

Sublingual Misoprostol 400 Mcg Versus Intramuscular Oxytocin 10 Iu For Prevention Of Primary Post Partum Haemorrhage: An Open-Label Randomized Clinical Trial

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Abstract:

Introduction: Postpartum hemorrhage mostly due to uterine atony is responsible for about a third of maternal deaths. The present study is an attempt to compare the efficacy of i.v oxytocin and sublingual misoprostol for prevent of PPH. Our aims and objectives were to find out the efficacy of misoprostol for prevention of primary post partum haemorrhage in comparison with oxytocin and to find out its safety, side effects and acceptability.

Materials and methods: The open label randomized clinical trial included total of 800 antenatal patients meeting the eligibility criteria. The patients were randomly assigned to receive either Oxytocin (10 U im) or Misoprostol (400 mcg sublingual) within 1 minute of delivery. If bleeding was >500 ml or placenta was not separated by 30 minutes , active management of PPH was done medical or surgical means as required. Patients were keenly monitored for 24 hours. Analysis of the data revealed that both groups were compared with respect to the basic demographic parameters.

Results: Most of the patients in both did not have tachycardia and were normotensive although those in oxytocin group leaned more towards lower normal range .Pallor and icterus were equally prevalent in either groups. Incidence of retained placenta was 9 (2.25%) cases in misoprostol group and 6 (1.5%) in oxytocin group. (p=0.182). Incidence of PPH in misoprostol group was 7.5% and 5.25% in oxytocin group. The difference was not statistically significant. Severe PPH was noted in 4% patients in misoprostol group and 2.25% patients in oxytocin group (statistically not significant ;p= 0.329). Comparison of average blood loss in both groups showed 387±191.91 mL (misoprostol group) vs 386.03±149.23 mL (oxytocin group). The difference was not significant (p=0.937).

Conclusion: Our study established that both misoprostol and oxytocin are equally effective in prevention of primary PPH due to uterine atony.

Key words: Postpartum haemorrhage(PPH), Oxytocin, Misoprostol.

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I. Introduction:

Every day, approximately 1,000 women die from preventable causes related to pregnancy and childbirth; 99 % of these deaths occur in low-resource countries, with more than half occurring in Sub-Saharan Africa and one-third occurring in South Asia^{1,2}. The majority of maternal deaths are due to haemorrhage , infection , unsafe abortion , eclampsia or from health complications worsened during pregnancy .Maternal deaths are detrimental to social development and well being as some 1 million children are left motherless each year.

Postpartum hemorrhage is responsible for about a third of maternal deaths. All women who carry pregnancy beyond 20 weeks gestation are at risk for PPH and its sequelae .PPH accounts for 29.6% (WHO) of all maternal deaths worldwide. Primary PPH is considered when there is loss of blood from or within the genital tract exceeding 500 ml in vaginal delivery or 1000 ml in cesarean section or which causes deterioration in maternal health in first 24 hours postpartum (WHO). Estimates of blood loss at delivery are subjective and generally inaccurate .Studies have suggested that caregivers consistently underestimate actual blood loss. Another proposal suggests using a 10% fall in hematocrit value to define PPH .Various other authors have suggested that PPH should be diagnosed with any amount of blood loss that threatens the hemodynamic stability of the woman.

Uterine atony accounts for 70 % of primary postpartum hemorrhage and various approaches have been used for this condition^{3,4,5}. The other causes include Trauma (lacerations, hematoma, inversion , rupture), retained tissue and coagulopathies. Nowadays, the incidence of fatal PPH has decreased because of active management of third stage of labor which includes controlled cord traction, uterine fundal massage, and administration of a pharmacological uterotonic⁶.

WHO recommendations for prevention and treatment of PPH states that all women giving birth should be offered uterotonics during the third stage of labour to prevent PPH and IM/IV oxytocin (10U) is recommended as the uterotonic of choice. Other injectable uterotonics (i.e. ergometrine / methylegometrine , or the fixed drug combination of oxytocin and ergometrine) and misoprostol are recommended as alternatives for prevention of PPH in the settings where oxytocin is not available.

The present study is an attempt to compare the efficacy of i.v oxytocin and sublingual misoprostol for prevent of PPH. Our aims and objectives were to find out the efficacy of misoprostol for prevention of primary post partum haemorrhage in comparison with oxytocin and to find out its safety, side effects and acceptability.

