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Treating uterine atony with the non-pneumatic anti-shock garment in Egypt

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Abstract

Objective: **To determine whether the non-pneumatic anti-shock garment (NASG) reduces maternal morbidity and mortality from uterine atony.**

Method: **Women with uterine atony (blood loss of ≥1000 ml) and one clinical sign of shock were enrolled in a pre-intervention phase (*n*=169) and an intervention phase (*n*=269) at two referral facilities in Egypt. Differences in demographics, condition on study entry, treatment, and outcomes were examined. Relative risks and 95% confidence intervals (CI) were estimated for mean measured blood loss, emergency hysterectomy, and extreme adverse outcomes (EAO)—a combination of morbidity and mortality.**

Results: **In the intervention phase, mean measured blood loss was significantly reduced, emergency hysterectomy was significantly decreased, and there were fewer EAOs (11% to 3% in the NASG phase, relative risk=0.28, 95% CI: 0.12–0.63). A subgroup analysis of only women in severe shock demonstrated similar trends.**

Conclusion: **The NASG shows promise for reducing blood loss, emergency hysterectomies, and EAO from obstetric haemorrhage-related shock due to uterine atony.**

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality worldwide, particularly in low-resource settings where access to blood and surgery is limited. It is the most common type of obstetric haemorrhage, claiming an estimated 150 000 lives per year (Devine, 2009). PPH (blood loss exceeding 500 ml) complicates up to 18% of all deliveries, and severe haemorrhage (blood loss exceeding 1000 ml) is seen in 1–5% of all deliveries (Devine, 2009). PPH results in suffering for women and their families and creates considerable demands on the health system (Abouzahr, 1998). The most common cause of PPH is uterine atony (World Health Organization (WHO), 2000). This complication, when severe enough, can require an emergency hysterectomy to prevent maternal death (Ezechi et al, 2004).

One way to prevent uterine atony is through the active management of third-stage labour (AMTSL), which includes administering a uterotonic within 5 minutes of delivery, controlled cord traction, and uterine massage (WHO, 2000). Although AMTSL reduces the risk of PPH by up to 60% (Prendiville et al, 2000; Derman et al, 2006), thousands of women still haemorrhage and, without rapid recognition and treatment, die. In low-resource settings, a series of delays are responsible for the high death toll from PPH. The first delay may be in the decision to seek care, next are delays in obtaining transport, during transport from home/community level to comprehensive emergency obstetric care (CEmOC) facilities, and in obtaining definitive care at understaffed, undersupplied tertiary care facilities (McCarthy and Maine, 1992).

One new low-technology device for stabilizing women throughout these delays is the non-pneumatic anti-shock garment (NASG), a lower-body garment made of neoprene and Velcro™ (Zoex Corporation, Ashland, OR, USA). The garment has nine segments, which are closed tightly around a woman's legs and pelvis, and a foam compression ball that goes around the abdomen (*Figure 1*). The mechanisms of action involve circumferential compression of the legs and abdomen, which reduces the total vascular volume while expanding the central circulation, translocating blood back to vital organs. Application also increases preload, peripheral resistance and cardiac output. Additionally, tamponade of vessels (in particular the splanchnic plexus) reduces further blood loss.

The NASG has numerous qualities that enhance its applicability to low-resource settings. It is relatively inexpensive (approximately USD$170 per garment) and can be used up to 40 times with a simple decontamination and cleaning process between uses. Only minimal training is required, and uterine massage, vaginal procedures, and abdominal surgery can all be conducted with the NASG in place (with the abdominal segment being opened for the duration of surgical procedures).

Previous studies of the NASG have shown significantly reduced measured blood loss, more rapid recovery times, and decreased mortality and morbidity (Hensleigh, 2002;

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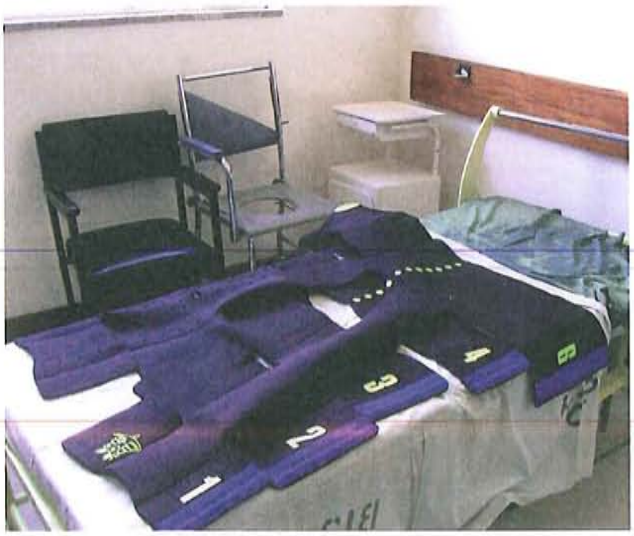

