Use of the non-pneumatic anti-shock garment (NASG) to reduce blood loss and time to recovery from shock for women with obstetric haemorrhage in Egypt

S. MILLER¹, J.M. TURAN², K. DAU¹, M. FATHALLA³, M. MOURAD⁴, T. SUTHERLAND¹, S. HAMZA⁵, F. LESTER⁶, E.B. GIBSON², R. GIPSON⁷, K. NADA,⁷ & P. HENSLEIGH⁸

¹Women's Global Health Imperative, University of California, San Francisco, CA, USA, ²Center for AIDS Prevention Studies, University of California, San Francisco, CA, USA, ³Assiut University Teaching Hospital, Assiut, Egypt, ⁴El Galaa Teaching Hospital, Cairo, Egypt, ⁵Ain Shams University Specialized Hospital, Abbassia, Cairo, Egypt, ⁶Department of Obstetrics, Gynaecology, and Reproductive Sciences, University of California, San Francisco, CA, USA, ⁷John Snow Inc., Maadi, Egypt and ⁸Department of Obstetrics and Gynaecology, Stanford University, CA, USA

Abstract

Obstetric haemorrhage is one of the leading causes of maternal mortality. In many lowresource settings, delays in transport to referral facilities and in obtaining lifesaving treatment, contribute to maternal deaths. The non-pneumatic anti-shock garment (NASG) is a low-technology pressure device that decreases blood loss, restores vital signs, and has the potential to improve adverse outcomes by helping women survive delays in receiving adequate emergency obstetric care. With brief training, even individuals without medical backgrounds can apply this first-aid device. In this secondary analysis of hospital data from a pre-post intervention study in Egypt (N = 364 women with obstetric haemorrhage and shock), 158 received standard care, while 206 received standard care plus the NASG. The NASG significantly reduced blood loss, time to recovery from shock, and, for those with postpartum haemorrhage due to uterine atony who received oxytocin, the NASG had a significant effect on blood loss independent of oxytocin. These results indicate that the NASG may be a valuable innovation for reducing maternal mortality in low-resource settings. Testing at community and household levels will be necessary in order to determine whether the NASG can help women survive the longest delays.

Keywords: Maternal mortality, safe motherhood, obstetric haemorrhage, maternal morbidity

Correspondence: E-mail: svellenmiller@hotmail.com

Introduction

Over 500,000 women die each year due to pregnancy-related causes, with one death occurring each minute (UNFPA 2004a, WHO, UNICEF and UNFPA 2004). Nearly 99% of maternal mortalities occur in developing nations, and approximately one-third of these deaths are caused by obstetric haemorrhage (WHO, UNICEF and UNFPA 2004, Khan et al. 2006). Maternal Mortality Ratios (MMR) range from 20/100,000 in developed regions to 920/100,000 in sub-Saharan Africa (SSA); the lifetime risk of maternal death, a figure that takes into account total fertility and how often during her reproductive life a woman faces pregnancy, ranges from 1 in 2800 in developed regions to 1 in 16 in SSA (WHO, UNICEF and UNFPA 2004). In recognition of the critical impact of maternal death on the social, physical, and economic status of developing nations, Goal 5 of the Millennium Development Goals (MDGs) is to improve maternal health, and includes the target of reducing maternal mortality 75% by 2015 (UN 2000).

Each year 18 million women, mostly poor women from developing countries, experience obstetric complications that can result in long-term disability, with approximately 30 morbidities occurring for each mortality (Fortney and Smith 1996, Prual et al. 2000). These morbidities differ in severity and include a variety of disorders including anaemia, infections, and vesicovaginal and/or rectovaginal fistula. Obstetric complications contribute to a large share of the global burden of disease, and a global loss of \$7.5 billion US Dollars in diminished potential productivity (Koblinsky et al. 2000, UNFPA 2004a). Individual women are not the only ones affected by maternal morbidities and mortality; children, families, communities and nations are also adversely affected. Moreover, if a mother dies, the chance that her newborn will die is 10 times greater than the newborn of a mother who lives (Koblinsky et al. 2000). Other children in the family will also suffer, with female children often forced to prematurely play an adult role in caring for and raising younger siblings. These female children often have to forego education in order to take over their deceased mother's household responsibilities (UN 2006). Communities lose foundational members and nations lose productivity. Maternal mortality and morbidity are thus individual tragedies and major global public health issues, reflecting glaring economic and gender disparities.

