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 Federation International of Gynecology and Obstetrics (FIGO) recommended research on anti-shock garments to reduce mortality among women suffering postpartum hemorrhage.(1) The non-pneumatic anti-shock garment (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, shunting blood from the lower body to the core organs, elevating blood pressure and increasing preload and cardiac output. The NASG is not an FDA-approved device, but is a 510(k) equivalent device, which did receive FDA clearance based on its similarity to the Pneumatic Anti-Shock Garment (PASG, aka, MAST suit).
Theoretically, all anti-shock garments work on the same principle: a compression suit which upon placement to a hypovolemic person, restores blood pressures—particularly to the core—by returning blood from the lower body.

PASG

The PASG was omnipresent in emergency pre-hospital trauma treatment until results of a randomized control 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).(2, 3) A third analysis was done by Mattox (1989) after continuing an additional year of data collection.(4) A study similar in both methodology and protocols to the above was carried out by Chang (1995).(5) 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=.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 and 59.0% PASG); $p < .05$.

Dickinson and Roberts (2000) 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.(6) Risk of death was higher in the PASG group, RR 1.13 (95% CI = 0.97 to 1.32), with longer ICU stays, RR 1.7 days (95% CI = 0.33 to 2.98).

McSwain (2000) argues 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.(7) 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(8) and summarized in Table 2. (9)

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 and 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/section 2) Placenta previa, caesarean section, 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 (RBC) 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 placement 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 laporotomy 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 accrete 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 woman post c-section for abdominal pregnancy	IV infusions, two surgeries to remove the infant and placenta, blood and blood products, 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.(10) 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.

NASG

The PASG—bulky, heavy, and difficult to use—has had no place in emergency obstetrics in low-resource settings. The NASG, developed in 1971 by teams associated with the National Aeronautics and Space Administration/Ames Research Centre (NASA/Ames), may overcome some of the deficiencies of the PASG.(11) In 1991, the NASG (Zoex Corporation, Ashland, OR, USA) was granted a US Food and Drug Administration 510(k) medical device regulations number. Based on the same principles as the PASG, circumferential counter pressure, but without air bladders, manometers, stop cocks, foot pump and tubing, and the associated risks of over-inflation and excessive pressures, the NASG is a promising first-aid treatment for hemorrhagic shock.(8, 12-19)

Comparative NASG Studies: 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.(12, 14) The first comparative NASG study was a pre-post pilot of severe obstetric hemorrhage in four Egyptian tertiary hospitals.(17) 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. Post-intervention women also received the NASG. Blood loss after study entry, the main outcome variable, was measured with a graduated, closed-end 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, $p<0.001$) and more severe signs of shock (mean SBP 97.5mmHg vs. 88.7mmHg, $p<0.0005$). In spite of this discrepancy at time of 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 morbidity combined).

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.(17)

Miller and colleagues have completed data collection on a similar pre-post pilot trial in 12 tertiary hospitals in Nigeria.(18) These hospitals are often understaffed, under-equipped, and lack blood transfusions. Results on over 580 women treated with NASG are pending analysis.

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 also can 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, US.(13) 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; along with 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.

RCTs of NASG

The NASG has not yet proven to significantly decrease morbidity or mortality. Furthermore, NASG studies have a) only been of less rigorous pre/post design and b) only been conducted in tertiary care centers. A cluster RCT, jointly funded by the National Institutes of Health, National Institutes for Child Health, and the Bill and Melinda Gates Foundation, has been initiated in Zimbabwe and Zambia to determine if early application of the NASG by midwives at the primary health care level, prior to transfer to a referral hospital, will decrease extreme adverse outcomes (mortality or severe-end organ failure). The study will also analyze potential side effects of NASG. Lead investigators include those from University of California, San Francisco; University of Zimbabwe; University Teaching Hospital, Zambia; the Reproductive Health Research Unit of the World Health Organization; and the Centro Rosario Institutio Estudios Perinatales.
(http://clinicaltrials.gov/ct2/show/NCT00488462?cntry1=AF%3AZW&rank=12). Results will be available in 3-5 years depending on recruitment.

RECOMMENDATIONS

More and more rigorous research is needed before recommending the clinical use of NASG or PASG in the setting of acute obstetrical hemorrhage.

Research recommendations include:

- Efficacy trials for morbidity and mortality reduction (RCT currently ongoing)
- Hemodynamics:
  - The mechanism of action in pregnancy/postpartum is not clear. How much blood flow is decreased to the uterus?
  - Should the NASG, if introduced into California hospital protocols, be used on women with placenta previa and a viable fetus?
  - What is the effect on cardiac output? SPR? Stroke Volume?
- Best methods of cleaning, reuse, and storage: The NASG manufactured by ZOEX was designed for one time use and the manufacturers do not recommend the use of

bleach; therefore, questions remain on how to clean, decontaminate, and reuse/whether to reuse.

EDUCATIONAL TOOLS, SAMPLE DOCUMENTS

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

The US distributor of NASG is ZOEX Corporation, Ashland Oregon: zoex@connpoint.net

A training video, meant for use by physicians and midwives in low resource settings, can be accessed on the website, www.nasgexchange.org. A password can be obtained from ebutrick@globalhealth.ucsf.edu to enter the training page of the website.

EVIDENCE GRADING

Level of Evidence: B. Recommendations based on limited or inconsistent evidence.

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