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Prevention of Post-Partum Hemorrhage: Comparison of Oxytocin and Misoprostol. A Two center study in the Bamenda and Nkwen Health Districts

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ABSTRACT

Background: *Postpartum hemorrhage is one of the most common obstetrical complications affecting up to 18% of deliveries. Globally, it is responsible for 35 – 55% of peripartum maternal deaths. In Cameroon, the maternal mortality rate is at 406 maternal death per 100,000 live births, with PPH being the leading cause accounting for about 25%. This study aimed to compare the efficacy and safety of misoprostol versus oxytocin in the prevention of postpartum hemorrhage in the Bamenda Health District and Nkwen Health District.*

Methods: *This was a hospital-based randomized clinical trial study in the Bamenda Regional Hospital and Nkwen District Hospital. The study was conducted from March 1st to May 31st 2021 including pregnant women who delivered at the maternity at these two hospitals. All their pregnancy was singleton gestation at term and haven given their informed consent. Women with known history of cardiac, renal, hepatic diseases or any coagulopathy, Cesarean delivery were excluded. We randomized 308 participants in a 1:1 ratio to receive 800 µg of oral misoprostol or 10IU of oxytocin intramuscularly during the active management of third stage of labor (AMSTL). The Hemoglobin (Hb) concentration and hematocrit (HCT) of the participants were measured before and 24hrs after delivery. Our primary outcome of interest was (Post-Partum Hemorrhage) PPH, defined as Hb change ≥ 1g/dl within 24hrs of delivery. Secondary outcomes included; mean Hb change, Hb change ≥2g/dl (severe PPH). Dichotomous outcomes between study groups were compared by estimating crude relative risks (RRs) with 95% confidence intervals. Logistic regression (the chi-square test) was done to determine the factors associated with the occurrence of postpartum hemorrhage, with a level of significance at 5%.*

Results: *After 24hrs, Postpartum hemorrhage (PPH) occurred in 41 (26.6%) and 47 (30.5%) participants in the misoprostol and oxytocin groups respectively (RR= 0.87, 95% C.I= 0.61 - 1.24, p=0.449). Severe postpartum hemorrhage occurred in 3 (1.9%) and 5 (3.2%) participants in the misoprostol and oxytocin groups respectively (RR= 0.6, 95% C.I=0.15 - 2.47, p=0.723). Past history of PPH (aOR=10.1 (3.5 – 28.6), p<0.0001), augmentation of labor (aOR=3.4 (1.6 – 7.1), p=0.0011), fetal birth weight ≥3.5Kg (aOR=2.5 (1.3 – 4.8), p=0.0074) and retained products (aOR= 8.4 (4.2 – 16.7), p<0.0001) were risk factors of PPH. Participants in the misoprostol group more commonly experienced shivering (RR 3.2, 95% CI 2.0 - 5.1, p<0.0001) and nausea/vomiting (RR 35.5, 95% CI 8.9 – 142.2, p<0.0001).*

Conclusion: *Oral misoprostol at the dose of 800µg is as effective as 10 IU IM Oxytocin in the prevention of PPH and is a potent alternative to oxytocin. Most common risk factors of PPH are past history of PPH, augmentation of labor, fetal weight ≥ 3.5kg and retained products. Side effects were mostly associated with 800µg of oral Misoprostol.*

Keywords
Post-partum hemorrhage, Misoprostol, Oxytocin, Active management of third stage of labor (AMSTL).

Background
Postpartum Hemorrhage (PPH) is commonly defined as a blood loss of 500 ml or more within 24 hours after birth, while severe PPH is defined as a blood loss of 1000 ml or more within the same timeframe, according to WHO. PPH affects approximately 2% of all women who give birth [1]. In 2017, it was the leading cause of preventable maternal mortality linked to birth out of nearly 295,000 deaths, 66.3% of these deaths occurring in sub-Saharan Africa alone and 27% is due to PPH [2]. Among the obstetrical complications, PPH affects up to 18 % of deliveries [2]. Cameroon is among the countries with the highest maternal mortality rate at 406 maternal death per 100,000 live births, with PPH being the leading cause accounting for about 25% [3]. Globally, PPH is responsible for 35 – 55 % of peripartum maternal deaths.

