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Original Article

Obstetrics and Gynaecology Section

Prophylactic Administration of Per Rectal Misoprostol vs Intramuscular Injection of Oxytocin in Third-stage of Labour for Prevention of Postpartum Haemorrhage: A Randomised Controlled Trial

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ABSTRACT

Introduction: In India, the routine Active Management of Third-Stage of Labour (AMTSL) with conventional intramuscular oxytocin, at the rural, resource-constrained areas, is often compromised due to lack of trained healthcare personnel and proper maintenance of cold chain system, causing maternal mortality and morbidity from Postpartum Haemorrhage (PPH). In these scenarios, tablet misoprostol, can be efficacious and convenient alternative.

Aim: To evaluate efficacy and safety of misoprostol administered per rectum with respect to intramuscular oxytocin for effective control of PPH in a Randomised Controlled Trial (RCT).

Materials and Methods: In this RCT, conducted in Sambhunath Pandit Hospital, kolkata, West Bengal, India from September 2015 to August 2016, total 80 eligible pregnant mothers in normal labour with prior consent and fulfilled criteria, were allocated to two separated groups (n=40) by computer generated randomisation table. Control group received 10 IU injection oxytocin and case group received 600 µg misoprostol tablet per rectally within one minute of cord clamping and cutting. The primary outcome measures were mean third-stage and mean postpartum blood loss up to eight hours after delivery. Secondary outcome variables were Mean Arterial Pressure (MAP) after eight hours postdelivery, haemoglobin and haematocrit after 24 hours of delivery and reported side effects. Data was entered into a Microsoft excel spreadsheet and statistical analysis was done by Statistical Package for the Social Sciences (SPSS) version 20.0.1 and Graph Pad Prism version 5.0.

Results: Total sample size was 80 equally divided into two groups, with a mean age of 23.20±3.1558 years and 23.7750±3.8927 years in case and control group respectively. The mean third-stage blood loss (332.4105±72.6632 mL versus {vs} 329.0088±59.4503 mL, p=0.8193) and mean total blood loss (426.5575±80.0215 mL vs 424.8783±61.5808 mL, p=0.9165) were statistically indifferent between misoprostol and oxytocin groups by two-sample t-tests. The mean for eight hours postpartum MAP (p=0.0894), 24 hours postpartum haemoglobin (p=0.4534) and haematocrit (p=0.1325) were statistically insignificant between the two groups by two-sample t-tests. Incidence of adverse effects like shivering, diarrhoea, compared by Pearson's Chi-square test, were found to be more but non significant in misoprostol group.

Conclusion: This study concludes that per-rectal misoprostol is equally effective as intramuscular oxytocin to control PPH without significant adverse effects.

Keywords: Active management of third-stage of labour, Resource-constraints, Safety, Uterotonics

INTRODUCTION

In obstetrics, one of the most challenging and life threatening incidents is PPH. In low socio-economic countries like India, PPH is one of the common causes of maternal death [1,2]. PPH is quantitatively defined as- "Blood loss more than or equal to 500 mL following vaginal delivery and 1000 mL or more following caesarean section". American College of Obstetricians and Gynaecologists (ACOG) defines PPH as postpartum blood loss causing 'haematocrit drop of 10% or more or need for blood transfusion'. Atonic uterus accounts for 80% among the causes of PPH [3].

Myometrial contractility is an integral factor for control of PPH and administration of uterotonics is a part in the AMTSL. A dosage of 10 units oxytocin is administered as either in infusion form or as bolus via intramuscular or intravenous route after child birth to prevent PPH. A 10 to 42% of woman receiving oxytocin is found to require additional oxytocic agents like ergot alkaloids, prostaglandins [4,5]. Oxytocin is not the ideal choice for prevention of PPH in patients of cardiac disease, pre-eclampsia as it causes tachycardia and sudden hypotension [6,7]. Moreover, it has some antiplatelet, negative ionotropic and antidiuretic adverse action [6]. Oxytocin is both heat-sensitive and photosensitive and requires cold chain storage system. Administration of oxytocin is an invasive procedure. Misoprostol is also an uterotonic which can be given via non invasive routes like vaginally, sublingually, per rectally [8]. It is rapidly absorbed and no cold chain is required for storage. Methylergometrine has the same storage problem and is contraindicated in cardiac and hypertensive patients. This emphasises the role and utility of misoprostol in developing countries. In a pharmacokinetic study, rectal administration of misoprostol was found to be superior to oral administration in third-stage of labour [9].

