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CLINICAL ARTICLE

A comparative study of the non-pneumatic anti-shock garment for the treatment of obstetric hemorrhage in Nigeria

Suellen Miller [a,*], Oladosu Ojengbede [b], Janet M. Turan [a], Imran O. Morhason-Bello [b], Hilarie B. Martin [a], David Nsima [c]

[a] Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, San Francisco, USA
[b] Department of Obstetrics and Gynaecology, University College Hospital, Ibadan, Nigeria
[c] Katsina General Hospital, Katsina, Nigeria

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ABSTRACT

Objective: To determine whether the non-pneumatic anti-shock garment (NASG) can improve maternal outcome. *Methods:* Women were enrolled in a pre-intervention phase (n = 83) and an intervention phase (n = 86) at a referral facility in Katsina, Nigeria, from November 2006 to November 2007. Entry criteria were obstetric hemorrhage (≥750 mL) and a clinical sign of shock (systolic blood pressure <100 mm Hg or pulse >100 beats per minute). To determine differences in demographics, condition on study entry, treatment, and outcome, *t* tests and χ^2 tests were used. Relative risk (RR) and 95% confidence interval (CI) were estimated for the primary outcome, mortality. *Results:* Mean measured blood loss in the intervention phase was 73.5 ± 93.9 mL, compared with 340.4 ± 248.2 mL pre-intervention ($P<0.001$). Maternal mortality was lower in the intervention phase than in the pre-intervention phase (7 [8.1%]) vs 21 [25.3%]) (RR 0.32; 95% CI, 0.14–0.72). *Conclusion:* The NASG showed potential for reducing blood loss and maternal mortality caused by obstetric hemorrhage-related shock.

1. Introduction

Obstetric hemorrhage is the leading cause of maternal mortality in resource-limited settings [1]. New technologies and strategies—such as oral misoprostol, oxytocin in Uniject (Becton, Dickinson and Company, Franklin Lakes NJ, USA), and active management of the third stage of labor (AMTSL)—can be used to prevent and manage uterine atony [2]; however, not all obstetric hemorrhage responds to uterotonic prevention or treatment, and women can still hemorrhage despite AMTSL [3,4]. The International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) advised exploring the potential of the anti-shock garment (ASG) to reduce mortality associated with obstetric hemorrhage [5].

The non-pneumatic ASG (NASG; Zoex Corporation, Ashland, OR, USA) is a low-technology first-aid device made of neoprene and hook-and-loop fastening tape (Velcro, Manchester, NH, USA). It comprises 9 horizontal segments: 3 for each leg (ankle, calf, and thigh), 1 for the pelvis, and 1 double segment with a small foam compression ball for the abdomen (Figs. 1, 2). This device shunts blood from the lower extremities to the core organs and decreases the transmural pressure and radius of uterine, abdominal, and lower-body vessels, thus decreasing blood flow.

The NASG is less expensive (approximately US $170 per suit versus up to US $720) than its predecessor (the pneumatic ASG [or medical anti-shock trousers]) [6] and can be decontaminated with bleach, laundered, and re-used up to 40 times [6]; in addition, it can be applied more quickly and easily, enables complete perineal access (enabling vaginal procedures without removing the garment), and has an easy-to-open abdominal segment, allowing the rest of the garment to remain intact for surgical procedures. The NASG has the potential to be a useful first-aid device when there are delays in obtaining transport, delays during transport from home/community level to comprehensive emergency obstetric care (CEmOC) facilities, and delays in obtaining definitive care at understaffed and under-supplied CEmOC facilities.

Previous pre/post studies have demonstrated significantly reduced measured blood loss and more rapid recovery time in the intervention phase [7–10]. Using a similar design, the aim of the present study was to analyze the impact of the NASG on maternal outcome in a tertiary care facility in Katsina, Nigeria.

2. Materials and methods

The present study was part of a larger NASG project conducted between March 2004 and December 2007 at 12 referral facilities in northern and southern Nigeria. The current study presents results

* Corresponding author. Safe Motherhood Programs, University of California, San Francisco, 50 Beale Street, Suite 1200, San Francisco, CA 94105, USA. Tel.: +1 415 597 9394; fax: +1 415 597 9300.
E-mail addresses: suellenmiller@gmail.com, smiller@globalhealth.ucsf.edu (S. Miller).

