Evaluation of the oxytocin use in the active management of third stage of labour among Sudanese women: a prospective, hospital-based study

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Background: Active management of third stage of labour (AMTSL) by administration of prophylactic uterotonic drugs immediately after delivery can reduce the rate of postpartum haemorrhage (PPH). This study aimed to evaluate oxytocin use in the prevention of primary PPH at Omdurman Maternity Hospital, Khartoum, Sudan.

Methods: An observational comparative, prospective, hospital-based study recruited 1,797 pregnant women with plan for normal delivery. Females at risk of PPH were selected and given oxytocin. The Sample was divided into two groups: group one women without identifiable PPH risk (low PPH risk group) and group two women with known PPH risk (risk group). Collected data has been analyzed using SPSS V.21.

Results: Only 110 of women (6.1%) developed PPH. Oxytocin 30 units, were mainly used for both high risk and low risk groups in AMTSL for prevention of PPH for both groups it was given as IV bolus plus IV infusion. Out of 110 women with PPH 89 women (81%) received only 1–2 units of blood and 20 women (18.2%) did not received any blood. Only one woman (0.9%) received 3 units of blood.

Conclusions: Prophylactic oxytocin reduces the rate of PPH in both groups however the rate is lower among the low risk group. The use of prophylactic oxytocin reduces the need for blood transfusion in Sudanese Women.

Keywords: Oxytocin; active management labor Sudan

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Introduction

The World Health Organization defines postpartum hemorrhage as blood loss of at least 500 mL after vaginal delivery (VD) and 1,000 mL after caesarean section (CS) (1). The PPH can also be defined as any degree of postpartum blood loss that is enough to compromise a woman's postpartum hemodynamic condition (2). Postpartum hemorrhage is the leading cause of maternal

mortality in low-income countries (25–43% of maternal deaths) and the primary cause of nearly one quarter of all maternal deaths globally. Most deaths resulting from PPH occur during the first 24 hours after birth: the majority of these could be avoided through the use of prophylactic uterotonics during the third stage of labour and by timely and appropriate management (1). Despite the fact that PPH can occur without risk factors, the main risk factors are factors relating to delivery (intra partum), and pre-existing maternal hemorrhagic conditions (3-6). The general international consensus [WHO, Royal College of Obstetricians and Gynecology (RCOG), National Institute of Clinical Excellence (NICE) and Federation of International Gynecologists & Obstetricians (FIGO) recommend Active Management of Third Stage of Labour (AMTSL)] in order to reduced risk of PPH, and severe PPH; a reduced risk of anemia; a decreased need for blood transfusion, and decreased need for additional medication (1,3,7). Among these interventions is administration of uterotonic medications after delivery of the baby (8). Omdurman Maternity Hospital Guidelines for Best Practice also recommend the use of uterotonics in AMTSL (9). The oxytocin dose used for PPH-prophylaxis varies widely between practitioners and obstetric units, ranging from 2 IU to 10 IU (international units) for both intravenous bolus and intramuscular injections. There is a general consensus that oxytocin is an effective intervention to prevent PPH (10). Omdurman Maternity Hospital Guidelines for Best Practice, the uterotonics drugs includes; Ergometrine 0.25 mg IM, or oxytocin 10 units, upon delivery of anterior shoulder and controlled cord traction for placenta delivery. In high risk cases, 30 units oxytocin in 500 mL NS for 3 hours/ or misoprostol 600 µg per rectum (9). The prevalence of PPH in Ireland showed that PPH rate increased from 1.5% in 1999 to 4.1% in 2009 (11). While in USA, the overall rate of PPH increased by 27.5% from 1995 to 2004 (12). In Sudan, the total number of notified maternal deaths was 1,110, out of 645,881 LB (live births). The maternal mortality ratio (MMR) in this study is 172/100,000 LB which is comparatively lower than MMR reported in 2010 and 2012. It is even lower compared to demographic health survey (DHS), safe motherhood survey (SMS), and Sudan household survey (SHHS) 2006–2010. Nevertheless, it is still higher than the target of millennium development goals (MDGs) which is 124/100,000 LB (13).

