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Non-pneumatic Anti-Shock Garments: Clinical Trials and Results

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INTRODUCTION

The International Federation of Gynecology and Obstetrics (FIGO)/International Confederation of Midwives (ICM) recommendations for active management of third-stage labor, including uterotonic prophylaxis with additional uterotonic treatment when necessary, clearly reduce the incidence of severe post-partum hemorrhage (PPH) due to uterine atony[1]. Despite this, many women suffer intractable PPH from atony or other obstetric etiologies, including genital lacerations, ruptured uterus, ruptured ectopic pregnancies, as well as placenta previa, accreta and abruption. Multiple blood transfusions are often required to resuscitate and stabilize these individuals, and the institution of hemostasis may require surgical interventions or procedures only available at tertiary levels with skilled providers. Until the time when quality comprehensive emergency obstetric care (CEmOC), including surgery and/or blood transfusions, is readily available for all women in all locations, strategies and technologies for treatment of hemorrhage and hypovolemic shock are of exceptional value, especially those that can be readily provided and easily applied, even by persons with little or no medical training. Among the most promising of technologies to reduce maternal mortality is the non-pneumatic anti-shock garment (NASG), a first-aid device that when appropriately used may reduce the mortality and morbidity associated with obstetric hemorrhage[2–8].

THE NON-PNEUMATIC ANTI-SHOCK GARMENT

The NASG is a simple device, proposed as the immediate first-aid treatment for reversing hypovolemic shock and decreasing blood loss secondary to obstetric hemorrhage, by application of lower body counter pressure. The NASG also has the potential to keep women alive during long transports from lower level facilities or home to the CEmOC facilities and during delays while waiting for definitive therapies at these facilities.

The NASG is a lightweight, washable and reusable (at least 40 times), neoprene compression garment that resembles the lower part of a wet suit. The NASG, manufactured by the Zoex Company, received a United States Food and Drug Administration (FDA) 510(k) medical device regulations number (FDA device # K904267/A, Regulatory Class: II, January 17, 1991) (Section 510(k) Medical Device Amendment, FDA, Office of Device Evaluation, 1991) and can be exported to countries outside the United States. The NASG is designed in horizontal segments, with three segments for each leg, a segment to be placed over the pelvis, and a segment over the abdomen that contains a small, foam compression ball (Figure 1).

Unlike the pneumatic anti-shock garment (PASG), or medical anti-shock trousers (MAST), both of which preceded the development of the NASG, there are no pumps, tubing, or gauges to add either complexity or risk of malfunction. Using the three-way elasticity of neoprene and the tight grip of the Velcro fasteners, the garment applies circumferential counter pressure to the lower body from the ankles all the way up to the level of the diaphragm (Figure 2). Excess pressure and

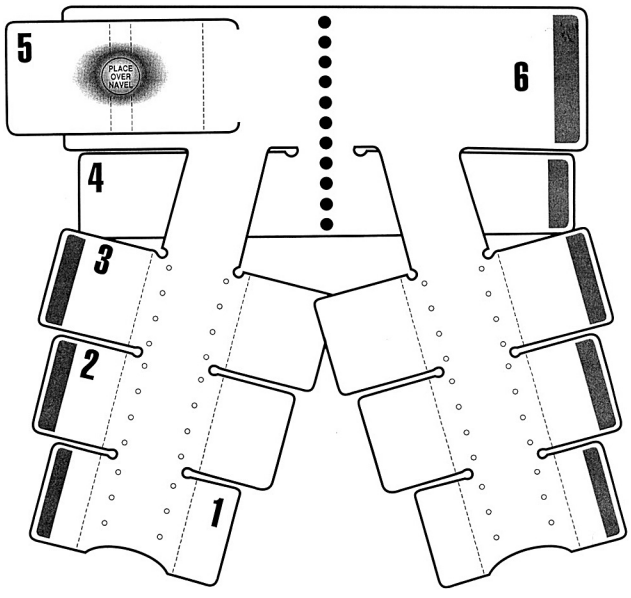

Figure 1 Schematic diagram of the non-pneumatic anti-shock garment (NASG)

resultant tissue ischemia, reported complications with the pneumatic PASG, are not an issue with the NASG.

Application of the garment requires about 2 minutes; about 10 minutes after application, most patients with severe shock regain consciousness and vital signs begin to recover. With the bleeding slowed and the blood pressure restored, clinicians' panic levels decrease, and there is time to deliberately assess the situation. The patient and her family can be given emotional support and prepared for transport to a referral-level facility. In addition, patients can remain in a stable condition for hours while blood transfusions are initiated and arrangements made for surgery or other required therapies.

Development of the NASG

The modern NASG is a non-pneumatic refinement of the PASG. The PASG was adapted from a device developed by George Crile in the early 1900s before the advent of technologies for blood transfusions. Crile, a surgeon who wrote textbooks on blood pressure and shock, designed the first inflatable pressure suit to maintain blood pressure during surgery. This pneumatic suit underwent multiple modifications and was further refined for use as an anti-gravity suit (G-suit) for the Army Air Corps in 1942. During the Vietnam War, the G-suit was modified for stabilizing and resuscitating soldiers with traumatic injuries before and during transport. The G-suit was then modified to a half-suit, which became known as military anti-shock trousers (MAST).

The PASG: pneumatic predecessor of the NASG

The MAST/PASG has been used since the 1970s by emergency rescue squads in the United States to stabilize patients with a variety of disorders: pelvic and lower limb fractures, hypovolemic shock, septic shock, and to control intra-abdominal, pelvic, thigh and obstetric–gynecological hemorrhages[9,10]. More recently, Andrea and colleagues reported using MAST devices to stabilize two women with intractable uterine bleeding while preparations were made for transcatheter embolization[11].

The PASG requires inflation and careful management of pressure levels, both to maintain adequate pressure and to prevent over-inflation which could result in compartment syndromes, ischemia and necrosis. Moreover, the valves and manometers that maintain inflation are subject to leak and malfunction. In addition, specialized training for safe and effective usage is necessary, which makes widespread application of the PSAG in developing countries problematic. The high cost (596–1099 US$ plus potential costs for maintenance and replacement parts) further restricts utilization[12].

