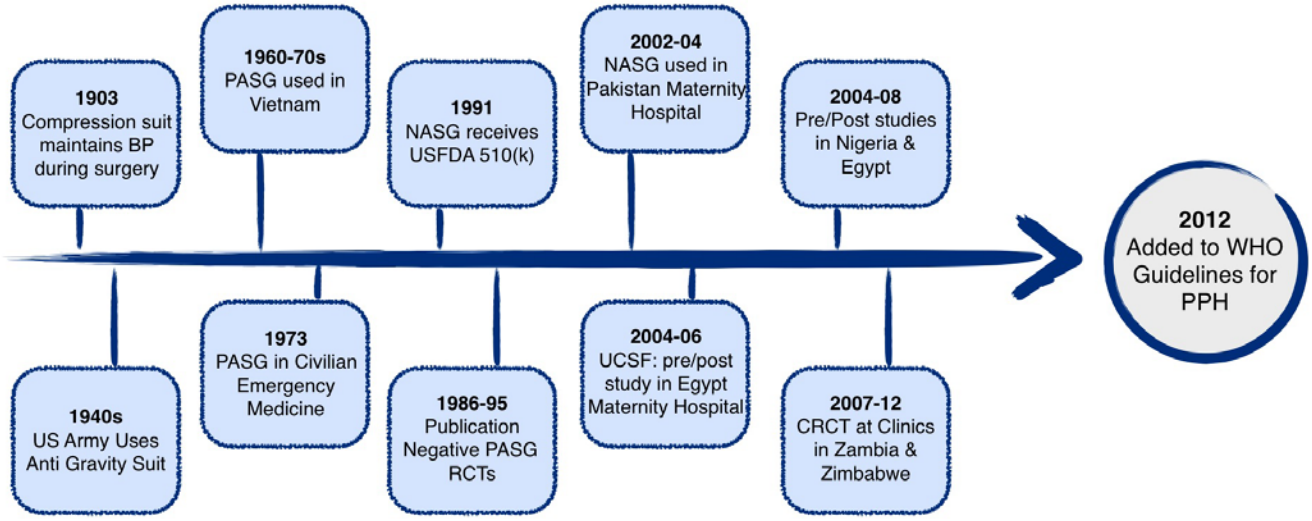
Historical Development of the NASG



First Anti-Shock Garment, 1903

In 1903, George Crile developed the first hypovolemic compression suit. It increased peripheral resistance, reduced bleeding and sustained blood pressure. Crile's device was temporarily abandoned after the introduction of safe blood transfusion technology [1]. The concept was re-introduced during World War II when the anti-gravity suit (G-suit) was developed to prevent syncope during rapid ascent. During the Vietnam War, G-suits were used to resuscitate and stabilize battlefield casualties [2]. The G-suit was later modified from a full body suit to a half-suit [3] called Military / Medical® Anti-Shock Trouser (MASTs), or Pneumatic Anti-Shock Garments (PASGs).

Mechanisms of Action

All ASGs have the same mechanisms of action. Circumferential compression of the abdomen and legs reduces total vascular volume (container size) while expanding the central circulation. In animal studies, the translocation of blood has been estimated to be 750-1000 ml (up to 30%) [4]. Garment application results in increased preload, peripheral resistance and cardiac output; the tamponade of vessels, particularly the splanchnic plexus, may diminish further bleeding [5,6]. The physiological bases for these benefits, Poiseuille's Law, Laplace's Law and the Bernoulli Principle (Table 1), have been described in detail elsewhere [4,7].

Table 1 Laws of physics underlying the mechanisms of action of anti-shock garments
Poiseuille's Law: $F = (P_1 - P_2) R^4 / 8N \cdot L$ F, flow; P1, entrance pressure; P2, exit pressure; R, radius; N, viscosity; L, length Flow rate through a blood vessel is related to the vessel's radius; rate per unit time is related to the fourth power of the radius [4,7]
Laplace's Law: $T = P \cdot R$ T, tension inside blood vessel; P, transmural pressure; R, vessel radius External counter-pressure compresses lower body and splanchnic vessels, reduces transmural pressure and vessel radius. These synergistic effects reduce the difference in tension across the vessel, reducing blood loss [7]
Bernoulli Principle: $Q = (A \cdot P + 2V) / E$ Q, rate of leakage; A, area of laceration/tear/opening; P, transmural pressure; E, density of blood; V, speed or velocity of blood flow Rate of leakage from open blood vessels depends on the size of the defect and the intraluminal pressure and the extraluminal pressure (together represented by transmural pressure). External pressure compresses torn vessel walls and reduces the area of the defect [4,7]

Animal Studies

Much of the supportive data for the physiological effects of ASGs come from animal studies (Table 2) that have demonstrated decreased bleeding, increased systolic blood pressure (SBP) and increased survival [8-11].

