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NON-PNEUMATIC ANTI-SHOCK GARMENT

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INTRODUCTION

The FIGO/ICM recommendations for active management of third-stage labor, including uterotonic prophylaxis with additional uterotonic treatment when necessary, reduce the incidence of severe postpartum hemorrhage due to atony. However, at least 1% of all women still suffer intractable postpartum hemorrhage from uterine atony or other obstetric causes, such as genital lacerations, ruptured uterus, ruptured ectopic pregnancies, or placenta previa, accreta, and abruption. Multiple blood transfusions are often needed to resuscitate and stabilize these women and hemostasis may require surgical interventions. Until the time when quality comprehensive emergency obstetric care (CEOC), including surgery and/or blood transfusions, is readily available for all women, strategies and technologies for hemorrhage treatment and hypovolemic shock resuscitation are needed such that they can be readily provided and easily applied, even by persons with no medical training. Promising technologies to reduce maternal mortality include the non-pneumatic anti-shock garment (NASG) as a technology for reducing the mortality and morbidity associated with obstetric hemorrhage[1,2].
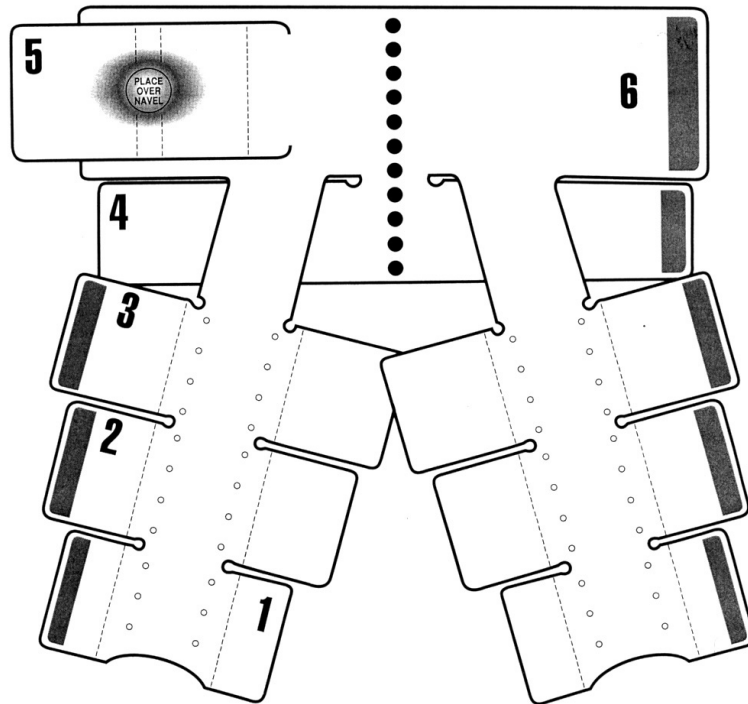
THE NON-PNEUMATIC ANTI-SHOCK GARMENT

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 CEOC facilities for definitive therapies.

The NASG is a lightweight, relatively inexpensive (US$160.00 per garment), washable and reusable (at least 50 times), neoprene 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 on each leg, a segment over the pelvis, and a segment over the abdomen that contains a small, foam compression ball (see schematic in Figure 1).

Unlike the pneumatic anti-shock trousers (PAST), or medical anti-shock trousers (MAST), which preceded the NASG, there are no pumps, tubing, or gauges to add complexity and risk of malfunction. Using the three-way elasticity of neoprene and the tight grip of the Velcro fasteners, the garment can apply 30–40 mmHg of circumferential counter pressure to the lower body from the ankles up to the level of the diaphragm (see Figure 2). This amount of pressure is effective in reversing hypovolemic shock by shunting blood from the capacitance veins of the abdomen and lower extremities to the vital core organs, the heart, lungs and brain. The effect of this autotransfusion, estimated to be 500–1500 ml, is almost immediate upon application. The moderate NASG pressures are generated by manually stretching the neoprene material. Excess pressures and the resultant tissue ischemia, known complications with the pneumatic PAST, are

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

Figure 2   Patient wearing the non-pneumatic anti-shock garment in hospital

not an issue. Application of the garment requires about 2 min and, within 2–5 min after its application, most patients with severe shock regain consciousness and vital signs begin to recover. With the bleeding slowed and the blood the pressure restored, panic levels decrease, and there is time to deliberately assess the situation. Patients can remain in stable condition for hours while blood transfusions are initiated and arrangements made for surgery or other required therapies. The patient and her family can be given emotional support and prepared for transport to a referral-level facility or any required surgical procedures. If the hemorrhage is due to uterine atony, the continued infusion of uterotonics and passage of time may be all that is required for management.