II. Materials and methods:

The open-label randomized clinical trial was performed in labour ward and adjacent postnatal observation ward, Medical College , Eden Hospital in the Department of Obstetrics and Gynaecology from June 2015 to May 2016 (1 year period) among the term uncomplicated antenatal mothers in active labour. Randomization was done by computerized random sequence generator. Inclusion criteria's were term pregnant mothers with anticipated uncomplicated vaginal delivery aged above 18 years. Exclusion criteria were multifetal pregnancy, prolonged first or second stage of labour, operative vaginal delivery (forceps or ventouse), preterm labour, known congenital uterine anomaly, confirmed intrauterine fetal death, maternal malaria or other bacterial infection, maternal heart disease, antepartum haemorrhage, malpresentation, preeclampsia/eclampsia syndrome, known maternal coagulation disorder.

Sample size was calculated based on the effect size of a well designed previous study (Atukl, 2014), keeping the significance level (α) at 0.05 and power of 90% (1- β) we calculated a minimum sample size of 313 in each group. We recruited 400 patients in each arm. After taking informed consent the mothers who were eligible and agreed for the study underwent haemoglobin (Hb%) and PCV testing before delivery. General and obstetric examination was done and vitals were recorded. After delivery they were randomly assigned to receive either misoprostol 400 mcg sublingually or oxytocin 10 IU intramuscularly within 1 min of birth of the baby. Delayed cord clamping was preferred. Placenta and afterbirths were delivered by controlled cord traction and placenta was examined for its completeness. Other cares like bladder emptying, repair of episiotomy and lacerations were done accordingly. When bleeding persisted, estimated blood loss was >500 mL or placenta was not delivered by 30 mins active medical or surgical management of PPH was done according to protocol. Vitals were recorded again 30 mins after birth and the patients were monitored upto 24 hrs postpartum. Pallor was re-evaluated at the end of 24 hrs. Blood loss was measured by draining the plastic sheets on the labour table into calibrated containers, by weighing the soaked gauze, cotton etc and subtracting their dry weight and by weighing the wet pads used in the first 24 hrs and subtracting their dry weight. Hb% and PCV was again recorded 24 hrs after delivery. The following parameters were studied to compare between the two groups: 1) Hb% and PCV before and 24 hrs after delivery, 2) Vital signs before and 30 mins after delivery 3) Estimation of blood loss in 3rd stage of labour upto 24 hrs after delivery using the above mentioned methods, 4) Need of additional uterotonics or additional methods for active management of PPH (if needed), 5) Requirement of blood transfusion, 6) Recording of duration of 3rd of labour. Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

III. Results and analysis:

800 randomly selected antenatal patients were selected and were randomly divided in two equal groups of 400, on whom the study was done. One group received misoprostol 400 mcg sublingual and the other oxytocin 10 IU intramuscular after delivery of the baby for prevention of primary postpartum haemorrhage. This study intends to investigate the comparative efficacy and side effects profiles of the two drugs, misoprostol and oxytocin for prevention of primary postpartum haemorrhage.

Table no 1 showed frequency distribution of age in years, parity and BMI of patients in the two groups. Both groups had similar composition with maximum patients in the group of 21-25 years (44.75% and 44.5% respectively). There was no significant difference ($p=0.669$) in age group composition. Most patients in both groups were nullipara (71.75% and 69.25% respectively). There was no significant difference between composition of the two groups according to parity ($p=0.846$). There was also no significant difference in BMI composition of the two groups ($p=0.547$).

Table 2 shows comparison between two groups in respect to different outcome parameters. Most patients did not have brady or tachycardia. Only 3% in misoprostol group and 3.5% in oxytocin group had pre-existing tachycardia. The difference in composition was significant ($p=0.038$). Tachycardia was seen in 16.75% and 22% patients in the two groups respectively. But the difference in composition of the two groups was not significant ($p=0.275$). All the patients were normotensive. The difference in composition of the two groups was significant ($p=0.002$). Oxytocin group had significantly more patients with low normal SBP (101-110 mm Hg range). Most patients remained normotensive. The difference in composition of the two groups was not significant ($p=0.912$). Following the trend of SBP most patients had normal DBP but the difference in composition of the two groups was significant ($p<0.001$) since the oxytocin group had more patients with low normal DBP (60-70 mm Hg). The difference in composition of the two groups was not significant ($p=0.124$). In respect to incidence of hypotension in two groups after delivery the table showed that none of patients was more in the oxytocin group (17 vs 11, 4.25% vs 2.75%) and the result was not significant ($p=0.248$). There were 17 (4.25%) and 15 (3.75%) patients in each group respectively with pallor. The difference was not significant ($p=0.718$). In respect to pallor 24 hrs after delivery, distribution of patients was 32 (8%) in misoprostol group and 18 (4.5%) in oxytocin group. The difference was significant ($p=0.041$). Placenta was mostly delivered within 20 mins (93% and 95.5% in both groups). It was retained >30 min in 9 (2.25%) cases with misoprostol and 6 (1.5%) cases with oxytocin. Difference was not significant ($p=0.182$). 43 (10.75%) in the misoprostol group had fever, compared to only 2 (0.5%) in the oxytocin group. The difference was significant ($p<0.001$).