Figure 1. Placement of the non-pneumatic anti-shock garment

Brees et al, 2004; Miller et al, 2006; Miller et al, 2007; Miller et al, 2009; Miller et al, 2010a; Miller et al, 2010b). In this report, we examine the impact of the NASG on women with a primary diagnosis of uterine atony in CEmOC facilities in Egypt.

Method

Setting

This study was part of a larger NASG project conducted between June 2006 and May 2008 at two referral hospitals in Cairo, Egypt (n=990): El Galaa Maternity Teaching Hospital and Assiut University Women's Health Center (Miller et al, 2010b). This paper reports on a sub-analysis of 438 women with hypovolaemic shock secondary to severe obstetric haemorrhage due to uterine atony. The study was a pre-intervention/intervention design, with 169 women with uterine atony in the pre-intervention phase who were treated with a standardized evidence-based protocol and 269 women with uterine atony in the NASG phase who were treated with standardized protocol plus the NASG.

Protocol

Study eligibility criteria were aetiology of uterine atony, with an estimated initial blood loss of ≥1000 ml and at least one sign of shock (systolic blood pressure (SBP) <100 mmHg or pulse >100 beats per minute (BPM)). 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 and pulse <100 BPM) for 2 hours. At the beginning of the study, the clinicians were trained in evidence-based protocols for obstetric haemorrhage. These standard protocols for the treatment of haemorrhage and shock were administered regardless of the phase of the study. Interventions included administration of crystalloid intravenous (IV) fluids (≥1500 ml in the first hour), administration of uterotonic medications, uterine massage, 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.

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 and were then replaced as soon as the surgery was completed.

Outcomes measured were emergency hysterectomy, extreme adverse outcomes (EAO)—a combined measure of maternal mortality or severe morbidity (which includes more than 24 hours of: adult respiratory distress syndrome, renal failure, cardiac failure, and/or severe central nervous system impairment (including seizures, prolonged unconsciousness, and motor or cognitive impairment))—and cumulative blood loss, which was measured hourly after study admission using a calibrated, closed-end, plastic blood collection drape (BRASS-V Fixable Drape™, Madurai, India). Intraoperative blood and procedural blood was suctioned and measured using a graduated suction bottle. Also measured were side-effects that might have been associated with use of a compression garment, such as respiratory symptoms/dyspnoea, reduced urine output, nausea, vomiting, and abdominal pain.

The key indicator of the severity of the woman's condition at study entry was mean arterial pressure (MAP) ((2*diastolic blood pressure + systolic blood pressure)/3) (McAuley, 2005).

Women with MAP <60 mmHg, including those with non-palpable SBP, were considered to be in more severe shock. Treatment variables included receipt of ≥1500 ml of crystalloid IV fluids and blood during the first hour from study admission.

The 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. Data forms were reviewed by both the trained data supervisors and the Egyptian principal investigator. The data forms were further checked by the data team at the University of California, San Francisco (UCSF) for errors and inconsistencies prior to analysis.

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. As there was a skewed distribution, measured blood loss was log-transformed prior to analysis by t-tests. Relative risks (RR) and 95% confidence intervals (CI) were computed for EAOs and emergency hysterectomy. Data were analyzed using SPSS 16.0 for Windows and STATA version 10.

Ethics

Verbal consent was gained from the women to use their data in the pre-intervention phase, and written consent was gained from the women to use the NASG on them and to use their data in the intervention phase. For women who were unconscious or confused at the time of study admission, a US Federal Waiver of Consent (45 CFR 46, 45 CFR 164.512) permitted the commencement of treatment without consent, but for use of the data collected, written consent was required once the patient returned to normal sensorium or a relative gave it on her behalf. Approval for the study was obtained from the UCSF Committee on Human Research (CHR) (approval number H6899-23524) and the Institutional Review Boards of the El Galaa Maternity Teaching Hospital and Assiut University Women's Health Center.