In India, even today, large number of deliveries occurs without trained birth attendants in rural settings where refrigeration and cold-chain facilities are unavailable. Different studies reported that the use of rectal misoprostol was an effective first-line or second-line treatment for the management of PPH unresponsive to oxytocin [10-12]. In the study of Chong YS et al., concluded that the drug was not as successful as expected [13]. Contradictory results about the efficacy of rectal misoprostol for prevention of PPH has been reported by various studies, and also there are limited studies available in this field, so the present study was designed [14,15]. The efficacy of per

rectal tablet misoprostol (600 µg) to the routine prophylactic dosage of intramuscular oxytocin injection (10 IU) was assessed in total 80 eligible pregnant mothers at normal labour with prior consent and fulfilled criteria. The primary outcome measures were mean third-stage and mean postpartum blood loss up to eight hours. Secondary outcome variables were eight hours postdelivery MAP, 24 hours of postdelivery haemoglobin, haematocrit and the reported side effects.

MATERIALS AND METHODS

This randomised controlled study was carried out on the patients admitted for vaginal delivery in labour room in Sambhunath Pandit Hospital, Kolkata, West Bengal, India from September 2015 to August 2016. It was a double-blinded study where the participants and investigators were blinded to the intervention received. Permission was taken from the institutional Scientific Review and Ethical committee (REF.NO.3/SNPH/IEC/7/2015) before conduction of this study. This trial has been registered to the National Board of Examinations, New Delhi. (Registration No: Obstetrics & Gynaecology/NBE/HYD/2015/TP-108/204079/10).

Inclusion criteria: The inclusion criteria were women with gestational ages from 37 to 41 weeks and patients in active labour (1st and 2nd stage).

Exclusion criteria: The exclusion criteria were elective and emergency caesarean section, severe anaemia (Haemoglobin <8 gm%) multiple gestation, antepartum haemorrhage, malpresentation/malposition, polyhydramnios, prolonged labour or obstructed labour, history of previous rupture uterus, grand multipara, macrosomic baby, fibroid uterus, severe pre-eclampsia, known hypersensitivity to prostaglandins and induction of labour with oxytocin or prostaglandins.

Sample size calculation: The minimum number of subjects for this study would have been 79.04~80 with 90% power, 95% of confidence level. A total of 80 participants were equally divided into two groups (n=40). The used formula for sample size calculation of equivalence design RCT with continuous variable outcome was:

$$N = 2x\frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{d^2} x\, S^2$$

N=required sample size:

$Z_{1-\alpha/2}$=Z value for α level at 0.05=1.96

$Z_{1-\beta}$=Z value for β level at 10%=1.28

S=Polled standard deviation of both comparison groups (Average SD)

