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Clinical benefit of MKANDA SALAMA KIT in a real-world population with Postpartum Hemorrhage. A prospective observational study

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Abstract

Based on Tanzania administrative data and policy Implication report of 2018, revealed that Postpartum hemorrhage contributed to about 29% of all maternal deaths in Tanzania. MKANDA SALAMA KIT (MSK) is the new innovated technological device designed to stop Postpartum hemorrhage (PPH). To determine the effects of MSK on the clinical symptoms improvement, hemodynamic restoration, and bleeding stoppage in post- delivery mothers with PPH. The primary outcome was the composite of Postpartum hemorrhage maternal death and PPH rehospitalization within 42 days follow-up time; secondary outcomes were all causes of maternal death and the occurrence of rehospitalization for worsening PPH -data from 120 women with PPH aged from 13 to 39 years from December 2020 to May 2021 (6 months) at St. Francis referral hospital labor ward were included. Patients were grouped into mild PPH, moderate PPH, and severe PPH. A multinomial regression model was used to determine the associations between risk and outcomes using Statistical Package for Social Sciences software version 21.0". 23% had a previous history of PPH, 36% had maternal hypertension, 45% had anemia, and 12% had maternal diabetes. Mild PPH was 20%, moderate PPH was 37%, and severe PPH was 43%. MSK significantly improved clinical symptoms and signs of all PPH categories by 84%. A significant restoration to normal all hemodynamic parameters was observed to all patients by 79% MSK significantly stopped mild PPH by 100% within 10-20 minutes, while stopped moderate PPH by 70.3% within 10-20 minutes and stopped severe PPH by 63.5% within 10-20 minutes. There was no rehospitalization during follow-up time and no death was reported. MSK significantly improved clinical symptoms, hemodynamic parameters and stopped bleeding in PPH patients, timely application of MSK can significantly prevent PPH maternal death and PPH rehospitalization.

Keywords: *Low-income countries, Maternal Morbidity, Maternal Mortality, Mkanda Salama Kit, and Postpartum hemorrhage*

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Introduction

Maternal mortality is a global public health problem with an estimate of 295,000 deaths with over 66% of these deaths occurring in Sub-Saharan Africa (WHO, 2015). Obstetric haemorrhage accounts for up to 34%

of these deaths and remains the leading cause of maternal deaths in low-income countries (Bishanga *et al.,* 2018). Despite the fact that it is largely preventable, postpartum haemorrhage (PPH) is the most common and deadliest form of obstetric bleeding (WHO, 2012). Maternal mortality ratio (MMR) in Tanzania ranges among the highest in the world at 556 per 100,000 live births and has remained stubbornly high over the last decade despite efforts to reduce it (MoHCDGEC, 2016). Similar trends areseen in Tanzania with 25% to 29% of the maternal deaths occurring due to Postpartum haemorrhage (Makuwani *et al.,* 2020; Say *et al.,* 2014).

The widely known causes of Postpartum haemorrhage include uterine atony, genital tracts injuries, failure of blood coagulation system, retained or adherent placenta andtrauma (Ononge *et al.,* 2016). However, uterine atony is termed to be a principle cause of Postpartum haemorrhage (Mvandal and Coletha, 2021) among all the cause. Major risk factors for Postpartum haemorrhage includes, past history of Postpartum haemorrhage, multiple pregnancy, foetal macrosomia, prime-gravida, grand multi-parity, older age, pre- term births, genital tract injuries, non-use of oxytocic's for Postpartum haemorrhage prophylaxis, labour induction and argumentation, caesarean birth, intra-uterine fetal deaths, hypertensive disorders of pregnancy, fibroid tumours, placenta previaand obesity (Mvandal and Coletha, 2021; Oberg *et al*., 2014).

Postpartum haemorrhage can be prevented depending on the cause. The main world health organisation (WHO) recommended PPH prevention measure is the active management of the third stage of labour (AMTSL). Active management ofthird stage of labour is classified into three phases, which include the administration of uterotonic (preferably oxytocin), followed by controlled cord traction (CCT), bimanual uterine compression, external aortic compression, and the use of non-pneumatic anti-shock garments as temporizing measures until substantive care is available (WHO, 2012). Another technique which is a temporizing measure in the management of severe haemorrhage is externally applied aortic compression (Riley and Burgess, 1994). Apart from Active management of third stage of labour, uterineballoon tamponade is recommended by FIGO as a second line treatment for the treatment of PPH in uterine atony when uterotonics do not respond (Mishra *et al.,* 2016).

