Anti-Shock Garments for Obstetric Hemorrhage

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Abstract: Annually, over 500,000 women die from complications of pregnancy and childbirth; the majority die from hemorrhage and shock. Obstetrical hemorrhage of all etiologies, such as uterine atony, ruptured uterus, and ruptured ectopic, can cause massive blood loss resulting in severe shock. Unless women can access fluid replacement, blood transfusions, and, often, surgery, the shock leads to organ failure and death. Therefore, the majority of maternal hemorrhage deaths occur in developing countries. The non-pneumatic anti-shock garment (NASG) is a light-weight, reusable, neoprene and Velcro compression device that can be rapidly applied to a hemorrhaging woman to shunt blood from the lower extremities to the core organs, heart, lung and brain, and to decrease blood loss. We review literature on the history, mechanisms of action, and use of Anti-Shock Garments (ASGs) in emergency medicine, focusing on the use of inflatable or Pneumatic ASGs (PASGs) for obstetrical, gynecological, and urological hemorrhage. We describe similarities and differences between the PASG and the newer NASG. We then review recent studies on the NASG for obstetrical hemorrhage in Pakistan, Nigeria, and Egypt, and conclude with recommendations for the types of research necessary to bring the NASG into wider use.

Keywords: Maternal mortality, obstetric hemorrhage, postpartum hemorrhage, anti-shock garment.

INTRODUCTION

The global burden of disease from maternal morbidity and mortality is great. Every year, an estimated 529,000 women die from complications of pregnancy and childbirth; 99% of these deaths occur in developing countries [1]. The estimated global maternal mortality ratio (MMR) is 440/100,000 live births with a range from 20/100,000 in developed regions to 920/100,000 in sub-Saharan Africa [2]. This unacceptably high MMR in developing countries is of such great concern that the United Nations Millennium Development Goal 5 is to improve maternal health by reducing MMRs by 75% by 2015 [3].

For every maternal mortality, there are 30 maternal morbidities [4, 5], which compromise women's lifetime health, productivity, quality of life, family health, and ability to participate in community life. In developing countries, an annual estimate of 18 million women experience obstetric complications that result in long-term disability [6]. Pregnancy and childbirth related illness and injury are the second leading cause of lost years of healthy life among women of reproductive age in developing countries [7].

Obstetric complications leading to maternal morbidity or mortalities include obstetric hemorrhage, toxemia, sepsis, anemia, obstructed labor, and abortion; obstetric hemorrhage contributes to about half of maternal deaths [8, 9]. Postpartum hemorrhage (PPH), the most common cause of obstetric hemorrhage and one of the five leading causes of maternal mortality in developed and developing countries

[10], is defined as vaginal bleeding in excess of 500mL after vaginal delivery and in excess of 1000mL after cesarean delivery [10]. Other causes of obstetric hemorrhage include ectopic pregnancy, complications of abortion, both induced and spontaneous, abruption of the placenta, placenta previa, placenta accreta, ruptured uterus, and complications of operative vaginal deliveries and surgical deliveries. Pre-eclampsia, eclampsia, abruption, and retention of a dead fetus can cause disseminated intravascular coagulopathy (DIC), which can result in uncontrollable hemorrhage [11].

A delays framework [12, 13] has been used to explain why so many women die of obstetric complications in developing countries. In the case of obstetric hemorrhage, when a woman begins to bleed heavily, there is a delay in recognizing a true hemorrhage. Subsequently, there is an additional delay in obtaining transportation: families do not have access to vehicles, vehicle owners cannot afford to lose productive time driving neighbors to the hospital, roads are washed out, etc. Furthermore, additional delays occur once the woman reaches the hospital: it may not be staffed with skilled attendants, may not have blood available for transfusions, or may not be open 24 hours a day, 7 days a week, and hence be closed when she arrives. Frequently, women must travel to multiple medical facilities (clinics, health posts, lower level hospitals, etc.) before reaching the level of care they need.

Obstetric hemorrhage can be managed in developed countries with uterotonic medications, blood transfusions, and surgery, but is often fatal in developing countries where a large percentage of births occur at home without skilled attendance [11] and where there is limited access to high quality Comprehensive Emergency Obstetric Care

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(CEmOC)[1] definitive treatment with blood transfusions and/or surgery [9, 14]. New strategies or technologies that can reduce this burden of disease will greatly contribute to improved health of women, families, communities and nations.