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Fig. 1. An opened non-pneumatic anti-shock garment.

from Katsina General Hospital, Nigeria, which is a 58-bed facility that deals with approximately 6000 births annually—many of which are associated with high-risk complications and are "unbooked." The 2005 maternal mortality ratio for the facility (1649/100 000) was based on 89 maternal deaths per 5395 live births; however, as is the case with many facilities in both high- and low-resource settings, maternal mortality may have been underreported [11].

During the pre-intervention phase (5.5 months: November 17, 2006–May 6, 2007), women with hypovolemic shock secondary to any form of obstetric hemorrhage, regardless of whether the hemorrhage began outside or inside the facility, were treated with a standard hemorrhage-and-shock protocol, which did not include use of the NASG. During the intervention phase (6 months: May 11, 2007–November 19, 2007), application of the NASG on study entry was added to the standard treatment. Study eligibility criteria were obstetric hemorrhage of any etiology at any stage of pregnancy (except with a viable fetus) or post partum, an estimated initial blood loss of at least 750 mL, and at least 1 sign of shock (pulse ≥ 100 beats per minute and/or systolic blood pressure [SBP] ≤ 100 mm Hg). For women with concealed blood loss, such as those with ectopic pregnancy or a ruptured uterus, the criteria were estimated based on vital signs, level of consciousness, and urine output [12].

The study protocol was approved by the University of California, San Francisco (UCSF) Committee on Human Research (approval number H6899-23524) and given ethical clearance by the National Reproductive Health Research Committee of the Nigerian Federal Ministry of Health. In the pre-intervention phase, women gave informed consent for their data to be used. All women involved in the intervention phase provided informed consent for use of the NASG and permission to use their data; a US Federal waiver of consent/authorization for minimal-risk research (45 CFR 46, 45 CFR 164.512) was obtained so that women who were unconscious or confused at study entry were enrolled and treated, although their data were used only if they gave informed consent after regaining normal sensorium or if a relative gave consent on their behalf.

Once a woman was enrolled in the study, her vital signs and blood loss were monitored until the cause of bleeding was found and treated, her vital signs were stable (SBP > 100 mm Hg, pulse < 100 beats per minute) for 2 hours, and blood loss had decreased to approximately 25–50 mL[3] per hour. The study trained the clinicians in evidence-based protocols for obstetric hemorrhage and shock; these standard protocols were administered in both phases of the study. Interventions included administration of crystalloid intravenous fluids (≥ 1500 mL in the first hour); administration of uterotonic medications for uterine atony (given in the following order: intravenous or intramuscular oxytocin, intramuscular ergometrine, and rectal misoprostol); uterine massage; vaginal procedures (suturing of lacerations, manual removal of placenta, and dilatation and curettage for retained tissue); provision of blood transfusions; and surgery. If a woman in the intervention phase required a vaginal procedure, all sections of the NASG were left in place. If she needed a laparotomy, the protocol required the abdominal and pelvic segments to be opened immediately before making the incision, and then replaced as soon as the surgery was completed.

The primary outcomes were maternal mortality or severe morbidity before discharge from the hospital. Severe maternal morbidities were defined as severe organ failure of the following systems: renal failure (anuria, with persistent elevated creatinine); pulmonary failure (requiring intubation and respiratory assistance); cardiac arrest; or severe central nervous system involvement (seizures, confusion, or unconsciousness) persisting 24 hours after resuscitation. The secondary outcome was cumulative blood loss, which was measured hourly after study admission using a calibrated closed-end plastic drape [13]. Intraoperative blood loss was suctioned and measured using a graduated suction bottle.

The key indicator of the severity of condition at study entry was mean arterial pressure (MAP: [2 × diastolic blood pressure + SBP]/3). Women with MAP lower than 60 mm Hg were considered to be in severe shock [14]. Analyses were also conducted for subgroups according to severity of shock and diagnosis group (women with and without a diagnosis of uterine atony). Treatment variables included receipt of at least 1500 mL of crystalloid intravenous fluids and receipt of a blood transfusion during the first hour of treatment.

