

First aid for obstetric haemorrhage: the pilot study of the non-pneumatic anti-shock garment in Egypt

S Miller,^a S Hamza,^b EH Bray,^c F Lester,^d K Nada,^e R Gibson,^e M Fathalla,^f M Mourad,^g A Fathy,^b JM Turan,^a KQ Dau,^a I Nasshar,^h I Elshair,^e P Hensleighⁱ

^a Women's Global Health Imperative, Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco, San Francisco, CA, USA ^b Ain Shams University Specialized Hospital, Abbassia, Cairo, Egypt ^c Maternal and Child Health Program University of California, Berkeley, School of Public Health, Berkeley, CA, USA ^d Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco, School of Medicine, San Francisco, CA, USA ^e John Snow Inc., Maadi, Cairo, Egypt ^f Assiut University Teaching Hospital, Assiut, Egypt ^g El Galaa Teaching Hospital, Cairo, Egypt ^h Al Minya University Teaching Hospital, Al Minya City, Egypt ⁱ Department of Obstetrics and Gynecology, University of Stanford, CA, USA

Correspondence: Dr S Miller, Women's Global Health Imperative, Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco, 50 Beale Street, Suite 1200, San Francisco, CA 94105, USA. Email smiller@globalhealth.ucsf.edu; suellenmiller@hotmail.com

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Objective To compare the effect of non-pneumatic anti-shock garment (NASG) on blood loss from obstetric haemorrhage with standard management of obstetric haemorrhage.

Design Observational study of consecutive obstetric haemorrhage cases before and after introduction of the NASG.

Setting Four tertiary care maternity facilities in Egypt.

Sample The sample consisted of women with obstetric haemorrhage and signs of shock and the entry criteria were: >750 mL of blood loss and either pulse of >100 beats per minute or systolic blood pressure of <100 mmHg. A total of 158 women were in the preintervention group and 206 in the postintervention group.

Methods All the women with haemorrhage meeting the eligibility criteria were treated according to the standard protocol for 4 months (May–August 2004); blood loss was measured and recorded. The NASG was then introduced, and all the women

meeting the eligibility criteria were treated according to the standard haemorrhage protocol plus the NASG for 4 months (September–December 2004).

Main outcome measures Measured blood loss collected in a closed-end, graduated, plastic, under buttocks collection drape.

Results Median measured blood loss in the drape following study entry was 50% lower in those treated with the NASG (250 versus 500 mL, $P < 0.001$). There was also a non-statistically significant decrease in morbidity and mortality.

Conclusions This is the first comparative study of the NASG with a standard obstetric haemorrhage treatment protocol. The NASG shows promise for management of obstetric haemorrhage, particularly in lower resource settings. Larger studies will be needed to determine if the NASG contributes to statistically significant decreases in morbidity and mortality.

Keywords Emergency obstetric care, obstetric haemorrhage.

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Introduction

Every year, an estimated 529 000 women die from complications of pregnancy and childbirth, with 99% of these deaths occurring in the developing countries.¹ Egypt has been successful in decreasing the maternal mortality ratio (MMR) from 174/100 000 live births in 1992–93 to 84/100 000 births in 2000.² However, too many women are still dying from

obstetric haemorrhage, with 60% of maternal deaths in Egypt attributed to haemorrhage.² The non-pneumatic anti-shock garment (NASG)³ was suggested as a first-aid device to reverse shock and decrease bleeding among women with severe obstetric haemorrhage and hypovolaemic shock in Egypt.

The NASG (Zoex Corporation, Ashland, OR, USA) is a simple, relatively inexpensive, lightweight, reusable compression

suit, comprising five neoprene segments that close tightly with Velcro around the legs, pelvis, and abdomen. The abdominal segment incorporates a small foam pressure ball to supply uterine compression (Figures 1 and 2). The entire garment, when tightly applied by one person, supplies 20–40 mmHg circumferential pressure. This lower body circumferential counterpressure shunts blood from the lower extremities and abdominal area to the essential core organs: heart, lungs, and brain. Within minutes of application, women suffering from shock have been seen to regain consciousness and normalise their vital signs.^{3,4} In addition to reversing shock, exerting circumferential pressure decreases both the transmural pressure and the radius of uterine, abdominal, and other lower body arteries.⁵ According to the physics of blood flow as expressed by the LaPlace law, the Poiseuille's law, and the Bernoulli principle, this reduction in transmural arterial pressure is effective in reducing blood loss.⁵