POSSIBLE ROLE FOR ANTI-SHOCK GARMENT IN DECREASING MATERNAL MORTALITY AND MORBIDITY ASSOCIATED WITH OBSTETRIC HEMORRHAGE

Active Management of Third Stage Labor (AMTSL) including prophylactic uterotonics has been widely recommended by the International Federation of Gynecologists and Obstetricians (FIGO) and the International Confederation of Midwives (ICM) for reducing the incidence of PPH due to uterine atony [15]. However, even with prophylaxis, approximately 1-3% of all women will still experience postpartum bleeding from uterine atony or other forms of obstetrical hemorrhage [16]. In severe cases of persistent hemorrhage, when administration of uterotonics does not stop PPH, or when the hemorrhage is due to causes other than uterine atony, surgery may be the only definitive intervention [17]. However, surgery and other shock and hemorrhage management strategies, such as the prompt repair of lacerations, rapid infusion of crystalloid intravenous fluids, transfusion of blood and blood products, and other surgical procedures may be unavailable and/or unaffordable in some developing countries [18].

These hemostatic and resuscitative measures are usually limited to facilities able to provide CEmOC[1], and these definitive resuscitative measures are frequently outside the scope of training of many birth attendants [11]. Many women are transported over long distances to the "nearest" hospital, and, if they survive the trip, often encounter additional delays in receiving appropriate treatment. When delays occur, a woman can bleed enough to go into shock. Unless this is reversed, her vital organs, including the kidney, heart, lungs and brain, can be irreversibly damaged. A bleeding woman who develops hypovolemic shock from PPH can die within 2 hours [19]. This is often far more time than it takes to travel from a rural village to a CEmOC hospital. Furthermore, even when surgery is available, in an effort to rapidly stop massive hemorrhage, surgeons may resort to emergency hysterectomy, leading to further complications and infertility.

Tsu *et al*, [9], reporting on a meeting of maternal health specialists on new and underutilized technologies to reduce maternal mortality, recommended studying the Anti-shock Garment (ASG) as a method to reduce deaths from obstetric hemorrhage. The ASG is a generic term for any compression device that shunts blood from the extremities to the core

organs, heart, lung, and brain, thus reversing shock. A pneumatic anti-shock garment (PASG) has been used for a variety of indications since the mid 1970s. The newest adaptation of the ASG is the non-pneumatic anti-shock garment (NASG), a lightweight, reusable compression suit, comprising five neoprene segments that close tightly with Velcro around the legs, pelvis and abdomen. The NASG has the potential to provide fast, simple resuscitation for women suffering from severe obstetric hemorrhage, by reducing blood loss, decreasing time for restoration of vital signs, and enhancing organ perfusion before definitive treatment is available. Due to its simplicity and relatively low cost, the NASG may play an important role in overcoming delays that contribute to unnecessary deaths from obstetric hemorrhage.

In this article, we review the available literature on ASGs, including its history, mechanisms of action, and use in emergency medicine. After a general overview, we review the published literature on the use of the pneumatic anti-shock garment (PASG) for obstetrical, gynecological, and urological hemorrhage. We describe similarities and differences between the PASG and the NASG. Next, we review recent research on the NASG for obstetrical hemorrhage in Pakistan, Nigeria, and Egypt, and then discuss future research needs.

SEARCH STRATEGY AND TERMINOLOGY

In this review, we use the term ASG for any garment-type compression device. The term PASG or MAST will be used for the pneumatic (inflatable) devices used from the 1970s to the present day, and NASG will refer to the most recent adaptation of the device, which does not require inflation. We conducted a review of the literature to identify all articles that evaluated the use of the PASG or MAST and NASG. We conducted separate searches of the PubMed database and the Cochrane Central Search Library and Elsevier EMBASE for all articles, abstracts, and reviews published through May 2006. The search terms for Pub Med were the medical subject heading (MeSH), "G suit", and text words "MAST", "AST" "Antigravity suits", "pneumatic suits" "NASG", "use of NASG/PASG/MAST in obstetric hemorrhage" and "use of NASG/PASG/MAST in postpartum hemorrhage." Pub Med returned 839 references with the initial search, each of which was hand searched, and studies on varicosities, scars, and aerospace kinetics were discarded. This left 239 articles, of which 46 involved studies on any type of ASG and human patients with obstetrical/ gynecological hemorrhage or trauma, these 46 were reviewed for this article.

The references in identified papers were hand searched for further information. In addition, we searched the Journal of Trauma, The Annals of Emergency Medicine, and The Journal of Emergency Medicine. We contacted Dr. Ralph Pelligra of AMES Research Center-National Aeronautics and Space Agency (NASA/AMES), a member of the team that developed the NASG, to identify articles that were not found in electronic databases and to obtain historical information.