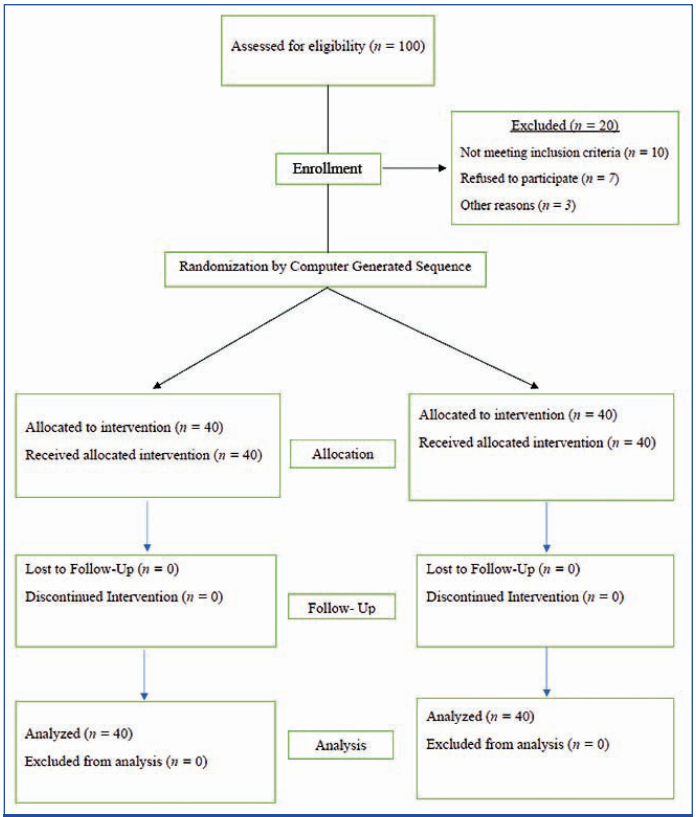
d=Clinically acceptable margin.

All mothers who underwent vaginal delivery and fulfilled the inclusion and exclusion criteria were included with their due consent [Table/Fig-1]. Randomisation and allocation was done by a computer-generated randomiser program. Sample population received treatment as randomised number indication and distributed in two equally numbered groups.

- **Group I (Cases):** Received misoprostol tablet (600 µg) per rectally after delivery of the baby.
- **Group II (Controls):** Received intramuscular injection oxytocin 10 IU after delivery of the baby.

Detailed history, thorough clinical examination, routine investigations were carried out in each case and data recorded. Every mother was examined for MAP, pulse, any medical disorder, foetal lie, presentation and estimation of foetal weight. Vaginal examination (if needed and not contraindicated) was done for both the groups. Complete blood count with haematocrit and haemoglobin along with an obstetric ultrasonography were conducted for all patients.

In the case group, misoprostol tablet 600 µg, was administered per rectally to the case population and 10 IU injection oxytocin intramuscularly administered to the control group. The study medications were administered within one minute of clamping and cutting the cord.



[Table/Fig-1]: CONSORT diagram.

Standard care like controlled cord traction and uterine massage were provided to both groups. Blood loss was measured objectively using the BRASS-V™ Drape, placed under the buttocks before delivery. The calibrated blood collection chamber was opened after delivery of the baby and drainage of amniotic fluid. The blood collected in the drape was measured in a separate jar with 10 mL calibrations.

The blood loss during the first eight hours of delivery was observed on hourly basis. During third-stage of delivery the blood was collected in the calibrated blood collection chamber of BRASS-V ™ drape and measured. Blood soaked swabs (used at third-stage) were weighed in grams, and the known dry weight of the swabs (previously autoclaved pads which were weighed on digital paediatric weighing machine) was subtracted, this volume was added to the measured blood volume from (assuming specific gravity of blood as postpartum hourly blood loss was assessed by weighing the blood clots and used pads for first eight hours. Total blood loss (A) at third-stage and first eight hours postpartum blood loss measured by: A=(C-B)+D

- A- Approximate blood loss.
- B- Weight of dry pads and gauges.
- C- Weight of soaked pads and gauges used in third-stage and eight hours postdelivery.
- D- Collected blood in chamber of Brass-V drape.

Vital signs were monitored continuously during the delivery. Blood sample for haemoglobin and haematocrit estimation was obtained by automated cell counter, 24 hours after delivery. The primary outcome variables were mean blood loss and PPH up to eight hours postpartum. Secondary outcome variables included mean for MAP at eight hours postpartum, 24 hours postpartum haemoglobin and haematocrit, which were directly associated with blood loss and were noted meticulously in each case. Adverse effects (vomiting, diarrhoea, shivering, and fever, defined as a temperature >38.4°C) were monitored for first 24 hours after delivery.