However, we still have challenges which for some extent, contributes to the high Maternal mortality ratio. For instance, the country has succeeded in scaling up ofthe routine provision of AMTSL, but it's correct implementation has generally remained low (Kanama and Muganyizi, 2019). Many factors have been associated with the low practice of AMTSL. A study by Mfinanga *et al.,* (2009) found that correct practice of AMTSL in Tanzania was 17% with the uterotonic being given within 3 minutes of delivery (Mfinanga *et al.,* 2009). Despite the potential benefits of AMTSL in reducing PPH related maternal deaths, it must be performed correctly, strictly following all the recommended steps for the best outcomes. Structural improvements including a constant supply of injectable uterotonics is required, and having a number of skilled health personnel is mandatory for AMTSL effectiveness (Vogel *et al.,* 2019; Ayadi *et al.,* 2013).

The sluggish reduction in MMR in Tanzania provides a room for research scientist to come up with the interventions, including those which are independent on the availability of drugs and skilled staff to improve the quality of care to control PPH and contributes to reduction in MMR. For the past decade, scientist have invented highly technological equipment's to help control of PPH. These includes the non- pneumatic antishock garment (Access, 2022). The newly invented, and Tanzanian locally developed low-technology device for PPH control is *Mkanda Salama Kit,* an abdominal compression belt like garment made from locally available materials. *Mkanda Salama kit* plays a unique role in preventing PPH by decreasing blood loss through pulsatile abdominal compression stabilizing the woman until definitive care is accessed. Therefore, this study aimed to determine the efficacy of using *mkanda salama* among PPH confirmed patients at St. Francis Referral Hospitallabor ward in Ifakara, Tanzania.

Materials and Methods

Study design: This was a single-center, hospital-based, prospective observational study to determine the effects of Mkanda Salama Kit (MSK) on clinical symptom improvement, hemodynamic restoration, and bleeding stoppagein post-delivery mothers with postpartum hemorrhage (PPH).

Study population: The study population included all post-spontaneous vertexdelivery (SVD) women at St. Francis Referral Hospital labor ward.

Inclusion criteria: All women who had postpartum hemorrhage (PPH) after spontaneous vertex delivery (SVD) were included in the study.

Exclusion criteria: All women who had postpartum hemorrhage (PPH) after cesarean section (C/S) delivery were excluded from the study.

Sample size: The sample size for the study was 120 women with PPH, aged between 13 to 39 years. Patients were grouped into mild PPH, moderate PPH, andsevere PPH based on the degree of blood loss.

Sample size determination: The sample size for the study was determined using a power analysis. The power analysis showed that a sample size of 120 participants would be required to detect a difference in the incidence of mild, moderate, and severe PPH between the intervention and control groups with a power of 80% and a significance level of 0.05

Investigational Kit: The investigational Kit used in the study was Mkanda Salama Kit which is a belt like-garment, that can be wrapped around the abdomen below the umbilicus, to compress the uterus, and possibly minimal compression of the abdominal aorta to arrest the active bleeding. Mkanda Salama, translated as ''Safe Wrap'', is designed to control PPH until necessary interventions are carried out. It is strapped around a woman with PPH while they are transferred to hospitals. Mkanda Salama massages the uterus and compresses abdominal aorta thus reduce blood loss and buy time for appropriate interventions, especially in situations where a woman requires advanced interventions that are not immediately available such as needing to be transferred to higher level or the theatre. Mkanda Salama Kit is a user friendly, non-invasive, easy to use and affordable medical device. It is reusable and its human centered design ensures that its effectiveness isnot affected by either user's ignorance or physical strength. It can also be used by low skilled birth attendants. This means that Mkanda Salama Kit can be owned by any pregnant mother as a precautionary device, by traditional birth attendants, ambulance services, makeshift health camps and nearby health facilities that might need to refer a hemorrhaging mother.

Results

Assessment of patients: The patients were assessed by trained research assistants before and after wearing the Mkanda Salama Kit. The assessments included a physical examination which was conducted to assess the severity of thePostpartum hemorrhage.

Definition of mild, moderate, and severe PPH: Mild PPH was defined as a blood loss of less than 500 ml. Moderate PPH was defined as a blood loss of 500 to 1000 ml. Severe PPH was defined as a blood loss of more than 1000 ml.