Summary of Historical Development

Before the advent of blood transfusion technologies, George W. Crile developed the first compression suit in

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[1] Basic emergency obstetric care (BEmOC), provided in health centers and small maternity homes, includes the capabilities for the administration of antibiotics, oxytocics, or anticonvulsants, manual removal of the placenta, removal of retained products following miscarriage or abortion, and assisted vaginal delivery with forceps or vacuum extractor. Comprehensive emergency obstetric care (CEmOC), typically delivered in district hospitals, includes all basic functions above, plus Caesarean section and safe blood transfusion. According to guidelines jointly issued by WHO, UNICEF, and UNFPA, it is recommended that for every 500,000 people there should be four facilities offering BEmOC and one facility offering CEmOC. http://www.unfpa.org/mothers/obstetric.htm

order to maintain patients' blood pressures during surgery [20]. Crile tested the concept of counterpressure to reduce bleeding. He found that applying external pressure on an extremity, (e.g. compressing the paw of an animal), first with his hand and then by wrapping the extremity tightly with bandages, resulted in an increase in blood pressure [20].

Crile translated this observation into the design and production of a pressurized rubber suit, which, in 1909, he modified into an inflatable compression garment [21, 22] He illustrated the effect of the suit in a published case of an exsanguinated patient [23]. The patient received a protocol standard for the time of stimulants and saline infusions, with little response. The suit was applied when the patient was gasping, unconscious and with no palpable pulse. On applying the suit the patient regained consciousness, the pulse became palpable, and blood pressure increased to 110 mmHg. Crile does not state if the patient survived after this resuscitation.

Crile's pressure suit was later abandoned due to unspecified "technical difficulties in its application" and to the introduction of modern blood transfusion techniques with citrated blood in 1914 [24]. However, the counter-pressure suit was resurrected during World War II as the Antigravity Suit (G-suit) to protect the Army Air Corps against syncope during rapid ascent [21, 22, 25]. Later, the G-suit was also used in emergency medical treatment. In 1966, Gardner reported using the G-suit to control post-operative hemorrhage [26]. During the Vietnam War, the G-suit was used for stabilizing and resuscitating soldiers with traumatic injuries to the abdomen, pelvis, and lower extremities[21, 27]. In 1969, Cutler and Daggett described its use in eight patients with hemorrhagic shock due to massive trauma and reported a 50% survival rate [22]. The G-suit was further adapted into a half suit, known as the military anti-shock trousers (MAST) in 1973 by Lt. Col. Burton Kaplan [28].

Beginning in the mid l970s, the MAST/PASG was used by emergency medical teams in the United States to stabilize patients before and during transfer (pre-hospital care) [25, 28-30]. It gained widespread acceptance and use in the treatment of trauma and emergencies, including: pelvic and lower limb fractures, hypovolemic shock, septic shock, and control of intra-abdominal pelvic and upper leg hemorrhage, in addition to gynecological and obstetric hemorrhage[28-30]. It was not only included as essential equipment for ambulances by the American College of Surgeons' Committee on Trauma, but in 1977 its use was legislated as required ambulance equipment in two-thirds of the states in the United States [27, 31] .

However, the PASG has been called one of the most controversial pre-hospital interventions [32]. In the late l980s-1990s, the PASG fell into disfavor with emergency medicine, based on results of three randomized controlled trials (RCTs) [31], described below. Most recently, developments in ASGs have led to the NASG, designed by NASA/AMES to overcome some of the problems associated with the PASG. The NASG is promising for the treatment of obstetric hemorrhage, including PPH.

Mechanism of Action of ASGs

Any ASG, from Crile's pressurized suit to the PASG to the NASG, function by exerting circumferential counter pressure to the capacitance vessels of the lower body in order to shunt blood from the lower extremities and abdominal area to the vital organs: the brain, heart, and lungs. It also provides hemostasis for bleeding in the lower body [11].

McSwain [25, 33] describes the laws of physics that underlie the mechanisms of action of ASGs, including Poiseuille's Law, Bernoulli Principle, and the LaPlace Law (see Appendix **1**). The ASG increases blood pressure by increasing systemic vascular resistance. It decreases the vascular volume and increases vascular resistance in the parts of the body compressed by the ASG. In these compressed regions, the radius of blood vessels is decreased, thus slowing down blood flow. In hypovolemic patients, the ASG increases venous return and the resulting increase in preload is associated with increased cardiac output [33-37].

Non-randomized Human Trauma Studies

Animal studies have shown improved survival rates with the PASG [38, 39], and positive outcomes from non-randomized studies of human trauma patients have been reported. Neither of these relates specifically to women's health, and consequently they will not be given critical review in this paper. If interested, readers can find information regarding the trials in trauma review papers such as McSwain [25, 31, 33]. The general consensus of these studies on trauma patients was that the PASG decreased bleeding and rapidly restored vital signs, but that there were adverse effects, such as masking of symptoms [22] and compartment syndrome [21] due to over inflation, complaints that the application of the PASG was time consuming, and a lack of evidence that the PASG reduced mortality or morbidity.

RCTs

On the basis of the reassuring visual decrease in bleeding and immediate recovery of vital signs and consciousness described in case studies and observed by pre-hospital emergency medical practitioners, the PASG was, as previously described, incorporated into pre-hospital treatment protocols by the American College of Surgeons' Committee on Trauma in 1977 [30, 31]. It was not until the late l980s/early 1990s, however, that RCTs were published.