The primarily cause of PPH is due to uterine atony which can largely be prevented by use of prophylactic uterotonics after delivery [4]. The active management of the third stage of labor (AMTSL) is an evidence-based intervention which has been recommended for the prevention of PPH. The administration of uterotonics is an integral part of AMTSL in which the use of 10 IU oxytocin IM is recommended [1]. However, the use of oxytocin has historically been limited in low-income settings by several factors (the need for it to be administered by trained personnel, cold chain storage, and the need for syringes and sterile needles) [5]. In view of these limitations, misoprostol was initiated for the prevention of PPH. Several studies have proven its effectiveness in the management of PPH [5]. Misoprostol is a synthetic prostaglandin analogue with uterotonic properties. It has some advantages over oxytocin such as potential for sublingual, oral, and rectal administration, enabling a more rapid onset of action and greater bioavailability when administered sublingually, it does so by avoiding the first-past effect. Despite these advantages, misoprostol remains second line option to oxytocin according to most recommended agencies (WHO 2012, international federation of gynecologist) because of insufficient or conflicting evidence of its efficacy [1]. Furthermore, the conservation requirement of oxytocin makes it not appropriate for use in most rural settings of our region where electricity is a challenge [5].

Since 2011, Cameroon has experienced an increase in maternal mortality despite the advent of uterotonics [3]. PPH still remain high especially in rural areas either because of inadequate trained personnel's or because of inappropriate use of oxytocin and less use of misoprostol [5]. However such studies have not been done in Cameroon particular in health district of Bamenda. Thus, we sought to assess in this study the efficacy and safety of misoprostol and oxytocin in the prevention of PPH. What's more, to determine the risk factors of PPH as well as the various immediate side effects of oxytocin and misoprostol in BRH (Bamenda Regional Hospital) and NDH (Nkwen District Hospital), respectively the two main hospitals in Bamenda Health district and Nkwen Health District in the NWR (North West Region) of Cameroon.

Materials and Methods
Participants and Study Design
This was a hospital-based randomized clinical trial study in the Bamenda Regional Hospital and Nkwen District Hospital. The study was conducted from March 1st to May 31st 2021 including pregnant women who delivered at the maternity in these two hospitals. All their pregnancies were singleton gestation with gestational age between 37 and 42 completed weeks and haven given their informed consent. Women with known history of cardiac, renal, hepatic diseases or any coagulopathy, Cesarean deliveries were excluded.

Study Procedure
After obtaining ethical clearance, the parturient were randomly separated by simple random sampling into 2 groups in a 1:1 ratio. The parturient were monitored in labor using a pathogram and the hemoglobin concentration and hematocrit were measured during labor. During AMSTL (Active Management of the Third Stage of Labor), one group of parturient received 10 IU oxytocin IM and the other received 800µg of misoprostol orally (sublingual route). Twenty-four hours in the post-partum, a control of hemoglobin concentration and hematocrit of the parturient was measured. The values obtained after delivery was compared to the initial hemoglobin concentration and hematocrit during labor and the difference calculated. The measure of hemoglobin concentration and hematocrit was done using a URIT – 12 hemoglobin meter manufactured by the URIT Medical Electronic Co. Ltd manufactured in 2019.

Study variables and Outcomes
- PPH, defined as Hb change ≥ 1g/dl within 24hrs of birth,
- Severe PPH, defined Hb change ≥ 2g/dl within 24 h of birth,
- Mean postpartum hemoglobin ($\mu \pm$ S.D),
- Hb changes (mean Hb change ($\mu \pm$ S.D) and <10% drop in Hb),
- Mean postpartum hematocrit ($\mu \pm$ S.D), mean HCT change ($\mu \pm$ S.D),
- Others variables: retained products, duration of the third stage of labor and need for blood transfusion, socio-demographic characteristics, information on obstetric history, details on labor and delivery.

Data Collection
The data was collected with phones and tablets, using Epi collect which had a pre-tested and corrected questionnaire created in it. Data was then downloaded from the software in a Microsoft Excel® spreadsheet format to analyze.