Of the five major direct causes of maternal mortality and morbidity (haemorrhage, eclampsia, sepsis, complications of abortion, obstructed labour), the leading cause in most developing countries is obstetric haemorrhage. A World Health Organization (WHO) study published in April 2006 found that 33.9% of maternal deaths in Africa were due to haemorrhage (Khan et al. 2006). Severe bleeding related to pregnancy and childbirth takes many forms, including haemorrhage after abortion or miscarriage, ectopic pregnancy, hydatidiform mole, placenta previa, ruptured uterus, placental abruption, uterine atony, and genital lacerations (postpartum haemorrhage: PPH), post-caesarean haemorrhage, and retained placenta. Any of these can lead to haemorrhage severe enough to cause hypovolaemic shock and, if not treated, death. Treatment for obstetric

haemorrhage and hypovolaemic shock involves identifying the cause of the bleeding, reversing shock, restoring fluid balance, replacing blood, and, sometimes, surgery to correct the cause of bleeding. While these are therapies readily available in developed countries, they are inaccessible, unavailable, and often unaffordable in low-resource settings (Hofmeyr and Molala 2001, Miller et al. 2005).

The delays framework

A delays framework is often used to explain why poor, vulnerable women die from obstetric complications in developing countries (Thaddeus and Maine 1994). First, there may be a delay in problem recognition at the home/community level. For example, in the context of obstetric haemorrhage, this could involve a lack of recognition of how much bleeding is too much during home deliveries, and/or a delay in making the decision to transfer women from their homes to health facilities. The second delay occurs in getting women to emergency obstetric services (UNFPA 2004b). Blood replacement and surgery can generally only take place in referral level facilities, specifically, Comprehensive Emergency Obstetric Care (CEmOC) facilities (Miller et al. 2004, UNFPA 2004b). These facilities are rarely available in the poorest rural areas of developing countries, where the majority of women give birth at home with unskilled attendants. The UN Process Indicators, designed by UNICEF, WHO and UNFPA, describe the protocol that a national maternal health programme should follow when prioritizing their activities to provide standard obstetric care (Bailey and Paxton 2002). These Process Indicators recommend one CEmOC facility per 500,000 population (UNICEF, WHO and UNFPA 1997). However, due to inadequate resources for maternal health, unsupportive national policies, ineffective programme strategies, and lack of infrastructure, particularly in rural areas, these guidelines are seldom met (Pearson and Shoo 2005). In addition, there are no recommendations about distance or time to reach a CEmOC facility and, in reality, many women must travel hours or days to obtain CEmOC. For a woman bleeding from PPH due to uterine atony, who can exsanguinate in 2 hours, the distance to CEmOC may be insurmountable (Li et al. 1996). Transportation is often a major obstacle in low resource settings, and women may need to be transported by private vehicle, bus, taxi, bike, stretcher, or even carried (UNFPA 2004b). Sometimes a family may decide the distance or costs for fuel are too great; transport and hospitalization are impossible to overcome and the woman will bleed to death at home.

A third delay in obtaining emergency care for haemorrhage often occurs after reaching a referral level facility (UNFPA 2004b). The availability of 24 hour/7 day per week coverage for blood transfusions, lab technologists, anaesthesiologists, surgery technicians, and surgeons is rare in many countries. Even at the referral level, blood banks may not be available. Moreover, long delays ensue while the operating team is found, blood donors are located, and blood is donated, typed, and cross-matched. Delays up to 36 hours for blood transfusions have been documented in Pakistan and other areas without blood banks (Brees et al. 2004).

Thus, women die not only from the haemorrhage, but also from the delays in receiving appropriate emergency care. Therefore, maternal mortality due to obstetric haemorrhage in low resource settings is an example of how a direct cause of death is exacerbated by social, economic, political, and gender inequities.