Efficacy of the PASG for pre-hospital trauma care

In 1988 McSwain reviewed the physical principles responsible for the physiologic effects of lower-body counter pressure with application of the PASG[9]. Numerous studies in hypovolemic animals and humans demonstrated that the PASG increased blood

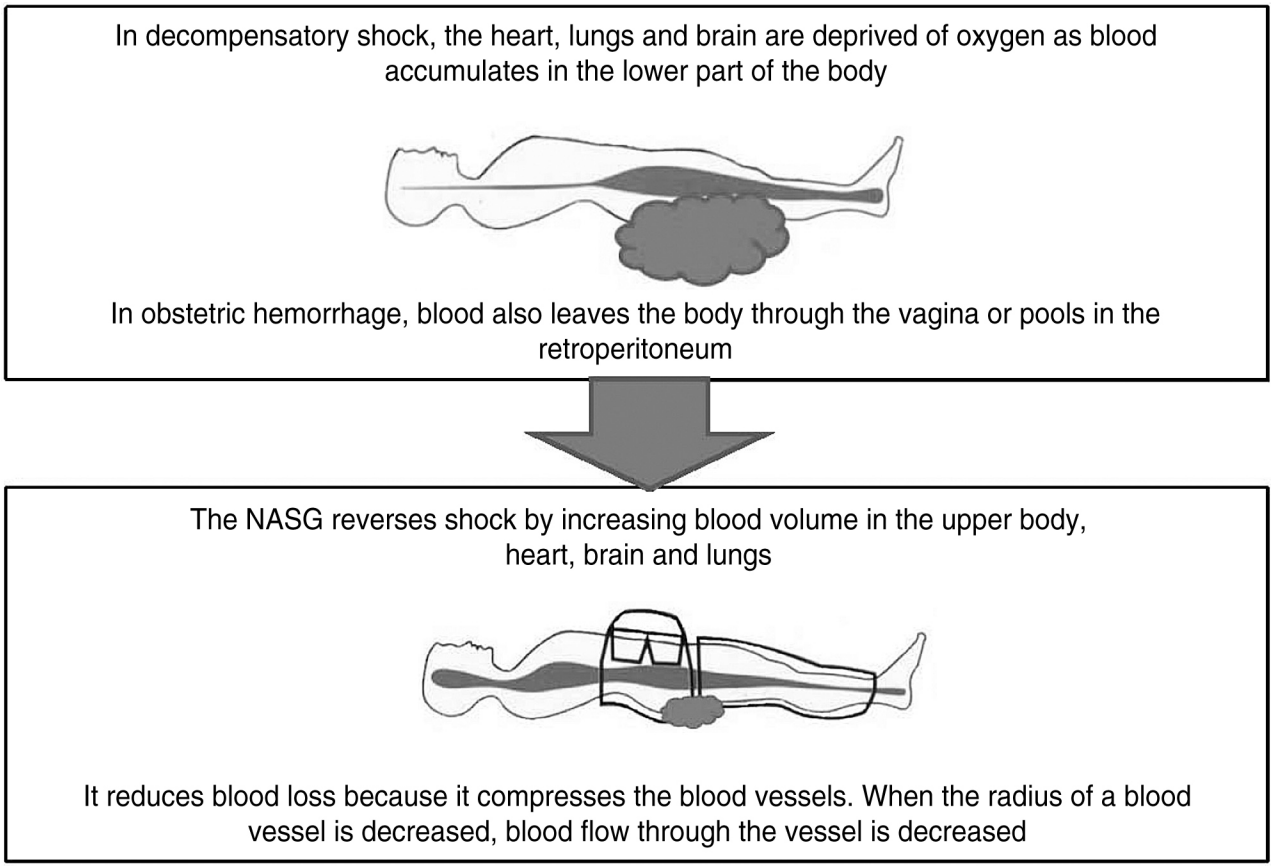

Figure 2 Possible mechanisms of action of the non-pneumatic anti-shock garment

pressure by decreasing the vascular volume and increasing vascular resistance within the compressed region of the body. When blood flow or arterial vascular size is measured above the device, the flow is greater and vessels are larger. In the compressed region, the radius of blood vessels is decreased, thus diminishing blood flow. In the hypovolemic model, the PASG increases venous return and the increase in preload is associated with increased cardiac output[13].

Although animal studies show improved survival rates except for thoracic injuries[14,15], it is uncertain if the rapid, positive changes in vital signs and blood loss affect survival in humans. Despite widespread acceptance of the PASG for use in military and civilian trauma injuries, including being required on ambulances in the late 1970s and 1980s[16], and the appearance of reports of small series demonstrating successful treatment of various bleeding conditions in adults and children, no definitive prospective randomized treatment trials show improvement in survival. The three United States-based, prospective, alternate-day, randomized treatment trials of civilian trauma cases failed to find consistent results and are confounded by inclusion of injuries to the upper body, a contraindication to use of the PASG[17–19]. In some studies, the pH on hospital admission was lower with PASG use; at the same time, intensive care unit and hospital stays were longer and survival worse. A factor confounding the interpretation of these reports is that these studies were all conducted in a metropolitan setting where high-level hospital care was available within minutes; in such circumstances, even a brief delay in applying the PASG may have been a detriment to the benefits of early hospital care.

Current status of PASG for trauma and other indications

Although it is no longer required as essential equipment for ambulances, the PASG remains on the curriculum and in the textbooks for emergency medical technicians in the US[20,21]. A position paper on the PASG by the National Association of EMS Physicians cited the lack of controlled trials, but, on the basis of other reports, deemed the PASG as 'Class I 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 described as 'Class IIb acceptable, but uncertain efficacy, may be helpful, probably not harmful'. PASG proponents particularly recommend its use for bleeding in the abdomen, retroperitoneum, pelvis, or thighs[22]. The current recommendations in the US are that, while its effects on survival are unknown, it is probably indicated in patients with bleeding in the very areas (abdomen, retroperitoneum and pelvis) that are the bleeding sites for women with obstetric hemorrhage. Research on euvolemic female volunteers demonstrated that the PASG decreases aortic blood flow over a small area immediately distal to the renal arteries by up to 90%, but has little or no effect above this point[23]. This finding provides support for PASG use to decrease uncontrollable hemorrhage from the iliac, pelvic and leg vessels, but not for injuries above them[8]. In France, use of the 'pantalon antichoc' is questioned for widespread use, but its use for PPH, disseminated intravascular coagulopathies (DIC) associated with pregnancy and labor, and other obstetric and gynecological bleeding is endorsed[24].

It is not known whether outcomes might be different if the PASG (or the NASG) were to be used in low-resource settings with longer transport times, slower responses at the hospital level and longer delays in obtaining definitive therapy such as blood transfusions and/or surgery.

POTENTIAL BENEFITS OF THE NON-PNEUMATIC ANTI-SHOCK GARMENT FOR OBSTETRIC HEMORRHAGE IN LOW-RESOURCE SETTINGS

In 1971, a team working on technology spin offs at the National Aeronautics and Space Administration (NASA)/Ames Research Center developed a prototype pressure suit designed to protect hemophiliac children from bleeding into elbow and knee joints by straightening and compressing the joint until medical attention was available[25]. This pressure suit, the NASG, was adapted from PASG/MAST garments. Both PASG and NASG provide circumferential counter pressure in the lower body, but the NASG is simpler in design, more quickly and easily applied, less expensive and avoids the risk of over-inflation and excessive pressure[26] (Figure 3).

