International Journal of Gynecology and Obstetrics (2005) **90**, 51—55

International Journal of
GYNECOLOGY
& OBSTETRICS

www.elsevier.com/locate/ijgo

SPECIAL ARTICLE

Controlling postpartum hemorrhage after home births in Tanzania

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Received 17 November 2004; accepted 16 March 2005

KEYWORDS
Postpartum hemorrhage;
Misoprostol;
Traditional birth attendants

Abstract

Objectives: Determine safety of household management of postpartum hemorrhage (PPH) with 1000 μg of rectal misoprostol, and assess possible reduction in referrals and the need for additional interventions. *Methods:* Traditional birth attendants (TBAs) in Kigoma, Tanzania were trained to recognize PPH (500 ml of blood loss). Blood loss measurement was standardized by using a local garment, the "kanga". TBAs in the intervention area gave 1000 μg of misoprostol rectally when PPH occurred. Those in the non-intervention area referred the women to the nearest facility. *Results:* 454 women in the intervention and 395 in the non-intervention areas were eligible. 111 in the intervention area and 73 in the non-intervention had PPH. Fewer than 2% of the PPH women in the intervention area were referred, compared with 19% in the non-intervention. *Conclusion:* Misopros-

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0020-7292/$ - see front matter
doi:10.1016/j.ijgo.2005.03.007

tol is a low cost, easy to use technology that can control PPH even without a medically trained attendant.

1. Introduction

Globally, postpartum hemorrhage (PPH) accounts for a quarter of all maternal mortality [1], and in parts of Sub-Saharan Africa the proportion is even higher (Burkina Faso, 59%; Ivory Coast, 37%; Guinea, 43%) [2]. The high prevalence of anemia among women in developing countries predisposes them to PPH, and even a modest blood loss can be life threatening.

The WHO recommends active management of the third stage of labor with uterotonics, preferably oxytocin [1]. However, this use is limited due to the instability of oxytocics in tropical climates [3] and lack of health professionals to administer injectables. More importantly, the greatest risk of maternal death is among women who deliver at home, either alone or with a traditional birth attendant (TBA) [4]. To date, efforts to reduce maternal mortality through training traditional birth attendants have been disappointing [5].

Misoprostol is a proven uterotonic increasingly used in obstetrical and gynecological practice, including the control of PPH [6–10]. It can be administered orally, rectally, vaginally or sublingually; it is inexpensive, easy to store, stable in field conditions, and it has an excellent safety profile [11]. An expert meeting on safe motherhood in Bellagio identified misoprostol as an underused technology to reduce maternal mortality [12]. Where a trained health professional is not present, misoprostol is the only option currently available to prevent or treat PPH.

This paper presents results from a pilot intervention trial conducted by the Maweni Regional Hospital in Kigoma, Tanzania. It was not primarily designed to test the effectiveness of misoprostol to treat PPH, but to determine whether TBAs can diagnose and treat PPH with misoprostol. The gold standard, randomized placebo controlled trial would have been logistically impossible to conduct in such a resource-poor setting. Moreover, it would have been ethically unacceptable to conduct a placebo trial where there is no back-up therapy to save a woman's life during home delivery attended by a TBA.

2. Methods

The study was a field intervention trial composed of an intervention and non-intervention (the control group) specified non-adjacent geographical areas. Blood loss measurement procedure was standardized, by using a local "kanga" (East Africa's standard size) for blood collection after delivery. Prior to the study implementation a blood loss awareness assessment was carried out with the TBAs selected to participate in the study. Using focus groups, in-depth interviews and participatory observation the authors discovered that: (a) the women place a kanga (the colorful, rectangular, cotton garment all women own) under the buttocks after delivery; (b) all kangas are the same size; and (c) after measurement verification, it was established that two kangas soaked with blood (after delivery of the baby) represented slightly more than 500 ml.

Thirty TBAs were selected and trained for intervention and non-intervention areas. TBAs were trained to follow study inclusion criteria (term pregnant women able to give informed consent; were over 18 years of age; and had no history of bronchial asthma, or prior cesarean section), and to stay with the parturient for at least 4 h after delivery, or until referring the women to the health facility.