Table 2
Pneumatic anti-shock garments (PASG) animal studies

Author; year [ref. no.]	Study Design	Outcomes
Gardner and Storer; 1966 [8]	Case series of 8 dogs with transected intra-abdominal aortas treated with pneumatic abdominal sleeve	Sustained mean SBP 74 mm Hg (40-110 mm Hg); when sleeve deflated after 1 hour, 6 of 8 dogs lost blood pressure and died within 5 minutes; 2 dogs survived 30 and 40 minutes after deflation; both showed sealing at the aortic incision
Gardner; 1969 [9]	Comparative study of 16 dogs with wounds to the iliac artery (8 PASG, 8 control)	All controls died within minutes of the surgical incision; 8 PASG-treated dogs survived until the PASG was deflated 60 minutes later; 75% of survivors died within 5 minutes of deflation
Aberg et al; 1986 [10]	Comparative study of 30 rats (5 control, 5 PASG alone, 10 saline infusion alone, 10 PASG with saline infusion) subjected to lethal hepatic and retro-hepatic caval vein injury	PASG-alone group showed increase in median survival time: 120 minutes (114-120) vs. 10 minutes (9-26) in control group; 9 of 10 animals with combined PASG and infusion treatment developed pulmonary oedema

PASG in Emergency Medicine

PASGs were introduced into civilian emergency medicine in 1973; the successful report of this introduction [12] initiated a wave of acceptance [13]. PASGs were used for shock and trauma, including pelvic and lower limb fractures, hypovolemic and septic shock [4,12,14-16]. Despite the lack of positive randomized control trials (RCTs), in 1977 the American College of Surgeons' Committee on Trauma included PASGs as essential equipment for ambulances[17].

Contraindications included injuries above the diaphragm and congestive heart failure or pulmonary edema [12]. A variety of reported adverse effects of PASG use include: decreased urine output, increased intraoperative blood loss, hypoxia, ischemia, dyspnea or other forms of respiratory distress, increased acidosis and the development of compartment syndrome [1,4,14,18-25].

A team of researchers conducted a 2.5 year randomized prospective study of PASG for pre-hospital treatment of hypotensive trauma patients in urban Houston, Texas, USA. Patients with entry SBP ≤ 90 mmHg were randomized into control and PASG groups by alternate-day methodology. There were no significant differences in paramedic management, demographics, or injury type. Two key analyses were published [19,25]; a third analysis [21] included one additional year of enrolment. Chang later conducted a similar RCT [26]. All four reports (Table 3) failed to demonstrate efficacy of PASG in reducing morbidity or mortality.

Table 3
Pneumatic anti-shock garments (PASG) randomized controlled trials in human emergency medicine

Author; year [ref. no.]	Number; type of trauma	Outcomes
Pepe et al.; 1986 [21]	401 patients: 74 primary truncal injuries, 175 penetrating abdominal injuries, 152 penetrating thoracic injuries	No statistically significant differences in survival; compartment syndrome in three PASG patients
Bickell et al.; 1987 [15]	201 patients (97 PASG, 104 control) all with gunshot or stab wounds to anterior abdomen	Survival rates higher in the non-PASG group (77.9% vs. 69.1% in PASG group, p = 0.097)
Mattox et al.; 1989 [17]	784 patients (345 PASG, 439 control)	PASG required longer stays in intensive care unit (ICU) (3.7 ± 12.5 days vs. 1.9 ± 6.5, p <0.05) and had lower survival rates (69% survival rate for PASG patients vs. 75% for control, p <0.05)
Chang et al.; 1995 [22]	248 trauma patients (95 PASG, 153 control)	PASG group had longer hospitalizations 11.2 ± 34.3 days vs. 8.5 ± 17.0 days for control, ns) and lower survival rates (59.0% PASG vs. 62.1% control, ns)

A Cochrane meta-analysis (n=1075) found the PASG group had a non-statistically significant higher risk of death, RR 1.13 (95% CI = 0.97 to 1.32), and longer stays in the ICU, RR 1.7 days (95% CI = 0.33 to 2.98) [27]. The authors also noted the poor quality of the trials.

The results from these pre-hospital RCTs may be confounded by the inclusion of patients with upper body injuries and by the urban setting with rapid transport to trauma hospitals available; the time required for PASG application may have delayed such transport [13]. Additionally, these RCTs did not control for confounders such as age, haemorrhage severity or time to garment application [28].