The NASG is particularly suited for use in low-resource settings. It is lighter and more flexible than the PASG, is more comfortable for a woman to wear for long periods of time, something which is necessary with the long transport times and delayed treatment conditions of low-resource settings. As with the PASG, within minutes of being placed in the NASG, a patient's vital signs are restored and, if confused or unconscious, their sensorium generally clears[3]. Women can remain in the NASG for as long as is required to restore their circulatory volume with crystalloids and to replace blood. In many prior reports

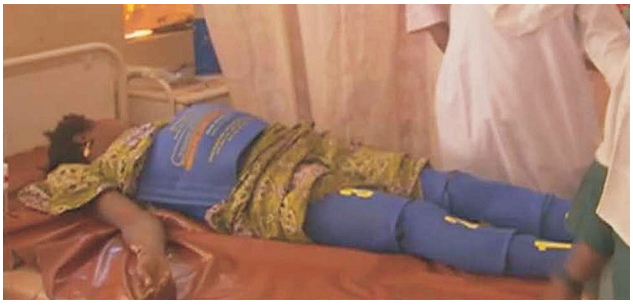

Figure 3 Patient wearing the non-pneumatic anti-shock garment in hospital. Reproduced with kind permission of Dawn Shapiro, 2010

of cases where blood transfusions were not readily available, this has often required 18–24 hours and, in one case, a woman remained safely in the NASG for almost 60 hours[27]. In Egypt, the mean time documented in the NASG was 269 minutes (more than 4 hours) ($n = 554$), and in Nigeria mean times documented were 690 minutes (more than 10 hours) ($n = 273$)[28].

A second benefit of the NASG for obstetric indications is that the design of the garment permits complete perineal access. Genital lacerations can be repaired, speculum or bimanual examinations performed, and manual removal of placenta or emptying of the uterus with vacuum aspiration or curettage can be accomplished with the NASG *in situ*. Stated another way, the source of most obstetric hemorrhages can be located and attended to while the garment maintains vital signs.

A third benefit of the NASG is that it significantly reduces further blood loss. When the NASG is applied, the external circumferential counter pressure is distributed evenly throughout the abdominal cavity and to the outside of the circulatory vessels, thereby tamponading venous bleeding. In the event of an arterial injury, continued bleeding results from the tension in the wall of the artery keeping the defect open. However, the NASG compresses all the intra-abdominal vessels including the internal iliac and uterine arteries. This compression reduces the radius of the arteries and reduces the transmural pressure (the difference between the pressure inside the artery and the pressure outside the artery) which, in turn, reduces the tension in the arterial wall, closing the defect and reducing blood loss[13]. Because the applied pressures could interfere with uterine blood flow, the NASG is not recommended for obstetric bleeding when the fetus is still viable, such as might be the case with placenta previa or abruption at more than 28 weeks. Post-delivery, however, or very early pregnancy (abortion, ectopic, trophoblastic disease of pregnancy) or when the fetus is not viable or is dead, the NASG can be used for any obstetric hemorrhage.

Another potential benefit for the use of the NASG for obstetric hemorrhage in low-resource settings is that persons with no medical background can learn to apply the garment rapidly and safely with minimal training. Hands-on practice in application and removal of the NASG takes approximately 1 hour. Once the garment has been properly applied, patients can be safely transported and/or await definitive treatment in a more stable physical condition. This final point is critical, as the majority of maternal deaths due to obstetric hemorrhage occur in areas where skilled birth and critical care attendance are limited or absent.

Decreased blood loss and reduced need for emergency hysterectomy, as well as diminished maternal morbidity and mortality, have currently been documented in case series, pilot studies and pre-intervention phase/NASG-intervention phase comparative studies in tertiary care centers in Pakistan, Nigeria and Egypt[28–37]. As of May, 2012, we have documented care with the NASG on over 5500 women.

SUGGESTED PROTOCOL FOR USING THE NON-PNEUMATIC ANTI-SHOCK GARMENT

The NASG is recommended for cases of obstetric hemorrhage meeting the American College of Surgeons' criteria for class II hypovolemic shock: more than 750 ml blood loss, pulse more than 100 bpm and blood pressure normal or slightly decreased[38]. The NASG is not recommended for use with a viable fetus, for patients with mitral stenosis, congestive heart failure, pulmonary hypertension, or in clinical conditions where bleeding sites are supra- diaphragmatic. It is axiomatic that the availability of the NASG does not negate the importance of preventive measures such as the active management of the third stage of labor or administration of uterotonics to treat uterine atony. Rather, the NASG can be part of the resuscitation measures aimed at 'damage control', that is, non-definitive control of the source of bleeding[39]. The authors recommend cardiovascular resuscitation using limited crystalloid infusion with the goal of 'permissive hypotension'[40–46]. This means infusing 1000–1500 ml of saline rapidly followed by a slower rate of infusion, 150 ml/h, to achieve a systolic blood pressure of 80–100 mmHg and urine output of at least 30 ml/h. Supplemental oxygen should be given until the patient is resuscitated, hemorrhage arrested and circulation fully normalized.

NASG application

The technique for application is for one person to stretch the neoprene panels with all their strength and fasten them with the Velcro as tightly as possible. The lowest (ankle) segment is applied first and the abdominal segment last. Anyone, at any level of the health care system or community, can be trained to apply the NASG rapidly and correctly. On the other hand, management of the women in the NASG requires more complex skills and training.

After application, if the woman experiences difficulty breathing, the abdominal panel should be loosened slightly, but not removed. However, if dyspnea continues, the NASG should be removed and the cause of the respiratory problem evaluated. A woman with normal cardiorespiratory function should experience no problems with ventilation. If there is no prompt response in terms of vital signs with placement of the NASG, the application should be checked for adequate tightness, and additional saline infusion given promptly. As soon as the patient is stable, there must be a diligent evaluation for the specific source and cause of the blood loss.

Timing of NASG application in resuscitation protocol

The ideal time to apply the NASG in the course of hypovolemic shock resuscitation depends largely on

the capacity of the facility level and the respective staff who are applying it and whether the woman can rapidly receive definitive therapy. In the lowest levels of the health care system, or even at the highest levels, if blood and/or surgery will be delayed, the NASG should be one of the first measures taken. Application can help in filling the blood vessels of the arms, thus making IV resuscitation more rapid, easy and, perhaps, not requiring surgical cut-down. In more highly resourced settings, the NASG has been applied when medical therapies have failed to stop bleeding, and during delays in obtaining surgery, or, when surgery has been tried, but bleeding continues or when awaiting arterial embolization (interventional radiology) teams[11,47].

