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ABSTRACT

Background: Uterine massage may significantly reduce post partum blood loss and could be patient-driven.

Objective: To assess the effectiveness of an alarm reminder system for self uterine massage in the prevention of post partum blood loss.

Design: A random controlled trial.

Setting: Meru District Hospital, Kenya.

Subjects: One hundred and twenty seven (127) women were randomly assigned to a 15 minute alarm reminder system (71) and non-alarm (56) control arm during the fourth stage of labour.

Results: Uterine massage compliance was better in the alarm group compared to the non-alarm group (Average massage of seven and two in two hours respectively P-value <0.0001), however the difference in blood loss was not significant 45.6 ml (95% CI 43-46) vs 47.1 ml (95% CI 43-52)ml p-value 0.892.

Conclusion: Uterine massage compliance is remarkably increased by the use of an alarm reminder.

INTRODUCTION

Haemorrhage contributes a greater proportion of maternal deaths worldwide, with the burden being more in Sub-Saharan Africa (1-3). Several strategies to reduce these mortalities have been devised, the most effective being the active management of third stage of labour (AMTSL), which has been demonstrated to reduce the incidence of post partum haemorrhage (PPH) by over 60% (4).

The International Federation of Gynaecologists and Obstetricians (FIGO) and the International Confederation of Midwives (ICM) also recommend fundal massage after delivery of the placenta followed by palpation of the uterus every fifteen minutes for two hours as a strategy to reduce further blood loss (2). Despite the existing evidence and recommendations, the uptake of these measures in most developing countries is low with a 15% compliance with the practice of AMTSL being reported in Egypt (5). A survey done in Tanzania revealed insufficient knowledge of the correct use of AMTSL; 91% of

healthcare providers made no correct statements regarding the various components of AMTSL as well as timely administration of oxytocin (6).

Most of these preventive strategies are health worker-driven. On the other hand uterine massage, a strategy that has been suggested in the prevention of post partum haemorrhage may be patient-driven provided the patients are well educated and motivated to undertake the exercise. This could be useful especially in facilities with limited human resources to continuously monitor the fourth stage of labour.

We therefore, hypothesised that patient directed uterine massage could significantly reduce the amount of blood loss during the fourth stage of labour and that the use of alarm reminders every fifteen minutes could enhance compliance to uterine massage.

MATERIALS AND METHODS

A randomised control trial was undertaken at the Meru District Hospital for a period of one month, June

to July 2010. Women were recruited upon presentation in early first stage of labour. A written informed consent was then obtained. All consenting women were then allocated to the two arms of study (that is, alarm and non-alarm) by simple randomisation using a sealed opaque envelop. This was performed by the principal investigator and a study midwife. The principal investigator but not the midwife was blinded to the allocation of each participant. Blinding of study participants was not possible, participating in the study did not alter the course of management of labour until after third stage was completed.

Patients were excluded at recruitment if they had a multiple pregnancy, previous Caesarean section or myomectomy scar, were known to have a coagulopathy, had a previous history of PPH, had multiple uterine fibroids (documented), or were on anticoagulants (for example warfarin, heparin). Patients with evidence of psychiatric illness and hearing disability were also excluded. After the third stage of labour a mother was excluded from the study if she sustained any genital tract tears, needed to be examined under anaesthesia or needed additional interventions besides AMTSL to prevent further bleeding.

The non-alarm group was offered AMTSL as per the unit protocol which is administration of 10 IU of oxytocin intramuscularly within one minute of delivery after ruling out a second twin, controlled cord traction, and uterine massage, after which they were instructed on uterine massage every 15 minutes for a total period of two hours post delivery. The women in the alarm group were also offered AMTSL and in addition had an alarm available to ring every 15 minutes for two hours to remind them when uterine massage was due.

Each study participant was issued a dry sanitary towel whose weight had been taken to aid in determining the volume of blood lost. All study subjects were catheterised using a Foleys catheter gauge sixteen as soon as they entered the post natal ward and a qualified study midwife monitored patients' compliance to uterine massage every fifteen minutes by direct visualisation through a blinder from an undisclosed location.