STATISTICAL ANALYSIS

Categorical variables like gravida, parity etc., were expressed as number of patients and percentage of patients. Blood loss, haemoglobin and Packed Cell Volume (PCV) and their changes,

MAP etc., were expressed as mean and standard deviation and compared using paired t-test. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Unpaired proportions were compared by Pearson's Chi-square test (χ^2 test) or Fischer's-exact test and appropriate Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. In each case, the formula for a test statistics that either exactly followed or closely approximated a *t*-distribution under the null hypothesis was given. Also, the appropriate degrees of freedom were given in each case. Each of these statistics could be used to carry out either a one-tailed test or a two-tailed test. Once a t-value was determined, a p-value was found using a table of values from Student's t-distribution. The p-value ≤0.05 was considered for statistically significant as alpha (α) level taken as 5%. For statistical analysis data was entered into a Microsoft excel spreadsheet and then analysed by SPSS version 20.0.1 and Graph Pad Prism version 5.0.

RESULTS

The study population included the women ranging from 18 to 35 years. The mean age was 23.20±3.1558 years and 23.7750±3.8927 years in case and control group respectively with p-value of 0.478 and the total mean age was 23.4875 years [Table/Fig-2]. The [Table/Fig-2] also shows distributions of gravida (p=0.1209) and parity (p=0.1146). The mean±SD results for MAP was 84.625±5.3526 vs 84.475±5.3011 mm of Hg, pulse was 94.3817±6.3486 vs 96.1485±4.3381 bpm, foetal lie (longitudinal), presentation (cephalic), estimated foetal weight was 3256.0615±105.3213 vs 3184.4077±197.3671 grams for case and control groups respectively. Vital signs (Mean±SD) results for pulse was 96.6251±4.6216 bpm, mean systolic BP was 136.87±5.461 mm of Hg and mean respiratory rate was 26.351±3.1542 was breaths per minute) were monitored continuously during the delivery. Distributions of mean for BMI, period of gestation, antepartum haemoglobin, haematocrit and antepartum MAP shows no significant differences (p=0.9716, p=0.6395, p=0.2113, p=0.4583 and p=0.9001, respectively in [Table/Fig-3,4].

Variable	Group	Group I n (%)	Group II n (%)	Total n (%)	p-value
Age group (years)					
18 to 20		12 (30%)	9 (22.5%)	21 (26.25%)	0.478
21 to 25		20 (50%)	20 (50%)	40 (50%)	
26 to 30		8 (20%)	9 (22.5%)	17 (21.25%)	
31 to 35		0	2 (5%)	2 (2.5%)	
Total (n)		40	40	80	
Gravida					
1		22	25	47	0.1209
Row %		46.8	53.2	100.0	
Col %		55.0	62.5	58.8	
2		14	15	29	
Row %		48.3	51.7	100.0	
Col %		35.0	37.5	36.3	
3		4	0	4	
Row %		100.0	0.0	100.0	
Col %		10.0	0.0	5.0	
TOTAL		40	40	80	
Row %		50.0	50.0	100.0	
Col %		100.0	100.0	100.0	
Parity					
0		22	26	48	0.1146
Row %		45.8	54.2	100.0	
Col %		55.0	65.0	60.0	
1		14	14	28	
Row %		50.0	50.0	100.0	
Col %		35.0	35.0	35.0	
2		4	0	4	
Row %		100.0	0.0	100.0	
Col %		10.0	0.0	5.0	
TOTAL		40	40	80	
Row %		50.0	50.0	100.0	
Col %		100.0	100.0	100.0	

[Table/Fig-2]: Distribution of age, gravida and parity in case and control groups.
Two-sample t-tests were done for difference in mean involved independent samples (distribution of mean age). Z-test (Standard Normal Deviate) was used to test the significant difference of proportions of age. Gravida and parity were compared by Pearson's Chi-square test (χ^2 test)

Variable	Group	Mean±SD	Minimum	Maximum	Median	p-value
BMI	Group I	26.4833±1.6996	22.94	29.73	26.325	0.9716
	Group II	26.4648±2.8012	21.4903	33.284	26.4044	
POG (Weeks)	Group I	38.975±1.4049	37	41	39	0.6395
	Group II	38.825±1.448	37	41	39	

