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Prospective Comparison of Rectal Misoprostol versus Oxytocin Infusion for Prevention of Post-Caesarean Section Primary Postpartum Hemorrhage

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The drug of choice recommended by the WHO for the prevention of primary postpartum hemorrhage after vaginal or post Caesarean delivery is oxytocin. However, oxytocin is labile in hot tropical climates as in Africa with reduced efficacy. Misoprostol may be an alternative as it has most properties of oxytocin.
Aim: The aim of the study is to compare the efficacy and safety of rectal misoprostol with oxytocin in preventing primary postpartum haemorrhage after Caesarean delivery.
Study Design: This study was a double blind, randomized controlled trial - non-inferior design.
Methodology: One hundred and forty women who were suited for Caesarean delivery were randomly selected into two groups of 70 parturients each. One arm of the study had 40 IU of oxytocin in 1 litre of normal saline and the other arm had 600 ug of rectal misoprostol after Caesarean section, to prevent primary postpartum haemorrhage.
The 24-hours blood loss per vaginam was collected and compared between the study arms, as the primary outcome measure.
Analysis: All data extracted were entered into SPSS version 25.0 and analyzed. The statistical significance was set at p-value of 0.05.

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Results: There was no statistically significant difference between the Misoprostol and Oxytocin groups in preventing primary postpartum hemorrhage after Caesarean section. (106.8 ± 48.6 ml vs. 131.7 ± 161.4 ml, p= 0.839).
Conclusion: Rectally administered misoprostol was as effective as oxytocin infusion in the prevention of primary postpartum hemorrhage after vaginal or Caesarean delivery, giving Obstetricians choices of drugs to use.

Keywords: Misoprostol, Oxytocin infusion; Caesarean section; postpartum hemorrhage; vaginal delivery; Obstetric interventions.

1. INTRODUCTION

The Sub-Saharan Africa has one of the highest maternal mortality ratio (MMR) of 533 maternal deaths per 100,000 deliveries in the world sub regions and obstetric hemorrhage is one the six leading causes of these maternal deaths in sub-Saharan Africa [1-3].

Whatever be the mode of delivery of a pregnant woman, the cardinal symptom is hemorrhage and the degree of loss may be quantified further by route of delivery of the baby: For vaginal and Caesarean deliveries, blood loss per vaginal equal or above 500ml and for Caesarean section blood loss of equal or greater than 1000 ml in the first 24 hours is termed primary post-partum hemorrhage respectively. Any amount of blood loss that affects the hemodynamic status of the patient is also termed primary post-partum hemorrhage [4]. The best practice for every Obstetrician is to stem the tide of bleeding in labor or after child birth. This is because, these are the two most vulnerable points where women are at high risk of dying. While the uterine anatomy is specifically built for the purpose of improving the hemostatic stability of the would-be mother in anticipation of hemorrhage in labor, delivery or immediately after childbirth. The hemostatic process is also helped by the physiological changes in pregnancy which prepares the impending parturient for excessive blood loss like increased blood volume, increased clothing factors in pregnancy that would compensate for anticipated blood loss at the point of delivery. However it has become conventional in obstetric practice to augment natural hemostasis process at delivery with either the use of two uterotonic drugs –Oxytocin or misoprostol and other drugs. The uterotonic drugs mimic the natural rhythmic uterine contractility thereby maintain hemostasis after delivery. This pattern of uterine contraction is to allow the latter to maintain its blood supply in the interval of the contractions and prevent it from ischemia and organ damage. For the purpose of this study, we will dwell on oxytocin and misoprostol, the two utero-tonic drugs conventionally used for prevention of primary post-partum hemorrhage after vaginal or Caesarean delivery. We will compare the efficacy of the two drugs, their potential use in tropical climate, storage, side effects, accessibility in terms of routes of administration, cost and also compare the two drugs, whether one has advantage(s) over the other in terms of prevention of primary post-partum hemorrhage which is a challenge in sub-Saharan Africa.