Statistical Analysis
Data was analyzed using STATA. 14. The socio-demographic characteristics of the population have been estimated in effective and percentage. Dichotomous outcomes between study groups were compared by estimating crude relative risks (RRs) with 95% confidence intervals. Logistic Regression (the chi-square test) was used to determine the factors associated with the occurrence of postpartum hemorrhage, with a level of significance at 5%. The Z test of proportions was then used to determine the absolute risk. Student's t test was used for continuous variables.

Results

Characteristics of the Study Population

A total of 308 participants were recruited, 202 in the Bamenda Regional Hospital and 106 in the Nkwen District Hospital. After a random sampling, we have a total of 154 participants in the group of women who received misoprostol and 154 participants in the group of women who received oxytocin.

The mean age was 29.2 ± 5.1 and 29.2 ± 5.2 in the Oxytocin and Misoprostol groups respectively. The ages ranged from 18 to 41 years in both groups. Most (59.1% and 59.7%) of the participants in the Oxytocin and Misoprostol groups respectively were aged between 25 – 32 years. There was no difference in the demographic characteristics in both groups (Table 1).

Comparing the efficacy of misoprostol and oxytocin in the prevention of PPH in the Bamenda and Nkwen Health Districts

- In this study, we found no significant difference in the mean postpartum Hb (μ =10.8 and μ =10.9 for Oxytocin and Misoprostol groups respectively, *p*=0.446) and the mean Hb change (μ =0.9 and μ =0.9 for Oxytocin and Misoprostol respectively, *p*=0.317) in both treatment groups.

Postpartum hemorrhage (Hb change ≥1g/dl) was lower in the misoprostol group (26.6%) compared to the oxytocin group (30.5%), but the difference was not significant (RR= 0.87, 95% C.I=0.61 - 1.24, *p*=0.449); absolute risk difference 3.9%, (95% C.I=0.7% - 4.7%).

The incidence of severe postpartum hemorrhage (Hb change ≥2g/dl) was lower in the misoprostol group (1.9%) compared to that in the oxytocin group (3.2%), but the difference was not significant (RR= 0.6, 95% C.I=0.15 - 2.47, *p*=0.723); absolute risk difference 1.3%, (95% C.I=0.8% – 5.2%) (Table 2).

Risk Factors of PPH in Bamenda and Nkwen Health Districts

After the multivariate analysis, history of PPH, augmentation of labor, fetal birth weight ≥3.5Kg and retained products were risk factors of PPH.

Women with a history of PPH were 10.1 times more likely to have PPH (cOR=10.1, p<0.0001) compared to those who did not. Participants in whom labor was augmented were 3.4 times more likely to have PPH (cOR=3.4, p=0.0011) compared to those in whom labor was not augmented and women with retained products of conception were 8.4 times more likely to have PPH (cOR=8.4, p<0.0001) compared to those who did not. In this study, women with a fetal birth weight of ≥3.5Kg were 2.5 times more likely to have PPH (cOR=2.5, p=0.0074) compared to those with a fetal birth weight between 2.5 and 3.4Kg (Table 3).

Immediate Side Effects of Oxytocin And Misoprostol

Side effects were more common in the misoprostol group than in the oxytocin group.

Majority (46.1%) of participants in the misoprostol group experienced shivering compared to 1.3% in the oxytocin group. This difference observed was significant (RR= 35.5, 95% C.I=8.9 - 142.2, p<0.0001; absolute risk difference 33.1%, 95% C.I=27.7% – 38.1%).

Nausea/Vomiting was experienced by 39% of the women in the misoprostol group compared to 12.3% in the oxytocin group, and this difference was significant (RR= 3.2, 95% C.I=2.0 - 5.1, p<0.0001; absolute risk difference 26.7%, 95% C.I=19.3% - 35.4%). There was no significant difference observed in the occurrence of diarrhea in the misoprostol group (3.9%) compared to the oxytocin group (7.1%), temperature greater than 38^0C, headache and other side effects such dizziness, dyspnea, and palpitations (Table 4).