In 1987, 1989, and 1995, three human PASG RCTs were published [40-42]. These studies are the sole RCTs that have been conducted on the PASG, and each focused on the use of the PASG to manage trauma victim care in urban settings. No RCTs for obstetric indications has yet been conducted. Mattox *et al*. [42] randomized, by alternating day assignment 911 adult patients who were different from each other in race/ethnicity, socioeconomic status, age, gender, and type and extent of traumatic injuries, but similar in that none had been screened for any medical complications that might be contraindications for PASG use. All patients had some form of trauma and a systolic blood pressure of ≤ 90mmHg. Randomization was to either paramedical pre-hospital

treatment with PASG or no-PASG. All patients received equivalent treatment after hospital arrival. The PASG patients required longer stays in the ICU (3.7 ±12.5 vs. 1.9 ± 6.5, p<0.05), longer hospital stays (non-significant), and, most importantly, were found to have lower frequency of survival (69% of PASG patients compared to 75% of non-PASG patients, p<0.05). However, in this study, the device was used for some patients with penetrating thoracic trauma, a now known as a contraindication for PASG use [32].

Chang *et al*. [41], using the same alternating day assignment and same protocol as Mattox *et al*., randomized 291 patients to either PASG or no-PASG treatment groups before transport to trauma centers. The PASG was found not to be effective in decreasing hospital stay or mortality.

Bickell *et al*. [40], randomly assigned 201 hypotensive patients with penetrating anterior abdominal injuries to PASG or no-PASG pre-hospital treatment by alternate day allocation. They too did not find significant differences in survival rates. A meta-analysis [43] of these studies found that risk of death was higher in the PASG group, RR 1.13 (95% CI 1.0, 1.3).

After the publication of these RCTs, the PASG fell into disfavor with emergency medicine for all patients. However, as previously stated, these trials included all trauma patients, regardless of age, location, or type of injury or if the injury was a known contraindication of the PASG. Non-randomized trauma studies on patients with intra-abdominal or retroperitoneal hemorrhage indicate improved survival with the PASG [27, 35, 44]. This is relevant to the concept of using any ASG for obstetric hemorrhage.

Current Status of PASG in Emergency Medicine

A position paper on the PASG by the National Association of EMS Physicians [45] noted the lack of controlled trials, but on the basis of other, less rigorous studies, deemed the PASG as "Class 1 usually indicated and effective for hypotension due to ruptured aortic aneurysm, but of uncertain efficacy for other emergency situations." Its use for uncontrolled gynecologic hemorrhage, urologic hemorrhage, and ruptured ectopic pregnancy was designated a "Class llb acceptable, but uncertain efficacy, maybe helpful, probably not harmful."

In spite of the negative or neutral RCT results, proponents of the PASG including emergency medical practitioners [32] still recommend the use of the PASG for patients with a pelvic fracture, or those bleeding in the abdomen, retro-peritoneum, pelvis or thighs [33]. Likewise, in France, use of the "pantalon antichoc" (ASG) is questioned for widespread use, but endorsed for use with postpartum hemorrhage, disseminated intravascular coagulo-pathies associated with pregnancy and labor, and other obstetrical and gynecological bleeding [46, 47]. A Doppler study of regional blood flow using a fully inflated PASG on 10 healthy adults showed that PASG inflation caused a decrease in blood flow distal to the renal arteries, providing support for the use of the PASG to decrease uncontrollable hemorrhage from iliac, pelvic, and leg vessels [47].

Use of PASG/MAST for Obstetric Hemorrhage

The PASG is included as an approved treatment for intractable PPH hemorrhage in the American College of Obstetrics and Gynecology Guidelines [48]. The recommen-dations on the use of the PASG for obstetric hemorrhage are based on case reports, as no RCTs for obstetrical indications have yet been conducted. One of the first reports on the "antigravity suit" or G suit was published in 1958 [49], the authors describe a woman with a placenta percreta who had uncontrollable hemorrhage and received more than 58 units of blood before the antigravity suit was applied. The authors state that its application marked the "turning point" in the patient's treatment. The patient had received an abdominal hysterectomy after attempts to remove the adherent placenta failed, the uterus was described as having no anterior wall, with the placenta having invaded and replaced the myometrium. Hysterectomy did not resolve the bleeding and the patient had internal iliac artery ligation. She continued bleeding, despite receiving 57 units of blood and large uterine packs, and, at 18.5 hours post delivery, had a BP of 86/62, pulse 144. At this point, the G-suit was applied, and the patient's BP returned to 104/72. Only one additional unit of blood was needed.