1.1 Pharmacokinetics of Oxytocin

Oxytocin is a Nona peptide hormone secreted from the hypothalamus, but stored in the posterior pituitary gland. The commercially available preparation has little or no antidiuretic or vasopressor action when given at the recommended dosage. Oxytocin injection is stored at a temperature between 2c and 8 c but not exceeding 25c in tropical climates, because its efficacy reduces in these hot tropical climates as in sub –Saharan jAfrica [5]. Oxytocin is destroyed in the gastrointestinal tract, thus it must be given parentally. Uterine response to oxytocin is almost immediate with intravenous administration but takes between three and five minutes with intramuscular administration with uterine response subsiding in approximately two to three hours for intramuscular administration and one hour for intravenous administration [6,7]. The drug is rapidly degraded in the liver and kidneys and excreted in urine. The drug is contraindicated once cephalo-pelvic disproportion in labor has been confirmed. Side effects of the drug include: (water intoxication, fetal distress, precipitate labor, uterine rupture, etc.) which are usually due to inappropriate use or too high a dose of the drug.

1.2 Pharmacology of Misoprostol

Misoprostol is a synthetic prostaglandin E_1 analogue. The drug was originally used to treat

peptic ulcer disease but later found to have uterotonic qualities and since been deployed in obstetric practice [8-10]. Like oxytocin, misoprostol has been used for labor induction, cervical ripening, and prevention of primary post hemorrhage after vaginal or Caesarean delivery. Misoprostol is stable in in hot climates. Misoprostol can also be given through different routes like vaginal, rectal. Sublingual, oral routes [9, 10]. With these similarities and differences with oxytocin, we found it justifiable to compare the two drugs so that Physicians could have a wider spectrum of drugs to choose from in the prevention of post-partum hemorrhage.

2. METHODOLOGY

This is a, double blind randomized control trial sampling, (non-inferior design) conducted at the Federal Medical Centre, Yenagoa, Nigeria, to compare Misoprostol to Oxytocin in terms of their effectiveness in preventing primary postpartum hemorrhage consequent on Caesarean delivery. One hundred and forty women with clear indications for elective or emergency Caesarean section were divided randomly into two groups of 70 women each.

One arm of the study had 40 IU of oxytocin in 1 litre of normal saline and the other arm had 600 ug of rectal misoprostol after Caesarean section to prevent primary postpartum haemorrhage.

Blood loss per vaginam was measured by the sum total of the weight gain of the perineal pads used in the 24 hours study period. Perineal pads were weighed using the Mettler PB 153 weighing scale, which had a sensitivity of 0.001 g. The dry weight of a perineal pad was 14 g.

It was assumed that 1 ml of blood weighed approximately 1 g (gram). The 24-hours blood loss per vaginam was collected and compared between both study groups.

Permission was sought from the hospital ethical committee and it was granted. The consent of the subjects for the study were also sought and obtained. The exclusion criteria for the study included. those who did not give their consent, those with no overt risk factors for primary post-partum haemorrhage, allergy to misoprostol, and Caesarean sections for dire emergencies such as umbilical cord prolapse and suspected fetal distress. Also, patients with known history of hepatic, renal and haematological disorders and active antepartum hemorrhage were excluded from the study.

3. RESULTS

3.1 Baseline Clinical Characteristics of Participants in the Study Groups

Table 2 shows a baseline description of the clinical features of participants in both study arms

Table 1. Socio-demographic characteristics of participants in the Misoprostol and Oxytocin infusion study groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion group N = 70 (%)	Test of Significance	df	P Value
Age group						
< 25 years	9 (6.4)	6 (8.4)	3 (4.3)	3.19[a]	3	0.363
25 – 29 years	37 (26.4)	20 (28.6)	17 (24.3)			
30 – 34 years	34 (24.3)	13 (18.6)	21 (30.0)			
≥ 35 years	60 (42.8)	31 (43.3)	29 (41.4)			
Mean Age ± SD in years	32.4 ± 5.7	32.4 ± 6.2	32.4 ± 5.2	0.05[b]	138	0.965
Ethnicity						
Ijaw	91 (65.0)	46 (65.7)	45 (64.3)	4.92[a]	3	0.178
Igbo	19 (13.6)	6 (8.6)	13 (18.6)			
Urhobo/Isoko	11 (7.9)	3 (4.3)	8 (11.4)			
Others	19 (13.6)	10 (14.3)	9 (12.9)			
Parity						
Nullipara	29 (20.7)	16 (22.9)	13 (18.6)	0.81[a]	3	0.846
Primipara	26 (18.6)	14 (20.0)	12 (17.1)			
Multipara	50 (35.7)	23 (32.9)	27 (38.6)			
Grandmultipara	35 (25.0)	17 (24.3)	18 (25.7)			
Median Parity (Range)	2.0 (0.0 – 8.0)	2.0 (0.0 – 8.0)	2.0 (0.0 – 0.5)			

