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

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BACKGROUND AND LITERATURE REVIEW

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). 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 which 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" (2, 3); FIGO likewise included the NASG in their 2012 "FIGO Guidelines: Prevention and Treatment of PPH in Low-Resource Settings" (4).

PASG

The PASG was omnipresent in emergency pre-hospital trauma treatment until results of a randomized controlled trial were published in the late 1980s-1990s. All trauma victims transported to Ben Taub General Hospital, Houston, with entry systolic blood pressure ≤ 90 mmHg were admitted to the study; patients were randomized into control and PASG-intervention groups by alternate-day methodology. There were no significant differences in standard paramedic management or group demographics as a whole or when split into population subsets by injury type. Two key analyses came out of this research—Pepe (1986) and Bickell (1987) (5, 6). A third analysis was done by Mattox (1989) after continuing an additional year of data collection (7). A study similar in both methodology and protocols to the above was carried out by Chang (1995) (8). None of the studies (Table 1) demonstrated that the PASG could reduce morbidity or mortality for pre-hospital trauma treatment in urban settings.

TABLE 1. RCTS USING ALTERNATE-DAY RANDOMIZATION OF PASG IN EMERGENCY MEDICINE

Author (Year)	Sample size (n)	Outcomes
Pepe (1986)	n = 728	No statistically significant differences in survival outcomes between treatment groups. Compartment syndrome was observed in three PASG patients due to over-inflation.
Bickell (1987)	n = 201	Survival rates were higher in the non-PASG group, 77.9% control vs. 69.1% in PASG group, ($p = 0.097$)
Mattox (1989)	n = 784	PASG patients had longer stays in the intensive care unit (3.7 ± 12.5 days vs. 1.9 ± 6.5, $p<0.05$), and lower survival rates (69% in PASG patients vs. 75% for non-PASG patients, $p<0.05$)
Chang (1995)	n = 291	Length of hospital stay 8.5 ± 17.0 days in non-PASG group vs. 11.2 ± 34.3 days in PASG group and mortality outcomes (62.1% non-PASG vs. 59.0% PASG, $p = 0.05$).

Dickinson and Roberts conducted a meta-analysis of the 1,075 combined randomized patients in the Chang (n=291) and Mattox (n=784) studies to assess differential death outcomes and duration in the

intensive care unit (9). Risk of death was higher in the PASG group, RR 1.13 (95% CI = 0.97 – 1.32), with longer ICU stays, RR 1.7 days (95% CI = 0.33 – 2.98).

McSwain, a PASG proponent, argued that in urban areas with transport to specialized trauma hospitals, the delay caused by PASG application may have been a detriment to the benefits of early care, but that there might be place for PASGs in rural areas (10). Additionally, these RCTs did not control for factors such as age, hemorrhage severity, or time to garment application, which must be taken into account.

While there are no PASG RCTs for obstetric hemorrhage, there are case studies, described elsewhere and summarized in Table 2 (11).

TABLE 2. PASG CASE STUDIES OF OBSTETRIC HEMORRHAGE.