Results

Data were collected on 438 women with a primary diagnosis of uterine atony, 169 in the pre-intervention phase and 269 in the NASG phase. Demographically, there were no statistically significant differences in age, parity, or duration of pregnancy between the pre-intervention and NASG groups. Condition on study entry shows that more women in the pre-intervention group had a MAP <60 mmHg (P=0.01) and that more pre-intervention women began bleeding at home or at the clinic rather than at the hospital (30% pre-intervention vs 19% NASG, P<0.01) (*Table 1*).

On the whole, treatment was slightly slower or less aggressive for women in the NASG phase, with fewer women receiving ≥1500 ml of fluid in the first hour (97% pre-intervention vs 77% NASG, P<0.01), or a blood transfusion in the first hour (98% vs 83%, P<0.01). Women in the pre-intervention phase had longer waits from the start of haemorrhage to first blood transfusion (108 minutes vs 79 minutes, P=0.04), although once enrolled in the study NASG women had a longer interval before receipt of their first blood transfusion (34 minutes pre-intervention vs 42 minutes NASG, P<0.01) and women in the NASG phase received in total a smaller volume of whole blood (1061 ml pre-intervention vs 642 ml NASG, P<0.01).

Table 1. Demographics and condition on study entry (n=438)

	Pre-intervention (n=169)	Post-intervention (n=269)	Statistical test
	Demographics		
Mean age (years)	28.1 SD=5.8	29.3 SD=5.9	t-test P=0.03
Mean parity	2.3 SD=2.0	2.6 SD=1.7	t-test P=0.05
Mean duration of pregnancy (weeks) (n=376)*	38.4 SD=2.8	38.4 SD=3.1	t-test P=0.85
	Condition on study entry		
Mean estimated blood loss (ml) (n=389)	1205.8 SD=497.6	1194.5 SD=319.0	t-test P=0.80
Women with MAP <60 (n)†	20.7% (35)	11.9% (32)	χ^2 P=0.01
Haemoglobin at study admission (g/dL)	7.1 SD=1.8	7.3 SD=1.1	t-test P=0.87
Unconscious at study entry (n)	4.9% (8)	1.9% (5)	χ^2 P=0.08
Bleeding began at clinic/home (n)	30.2% (51)	19.3% (52)	χ^2 P<0.01
Minutes from haemorrhage start to study admission. For those who began bleeding at:	74.6 SD=165.1	38.6 SD=84.4	t-test P=0.01
Home/clinic (n=76)	235.7 SD=257.8	174.9 SD=174.0	P=0.23
Hospital (n=332)	16.3 SD=27.2	17.1 SD=14.1	P=0.77

*Does not include pre-term pregnancies. †Includes women with non-palpable blood pressure. MAP, mean arterial pressure; SD, standard deviation.

Significantly more women received prophylactic uterotonics in the NASG phase (79% pre-intervention vs 87% NASG, P=0.03). Although the receipt of treatment uterotonics any time after study admission was similar between groups (98% pre-intervention vs 99.6% NASG, P=0.08), more women in the NASG phase received treatment uterotonics within the first hour (96% pre-intervention vs 99% NASG, P=0.03). On the whole, the mean number of doses administered was smaller in the NASG phase (3.4 pre-intervention vs 2.5 NASG, P<0.01) (*Table 2*).

Regarding study outcomes (*Table 3*), measured blood loss during the study period was significantly reduced in the NASG phase from 409 ml to 236 ml (P<0.01). Mean intraoperative blood was not significantly different between the phases. Emergency hysterectomies for intractable PPH were reduced from 12% to 5% (RR=0.41, 95% CI=0.21–0.80) and EAOs were reduced from 11% to 3% (RR=0.28, 95% CI=0.12–0.63). The mean number of hours spent in hospital

Table 2. Treatment (*n*=438)