In 1979, Hall and Marshall [50] studied the effect of the PASG in the management of four women with ectopic pregnancies awaiting surgery. The administration of the PASG resulted in an improvement in blood pressure and pulse, even before fluids were administered. The authors concluded that the PASG was useful for temporary manage-ment of massive obstetric hemorrhage.

In 1979, Pelligra and Sandberg [30] described the use of the PASG in three women with obstetrical hemorrhage, the first had an intra-abdominal pregnancy delivered by laparotomy, the second a placenta previa, and the third a laparotomy and hysterectomy for placenta accreta. All three women were placed in the PASG after routine resuscitative measures failed to control the hemorrhage. Two of the three women had multiple surgeries as part of efforts to secure hemostasis prior to the application of the PASG. Prompt recovery and stabilization were reported in all women. The authors also stated that the PASG reduced the need for further blood transfusion in the third case.

In 1993, Sandberg and Pelligra [51] further reviewed the use of the PASG in the management of hemorrhage in the cases of two women with abdominal pregnancies. One of the cases had been described previously in the 1979 report [30]. Similar to that description, applications of the PASG lead to a remarkable improvement in blood pressure and decrease in blood loss.

The PASG has also been used in gynecology. In 1984, Pearse *et al*. [28] reported the use of the PASG in a 42-year-old woman with stage IB carcinoma of the cervix, who developed severe hypovolemic shock from hemorrhage during surgery. Standard resuscitative therapy did not stop the bleeding and coagulopathy developed. The PASG was then put in place to secure hemostasis. There was immediate improvement in blood pressure and pulse; the PASG was kept on for 72 hours.

In 1999, Bengt *et al.* [52] also described the use of the PASG as a temporizing measure before definitive radiological intervention in two women with uterine bleeding. One woman had placenta accreta, while the other suffered undiagnosed, severe uterine bleeding. Both women were in shock and the bleeding did not respond to uterotonics, pressors, infusion of intravenous fluids, nor transfusion of blood and blood components. The authors concluded that the PASG successfully stabilized the women while awaiting transcatheter embolization.

In 2004, Ramachandran and Kirk [53] published a case report of PASG use for a 30 year old primigravida with hypovolemic shock and severe hemorrhage post cesarean section for abdominal pregnancy. Despite resuscitative measures of rapid IV infusions, two surgeries to remove the infant and the placenta, blood and blood products transfusion (36 U red cells, 20 U fresh frozen plasma, 7 U platelets and 10 U cryoprecipitate), and abdominal packing, she remained hypotensive, continued to bleed, and developed DIC. The application of the PASG resulted in a significant rise in blood pressure and decrease in bleeding [53]. Both the mother and the baby survived, although the mother remained in the hospital for three weeks.

Thus, studies show that the ASG maintains a role in obstetric and gynecological care, although its use is not yet supported by high quality evidence provided by controlled trials.

NASG

The NASG was adapted from the PASG/MAST by NASA/AMES in 1971 [54]. Although simpler in design, the effects of the NASG are so similar to the PASG that the United States Food and Drug Administration (FDA) granted the NASG a 501(k) medical device regulations number, without further clinical trials. The NASG is a lightweight, relatively inexpensive, washable neoprene garment. It is designed in horizontal segments, three segments on each leg, a segment over the pelvis and a segment over the abdomen that contains a small, foam compression ball. Using the three-way elasticity of neoprene and the tight Velcro fasteners, the garment can apply 20 to 40 mmHg of circumferential counter pressure to the lower body from the ankles to the level of the diaphragm. This amount of pressure is effective in reversing hypovolemic shock by shunting blood from the lower extremities and pelvis to the vital core organs.

Advantages of NASG for Management of Obstetrical Hemorrhage in Low Resource Settings

To our knowledge the PASG has not been used for obstetrical hemorrhage in many low resource settings. Although the physiological effects of the NASG and the PASG are similar, there are many differences which favor the use of NASG for management of obstetrical hemorrhage. The PASG requires inflation and careful management of pressure levels, both to maintain adequate pressure and to prevent over inflation resulting in compartment syndrome, ischemia, and necrosis [55]. Also, the valves and manometers required to maintain inflation are subject to leaks and malfunctions, thus specialized training is required for safe and effective use of the PASG. This makes widespread use in developing countries by persons without a medical background unfeasible.

The NASG is less expensive [wholesale price $160.00 per NASG compared to $550.00 for the PASG (personal communication, William Holden, David Clark Company, Inc.)] and is more quickly and easily applied. The training required to use the NASG safely and effectively is minimal. A single provider, regardless of education or medical background, can be trained to place a woman safely in the garment. Such training, which includes hands-on practice, takes approximately one hour. Removal of the suit and its use during surgery require further training, and should only be performed in facilities capable of providing IV fluids and by trained providers.