DEVELOPMENT OF THE NASG

The modern NASG is a non-pneumatic refinement of the pneumatic anti-shock garment (PASG). The PASG was adapted from a device developed by George Crile, in the early 1900s before the advent of technologies to allow 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 resuscitating and stabilizing 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 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, and thigh hemorrhage, as well as for gynecological and obstetric hemorrhage[3–6]. Andrea and colleagues used the MAST to stabilize women with intractable uterine bleeding while preparations were made for transcatheter emobization[7]. The PASG is included as a recommended treatment for intractable hemorrhage in the 1998 guidelines of the American College of Obstetricians and Gynecologists[8].

The PASG requires inflation and careful management of pressure levels, both to maintain adequate pressure and to prevent over-inflation resulting in compartment syndromes, ischemia, and necrosis. The valves and manometers that maintain inflation are subject to leaks and malfunctions. In addition, specialized training for safe and effective use of the MAST is necessary, which makes widespread use in developing countries difficult.

EFFICACY OF THE PASG FOR TRAUMA

McSwain reviewed the physical principles responsible for the physiologic effects of lower-body counter pressure with application of the PASG[3]. Numerous studies in hypovolemic animals and humans demonstrate that the PASG increases blood 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 slowing down blood flow. In the hypovolemic model, the PASG increases venous return and the increase in preload is associated with increased cardiac output[9].

These changes in vessels and blood flow are also associated with the translocation of blood from the lower body enclosed in the device to the upper body (heart, lungs and brain), a volume which is estimated at 750–1000 ml[10]. In summary, the physiologic bases for restoration of blood pressure are: the reduced vessel size beneath the device, which produces increased systemic vascular resistance, the decreased container size, the translocation of blood to the upper body, and increased preload resulting in increased cardiac output.

Although animal studies show improved survival rates except for thoracic injuries[11,12], 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 military and civilian trauma injury and reports

of small series demonstrating successful treatment of various bleeding conditions in adults and children, there are no definitive prospective randomized treatment trials to show improvement in survival. The three United States-based, prospective, alternate-day, randomized treatment trials of civilian trauma cases did not find consistent results and are confounded by inclusion of injuries to the upper body, a contraindication to use of the PASG[13–15]. In some studies, the pH on hospital admission was lower with PASG use, intensive care unit and hospital stays were longer, and survival worse. These studies were all conducted in a metropolitan setting where high-level hospital care was available within minutes, and even the brief delay in applying the PASG may have been a detriment to the benefits of early hospital care.

Despite the lack of randomized, controlled trials supporting its use, the Committee on Trauma of the American College of Surgeons included the PASG as essential equipment for ambulances[16] and the PASG remains on the curriculum and in the textbooks for emergency medical technicians in the United States[17,18]. A position paper on the PASG by the National Association of EMS Physicians[19] 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 a '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[9]. 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. Likewise, in France, use of the 'pantalon antichoc' is questioned for widespread use, but its use for postpartum hemorrhage, disseminated intravascular coagulopathies associated with pregnancy and labor, and other obstetric and gynecological bleeding is endorsed[20].

What is unknown about the PASG is what the difference in outcomes might be if the PASG (or the non-pneumatic adaptation, the NASG) were to be used in low-resource settings where there are longer transport times, slower responses at the hospital level, and longer delays in obtaining definitive therapy by blood transfusions and/or surgery.

POTENTIAL BENEFITS OF THE NASG IN LOW-RESOURCE SETTINGS

The NASG was adapted from the PASG by the National Aeronautics and Space Administration (NASA) in 1971, when the 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[21]. 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[22].

The NASG is particularly suited to use in low-resource settings. Lighter and more flexible than the PASG, it is more comfortable for a woman to be inside the suit for longer periods of time, something necessary in 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[1]. Women can remain in the NASG for as long as is required to restore their circulatory volume with crystalloids and to replace blood. In prior reports of cases where blood transfusions were not readily available, this has often required 18–24 h, and, in one case, a woman remained safely in the NASG for 57 h[23]. Compared to the PASG, with pressures of 100 mmHg or more, the NASG only applies 30–40 mmHg. Higher pressures appear to be responsible for skin and muscle ischemia and adverse effects on pH as well as the occasional anterior compartment syndrome.