Clinician data collectors (physicians, nurses, and midwives) were all trained in standardized protocol for the management of obstetric hemorrhage and shock, blood collection and measurement, and completion of data collection forms. After the pre-intervention phase, the clinician data collectors were trained to use the NASG. All data were collected by the clinicians while or immediately after they cared for the patient in shock. All data forms were reviewed for completeness by trained data supervisors and were reviewed by the Nigerian principal investigator. Data were entered into a Microsoft Access (Microsoft, Redmond, WA, USA) database at UCSF and were checked for errors and inconsistencies before analysis.

Demographic characteristics, condition on study entry, and treatment received in the 2 study phases were compared using *t* tests and χ^2 tests. Owing to the skewed distribution, measured blood loss was log transformed before analysis with *t* tests. Relative risk (RR) and 95% confidence interval (CI) were computed for mortality. Stratified analyses were conducted to examine mortality in subgroups categorized by severity of condition at study entry (MAP ≥ 60 mm Hg and

Fig. 2. A non-pneumatic anti-shock garment applied to a woman. Written informed consent to publish the image was obtained from the woman.

MAP<60 mm Hg) and diagnosis group (uterine atony or no uterine atony). Logistic regression was used to adjust for the potential confounding factor of the amount of intravenous fluids administered in the first hour. Data were analyzed using SPSS version 16.0 (SPSS, Chicago, IL, USA) and STATA 10 (StataCorp, College Station, TX, USA). The analysis was conducted at a 0.05 level of significance.

3. Results

Records were completed for 169 women: 83 in the 5.5-month pre-intervention phase and 86 in the 6-month intervention phase. Age and week of pregnancy were similar between the 2 study phases, although women in the pre-intervention phase had lower parity than women in the intervention phase (Table 1). Diagnoses were similar between the study phases; approximately 65% of women in both phases had an obstetric hemorrhage etiology other than uterine atony. As indicated by vital signs and estimated initial blood loss, a higher proportion of women in the intervention phase were in severe shock at study entry, although these differences are not statistically significant (Table 1). Few women in either phase received a transfusion within the first hour of study admission; median time to first blood transfusion after study admission was 3.1 hours, and for 50.7% of women this delay was longer than 3 hours. There was not a significant difference between the intervention phase and the pre-intervention phase in the proportions of women who received a blood transfusion during the first hour. Significantly more women in the intervention phase received at least 1500 mL of intravenous fluids in the first hour (Table 2). The percentage of women who had an operation was nearly identical between the groups (approximately 23% in each group); more women had vaginal procedures in the pre-intervention phase than in the intervention phase (40 [48.2%] vs 32 [37.2%], respectively; odds ratio 1.89 [95% CI, 1.04–3.44]).

Maternal mortality was significantly lower in the intervention phase than in the pre-intervention phase (7 [8.1%] vs 21 [25.3%]; RR 0.32 [95% CI, −0.14 to 0.72]). This significant reduction remained (data not shown) after statistically controlling for the fact that more women in the intervention phase received at least 1500 mL of intravenous fluids in the first hour after study admission (50.0% vs 33.7%; $P=0.032$). Severe maternal morbidity was rare; 1 woman in the pre-intervention phase suffered renal failure and none of the women in the intervention phase experienced severe maternal morbidity. Mean measured blood loss was significantly lower for women in the intervention phase than for women in the pre-intervention phase (73.5 mL vs 340.4 mL; $P<0.001$), including significantly lower intraoperative blood loss (Table 2).

Table 1
Demographics and condition on study entry of women with severe obstetric hemorrhage.[a]

	Pre-intervention (n = 83)	Intervention (n = 86)
Demographic characteristics		
Age, y	29.6 ± 7.2	30.4 ± 7.6
Parity	5.7 ± 3.5	6.8 ± 3.8
Weeks of pregnancy (n = 135) [b]	36.63 ± 5.3	37.61 ± 3.5
Condition at study entry		
Non-uterine atony diagnosis [c]	53 (63.9)	56 (65.1)
Estimated initial external blood loss, mL (n = 163) [d]	1413.1 ± 491.3	1304.2 ± 495.2
Women with initial MAP <60 mm Hg or non-palpable blood pressure (n = 168)	53 (63.9)	64 (75.3)

Abbreviation: MAP, mean arterial pressure.
[a] Values are given as mean ± SD or number (percentage).
[b] Excludes those with complications of abortion, or ectopic or molar pregnancies.
[c] Ectopic pregnancy, molar pregnancy, placenta previa, placenta accrete, abruption, ruptured uterus, lacerations, or genital trauma.
[d] Only women with non-zero blood loss at study admission.