The NASG is also washable and reusable at least 50 times (personal communication, Dr. Mohammed Mourad, El Galaa Hospital, Egypt). Lighter and more flexible than the PASG, it is easier for a woman to "wear" the NASG for longer periods of time, often necessary in the long transport conditions of low resource settings. While the PASG is bulky and obscures the perineum, the design of the NASG permits complete perineal access, so that urinary catheters can be placed, genital lacerations can be sutured, speculum or bimanual examinations can be performed, and manual vacuum aspiration or uterine exploration or curettage can be accomplished with the NASG in place. Thus, the source of much obstetrical bleeding can be located and repaired while the garment maintains vital signs.

Review of Studies of NASG for Obstetrical Hemorrhage in Low Resource Settings

The first published report on the use of the NASG in obstetric hemorrhage was by Hensleigh [14], who described a case series of 6 women with obstetric hemorrhage and shock in a large maternity hospital in Sialkot, Pakistan. The estimated blood loss prior to placement of the NASG was between 1200 mL and 4000 mL. The obstetric diagnoses included: placenta previa, uterine atony with retained placenta, lacerations of the cervix and vagina, placenta accreta, and placental abruption. One woman was unconscious, one had mental confusion, two had no palpable pulse, and the four others had pulses of $\geq$ 120 beats per minute (BPM). The effect of the NASG on resuscitation was measured by restoration of blood pressure to mean arterial pressure (MAP) of 70 mmHg and clearing of sensorium. All of the women had MAP > 70 mmHg within 5 minutes of NASG application. Other resuscitative measures included: crystalloid infusions, hysterotomies in two women, repair of genital lacerations, and blood transfusions. Women who were placed in the NASG not only experienced rapid resuscitation from hypovolemic shock, but also remained stable while awaiting definitive treatment. The mean time that women remained in the NASG was 24.3 hours. No adverse effects were observed apart from a transient decrease in urine output.

Brees *et al.* [18] reported a second series of fourteen consecutive cases of obstetric hemorrhage and hypovolemic shock in the same hospital in Sialkot, Pakistan. Women with blood loss of $\geq$ 750 mL, systolic blood pressure of $\leq$ 100 and pulse $\geq$ 100 were included in the study. Blood loss before

NASG application was estimated to be between 2000 and 4500 mL. Hemorrhage etiologies included: post caesarean hemorrhage, placenta previa, perforated septic abortion, uterine atony, cervical lacerations, abruption, uterine rupture, and delayed secondary PPH. The range of time in the NASG was 18-57 hours with a mean time of 31 hours. It took on average 5 hours to obtain blood donors and commence transfusions; the women were transfused with between one and six units of blood. Thirteen of the fourteen women survived, and the only case of mortality had multiple organ failure and severe anemia before the application of the NASG. In addition, there was an unnecessary delay in the application of the garment in this case; the patient died on post-operative day 19.

In the first comparative study of the NASG's use in obstetrics, Miller *et al.* [56] conducted a pre-post pilot study of consecutive obstetric hemorrhage cases in 4 tertiary care hospitals in Egypt. The purpose of this study was to compare the outcomes of standard management of obstetric hemorrhage (pre-intervention group) to the outcomes with the NASG and standard management (post-intervention group). The women included in the study had already experienced >750 mL of blood loss and either a pulse of >100 BPM or systolic blood pressure of <100 mmHg at the time of study admission. A total of 364 women were enrolled with 158 women in the pre-intervention and 206 in the post-intervention groups. The main outcome, blood loss, was measured using a closed-end, graduated, plastic drape placed under the buttocks. For four months, all women that met the eligibility criteria were treated according to the hospitals' standard protocol for obstetric hemorrhage and shock. This included the administration of crystalloid intravenous fluids, use of uterotonic medications (IV oxytocin and rectal misoprostol), uterine massage, determination of the source of bleeding, surgery when necessary, and blood transfusions. For the next four months, women meeting the eligibility criteria were treated using the same standard protocol and the NASG. The women in the post-intervention NASG group had a statistically significant greater loss of blood and more severe signs of shock at study entry compared with the women in the pre-intervention group. Despite this, the study showed a statistically significant 50% lower measured median blood loss in the post-intervention NASG group compared to the pre-intervention group (250 mL versus 500 mL, p < 0.001). There were also non-statistically significant decreases in morbidity and mortality. However, there was a 78% decrease in severe adverse outcomes, a variable representing the combination of severe morbidity and mortality: 3.2% (n=5) in the pre-intervention group and 1% (n=1) for the post-intervention NASG group (RR 0.31, CI, 0.66-1.56).

In a further analysis of the pre-intervention / post-intervention NASG data from Egypt by Miller *et al.* [6], the NASG was documented to decrease the time to recovery from hypovolemic shock as well as decreasing blood loss. Recovery from hypovolemic shock was defined as a decrease in pulse from $\geq$ 100 BPM to < 100 BPM and a return to normal Shock Index (SI).