A second benefit of the NASG for obstetric indications is that the design of the garment permits complete perineal access so that genital

lacerations can be repaired, speculum or bimanual examinations can be performed, and manual removal of placenta or emptying of the uterus with manual vacuum aspiration or curettage can all be accomplished with the NASG in place. Thus, 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 – 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 intraabdominal 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. Although the mean pressure applied by the NASG is only in the range of 30–40 mmHg, this low pressure, which is below arterial pressures, can still stop arterial bleeding when applied externally to the abdomen and the lower extremities[24]. 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. Post-delivery, however, 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 safely with minimal training. Such training, which includes hands-on practice in application and removal of the NASG, takes approximately 1 h. Once the garment has been properly applied, patients can safely be 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.

The improvement in maternal morbidity and mortality can presently only be discussed as potential benefits, because there have been no definitive trials of the NASG, and there is only very limited experience with its use for obstetric hemorrhage in low-resource settings. The case series and pilot studies discussed below indicate how the NASG functions to decrease blood loss, reverse shock, and stabilize women for many hours while awaiting blood transfusions. As such, use of the NASG might contribute to decreased maternal mortality and morbidity. Experience with transport from lower-level facilities to referral centers, while theoretically beneficial, is only anecdotal at this point.

SUGGESTED PROTOCOL FOR USING THE NASG

The NASG is recommended for cases of obstetric hemorrhage meeting the American College of Surgeons' criteria for Class II hypovolemic shock: > 750 ml blood loss, pulse > 100 and blood pressure normal or slightly decreased[25]. 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 there could be bleeding sites above the level of the diaphragm. 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. The authors recommend cardiovascular resuscitation using limited crystalloid infusion with the goal of 'permissive hypovolemia'[26–30]. This means infusing 1000–1500 ml of saline rapidly followed by a slower rate of infusion, 150 ml/h, to achieve a mean arterial pressure of about 60 mmHg (blood pressure 80–50 mmHg) and urine output of 30 ml/h. Supplemental oxygen should be given until the patient is resuscitated, the hemorrhage arrested, and the circulation fully normalized.

Application of the NASG

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. 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.

If pelvic examination or vaginal procedures are needed, the NASG should be left in place; if laparotomy is necessary, open the abdominal segment. Often there will be a drop in blood pressure when this panel is removed; this should respond to additional saline infusion.

Removal of the NASG

The NASG is left in place as long as needed to achieve hemostasis and replace red blood cell volume with transfusion of donor blood. The NASG can be removed when the hemoglobin level is > 7 or the hematocrit 20%, the pulse < 100, and the systolic pressure > 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 beats/min after a segment is removed, replace the NASG and consider the need for more saline or blood transfusions. If there is recurrent bleeding, replace the NASG and determine the source of bleeding.

EXPERIENCES WITH THE NASG

Case series in Pakistan

Recently, examples of the potential benefits of using the NASG in cases of obstetric hemorrhage in a resource-challenged setting were documented in two published reports based on a series of 150 obstetric cases in one hospital in Silkot, Pakistan[1,23]. There was no blood bank in the hospital; if blood transfusions were necessary, they could only be obtained through direct donor transfusion. The researchers documented that patients placed in the NASG experienced rapid resuscitation from hypovolemic shock, as well as an extended period of stabilization while awaiting definitive treatment. In a combined analysis of the two reports[24], there appeared to be no adverse effects of prolonging this stabilization period, even though the average interval from diagnosis of hemorrhage to blood transfusion was 5 h 30 min, and the mean time in the NASG was more than 30 h.

Pilot studies of the NASG

Based on the successes of the case series in Pakistan, the authors and their in-country colleagues are conducting NASG pilot studies in comprehensive emergency obstetric care facilities in Nigeria (Dr Dosu Ojengbede, University of Ibadan), teaching facilities in Egypt (John Snow International), and in primary and secondary health facilities in Mexico (Population Council and IMSS-Opportunidades). These studies compare use of a standardized protocol of shock and hemorrhage care in the pre-intervention period with the same standardized protocol plus the NASG in the post-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 after admission to the study is measured using a specially designed, closed-end, calibrated plastic blood collection drape. Prior studies of this drape indicate that it is more accurate than visual assessment in measuring postpartum blood loss[31]. Secondary outcomes include severe acute maternal morbidities (SAMMs: acute respiratory distress syndrome, cardiac deficiency, central nervous system damage, and renal failure) and need for emergency hysterectomy. The standard protocol included: active management of third-stage labor, immediate use of uterotonics for suspected postpartum uterine atony, training in limited intravenous crystalloid fluid

replacement[32,33], and, in the post-intervention, prompt application of the NASG.