[Table/Fig-3]: Distribution of Mean BMI & Mean Period of Gestation (POG in Weeks) in two groups.
Two-sample t-tests were done for distribution of difference in mean involved unpaired samples (mean BMI and mean POG)

Variable	Group	Mean±SD	Minimum	Maximum	Median	p-value
Mean antenatal haemoglobin (gm/dL)	Group I	9.7625±1.512	8	13.4	9.3	0.4583
	Group II	9.56±0.8167	8	12	9.5	
Mean antenatal haematocrit (%)	Group I	35.4±3.7197	30	45	34.5	0.2113
	Group II	34.55±2.0872	31	40	35	
Antepartum mean of MAP (mm of Hg)	Group I	84.625±5.3526	75	94	84	0.9001
	Group II	84.475±5.3011	76	96	85	

[Table/Fig-4]: Distribution of mean antenatal haemoglobin (gm/dL), haematocrit (%) and antepartum mean of Mean Arterial Pressure (MAP in mm of Hg) in two groups.
Two-sample t-tests was done for distribution of difference in mean of antenatal haemoglobin, haematocrit and mean of MAP

The mean third-stage blood loss (p=0.8193) and total postpartum blood loss (p=0.9165) were statistically indifferent between misoprostol group and oxytocin group: (332.4105±72.6632 mL and 426.5575±80.0215 mL) vs (329.0088±59.4503 mL and 424.8783±61.5808 mL), respectively [Table/Fig-5,6]. In the present study, after eight hours postpartum, mean for MAP in case group was 84.4500±5.1338 mm of Hg and in control group 84.4250±5.3918 mm of Hg with p-value of 0.0894 [Table/Fig-7]. The 24 hours postpartum haemoglobin (9.4950±1.4146 gm/dL and 9.3025±0.7804 gm/dL) and haematocrit (34.7000±3.6809 and 33.6750±2.1530 in %) were almost equal between case and control population [Table/Fig-8]. Difference in distribution of mean haemoglobin (gm/dL) (24 hours postpartum) in two groups was not statistically significant (p=0.4534) and also the 24 hours postpartum haematocrit (p=0.1325). In the present study, the rate of blood loss >500 cc

Blood Loss (mL)	Group	Mean±SD	Minimum	Maximum	Median	p-value
Brass V Drape	Group I	217.7855±75.6611	111.32	377.36	212.175	0.9425
	Group II	216.6338±66.3102	110	389	199	
Soaked gauge	Group I	117.125±35.4077	60	190	120	0.6225
	Group II	120.975±34.2581	56	196	118	
Total third-stage blood loss (mL)	Group I	332.4105±72.6632	171.32	476.6	325.715	0.8193
	Group II	329.0088±59.4503	218	485.5	328	

[Table/Fig-5]: Distribution of mean third-stage blood losses (in mL) in two groups.
Two-sample t-tests were done for distribution of difference in mean of third-stage blood loss

Variable	Group	Mean±SD	Minimum	Maximum	Median	p-value
Total blood loss (mL)	Group I	426.5575±80.0215	253.39	589.15	423.26	0.9165
	Group II	424.8783±61.5808	289.69	570.24	417.16	

[Table/Fig-6]: Distribution of mean total blood loss (mL) in two groups.
Two-sample t-tests was done for distribution of difference in mean total blood loss

Variable	Group	Mean±SD	Minimum	Maximum	Median	p-value
Post-partum MAP (mm of Hg)	Group I	84.45±5.1338	75	95	85	0.0894
	Group II	82.425±5.3918	70	96	82	

[Table/Fig-7]: Distribution of mean for Mean arterial Pressure (MAP in mm of Hg) at eight hours postpartum between two groups.
Two-sample t-tests was done for distribution of difference in mean involved Post-partum MAP

Variable	Group	Mean±SD	Mini-mum	Maxi-mum	Median	p-value
Mean 24 hours post-partum Haemoglobin (gm/dL)	Group I	9.495±1.4146	7.8	12.5	9	0.4534
	Group II	9.3025±0.7804	8	11.5	9.25	
Mean 24 hours post-partum Haematocrit (%)	Group I	34.7000±3.6809	30	44	34	0.1325
	Group II	33.675±2.1530	30	39	34	