TBAs in the intervention area were instructed to administer rectally 5 tablets of misoprostol (1000 μg; Zizhu Pharmaceutical, Beijing) to all women delivering vaginally with subsequent blood loss of 500 ml or more. They were instructed to refer women to the nearest facility 20–30 min after administration of misoprostol if no significant change in blood loss was observed (e.g. 1–2 more kanga were soaked), and/or if the patient presented deterioration of important signs such as rapid respiration, sweating or high temperature, or general weakness, regardless of the amount of blood loss. TBAs in the non-intervention area were trained to record postpartum blood loss of 500 ml or more and refer all of them to the nearest facility. All TBAs were counseled to refer women for any reason regardless of PPH status, based on their best judgment drawn from what they learned during training regarding safe delivery procedures. At the health facility, interventions administered

Table 1 Characteristics of the study population

	Intervention		Non-intervention	
	n = 454	(53.5%)	*n* = 395	(46.5%)
Mean age in years (S.D.)	24.6	(4.8)	26.7	(6.5)
Education				
None	65	(14.5)	99	(25.1)
Primary	369	(82.2)	287	(72.8)
Secondary+	15	(3.3)	8	(2.0)
Mean parity (S.D.)	2	(1.7)	2.4	(2.0)
Symptoms after delivery				
Sweating	172	(37.9)	134	(34.8)
Shivering	144	(31.7)	157	(40.6)
Vomiting	63	(14.0)	76	(19.6)
PPH (blood loss $\geq$500 ml)	111	(24.5)	73	(18.5)
Sex of newborn				
Male	252	(56.0)	241	(61.6)
Female	198	(44.0)	150	(38.4)
Condition of newborn				
Well	448	(99.7)	381	(98.2)
Not well	5	(1.1)	2	(0.5)
Dead	1	(0.2)	5	(1.3)

to the referred women followed the local protocol for PPH management available for all women, and the decisions were taken on a case-by-case basis depending on the patient needs and resources available.

To ensure that all maternal deaths among the study population were recorded, field supervisors carried out community maternal mortality audits, by interviewing village leaders who register all deaths and visiting households with maternal deaths.

All TBAs completed the same simple data form for each enrolled woman. Each form was checked for accuracy and entered into a database in Epi-info 2000, and analyzed in Stata version 8.

The study, which complied with the Helsinki declaration for research on human subjects, was approved by the Tanzanian Ethics Committee for Research. All women enrolled in the study gave informed consent. There were no monetary incentives, but TBAs in both groups received a lantern, soap, gloves, and a plastic apron.

3. Results

From August 2003 to July 2004 a total of 906 women were screened by the TBAs. Of those, 849 were eligible and enrolled in the study. The non-eligible included one 14 year old, one who died on

Table 2 Main outcomes of the study

	Intervention		Non-intervention		Odds ratio (95% CI)	
	n	(%)	*n*	(%)		
PPH (blood loss $\geq$500 ml)	111	(24.5)	73	(18.5)	1.3	(1.0—1.7)
Referrals	8	(1.8)	75	(19.0)	0.1	(0.0—0.2)
Additional interventions among PPH cases	*n* = 111		*n* = 73			
Type of additional interventions[a]	1[b]	(0.9)	69[c]	(94.5)		
IV fluid	1	(0.9)	25	(34.3)		
Blood transfusion	1	(0.9)	16	(21.9)		
Manual removal of placenta	0	0.0	17	(23.3)		
Repair of tears	0	0.0	4	(5.5)		
Hysterectomy	0	0.0	1	(1.4)		
Other medical interventions[d]	0	0.0	7	(9.6)		

[a] Number of cases do not add up to total referred, some women had more than one intervention.
[b] Hospital records not available for one patient; 3 patients did not need additional interventions; another 3 were referred for other reasons than PPH.
[c] Hospital records not available for 4 patients; 4 patients did not need additional interventions; 2 cases referred for other reasons than PPH.
[d] Medical interventions included: Amoxyl tablets, methergin, and misoprostol.

Table 3 Description of PPH referred cases from the intervention area

Patient	Age	Parity	Symptoms 20 min after misoprostol						Comments
			Blood loss ≥1000ml	Increased temperature	Rapid pulse	Rapid respiration	Sweating	Shivering	Vomiting	
1	21	4	–	–	–	–	–	–	–	PPH stopped after misoprol
2	18	0	–	–	–	–	–	–	✓	Referred for other reason
3	25	1	–	–	–	–	–	–	–	PPH stopped after misoprol
4	31	5	–	–	–	–	–	–	–	PPH stopped after misoprol
5	28	0	–	–	–	–	✓	✓	✓	Hospital record not available
6	34	4	–	–	–	–	✓		✓	Referred for other reason
7	28	2	–	–	–	–	✓	✓	✓	Referred for other reason
8	32	3	✓	✓	✓	✓	✓	✓	✓	Patient had severe PPH

