

ANTI-SHOCK GARMENTS: NON-PNEUMATIC ANTI-SHOCK GARMENT (NASG) AND PNEUMATIC ANTI-SHOCK GARMENT (PASG)

Suellen Miller, PhD, CNM, MHA, University of California, San Francisco

EXECUTIVE SUMMARY

- The non-pneumatic anti-shock garment (NASG) is a non-pneumatic compression device that can reduce bleeding and reverse shock secondary to obstetric hemorrhage.
- Although it is mainly used in low-resource settings it has applications in developed countries as well, anytime there is intractable hemorrhage or delays in accessing blood and/or surgery.
- The NASG can be used for obstetric hemorrhage occurring in rural areas where women have to be transported by ambulance or by air.
- The NASG can be used for out-of-hospital birth centers or home births.
- NASGs can reduce blood loss and reverse shock for women with intractable hemorrhage while awaiting arterial embolization.
- The NASG has been used as a “last-ditch” technology for women with intractable hemorrhage where hysterectomy is to be avoided.

BACKGROUND

In 2006, the Joint Statement of the International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO) recommended research on anti-shock garments to reduce mortality among women suffering postpartum hemorrhage.^{1,2} Currently, there are two types of anti-shock garments in use. The pneumatic anti-shock garment, or PASG, was developed in the 1970s and used to transport wounded soldiers during the Vietnam War, hence its other name, Medical Anti-Shock Trousers, or MAST. The other type of anti-shock garment is a non-pneumatic version. While the PASG is not often used for obstetric hemorrhage, the non-pneumatic anti-shock garment (NASG) has been used for obstetric hemorrhage in low-resource settings for the past ten years. The NASG is a first-aid device that reverses hypovolemic shock and decreases obstetric hemorrhage. It consists of articulated segments of neoprene that close tightly with Velcro, increasing blood flow from the lower body to the core organs, elevating blood pressure and increasing preload and cardiac output. Following ten years of research and evaluation, the World Health Organization (WHO) added the NASG to their “Recommendations for Prevention and Treatment of PPH”^{3,4}.

FIGO likewise included the NASG in their 2012 “FIGO Guidelines: Prevention and Treatment of PPH in Low-Resource Settings”.⁵

NASG

The NASG was developed in 1971 by teams associated with the National Aeronautics and Space Administration/Ames Research Center (NASA/Ames) in order to overcome some of the deficiencies of the PASG, such as over-inflation, compartment syndrome, and ischemia.⁶ In 1991, the NASG (Zoex Corporation, Ashland, OR, USA) was granted a United States Food and Drug Administration (US FDA) 510(k) medical device regulations number. Based on the same principle as the PASG, circumferential counter-pressure, but without air bladders, manometers, stopcocks, foot pumps and tubing, and without the associated risks of over-inflation and excessive pressures, the NASG is a promising first-aid treatment for hypovolemic shock resulting from obstetric hemorrhage.^{7,8}

NASG MECHANISMS OF ACTION AND NASG BLOOD FLOW STUDIES

Theoretically, all anti-shock garments work on the same principle: a compression suit which restricts blood flow to the lower body while increasing the blood pressure and cardiac output in the non-compressed area, where the oxygen-dependent core organs (heart, lungs, brain) benefit from increased blood flow. Doppler flow studies of the NASG in twelve healthy adult volunteers showed a mean decrease in blood flow in the distal aorta of 33% or 0.65 l/min ($p = 0.04$).⁹ Lester et al studied blood flow in healthy postpartum volunteers and found an increased Resistive Index (RI) in the internal iliac vessels with full application of the NASG, indicating reduced flow, from 0.83 to > 1.05 , Wilcoxon matched pairs signed rank test ($p = 0.02$).¹⁰ A more complete description of the mechanisms of action can be found elsewhere.¹¹

