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The non-pneumatic anti-shock garment for postpartum haemorrhage in Nigeria

By O Ojengbede, H Galadanci, IO Morhason-Bello, D Nsima, C Camlin, JL Morris, E Butrick, C Meyer, Aminu I Mohammed, S Miller

Maternal mortality remains a serious public health issue globally. Postpartum haemorrhage (PPH) is the most common type of obstetric haemorrhage, with 150 000 lives lost per year (Devine, 2009), and so interventions are needed to reduce its incidence and to manage it when it happens. PPH has been defined as blood loss upwards of 500 ml and can occur in up to 18% of deliveries. Severe haemorrhage has been defined as blood loss upwards of 1000 ml and can occur in 1–5% of all deliveries (Devine, 2009). The biggest cause of PPH is uterine atony (World Health Organization (WHO), 2000), a complication that can sometimes require blood transfusions and surgery. In developing countries, delays in recognition of haemorrhage, decision to refer, transport to a tertiary facility, and timely receipt of quality, appropriate care, can often lead to emergency hysterectomy and death (McCarthy and Maine, 1992; Ezechi et al, 2004).

Active management of third stage labour (AMSTL) is recommended for all women to prevent uterine atony and includes administration of a uterotonic within 5 minutes of delivery, controlled cord traction, and uterine massage (WHO, 2000). Research has shown AMSTL to reduce the incidence of PPH by up to 60% (Prendiville et al, 2000; Derman et al, 2006), but for many women, haemorrhage will still occur and delays in accessing definitive treatment put them at great risk.

A new device called the non-pneumatic anti-shock garment (NASG) (Zoex Corporation, Ashland, OR, USA) may prove a useful intervention for stabilizing women with obstetric haemorrhage. This low-technology device is a garment made of neoprene that fits around the lower body. The garment has nine segments which close tightly with Velcro around a woman's legs, pelvis and abdomen, with a foam compression ball in the abdominal segment (*Figure 1*). A recent Doppler imaging study of blood flow to the uterus of postpartum women has demonstrated that application of the NASG results in a significant increase in the resistive index (RI) of the internal iliac artery (which is responsible for supplying the majority of blood flow to the uterus via the uterine arteries) (Lester et al, 2011). At baseline, the median RI of the internal iliac artery was 0.83 (standard deviation (SD) 0.11), which increased to 1.05 (SD 0.15) on full application of the NASG ($P=0.02$). Another Doppler imaging study has shown the NASG to decrease blood flow in the distal aorta (Hauswald et al, 2010). At baseline the mean flow was measured as 1.99 litre/min. Mean flow decrease was 0.65 with the NASG (95% confidence interval (CI) 0.03–1.26; $P=0.04$).

Abstract

Objective: This study examines whether the non-pneumatic anti-shock garment (NASG) reduces blood loss and mortality from uterine atony.

Method: The sample was taken from delivering women at four referral facilities in Nigeria who suffered obstetric haemorrhage, from which a subset of women with aetiology of post-partum uterine atony were examined. Data were collected by hospital staff and included 139 women, 54 in the pre-intervention phase and 85 in the NASG intervention phase. Differences in demographics, condition on study entry, treatment and outcomes were examined. Relative risks and 95% confidence intervals were used for primary outcomes of blood loss and mortality.

Results: Median measured blood loss decreased from 360 ml pre-intervention to 30 ml in the NASG phase ($P<0.001$). Mortality was reduced 72% for women treated with the NASG from 16.7% pre-intervention to 4.7% during the NASG phase (relative risk=0.28, 95% confidence interval 0.09–0.87).

Conclusion: The NASG shows promise for reducing blood loss and death from haemorrhage and shock due to uterine atony.

The NASG may be especially useful in low-resource settings due to the fact that training in its use is minimal and women can remain in it for long periods of time with no ill effect. A new manufacturer has said that it can be sold at US\$55 per garment (RTI International, 2011). As it can

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Figure 1. A patient being treated in the NASG

be used up to 40 times (with a simple decontamination and cleaning process between uses), the NASG has a potential cost per use of under US\$1.50. It is easy to treat women in the NASG as it remains in place during uterine massage and vaginal procedures, and only the abdominal segment is opened during surgical procedures. Veins can be easier to find with the NASG applied, allowing for quick initiation of intravenous fluids.