Baseline vital signs were taken upon completion of the third stage of labour and repeated after the first and second hour. The first sanitary pad was placed after the patient was settled into the post natal ward and taught how to self massage depending on the allocated group. The massage instructor equipped with personal protective equipment weighed the sanitary pads using a digital weighing scale. Blood

loss was calculated by deducting the dry weight of the pad from the weight of the soaked pad and the difference recorded against the method of reminder utilised. At the beginning of the second hour, a dry sanitary pad was re-administered and weighed an hour later to determine the volume of blood lost. Additional pads were issued as and when required.

A dry pad was placed and uterine massage was performed in both study groups after two hours to expel any clots in the uterus and posterior fornix and blood loss ascertained.

Participants who were found to have a blood pressure of less than 90/60 mmHg, heart rate of more than 110 beats per minute; respiratory rate of more than 30 breaths per minute or a temperature of less than 36.5 degrees Celsius, had resuscitation measures undertaken and did not continue with the study protocol, this was because women experiencing excessive bleeding need urgent interventions to help arrest bleeding that could be potentially life threatening, however their compliance to massage was noted up to the time excess bleeding was noted.

The primary outcome measures were compliance to uterine massage at 15 minutes interval and the cumulative blood loss after two hours.

A total of 130 participants needed to be studied to detect a 15% difference in the primary outcome measure with an 80% precision and a type 1 error probability of 0.05.

Data were analysed using the Statistical Package for Social Scientists (SPSS version 17). Descriptive statistics were summarised by means and proportions and tabulated. The Student t-test was used to determine the difference between means and the Pearson correlation to demonstrate the strength of correlation between continuous variables. Logistic regressions were also conducted to evaluate for confounders. A p-value of <0.005 was considered statistically significant.

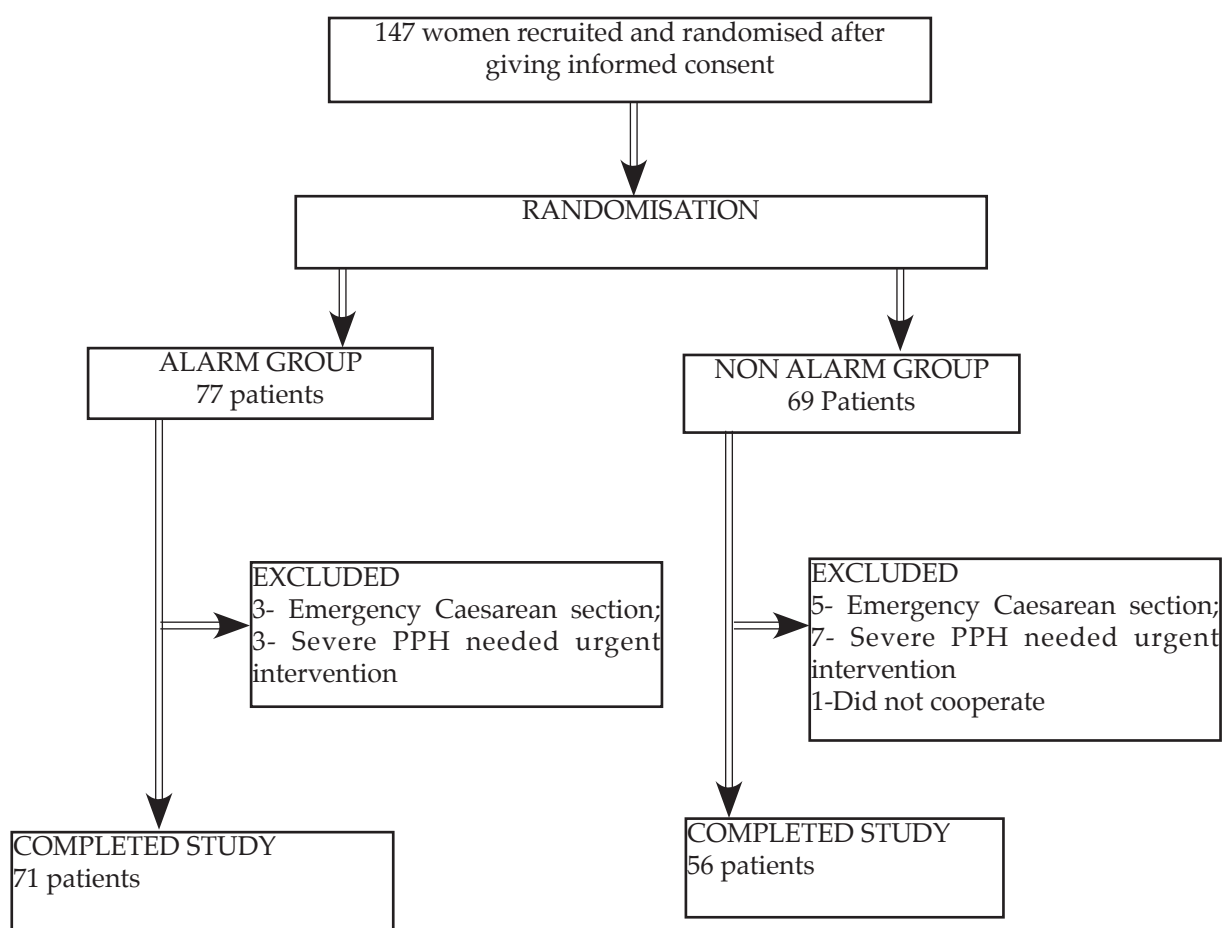
Analysis was done per protocol and those patients who dropped out of the study were not included in the final analysis but were accounted for.