Table no 3 showed the comparison of total blood loss in the two groups. PPH (i.e. blood loss >500 mL) occurred in 7.5% patients in misoprostol group (4% severe) and in 5.25% of patients in oxytocin group (2.25% severe). The difference was not significant ($p=0.329$). More than 10% decline in Hb was seen in 23 (5.75%) patients in the misoprostol group and 8 (2%) patients in the oxytocin. The difference was significant ($p=0.001$). More than 10% decline in PCV was seen in 23 (5.75%) patients in the misoprostol group and 4 (1%) patients in the oxytocin. The difference was significant ($p<0.001$). 35 (8.75%) and 22 (5.5%) patients received blood transfusion in the misoprostol and oxytocin groups respectively. The difference was not significant ($p=0.074$). It was also seen that there was significant fall in mean Hb concentration and PCV in the misoprostol group ($p=0.002$ for Hb and $p=0.040$ for PCV).

IV. Discussion:

Most of the patients in both groups were in the age group of 21-25 years (44.75% vs 44.5% in misoprostol vs oxytocin). Most of them were primiparas (71.75% vs 69.25%), with no living issue. Number of patients with parity ≥ 2 were 19 (4.75%) in misoprostol group and 18 (4.5%) in oxytocin group. These differences in age ($p=0.669$), parity ($p=0.846$) and living issue ($p=0.714$) were not statistically significant. Regarding BMI most patients belonged to the normal BMI range of 20.1-25.0 Kg/m² (74.75% vs 71.5%). Number of overweight patients in both groups were 4 (1%) in misoprostol group and 8 (2%) in oxytocin group. The differences in BMI composition of two groups were not statistically significant ($p=0.547$). The difference of mean BMI of two groups was also not significant statistically (21.77 ± 2.07 vs 21.98 ± 2.35 ; $p=0.193$). Comparison of vital signs before delivery showed, most patients did not have tachycardia (pulse rate 71-80/min- 41.25% vs 34.25%, 81-90/min- 30% vs 27%), most of them were normotensive (SBP 111-120 mm Hg- 50.25% vs 39.25%, 101-110 mm Hg- 24.25% vs 35%; and DBP 71-80 mm Hg 55% vs 57.75%, 60-70 mm Hg- 20.25% vs 30.75%). These differences were significant as the oxytocin group had significantly more number of patients in the lower normal range ($p=0.002$ for SBP and $p<0.001$ for DBP); but there were no hypo (BP <90/<60 mm Hg), or hypertensive (BP >140/>90 mm Hg) patients to begin with. Pallor was present in 17 (4.25%) and 15 (3.75%) patients in each groups respectively; but the difference was not significant ($p=0.718$). Similarly, icterus was present in 2 (0.5%) patients in misoprostol group and 3 (0.75%) in the oxytocin group. This difference was also not significant ($p=0.654$). None of the patients in the two groups were febrile (temp >100 degree F) before delivery. Most patients had delayed cord clamping (i.e. ≥ 1 minute after birth) (96.5% vs 97.25%). The difference not significant ($p=0.542$). Mean interval from delivery to cord clamping was 1.29 ± 0.22 minute in misoprostol group vs 1.2 ± 0.15 minute in the oxytocin group. The difference was significant ($p<0.001$). Average delivery to placenta expulsion time was 5-20 minutes in both groups (93% vs 95.5%). Incidence of retained placenta (delivery to placenta expulsion >30 minutes) was 9 (2.25%) cases in misoprostol group and 6 (1.5%) in oxytocin group. The difference was not significant ($p=0.182$). But the comparison of the mean interval of delivery to placenta expulsion found significant difference in the two groups (11.41 ± 6.77 min vs 10.49 ± 5.72 min; $p=0.038$). Additional uterotonics were required in 37 (9.25%) patients in the misoprostol group. The number was 24 (6%) in the oxytocin group. The difference was not significant ($p=0.083$). Additional measures in the form of manual removal of placenta was required in 3 (0.75%) patients of the misoprostol and 1 (0.25%) patient of the oxytocin group. This difference was also not significant ($p=0.316$). Assessment of vitals after delivery showed the followings:

Tachycardia was observed in 67 (16.75%) of patients in the misoprostol group compared to 88 (22%) in the oxytocin group 30 minutes after delivery; where the pre-delivery numbers were 12 (3%) and 14 (3.5%) respectively. Average increase in PR was 7.44 ± 8.49 vs 8.06 ± 8.08 in two groups. Difference was not significant ($p=0.290$). Although most patients remained normotensive 30 minutes after delivery in both groups, significant hypotension (defined by BP $<90/<60$ mm Hg) was observed in 11 (2.75%) patients in the misoprostol and 17 (4.25%) patients in the oxytocin group. The difference was not significant ($p=0.248$). No patients developed hypertension in either groups. Average drops in SBP and DBP were 1.52 ± 5.82 mm Hg vs 1.17 ± 6.42 mm Hg for SBP ($p=0.420$; not significant) and 1.48 ± 5.26 mm Hg vs 0.27 ± 6.09 mm Hg for DBP ($p=0.003$; significant). Fever (temp >100 degree F) was observed in 43 (10.75%) patients with misoprostol compared to only 2 (0.5%) with oxytocin. This difference was statistically significant ($p<0.001$). Thus fever is a very common side effect of misoprostol. Average increase in temperature in both groups 0.29 ± 0.89 degree F for misoprostol and minus 0.04 ± 0.31 degree F for oxytocin. This mean difference was also statistically significant ($p<0.001$). Comparison of blood loss in both groups showed the incidence of PPH (total blood loss in 24 hrs >500 mL) in both groups as 30 (7.5%) in misoprostol group and 21 (5.25%) in oxytocin group. Severe PPH (>1000 mL blood loss) was seen in 16 (4%) patients with misoprostol compared to 9 (2.25%) with oxytocin. The differences were not significant ($p=0.329$). Vast majority of patients had blood loss below 500 mL (92.5% vs 94.75%). Thus both drugs appeared to be effective in preventing PPH in more than 90% patients. Comparison of average blood loss in both groups showed 387 ± 191.91 mL (misoprostol group) vs 386.03 ± 149.23 mL (oxytocin group). The difference was not significant ($p=0.937$). More than 10% decline of haemoglobin concentration 24 hrs after delivery was seen in 23 (5.75%) in misoprostol and 8 (2%) in oxytocin group. The difference was significant ($p=0.001$). Mean fall of Hb% was 0.34 ± 0.41 g/dL vs 0.27 ± 0.28 g/dL in two groups and it was significant too ($p=0.002$). Fall of PCV followed a similar trend. More than 10% decline of PCV was seen in 23 (5.75%) with misoprostol compared to 4 (1%) with oxytocin. The difference again was significant ($p<0.001$). Mean PCV decline was $1.18 \pm 1.1\%$ vs $1.04 \pm 0.9\%$. This was also significant ($p=0.040$). Blood transfusion was needed in 35 (8.75%) patients in misoprostol group compared to 22 (5.5%) in the oxytocin group. But the difference was not significant ($p=0.074$).

When existing literature in the concerned topic were sought for, in accordance with our current study most studies found that both oxytocin and misoprostol are capable of minimizing blood loss following delivery in more than 90% of individuals^{5,6,7,8}. Study by Saurf, Mauze and Shouayab⁵ (misoprostol 200 mcg s/l vs oxytocin 5 IU i/m) showed effectiveness of both drugs in prevention of primary PPH but oxytocin was marginally more efficacious. Similar results were reported by various authors using various dosage and different routes of administration. Examples include studies by Choudhuri, Biswas and Mandal in India⁶, by Atukel, Siedner, Osua and Agaba in Uganda⁷ (misoprostol 600 mcg vs oxytocin 10IU), by Beverly, Winikoff, Durochar, Darwish and Nguyen in Ecuador, Egypt and Vietnam⁸ (misoprostol 800 mcg vs oxytocin 40 IU in i/v infusion), and by Rajaei, Karimi and Shahboodaghi¹¹ (misoprostol 400 mcg vs oxytocin 20 IU). Examples of studies that found misoprostol more efficacious than oxytocin includes studies by Bellad, Tara, Ganachari and Mallapur in India⁹ and by Gul, Zeteroglu, Karayel et al¹² (misoprostol 600 mcg vs oxytocin 20 IU). Some studies investigated the efficacy of misoprostol alone for prevention of PPH and found it to be quite effective. Examples being studies by Derman, Kodkany, Gordar, Geller and Naik¹⁰ and by Matagrano and Gabay¹³. Still there were some studies that showed almost equal efficacy of the two drugs^{33,34,35}. A study comparing misoprostol and syntometrine (oxytocin+ergometrine) found both to be equally effective³⁶. These findings were quite corroborative with our present study as we also found both drugs to be effective in prevention of PPH in more than 92% of patients proving their efficacy for the same. Incidence of PPH has been stated in most studies to be 3-6% with misoprostol^{6,9} and 5.5-9% with oxytocin^{6,9} which is also corresponding with our current study in which the incidences are 7.5% with misoprostol and 5.25% with oxytocin. Most studies have mentioned pyrexia to be a very common side effect of misoprostol (44% vs 6%)^{8,36} which is also a finding of our present study as well (10.75% vs 0.5%, misoprostol vs oxytocin), and the difference was significant. Fall of blood pressure has been noticed to be a more frequent finding with oxytocin⁵, which is also confirmed in our study (4.25% vs 2.75%, oxytocin vs misoprostol), although the difference was not significant. In a nutshell, our study found both misoprostol and oxytocin and misoprostol effective in prevention of primary PPH with oxytocin slightly better than misoprostol; but those with misoprostol had significantly higher incidence of $>10\%$ fall of haemoglobin and PCV and significantly higher incidence of fever. Hypotension though more common with oxytocin was not found to be significantly higher number of patients than those with misoprostol. On the contrary mean fall of SBP and DBP was significantly more in the misoprostol group.