Previous studies of the NASG have shown significantly reduced measured blood loss, more rapid recovery times, and reduced maternal mortality and morbidity (Hensleigh, 2002; Brees et al, 2004; Miller et al, 2006a; Miller et al, 2007; Miller et al, 2009; Miller et al, 2010a; Miller et al, 2010b). In Nigeria and Egypt, among 1442 women suffering severe hypovolaemic shock secondary to obstetric haemorrhage of all aetiologies, blood loss was decreased by 46% in the NASG phase ($P < 0.001$), mortality was reduced from 6.3% to 3.5% (relative risk (RR) 0.56, 95% CI 0.35–0.89), severe morbidities from 3.7% to 0.7% (RR 0.20, 95% CI 0.08–0.50), and emergency hysterectomy from 8.9% to 4.0% (RR 0.44, 95% CI 0.23–0.86). A multiple logistic regression model showed a 55% reduced odds of mortality during the NASG phase (odds ratio (OR) 0.45, 95% CI 0.27–0.77) and a number needed to treat for benefit (NNTb) to prevent either mortality or severe morbidity of 18 (12–36).

In this article, the impact of the NASG on women with a primary diagnosis of PPH due to uterine atony in four comprehensive emergency obstetric care (CEmOC) facilities in Nigeria will be considered. Nigeria has one of the highest rates of maternal mortality in the world with 1 in 18 lifetime risk of dying from pregnancy and childbirth-related complications, and extremely low numbers of assisted deliveries (United Nations Children's Fund (UNICEF), 2008). This article will explain how the study was conducted, the results and implications for further research and use of this garment in Nigeria and elsewhere.

Methods

Setting

This analysis was part of a larger NASG project conducted between March 2004 and May 2007 at 12 hospitals in Northern and Southern Nigeria ($n = 990$). This article reports on a sub-analysis of 139 women with hypovolaemic shock secondary to severe obstetric haemorrhage due to uterine atony in four of the hospitals: Murtala Mohammed Specialist Hospital (MMSH), Katsina General Hospital and Aminu Kano Teaching Hospital in Northern Nigeria, and University College Hospital in Southern Nigeria. These four hospitals were selected for the analysis due to having comparable numbers of pre-intervention phase and NASG (intervention) phase patients enrolled. They represent large tertiary level teaching facilities with approximately 1250–10 000 deliveries each annually.

Protocol

The study was a pre-intervention phase/intervention phase design. As described in greater detail elsewhere (Miller et al, 2009), during the pre-intervention phase, standardized, evidence-based obstetric haemorrhage prevention and management was reviewed with the facility staff clinicians (mainly nurse-midwives, nurses and physicians). Treatment and outcomes were recorded on all eligible patients. Inclusion criteria for the parent study were women with severe obstetric haemorrhage with an estimated initial blood loss of ≥ 750 ml and at least one sign of shock (systolic blood pressure (SBP) < 100 mmHg and/or pulse > 100 beats per minute (BPM)). Women were enrolled regardless of whether the delivery took place outside the hospital (at home or in a clinic) and were transferred while bleeding, or whether they delivered and started bleeding at the hospital.

At the end of the pre-intervention phase, another training session took place with clinicians at the same facilities. The standard, evidence-based prevention and management of PPH was reviewed, and the NASG added as the intervention. Data were then collected on treatment and outcomes during this intervention phase.

On study enrolment, a blood collection drape (BRASSS-V Fixable Drape™ Madurai, India) was placed under the woman's buttocks to accurately measure blood loss. Patients received an evidence-based protocol for the treatment of PPH. These standard protocols for the treatment of haemorrhage and shock were administered regardless of the phase of the study (both pre-intervention phase and NASG intervention phase) and management included administration of crystalloid intravenous fluids (> 1500 ml in the first hour), administration of uterotonic medications and uterine massage. The treatment of uterine atony also included necessary vaginal procedures (bimanual compression, manual removal of placenta and dilatation and curettage for retained tissue), provision of blood transfusions and/or surgery (arterial ligation, B-lynch compression sutures, hysterectomy) if required. Vital signs, level of consciousness, urine output and blood loss were monitored throughout the duration of the study. Women were deemed stable and discharged from the study after the cause of bleeding was found and treated, blood loss

had decreased to ≤ 50 ml per hour, and vital signs were stable (SBP > 100 , pulse < 100 BPM) for 2 hours.