Discussion

The incidence of PPH (Hb change ≥1g/dl) was 26.6% and 30.5% in the misoprostol and oxytocin group respectively. This incidence was higher than that found by Kundoyiwa et al. in Zimbabwe, Atukunda et al. in Uganda, and Musa AO et al. in Nigeria [5-7]. It can be explained by the difference in methods of measuring PPH. The other studies used estimated blood loss recorded by birth attendance during delivery, which is very subjective and another reason could be that our study was carried out largely in the BRH

Table 1: Characteristics of the study population.

Characteristics		Oxytocin (N=154) n (%)	Misoprostol (N=154) n (%)	X^2	p-value
Age (μ ± S.D)		29.2 ± 5.1	29.2 ± 5.2	0.106	*0.7450*
Marital status				0.90	0.9560
	Single	28 (18)	26 (17)		
	Widowed/Separated	3 (2)	3 (2)		
	Married/Cohabiting	123(80)	125 (81)		
Occupation	Business/Self Employed	68 (44)	64 (44)	2.539	0.4680
	Formal employment	38 (25)	50 (32)		
	House wife	24 (16)	19 (12)		
	Student	24 (16)	21 (14)		
Level of education				5.116	0.1640
	No formal education	18 (12)	9 (6)		
	Primary	24 (16)	22 (14)		
	Secondary	60 (39)	56 (36)		
	University	52 (34)	67 (44)		

Table 2: Comparing the efficacy of misoprostol and oxytocin in the prevention of PPH in the Bamenda health district.

Outcomes	Oxytocin (N=154)	Misoprostol (N=154)	RR (95%CI)	t	p-value	Absolute risk difference (95% CI)
Primary						
Hb g/dl (μ ± S.D)	10.8 ± 1.3	10.9 ± 1.3	NA	0.76	0.446	NA
Hb change g/dl (μ ± S.D)	0.9 ± 0.7	0.9 ± 0.4	NA	1.01	0.317	NA
Hb change ≥1g/dl (PPH)	47(30.5%)	41 (26.6%)	0.87 (0.61 – 1.24)	NA	0.449	3.9 (0.7 - 4.7)
Secondary						
Hb change ≥2g (severe PPH)	5 (3.2%)	3 (1.9%)	0.6 (0.15 – 2.47)	NA	0.723	1.3 (0.8 – 5.2)
>10% Hb drop	30(19.5%)	24 (15.6%)	0.8 (0.49 – 1.30)	NA	0.369	3.9 (0.5 – 4.4)
Mean duration of 3rd stage of labor (minutes) μ ± S.D	4.3 ± 1.6	3.5 ± 2.0	NA	3.4	0.053	NA
Mean postpartum HCT	3.3 ± 3.7	3.31 ± 3.3	NA	0.85	0.396	NA
Mean HCT change (μ ± S.D)	1.5 ± 1.8	1.1 ± 1.2	NA	1.78	0.076	NA
Need blood transfusion	0	0	-	NA	-	-

%= percent, N=sample size, μ = mean, S.D = Standard Deviation, RR=Relative Risk, p-value= Probability Value, CI=Confidence Interval.

Table 3: Multivariate Analysis Showing the Risk Factors of PPH.

Characteristics	Multivariate Analysis PPH			
	PPH PRESENT (N=88) n (%)	**PPH ABSENT (N=220) n (%)**	**aOR (95%CI)**	***P-value***
History of PPH				
No	72 (25.5)	211 (74.6)	Ref	
Yes	16 (64)	9 (36)	10.1 (3.5 – 28.6)	**<0.0001***
Parity				
1	29 (43.9)	37 (56.1)	Ref	
2-4	45 (24.2)	141 (75.8)	0.5 (0.2 – 1.3)	0.1436
≥5	14 (25)	42 (75)	0.3 (0.1 – 1.1)	0.0708
Onset of Labor				
Spontaneous	79 (27)	214 (73)	Ref	
Induced	9 (60)	6 (40)	0.5 (0.1 – 3.4)	0.4906
Mode of delivery				
Spontaneous VD	68 (24.6)	208 (75.4)	Ref	
Induced VD	6 (66.7)	3 (33.3)	2.8 (0.2 – 33.3)	0.4098
Instrumental VD	14 (60.9)	9 (39.1)	1.2 (0.3 – 5.2)	0.8518
Augmentation of labor				
No	43 (19.6)	176 (80.4)	Ref	
Yes	45 (50.6)	44 (49.4)	3.4 (1.6 – 7.1)	**0.0011***
Fetal birth weight				
2.5Kg-3.4Kg	29 (18.5)	128 (81.5)	Ref	
≥3.5Kg	59 (39.1)	92 (60.9)	2.5 (1.3 – 4.8)	**0.0074***
Trauma to genital tract				
None	49 (24.6)	150 (75.4)	Ref	
1^0 perineal tear	12 (21.8)	43 (78.2)	0.7 (0.3 – 1.8)	0.4793
2^0 perineal tear	15 (37.5)	25 (62.5)	0.5 (0.2 – 1.5)	0.1881
3^0 perineal tear	12 (85.7)	2 (14.3)	3.6 (0.4 – 31.5)	0.2436
Retained products				
No	36 (16.1)	187 (83.9)	ref	
Yes	52 (61.2)	33 (38.8)	8.4 (4.2 – 16.7)	**<0.0001***