Management of patient in the NASG

Care for the women in a NASG should proceed depending on her condition and the level of facility or health care system. The source of bleeding should be ascertained and measures taken to stop it depending on its origin, i.e., massage and uterotonics for uterine atony, repair of lacerations, etc. If the patient needs transportation, at a minimum she should receive IV fluids and oxygen, with close monitoring of vital signs. Vaginal procedures, such as speculum exam, manual removal of tissue (vacuum or curettage), can all be performed with the NASG in place. If laparotomy is necessary, the abdominal segments can be opened, but only immediately prior to making the incision, all other segments should remain closed. Often there will be a drop in blood pressure when this panel is removed; this should respond to additional crystalloid infusion. The abdominal panel should then be closed immediately after surgery; the NASG can be closed over the bandage. It does not seem to increase pain in the incision area, but seems to serve a splinting function.

NASG removal

The NASG is left in place as long as needed to achieve hemostasis and replace red blood cell volume with transfusions of blood and blood products. The NASG can be removed when the hemoglobin level is more than 7 g/dl or hematocrit 20%, pulse of less than 100 bpm and the systolic pressure more than 100 mmHg. Removal of the NASG begins with the lowest segment (#1) and proceeds upwards, allowing 15 min between removing each segment for redistribution of blood. If the blood pressure falls by 20 mmHg or the pulse increases by 20 bpm after a segment is removed, replace the NASG and consider the need for more saline or blood transfusions. If recurrent bleeding becomes apparent, replace the NASG and determine the source of bleeding.

STUDIES OF THE NON-PNEUMATIC ANTI-SHOCK GARMENT FOR OBSTETRIC HEMORRHAGE

Early examples of the potential benefits of using the NASG in obstetric hemorrhage in resource-challenged settings were documented in two published reports based on a series of 20 obstetric cases from one hospital in Sialkot, Pakistan[3,27]. These reports documented rapid resuscitation from hypovolemic shock, as well as an extended period of stabilization while awaiting definitive treatment for patients treated with the NASG. A combined analysis of data contained in these reports[48] showed no adverse effects of a prolonged time spent in the NASG. On the basis of these case series, NASG pilot studies were conducted (John Snow Inc., Egypt and University of California, San Francisco) and comparative pre-intervention/NASG intervention studies in CEmOC facilities in Nigeria* and Egypt† undertaken.

Comparative design used in Egypt and Nigeria studies

These studies compare the outcomes of a standardized protocol of shock and hemorrhage management in a pre-intervention (observational) phase with the same protocol plus the NASG in the intervention phase). The primary outcome was volume of measured blood loss after initiation of treatment with or without the NASG. To obtain a relatively objective measure of blood loss, maternal bleeding was measured using a specially designed, closed-end, calibrated plastic blood collection drape. Prior investigations with the use of this drape indicate that it is more accurate than visual assessment in measuring postpartum blood loss[49]. Other outcomes included mortality, severe acute maternal morbidities (SAMMs) associated with obstetric hemorrhage (acute respiratory distress syndrome, cardiac deficiency, central nervous system damage and renal failure)[50], and the need for emergency hysterectomy for intractable bleeding associated with uterine atony. The standardized, evidence-based protocol included active management of third-stage labor, immediate use of uterotonics for suspected postpartum uterine atony, training in administration of intravenous crystalloid fluid[51,52], thorough assessment for the source of bleeding, manual procedures such as bimanual compression, vaginal procedures, surgery, replacement of lost blood and, in the intervention phase, prompt application of the NASG.

Inclusion criteria for study enrollment included obstetric hemorrhage with hypovolemic shock (estimated blood loss ≥750 ml, systolic blood pressure <100 mmHg and/or pulse >100 bpm). All obstetric hemorrhage etiologies were included, *early pregnancy hemorrhage* (ectopic pregnancy, molar pregnancy, complications of abortion, retained placenta/tissue,

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DIC), *antepartum hemorrhage* (placenta previa, abruption, ruptured uterus, DIC), and *postpartum hemorrhage* (placenta accrete, uterine atony, retained placenta/tissue, lacerations, DIC).

Results from Egyptian pilot study

The four study sites in Egypt comprised high-volume referral CEmOC teaching facilities (El Galaa, Alexandria, Assiut and Al Minya)[30]. All were staffed by senior obstetricians and obstetric residents with immediate access to banked donor blood and surgery if required. In the pilot assessment, pre-intervention data, including measured blood loss, were collected for 3 months, after which all providers were trained in the use of the NASG. The only change to the pre-intervention clinical management was the use of the NASG. NASG-intervention data were collected for another 3 months.

The sample comprised 158 hypovolemic shock patients in the pre-intervention phase and 206 hypovolemic shock patients in the NASG-intervention phase. A range of primary diagnoses was present with no statistically significant differences between pre-intervention phase and NASG-intervention phase patients. Women in the NASG-intervention phase had more severe signs of shock ($p < 0.001$) than those in the pre-intervention phase. Despite this, NASG-intervention phase patients had 50% less median measured blood loss after study entry ($p < 0.001$). There was a non-statistically significant, but clinically important (69%) lower incidence of SAMMs and mortalities, which were combined as 'extreme adverse outcomes' (EAO). Specifically, the EAO rate was 1.0% (2/206) in the NASG-intervention phase patients compared to 3.2% (5/158) in the pre-intervention patients) (OR 0.31, 95% confidence interval (CI) 0.06–1.56). In larger study samples, this difference could well attain statistical significance and serve as a marker of the utility of the technology, considering the recent moves worldwide to diminish EAO.

Decreased shock recovery times

A post-hoc analysis of the Egyptian pilot study data was conducted to examine the lengths of recovery time from shock. Results indicated that median recovery times were nearly twice as rapid (1.6–2.0 times) for women treated during the NASG-intervention phase compared to time to recovery of women in the pre-intervention phase. The reduction in recovery times was even greater when adjustments were made for severity of the woman's condition at study entry[28].

Expanded comparative studies in Egypt and Nigeria

These pilot results were judged promising, but thought to require a larger sample over a longer period of time in order to demonstrate differences in EAO. Therefore a year later a larger pre-intervention/NASG-intervention study in two of the four facilities in Egypt[32] and at four facilities in Nigeria was conducted[31,35]. The methods described above for the Egyptian pilot study were replicated in Nigeria. The Nigerian NASG program was carried out in 12 urban, referral hospitals throughout Northern and Southern Nigeria. Some of these secondary and tertiary CEmOC facilities were teaching hospitals, and the others were state hospitals. Many facilities had high numbers of obstetric deliveries, a high proportion of un-booked patients, and a large number of high-risk complications. A total of 756 women were enrolled in Nigeria from 2004 to 2008. (By design, eight of the facilities were NASG-intervention use only, without a pre-intervention phase.)