After the pre-intervention phase, clinicians were trained in the use of the NASG and its place in the standardized protocol for management of obstetric haemorrhage and shock. On enrolment in the intervention phase, the NASG was applied at the same time as the blood collection drape. It is applied starting at the ankles, then the calves, thighs, pelvis and abdomen. The NASG remained in place until study discharge. If the woman required a vaginal procedure, all sections of the NASG were left in place. If she required surgery, the abdominal and pelvic segments were opened immediately prior to making the incision then replaced as soon as surgery was completed. After the patient was stable for 2 hours, removal would follow the same procedure as application, commencing at the ankle, moving up, and allowing 15 minutes between each segment. After each 15 minutes from segment removal, the pulse and blood pressure were measured. If these remained stable, removal continued; if blood pressure fell by 20 mmHg or pulse increased by 20 BPM, all segments were rapidly replaced and the patient re-evaluated for need of further fluids, blood or treatment.

Clinician data collectors were physicians, nurses and midwives who were trained in a standardized protocol for management of obstetric haemorrhage and shock, blood collection and measurement, completion of data collection forms, and use of the NASG. Data were collected during or immediately after treatment of the patient. Both the trained data supervisors and the Nigerian Principal Investigators reviewed data forms. Data were entered into a Microsoft Access database at the University of California, San Francisco (UCSF) and checked for errors and inconsistencies prior to analysis.

Outcomes measured were cumulative blood loss which was measured hourly after study admission using the calibrated, closed-end, plastic blood collection drape. The other main outcome was number of mortalities during the duration of the study. The key indicator of the severity of the woman's condition at study entry was mean arterial pressure (MAP) ($[2 \times \text{diastolic blood pressure} + \text{systolic blood pressure}] / 3$). Women with MAP < 60 mmHg, including those with non-palpable SBP, were considered to be in more severe shock (McAuley, 2005). Treatment variables included receipt of ≥ 1500 ml of crystalloid IV fluids and blood during the first hour from study admission, receipt of blood any time after study admission, and uterotonics given at any time.

Comparative analyses for demographic characteristics, condition on study entry and treatment received for women in the two study phases were conducted using *t*-tests and chi-square tests. Relative risks (RR) and 95% confidence intervals (CI) were computed for measured blood loss and mortality. Data were analysed using Statistical Package for the Social Sciences (SPSS) 16.0 for Windows and STATA version 10.

Ethics

Verbal consent was granted by women for the study to use their data in the pre-intervention phase, and written consent was given by women to use the NASG and to use their data in the intervention phase. For women who were unconscious or confused at the time of study admission, a U.S. Federal

Table 1. Demographics, diagnoses and condition on entry to study, by phase (n=139)

	Pre-intervention (n=54)	Post-intervention (n=85)	Statistical test
Demographics			
Mean age*	30.6 (6.4)	30.9 (6.0)	$P=0.821$
Mean parity*	6.3 (3.3)	5.2 (3.3)	$P=0.053$
Median parity (IQR)	6 (4–9)	5 (2–7)	$P=0.069$
High parity (>4)	35 (64.8)	48 (56.0)	$P=0.330$
Mean duration of pregnancy†	38.0 (2.7)	37.5 (2.8)	$P=0.330$
Median weeks (IQR)	38 (38–40)	38 (37–39)	$P=0.152$
Condition on study entry			
Mean estimated blood loss (ml)	1447.2 (447.6)	1458.0 (591.8)	$P=0.909$
Median blood loss (IQR)	1500 (1000–1800)	1500 (1000–2000)	$P=0.852$
Women unconscious at study entry	5 (9.4)	6 (7.2)	$P=0.646$
Women with MAP or non-palpable blood pressure (%)	35 (64.8)	65 (76.5)	$P=0.136$

NASG=Non-pneumatic anti-shock garment; IQR=Interquartile range; MAP=Mean arterial pressure. Data are *n* (column %), mean (SD) or median (IQR). Tests of significance of differences by study phase were chi-square for categorical variables, *t*-tests (assuming unequal variances) for normally-distributed continuous variables and Wilcoxon rank-sum tests for non-normal distributions. * Data missing for one case. † Data missing for nine cases.