Variables of interest: The variables of interest for analysis were; Age, Parity, Degree of blood loss, Symptoms and Hematologic parameters.

Data collection: Data collection was conducted by trained research assistantswho were familiar with the study's protocol and ethical considerations. The research assistants obtained the participants' medical history and physical examination findings from the participants' medical records.

Statistical analysis: The incidence rates of each outcome [Primary outcomes and secondary outcomes] were estimated by the Kaplan Meier method and compared using the Log Rank. A multinomial regression model was used to determine the associations between risk and outcomes. Descriptive statistics such as mean, median, and standard deviation were used to summarize continuous data,while frequencies and percentages were used to summarize categorical data.

Ethical considerations: The study was approved by the Ethics Review Committee of St. Francis Referral Hospital. Informed consent was obtained from all participants before enrollment in the study. Participants were assured of confidentiality and the right to withdraw from the study at any time without penalty.

Patient Baseline Characteristics at baseline based on PPH groups [n=120]

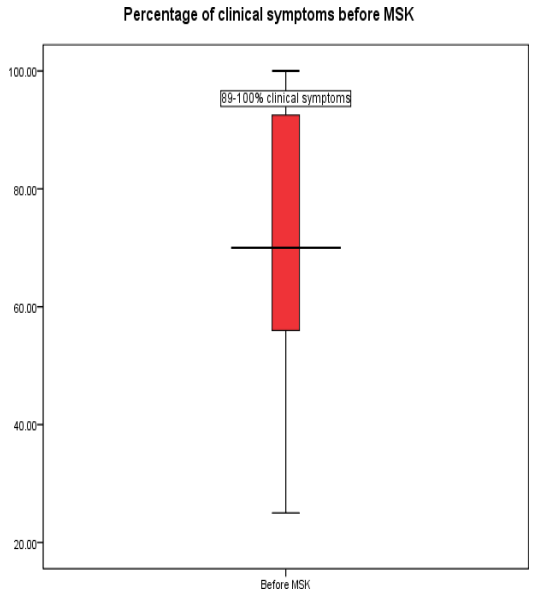
Table 1. Patient baseline characteristics at baseline based on PPH groups (n=120).

	Mild PPH (n=24)	Moderate PPH (44)	Severe PPH (n=52)	*p- value*
Age, years	25.8±5.4	26.8±6.0	27.1±7.2	*0.002*
SBP	100.1±12.9	89.3±13.3	80.7±9.5	<0.001
DBP	67.4±11.5	63.7±9.2	60.1±6.5	0.054
PR	121.1±22.9	121.1±22.9	121.1±22.9	0.176
BMI	19.2±3.4	20.5±2.3	21.2±4.6	0.068
Maternal Anaemia	11(45.8)	17(42.5)	24(46.2)	0.003
Retained Placenta	16(22.8)	16(22.8)	16(22.8)	<0.001
Uterine rupture	2(8.3)	4(9.1)	6(11.5)	<0.001
Uterine atony	13(54.2)	18(41)	22(42.3)	<0.001
Previous PPH	8(33.3)	9(20.4)	11(21.2)	0.002
Maternal hypertension	10(42)	13(29.5)	20(38.5)	<0.001
Maternal Diabetes	3(12.5)	5(11.4)	6(11.5)	*0.006*
Multifetal pregnancy	9(37.5)	8(18.2)	11(21.2)	<0.001
HELLP syndrome	3(12.5)	7(15.5)	12(23.1)	*0.062*
Rectal Misoprostol	22(83.3)	40(91)	46(88.5)	<0.001
Methyldopa	10(42)	13(29.5)	20(38.5)	*0.052*
FEFO	24(100)	44(100)	52(100)	*0.002*

SBP, Systolic blood pressure; DBP, Diastolic blood pressure; PR, Pulse rate; BMI, Body mass index; HELLP, Hemolysis, elevated liver enzymes, low platelet; FEFO, Ferrous sulphate and Folic acid.

Table 1 above shows the baseline characteristics of the patients categorized by Postpartum hemorrhage [PPH] severity groups. It was observed that the prevalenceof previous Postpartum hemorrhage was higher in the severe Postpartum hemorrhage group compared to the other groups (16.7% vs. 20.4% and 28.8%, p =0.076). Additionally, older women were more prevalent in the severe Postpartum hemorrhage group, with a mean age of 27.1 ± 7.2 years.