	Pre-intervention (*n*=169)	Post-intervention (*n*=269)	Statistical test
Minutes from haemorrhage start to first blood transfusion	107.7 SD=163.6	78.5 SD=89.3	t-test *P*=0.04
Received prophylactic uterotonics	78.7% (133)	86.6% (233)	$\chi 2$ *P*=0.03
Minutes from study entry to first IV fluids	1.1 SD=2.57	1.4 SD=3.23	t-test *P*=0.30
Minutes from study entry to first blood transfusion	33.6 SD=10.7	42.3 SD=36.6	t-test *P*<0.01
	Within first hour of study admission		
Received ≥1500 ml of IV fluids*	96.5% (163)	77.3% (208)	$\chi 2$ *P*<0.01
Received a blood transfusion	98.2% (166)	83.3% (224)	$\chi 2$ *P*<0.01†
Received any uterotonics	95.9% (162)	99.3% (267)	$\chi 2$ *P*=0.03†
	Any time after study admission		
Received a blood transfusion	99.4% (168)	97.4% (262)	$\chi 2$ *P*=0.16†
Volume of whole blood transfused (ml)	1061.3 SD=591.9	642.2 SD=363.1	t-test *P*<0.01
Received treatment uterotonics	97.6% (165)	99.6% (268)	$\chi 2$ *P*=0.08†
Mean number of doses of uterotonics	3.4 SD=1.2	2.5 SD=1.2	t-test *P*<0.01

*The protocol asked for 1500 ml to be administered in the first hour of resuscitation; however, in some cases only 1000 ml were administered in the first hour, with the remaining 500 ml being administered in the second hour. †Fisher's exact test used, as 1 or more cells had frequencies of less than 10. SD, standard deviation.

after study admission was reduced in the NASG phase (80 hours pre-intervention vs 55 hours NASG, *P*<0.01).

As women in the NASG were in significantly better condition at study entry, we repeated the outcomes analysis comparing only women who had MAP <60 mmHg (*n*=26 in the pre-intervention and *n*=27 in the NASG phases). The NASG still appears to have had a positive effect on outcomes; however, only mean hours in hospital after admission and measured blood loss remain statistically significant, perhaps owing to the small sample size (*Table 4*).

There were fewer reports of side effects, which included respiratory symptoms/dyspnoea, reduced urine output, nausea, vomiting, and abdominal pain, for women in the NASG group. Of these, two were significantly reduced: respiratory symptoms/dyspnoea (13% pre-intervention vs 5.6% NASG, RR=1.09, 95% CI=0.02–1.16) and reduced urine output (9.5% pre-intervention vs 2.6% NASG, RR=1.08, 95% CI=1.02–1.13).

Discussion

The introduction of the NASG in two referral facilities in Egypt resulted in decreased maternal blood loss, time spent in hospital, emergency hysterectomies, morbidities, mortalities, and combined EAOs for 438 women with PPH due to uterine atony. As the women in the NASG phase were in better condition on study entry, a sub-analysis of only those women in severe shock (*n*=67) was also conducted. Although the results were not statistically significant for the primary outcomes, the trends were in the same direction as the overall analysis, with decreases noted for emergency hysterectomy (45% decrease), mortality (51% decrease), morbidity (44% decrease), and combined EAOs (45% decrease).

That more women in NASG phase received a prophylactic uterotonic may be a temporal association due to increased acceptance of AMTSL that may have occurred during the study. At the onset of data collection in the pre-intervention phase, AMTSL, especially with regards to delivery of a uterotonic within 5 minutes of birth, was not commonly practised, but with training and increased acceptance they became standard during the course of the study.

That fewer women in the NASG group received ≥1500 ml of fluid in the first hour, fewer blood transfusions in the first hour, and fewer doses of uterotonics, may be because they were in less severe condition on study entry, or because with the use of the NASG and the subsequent stabilization of critical patients, clinicians felt less urgency to perform these interventions. The potential effect of the garment on physician response has implications for future inclusion in emergency response to shock. Training should emphasize the need for consistent adherence to haemorrhage treatment protocols and maintaining aggressive therapy even when the NASG may appear to make the situation seem less urgent.

A potential concern with the NASG was increased blood loss during surgery, as the garment shunts blood from the lower body and the abdominal section is opened during the surgery. However, these findings show that there was no increased intra-operative blood loss between phases. Another potential concern about compression garments is that they may reduce urine output, a theory not supported by these findings. Women treated with the NASG also did not have an increase in other potential side effects such as nausea or dyspnoea.