[Table/Fig-8]: Distribution of mean haemoglobin (gm/dL) and haematocrit (%) at 24 hours postpartum period in two groups.
Two-sample t-tests was done for distribution of difference in mean of Post-partum haemoglobin and haematocrit

or PPH was observed at eight hours postpartum period in four patients (10%) of misoprostol group and three patients (7.5%) of oxytocin group; but was statistically insignificant (p=0.68916) [Table/Fig-9]. The adverse effects observed in misoprostol and oxytocin groups, as in [Table/Fig-10], were vomiting in 11 (27.5%) and 6 (15%), shivering in 8 (20%) and 4 (10%), diarrhoea 8 (20%) and 5 (12.5%), temperature >38.4°C 5 (12.5%) and 2 (5%), respectively. The distribution of adverse effects was not statistically significant between two groups as p-values were 0.17177, 0.2104, 0.36324, and 0.23522, respectively. All the adverse effects were self-limiting and no patient required any intervention to control the effects except shivering where only covering with blankets were required.

Group	N	Postpartum Haemorrhage	Percentage (%)	p-value
Group I	40	4	10	0.68916
Group II	40	3	7.5	
Total	80	7	8.75	

[Table/Fig-9]: Incidence of postpartum haemorrhage (Total blood loss >500 mL) after eight hours in two groups.
Z-test (Standard Normal Deviate) was used to test the significant difference of PPH incidence

Effects	Number and percentage	Group I (Total=40)	Group II (Total=40)	Total	p-value
Vomiting	Present	11	6	17	0.17177
	Row %	64.7	35.3	100	
	Column %	(27.5)	(15)	(21.3)	
Shivering	Present	8	4	12	0.2104
	Row %	66.7	33.3	100	
	Column %	(20)	(10)	(15)	
Diarrhoea	Present	8	5	13	0.36324
	Row %	61.5	38.5	100	
	Column %	(20)	(12.5)	(16.3)	
Temperature (>38.4°C)	Present	5	2	7	0.23522
	Row %	71.4	28.6	100	
	Column %	(12.5)	(5)	(8.8)	

[Table/Fig-10]: Distribution of adverse effects between two groups within 24 hours postpartum.
Adverse effects were compared by Pearson's Chi-square test (χ^2 test)

DISCUSSION

In the rural and limited-resource areas of India, lack of trained healthcare and proper cold chain system is the main obstacle for routine AMTSL with conventional intramuscular oxytocin, which leads to maternal morbidity and mortality from PPH. The use of misoprostol tablet per rectum can be a convenient and equally effective substitute in this condition as per the findings with respect to primary and secondary outcome variables.

Difference of antepartum mean MAP in case and control populations was not statistically significant (p=0.9001) as per the present study findings. These results corroborated with the study of Bellad MB et al., who also reported no statistical significance in this aspect between misoprostol and oxytocin groups [16].

In the present study, the mean total blood loss was 426.5575± 80.0215 mL in cases and 424.8783±61.5808 mL in controls. This outcome was supported by Aziz S et al., who reported average amount of blood loss (mL) was 267.14±140.35 with oxytocin versus 302.86±160.4, with misoprostol, this difference was statistically non significant (p=0.236) [17]. Similar findings were published by Nisa MU et al., regarding blood loss after delivery (oxytocin group- 252 mL and misoprostol group- 304 mL, p=0.18) [18].

In this study at eight hours postpartum, mean for MAP in case group was 84.4500±5.1338 mm of Hg and in control group was 84.4250±5.3918 mm of Hg (p=0.0894). The observation of Owa OO et al., also supported the non significant changes in postpartum MAP values [19].