Shock Index, an indicator derived by dividing the pulse by the systolic BP, is considered a more reliable indicator of shock and severity of hypovolemia than either sign alone, particularly with concealed hemorrhage, as with ectopic pregnancies [57, 58]. A higher shock index indicates a greater risk of severe morbidity or mortality. The normal SI range for healthy euvolemic patients is between 0.5-0.7 [57]. Due to physiological changes in pregnancy and the higher blood plasma volume of pregnant women [59] an SI value of $\leq$ 0.9 was used [6]. Recovery from shock was found to be independent of other resuscitative measures such as the volume of IV fluids given and the timing of blood transfusions.

The data from 249 women with obstetric hemorrhage (104 pre-intervention and 145 post-intervention NASG group) with non-missing data for time to recovery and initial SI was analyzed for time to shock index recovery. Initial SIs ranged from 0.67-2.80, mean SI = 1.22. The median recovery time to SI <= 0.9 for the NASG group, 75 minutes, was statistically shorter when compared to the recovery time of 120 minutes for the pre-intervention group (log rank test =8.99, p=0.003). When adjusted for SI at admission at two different levels of severity, SI $\leq$1.22 and SI $\geq$ 1.22, the treatment groups were found to be statistically different from each other (log rank test 15.13, p=0.000).

In the same report [6], the authors analyzed data from 251 women (106 pre and 145 post) for time to pulse recovery. They demonstrated a median recovery time of 180 minutes for the pre-intervention group and 90 minutes for the post-intervention NASG group (log rank test =17.92, p<0.001). A log rank test after adjusting for pulse at admission also showed that the two treatment groups were statistically different (log rank test 21.20, p<0.000).

This same report [6] also described an independent effect of the NASG on decreased blood loss from PPH due to uterine atony among 69 pre-intervention cases and 76 post-intervention NASG cases, regardless of the volume of oxytocin received. When the dose of oxytocin was statistically controlled for, women in the post-intervention NASG group had 50% lower blood loss when compared with women in the pre-intervention group (299 mL versus 603 mL).

A recent report [60] described data combined from studies in Nigeria and Egypt. The studies included 120 Nigerian women and 143 Egyptian women with severe obstetrical hemorrhage and severe shock. The methods used in the Nigeria study were identical to the pre/post study described in the Egypt NASG study [56]. There were 104 women with severe obstetric hemorrhage, defined as EBL > 1000 mL and pulse > 100 BPM in the pre-intervention (standard management) group and 159 women with severe obstetric hemorrhage in the post-intervention (standard management plus NASG) group. The median measured blood loss in the drape after study admission was 700 (0-3500) for the pre-intervention group as compared to 250 (0-880) in the post-intervention NASG[2] group. The median difference for blood loss was 490 mL, 95% CI: 350-600.

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[2] Eleven women (10.6%) in the pre-intervention group and 18 women (11.3%) in the NASG group had ectopic pregnancies with little to no external hemorrhage, these women were in severe shock with large volume of concealed bleeding.

There were not statistically significant differences in morbidity or mortality

CONCLUSION

Anti-shock garments have a long and somewhat controversial history. The PASG, while no longer the pre-hospital treatment of choice for the majority of lower body trauma cases, is still indicated and approved for intractable hemorrhage in the pelvis and retroperitoneum, and is particularly useful for long transports from rural areas. The successful use of the PASG in obstetrics/gynecology for ectopic hemorrhage, postpartum and post cesarean bleeding, abdominal pregnancies, placenta accreta and percreta, and as a temporizing measure to stabilize patients awaiting arterial embolization has been documented in case studies [28, 30, 47-53]. However, no RCTs of any ASG (PASG or NASG) for obstetric hemorrhage have been conducted.

Research on the NASG has been limited to case series and small, non-randomized, unblinded, pre-post pilot studies. In these studies, the NASG appeared to be effective in significantly reducing blood loss as well as in reducing time to recovery from shock. Additionally, there was a non-significant trend towards a reduction in severe adverse outcomes. However, the NASG's effectiveness in reducing death and acute morbidity due to obstetric hemorrhage—the ultimate goal—has yet to be tested using a rigorous, robust study design. Like the PASG, the immediate effects of decreased blood loss and restoration of vital signs with the NASG are impressive; however, the PASG did not reduce mortality, morbidity, length of hospital stay, or ICU admissions for trauma victims in urban settings when tested in RCTs.

However, there are many reasons to believe that the outcomes of an RCT of the NASG for obstetric hemorrhage in low resource settings with long delays in obtaining definitive care would be different from the PASG trauma RCTs. First, the NASG avoids some of the adverse outcomes of the PASG: namely, overinflation with subsequent compartment syndrome and ischemia. Second, when used for obstetric hemorrhage, the NASG would be applied to reduce bleeding in the pelvic region, the very region that studies have shown to benefit the most from compression [47]. Third, the NASG would be used as a first-aid, temporizing device for women who face multiple delays in obtaining emergency obstetrical care. While trauma patients in urban areas with short transport times may be better or equivalently managed by a "scoop and run" approach, this is not the case for the majority of poor, rural women who deliver far from health care facilities and/or come for care at facilities that do not have the staff or supplies to provide definitive therapies, including blood and/or surgery, rapidly.