Inclusion criteria were obstetric hemorrhage with shock (minimum requirements: estimated blood loss > 750 ml, systolic blood pressure < 100 mmHg and/or pulse > 100). There were a variety of obstetric hemorrhage etiologies, including postpartum hemorrhage due to atony or lacerations, ectopic pregnancies, ruptured uterus, complications of abortion, and a variety of placental pathologies. Overall, postpartum uterine atony and/or retained placenta or placental fragments accounted for 44% of all participants. Pre-intervention data were collected from May to September 2004. Post-intervention data collection has been completed in Egypt and is underway in Nigeria and Mexico.

NASG pilot study in Egypt

The study sites in Egypt comprised high-volume referral CEOC teaching facilities (El Galaa, Alexandria, Assiut, and Al Minya). All are staffed by senior obstetricians and obstetric residents with immediate access to banked donor blood and surgery. 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. Post-intervention data were collected for another 3 months.

The primary outcome was mean measured amount of blood lost after a woman entered the study. A sample size of 150 pre-intervention obstetric hemorrhage patients (no-NASGs) and 150 post-intervention obstetric hemorrhage patients (NASGs) was needed to detect a 50% difference in blood loss between the two groups with power (β) of 80% and a significance level (α) of 5%. The final study sample comprised 156 no-NASG and 204 NASG patients with obstetric hemorrhage who met the entry criteria. Diagnoses of obstetric hemorrhage covered a range of primary diagnoses with no statistically significant differences between no-NASGs and NASG patients. The three most common diagnoses were uterine atony, genital lacerations, and complications of abortion. The NASG

women had a statistically significant greater loss of blood on study entry and more severe signs of shock than did the no-NASG group. Estimated blood loss at entry to the study was 1000 ml for NASG cases and 750 ml for no-NASGs ($p < 0.001$), mean systolic blood pressure for NASG cases was 88.3 mmHg vs. 97.2 mmHg for no-NASGs ($p < 0.001$), and mean diastolic blood pressure was 56.7 mmHg for NASGs vs. 60.8 mmHg for no-NASGs ($p = 0.005$). A probable reason for the NASG group's worse condition on study entry was that the clinical researchers waited until women were in deeper shock before putting on the garment, a new technology that they were not accustomed to applying.

As shown in Table 1, NASG patients had 46% less mean measured blood loss (50% less median measured blood loss) than did those patients not treated with the NASG ($p < 0.001$). NASG and no-NASG patients had similar blood loss during surgery: NASG patients lost only 32 ml more ($p = 0.748$), and NASG patients had a lower amount of estimated 'other' blood loss (spilled on floor, on gauze or towels) compared to no-NASG cases ($p = 0.209$). Patients treated with the NASG had a statistically significant lower amount of post-study entry blood loss (drape + intraoperative + 'other') compared to no-NASGs ($p < 0.001$). The NASG group received 193.3 ml more blood than those not receiving the NASG ($p = 0.034$), and the NASG group also received 225.6 ml more of intravenous fluids ($p = 0.06$). There was a non-statistically significant 84% lower incidence of severe acute maternal morbidities (SAMMs) and mortalities, which were combined as 'extreme adverse outcomes'. One patient (0.5%) had an extreme adverse outcome among the NASG patients (renal failure), whereas five patients (3.2%) died or suffered SAMMs among the no-NASG patients (odds ratio (OR) 0.15, 95% confidence interval (CI) 0.02–1.31)[34].