Prevention and treatment of obstetric haemorrhage

Given the massive global burden of disease due to obstetric haemorrhage, recent efforts have been focused on providing evidence for both prevention and treatment, particularly on low-cost technologies that do not rely on highly skilled personnel (Tsu and Shane 2004). Of all the causes of obstetric haemorrhage, PPH, defined as >500 mL blood loss per vaginal delivery and >1000 mL blood loss per caesarean section (Brown and Crumbleholme 1993), has received the most attention (El-Refaey and Rodeck 2003). Prevention and treatment of PPH with uterotonics has been found to be particularly effective. Uterotonics, which include parenteral oxytocin, methergine, and syntometrine, have been recommended for prophylaxis of PPH in all clinical settings where safe injection is possible (Gülmezoglu et al. 2001, Tsu et al. 2004, Geller et al. 2006) and oral, rectal, or sublingual misoprostol suggested for settings where safe injection is not possible (Tsu and Shane 2004, Walraven et al. 2005).

Further, the International Confederation of Midwives (ICM), International Federation of Gynaecologists and Obstetricians (FIGO), American College of Obstetricians and Gynaecologists (ACOG), American College of Nurse-Midwives (ACNM), and others, have issued guidelines recommending Active Management of Third Stage of Labour (AMTSL) for every birth, especially in low resource settings (McCormick et al. 2002, ICM/FIGO 2003, Tsu and Shane 2004, Vivio and Williams 2004). The three components of AMTSL, administration of uterotonics immediately following the birth of the baby, controlled cord traction, and uterine massage after delivery of the placenta, have not been rigorously tested as separate components. A recent meta-analysis of AMTSL with parenteral uterotonics reported reduced relative risk of PPH > 500 mL at 0.38 and reduced relative risk of PPH > 1000 mL at 0.33 (Prendiville et al. 2006).

Uterotonic medications are not only recommended for prevention of PPH from uterine atony, but are also the recommended treatment for PPH (El-Refaey and Rodeck 2003, Hofmeyr et al. 2005). However, not all obstetric haemorrhage is due to uterine atony, and not all cases of uterine atony respond to uterotonics. In severe cases of intractable haemorrhage, bleeding will not respond to the administration of uterotonics, and surgery is the only recourse to halt bleeding (Ornan et al. 2003). Moreover, once a woman has bled sufficiently to go into shock, fluids and blood must be administered to restore haemodynamic stability and prevent tissue death. Hypovolaemic shock is a condition in which the body does not have enough blood volume to circulate oxygen to vital organs. Unless the shock is reversed, these organs, (heart, lung, brain, and kidneys) will fail or suffer irreversible damage. Uterotonics cannot treat shock. Thus, what is also needed, in

addition to AMTSL and increased access to a variety of uterotonics, is a low-cost, easily used method to reverse shock and restore vital signs until blood transfusion and fluid replacement can be effected (Miller et al. 2004).

Background on the NASG and summary of previously reported findings

The non-pneumatic anti-shock garment (NASG) is a first-aid device that can be used to stabilize, resuscitate, and keep a woman alive while overcoming the delays that contribute to maternal mortality in low-resource settings. The NASG, a relatively new device for reversing shock and decreasing bleeding from all forms of obstetric haemorrhage (Zoex Corporation, Ashland, OR, USA), is a lightweight neoprene garment that resembles the bottom half of a wetsuit. It was developed in the early 1970s by the National Aeronautics and Space Administration (NASA) as a modification of the inflatable Pneumatic Anti-Shock Garment (PASG), and is simpler in design, more quickly and easily applied, less expensive and avoids the risk of over-inflation and excessive pressure of the PASG (Pelligra 1994).