Importantly, in both developed and developing countries, 60% of maternal mortality occurred after delivery, 45% of which occurred during the first day, and up to 65% within the first two weeks. Hemorrhage is the leading cause of death in this review 311 (28.0%), and it is comparable to that found by WHO (27.1%) worldwide and in developing countries (14) Common causes of PPH are related to failure of the healthcare system, inaccurate estimation of blood loss after delivery and lack of skills to prevent and manage PPH (15). Several guidelines and randomized clinical trials recommended the use of oxytocin as part of AMTSL (1,8,16,17). Therefore, the aim of this study was to evaluate oxytocin use in the prevention of primary PPH at Omdurman Maternity Hospital, Khartoum, Sudan.

Methods

Study setting

An observational comparative, prospective, hospital-based study recruited 1,793 pregnant women with plan for normal delivery. Females at risk of PPH were selected and given oxytocin. The sample was divided into two groups: group one women without identifiable PPH risk (low PPH risk group) and group two women with known PPH risk (risk group). The risk factors considered in this study were (over distended uterus, grandmultipra, previous antepartum hemorrhage, previous PPH or previous history of retained placenta, pre-eclampsia or pregnancy-induced hypertension, existing uterine abnormalities, maternal age (40 years or older).

Sample size

The total collected number of women who delivered vaginally during the study period was 1,961 and the excluded women were 168 so the total sample size for this study was 1,793 women.

Data collection

A data collection tool was designed. It consisted of a questionnaire and a check list for registration of the observed different oxytocin doses given for each woman and the route of administration in both induction of labour and in the AMTSL. The questionnaire was pretested and modified accordingly. The data collection form addressed the following variables: age, parity, risk factors, oxytocin dose, route of administration, onset of labour and the onset of development of PPH, etc…. The dose and route of administration of oxytocin used was compared and assessed

based on Omdurman Maternity Hospital guidelines.

In this study the independent variables were the different doses of oxytocin, and the dependent variable was the effect of the different doses in the prevention of PPH. Our primary outcome of interest was the primary PPH, which is defined as blood loss of about 500 mL or more within 24 hours of delivery. Data collection form was used to gather information for all women including those at risk for PPH (risk group), and women who had no known risk factors for developing PPH (low risk group). Data was collected by trained group of data collectors (four sister nurses and the primary investigator). Filing the form was done by direct woman interview, and observation during the follow up for each patient regarding the occurrence of PPH. The data was checked by the investigator for accuracy and completeness. Registrars and midwifes, sometimes consultants on call were involved in any unclear information, and on documentation and reporting of PPH whenever it occurs. Women re-admitted with PPH after discharge within 24 hours of delivery has been checked and included.

Data analysis

Collected data has been coded, and no names had been used in the edited data. The analysed by a skilled trained biostatistician using statistical package of social sciences (SPSS) Version 24 and Microsoft excel programme 2010 Parameters used; confidence 95% and P value significant was set at 0.05. Statistical tests used; descriptive statistics, graphs, cross tabulation and chi-square.

Ethical clearance

Ethical clearance obtained from ethical committee in Omdurman Maternity Hospital. Females were informed about the aim of the study and have been included after they being consented.

Results

The total number of women who were presented to the labour ward in Omdurman Maternity Hospital and delivered vaginally during the study period and fulfilled the criteria, were 1,793 women. Women excluded from the data analysis were 168 women. The majority of the study samples were in the low risk group in the risk group. Almost two third of the women in the low risk group [65] were from the age group 21–30 years old and around half of the women (49.3%) in the risk group were in the same range of age. Around half (57.8%) of the risk group were grand multipara, while 54% and 28% of the women were multipara for the low risk group and risk group respectively, and 46% and 13.9% of the women were primigravida for the low risk and risk group respectively. The majority of women in both groups (90.9% from the risk group and 94.5% of the low risk group) had 37–42 gestational weeks. When comparing risk and low risk groups, 60.7% of the risk group had a spontaneous onset of labour, 37.5% were induced with oxytocin alone and 1.8% were induced with oxytocin and other uterotonics. In contrast, 42.8% of the low risk group had spontaneous delivery, 56% were induced with oxytocin alone and 1.2% were induced with oxytocin and other uterotonics (*Table 1*).