A number of reports have examined data from women in both countries with all etiologies of bleeding[34] as well women from both countries where PPH was the etiology of the hemorrhage[33]. Egypt-only analyses include data from all obstetric hemorrhage etiologies[32], uterine atony only[53], and non-atonic etiologies only[37]. Nigeria-only analyses include data for all obstetric hemorrhage etiologies in one facility[31], for PPH etiologies in the four facilities[35], and for uterine atony only in 12 facilities[54]. Results demonstrated similar trends for all studies, except for the Egyptian non-atonic hemorrhage only, with better outcomes for women in the NASG-intervention phase including statistically significant reduced rates of morbidity, mortality, emergency hysterectomy (for uterine atony) and reduced blood loss.

In the remainder of this chapter, we discuss outcomes for women in both countries with all hemorrhagic etiologies, with PPH etiologies only, and the non-atonic etiologies in Egypt; in addition we discuss a post-hoc analysis of the effect of NASG for ameliorating negative outcomes specifically associated with delays[36] and the results of some qualitative studies of provider and patient acceptance[55–57].

Analysis of data on 1442 women with obstetric hemorrhage in Nigeria and Egypt

These results derive from data on 1442 women with hypovolemic shock secondary to obstetric hemorrhage (607 pre-intervention and 835 NASG-intervention phase). As shown in Table 1[34], there were no significant differences in demographic characteristics, but etiologies were different with significantly more ectopic pregnancy, ruptured uteri and placenta previa during the pre-intervention phase and more uterine atony, complications of abortion and lacerations during the NASG-intervention phase use. During the pre-intervention phase, significantly more women entered the study who had started bleeding at home or at another facility rather than having begun their bleeding in the hospital ($p < 0.001$). Women in the NASG-intervention phase were in worse condition on study entry (38.5% had mean arterial pressure (MAP) less than 60 mmHg vs. 29.9% in the pre-intervention phase, $p = 0.001$). Regarding treatment, significantly fewer women in the NASG phase received either 1500 ml or more crystalloid fluids or a

Table 1 Egypt and Nigeria combined etiologies: diagnoses and condition on entry ($n = 1442$). Data are expressed as numbers with percentages in parentheses. From Miller *et al.*, *BMC Pregnancy and Childbirth* 2010;10:64, with permission

	Pre-intervention phase (n = 607)	*NASG-intervention phase (n = 835)*	*p Value*
Primary definitive diagnosis			
Uterine atony	190 (33.0)	319 (38.2)	0.007
Ectopic pregnancy	95 (15.7)	85 (10.2)	0.002
Complications of abortion	45 (7.4)	93 (11.1)	0.02
Abruption of placenta	79 (13.0)	98 (11.7)	0.47
Vaginal, cervical or genital lacerations	25 (4.1)	65 (7.8)	0.004
Retained placenta or tissue	71 (11.7)	83 (9.9)	0.29
Ruptured uterus	46 (7.6)	32 (3.8)	0.002
Placenta previa	40 (6.6)	31 (3.7)	0.01
Placenta accreta	6 (1.0)	9 (1.1)	1.000*
Molar pregnancy	7 (1.2)	11 (1.3)	1.000*
Condition on study entry			
Where hemorrhage began			<0.001
Transferred in bleeding	382 (72.9)	333 (56.4)	
Began bleeding in hospital	142 (27.1)	258 (43.6)	
Estimated revealed blood loss at study entry†			—
Mean ml (SD)	1210.0 (507.7)	1327.5 (480.7)	
Median ml (IQR)	1000 (1000–1500)	1200 (1000–1500)	<0.0001
Women with MAP <60 mmHg or non-palpable BP‡	181 (29.9)	321 (38.5)	0.001

NASG, non-pneumatic anti-shock garment

Tests of significance of differences by study phase were c^2 for categorical variables, *t* tests (assuming unequal variances) for normally distributed continuous variables and Wilcoxon rank-sum tests for non-normal distributions

*Fisher's exact test used

†Data missing for 250 patients

‡MAP (mean arterial pressure) <60 category includes those with non-palpable blood pressure (BP). Data missing for two patients

blood transfusion in the first hour ($p < 0.001$); by the end of the second hour from study admission, however, 87.5% in the pre-intervention phase and 86.6% in the NASG phase had received more than 1500 ml ($p = 0.62$).

Despite being in worse condition on study entry and receiving the recommended treatment fluids and blood more slowly, negative outcomes were significantly reduced in the NASG phase. Mean measured blood loss decreased from 444 to 240 ml ($p < 0.001$), maternal mortality decreased from 6.3% to 3.5% (RR 0.56, 95% CI 0.35–0.89), severe morbidities declined from 3.7% to 0.7% (RR 0.20, 95% CI 0.08–0.50), and the rate of emergency hysterectomy (for intractable uterine atony) fell from 8.9% to 4.0% (RR 0.44, 0.23–0.86).

As shown in Table 2, in a multiple logistic regression model, women with a MAP less than 60 mmHg had over eight times the odds of mortality (OR 8.42, 95% CI 3.13–22.66) relative to those with MAP 60 mmHg or more. No other control variables (parity, primary diagnosis or facility) were significantly associated with mortality, but NASG intervention was associated with 55% lower odds of mortality (OR 0.45, 95% CI 0.27–0.77). In the model of factors associated with severe maternal morbidity, women with a MAP less than 60 mmHg had almost five times the odds of morbidity (OR 4.83, 95% CI 1.80–12.94) relative to those with MAP 60 mmHg or more. Those with a parity of five or more had 2.4 times the odds of morbidity (OR 2.43, 95% CI 1.06–5.58), but where the bleeding began and the type of facility were not associated with the outcome. The NASG intervention was significantly associated with 80% lower odds of a morbidity (OR 0.20, 95% CI 0.07–0.56).

Because the odds of morbidity and of mortality were so high for women in severe shock, independent of the study phase, a stratified analysis by severity of condition (MAP <60 mmHg vs. MAP ≥60 mmHg) was conducted for each of the two outcomes, using the same model specification from the multiple logistic regression. An ameliorative effect of the intervention for reduced morbidity was seen in both women with MAP less than 60 (aOR 0.20, 95% CI 0.05–0.80,) and MAP 60 mmHg or more (aOR 0.18, 95% CI 0.04–0.90). For the stratified mortality model, the NASG intervention was significantly associated with a reduced odds of death in women with MAP less than 60 mmHg (aOR 0.46, 95% CI 0.26–0.80), but not in women with MAP 60 mmHg or more (aOR 0.68, 95% CI 0.14–3.22).