Study limitations

Non-randomized studies risk possible selection bias, as enrollment is 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

> *The introduction of the NASG in two referral facilities in Egypt resulted in decreased maternal blood loss, time spent in hospital, emergency hysterectomies, morbidities, and mortalities.*

Table 3. Outcomes of uterine atony only by phase (*n*=438)

	Pre-intervention (*n*=169)	Post-intervention (*n*=269)	Statistical test
Mean hours in hospital after study admission (*n*=423)	80.2 SD=81.3	54.6 SD=43.7	t-test *P*<0.01
Mean intra-operative blood collected (ml) (*n*=45)	336.0 SD=279.5	254.4 SD=265.8	t-test *P*=0.35
Mean measured blood loss (ml)* (*n*=435)	409.0 SD=235.5	235.8 SD=147.1	t-test *P*<0.01
Emergency hysterectomy	11.8% (20)	4.8% (13)	RR=0.41 95% CI=0.21–0.80
Mortality	5.9% (10)	1.5% (4)	RR=0.25 95% CI=0.08–0.79
Morbidity† (*n*=424 women who survived)	5.0% (8)	1.5% (4)	RR=0.30 95% CI=0.09–0.98
Extreme adverse outcome‡	10.7% (18)	3.0% (8)	RR=0.28 95% CI=0.12–0.63

*For cases in which the blood collection drape was used and there were data for blood loss. †Includes acute renal failure, acute respiratory distress syndrome, heart failure, and cerebral impairment (seizures, unconsciousness, motor or cognitive loss). ‡Extreme adverse outcomes are mortality or morbidity. SD, standard deviation.

Table 4. Outcomes of uterine atony only for patients with MAP <60 mmHg by phase (*n*=67)

	Pre-intervention (*n*=169)	Post-intervention (*n*=269)	Statistical test
Mean hours in hospital after study admission (*n*=53)	186.8 SD=115.5	92.5 SD=61.6	t-test *P*<0.01
Mean intra-operative blood collected (ml) (*n*=32)	303.6 SD=271.5	177 SD=138.4	177 *P*=0.10
Mean measured blood loss (ml)* (*n*=65)	480 SD=409.6	308.6 SD=199.0	t-test *P*=0.04
Emergency hysterectomy	51.48% (18)	28.1% (9)	RR=0.55 95% CI=0.29–1.04
Mortality	25.7% (9)	12.5% (4)	RR=0.49 95% CI=0.17–1.43
Morbidity† (*n*=54 women who survived)	19.2% (5)	10.7% (3)	RR=0.56 95% CI=0.56–2.10
Extreme adverse outcome‡	40.0% (14)	21.9% (7)	RR=0.55 95% CI=0.25–1.18

*Cases in which the blood collection drape was used and there were data for blood loss. †Includes acute renal failure, acute respiratory distress syndrome, heart failure, and cerebral impairment (seizures, unconsciousness, motor or cognitive loss) ‡Extreme adverse outcomes are mortality or morbidity. MAP, mean arterial pressure; SD, standard deviation.

of haemorrhage could also have improved over time. As this study was integrated into busy, understaffed, under-stocked referral facilities, adherence to clinical protocols was also a challenge, although the results may reflect how the NASG functions in such 'real' environments. Finally, the difference in condition on study entry favoured better outcomes for the NASG group; however, the strong positive effect of the NASG persisted, albeit not with statistical significance, when only those women with MAP <60 mmHg were compared.

Conclusion

Even with the use of prophylactic uterotonics, women will still experience haemorrhage due to uterine atony. And even in CEmOC facilities, delays in obtaining definitive treatment can occur, and for women with uterine atony these delays can sometimes lead to irreparable organ damage and death. The NASG appears to be useful for stabilizing women throughout these delays. The garment seems to decrease further blood loss, reduce the incidence of emergency hysterectomy, and decrease the number of mortalities and morbidities. Further, it has been shown to do so without any of the adverse effects that are sometimes a concern with tight compression garments. Although this study in Egypt suggests the promise of the NASG for uterine atony cases at the referral hospital level, further research with a randomized design to avoid bias at study entry and at the level of primary health-care facilities on women referred to a CEmOC facility is essential in understanding the true potential of the NASG for PPH in low-resource settings. AJM

Key Points

- The non-pneumatic anti-shock garment (NASG) is a low-technology first-aid device for use on women with hypovolaemic shock secondary to severe obstetric haemorrhage.
- The NASG was applied on 438 women with postpartum haemorrhage due to uterine atony in two tertiary facilities in Egypt.
- Results show that women in the NASG phase experienced better outcomes than women in the pre-intervention phase with regards to mean measured blood loss, rate of emergency hysterectomy and extreme adverse outcomes—a combination of morbidity and mortality.

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