Oxytocin doses and routes of administration

In the risk group, the highest percentages of women (61.8%) were given 30 units of oxytocin for active management of 3rd stage of labour, 25.4% were given 20 units and 1.8% were given 10 units. Comparatively, in the Low risk group, 44.4% of women were given 30 units of oxytocin, and 39.9% were given 20 units, while 10 units of oxytocin were given to 6.8%. The majority of women in this study 1,593 (88.6%) were given Oxytocin via both IV and infusion, 91.5% and 87.4% in the risk group and low risk group respectively. That was followed by infusion route which was used by 6.1% of the risk group and 9.7% of the low risk group (*Table 2*).

Rate of PPH among the groups who received prophylactic oxytocin in AMTL

Minority; 110 (6.1%) of the women had developed PPH out of the 1,793 women. For each group the rate of PPH was 9.2% for the risk group while the low risk group rate was almost nearly half of the rate of the risk group rate and it was 4.7% (*Table 3*).

Blood transfusion for women who developed PPH

Of 110 patients who developed PPH, the majority 84 (76.4%) women were received 1 unit of blood, with 33 (30%) and 51 (46.4%) women in the risk and Low risk group respectively, only one woman received 3units of blood, while 20 (18.2%) women were diagnosed as having PPH, didn't need blood transfusion.

Table 1 Distribution of the participant's information among the PPH risk group and the low risk group (n=1,793)

Variable	PPH risk group (n=566, 31.7%) percentage presented below	Low risk group (n=1,227, 68.3%) percentage presented below
Age group		
≤20	7.4	24.5
21–25	19.1	38.7
26–30	29.9	26.2
31–35	26.7	9.2
36–40	14.0	1.3
>40	3.0	0
Parity		
Primigravida	13.8	46.0
Multipara (1–4)	28.4	54.0
Grandmultipara	57.8	0
Gestational weeks		
24–27	0.7	0.1
28–36	6.9	3.8
37–39	67.8	67.6
40–42	23.1	26.8
>42	1.4	1.66
Onset of labour		
Spontaneous	60.6	42.8
Induced with oxytocin alone	37.6	56.0
Induced with oxytocin + other	1.8	1.2

PPH, postpartum haemorrhage.

Outcome of the baby among the two groups

Regarding the health of the babies, 89.3% of babies who were born to mothers at risk were alive and well, while in the low risk group, 93.1% were alive and well. In the risk group, 7.5% of babies were transferred to the nursery and 2.3% stillbirth. With regards to the low risk group, 4.5% of babies were transferred to the nursery and 2.2% were still birthed.

Regarding antenatal risk factors for PPH

Grandmultipra women represent the majority of the antenatal risk factors for PPH 57.7% followed by others antenatal risk factors 18.1% while only 9.5% of the women had an over distended uterus antenatal risk factors and 6.8% of the women had no antenatal risk factors for PPH, and 4.6% had previous antepartum haemorrhage.

Intrapartum risk factors for PPH

Majority of women in the risk group had no intrapartum risk factor for PPH 86.1%, while 12.5% had a tonic related intrapartum risk factor for PPH and followed by 1.2% women had traumatic related risk factors for PPH.

Age, gestational weeks, outcome of the baby (weight) for patients who developed PPH (risk and low risk groups), who had received prophylactic oxytocin in AMTSL

With concern to the age for the patients who developed

Table 2 Distribution of the oxytocin doses, routes of administration among the PPH risk group and the low risk group(n=1,793)

Variable	Risk group, n=566		Low risk group, n=1,227	
	Frequency	%	frequency	%
Oxytocin doses for AMTSL (units)				
5	3	0.5	2	0.2
10	10	1.8	14	1.1
15	13	2.3	83	6.8
20	144	25.4	36	2.9
25	12	2.1	490	39.9
30	350	61.8	45	3.7
40	31	5.5	545	44.4
50	3	0.5	12	1.0
Oxytocin route of administration				
Direct IV	8	1.4	24	2.0
Infusion	34	6.0	119	9.7
Iv & infusion	518	91.5	3	87.4
Im.	3	0.5	6	0.5
Iv & infusion + Im.	2	0.4	2	0.2
Infusion + Im.	1	0.2	1	0.1
Not used	0	0	2	0.2

PPH, postpartum haemorrhage; AMTSL, active management of third stage of labour.