Current Status in Emergency Medicine

After publication of these RCTs, PASG use became controversial [24,27,29,30]. In 1997, the PASG was deemed "effective" by the National Association of EMS Physicians [15] only for ruptured abdominal aneurysms and "potentially beneficial" for pelvic fracture or lower extremity haemorrhage [31]. Some emergency medical practitioners still recommend PASG for pre-hospital care [13] and it remains in emergency medicine curricula and textbooks [29,32].

PASG for Obstetric Haemorrhage

While there are no PASG RCTs for obstetric haemorrhage, there are case studies described elsewhere [7] and summarized in Table 4 [23,33-37].

These cases indicate that the PASG may be useful in managing obstetric haemorrhage as a temporizing measure before definitive treatment or as a last resort when other methods have failed. Further support for PASG use for obstetric haemorrhage is a Doppler study of regional blood flow on ten healthy adults [38]. PASG inflation resulted in decreased aortic blood flow from the superior mesenteric to immediately below the renal arteries. In France, the "pantaloon antichoc" is endorsed for postpartum haemorrhage, DICs of pregnancy, and other obstetric and gynecological bleeding [39].

Investigations are on-going in Nepal currently with an improvised PASG. Hauswald and Kerr are conducting trials of this device, improvised from canvas, bicycle tire inner tubes, and a soccer ball. Results of outcomes have not yet been published, but Doppler flow studies indicate decreased blood flow in the pelvis with proper application [40].

Currently there is interest in treating women with hypovolemic shock secondary to obstetric haemorrhage in low resource settings with a lower-technology, easy to apply first-aid device such as the NASG [5,41-43].

Table 4
Pneumatic anti-shock garment (PASG) case studies of obstetric haemorrhage

Author; year [ref. no.]	Number; aetiologies	Interventions before PASG	Outcomes after PASG
Gardner et al.; 1958 [33]	1 woman with placenta percreta and uncontrollable haemorrhage	Patient received >57 units of blood during failed surgery for adherent placenta, abdominal hysterectomy, and ligation of internal iliac arteries; had uterine packing. BP 86/62, pulse 144, haemorrhage continued	After PASG only one additional unit of blood was required; patient stabilized with BP 104-72
Hall and Marshall; 1979 [34]	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 and Sandberg; 1979 [23]	3 women with obstetric haemorrhage: 1. Intra-abdominal bleeding post - caesarean section 2. Placenta praevia, caesarean section, disseminated intravascular coagulopathy (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, and 4 units FFP 3. 63 units blood, 25 units FFP, 18 units cryoprecipitate, and 132 platelet packs	1. Condition stabilized within 1 hour of PASG placement 2. Transferred 56 km to fully equipped facility where patient received additional blood products and remained stable 3. Responded quickly when PASG placed
Sandberg and Pelligra; 1983 [35]	3 women with obstetric haemorrhage (one was previously reported in Pelligra and Sandberg 1979) described above	1. Intrauterine gestation treated by laparotomy after >5000 mL of blood loss 2. Hysterectomy following spontaneous foetal death	Application of PASG led to increased blood pressure and decreased blood loss for both women
Andrae et al.; 1999 [36]	2 women with hypovolaemic shock due to uterine bleeding	Both received uterotonics, pressors, IV fluids, blood and blood components 1. Placenta accreta 2. Undiagnosed severe uterine bleeding	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 and Kirk; 2004 [37]	1 woman post-caesarean 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 DIC	PASG effected decreased bleeding, increased blood pressure; coagulation profile improved rapidly

NASG

The NASG is a lightweight, relatively inexpensive, washable neoprene suit comprised of articulated horizontal segments with three segments on each leg, one segment over the pelvis and another over the abdomen, which includes a foam compression ball (Figure 1). Using the three-way elasticity of neoprene and the tight closure of the Velcro™, the garment applies 20 to 40 mmHg circumferential counter-pressure to the lower body to reverse hypovolemic shock by shunting blood to the vital core organs [7].

Figure 1. Patient wearing non-pneumatic anti-shock garment (NASG).

The garment was developed in 1971 by Dr. Ralph Pelligra of the National Aeronautics and Space Administration/Ames Research Centre (NASA/Ames) [41]. In 1991 the NASG (Zoex Corporation, Ashland, OR, USA) received a US Food and Drug Administration 510(k) medical device regulations number. Based on the PASG's circumferential counter-pressure, but without air bladders, manometers, stop cocks, foot pump and tubing, and the associated risks of over-inflation and subsequent ischemia, the NASG is a promising first-aid treatment for hemorrhagic shock [5,7,42-47].