Table 2
Treatment and outcome.[a]

	Pre-intervention (n = 83)	Intervention (n = 86)	*P* value
Treatment			
Women who received ≥1500 mL of intravenous fluids during the first hour	28 (33.7)	43 (50.0)	0.032 ($\chi^2=4.59$)
Women who received a blood transfusion during the first hour	10 (12.0)	6 (7.0)	0.260 ($\chi^2=1.27$)
Women with uterine atony who received any uterotonics (n = 60)	28 (93.3)	29 (96.7)	1.000 [b] ($\chi^2=0.35$)
Outcome			
Mortality	21 (25.3)	7 (8.1)	RR 0.32 (95% CI, 0.14–0.72)
Morbidity (n = 141)	1 (0.02)	0 (0.00)	—
Measured blood loss, mL (n = 166) [c]	340.4 ± 248.2	73.5 ± 93.9	<0.001 ($t=9.11$) [d]
Measured intraoperative blood loss, mL (n = 36)	323.2 ± 180.1	147.1 ± 206.8	0.010 ($t=2.74$)

Abbreviations: RR, relative risk; CI, confidence interval.
[a] Values are given as number (percentage) or mean ± SD unless otherwise indicated.
[b] *P* value calculated by Fisher exact test because 1 or more cells had an expected count of fewer than 5.
[c] Cases in which the blood collection drape was used and there were data for blood loss.
[d] *t* test conducted on the logarithm of blood loss because of the skewed distribution.

Among the women who were in a severe condition on study entry (MAP<60 mm Hg; 117 [70%]), those in the intervention phase had a significantly lower risk of dying than did those in the pre-intervention phase (72% reduction), in addition to significantly lower mean blood loss. Among the women in a less severe condition on admission (MAP≥60 mm Hg; 51 [30%]), those in the intervention phase had significantly lower mean measured blood loss and a non-significant reduction (52%) in mortality compared with those in the pre-intervention phase (Table 3). In the subgroup of 109 (64%) women without a diagnosis of uterine atony, patients in the intervention phase had significantly lower blood loss ($P<0.001$) and mortality than those in the pre-intervention phase (64% reduction). Among the 60 (36%) women with a diagnosis of uterine atony, those in the intervention phase had significantly lower blood loss and a non-significant reduction (75%) in mortality (Table 4).

4. Discussion

The introduction of the NASG in a low-resource tertiary care facility in northern Nigeria resulted in lower maternal blood loss and reduced maternal mortality due to hemorrhage.

Table 3
Blood loss and mortality outcome by level of severity at study entry (n = 168).[a]

	Pre-intervention	Intervention	*P* value
Severe cases	(n = 53)	(n = 64)	
Mortality	18 (34.0)	6 (9.4)	RR 0.28 (95% CI, 0.12–0.65)
Measured blood loss, mL (n = 114) [b]	360.0 ± 245.1	71.0 ± 89.1	<0.001 ($t=7.97$) [c]
Less severe cases	(n = 30)	(n = 21)	
Mortality	3 (10.0)	1 (4.8)	RR 0.48 (95% CI, 0.05–4.27)
Measured blood loss, mL [b]	305.8 ± 254.1	79.5 ± 110.6	<0.001 ($t=4.56$) [c]

Abbreviations: RR, relative risk; CI, confidence interval.
[a] Values are given as number (percentage) or mean ± SD unless otherwise indicated.
[b] Cases in which the blood collection drape was used and there were data for blood loss.
[c] *t* test conducted on the logarithm of blood loss because of the skewed distribution.

