. Majority of the patients in the groups had spontaneous onset of labour. (Group A 80% (96/120) Group B 84% (101/120). Labour was induced in 20% (24/120) in Group A and in 16% (19/120) in Group B. Type of Labour in the two groups does not differ significantly.

Table 4: Method of Delivery

Method of Delivery	No. of cases in			
	Inj. Oxytocin Gp		Tab. Misoprostol Group	
	No	%	No	%
Normal vaginal delivery	120	100	120	100

Comparing the mode of delivery in both the groups, all of patients delivered vaginally in Group A and Group B

Table 5: Duration of III stage of labour

Duration of III stage of labour (in minutes)	Inj.Oxytocin Group		Tab.Misoprostol Group	
	No.	%	No.	%
≤ 2 minutes	-	-	-	-
3-5 minutes	37	31%	30	25%
5-7 minutes	45	37%	46	38%
7-9 minutes	38	32%	44	37%
>9minutees	-	-	-	-
TOTAL	120	100	120	100
Mean	5.45		5.62	
S.D.	0.68		0.71	
'p'	0.229			

In group A ,the duration of third stage of labour was 5-7 minutes in 37%, 7-9 minutes in 32% and 3-5 minutes in 31% women
In group B,third stage of labour lasted for 5-7 minutes in 38%,7-9 minutes in 37% and 3-5 minutes in 25% women.
The mean duration of third stage of labour in the injection Oxytocin group is lower than in the tablet Misoprostol group.

Table 6: Blood loss

Blood loss (in ml.)	Inj. Oxytocin Group		Tab. Misoprostol Group	
	No.	%	No.	%
101-150	48	40	45	37.5
151-200	31	26	28	23.3
201-250	14	12	14	11.66
251-300	17	14	22	18.3
301-350	-	-		
351-400	-	-		
401-450	-	-	3	2.5
451-500	3	2	-	-
More than 500 ml	7	6	8	6.66
Mean	224.4		240.4222	
S.D.	212.9			
'p'	0.132 In Significant			

- Mean Blood loss for Group A – 224.4 ml
- Mean Blood Loss for Group B – 240.4 ml

The mean blood loss in the injection Oxytocin group is lower than mean blood loss in the tablet Misoprostol group but the difference is not statistically significant.

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

PPH	Inj.Oxytocin group	
	No.	%
> 1000 ml	2	1.66%
500-1000 ml	5	4.16%
Nil	113	94.18%

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

PPH	T. Misoprostol Group	
	No.	%
> 1000 ml	2	1.6%
500-1000 ml	6	5%
Nil	112	93.4%

The incidence of PPH is 5.82% in Group A and 6.6% in Group B. The difference is not statistically significant.

Table 8: Patient requiring additional oxytocics in each group

	Group A		Group B	
	No.	%	No.	%
Use of additional oxytocis	11	9.1%	16	13.3%

In the present study total 27 patients out of 240 required additional oxytocics to decrease third stage blood loss. Out of 27 patient 11 were from group A and 16 from group B.

Table 9: Patient requiring blood transfusion

	Group A		Group B	
	No.	%	No.	%
Need For Blood Transfusion	7	5.80%	9	13.30%

The need for blood transfusion was 5.80% in oxytocin group and 13.30% in misoprostol group.

Table 10: Maternal Side effects

	Group A		Group B	
	No.	%	No.	%
Nausea	6	5%	8	6.6%
Vomiting	3	2.5%	6	5%
Shivering	8	7%	15	12.5%
Diarrhea	1	0.8%	2	1.6%
Headache	9	7.5%	6	5%
Fever	3	2.5%	10	8.3%
Hypotension	4	3.3%	0	-

Side effects like nausea occurred in 5% in group A and 6.6% in group B.
Vomiting occurred in 2.5% in group A and 5% in group B.
7% complain of shivering in group A while 12.5% in group B.
Diarrhea occurred in 0.8% in group A and 1.6% in group B.
7.5% complain of headache in group A and 5% in group B.
2.5% had fever in group A while 8.3% in group B.
Hyotension was found to be 4 % in only group A.

Table 11: Change inHb

Hb.	Inj.Oxytocin Group		Tab.Misoprostol Group		'p'
	Mean	S.D	Mean	S.D	
At admission	9.0	0.89	8.96	0.89	0.9252 (Not Significant)
After delivery	8.78	0.98	8.64	0.87	0.3677 (Not Significant)

Hemoglobin level at admission is compared to hemoglobin level after delivery in both groups.
Statistically there was no significant difference in changes of hemoglobin in two groups

Conclusion

Misoprostol 800 microgram given rectally is equivalent to intramuscularly administered 10 units oxytocin for prevention of primary PPH during active management of third stage of labour among women undergoing uncomplicated delivery. The simplicity and ease with which misoprostol can be administered suggests that it can have wide application in low resource settings .The transient and self resolving nature of the side effects associated with misoprostol, and the effectiveness and ease of administration compared with injectable oxytocin can be particularly useful in peripheral health care facilities where a skilled delivery attendant is not available to administer an injection.

Thus, misoprostol is a very valuable drug in the armamentarium of doctors in rural setting and especially midwives, who work in the periphery in developing countries, where these parenteral drugs could not be stored at the desired temperature and where parenteral drugs are impractical to administer or simply not available.

Therefore,it is concluded that misoprostol is an effective uterotonic and a simple therapeutic option for healthcare providers in developing countries to use in the battle against obstetric hemorrhage.

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