[a]Test of significance is Chi-square test, [b]Test of Significance is t-Test. SD – Standard deviation

Table 2. Baseline clinical characteristics of parturient and caesarean section features in the study groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion group N = 70 (%)	Test of Significance	df	pValue
Gestational Age in weeks, Mean ± SD	38.3 ± 1.2	38.2 (1.1)	38.3 (1.4)	-0.42[b]	138	0.678
Gestational Age in days, Mean ± SD	267.9 ± 9.3	268.2 ± 8.0	267.5 ± 10.5	0.42[b]	138	0.972
Type of CS						
Emergency	97 (69.3)	51 (72.9)	46 (65.7)	0.84[a]	1	0.360
Elective	43 (30.7)	19 (27.1)	24 (34.3)			
Pre-operative PCV						
Mean ± SD in %	35.9 ± 5.5	35.6 ± 6.0	36.1 ± 5.1)	-0.54[b]	138	0.592
Duration of Surgery						
Mean ± SD in hours	1.2 ± 0.3	1.2 ± 0.2)	1.2 ± 0.3	-1.72[b]	138	0.188
EBL at Surgery (ml)	600.4 ± 178.3	603.5 ± 153.8	597.4 ± 200.9	0.204[b]	138	0.839

[a]*Test of significance is Chi-square test,* [b]*Test of Significance is t-Test. SD – Standard deviation, CS – Caesarean section, PCV – Packed cell volume, EBL- Estimated blood loss*

Table 3. Indications for caesarean section in the misoprostol and oxytocin infusion groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion group N = 70 (%)	Test of Significance (Chi-square)	df	PValue
Severe Preeclampsia with unfavourable cervix						
Yes	27 (19.3)	12 (17.1)	15 (21.4)	0.41	1	0.520
No	113 (80.7)	58 (82.9)	55 (78.6)			
Breech Presentation						
Yes	9 (6.4)	4 (5.7)	5 (7.1)	0.12	1	0.730
No	131 (93.6)	66 (94.3)	65 (92.9)			
Multiple gestation						
Yes	3 (2.1)	1 (1.4)	2 (2.9)	0.34	1	1.000[a]
No	137 (97.9)	69 (98.6)	68 (97.1)			
Multiple previous CS						
Yes	4 (2.9)	2 (2.9)	2 (2.9)	0.00	1	1.000
No	136 (97.1)	68 (97.1)	68 (97.1)			
Previous CS + Multiple gestation						
Yes	3 (2.1)	2 (2.9)	1 (1.4)	0.34	1	1.000[a]
No	137 (97.9)	68 (97.1)	69 (98.6)			
Previous CS+ Hypertension						
Yes	6 (4.3)	4 (5.7)	2 (2.9)	0.69	1	0.404
No	134 (95.7)	66 (94.3)	68 (97.1)			
Previous CS+ Uterine Fibroid						
Yes	5 (3.6)	0 (0.0)	5 (7.1)	5.19	1	0.023
No	135 (96.4)	70 (100.0)	65 (92.9)			
Previous CS + Prolong latent phase of labour						
Yes	3 (2.1)	0 (0.0)	3 (4.3)	3.07	1	0.080
No	137 (97.9)	70 (100.0)	67 (95.7)			
Previous CS + Foetal Macrosomia						
Yes	9 (6.4)	8 (11.4)	1 (1.4)	5.82	1	0.016
No	131 (93.6)	62 (88.6)	69 (98.6)			
Previous CS + PET						
Yes	6 (4.3)	2 (2.9)	4 (5.7)	0.69	1	0.404
No	134 (95.7)	68 (97.1)	66 (94.3)			
Previous CS + Transverse Lie						
Yes	1 (0.7)	0 (0.0)	1 (1.4)	1.01	1	0.316