Improvement of Clinical Symptoms and Signs in Postpartum hemorrhage Patients after use of Mkanda Salama Kit



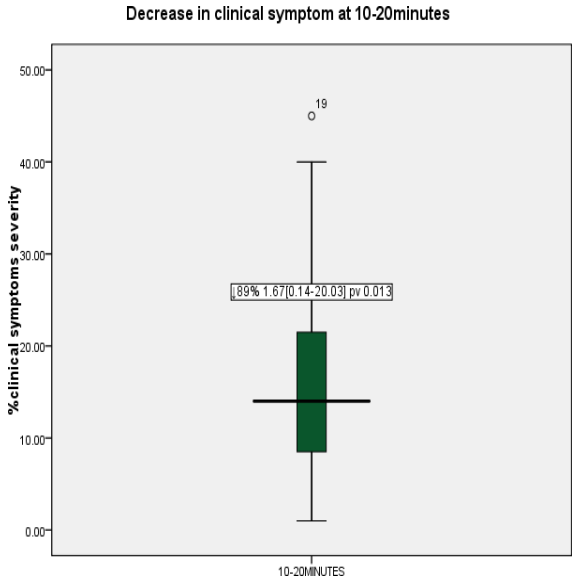


Figure 1 above demonstrates a significant improvement in clinical symptoms andsigns among all PPH patients after the application of Mkanda Salama Kit. The odds ratio (OR) for symptom improvement was 1.67 with a 95% confidence interval (CI) of 0.14-20.03. The p-value was 0.013,

indicating a statistically significant improvement

Hemodynamic stability of PPH Patients after use of Mkanda Salama Kit

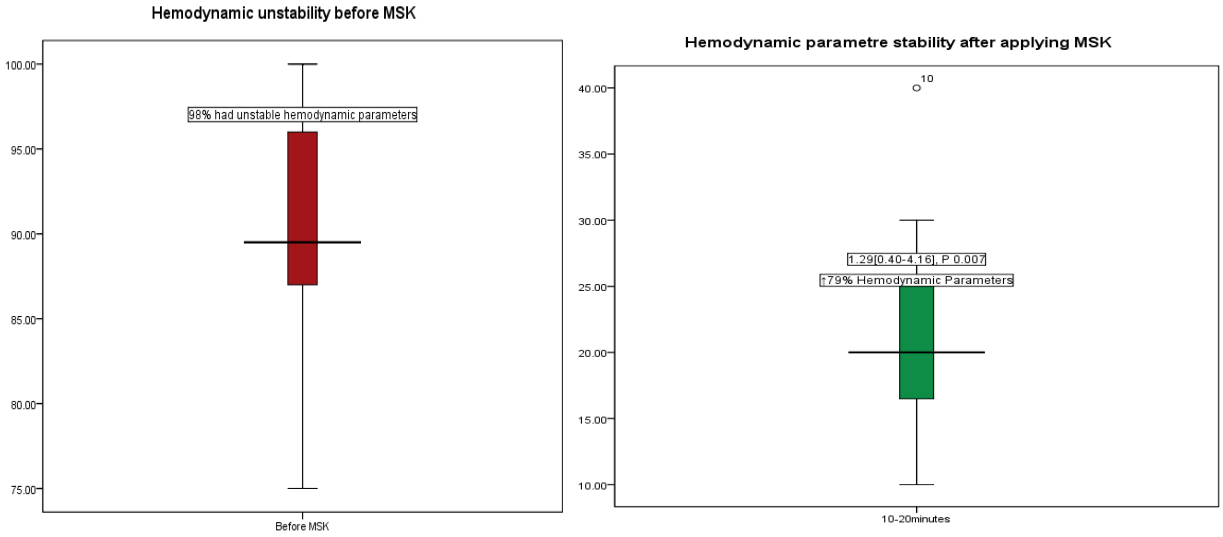


Figure 2 illustrates that Mkanda Salama Kit effectively restored normal hemodynamic parameters in all Postpartum hemorrhage patients, with a success rate of 79% within 10-20 minutes. The odds ratio for hemodynamic stability was
1.29 with a 95% CI of 0.4-4.16. The corresponding p-value was 0.007, indicating astatistically significant improvement.