Given the paucity of research on the NASG for obstetric hemorrhage there is much to be done before widespread acceptance and implementation in evidence-based practice can be recommended. Further research could include:

1. **A randomized cluster trial of the NASG in high volume, low resource settings with long delays in obtaining blood and/or surgery.** Such a design, while rigorous, would avoid the practical and ethical issues of individual randomization. Given the immediate visual results of NASG application (reduction of blood loss and restoration of vital signs), few providers would be able to withhold use of the NASG if it were available. Since the NASG is not yet a proven, effective technology, randomizing facilities to NASG or not NASG would avoid that dilemma. A study would need to be adequately powered to definitively demonstrate the efficacy of the NASG to reduce mortality, reduce morbidities, reduce the volume of blood transfusions, reduce the incidence of emergency hysterectomies, reduce the length of hospital stays, reduce the incidence of ICU admissions, etc.

2. **Effectiveness Studies of the NASG at the Primary Health Care level.** To date the pilot studies of the NASG have been at tertiary care centers capable of providing CEmOC, although with some delays. The delays in obtaining blood transfusions in both Pakistan and Nigeria were 5 [18] and 6.73 [61] hours respectively. However, IV fluids and other temporizing shock and hemorrhage management were available. Will the NASG reduce mortality and morbidity when applied at the lowest level of the health care system?

3. **Operations Research and Acceptability Studies.** If the NASG is shown to be efficacious, studies are necessary to answer questions such as: What training and supervision packages are necessary to implement and maintain proper use of the NASG at primary health care centers and at higher level facilities? What are patient responses to being treated with the NASG? What are the challenges to prompt and correct application and removal of the NASG? Could community education about the NASG result in reduction in delays in getting women with obstetric hemorrhage to health facilities?

In conclusion, the NASG is a promising new technology for the treatment of women with obsetetric hemorrhage in low-resource settings. It appears that its inclusion in the package of interventions for prevention and treatment of obstetric hemorrhage—including AMTSL, oral prophylactic misoprostol, the use of appropriate uterotonics for treatment of PPH, and rapid transport to EmOC when bleeding cannot be controlled [62] — may make a substantial contribution to reducing maternal mortality and morbidity. Given the importance of obstetric hemorrhage as a cause of maternal mortality, and the commitment of the national signatories to the Millennium Development Goal of reducing maternal mortality by 75% by 2015 (Goal 5), there is an urgent need for proven, effective, low-technology, easy-to-use tools that will decrease bleeding and reverse shock. In order to determine the contribution of the NASG in these efforts, further testing using rigorous study designs should be made a priority.

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APPENDIX 1

1. Poiseuile's Law: $F = \dfrac{(P_1 - P_2)\, R^4}{8NL}$

F= Flow, P_1 = entrance pressure, P_2 = exit pressure, R = radius, N = viscosity, L = length.

The rate of flow through a blood vessel is associated with the size of the vessel radius, so that the blood flow rate that can pass through a blood vessel per unit time is related to the fourth power of the radius. By placing external pressure on the vessels and reducing the vessel radius by one half, the NI-ASG will reduce the blood flow through the vessels by a factor of 16. Decreasing the vessel radius has three outcomes: a decreased volume of blood in those vessels compressed by the NI-ASG, a reduced flow of blood through the compressed part of the vascular system which increases flow in the rest (uncompressed areas) of the circulatory system, and, if the flow remains the same to those vessels with reduced diameters, more pressure is required to force it through, (systematic vascular resistance). All of this results in increased perfusion to the uncompressed parts of the body (core organs).

2. Laplace Law: $T = PR$

T= tension inside a blood vessel, P = transmural pressure, and R= vessel radius. The NI-ASG places external counterpressure, thus compressing lower body and splanchnic blood vessels, and reducing both the transmural pressure and the radius of the vessels. These synergistic effects reduce the difference in tension across the vessel, which in turn reduces blood loss.

3. Bernoulli Principle: Formula: $Q = A\, \dfrac{P}{E} + V2$

Q = rate of leakage, A = area of laceration/tear/opening, P = intraluminal pressure minus the extraluminal pressure (the transmural pressure), E = density of the blood, and V = speed or velocity of the blood flow. The rate of blood loss from a lacerated/torn/open blood vessel depends on the size of the defect, the intraluminal pressure, and the extraluminal pressure. External pressure will compress the torn vessel walls and reduce the size (area) of the defect.

(Adapted from McSwain, [25]).

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