Analysis of data from Nigeria and Egypt of PPH etiologies

An analysis was conducted on data from 854 women (343 pre-intervention and 511 NASG-intervention phase) with diagnoses of PPH, uterine atony, retained placenta, ruptured uterus, vaginal or cervical lacerations or placenta accreta; all were selected from the total of 1442 women with hypovolemic shock from obstetric hemorrhage. Study design, study definitions, entry criteria, clinical and study protocol were the same; analyses were performed on the outcomes of measured blood loss, emergency hysterectomy, mortality, morbidity (each individually) and a combined variable, adverse outcomes, defined as severe morbidity and mortality. Approximately 36% of women in both phases were in severe shock. See Table 3 for etiologies and condition on study entry[33].

Measured blood loss decreased by 50% between phases; women lost 400 ml of blood after study entry during the pre-intervention phase and 200 ml in the NASG-intervention phase ($p < 0.001$). Mortality (as an individual outcome) decreased from 9% ($n = 31$) in the pre-intervention phase to 3.1% ($n = 16$), (RR 0.35, 95% CI 0.19–0.62), while the combined adverse outcomes of mortality and morbidity decreased from 12.8% ($n = 44$) to 4.1% ($n = 21$), (RR 0.32, 95% CI 0.19–0.53). Rates of emergency hysterectomy for hemostasis of intractable PPH from uterine atony (only) decreased from 9% ($n = 20$) to 4% ($n = 14$) (RR 0.44, 95% CI 0.23–0.86).

A multiple logistic regression model was used to estimate the independent association between the

Table 2 Egypt and Nigeria combined etiologies: multiple logistic regression (n = 1442). From Miller *et al.*, *BMC Pregnancy and Childbirth* 2010;10:64, with permission

	Dependent variable: mortality				*Dependent variable: morbidity*			
Factor	*aOR*	*p Value*	*95% CI*		*aOR*	*p Value*	*95% CI*	
Severity of shock								
MAP <60 mmHg (or non-palpable BP)	8.42	<0.001	3.13	22.66	4.83	0.002	1.80	12.94
MAP 60 mmHg or higher	1				*1*			
Parity								
5 or more live births	1.33	0.35	0.73	2.42	2.43	0.04	1.06	5.58
0–4 live births	*1*				*1*			
Primary diagnosis								
Uterine atony	1.44	0.19	0.83	2.49	2.68	0.07	0.93	7.76
Other condition	*1*				*1*			
*Where bleeding began**								
Transferred in bleeding	—	—	—	—	1.82	0.51	0.30	10.93
Began bleeding in hospital	—	—	—	—	*1*			
Study phase								
NASG-intervention phase	0.45	0.004	0.27	0.77	0.20	0.002	0.07	0.56
Pre-intervention phase	*1*				*1*			

NASG, non-pneumatic anti-shock garment

Reference groups for categorical variables shown in italics. Hospital facility included as control variable in both models but not shown here The number of observations in Table 4 is less than 1442 because of missing data; n = 1038 for the morbidity model, and n = 1442 for the mortality model.

Robust standard errors used to adjust for clustering at the facility level

*Where bleeding began was not a significant predictor of mortality, but it was associated with morbidity, in bivariate analysis. Therefore it is included in the multiple logistic regression model of factors predictive of morbidity only

Table 3 Egypt and Nigeria PPH only: diagnoses and condition on entry (n = 854). Data are expressed as numbers with percentages in parentheses unless otherwise stated. The denominator is the entire population, unless otherwise noted. From Mourad-Youssif *et al.*, *Reprod Health* 2010;7:24, with permission

	Pre-intervention phase (n = 343)	*NASG-intervention phase (n = 511)*	*p Value*
*PPH Diagnoses**			
Uterine atony	197 (57.4)	324 (63.4)	0.079
Vaginal, cervical or genital lacerations	24 (7.0)	65 (12.7)	0.007
Retained placenta or tissue	69 (20.1)	80 (15.7)	0.092
Ruptured uterus	45 (13.1)	32 (6.3)	0.001
Placenta accrete	8 (2.3)	10 (2.0)	0.809†
Condition on study entry			
Where hemorrhage began			<0.001
Transferred in bleeding	145 (51.4)	104 (29.1)	
Began bleeding in hospital	137 (48.6)	253 (70.9)	
Estimated revealed blood loss at study entry‡			
Mean ml (SD)	1223.8 (509.5)	1288.7 (447.9)	—
Median ml (IQR)	1000 (1000–1500)	1000 (1000–1500)	0.008
Women with MAP <60 or non-palpable BP**	123 (35.9)	183 (35.9)	0.995

NASG, non-pneumatic anti-shock garment

Tests of significance of differences by study phase were χ^2 for categorical variables, t tests (assuming unequal variances) for normally distributed continuous variables and Wilcoxon rank-sum tests for continuous variables with non normal distributions

*PPH diagnosis includes primary or secondary diagnosis of any of the following >24 weeks with uterine atony, rupture, placenta accreta, vaginal/cervical lacerations, retained placenta or tissue

†Two-side Fisher's exact test used

‡Data missing for 37 patients

**MAP, mean arterial pressure <60 category includes those with non-palpable blood pressure (BP). Data missing for 1 patient

NASG and the combined outcome of mortality and severe morbidity. Findings suggested that severity of condition upon study admission was strongly associated with mortality after controlling for other variables in the model (MAP <60 mmHg had 19 times the odds of suffering the combined adverse outcomes variable (adjusted odds ratio (aOR) 19.1, 95% CI 6.95–52.65, $p < 0.001$). High parity and where bleeding began were not significantly associated with mortality/morbidity in the adjusted model. Importantly, being in the NASG phase remained significantly associated with reduced odds of adverse outcome (aOR 0.42, 95% CI 0.18–0.99, $p = 0.046$) (Table 4).