QUASI-EXPERIMENTAL NASG STUDIES FOR OBSTETRIC HEMORRHAGE

The first comparative NASG study was a pre-post pilot of severe obstetric hemorrhage in four Egyptian tertiary-level hospitals. All 364 women (158 pre-intervention phase, 206 post-intervention/NASG phase) had ≥ 750 mL EBL with signs of shock (pulse > 100 BPM, SBP < 100 mmHg) at study entry. All were treated with a standardized protocol; during the post-intervention phase, women also received the NASG. The NASG-treated women had better outcomes, with a statistically significant lower median measured blood loss (500 mL pre-intervention vs. 250 mL post-intervention, median difference -200, 95% CI -250 to -120, $p < 0.001$) and a non-statistically significant 69% decrease in extreme adverse outcomes (mortality and severe morbidity combined).^{12,13}

Further analysis of this data found that NASG-treated women experienced decreased shock recovery times, indicated by return to normal Shock Index (SI). Median SI recovery

time in 249 obstetric hemorrhage cases was significantly shorter in the NASG group (75 vs. 120 minutes, $p = 0.003$), independent of standard treatments, such as volume of IV fluids and/or waiting time for blood transfusions.¹⁴

Miller and colleagues have conducted a larger pre-intervention phase/NASG intervention phase study set in two tertiary facilities in Egypt and four tertiary facilities in Nigeria, $n = 1442$.¹⁵ In both phases of the trial, women with obstetric hemorrhage and hypovolemic shock (see criteria above) were treated with a standardized hemorrhage/shock protocol. Women in the NASG phase also received the NASG. Despite being in worse condition at the study start, negative maternal health outcomes were significantly reduced among women treated with the NASG. Mean measured blood loss after study entry was reduced 50% (median mL 400 vs. 200, $p < 0.0001$), maternal mortality decreased from 6.3% in the pre-intervention phase to 3.5% in the NASG phase (RR 0.56, 95% CI = 0.35 – 0.89), and emergency hysterectomy decreased from 8.9% in the pre-intervention phase to 4.0% in the NASG phase (RR 0.44, 95% CI = 0.23 – 0.86). In multiple logistic regression, there was a 55% reduced odds of mortality during the NASG (aOR 0.45, 95% CI = 0.27 – 0.77). A number of sub-analyses were conducted, based on hemorrhage etiologies or study country, with similar findings of reduced mortality.¹⁶⁻¹⁹

Using data from the pre-intervention phase/ NASG intervention phase study in Nigeria and Egypt¹⁵, Sutherland, et al. combined the data with costs from the study sites to conduct a cost-effectiveness analysis.²⁰ Results showed that providing NASGs to women in severe shock resulted in decreased mortality and morbidity, averting 357 DALYs in Egypt and 2,063 DALYs in Nigeria, with a net savings of \$9,489 in Egypt and a net cost of \$3.13/DALY averted in Nigeria.

El Ayadi and colleagues combined data from studies set in Nigeria/Egypt¹⁵, Zambia²¹, Zimbabwe²², and India²³, and used meta-analytic techniques to describe outcomes of NASG use on 3,561 women across a variety of tertiary care facilities.²⁴ They evaluated pooled odds ratios (POR). The POR for mortality for women treated with the NASG was 38% lower (POR 0.62, 95% CI = 0.44–0.86). For women in more severe shock, the NASG was associated with a 59% reduced odds of mortality (POR 0.41, 95% CI = 0.20–0.83).

RANDOMIZED CLUSTER TRIAL (RCT) OF NASG AT PRIMARY HEALTH CARE LEVEL

A cluster RCT was conducted in Zimbabwe and Zambia to determine if early application of the NASG by midwives at the Primary Health Care (PHC) level, prior to transfer to a referral hospital, decreased extreme adverse outcomes (EAO), mortality or severe-end organ failure morbidity, ClinicalTrials.gov number NCT00488462.²⁵ The study also analyzed potential side effects of the NASG. Entry criteria were estimated vaginal blood

loss \geq 500 mL and at least one other sign of hemodynamic instability (pulse $>$ 100 or SBP $<$ 100 mmHg). Thirty-eight PHCs were randomly assigned to providing women in hypovolemic shock to either standard obstetric hemorrhage/shock protocols or to the same protocols plus NASG prior to transport to the referral hospital (RH) for definitive treatment. All women received the NASG at the RH, $n=5$ RHs. In an intent-to-treat analysis, the intervention was associated with a non-significant 46% reduced odds of mortality (OR 0.54, 95% CI = 0.14–2.05, $p = 0.37$) and 54% reduction in composite EAO (OR 0.46, 95% CI 0.13–1.62, $p = 0.22$). Women with NASGs recovered from shock significantly faster (HR 1.25, 95% CI = 1.02–1.52, $p = 0.03$). No differences were observed in negative effects.²⁵