Table 3 Distribution of the rate of PPH among the PPH risk group and the low risk group (n=1,793)

Variable	Risk (n=566)		Control (n=1,227)	
	N	%	N	%
Patients developed PPH within 1 hour	46	8.1	57	4.6
Patients developed PPH within 1–2 hours	6	1.1	1	.1
Not developed	514	90.8	1,169	95.3

PPH, postpartum haemorrhage.

PPH (among the risk and low risk group). The highest percentage of women 76 (69.1%) were between the age group of 21–30 years, 25 (22.7%) of them in the risk group and 51 (46.4%) in the Low risk group followed by 22 (20%) women in age between 31–40 years.

Among the women who had developed PPH, 75% had a gestational age between 37–40 weeks, out of them 39 (35.5%) women in the risk group and 44 (40%) in the low risk group. The other frequencies were low, 4.5% and 20% for the gestational weeks 24–36 and >40 respectively.

Above half of the women who developed PPH had their babies weight between 3.1–3.5 kg, of them 25 (48%) in the risk group and 31 (28.2%) in the low risk group, 40 women had their babies weight between 2.5–3 kg, 16 (14.5%) of them in the risk group and 24 (21.8%) in the low risk group. (Most of the women in both low risk and risk groups delivered babies with normal weight ranging between 2.5–3.5 kg).

Tests of associations: chi-square test showed that the PPH was significantly associated with age, different doses

of oxytocin, onset of labour and route of administration of oxytocin (P=0.008, 0.000, 0.000, 0.004).

Discussion

In this study all the women (risk group and low risk group) were given oxytocin as a prophylaxis in AMTSL, but there was a variation in the doses used about two thirds the study population (65%) received 30 units prophylactic oxytocin in AMTSL, while 28% received 20 units, and minority (2.9%) received 10 IU oxytocin in AMTSL, among them only 1.1% for the low risk group, and 20 IU oxytocin was used for around the 3% of the women in the same group and 40 IU oxytocin was used for the 44.4% of them (P=0.000) . More adherence to guideline is needed in the management of low risk group with 10 IU oxytocin (9). Importantly, higher doses of oxytocin were associated with adverse reaction and no further clinical benefit (18). In this study the majority of patients received IV infusion. For example, the majority of women (91.40% of the risk group and 87% low risk group) received oxytocin in AMTSL via intravenous bolus plus infusion.

The oxytocin dose and route of administration used for PPH-prophylaxis varies widely between practitioners and obstetric units, ranging from 2 to 20 IU (international units) for both intravenous bolus and intramuscular injections (15). An IM or IV oxytocin dose of 10 IU is recommended as the uterotonic drug of choice by the WHO guideline for the prevention and treatment of PPH (1). Karen *et al.*, found that the ideal dose of oxytocin has not been directly studied but from their data the most effective dose appears to be 10 units administered intramuscularly or 20 units diluted in 500 mL of normal saline and given as an IV bolus (8). In a previous study on the prevention and management of PPH, with a comparison of four national guidelines, oxytocin as a prophylactic in AMTSL varied from one guideline to the other. The RCOG guideline recommends 10 units intramuscularly for uncomplicated vaginal deliveries and 5 IU intravenous slow infusion after caesarean delivery, 10 units oxytocin intramuscularly or 5–10 units intravenously over 1–2 minutes for low-risk vaginal deliveries were recommended by Prevention of Postpartum Haemorrhage guideline (16) and local protocol at the Maternity Hospital, Omdurman (9). It is clear that there is a wide disparity between these international guidelines and other studies' routes of administration (one direct route), compared to this study's results. Regardless of the route of administration, this study showed that the rate of primary PPH among participants was 6.1%, which is comparable to the rate of 4.1% quoted by Lutomski *et al.* in Ireland, in 2012 (11). In another systematic review and meta-analysis conducted to identify the regional variation in the prevalence of PPH, a rate of 10.8% was found ranging from 7.2% in Oceania to 25.7% in Africa (19). This reflects that the use of oxytocin in AMTSL in OMH was good practice and effective for the prevention of PPH. However, there was significant different in the rate of PPH in high risk group (9.2%), in comparison with low risk group (4.7%), P=0.000.