A greater percentage of patients in the NASG group had surgeries compared to no-NASG patients (49.0% vs. 37.8%, $p < 0.03$), perhaps due to their worse condition on study entry. The most common surgeries were Cesarean section and salpingectomy. Both groups spent

Table 1 Results from NASG Pilot study in Egypt

	No-NASG (n = 156) *Mean ± SD*	*NASG (n = 204)* *Mean ± SD*	*p Value*
Mean blood loss measured with drape (ml)	561.6 ± 447.4 (median 500)	303.5 ± 219.5 (median 250)	< 0.001[a]
Mean intraoperative blood loss (ml)[c]	394.1 ± 537.5	426.0 ± 641.2	0.748[b]
Estimated 'other' blood loss (ml)[c]	196.3 ± 333	140.2 ± 221.3	0.209 [b]
Blood loss post-entry to study (drape + intraoperative + other) (ml)	902.7 ± 696.5 (median 700)	591.3 ± 532.0 (median 450)	< 0.001[a]
Volume blood transfusion (ml)[d]	963.2 ± 668.4	1156.5 ± 707.8	0.034[b]
Volume intravenous fluids (ml)	2035.5 ± 1190.6	2261.1 ± 1033.3	0.057[b]
Extreme adverse outcomes	5 women (3.2%)	1 woman (0.5%)	OR 0.15, 95% CI 0.02–1.31

Selected variables: NASG
[a]Mann-Whitney *U* test used for comparison of groups with unequal variances; [b]from Student's *T* test; [c]for the 159 women who had operations, 59 in the no-NASG group and 100 in the NASG group; [d]for the 248 women who had blood transfusions, 95 in the no-NASG group and 153 in the NASG group

almost equal time in the hospital following admission, NASG patients a mean of 2.0 ± 1.5 days, and the no-NASGs a mean of 1.9 ± 1.6 days (*p* = 0.50). Both groups received comparable dose of oxytocin; for those with uterine atony, the mean total was 30.7 units for no-NASG and 32.0 for NASG patients.

A sub-analysis of women who entered the study with severe hemorrhage (> 1500 ml) revealed no difference in frequency by study group, no-NASGs 26.9%, NASG 31.4%, *p* = 0.36. However, the mean volume of blood lost in the drape for the NASG group was 66% less than for the no-NASGs (278.1 ± 221.5 ml NASG vs. 818.1 ± 641.3 ml no-NASG, *p* < 0.001). This was a greater mean blood loss difference by study group than among all patients (with and without severe hemorrhage at study entry). A non-statistically significant decrease was found for extreme adverse outcomes; among those who did not receive the NASG, such outcomes occurred in four patients (9.5%) and in only one NASG patient (4.6%) (OR 0.5, 95% CI 0.1–1.9).

The results among this sample of women in university teaching hospitals appear very promising. While the women with the NASG had lost more blood and had greater signs of shock, the primary outcome of measured mean blood loss was statistically significantly less. The non-statistically significant difference in extreme adverse outcomes is promising, but will require a larger sample over a longer period of time in order to demonstrate if there is a true difference in this most important outcome.

NASG pilot studies in Nigeria and Mexico

Pilot studies are currently underway at four urban acute obstetric hospitals in Nigeria and in rural primary health-care facilities (Unidades Medicales Rurales or UMRs) with long transport times to rural CEOC facilities in Mexico. The design and methodology of these studies are similar to those in the Egypt study. One difference is that, in Mexico, pre-weighed adult diapers are used to collect blood during long transports between the UMRs and the CEOC facilities where women are brought for definitive treatment. (The blood collection drapes used in the CEOC tend to slip off during the often multiple vehicle changes involved in transport from the UMRs.) The used diapers are weighed at the CEOC facilities and blood volume is calculated from the weight of the diaper; at the CEOC facilities, the diapers are then replaced

by the closed-end plastic blood collection drape. In Mexico, the number of no-NASG cases was ten and the number of NASG cases 27.

The following case history illustrates the application of the NASG in a rural Mexican community. A 25-year-old woman, gravida 2 para 1, delivered at home attended by a traditional birth attendant (TBA) who had been sensitized to the need for transport in the NASG by community outreach. When the woman began to hemorrhage from a retained placenta, the TBA arranged transport to a study UMR. The trip took over 2 h; on arrival at the UMR, it was estimated that the patient had lost more than 2000 ml blood and had a pulse of 160. The NASG was applied and the woman transported by ambulance another 2 h to a CEOC facility. Blood loss during the trip was measured at 300 ml. At the hospital, intravenous fluids were started, a manual removal of the retained placenta was performed, and two units of blood were transfused. The patient was discharged with a hemoglobin level of 8.