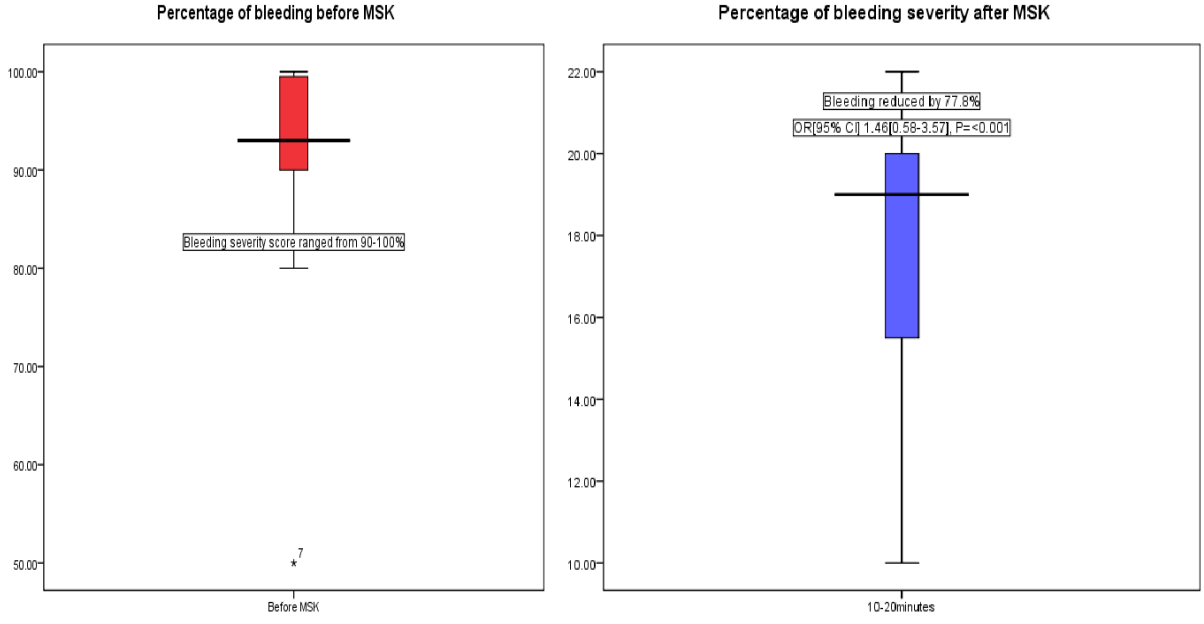


Figure 3 demonstrates that Mkanda Salama Kit significantly stopped bleedin

Figure 3. demonstrates that Mkanda Salama Kit significantly stopped bleeding in77.8% of cases within 10-20 minutes. The odds ratio for bleeding cessation was
1.46 with a 95% CI of 0.58-3.57. The p-value was less than 0.001, indicating astatistically significant effect