Ethics and Research Committees of the Kenyatta National Hospital and Meru District Hospital approved the study protocol.

RESULTS

A total of 127 mothers completed the study and were included in the final analysis, 71 in the alarm group and 56 in the non-alarm group (Figure 1).

Figure 1
Study Flow Diagram



Baseline Characteristics of Study sample: The characteristics of study participants are shown in Table 1. There was no significant difference in the baseline characteristics of the study sample as pertains level of education, parity, age and vital signs.

Table 1
Baseline characteristics of study participants

	Alarm n=71	Non Alarm n=56	p-value
Level of education	n(%)	n(%)	
None	9(12.5)	11(19.6)	-
Primary	4(5.6)	2(3.6)	-
Secondary	40(56.3)	34(60.7)	-
College/University	18(25.3)	9(16.1)	-
Parity	31(43.7%)	23(41.1%)	0.789
Primigravidae	40(56.3)	33(58.9%)	0.852
Multigravidae	23.7(5.3)	24.7(5.4)	0.914
Age Mean(SD)	23.7(5.3)	24.7(5.4)	0.914
Vital signs			
Mean systolic BP*(mmHg)	108	112	0.872
Mean diastolic BP(mmHg)	72	71	0.764
Respiratory rate (bpm†)	16	16	0.984
Temperature (°C)	37.1	37.3	0.912

*BP= Blood pressure

†bpm= breaths per minute

Total Mean Blood Loss and Uterine massage after two hours: The average number of uterine massages after two hours were significantly different with seven in the alarm group and two in the non alarm p-value (0.0001). The mean blood loss after two hours in both study groups was no statistically different. Alarm group (45.6 ml) and (47.1 ml) in the non alarm p-value (0.892) (Table 2).

Table 2
Total Mean Blood Loss and Uterine massage after two hours

	Alarm (n=71)	Non-alarm (n=56)	p-value
Uterine massages performed per 2hr session(95%CI)	7(6.7-7.2)	2 (1.7-2.6)	<0.0001
Mean blood loss at 2 hours(ml) (95%CI)	45.6(43-46)	47.1(43-52).	0.892
Vital signs at 1 and 2 hours after uterine massage			
Vital Signs(1hr)			
Systolic BP <90mmHg	0	0	-
Diastolic BP <60mmHg	10	10	-
Pulse Rate >100 bpm*	0	1	-
Respiratory Rate >30 bpm*	0	0	-
Temperature <36.5	19	16	0.293
Vital Signs (2hr)			
Systolic BP <90mmHg	0	0	-
Diastolic BP<60mmHg	5	6	0.291
Pulse Rate >100	0	0	-
Respiratory Rate >30	1	0	-
Temperature <36.5	6	12	0.013

*beats per minute

Compliance to uterine massage: The compliance to uterine massage was compared between the two groups and the results are presented in Table 3.