Table 4 New cases after misoprostol administration among women with PPH who did not present selected symptoms before misoprostol

	No. new cases	(%) of total PPH cases
High temperature	48	10.4
Rapid pulse	55	10.9
Rapid respiration	56	12.5
Sweating	42	35.7
Shivering	44	36.4
Vomiting	67	19.4

the way to the hospital before delivery, one referred for a cesarean section, and 54 who came from outside the study area. Women from both areas have relatively similar socio-demographic characteristics (Table 1), pregnancy outcomes and potential risk of postpartum hemorrhage (OR=1.3 95% CI 1.0—1.7) (Table 2). Although the mean blood loss cannot be accurately estimated, the percentage of women bleeding less than 2 kangas was 75% in the intervention area and 81% in the non-intervention area.

Eight women (2%) in the intervention area and 76 (19%) in the non-intervention area were referred to health facilities after delivery (OR=0.1 95% CI 0.0—0.2) (Table 2). Of those referred, 1% from the intervention area and 95% from the non-intervention area needed additional interventions due to PPH. Among women with PPH in the non-intervention area, one-third received IV fluids and 22% needed blood transfusions. The difference in the number of women who needed manual removal of placenta needs further exploration. Ongoing trials could answer whether misoprostol prevents retained tissue or this is an isolated finding.

In the non-intervention area 4 women referred due to PPH were unable to go to the health facility, probably because they could not afford the transport. The TBAs stayed with them for 4 h, kept them hydrated and verified that they did not soak 2 more kangas (1000 ml or more of blood loss).

Table 3 presents a summary of the eight referred cases in the intervention area. All the women referred for PPH were discharged from the facility after a few hours observation. Table 4 displays the symptoms recorded by TBAs for women given misoprostol. None of the women with side effects required referral and most symptoms lasted only a few minutes.

The only death from the study population involved a 45 year old woman, para 13, gravida 14, living in the non-intervention area. She presented at the TBA's home with ruptured membranes with meconium liquor, and died before delivery on the way to the hospital.

4. Discussion and conclusions

As with any other intervention study, the goal was to provide results on which public health policy could be based and/or a reliable and informative null finding could be obtained to encourage research in related areas. Intervention trials follow the basic design of a clinical trial with one major exception, the application of an intervention at the community level. These studies can also provide valuable insights into making informed decisions.

Kigoma TBAs diagnosed PPH satisfactorily and those in the intervention area used rectal misoprostol effectively to treat PPH after home births. This technically simple intervention can have a powerful effect in preventing death during home delivery, where the risk of maternal death is greatest. The therapeutic use of misoprostol also saves health service resources and saves families from spending money on transportation and hospitalization.

The diagnosis by the use of kanga, built on an existing practice, proved simple to adapt, and even though it does not give a perfect measurement, it is more accurate than most clinical estimations. Kangas are widely used in Africa and TBAs could be taught to use misoprostol to treat PPH on a wide scale. The threshold of 2 kangas ($\geq$500 ml)was by itself an important finding. Prior to the study, TBAs would refer women to a nearest health facility after 4 kangas were soaked with blood, representing $\geq$1000 ml of blood loss. In cases were the nearest facility is within hours by car or sometimes by boat, the 4 kangas threshold may have put many women at risk of dying from PPH.

The pyrexia and shivering associated with misoprostol use do not appear to be of major concern, and can be managed by TBAs in household settings.

Women and TBAs know about and fear PPH. Many safe motherhood programs in Sub-Saharan Africa have discontinued training TBAs, mainly due to the fact that their training had little or no impact on maternal health [13,14], but the use of misoprostol could have a significant impact on maternal mortality by reversing this trend. It is notable that the status of the TBAs in the intervention area rose rapidly and as those in the non-intervention area heard about misoprostol they began immediately to ask for it. In resource-poor settings where most of the deliveries take place at home, misoprostol can be a life-saving drug and should be considered central to any strategy designed to reduce maternal mortality. Where TBAs can dispense misoprostol, treatment is likely to remain preferable to prevention as it lowers the cost and avoids subjecting every woman to possible side effects. In some settings an alternative method of measuring blood loss may need to be devised but if this is not possible, then all women could be given 600 μg of misoprostol after delivery of the baby as a preventive measure.

For the first time since the launch of the safe motherhood campaign in the 1980s, a low cost, easy to use technology is available for reducing postpartum hemorrhage — the largest single cause of maternal death — even after home births and without a medically trained attendant.

Acknowledgments

The study was supported by the Kigoma Regional Medical Office and Ventures Strategies for Health and Development.

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