Despite a lack of statistical significance, the 54% reduced odds of EAO, the significantly faster shock recovery, and the similarity in decreased mortality rates of approximately 50% across a variety of settings, facility levels, and OH etiologies, suggest there might be treatment benefits from early application of NASGs for delays obtaining definitive treatment for hypovolemic shock. A pragmatic study with rigorous evaluation is suggested for further research. A presentation by the authors of the above study examined the per-protocol analysis; while still not statistically significant due to small sample size, women who actually received the NASG experienced a 64% reduced odds of mortality (OR = 0.36, 95% CI 0.08–1.57, $p = 0.17$).²⁶

CASE REPORT OF NASG FOR PPH IN HIGH-RESOURCE SETTINGS

While the NASG is being studied for efficacy in reducing maternal mortality and morbidity in low-resource settings, it can also be used in high-resource settings. El Sayed, et al. reported on an 18-year-old woman with intractable PPH at the Lucile Packard Children's Hospital, Stanford University, California, USA.²⁷ The woman, bleeding profusely after vaginal twin delivery, received multiple interventions, including Ringer's Lactate infusions, each with 35 units of oxytocin per liter; two doses of 0.2 mg methergine IM; three doses of 250 mcg hemabate IM; 800 mcg misoprostol per rectum; and transfusions of packed RBCs, recombinant factor VII, uterine massage, and uterine curettage. Having exhausted standard treatment measures, the surgeons packed the uterus and applied the NASG. Within minutes of NASG placement, bleeding subsided, pulse decreased, and blood pressure rose. The patient remained hemodynamically stable with normal vaginal bleeding. The NASG was removed on postpartum day 1, without complications or recurrent bleeding. Indications for use in high-resource settings include transport from rural areas to areas capable of treating severe PPH; use while awaiting arterial embolization team, operating room, or anesthesiology; anytime there is a delay in achieving definitive treatment; and/or as in the El Sayed case report, when all else has failed, as a "last-ditch" effort to stabilize and resuscitate.

RECOMMENDATIONS

Given that WHO and FIGO have now added the NASG to their guidelines for PPH²⁸⁻³⁰, and WHO is adding the NASG to their list of Essential Devices for 2014 (personal communication, Velazquez Burumen, 2013), it is no longer necessary to conduct expensive and lengthy efficacy trials. Implementation science and pragmatic operations research are needed to answer a number of remaining questions:

- Hemodynamics
 - The mechanism of action in pregnancy/postpartum is not clear. How much blood flow is decreased to the uterus? Is blood only decreased in the lower body or is there actually blood shunted to upper body? If blood is shunted, what volume of blood is shunted?
 - What is the effect on cardiac output? SPR? Stroke Volume?
- Practical Applications
 - Would equipping ambulances serving rural populations with NASGs have any effect on maternal health outcomes? What about air transports for extremely remote areas?
 - Should the NASG, if introduced into California hospital protocols, be used on women with placenta previa and a viable fetus?
 - Is there a role for NASG in management of women with heavy bleeding from second trimester abortion? Post-caesarean hemorrhage?

EDUCATIONAL TOOLS AND SAMPLE DOCUMENTS

Note that the NASG is not FDA-approved, but does have FDA 510(k) certification, and is substantially similar to an FDA-approved device, the Pneumatic Anti-Shock Garment (PASG), so that it can be marketed in the US and internationally.

NASGs can be obtained from BlueFuzion Group: NASG@bfgroup.asia

A training video and other training materials, links to research publications, and other information about the NASG can be found at www.lifewraps.org.

EVIDENCE GRADING

Level of Evidence: II-3 A. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on high quality and consistent evidence

Level of Evidence: II-3 B. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on limited or inconsistent evidence

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