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion group N = 70 (%)	Test of Significance (Chi-square)	df	PValue
No	139 (99.3)	70 (100.0)	69 (98.6)			
Abruptio placenta						
Yes	6 (4.3)	3 (4.3)	3 (4.3)	0.00	1	1.000
No	134 (95.7)	67 (95.7)	67 (95.7)			
Abruptio placenta+ Preeclampsia						
Yes	3 (2.1)	3 (4.3)	0 (0.0)	3.07	1	0.080
No	137 (97.9)	67 (95.7)	70 (100.0)			
Cephalopelvic disproportion						
Yes	23 (17.1)	10 (14.3)	13 (18.6)	0.47	1	0.494
No	117 (83.6)	60 (85.7)	56 (81.4)			
Cephalopelvic disproportion + Hypertension						
Yes	1 (0.7)	0 (0.0)	1 (1.4)	1.01	1	0.316
No	139 (99.3)	70 (100.0)	69 (98.6)			
Uterine Fibroid + Fetal Macrosomia						
Yes	1 (0.7)	0 (0.0)	1 (1.4)	1.01	1	0.316
No	139 (99.3)	70 (100.0)	69 (98.6)			
Fetal Macrosomia+ Prolong latent phase						
Yes	1 (0.7)	0 (0.0)	1 (1.4)	1.01	1	0.316
No	139 (99.3)	70 (100.0)	69 (98.6)			
Obstructed labour						
Yes	9 (6.4)	5 (7.1)	4 (5.7)	0.12	1	1.000
No	131 (93.6)	65 (92.9)	66 (94.3)			
Placenta praevia						
Yes	10 (7.1)	7 (10.0)	3 (4.3)	1.72	1	0.326
No	130 (92.9)	63 (90.0)	67 (95.7)			
Failed instrumental Delivery						
Yes	4 (2.9)	3 (4.3)	1 (1.4)	1.03	1	0.620
No	136 (97.1)	67 (95.7)	69 (9.6)			

of the trial. Both study arms were similar in terms of mean gestational age, type at Caesarean delivery, pre-operative hematocrit and the duration of surgery ($p > 0.05$). Table 2 also shows that the intra-operative blood loss for both study groups were not significantly different (603.5 ml ± 153.8 ml vs 597.4 ml ± 200.9 ml, p= 0.839).

3.2 Distribution of Known Risk Factors for Primary Postpartum Haemorrhage amongst the Parturients

In Table 4, the most common risk factor for primary postpartum hemorrhage in this study is maternal age > 35 years (36.4 %), though the proportion of women in the Misoprostol group with this risk factor (37.1 %) was slightly higher than those in the Oxytocin infusion group (35.7 %), there was no significant difference (X^2 = 0.03: p- 0.861). Other risk factors for primary postpartum haemorrhage include previous uterine surgery (31.4 %), use of magnesium sulphate (26.4 %) and grandmultiparity (25.0 %). Yet, there was no statistically significant difference between both trial groups in terms of distribution of known risk factors for primary post-partum hemorrhage.

3.3 Intra- And Post-Operative Features in the Study Groups (Table 5)

Table 5 shows that the primary outcome measure of this study, 24 hours post-operative blood loss per vaginam for the Misoprostol group and the Oxytocin infusion group were 106.8 ± 48.6 ml vs 131.7 ± 161.44 ml, respectively, p = 0.839. Thus, there was no statistically significant difference in the 24 hours post-operative estimated blood loss per vaginam between both study groups.

In this study, Misoprostol and Oxytocin infusion study groups were similar in requirements for additional oxytocic intraoperative (22.9% vs 14.3%, p = 0.192) and 24-hour post-operative (0.0 % vs 2.9 %, p = 0.154).

Regarding the need for blood transfusion in the first 24 hours post-Caesarean section, only one participant in the study required blood transfusion due to primary postpartum haemorrhage from uterine atony and she belonged to the Oxytocin