Author (Year)	n, etiologies	Interventions attempted before PASG	Outcomes after PASG application
Gardner (1958)	1 woman with placenta percreta and uncontrollable hemorrhage	Patient received >57 units of blood during failed surgery for adherent placenta, abdominal hysterectomy, ligation of internal iliac arteries, uterine packing, BP 86/62, pulse 144, hemorrhage continued	After PASG only one unit of blood required; patient stabilized with BP 104/72
Hall & Marshall (1979)	4 women with ruptured ectopic pregnancies for pre-surgical treatment	None reported; IV fluid replacement began at same time as PASG application	All had decreased blood loss, improved vital signs, and improved organ perfusion
Pelligra & Sandberg (1979)	3 women with obstetric hemorrhage: 1. Intra-abdominal bleeding post-C/S 2. Placenta previa, C/S, DIC 3. Post-hysterectomy, placenta accreta	1. 31 units whole blood, 8 units fresh frozen plasma (FFP), 4 units platelets, 7 units packed red blood cells (RBCs), and cryoprecipitate over 30 hours 2. 8 units packed RBCs, 6 units platelets, 4 units FFP 3. 63 units blood, 25 units FFP, 18 units cryoprecipitate and 132 platelet packs	1. Condition stabilized within one hour of PASG treatment 2. Transferred 56 km to fully equipped facility where she received additional blood products and remained stable 3. Responded quickly when PASG placed
Sandberg & Pelligra (1983)	3 women with obstetric hemorrhage (one was previously reported in Pelligra & Sandberg 1979)	1. Intrauterine gestation treated by laparotomy after >5000 mL of blood loss 2. Hysterectomy following spontaneous fetal death	Application of PASG led to increased BP and decreased blood loss for both women
Andrae (1999)	2 women with hypovolemic shock due to uterine bleeding: 1. Placenta accreta 2. Undiagnosed severe uterine bleeding	Both received uterotonics, pressors, IV fluids, blood, and blood components	PASG provided temporizing stabilization; bleeding ceased while PASG was in place, but started again after PASG removal; radiological intervention by transcatheter embolization was needed for full recovery
Ramachandran & Kirk (2004)	1 women post C/S for abdominal pregnancy	IV infusions, two surgeries to remove the infant and placenta, blood and blood projects, abdominal packing. Patient remained hypotensive, continued bleeding and developed Disseminated Intravascular Coagulopathy (DIC)	PASG effected decreased bleeding, increased BP; coagulation profile improved rapidly

These cases indicate that the PASG may be useful in managing obstetric hemorrhage as a temporizing measure before definitive treatment or as a last resort measure when other methods have failed, but more studies are indicated given the age and type of studies. Further support for PASG use for obstetric hemorrhage is a Doppler study of regional blood flow on ten healthy adults (12). PASG inflation resulted in an immediate decrease in aortic blood flow below and proximal to the renal arteries; the vessels more distal from the renal pelvis showed a lower response.

IMPROVISED PASG

Currently, Hauswald et al are conducting studies in Nepal of an "improvised PASG" called the Maternal Circumferential Abdominal-Pelvic Pressure (CAPP) device (13). This improvised PASG uses inflation to decrease blood flow to the pelvic organs and control postpartum hemorrhage. The devices are inexpensive, constructed using local materials such as bicycle tires, and can be made on-site in the developing world. In their published study, Hauswald et al made the CAPP by placing three bicycle tubes, one tube on each leg and one on the lower abdomen/pelvis, wrapping the body parts firmly with sheets, and inflating the tube tires to approximately 3.5 bar (45 psi). Using Doppler flow measurements, they measured blood flow in the distal aorta at 1.99 l/min at baseline; after application and inflation of the CAPP, they found a 56% mean flow decrease of 1.11 (95% CI = 0.64 – 1.57, p = 0.0003). Research continues on the device, replacing the abdominal tire tube with a fully inflated soccer ball (14). This device will need to undergo further testing before it will be in use outside of studies.

NASG

The PASG – bulky, heavy, and difficult to use – has had no place in emergency obstetrics in low-resource settings. Furthermore, the risk of over-inflation and the possibility of applying too much pressure have resulted in a controversial reputation for the PASG. The NASG, developed in 1971 by teams associated with the National Aeronautics and Space Administration / Ames Research Center (NASA/Ames), may overcome some of the deficiencies of the PASG (15). 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 (11, 16).

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) (13). 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) (17). A more complete description of the mechanisms of action can be found elsewhere (18).

QUASI-EXPERIMENTAL NASG STUDIES FOR OBSTETRIC HEMORRHAGE

NASG use for obstetric hemorrhage in low-resource settings was first explored in two case series at a tertiary-level maternity hospital in Sialkot, Pakistan (19, 20). The first comparative NASG study was a pre-post pilot of severe obstetric hemorrhage in four Egyptian tertiary-level hospitals (21). 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, including crystalloid fluids, uterotonics, blood transfusions, and vaginal procedures or abdominal surgeries as needed. During the post-intervention phase women also received the NASG in addition to the standardized protocol. Blood loss after study entry, the main outcome variable, was measured with a graduated, closed-ended blood collection device. NASG-phase women entered the study in worse condition with statistically significant greater EBL (975 mL vs. 750 mL median blood loss in pre-intervention phase women, $p<0.001$), and more severe signs of shock (mean SBP 97.5 mmHg versus 88.7 mmHg, $p<0.0005$). In spite of being in worse condition on study entry, 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) (21, 22).