The 24 hours postpartum haemoglobin (9.4950±1.4146 gm/dL and 9.3025±0.7804 gm/dL, p=0.4534) and haematocrit (34.7000±3.6809 and 33.6750±2.1530 in %, p=0.1325) were comparable between case and control populations. The findings of mean changes in postpartum haemoglobin and haematocrit were found to be identical with the study performed by Parsons SM et al., which showed that there was no significant difference between the treatment groups (misoprostol group 1.19 gm/dL and oxytocin group 1.16 gm/dL: relative difference 2.6%; at 95% CI) [11]. The study done by Firouzbakht M et al., observed no significant difference between the two groups' haematocrit value in the postpartum period (p>0.05) [20]. The research of Nasr A et al., also elicited no significant difference in haemoglobin or haematocrit values 24 hours postpartum [21].

The incidence of PPH after eight hours (0% in misoprostol and 7.5% in oxytocin groups) in the present analysis was comparable with the survey of Firouzbakht M et al., which exhibited the incidence of PPH was 12% in the study group and 10% in the control group (p>0.05) [20]. The observation by Nasr A et al., to compare rectal misoprostol versus intravenous oxytocin for PPH prevention had the outcome identical to the present study that two groups were not significantly different in terms of 24 hours PPH [21]. Another article by Haque N et al., evaluating rectally administered misoprostol as a prophylaxis versus conventional intramuscular oxytocin in PPH presented no significant difference between the two groups in terms of reducing the incidence of PPH; therefore they reported that rectally administered misoprostol may be an effective alternative to conventional intramuscular oxytocin in the prevention of PPH [22]. The present study analysis found 600 µg per rectal misoprostol was equivalently effective to 10 IU intramuscular oxytocin in reducing mean postpartum blood loss and PPH. It was supported by the Cochrane Review, which aggregated data from studies that both visually estimate blood loss and objectively measured Post-partum blood loss and found virtually no difference in PPH prevention and no significant difference in mean blood loss in comparison to sublingual misoprostol and injectable uterotonics [8]. Other supportive results were noticed in the review performed by Parsons SM et al., the study of Firouzbakht M et al., the analysis of Haque N et al., and the study done by Nasr A et al., with respect to reduction in mean postpartum blood loss [11,20-22].

Incidence of adverse effects like shivering and diarrhoea was more in misoprostol group but statistically similar to oxytocin group. These findings were analogous to the research done by Mirteimouri M et al., showing no significant difference the between two groups (for nausea p=0.57 and headache p=0.331 [23]. Cochrane database systematic review studies comparing 600 µg oral misoprostol or 400 µg sublingual misoprostol with injection oxytocin, the incidence of side-effects in women receiving 600 µg oral misoprostol or 400 µg sublingual misoprostol was alike [8]. The incidence of temperatures

±38°C was only 1.2% in women receiving a relatively low dose (400 µg) of sublingual misoprostol. Study done by Chaudhuri P et al., showed only the incidence of shivering was higher in misoprostol group (8.3 % vs 1.1 %, p=0.018) but frequency of high temperature, vomiting was similar in both groups [24]. Elsedeek MS reported that the postpartum temperature rise in first 24 hours of delivery was seen in 11 (5.5%) and 13 (6.5%) for case and control group respectively (p=0.20) [25]. In WHO multicentric two treatment trials, pyrexia was more common in the misoprostol group (392 women; RR: 2.78; 95% CI: 1.39-5.53) [26]. Fever was significantly higher among misoprostol patients (18.7% vs 0.8%) in discussion of Nasr A et al., which were not in accordance with the findings of this study. This difference was might be due to higher dose of misoprostol used in their study [21].

Limitation(s)

This study was done in a government hospital in Kolkata, India in a limited sample population which might not be the representative of the entire population, with a greater sample size, incidence of PPH might be more which may require various other modalities of management. Other limitations include limited side effects of the drugs were observed. The effects according to the different gestational age, parity, BMI were not studied separately and only immediate follow-up of study subjects was done.

CONCLUSION(S)

Administration of 600 µg misoprostol per rectally at third-stage of labour was equally effective as 10 IU of intramuscular oxytocin for reduction of blood loss and prevention of PPH. Adverse effects were not statistically significant. Misoprostol is less expensive and does not require refrigeration; route of administration is non invasive and simpler than other uterotonics. These makes misoprostol tablet a safe, effective and cheaper alternative to oxytocin in resource-limited areas.

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