In a workshop on 'New and Underutilized Technologies to Reduce Maternal Mortality', held in Bellagio, Italy, July 2003, maternal health specialists recommended a large-scale randomised or quasi-experimental trial to determine if the NASG could reduce maternal morbidity and mortality in low-resource settings.⁶ The study described below is one of three pilots currently being conducted as first steps to undertaking this larger study.

Methods

A prepost pilot trial of the NASG was conducted in three university teaching hospitals (Assiut, Alexandria, and Al Minya) and in one teaching hospital (El Galaa) in Egypt. The primary outcome variable was the volume of blood loss,

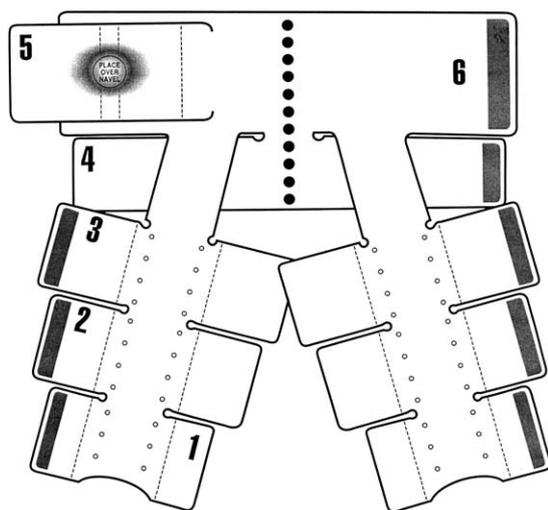


Figure 1. Schematic diagram of NASG. Reproduced with permission from Hensleigh PA. *BJOG* 2002;109:1377–84.³

measured in a graduated collection drape, following recruitment. In previous tests of the collection drape, the measured blood loss was 1400 mL. A sample size of 150 preintervention women and 150 postintervention women was calculated as being needed to be able to detect a 50% or greater reduction in measured blood loss in the drape, with power (1- β) of 0.80 and a significance level (α) of 0.05.⁷

Women at any stage of pregnancy were included in the study if they were in clinical shock and had at least a heartbeat on arrival at the hospital, following obstetric haemorrhage (including abortion and ectopic pregnancy). The entry criteria were an estimated blood loss of over 750 mL and either a pulse of >100 beats per minute (bpm) or a systolic blood pressure (BP) of <100 mmHg. Women with an unobtainable BP or an unpalpable pulse were included in the study only if the heart was still beating and if they had been bleeding for less than 2 hours. However, as this was a clinical intervention, the study coordinators urged the clinicians to use the NASG on any case in which they felt it might resuscitate the patient. The postintervention phase included two women on whom the NASG was used but who did not meet the entry criteria. Their data are not included in this study.

A graduated, closed-end, plastic blood collection drape was placed under the woman's buttocks when she met the study entry criteria. The primary outcome was blood loss measured in the drape. Other outcomes included blood loss measured in the suction bottle during surgery for those requiring surgery ('intraoperative blood loss'), blood loss measured in the suction bottle during vaginal procedures involving suction, and 'other' for estimated blood lost on floor, gauze, spilled, etc., during surgery. Although blood in the peritoneal cavity was suctioned and measured, intraoperative blood loss was not felt to be reflective of the true results of placing the woman in the NASG as blood suctioned from the peritoneal cavity and uterus may have pooled there before the NASG was placed. The measured quantity of blood in the suction bottle for vaginal procedures was minimal. Therefore, blood loss in the drape was felt to be the most accurate measurement of the effect of the NASG and to be the only outcome that did not include estimates.



Figure 2. Patient in NASG.