Prognosis of patients after use of Mkanda Salama Kit

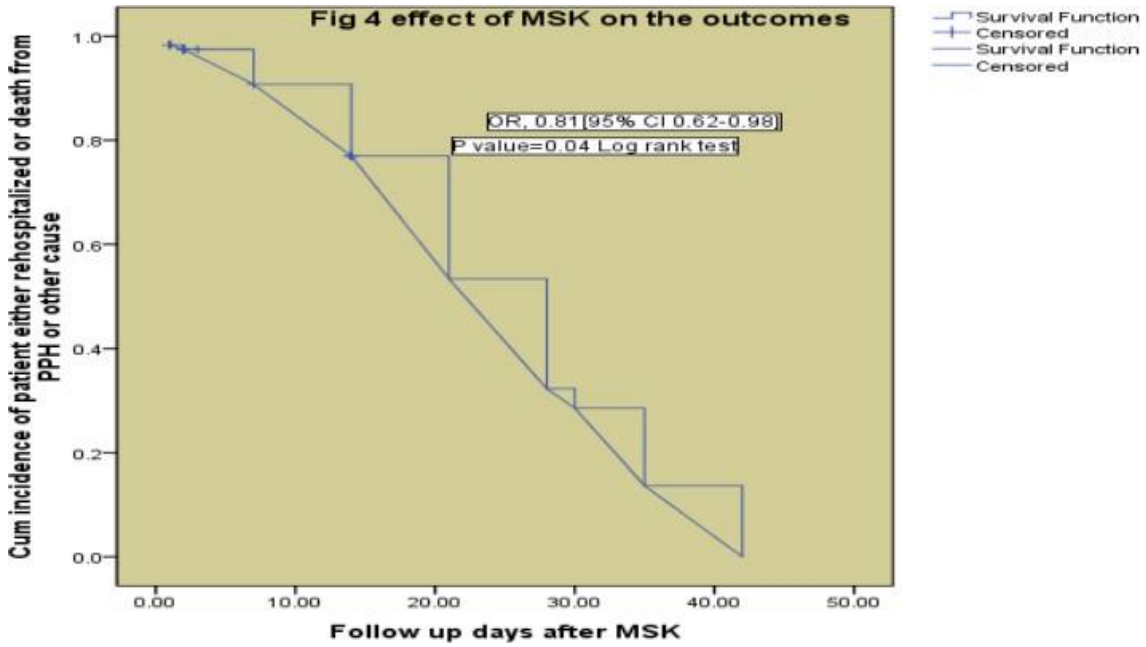


Figure 4 above shows a significant reduction in the incidence of Postpartum hemorrhage - related rehospitalization or maternal death among all patients after using the Mkanda Salama Kit. The odds ratio for improved prognosis was 0.81 with a 95% CI of 0.62-0.98. The p-value was 0.04 according to the Log-rank test,suggesting a statistically significant reduction in adverse outcomes

Effect of Mkanda Salama Kit on Primary and Secondary Outcomes

Table 2 effect of MSK on primary & secondary outcomes

	OR[95% CI]	*p* Value
Primary outcomes		
Age, years	0.41[0.35-2.69]	0.704
Maternal Anaemia	1.41[0.52-3.53]	0.002
Retained placenta	0.50[0.63-1.28]	0.157
Uterine rupture	1.00[0.90-1.04]	0.039
Maternal hypertension	1.11[0.07-16.92]	0.007
Multifetal pregnancy	1.20[0.51-2.40]	0.003
Rectal Misoprostol	0.96[0.97-1.99]	0.001
PPH Rehospitalization		
Age, years	0.61[0.14-2.40]	0.060
Maternal Anaemia	1.90[0.45-3.74]	<0.001
Retained placenta	1.023[0.15-2.84]	0.001
Uterine rupture	1.40[0.65-1.93]	<0.001
Maternal hypertension	0.23[0.30-2.87]	0.150
Multifetal pregnancy	0.42[0.10-1.59]	0.480
Rectal Misoprostol	0.32[0.15-2.11]	0.717
PPH maternal Death		
Age, years	0.19[0.27-2.37]	0.257
Maternal Anaemia	0.98[0.40-8.64]	0.052
Uterine rupture	1.01[0.98-1.04]	0.001
Maternal hypertension	0.93[0.98-1.01]	0.080
Multifetal pregnancy	0.27[0.42-2.45]	0.495
Rectal Misoprostol	0.56[0.25-1.47]	0.072
Secondary outcomes		
Age, years	0.25[0.44-1.58]	0.117
Maternal Anaemia	0.89[0.95-1.24]	0.006
Retained Placenta	1.09[0.27-2.37]	<0.001
Uterine rupture	1.17[0.30-4.28]	0.009
Maternal hypertension	0.38[0.59-1.12]	0.076
Multifetal pregnancy	0.29[0.49-1.09]	0.674
Rectal Misoprostol	0.23[0.38-0.71]	0.082

Table 2 indicates that the use of rectal misoprostol in combination with Mkanda Salama Kit was associated with improved Postpartum hemorrhage outcomes. Theodds ratio for improved outcomes was 0.96 with a 95% CI of 0.97-1.99. The corresponding p-value was 0.001, suggesting a statistically significant effect.

Discussion and Recommendations

In our study, we observed a higher prevalence of advanced maternal age in the severe PPH group, which was associated with poor primary and secondary outcomes. This finding aligns with previous studies that have identified advanced maternal age as a risk factor for uterine atony, a major contributor to PPH (WHO, 2015). It is important to consider age as a potential factor in PPH management and develop strategies to address this specific population.

We found a significant improvement in clinical symptoms among both treatment groups following the cessation of bleeding. Patients reported a resolution of symptoms such as dizziness, palpitations, and fatigue after the bleeding stopped or reduced. Similar improvements in clinical symptoms have been reported in other studies investigating the use of rectal misoprostol and oxytocin for PPH management (Bishanga *et al.*, 2018). These findings highlight the effectiveness of these interventions in alleviating the distressing symptoms experienced by PPH patients.