Table 3
Compliance to uterine massage

Massage time interval	Alarm n=71 n(%)	Non alarm n=56 n(%)	p-value
15 minutes	62 (86.1)	23(42)	<0.0001
30 minutes	63(87.5)	16(29)	<0.0001
45 minutes	61(84.7)	22(40)	<0.0001
60 minutes	64(88.8)	19(35)	<0.0001
75 minutes	64(89)	11(20)	<0.0001
90 minutes	55(76)	13(24)	<0.0001
105 minutes	61(84.7)	9(16)	<0.0001
120 minutes	67(93)	9(16)	<0.0001

There was significant difference in rates of compliance to uterine massage between the two groups at all the 15-minute time intervals (p-value <0.0001).

Alarm Group: Three patients in the alarm group developed post partum haemorrhage before being taken to the post natal ward for massage monitoring therefore their blood loss estimation and compliance could not be ascertained. There was no blood transfusion administered in this group.

Non Alarm Group: The non alarm had five patients who developed post partum haemorrhage while in labour ward managed actively two of them sustained cervical tears requiring examination under anaesthesia and three with uterine atony requiring continuous oxytocics. Two patients in the non alarm group developed excess bleeding and had deteriorating vital signs requiring active intervention and blood transfusion after 45 minutes into the study with zero compliance. The average blood loss was 98 ml, requiring two pints of blood transfusion each.

DISCUSSION

This is the first study to report on this novel strategy to improve compliance with post delivery uterine massage. We found that the alarm significantly improved compliance, our results of 29% compliance in the non alarm are in keeping with 6.1 -70.8% compliance reported by Cynthia *et al* within the first thirty minutes (7), however the 87% compliance in the alarm group is higher than the rates reported in literature, this confirms that our findings indeed use of alarm improves compliance.

In this randomised control trial the use of self uterine massage in the fourth stage of labour did not significantly reduce the total volume of blood loss in two hours post delivery. Even though the use of reminders by an alarm system was associated with a higher compliance rate to the practice of self uterine massage, this did not translate into reduction in blood loss.

There are reports of increased blood loss in the fourth stage of labour even after active management of third stage of labour, however there are very few studies addressing preventive strategies (7,8). We had hypothesised that self uterine massage could result in significant reduction in further blood loss after the fourth stage of labour and may be adopted as a possible preventive strategy but this was not proven by our study and hence the need for larger sample size studies to evaluate this end point especially post partum haemorrhage.

We reported two patients in the non-alarm group at 45 minutes with excess bleeding that required active intervention. We noted that these two did not comply with uterine massage. Even though this finding was not statistically significant we thought it was relevant because there were no incidences of excess bleeding in those patients who complied with uterine massage.

Our study was limited by the inability to regulate the strength/firmness of uterine massage by the study participants. So while we may have reported compliance in the alarm group, it was not possible to evaluate the effectiveness of the actual process of uterine massage. It was also difficult to blind the observer monitoring uterine massage compliance against the reminder method used and this may have introduced observer bias.

Mothers were allowed to breastfeed on demand, this could also have influenced amount of blood lost by improving uterine tone, however this could not be assessed objectively and may require a different study design to ascertain its efficacy along with massage. It may be challenging to implement an alarm system in open wards, as sound signal contamination from multiple rings is a possibility. This may be countered by use of vibrator devices in future studies of this nature as opposed to sound systems.

Being a single centre study we would confidently generalise our findings to other populations. However, we managed to accurately measure blood loss using a digital weighing scale and all the sanitary pads used in the study were accounted for. This is usually a major challenge in studies of this nature. The findings of this study demonstrate that uterine massage compliance is improved by use of reminder systems especially the alarm; however this does not significantly reduce blood loss post delivery, more studies with larger sample sizes are required to establish this fact and investigate how useful this procedure would be in the prevention of massive post partum haemorrhage.

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