Table 4: Comparing the Side Effects Experienced in the Treatment Groups.

Outcomes	Oxytocin (N=154) n (%)	Misoprostol (N=154) n (%)	RR (95%CI)	p-value	Absolute risk difference (95%CI)
Nausea/Vomiting	19 (12.3)	60 (39.0)	3.2 (2.0 – 5.1)	<0.0001	26.7 (19.3 – 35.4)
Shivering	2 (1.3)	71 (46.1)	35.5 (8.9 – 142.2)	<0.0001	33.1 (27.7 – 38.1)
Diarrhea	11 (7.1)	6 (3.9)	0.6 (0.2 – 1.5)	0.2120	3.2 (0.8 – 3.9)
Temp > 38	9 (5.8)	6 (3.9)	0.7 (0.3 – 1.8)	0.4270	1.9 (0.5 – 2.9)
Headache	25 (16.2)	19 (12.3)	0.8 (0.5 - 1.3)	0.3290	3.9 (0.7 – 5.2)
Others	1 (0.6)	6 (3.9)	6.0 (0.7 – 49.3)	0.0600	3.3 (0.6 – 4.8)

RR=Relative Risk, %= percent, N=sample size, p-value= Probability Value, CI=Confidence Interval, n= frequency.

which is the main referral center of the region. The incidence is much higher in our study, it could also be explained by the fact that we considered any change in Hb ≥1g/dl (≈500mls of blood loss) as PPH, which could not be true for all cases.

Out of Africa, this incidence is higher than that obtained by MB Ballard et al. in India, this is probably due to the difference in study population and a higher and better health system in India providing for a better follow up of pregnancy and delivery [8]. This difference in incidence of PPH found was not statistically significant in our study, (RR= 0.87, 95% C.I=0.61 - 1.24, *p*=0.449; absolute risk difference 3.9%, 95% C.I=0.7% – 4.7%). This results is similar to that obtained by Parson SM et al. in Ghana in 2006 and that obtained by Parson et al. in Ghana again in 2007 [9,10]. This similarity could be explained by similarities in study population, study design, same route and dose of administration of misoprostol. Walley et al. in Ghana 2000, T. W Kundodyiwa et al. in Zimbabwe in 2001, Mohammad R et al. in Nigeria in 2019, Aguemon et al. in Benin 2018, Musa AO et al. in Nigeria in 2015 all reported a similar results of no significant difference in the PPH in the oxytocin and misoprostol groups [6,7,11-13]. Contrarily to our results, Atukunda et al. in 2014 in Uganda reported a significant difference between the two groups. This was probably due to a lower dose of misoprostol and different route of administration used in their study (600ug misoprostol sublingually) [5]. A.E.H. Elbohoty et al. in Cairo Egypt in 2016, reported a similarity in the effectiveness of oxytocin and carbetocin 100 µg/ml IV, but a significant superior effect of both over misoprostol 200 µg sublingual [14]. This was probably due to lower doses of misoprostol used in their study. Out of Africa, MB Bellad et al. in Belguan India in 2012 reported a significant superiority of misoprostol over oxytocin, Minoo Rajaei et al. in Iran in 2014, also reported as similar significant superiority of misoprostol over oxytocin [8,15].This could be explained by the difference in route of administration of oxytocin. They used 20 IU oxytocin in 2000ml Ringer's solution at a rate of 600 mL/hr.