Table 4. Distribution of known risk factors for post-partum haemorrhage among participants in the study groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion Group N = 70 (%)	Test of Significance (Chi-square)	df	pValue
Prolong Labour						
Yes	20 (14.3)	10 (14.3)	10 (14.3)	0.00	1	1.000
No	120 (85.7)	60 (85.7)	60 (85.7)			
Induction of Labour						
Yes	5 (3.6)	2 (2.9)	3 (4.3)	0.21	1	0.649
No	135 (96.4)	68 (97.1)	67 (95.7)			
Augmentation of labour						
Yes	30 (21.4)	12 (17.1)	18 (25.7)	1.53	1	0.217
No	110 (78.6)	58 (82.9)	52 (74.3)			
Grandmultiparity						
Yes	35 (25.0)	17 (24.3)	18 (25.7)	0.04	1	0.846
No	105 (75.0)	53 (75.7)	52 (74.3)			
Class II Obesity						
Yes	13 (9.3)	5 (7.1)	8 (11.4)	0.76	1	0.382
No	127 (90.7)	65 (92.9)	62 (88.6)			
Polyhydramnios						
Yes	3 (2.1)	1 (1.4)	2 (2.9)	0.34	1	1.000
No	137 (97.9)	69 (9.6)	68 (97.1)			
Placenta praevia						
Yes	10 (7.1)	7 (10.0)	3 (4.3)	1.72	1	0.326
No	130 (92.9)	63 (90.0)	67 (95.7)			
Abruptio placenta						
Yes	7 (5.0)	4 (5.7)	3 (4.3)	0.15	1	1.000
No	133 (95.0)	66 (94.3)	67 (95.7)			
History of PPH						
Yes	6 (4.3)	1 (1.4)	5 (7.1)	2.79	1	0.095
No	134 (95.7)	69 (98.6)	65 (92.9)			
Use of MgSO4 (Pre-eclampsia)						
Yes	37 (26.4)	17 (24.3)	20 (28.6)	0.33	1	0.565
No	103 (73.6)	53 (75.3)	50 (71.4)			
General Anaesthesia						
Yes	7 (5.0)	3 (4.3)	4 (5.7)	0.15	1	0.698
No	133 (95.0)	67 (95.7)	66 (94.3)			
Previous uterine Surgery						
Yes	44 (31.4)	18 (25.7)	26 (37.1)	2.12	1	0.145
No	96 (68.6)	52 (74.3)	44 (62.9)			
Maternal Age > 35 years						
Yes	51 (36.4)	26 (37.1)	25 (35.7)	0.03	1	0.861
No	89 (63.6)	44 (62.9)	45 (64.3)			

infusion arm of the trial, this was also not statistically significant. (0.0 % Misoprostol group vs 1.4 % Oxytocin infusion group, p = 0.316). There were no statistical differences observed between the Misoprostol and Oxytocin infusion study groups with regards to 24-hours post-operative hematocrit level (30.3%±5.8% vs 31.7%±3.7 %, p = 0.182).

3.4 Side Effects of Study Medications among Participants in the Study Arms (Table 6)

Table 6 shows a significantly higher proportion of shivering and fever in the Misoprostol trial arm than in the Oxytocin arm (55.7% vs 5.7%; p-0.001) and (38.6% vs 10.0%; p- 0.001) respectively. Also noted was an increased incidence of nausea amongst the Oxytocin infusion group compared to the Misoprostol group (4.3% vs 0.0%). However, this was not statistically significant (p = 0.080). There was no case of vomiting in this study.

4. DISCUSSION

Oxytocin use as uterotonic agent in the prevention of primary postpartum hemorrhage has been in Obstetric practice for decades However, Oxytocin with its challenges of storage

in tropical climates and consequent reduction in efficacy cannot still be discarded because of these difficulties with its use. Oxytocin still compares favorably with other uterotonic agents. In this study, it was found that the new drug, misoprostol was not statistically significant to Oxytocin in the prevention of primary post-partum hemorrhage after Caesarean section. The result of this study were similar to studies done in Asia and Nigeria where misoprostol was snot statistically significant to Oxytocin in the prevention of post- partum hemorrhage [11,12]. This brings to fore the non-inferior design status of this study, meaning the new drug, misoprostol on trial is not more efficacious than oxytocin that has been used conventionally in the prevention of primary post-partum hemorrhage in the past.

However, our findings from this study were at variance from two other studies on same subject done in Asia on the comparison of the efficacy of rectal misoprostol and intravenous oxytocin in the prevention of post - partum hemorrhage after Caesarean section [13,14]. This disparity may have been due to the higher dose of rectally administered misoprostol of 800 ug used in both studies by the authors [13,14]. In these studies, misoprostol was found to reduce 24-hours post-Caesarean section blood loss per vaginam effectively than oxytocin infusion [13, 14]. This observation points towards a possible benefit of administering a higher dose of rectal misoprostol of 800 ug as against 600 of ug used in our study in preventing postpartum hemorrhage after Caesarean section.