In contrast to the community setting in Mexico, the Nigerian study is set in urban CEOC hospitals. Before introducing the NASG protocol, data were collected for 3 months, as in the other pilots. While data are still being collected in this study, an interim analysis includes 27 no-NASG patients and 63 with NASG. The most common diagnoses are antepartum hemorrhage and postpartum hemorrhage, i.e. 12 women (44%) in the non-NASG group versus 39 (65%) in the NASG group. The estimated blood losses on study entry were similar for both groups (1258 ml vs. 1487 ml), but the NASG women had more severe symptoms of shock, with a mean blood pressure of 53/23 mmHg compared to 91/55 mmHg. The percentage with Class 3 or Class 4 shock in the NASG group was also greater, 85% vs. 22%. According to the protocol, measurements of blood loss were to be made using the same closed-end blood collection drapes used in the Egypt study. However, in some cases, this could not be accomplished and visual estimates were made of blood loss. In all cases, the amounts of blood lost and replaced were reconciled with the admission and subsequent hematocrit values. The difference in measured plus estimated blood loss after study entry was more than a liter greater in the no-NASG group, 1385 ml vs. 257 ml.

An interim analysis from the Nigeria study concerns the recovery of 33 women with severe postpartum hemorrhage[35]. This subset of women met three of the four American College of Surgeons' Class III or IV shock criteria: > 1500 ml blood loss, packed cell volume < 20%, pulse > 120, blood pressure < 80/50 mmHg, and altered mental status. During resuscitation, the vital signs were recorded every 15 min. Although not always accomplished, the protocol advised giving 1500 ml saline rapidly, followed by additional saline to achieve minimum blood pressure of 80/50 mmHg, corresponding to a mean arterial pressure of 60 mmHg.

Thirty-two women survived without morbidity; one woman expired. Among the 32 surviving women, the estimated mean blood loss upon study entry was 1471 ml and mean packed cell volume 18.9%. Mean measured and estimated blood loss with the NASG in place was 220 ml. Mean volume of blood transfused was 1442 ml and the discharge packed cell volume 23.8%. After placing the NASG, 28 of the 32 women had improvement in their vital signs by the next 15-min recording. The resuscitation interval (the time from placement of the NASG until achieving a mean arterial pressure ≥ 60 mmHg) was 52 min. The patients with more rapid intravenous saline infusion responded more rapidly; those receiving an infusion at > 1000 ml/min recovered in 24 min while those receiving < 1000 ml/min took 83 min.

Preliminary analysis: Nigeria and Egypt severe hemorrhage

A recent analysis was conducted combining the Egypt data[34] and data from six tertiary-care hospitals in Nigeria on all women ($n = 263$) with severe hemorrhage (estimated blood loss on admission ≥ 1000 ml, pulse > 120). There were 104 in the pre-intervention, standard-care group, and 159 treated with standard care and the NASG. There were no differences in the pre-intervention and NASG groups by country or age. There were a variety of diagnoses; the leading cause of hemorrhage was uterine atony, approximately 33%. The patients' conditions

on study entry were statistically similar in the two groups. The difference in median blood loss in the drape after treatment was statistically significantly different; those in the NASG group lost 64% less, 250 ml vs. 700 ml (median difference 490 ml, 95% CI: 350–600 ml). Neither mortality alone, $n = 7$ (6.7%) for pre-intervention vs. 3 (1.9%) for the NASG groups, nor severe morbidity, $n = 5$ (5.3%) vs. 2 (1.3%), were statistically significantly different. However, a combined severe adverse outcome variable, a combination of mortality and SAMMs, was statistically significantly different, with those in the NASG group less likely to suffer a severe adverse outcome, RR = 0.28, 95% CI 0.10–0.77[36].

CONCLUSIONS

The data from these pilot trials are promising. The Pakistan data, while only descriptive, indicate that women can remain stabilized for long periods while awaiting blood transfusion, a situation typical in low-resource settings. The Egypt study 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 standardized hemorrhage and shock protocol compared with women with similar diagnoses and clinical symptoms treated only with standardized hemorrhage protocols. The data from Mexico are extremely preliminary, but may indicate the utility of the garment for stabilization and transport of hemorrhaging women who deliver outside of facilities and who are not attended by skilled providers. The preliminary Nigerian data also indicate promising use in facilities to which women with severe shock are brought as a last resort.

At this time, with only these pilot studies and descriptive case series, definitive evidence for the use of the NASG for management of obstetric hemorrhage and hypovolemic shock is not available. In order to demonstrate that the NASG not only decreases blood loss and facilitates resuscitation from shock, but also decreases maternal mortality and morbidity, a much larger trial with a strong experimental design is needed. Given that, 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 or by strong evidence from multiple quasi-experimental trials.

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