Ameliorating effect of NASG on delays in women with PPH and PAH

One post-hoc analysis examined the effects of delays on adverse outcomes in both phases for women with postabortion hemorrhage and PPH in Egypt and Nigeria[36]. This analysis was conducted to determine whether the NASG ameliorated effects of delays in transport to and treatment at hospitals and whether the NASG affected the timing of delivery of other interventions necessary for recovery. This analysis included 349 women from the facility in Cairo, 274 from Assiut, 57 from Southern Nigeria and 124 from Northern Nigeria and compared associations of delays with extreme adverse outcomes (EAO). The analysis showed that 20% of women in the pre-intervention phase who experienced a delay more than 60 minutes from the beginning of their hemorrhage to study admission experienced an adverse outcome compared to only 6% of those in the NASG-intervention phase

Table 4 Egypt and Nigeria PPH only: multiple logistic regression models of factors predictive of combined outcome severe maternal morbidity and mortality ($n = 639$). From Mourad-Youssif *et al.*, *Reprod Health* 2010;7:24, with permission

	Dependent variable: combined severe morbidity and mortality			
Factor	*Adjusted OR*	*p Value*	*95% CI*	
Severity of shock				
MAP <60 mmHg (or non-palpable BP)	19.1	<0.001	6.95	52.65
MAP 60 mmHg or higher	1			
Parity				
5 or more live births	2.29	0.050	1.00	5.26
0–4 live births	1			
*Where bleeding began**				
Transferred in bleeding	1.88	0.222	0.68	5.15
Began bleeding in hospital	1			
Study phase				
NASG-intervention phase	0.42	0.046	0.18	0.99
Pre-intervention phase	1			

NASG, non-pneumatic anti-shock garment; MAP, mean arterial pressure; BP, blood pressure

Reference groups for categorical variables shown in italics. The number of observations in Table 4 is less than 854 because of missing data. Hospital facility was used as a control variable in the model but not shown in Table 4

$\chi^2 = 13.71$, $p = 0.000$), despite more women in the NASG-intervention phase experiencing in-hospital delays in receiving IV fluids and blood. The conclusion was drawn that use of the NASG reduces the adverse impact of delays, but that stabilization with the NASG does not replace treatment, and that delays in fluid/blood administration with the NASG must be avoided.

NASG for non-atonic etiologies: Egypt

Only one analysis from these pre-intervention phase/NASG-intervention phase studies on a variety of etiologies had different outcomes. This was an analysis of 434 non-atonic hemorrhage etiologies from the Egypt sites (226 pre-intervention phase and 208 NASG-intervention phase) with non-atonic etiologies, ectopic gestation, trophoblastic disease of pregnancy, placenta previa, accreta or abruption, ruptured uterus, or vaginal or cervical lacerations[37]. These etiologies comprised 44% of the 1442 women in the combined two-country database. Women were similar in age and parity, but more women in the NASG-intervention phase were in severe shock, (15.6% pre-intervention phase vs. 24.5% NASG-intervention phase had MAP less than 60 mmHg on study entry ($p = 0.020$)). Despite their worse condition on study entry, significantly fewer women in the NASG-intervention phase received 1500 ml or more fluid in the first study hour (93.4% pre-intervention vs. 64.9% NASG-intervention phase, $p < 0.0001$) and fewer received a blood transfusion in the first hour after study admission (96.5% pre-intervention vs. 86.5% NASG-intervention phase, $p < 0.0001$). Outcomes by phase were significantly lower only for measured blood loss, those in the NASG-intervention phase having lost 257.7 ml during treatment, while those in the pre-intervention phase lost 370.4 ml ($p < 0.0001$). Other outcomes, mortality, morbidity and the combined EAO outcomes were not reduced for the NASG-intervention phase. In fact, mortality actually increased, from 0.4% (1/226) pre-intervention phase to 1.9% (4/208) in the NASG-intervention phase (RR for mortality 4.35, 95% CI 0.49–38.57). Possible explanations for these outcomes, which are different to the other outcomes of NASG analyses to date, might be the smaller sample size, rarity of adverse outcomes, the worse condition of the women on admission to the study, or the less timely use of resuscitation measures (IV fluids and blood). It cannot be determined from this analysis whether the NASG does not work as well for non-atonic etiologies; indeed, it would require a much larger study powered for these etiologies and in which treatment begin similarly in both phases.

Study limitations for all NASG comparative pre-intervention/intervention phase studies

All analyses conducted on the Nigeria and/or Egypt comparative data are limited by the study design. The effect of time and experience in managing women in hypovolemic shock could have worked in favor of the NASG phase, as it followed the pre-intervention phase. Selection bias, always present in a non-randomized trial where not every patient in a facility is enrolled, could have also played a part. The participating hospitals were very busy and had limited staff; it is thus possible that not all patients who met study criteria were enrolled. There were also imbalances in the numbers of patients with different hemorrhage etiologies: more patients in the NASG phase[33,34] had uterine atony. Finally, NASG phase patients tended to enter the study in worse condition, yet received less timely and appropriate care. A possible explanation for this observation is that the rapid and visible effect of the NASG (blood loss slows down and vital signs return to normal) decreased panic among providers. If so, this must be prevented with better training and monitoring.

NASG qualitative studies

Berdichevsky and colleagues conducted a qualitative study to explore responses to the NASG in rural health facilities in Mexico[55]. The study included in-depth, semi-structured interviews with clinical and administrative staff ($n = 70$) involved in pilot studies of the NASG at primary health care facilities and rural hospitals. Researchers found that staff response to the garment fell into four categories: owning, doubting, resisting and rejecting. Overall, however, positive reactions were voiced regarding the garment as a relevant technology for saving women's lives. These findings may guide future implementation of the garment and other new technologies. In addition to the Berdichevsky study, three health sciences/public

health students have conducted research on the NASG for master's theses in Nigeria and Zambia. These young authors documented challenges and opportunities for diffusion of innovation with the NASG[56,57].

NASG mechanisms of action studies

Studies have been conducted on the mechanisms of action of the NASG (see Chapter 39).

THE NASG HAS A UNIQUE ROLE IN HEMORRHAGE TREATMENT

Because the NASG plays a unique role in reversing shock, maintaining vital signs and keeping the heart, lung and brains perfused with oxygen, it can be used with all other maternal hemorrhage therapies. The NASG does not compete with other technologies, pharmacological or surgical, in obstetric hemorrhage and shock management. It is meant to be used with, not instead of other approaches. For example, for PPH, medical management with uterotonics is the first line of treatment and it is not suggested to use an NASG *instead* any uterotonic medication. Rather, if uterotonics fail to stop atonic hemorrhage, the NASG can be used with uterotonics to decrease blood loss. Furthermore, even if a woman with atonic hemorrhage stops bleeding, if she has lost so much blood that she is in shock, the NASG can be applied to reverse shock and stabilize the woman until she can have a blood transfusion. For other obstetric hemorrhage etiologies that do not respond to uterotonics (such as rupture, abruption, accreta), the NASG is the only technology to use while awaiting definitive therapy. Similarly the NASG can be used with balloon tamponade. The balloon tamponade can often be used as definitive therapy of atonic uterus, but its application does not reverse shock. Only the NASG reverses shock. Therefore, the two devices could be used together, the balloon to treat the cause of the bleeding and the NASG to reverse shock.