Table 5. Intra- and post-operative features in the study groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion group N = 70 (%)	Test of Significance	df	pValue
Additional intra-operative Oxytocic						
Yes	26 (18.6)	16 (22.9)	10 (14.3)	1.70 [a]	1	0.192
No	114 (81.4)	54 (77.1)	60 (85.7)			
Additional Post-Operative Oxytocic						
Yes	2 (1.4)	0 (0.0)	2 (2.9)	2.03 [a]	1	0.154
No	138 (98.6)	70 (100.0)	68 (97.1)			
Need for blood transfusion due to uterine atony						
Uterine atony	1 (0.7)	0 (0.0)	1 (1.4)	1.01[a]	1	0.316
No atony	139 (99.3)	70 (100.0)	69 (98.6)			
Need for blood transfusion due to other indications						
Adhesion	9 (6.4)	2 (2.9)	7 (10.0)	9.25 [a]	2	0.010
Low PCV	10 (7.1)	9 (12.9)	1 (1.4)			
No	121 (85.7)	58 (82.9)	62 (88.6)			
24-hour post-operative haematocrit						
Mean ± SD	30.9 ± 4.8	30.3 ± 5.8	31.7 ± 3.7	-1.75 [b]	138	0.182
Estimated blood loss per vaginam (EBL in ml)						
Mean ± SD	119.3 ± 119.5	106.8 ± 48.6	131.7 ± 161.4	0.204 [b]	138	0.839

[a] Test of significance is Chi-square test, [b] Test of significance is t-Test

Table 6. Side effects of study medications among participants in the study groups

Characteristics	Total N = 140 (%)	Misoprostol group N = 70 (%)	Oxytocin infusion Group N = 70 (%)	Test of Significance	Df	pValue
Shivering						
Yes	43 (30.7)	39 (55.7)	4 (5.7)	41.1[a]	1	0.001**
No	97 (69.3)	31 (44.3)	66 (94.3)			
Nausea						
Yes	3 (2.1)	0 (0.0)	3 (4.3)	3.06[a]	1	0.080**
No	137 (97.9)	70 (100.0)	67 (95.7)			
Fever						
Yes	34 (24.3)	27 (38.6)	7 (10.0)	15.54[a]	1	0.001*
No	106 (75.7)	43 (61.4)	63 (90.0)			
Temperature in ^{o}C among those with Fever						
Mean ± SD	37.9 ± 0.3	37.9 ± 0.3	37.8 ± 0.1	0.48	32	0.638

Statistical significance; [a]Chi-square reported is the Fisher's exact Chi-square*

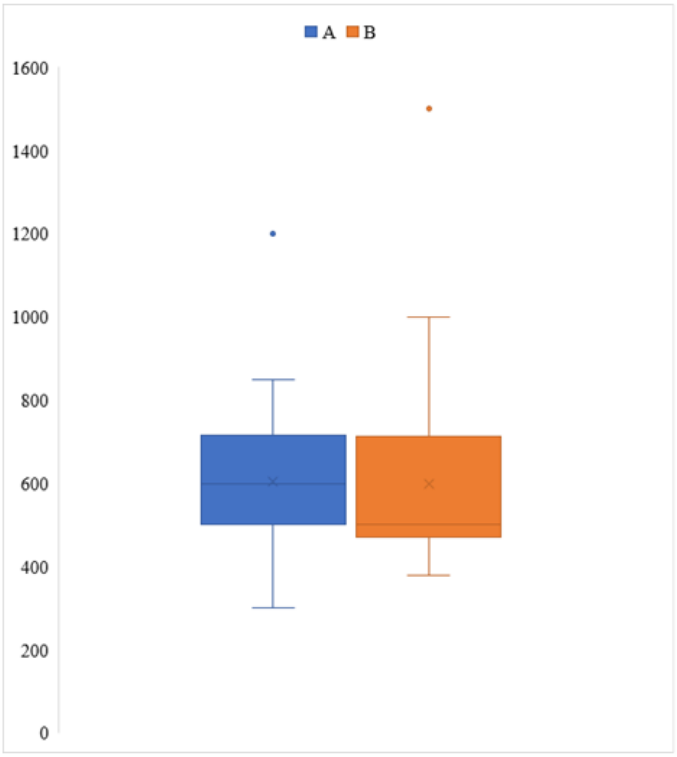

Fig. 1. Box and whisker showing estimated blood loss at surgery in the participants of the study. A = Misoprostol study group, B = Oxytocin infusion study group