Administration of oxytocin was associated with significant decrease in the need for blood transfusion in this study (P=0.000), and this is consistent with other studies (1-3). For instance, in this study over 80% of females who developed PPH needed blood transfusion of 1–2 units and only one patient needed more than two units. On the other hand, 20 women didn't need blood transfusion. Furthermore, in this study many women had either only antenatal, or intrapartum risk factors for PPH and others had both antenatal with Intrapartum risk factors for PPH (P=0.0000). Several studies and international guidelines showed that most of the females who experience PPH do not have any known risk factors; but none of the guidelines provide an estimate of what proportion of females with PPH are without risk factors (9). This means that all females should be considered and managed as that they may develop PPH, and offered prophylactic oxytocin to reduce the chance of developing PPH, as recommended by the WHO guideline (1).

Majority of women in this study were in the range of age 21–30 years (69.1%) and this exclude the risk of the age more than 40 as risk factor for PPH. This is not vastly different from the results of Sheldon et al who found that 73.5% of women who developed PPH in their study were 20–34 years old (20). However, in other study some cases who developed PPH were at the extremes of reproductive age <20 and >40 years (P=0.008) (8). High parity and grand multiparity are well documented as risks for atonic PPH (3). But In our study, (49%) of females who developed primary PPH were multipara (1–4) while only 16.4% were grand multipara (P=0.768). This is consistent with the fact that high parity is a risk factor for PPH (16).

While labour induction or augmentation is significantly associated with an increase in risk of PPH (16), the improper use of oxytocin titration may lead to uterine hyper stimulation (16). In this study, it has been found that only 18 (16.4%) women who had developed primary PPH were induced or augmented with oxytocin. Of these, 13 women were in the risk group (P=0.000). Eight hundred

and eighty-three (98 %) of the induced women didn't developed PPH. On the other hand, 91 (82.7%) women who developed PPH delivered spontaneously without induction. This is in agreement with the study conducted by Kramer in Montreal (Canada) which indicated that labour induction and augmentation were independent risk factors for PPH (21), also another study concluded that; there was no excess risk of PPH in women who underwent induction of labor for non-standard indications and the higher risk of PPH associated with labor induction may be limited to unfavourable obstetrical situations (22). Rare causes of PPH like macrosomia (baby weight >4 kg) (5,14), in this study over 50% of the females who developed primary PPH had their babies weighing between 3.1–3.5 kg; only 3 (2.7%) of them had their babies weight >4 kg (P=0.023). This goes with another study carried out in Montreal (Canada), which indicated that the baby weight was an independent risk factor for PPH (21). On the other hand, in this study if we take a look into the outcome of the babies' health, the majority of them (89.30%), and (93.10%) the women in the risk and low risk groups respectively, were alive and well. The study is not without limitations. The study was conducted in one of the large centres in the capital Khartoum, therefore caution is needed if result is to be considered representative for the whole Sudan. The data for the cases included in this study was collected only during the day time and not over 24 hours and this may mean that outcome of other patients during different time of the day may not be included. Despite these limitations, we considered this study is novel and it have shown the benefit of oxytocin in decrease the rate of PPH.

Conclusions

Prophylactic oxytocin reduces the rate of PPH in both groups however the rate is lower among the low risk group. The use of prophylactic oxytocin reduces the need for blood transfusion in Sudanese Women.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/jphe.2019.12.04). MHA serves as an unpaid editorial board member of *Journal of Public Health and Emergency* from August 2017 to July 2021. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Ethical clearance obtained from ethical committee in Omdurman Maternity Hospital (No. OMH/2-6-2014). Females were informed about the aim of the study and have been included after they being consented.

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