Table 2. Treatment by phase (n=139)

	Pre-intervention (n=54)	Post-intervention (n=85)	Statistical test
Received ≥ 1500 ml of IV fluids in the first hour from study admission*	26 (48.15)	52 (61.2)	$P=0.131$
Received blood transfusion in the first hour from study admission	5 (9.3)	15 (17.7)	$P=0.218†$
Received blood transfusion any time after study admission	44 (81.5)	72 (83.7)	$P=0.618$
Uterotonics given any time after study admission**	51 (94.4)	77 (91.7)	$P=0.539$

Data are *n* (column %). * The protocol asked for 1500 ml to be administered in the first hour of resuscitation. † *P*-value calculated by Fisher's exact test since one or more cells had expected count of 5 or less. ** Data missing for one person.

Table 3. Outcomes by phase (n=139)

	Pre-intervention (n=54)	Post-intervention (n=85)	Statistical test
Mean blood loss as measured in the drape (ml)*	458.2 SD=292.7	55.6 SD=81.3	$P<0.001$
Median blood loss (IQR)	360 (225–600)	30 (0–78)	$P<0.001$
Mortality	9 (16.7)	4 (4.7)	RR=0.28 95% CI=0.09–0.87

IQR=Interquartile range; SD=Standard deviation; RR=relative risk; CI=Confidence interval
* Data are for 76 cases

waiver of consent (45 CFR 46, 45 CFR 164.512) permitted initiation of treatment without consent, but written consent was required once the patient returned to normal sensorium or a relative gave consent on her behalf. Approval for the study was obtained from by the University of California, San Francisco Committee on Human Research (CHR) (approval number H6899-23524) and given ethical clearance by the National Reproductive Health Research Committee of the Nigerian Federal Ministry of Health.

Results

For this sub-analysis, data was analysed for 139 women with a primary or secondary diagnosis of uterine atony, 45 in the pre-intervention phase and 85 in the NASG phase. There were no statistically significant differences between women in the two phases with respect to demographics, with women in both phases on average 30 years of age, parity 5/6, delivering at 38 weeks of pregnancy (Table 1). Women were also similar between phases with regards to condition on study entry. Women in both phases experienced severe haemorrhage (median blood loss for each phase was 1500 ml). A large proportion of women in both phases were in severe shock (65% pre-intervention *vs.* 77% NASG-intervention, $P=0.136$).

There were no significant differences in receipt of any of the treatment variables (Table 2). Roughly half of the women in the pre-intervention phase received the protocol administration of >1500 ml crystalloid fluids in the first hour, with slightly more receiving it in the NASG phase ($P=0.131$). More women in the NASG phase received blood products in the first hour (18% compared to 9% pre-intervention, $P=0.218$) but this non-significant difference disappeared rapidly in the next hour (data not shown) and during the study period. Over 90% of women in both phases received uterotonic treatment.

Results demonstrated that mean measured blood loss during the study was significantly reduced in the NASG phase from 458 ml to 56 ml ($P<0.0001$). Median blood loss also showed this significant decrease, from 360 ml to 30 ml. There was also a reduction in mortality from 17% in the pre-intervention phase to 5% in the NASG intervention phase (RR=0.28, 95% CI 0.09–0.87) (Table 3).

Discussion

The introduction of the NASG in these four referral facilities in Northern and Southern Nigeria resulted in statistically significant decreases in maternal blood loss and reduced risk of death for women with postpartum haemorrhage due to uterine atony. The findings from this study support the growing body of evidence that the NASG is a valuable tool for hospital staff to use in treating women with obstetric haemorrhage of various aetiologies. While uterine atony in some cases can be treatable with injectable uterotonics (and in some countries, with oral, rectal or sublingual uterotonic misoprostol), they are not successful in treating all women. The NASG offers another intervention hospital staff can use to prevent emergency hysterectomy and death.