Table 4
Blood loss and mortality outcome by diagnosis group.[a]

	Pre-intervention	Intervention	*P* value
Uterine atony	(n = 30)	(n = 30)	
Blood loss measured in drape, mL [b]	364.7 ± 219.3	42.3 ± 51.9	<0.001 ($t = 7.85$) [c]
Mortality	8 (26.7)	2 (6.7)	RR 0.25 (95% CI, 0.06–1.08)
Other hemorrhage diagnosis	(n = 53)	(n = 56)	
Blood loss measured in drape, mL (n = 106) [b]	326.7 ± 264.2	91.1 ± 107.4	<0.001 ($t = 6.09$) [c]
Mortality	13 (24.5)	5 (8.9)	RR 0.36 (95% CI, 0.14–0.95)

Abbreviations: RR, relative risk; CI, confidence interval.
[a] Values are given as mean ± SD or number (percentage) unless otherwise indicated.
[b] Cases in which the blood collection drape was used and there were data for blood loss.
[c] *t* test conducted on the logarithm of blood loss because of the skewed distribution.

The findings of the present study are similar to those from the Egypt NASG pilot study [9], despite the lower resources of the Nigerian facility and the more severe shock experienced by the women entering the present study. In both investigations, the measured blood loss was significantly lower for women treated with the NASG: 78% lower in Nigeria and 50% lower in Egypt. Maternal mortality and morbidity were also lower in both studies, significantly so in Nigeria. An interesting finding from both investigations was the high percentage of etiologies not due to uterine atony among the cases of severe obstetric hemorrhage.

Although the literature states that uterine atony causes the majority of mortalities from obstetric hemorrhage [15,16], both of these trials found that uterine atony was responsible for only approximately 30% of severe hemorrhage with hypovolemic shock. Furthermore, atonic postpartum hemorrhage (PPH) accounted for 38% of all maternal deaths in the pre-intervention phase and 29% among women treated with the NASG. Outcomes showed a non-significant trend toward reduced mortality following treatment of atonic PPH with the NASG, indicating that single interventions, such as oral misoprostol at the community level, may be inadequate for addressing maternal mortality caused by obstetric hemorrhage and that strategies involving a broader-based continuum of care from community to facility may be more successful [17].

There was a reversal in the rates of morbidity and mortality between the Egypt NASG pilot investigation and the present study. During the intervention phase of the former study, there were no maternal mortalities and 2 severe end-organ morbidities—both renal failure—whereas there were 7 mortalities and no morbidities in the intervention phase of the latter study. We believe that this was because women in the Nigerian hospital with severe morbidities requiring intensive care did not survive because there were no options for nephrology specialists, pulmonary specialists, or any of the other intensive care specialities that existed in the Egyptian study facilities.

Major limitations to the present study were inherent in the pre-intervention and intervention design. Selection bias is always possible in a non-randomized study in which enrollment is dependent upon clinician choice. Clinicians may have become more experienced in the evidence-based management of obstetric hemorrhage by the intervention phase, which could explain the higher proportion of women in this group receiving at least 1500 mL of crystalloid fluid in the first hour. In addition, the clinician data collectors were few in number, busy, and functioning under extreme emergency conditions; it is likely that some study-eligible women came to the facility in either phase but were not enrolled. A limitation of the clinical site that may have affected outcome was the lack of a functioning blood bank and/or the difficulty in obtaining and financing blood donation by relatives. Delays in receiving blood transfusions were common, with 51.7% of women who required transfusions waiting more than 3 hours. These challenges in adhering to clinical protocols and to collecting data are probably indicative of how the NASG might function in real-world conditions in busy, understaffed, and understocked facilities in low-resource settings where women arrive at referral centers in moribund conditions.

Prevention and management of obstetric hemorrhage due to uterine atony are improving with the introduction of new procedures and technologies. However, despite prophylaxis, some women will have intractable uterine atony and many will suffer other etiologies of obstetric hemorrhage that are insusceptible to uterotonics. Furthermore, most women in low-resource settings do not deliver in referral facilities and they may experience hemorrhagic shock for which immediate treatment is lacking. Strategies and technologies are needed to help these women survive during transport to CEmOC facilities and during delays in receiving treatment at the facilities. The NASG is a new technology that could make a difference by buying women time and keeping them alive with adequate oxygen perfusion to the core organs. The promising outcomes of these pilot and quasi-experimental studies demand a rigorous experimental study set in limited-resource CEmOC facilities, with a high volume of maternal referrals from satellite health facilities. Such a study could inform maternal health advocates, providers, and policy makers of whether the NASG can make a significant difference to maternal morbidity and mortality.

5. Conflicts of interest

The authors have no conflicts of interest.

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