Vital signs and blood loss were monitored until the woman was stable and blood loss had decreased to approximately 50–100 cm³/hour. Standard protocols for the treatment of haemorrhage and shock for the hospitals were followed, including administration of crystalloid intravenous fluids, use of uterotonic medications (IV oxytocin and rectal misoprostol) uterine massage, determining the source of bleeding, and providing blood transfusions and surgery as necessary. Vaginal procedures included manual removal of the placenta, suturing of lacerations, manual vacuum aspiration or suction curettage, and uterine evacuation using ring forceps (also known as 'sponge sticks' or 'sponge holders'). Surgery was performed when the haemorrhage continued despite the other interventions. Practitioners used a variety of surgical interventions (step-wise ligation of uterine arteries, B-Lynch suture, or hysterectomy) according to their experience and the clinical situation. The only difference in care for the women in the NASG group was that the NASG was placed on the woman when she met study entry criteria. The abdominal section of the NASG was stretched outwards to allow for abdominal palpation and bimanual compression. If the woman required a vaginal procedure, the NASG was left completely in place. If the woman required an abdominal procedure, the NASG was left in place and only the abdominal segment opened immediately prior to making the incision. That segment was then replaced as soon as the surgery was completed. Other than opening the abdominal segment for those requiring abdominal surgery, the NASG was left in place until the woman had stable vital signs (minimal criteria were pulse of <100 bpm and systolic BP of >100 mmHg) for at least 2 hours.

Physician/data collectors were trained in a standardised protocol for management of obstetric haemorrhage and shock, collection of blood using the closed-end drape, and completion of data collection forms before the preintervention phase. In September 2004, the sites were revisited and the physician/data collectors were trained in use of the NASG, before the postintervention phase.

The study protocol was approved by the University of California, San Francisco Committee on Human Research (CHR), the University of California, Berkeley Committee for the Protection of Human Subjects, and the CHRs of the individual participating hospitals. All the women involved provided an informed consent; a waiver was obtained so that women who were unconscious or confused at the time they were admitted to the study provided an informed consent during their recovery.

Frequencies, means, and medians were calculated for demographic and outcome variables. Tests of significance included Student's *t* test, chi-square test, Mann–Whitney *U* test for unequal variances, relative risks (with 95% CI), and median differences (with 95% CI). Data were analysed using SPSS 13.0 (SPSS Inc., Chicago, IL, USA).

Results

A total of 369 records were completed at the hospital study sites in Egypt. During the process of data cleaning, we identified five women (two preintervention and three postintervention) who did not meet the study entry criteria, and these women were excluded from the final analysis. Recalculation of the primary outcome (blood loss) with these women included did not affect the results. Three of the women did not meet the entry criteria on the basis of haemorrhage and/or vital signs and, as previously described, two women had no heart-beat on arrival. The resulting total sample size is 364, with 158 women in the preintervention group (control) and 206 in the NASG group.

As shown in Table 1, the women in the NASG group had significantly fewer previous pregnancies, although they were of similar age. The women in the NASG group also had a statistically significant greater loss of blood at the time of entry to the study and more severe signs of shock compared with women in the preintervention group. The causes of obstetric haemorrhage included a range of primary diagnoses; there were no statistically significant differences between women in the preintervention group and the NASG group. The three most common diagnoses were uterine atony, genital lacerations, and complications of abortion.

There was a statistically significant 50% decrease in median measured blood loss in the drape among women with obstetric haemorrhage, who were treated with the NASG, compared with women in the preintervention group (Table 2). The median volume of measured intraoperative blood loss for women undergoing surgery, this was not statistically significantly greater for women in the NASG group than for those in the preintervention group, but statistically significant for blood transfusion. Median total blood loss after entry to the study (measured and estimated) was statistically significantly less for those with the NASG. There were no statistically significant differences between the groups in numbers of abdominal surgeries or vaginal procedures performed. There were five cases of mortality or severe morbidities for the preintervention group, in which two women died, two had renal failure, and one had cerebral impairment (seizures and mental confusion). There were two women in the NASG group who suffered morbidities, both had cerebral impairment, one had seizures and one had mental confusion. There were no mortalities in the women in the NASG group.