The incidence of severe postpartum hemorrhage (Hb change ≥2g/dl ≈ loss of ≥1000mls of blood) was lower in the misoprostol group (1.9%) compared to that in the oxytocin group (3.2%), but the difference was not significant (RR= 0.6, 95% C.I=0.15 - 2.47, *p*=0.723; absolute risk difference 1.3%, 95% C.I=0.8% – 5.2%). Similar result was described by Mohammad et al. in Nigeria in 2016, Atukunda et al. in Uganda 2014 [5,14]. Another potential explanation for differences between our study and prior data, which have shown larger effect sizes for differences between prostaglandins and oxytocin, is our exclusion of women with cesarean deliveries and multiple pregnancies. Our selection criteria could underestimate true differences in bleeding risk in the general population, and specifically in higher risk women.

In our study, past history of PPH (cOR=10.1, p<0.0001), augmentation of labor (cOR=3.4, p=0.0011), fetal birth weight ≥3.5Kg (cOR=2.5, p=0.0074) and retained products (cOR=8.4, p<0.0001) were seen to be risk factors of PPH. This results is similar to study done in the Bonassama District Hospital, Cameroon in 2016, similar results were also obtained by previous study such as Parson et al. in 2006 and 2007, Walley et al. [9-11,16]. Factors such as multiple delivery, hypertensive disorders and other comorbidities such as Hypertension, Diabetes mellitus, cardiac diseases, renal diseases, liver disease and coagulopathies were not assessed in our study as the women were excluded.

Side effects were more common in the misoprostol group than in the oxytocin group. Our results are largely consistent with prior studies such as that done by Atukunda et al., Kundoyiwa et al. in Zimbabwe [5,6]. The relatively high percentage of side effects seen in the misoprostol group in our study as compared to previous studies could be explained by the fact that we used a higher dose of misoprostol 800µg than previous studies which ranged between 200- 600µg of misoprostol.

In general the differences in the results obtained in our study and that from prior studies could generally be explained by the facts that we used different doses of these drugs and different route of administration, we used 800µg oral misoprostol while many prior studies used doses ranging from 200µg -800µg and with several different routes such as sublingual and rectal which have a great effect on the time of onset of action of the drug, bioavailability and side effect profile of the drug, sublingual misoprostol has a more rapid onset of action and bioavailability than oral misoprostol because it is not affected by the first pass effect of the liver, rectal misoprostol also has a slightly shorter time of onset of action that oral misoprostol. Other possible reasons for the differences could be difference in methods of measurement of primary outcomes, difference in study design and study population.

Conclusion

Oral misoprostol at the dose of 800µg is as effective as 10 IU IM Oxytocin and is a potent alternative to oxytocin in the active management of third stage of labor and prevention of Post-partum hemorrhage in the Bamenda and Nkwen Health Districts.

The common risk factors of PPH in the Bamenda and Nkwen Health Districts are past history of PPH, augmentation of labor, fetal birth weight ≥3.5Kg, and retained products. Induction of labor, instrumental vaginal deliveries, genital tract lacerations were also associated with PPH.

The most common immediate side effects associated with oxytocin and misoprostol are shivering. Nausea/vomiting, diarrhea, headache, temperature >38^{0}C, other less common side effects are dizziness, dyspnea, and palpitations. These side effects are more common in misoprostol than in oxytocin.

Declaration

Ethical Approval

Ethical approval for this research to be carried was obtained from **The Institutional Review Board of the Faculty of Health Scieences, University of Bamenda**, decicion N^0 2021/029H/UBa/IRB. Administrative authorization was gotten from the Regional Delegation of Public Health of NWR, decision N^0 55/ATT/NWR/RDPH/BRIGAD, and from the administration of the Regional Hospital Bamenda, decision N^0 R005/MPH/RDOH/RHB/129 and Nkwen Distric Hospital, decision N^0 /MPH/RDPH/NDH/70. All participants signed written informed consent. The study was conducted following all principles of biomedical research as stated in the Helsinki Declaration.

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