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 (23).

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 (24). These hospitals are often understaffed, underequipped, and lack the capacity to provide blood transfusions. In both phases of the trial, women with obstetric hemorrhage and hypovolemic shock (see criteria above) were treated with a standardized hemorrhage/shock protocol, which included IV fluids, blood transfusions, and uterotonics for those with uterine atony. Women in the NASG phase of the study also received the NASG. Women in the NASG phase of the study (n = 853) were in worse condition on study entry, with 38.5% having a mean arterial pressure (MAP) <60 mm Hg, compared to 29.9% of women in the pre-intervention phase ($p = 0.001$). 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, $p<0.0001$), material 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 (25-28).

Using data from the study cited above (24), Turan et al examined if the NASG ameliorated effects of delays in transport to and delivery of treatment to 804 women with hypovolemic shock from PPH and post-abortion hemorrhage (29). They found that 20% of women treated with the normal protocol who experiences a delay of >60 minutes between the beginning of their hemorrhage and admission to the study had an adverse outcome (mortality or severe end organ failure morbidity) compared to only 6% who experiences an adverse outcome given the same delay, but who were treated with the same protocol plus the NASG ($\chi^2 = 13.71$, $p<0.001$).

Again using data from the pre-intervention phase/ NASG intervention phase study in Nigeria and Egypt (24), Sutherland et al combined the data with costs from the study sites to conduct a cost-effectiveness analysis (30). They used a standard population of 1,000 women presenting in shock to examine three

intervention scenarios: no woman in shock would receive the NASG; only a woman in most severe shock (MAP <60 mmHg) would receive the NASG; and every woman in shock would receive the NASG. Outcomes were mortality, severe morbidity, severe anemia, and Disability-Adjusted Life Years (DALYs). Costs included training in use of NASG, the NASG device, blood transfusions, IV fluids, and surgery. Results differed by country, but 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. Thus the NASG proved to be cost-beneficial in Egypt and highly cost-effective in Nigeria.

Smaller pre-intervention / NASG intervention studies have been conducted in Zambia and Zimbabwe (31, 32), and one implementation study has been conducted in India (33). El Ayadi and colleagues combined data from the Nigeria/Egypt study (24) and the Zambia, Zimbabwe, and India studies and used meta-analytic techniques to describe outcomes of NASG use on 3,561 women across a variety of tertiary care facilities (34). They evaluated pooled odds ratios (POR) for mortality among all women, and also examined a sub-group of 1,271 women with more severe shock (MAP<60 mmHg or unconscious). While hemorrhage etiologies varied somewhat, all other participant characteristics were similar. 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, jointly funded by the National Institutes of Health, National Institutes for Child Health, and The Bill and Melinda Gates Foundation, 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 (35). The study also analyzed potential side effects of the NASG that might limit its use. Entry criteria were estimated vaginal blood loss ≥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. The sample size for statistical power was not reached; of a planned 2,400 women, 880 were enrolled, 405 in the NASG intervention group. 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 (35).

Despite a lack of statistical significance, the 54% reduced odds of EAO and 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) (36).

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 (37). 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 measured, 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 PPH (2-4), 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?
- Programmatic Issues
    - What is the best ratio of NASGs to tertiary facilities, primary health facilities, and transport/ambulances in low resource settings?
    - Is there a lower limit for volume for supplying NASGs to TBAs and other community-based health care workers? If so, how do low volume providers keep up skills so they will be able to apply NASG in the rare emergency situation?
    - What are the best method(s) for exchange and return programs when NASGs are transported on women in hypovolemic shock from lower level facilities to referral facilities?

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.

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