Although it was not possible to capture information on the rate of correct and consistent use of AMSTL, there is

evidence that it is a familiar but poorly understood intervention for obstetric care providers in Nigeria. A recent study on labour and delivery professionals in tertiary obstetric centres in Nigeria showed that only 28% were able to correctly and exclusively identify the components of AMSTL as recommended by the International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) (Oladapo et al, 2009). Educational interventions are much needed to help reduce incidence of PPH, as well as interventions such as the NASG to treat it once it happens.

It is interesting to note how few patients in both phases received blood transfusions within the first hour of the study. Even though transfusions are often essential to treat a woman who has haemorrhaged to the point of shock, many hospitals in Nigeria do not have a blood bank on site. Up until 2009, one of the study hospitals, the Murtala Muhammad Specialist Hospital in Northern Nigeria had no blood bank on site and patients often had to wait for more than 5 hours for blood to be found and brought to the maternity ward. This is despite being a facility averaging over 3000 deliveries per month, most of which involve complications (since it is a tertiary care facility, it is for patients seeking urgent, specialized care) and having one of the highest rates of maternal mortalities from PPH (Pathfinder International, 2009). This underscores the need for stocked blood banks at all CEmOC facilities in Nigeria and elsewhere.

Study limitations

This non-randomized study had limitations, including a possible selection bias as enrollment was dependent on clinician choice. Also, it is possible that not all women who met the study eligibility criteria were enrolled in the study. Clinicians' skills in management of haemorrhage could also have improved over time so that those women seen in the NASG phase received improved treatment. Data on treatment is suggestive that patients in the NASG phase received slightly more treatment (IV fluids and blood transfusions) in the first hour, although this was not statistically significant. As this study was integrated into busy, understaffed, understocked referral facilities, adherence to clinical protocols was also a challenge, although results may reflect how the NASG functions in such 'real' environments.

“The findings from this study support the growing body of evidence that the NASG is a valuable tool for hospital staff to use in treating women with obstetric haemorrhage of various aetiologies.”

Conclusions

Even in CEmOC facilities, delays in obtaining definitive treatment for women with haemorrhage secondary to uterine atony can occur; these delays can sometimes lead to irreparable organ damage and death. The NASG was helpful for stabilizing women throughout these delays in this study, and may be an important tool for providers in other low-resource health facilities.

The findings from this study and others on the NASG in Nigeria (Miller et al, 2006b; Miller et al, 2009) have implications for clinicians and policymakers. Not only have clinicians seen the results of the NASG with their own eyes, they have embraced the technology as another tool they can utilize to save women's lives (as detailed in qualitative studies with providers at these research facilities) (Oshinowo, 2007; Liu, 2009). In addition, the NASG has already been accepted by at least four states in Nigeria as part of a 'Continuum of Care' package for PPH that is being implemented by a non-governmental organization (NGO), Pathfinder International (Geller et al, 2007).

While this study in Nigeria suggests the promise of the NASG for uterine atony cases at the referral hospital level, further research with an experimental study design at the level of primary health care facilities on women referred to a CEmOC facility in the NASG is currently being undertaken in Zambia and Zimbabwe (Clinicaltrials.gov, 2011). If evidence from this more rigorously designed and larger study indicates efficacy, it may encourage more widespread endorsement and scale up of the NASG in Nigeria at lower-level facilities as well as CEmOC facilities, and throughout developing countries, particularly in Africa, where maternal deaths from PPH remain unacceptably high.

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Key Points

- The non-pneumatic anti-shock garment (NASG) is a low-technology device to stabilize women with hypovolaemic shock secondary to severe obstetric haemorrhage
- In this pre-intervention phase/intervention phase study, the NASG was examined in women with postpartum hemorrhage due to uterine atony ($n=139$). The setting was four referral facilities in Northern and Southern Nigeria
- Results show that blood loss and mortality were significantly decreased for women in the NASG intervention phase