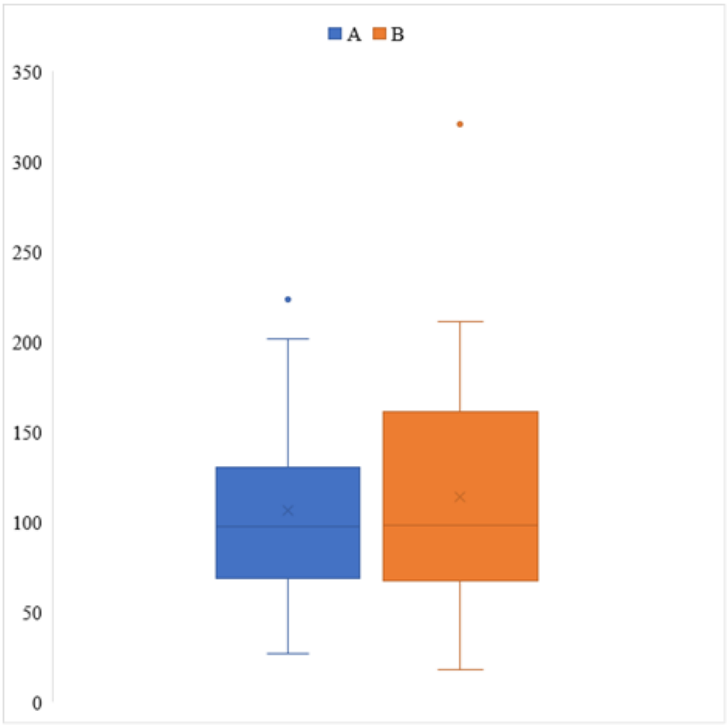

Fig. 2. Box and whiskers showing estimated blood loss per vaginam in the first 24 hours post-surgery in the participants of the study. A = Misoprostol study group, B = Oxytocin infusion study group

In this study, in the build up to the t-test of significance, we also examine some confounding variables that that could be risk factors to post-partum hemorrhage like: Prolonged labor, Augmentation of labor, Induction of labor, Granmultiparity, Polyhydramnios, Placenta previa,, Placental Abruption Previous history of post-partum hemorrhage, Use of magnesium sulphate Previous uterine surgery, maternal age greater than 35 years, but none of the afore mentioned indications for Caesarean section as risk factors for primary post-partum hemorrhage tested statistically significant. In this same study, when we tested the need for additional blood transfusion after administration of either misoprostol or Oxytocin in both arms of the study, the presence of adhesion intraoperative tested statistically significant for the need of an additional blood transfusion. What this results shows is that in future research on this same topic, presence of intraoperative adhesions is a compounding variable to prevention of primary post -partum hemorrhage using rectal misoprostol versus oxytocin as uterotonics and as such should be excluded from the study.

5. CONCLUSION

In this study. Misoprostol was non-statistically significant to Oxytocin in the prevention of primary post-partum hemorrhage following Caesarian delivery. This may afford Obstetricians alternative choices of misoprostol and Oxytocin to choose from. Secondly in low income countries, Nigeria, Misoprostol may be a choice in terms of cost effectiveness to Oxytocin.

6. LIMITATIONS AND STRENGTHS OF THE STUDY

Misoprostol, the alternate drug on trial, was administered rectally, concomitant fecal matter in the rectum could interfere with bioavailability. Tis may a subject of further research.

The strength of the study is that the alternate drug on trial, misoprostol has been shown to have some efficacy in preventing Post-partum hemorrhage and therefore the arm of the study that received this drug cannot be said to be receiving a placebo or less effective drug.

Another strength of the study is that it was a double-blind randomized control study and confounding variables were put to statistically significance test before administration. All eliminating bias.

CONSENT AND ETHICAL APPROVAL

Permission was sought from the hospital ethical committee and it was granted. The consent of the subjects for the study were also sought and obtained.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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