V. Conclusion :

Our study established that both misoprostol and oxytocin are equally effective in prevention of primary PPH with oxytocin slightly better than misoprostol; but those with misoprostol had significantly higher incidence of $>10\%$ fall of haemoglobin and PCV and significantly higher incidence of fever. Hypotension

though more common with oxytocin was not found to be present in significantly higher number of patients than those with misoprostol. On the contrary mean fall of SBP and DBP was significantly more in the misoprostol group.

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Table 1. Frequency distribution of demographic parameters between two groups

Parameters		Misoprostol	Oxytocin	p Value
Age (yrs)	17-20	95(23.75)	104(26)	0.669(NS)
	21-25	179(44.75)	178(44.5)	
	26-30	103(25.75)	92(23)	
	31-36	22(5.5)	26(6.5)	
	>36	1(0.25)	0(0)	
Parity	0	287(71.75)	277(69.25)	0.846(NS)
	1	94(23.5)	105(26.25)	
	2	17(4.25)	16(4)	
	3	2(0.5)	2(0.5)	
BMI (Kg/m2)	17.0-20.0	76(19)	85(21.25)	0.547(NS)
	20.1-25.0	299(74.75)	286(71.5)	
	25.1-28.0	21(5.25)	21(5.25)	
	>28	4(1)	8(2)	

Table 2. Comparison of outcome variables between two groups:

Parameters	Misoprostol	Oxytocin	p Value	Significance
	Mean ± Std. Deviation	Mean ± Std. Deviation		
Increase in Pulse Rate	7.44 ± 8.49	8.06 ± 8.08	0.290	Not Significant
Decrease in SBP (mm Hg)	1.52 ± 5.82	1.17 ± 6.42	0.420	Not Significant
Decrease in DBP (mm Hg)	1.48 ± 5.26	0.27 ± 6.09	0.003	Significant
Increase in Temp (F)	0.29 ± 0.89	-0.04 ± 0.31	<0.001	Significant
Delivery to cord clamping (min)	1.29 ± 0.22	1.2 ± 0.15	<0.001	Significant
Delivery to placenta expulsion (min)	11.41 ± 6.77	10.49 ± 5.72	0.038	Significant
Total Blood loss (mL)	387 ± 191.91	386.03 ± 149.23	0.937	Not Significant
Decrease in Hb (g/dL)	0.34 ± 0.41	0.27 ± 0.28	0.002	Significant
Decrease in PCV (%)	1.18 ± 1.1	1.04 ± 0.9	0.040	Significant

Table 3. Comparison of total blood loss and need for blood transfusion in two groups:

Parameters		Misoprostol	Oxytocin		p Value
Total Blood loss (mL)	<500	370(92.5)	379(94.75)	749(93.63)	0.329(NS)
	500-1000 (PPH)	14(3.5)	12(3)	26(3.25)	
	>1000 (severe PPH)	16(4)	9(2.25)	25(3.13)	
Blood transfusion needed	No	365(91.25)	378(94.5)	743(92.88)	0.074(NS)
	Yes	35(8.75)	22(5.5)	57(7.13)	

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