Advantages of NASG for Obstetric Haemorrhage

Despite the lack of RCTs, it is speculated that NASG use for obstetric haemorrhage in low resource settings might yield better results than the PASG trauma RCTs [7]. First, the NASG avoids some PASG-related adverse outcomes due to its design, being non-inflatable and applying a lower pressure to the body (20-40 mmHg vs. PASG ≤104 mmHg) [7,48]. Second, the NASG, used for obstetric haemorrhage, would be applied to reduce bleeding in the pelvic region, the region demonstrated to have the greatest effect from compression [38]. Third, the negative PASG RCTs might be associated with the studies' urban settings where transport to specialized trauma units is quick; non-PASG patients may have benefited from more rapid definitive treatment, as acknowledged by the studies' authors [19,21,26].

The majority of maternal mortalities occur far from health care facilities and/or at facilities unable to provide rapid definitive treatment [49-51]. The NASG could be a first-aid temporizing device for women who face delays in obtaining emergency obstetric care. The simplicity of the NASG adds to its utility for use in community settings where health care

providers may be alone or have minimal training [52-61]. Differences between the PASG and NASG are summarized in Table 5.

Table 5
Non-pneumatic anti-shock garments (NASG) vs. pneumatic anti-shock garments (PASG)

	PASG*	NASG
Personnel required	At least 2 authorized personnel (emergency medical technicians/ paramedics with NASG training and certification) [54,55]	1 person, no medical background required [5,7,45,46,47,49,50,61,63]
Complexity	High; may require removing patient's clothing or at least removing sharp objects from clothing, inflation at multiple points, may require binding in place with tape, possible pressure measuring with specialized equipment and re-inflation or deflation as necessary, managing PASG variations [51,54,56]	Low; easy to apply, may be worn over clothing, no inflation required [5,7,45,46,47,49,50,61,63]
Training necessary for application	Depending on regional protocols >10 hours, regular practice and periodic re-training and exam [55,56]	<1 hour basic training with practice [5,7,45,46,49,50,61,63]
Management during transport	Complex; may require reading manometers, re/deflating, monitoring vital signs [51,57]	Simple; at most requires monitoring vital signs and observation for dyspnea [5,47]
Management during and after resuscitation	1. Controlled fluid therapy by skilled attendant 2. PASG must be removed before diagnostic, vaginal, and/or surgical procedures are performed 3. Physician must be present for deflation [51,58]	1. Controlled fluid therapy by skilled attendant 2. Uterine massage (internal or external) and vaginal procedures can be conducted with NASG in place 3. Removal must be conducted in skilled facility [5,7,45,46,47,49,50,61,63]
Cost	Up to $725.00 plus pressure-reading equipment and pressure infuser, if required, and replacement parts [51,59,60]	$60-$300 depending on manufacturer
Maintenance	Machine wash/hand wash/wipe clean depending on type. Repair as necessary; monthly inspections recommended [51]	Simple cleaning required after each use; disinfect with bleach, launder, hang dry [7,61]
Adverse outcomes	Possible compartment syndrome, ischaemia and acidosis [1,4,14,18-25]	None known [5,7,45,46,47,49,50,63]
Other potential risks	Risk of pump failure, leaks, cuts or tears, may not stay closed [51,62]	None reported [5,7,45,46,47,49,50,63]

* May vary by PASG type and regional protocols.

NASG Studies

Published reports on NASG studies for obstetrics can be found on the www.safemotherhood.ucsf.edu/publications page. In one pilot [42], two large pre-post studies [62-69], a paper synthesizing outcomes on 3,561 women using the NASG [70], and in a randomized cluster trial of NASG at the primary health care level [71], the NASG consistently reduced maternal mortality by at least 50% and reduced time to recovery from shock significantly [43,64]. A cost–effectiveness analysis of data from Nigeria and Egypt showed the NASG to be highly cost-effective [72].

Summary

All ASGs operate on the same principles, shunting blood from lower extremities to the core, reversing shock and decreasing blood loss. PASGs have had a controversial history, with negative or no difference findings in RCTs for trauma patients. Only case studies have been published on the PASG use in obstetrics. The NASG may overcome some of the deficiencies of the PASG. There are theoretical reasons why the negative RCTs of the PASG may not be applicable to the NASG: its improved design overcomes the risks associated with inflation and its intended use specifically for countering the delays in obtaining emergency obstetric care in low resource settings. Currently, evidence suggests the NASG is a promising first-aid device for obstetric haemorrhage and shock that may help overcome delays in transport and in acquiring appropriate haemorrhage management at referral facilities. It may also play a role in sophisticated tertiary care units by keeping women stable whilst awaiting arterial embolization, or as a post-surgical or last resort measure for intractable obstetric haemorrhage.

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