Summary of pre-intervention phase/NASG-intervention phase studies to date

Data from these pre-intervention phase/NASG-intervention phase studies are promising for use of NASG for most obstetric hemorrhage etiologies, including PPH care level. The Egypt pilot was adequately powered to demonstrate a statistically significant difference in measured blood loss for women suffering obstetric hemorrhage, with symptoms of hypovolemic shock treated with the NASG and a standardized hemorrhage and shock protocol compared with women with similar diagnoses and clinical symptoms treated only with the standardized hemorrhage protocols. The Nigeria and Egypt analyses, either alone or as a combined database, except for the one analysis of non-atonic hemorrhage etiologies in Egypt, demonstrate stronger evidence of effectiveness at the tertiary level, although the study design has potential biases and is not as rigorous as a randomized control trial. The lack of statistical significant differences in the small, single country non-atonic hemorrhage etiology analysis certainly warrants more follow-up. Further, little is known about the efficacy, effectiveness and acceptability of the NASG at lower levels where women deliver at the community and at home; guidelines on obtaining the maximum efficacy of the garment have also yet to be established.

FUTURE DIRECTIONS

Randomized cluster trial of the NASG for transport from midwifery-led primary care centers to CEmOC facilities

In order to demonstrate that the NASG not only decreases blood loss, but also facilitates resuscitation from shock and decreases mortality and morbidity from PPH at the primary health care level, a much larger trial with a strong experimental design set at the community level is needed. An international collaborative between the University of California, San Francisco, the University of Zambia, University Teaching Hospital, Lusaka, and the University of Zimbabwe-University of California, San Francisco Reproductive Health Research Collaborative in Zimbabwe and the World Health Organization (Department of Reproductive Health and Research) is currently conducting such a trial in two sites in Zambia (Lusaka and the Copperbelt region) and one site in Zimbabwe (Harare): Clinicaltrials.gov: NCT00488462. This randomized cluster trial has been designed to demonstrate the efficacy of the NASG with a more rigorous research design, to investigate any potential side-effects associated with its use, and importantly, to determine whether the NASG provides even greater effect when implemented at a lower-level in the health system. Initiated in 2007, the research is in the final stage in which clinics in each cluster have been randomized, with half of the clinics using the NASG for immediate first-aid and transport and the other half providing the control cases. Control women will receive the NASG when they arrive at the referral facility. Further, the sample should be large enough that when looking at different etiologies, for example, the non-atonic etiologies, there may be enough power to see differences in outcomes if they exist. Significant differences in outcomes may lead to the inclusion of the NASG onto the World Health Organizations list of essential devices, which would enable bilateral and multilateral organizations to invest in the NASG and scale up its implementation. In 2012, FIGO published guidelines for PPH management and included the NASG as a 'potentially life-saving procedure' to be considered if uterotonic treatment fails[58]. In March 2012, when WHO convened a panel of experts to update their guidelines on PPH, they recommended the use of NASGs 'as temporizing measures until substantive care is available'[59].

Manufacture

A frequently raised issue about the NASG is its cost and sole manufacturing source. Until 2011, the NASG was only produced by Zoex, and only distributed by Stork Medical Company (URL: storkmedical.com). Stork sells three sizes of NASG: small, medium and large.

Having a sole manufacturer makes it difficult to procure for those countries that require competitive bids from more than one source. Further, the cost (US$295.00) may also be too high for some extremely low resource settings.

To reduce costs, a team at PATH established a package of quality standards, engineering documents and quality inspection procedures, and identified a list of potential manufacturers in India and China. PATH met with prospective manufacturers and, using a quantitative assessment tool, negotiated affordable pricing with a manufacturer in China for the large size garment and a manufacturer in India for the small size garment. PATH worked with the Chinese and Indian manufacturers to source raw materials and manufacture a pre-production batch of NASG garments. Verification testing was performed on the pre-production batch to establish that all performance and quality requirements were met prior to commercial distribution. Procurement, distribution and access remain a challenge, so PATH is working with third parties and governments to facilitate the availability and accessibility of the NASG to mothers everywhere (personal communication with Rick Kearns, PATH).

As of May, 2012, Maternova, a global marketplace for ideas and technologies for mothers and newborns (www.maternova.net), serves as an online distributor for the Chinese made NASG.

Understanding mechanisms of action and physiological effects

Further research is also required to examine the mechanisms of action of the NASG to establish a direct way to measure intra-abdominal pressure, gauge the ideal amount of pressure that should be exerted and thus provide guidelines for obtaining optimal effect (see Chapter 39).

NASG for use in developed countries

The possibility of exploring potential uses of the NASG in countries with well developed health care also exists. The US and the UK, for example, presently are seeing increased rates of placenta accreta, presumably as a result of scar tissue from prior cesarean section[60]. Some facilities in California, USA, keep NASGs in their labor suites[47]; as such, the NASG could be used to reduce blood loss and stabilize these patients for surgery if required. The NASG could also be used for women with complications in rural communities ill equipped to deal with complications; patients from such locations normally experience lengthy transport time to urban tertiary care facilities. Another potential use could be for women awaiting specialized equipment and expertise for uterine artery embolization, which might save them from having a hysterectomy. Finally, for women who refuse blood transfusions despite massive hemorrhage, such as Jehovah's Witnesses, the NASG might also provide benefit. Outcomes in terms of cost (number of transfusions, IVs, number of days in hospital or ICU for example) should be examined also to see whether the NASG can prove a cost-effective intervention in developed countries.

The NASG is lightweight, reusable, relatively inexpensive and can be used at the lowest level of the health care system; it has the potential to make a great contribution to reducing maternal mortality and morbidity from obstetric hemorrhage and hypovolemic shock if it proves efficacious in clinical trials.

PRACTICE POINTS

- The PASG for pre-hospital treatment of lower body trauma in high-resource urban settings fell out of use due to lack of difference or negative outcomes in randomized controlled trials; in contrast, the NASG shows promise for obstetric hemorrhage first aid in low-resource settings
- Application of the NASG could be part of a standardized hemorrhage and shock management algorithm; the timing of NASG application in the algorithm depends on patient acuity, level of staff available, level of health care facility level and the capacity for definitive treatment
- The NASG is segmented; it is applied sequentially on a woman in hypovolemic shock starting at the ankle segment and is removed in the same sequence. Removal should not be initiated until the woman has been hemodynamically stable for at least 2 hours. Removal is then performed incrementally every 15 minutes; vital signs must remain stable throughout removal or the NASG should be replaced and the source of bleeding re-examined
- Results from comparative pre-intervention phase/NASG-intervention phase trials in tertiary facilities in Egypt and Nigeria show the NASG may significantly reduce rates of hysterectomy for intractable uterine atony, and decrease morbidity, mortality, and decrease further blood loss for many obstetric hemorrhage etiologies
- A strong experimental design trial set at the community/primary health care level is necessary to determine whether the NASG will be effective in reducing maternal mortality and morbidity.

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