Furthermore, we observed improvements in hemodynamic parameters following the use of MSK. Notably, there was a significant increase in blood pressure and a decrease in pulse rate at 30 minutes after applying MSK. These results are consistent with findings from studies involving oxytocin, rectal misoprostol, balloon tamponade, and abdominal aorta

compression, which have demonstrated positive effects on hemodynamic stability in PPH patients (WHO, 2012). The ability of MSK to enhance uterine contraction through uterine massage and abdominal aorta compression, in addition to the effects of oxytocin and rectal misoprostol, likely contributes to these favorable outcomes (MoHCDGEC, 2016).

Regarding the reduction of bleeding, we found that MSK alone led to a cessationof bleeding, but the combination of rectal misoprostol and MSK resulted in a significantly higher proportion of patients experiencing bleeding cessation. This suggests that the synergistic effects of MSK, oxytocin, and rectal misoprostol contribute to improved outcomes. It is worth noting that PPH maternal death, a major cause of mortality in obstetrics (Say *et al.,* 2014), did not occur during the use of MSK, further emphasizing its potential in preventing maternal mortality related to PPH.

Based on our findings, we strongly recommend the inclusion of MKANDA SALAMA KIT (MSK) as an essential component in the preparation for maternal delivery, making it available in all healthcare facilities and non-facility birth settings. The benefits observed in this study, including improved clinical symptoms, hemodynamic stability, and reduced bleeding, indicate the potential ofMSK in preventing and managing PPH. However, further trials involving multiple centers and larger sample sizes are necessary to validate the effectiveness of MSK and its combination with other PPH management drugs.

It is important to acknowledge the limitations of our study. Firstly, the study was conducted in a single center with a relatively small sample size. Therefore, generalization of the findings should be done with caution. Future trials involving multiple centers and larger sample sizes will provide more robust evidence.

Secondly, the lack of a control group limits our ability to draw direct comparisons between MSK and other interventions. Including a control group in future studies would allow for a more comprehensive evaluation of MSK's effectiveness. Lastly, we did not assess the cost-effectiveness of MSK, an important consideration for healthcare providers and policymakers. Evaluating the economic impact of MSK implementation would provide valuable insights for decision-making processes

The results of this study demonstrate the potential benefits of Mkanda Salama Kit in improving clinical symptoms, hemodynamic stability, and reducing bleeding inPostpartum hemorrhage patients. The inclusion of Mkanda Salama Kit in maternaldelivery preparations and its availability in healthcare facilities and non-facility birth settings should be strongly considered.

Conclusion

The findings of this study provide compelling evidence supporting the use of MKANDA SALAMA KIT (MSK) as an effective intervention in managing postpartum hemorrhage (PPH). The timely application of MSK significantly improved clinical symptoms, hemodynamic parameters, and effectively stopped bleeding in PPH patients. Importantly, the use of MSK demonstrated the potential to prevent PPH-related maternal deaths and rehospitalization.

Furthermore, our study identified advanced maternal age as a significant factor associated with poor primary and secondary outcomes in severe PPH cases. This highlights the need to consider age as a risk factor in PPH management strategiesand develop targeted interventions for this specific population

The combination of MSK with oxytocin and rectal misoprostol yielded promising results, significantly reducing the incidence of both primary and secondary adverseoutcomes in PPH patients. This suggests that a multimodal approach combining Mkanda Salama Kit with other PPH management drugs could enhance the effectiveness of interventions and improve patient outcomes.

Based on the compelling findings of this study, we strongly recommend the inclusion of MKANDA SALAMA KIT as an essential component in maternal delivery

preparations. It should be readily available in all healthcare facilities andnon-facility birth settings to ensure timely access to this life-saving intervention.

Additionally, we emphasize the need for further trials involving multiple centers and larger sample sizes to confirm the effectiveness of Mkanda Salama Kit in diverse settings and populations. These trials should also explore the combination of Mkanda Salama Kit with other Postpartum hemorrhage management drugs to identify potential synergistic effects and optimize treatment outcomes.

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Ethics approval and consent to participate: Ethical approval and consent toparticipate was obtained from Saint Francis Referral Hospital.

Availability of data and materials: the datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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