A subgroup analysis of 109 women (43 preintervention cases and 66 NASG cases) who had ≥ 1500 mL blood loss at trial entry resulted in similar findings. The women with the NASG entered the study with slightly greater median blood loss (1600 mL, range 1500–3000 mL) than women in the preintervention group (1500 mL, range 1500–2000 mL). The median difference was 100 mL (95% CI 102, 310). The

Table 1. Demographic characteristics, diagnoses, and clinical condition on entry to study for preintervention and postintervention groups (chi-square or Fisher's exact test for categorical variables and Student's *t* test or Mann–Whitney *U* test for continuous variables)

Demographics/Diagnosis	Preintervention (n = 158)	NASG (n = 206)
Demographics		
Mean age (±SD)	27.3 ± 6.1	27.4 ± 5.7
Median parity (range)	2 (0–12)	1 (0–9)
Median gravidity (range)*	3 (1–13)	2 (1–11)
Diagnosis, n (%)		
Uterine atony	69 (43.7)	76 (36.9)
Genital lacerations	31 (19.6)	37 (18.0)
Complications of abortion	30 (19.0)	37 (18.0)
Retained placenta/fragments	11 (7.0)	15 (7.3)
Ectopic pregnancy	9 (5.7)	19 (9.2)
Abruption of the placenta	6 (3.8)	14 (6.8)
Ruptured uterus	5 (3.2)	7 (3.4)
Placenta praevia	4 (2.5)	6 (2.9)
Molar pregnancy	4 (2.5)	5 (2.4)
Inverted uterus	0	1 (0.5)
Condition on study entry		
Median estimated blood loss (mL, range)**	750 (750–2000)	975 (500–3000)
Mean pulse (bpm ± SD)	113.3 ± 10.8	113.5 ± 15.5
Mean systolic BP (mmHg ± SD)***	97.5 ± 17.7	88.7 ± 17.8
Mean diastolic BP (mmHg ± SD)***	61.1 ± 13.6	56.9 ± 13.3
Coagulopathy, n (%)	7 (4.4)	8 (3.9)

*Significantly different by Mann–Whitney ($P = 0.03$).

**Significantly different by Mann–Whitney ($P < 0.001$).

***Significantly different by Student's *t* test ($P < 0.005$).

median measured blood loss in the drape after study entry was statistically significantly lower for the NASG users (250 mL, range 0–800 mL) compared with 700 mL (range 0–2400 mL) for preintervention cases (median difference –400, 95% CI –600 to –250).

Discussion

This pilot study conducted in tertiary-level teaching hospitals in Egypt demonstrates that the use of the NASG for the treatment of obstetric haemorrhage is associated with a statistically significant 50% decrease in measured median blood loss compared with standard clinical management of obstetric haemorrhage. We also found a non-statistically significant 69% decrease in severe maternal morbidities and mortalities combined among those with the NASG. However, the sample size is too small to determine if the NASG prevents morbidity or mortality.

The study is not only limited by the small sample but also by the fact that this was a prepost design and unblinded. This raises the possibility of provider bias, particularly when estimating the amount of blood loss for study entry. However, the fact that the women in the NASG group had statistically significantly lower mean systolic and diastolic BP may pro-

vide support for their worse status on entry. The lack of systematically recorded prepost haemoglobins or haematocrits prevents us from using changes in these indicators for more objective data on recovery status. Nor did this study capture time of reversal of shock; in future studies, measurements of time to regain normal vital signs and consciousness should be documented.

Taking into account, the fact that the women in the NASG group may have had more severe initial haemorrhage and shock than those in the preintervention group (which would generally predict a poorer prognosis for this group), the 50% decrease in blood loss among women in the postintervention group compared with those in the preintervention group is all the more promising. The finding that the effect of the NASG was even more pronounced in those situations where bleeding was greater than 1500 mL at study entry may indicate that the NASG decreases blood loss and prevents severe morbidity even in cases of severe haemorrhage.

The difference in condition on study entry may have been due to physician delay in applying the NASG, as it was a new technology and they were not conditioned to use it as readily as standard treatment. Physicians may also have chosen to use the NASG on only those women whose condition caused them more concern.

Table 2. Comparison of outcomes for women with obstetric haemorrhage and shock treated with standard management (preintervention) and those treated with standard management and NASG

Variable	Preintervention (n = 158)	NASG (n = 206)	Median Difference or Relative Risk (95% CI)
Blood loss			
Median blood loss as measured in the drape (in mL, range)**	500 (0–2400), n = 152	250 (0–900), n = 194	–200 (–250 to –120)
Median intraoperative blood loss from suction bottle for those who had abdominal surgery (in mL, range)**, ***	850 (50–2000), n = 26	1000 (50–3000), n = 36	300 (0–600)
Median estimated other blood loss (gauze, floor, etc.) (in mL, range)****	200 (30–2000), n = 76	200 (20–1100), n = 110	–50 (–100 to 0)
Median total blood loss after entry to the study (in mL, range)**	650 (0–3700), n = 149	450 (0–2650), n = 180	–200 (–300 to –100)
Transfusion			
Transfusion given	96 (61.1%)	155 (75.2%)	1.23 (1.06–1.43)*
More than 1000 mL blood transfused*****	21 (21.9%), n = 96	49 (31.8%), n = 154	1.45 (0.93–2.27)*
Surgery and procedures			
Abdominal surgery	29 (18.4%)	51 (24.8%)	1.35 (0.90–2.02)*
Vaginal procedure(s) only	30 (19.0%)	51 (24.8%)	1.30 (0.87–1.95)*
Morbidity and mortality			
Severe morbidity or mortality*****	5 (3.2%)	2 (1.0%)	0.31 (0.06–1.56)*

*Relative risk (95% CI).

**Different numbers in each outcome reflect missing data.

***For women who had abdominal surgery and non-missing data for intraoperative blood loss (n = 62).

****For women who had other blood loss greater than 0 (n = 186).

*****For women who had blood transfusions and non-missing data (n = 250).

*****Severe morbidity is defined as renal disease, acute respiratory distress syndrome, cardiac deficiency, or central nervous system damage.

Although not statistically significant, the women in the NASG group had a higher frequency of abdominal surgery. The difference in surgical intervention may reflect a difference in diagnosis. Although not statistically significant, the NASG group had a higher percentage of women with ruptured ectopic pregnancy and placental abruption, both of which require surgical management. Although the number was small and the 95% CI wide, when women did undergo surgery, there was a non statistically significant difference in intraoperative blood loss. This finding raises issues of measurement of intraoperative blood loss with the NASG on surgical patients. For the women with ectopic pregnancies, abruption of the placenta, and uterine rupture, it is normal to find a large quantity of blood in the abdomen (haemoperitoneum). It is impossible to know how much of the blood suctioned from the operative site of women in this study was lost prior to the application of the NASG; therefore, it is difficult to determine the effect of the NASG on internal blood loss. In future studies, we plan to measure the haemoperitoneum, which will be immediately suctioned upon making the surgical opening, and then to replace the suction bottle and measure the blood that is lost during the course of the surgery.

Studies similar to the Egyptian pilot of the NASG are currently being conducted in Mexico and Nigeria. In these locations, there are longer delays in transport from lower level centres to the referral hospitals and longer delays at the referral

centres in obtaining blood transfusions and surgery. We anticipate longer periods of time for measurement of blood loss in the drape and, because of a delay in obtaining definitive treatment, we expect to see greater differences between women in the preintervention group and NASG group in volume of blood lost and incidence of morbidity and mortality. For example, in 2003, the facility-level MMR in the Egyptian study hospitals was 120/100 000 compared with the facility-level MMR in the Nigerian study hospitals of 624 /100 000. Thus, we may see a greater effect of introducing the NASG in places where definitive treatment is delayed.

Conclusions

This study is a first step towards evaluating the effectiveness of the NASG as a first-aid device in the management of obstetric haemorrhage and hypovolaemic shock in developing countries. The NASG is lightweight, reusable, does not require sterilisation, is relatively of low cost, requires minimal training, and can be applied by one trained provider. It may prove to be an important temporising measure in overcoming the delays that contribute to maternal morbidity and mortality in developing countries where women deliver far from emergency obstetric care. A more rigorous study design with a larger sample size is needed before recommending large-scale implementation of this potentially life-saving technology.

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