The NASG is ideal for low-resource settings because it can be bleached, washed, and reused at least 40 times. Thus, the current retail price of US\$160.00 becomes relatively inexpensive at US\$4.00 per use. Much like the PASG, the NASG functions by providing circumferential counter pressure to the lower body in order to shunt blood from the lower extremities and abdominal area to the essential core organs: heart, lungs and brain. The garment's five neoprene segments close tightly with Velcro around the legs, pelvis and abdomen to supply 20-40 mmHg circumferential pressure. The abdominal segment incorporates a small foam pressure ball to provide uterine compression. The garment also permits total perineal access so that genital lacerations can be repaired, speculum or bimanual examinations can be performed, and manual removal of the placenta or emptying of the uterus can all be accomplished with the NASG in place. Therefore, the causes of most obstetric haemorrhages can be located and repaired while the garment maintains vital signs. In addition to reversing shock and stabilizing the patient, exerting circumferential pressure decreases both the transmural pressure and the radius of uterine, abdominal, and other lower body arteries (McSwain 1988). According to the physics of blood flow as expressed by the LaPlace law, the Poiseuille's law, and the Bernoulli principles, reduction in arterial transmural pressure and radius results in decreased blood flow (Serway and Jewett 2004).

Case studies in Pakistan and pilot studies in Mexico and Nigeria have demonstrated that with NASG application, women suffering from shock rapidly regain consciousness (Hensleigh 2002, Brees et al. 2004, Miller et al. 2005). In Nigeria, women experiencing seemingly irreversible shock have been resuscitated after application of the NASG; hospital staff have called these women 'Ayorunbo', translated as, 'She who has been to heaven and returned' (Miller et al. 2005).

A pilot, pre-post intervention study at four Egyptian teaching hospitals¹, capable of providing CEmOC, examined the outcomes for pregnant, delivering, or post-partum women experiencing a minimum of 750 mL of blood loss from all

types of obstetric haemorrhage, who also had at least one sign of shock: either pulse >100 BPM or systolic blood pressure <100 mm Hg. The primary outcome measure was median blood loss for women treated with the normal protocol for obstetric haemorrhage and shock (pre-intervention group, all women with admission criteria seen at the hospitals between May and August 2004) compared to women treated with the same protocol and the NASG (NASGintervention group, all women meeting admission criteria seen at the hospitals between September and December 2004). In both groups, blood loss was measured using a closed-end, graduated, plastic measuring drape. The study resulted in a statistically significant 50% decrease in the median measured amount of blood loss among 206 women treated with the NASG compared to the 158 women receiving standard treatment for obstetric haemorrhage and shock, 250 mL vs. 500 mL, p < 0.001 (Miller et al. 2006a). While there was not sufficient power to detect statistically significant differences in maternal morbidity and mortality, the Egypt pilot study did show a 69% decrease in severe adverse outcomes, 3.2% (n=5) in the preintervention group and 1% (n=2) for the NASG group (RR 0.31, CI = 0.66-1.56). Two women died in the preintervention group; none died in the NASG group.

The present report is a further analysis of the Egyptian data and demonstrates that in addition to decreasing blood loss, the NASG decreased time to recovery from hypovolaemic shock, defined as a decrease in pulse from 100 BPM or more to less than 100 BPM and a return to normal shock index (SI), independent of other resuscitative measures, such as timing of administration of blood transfusions and volume of IV fluids given. These analyses were performed on all data regardless of obstetric aetiology. Additionally, this report examines the independent effect of the NASG, holding constant the volume of oxytocin received, on decreased blood loss from PPH (uterine atony).

Methods

Measures

Data on the woman's clinical course were recorded on a standardized data collection form by trained physician-data collectors. The study was approved by the Institutional Review Boards (IRBs) of the University of California, San Francisco (UCSF), University of California, Berkeley (UCB) and the respective hospitals in Egypt. Blood loss after admission to the study was measured using a calibrated blood collection drape. Studies of this calibrated blood drape indicate that it is more accurate than visual assessment in measuring postpartum blood loss (Geller et al. 2006). Pulse and blood pressures were taken every 15 minutes during the acute phase of the resuscitation, then every 30 minutes for the next 2 hours, then every hour, and finally, every 4 hours per the hospital protocol. In this study, the majority of women in both groups recovered by 6 hours after admission to the study. Measures used to evaluate recovery from hypovolaemic shock include pulse, with a pulse <100 BPM indicating recovery, and the shock index.

The shock index (SI) is a calculated variable of pulse divided by systolic blood pressure. As it combines both pulse and systolic blood pressure, the shock index has been proposed as a better clinical indicator of hypovolaemia than pulse or systolic blood pressure alone (Birkhahn et al. 2003). A higher shock index indicates greater risk of severe morbidity or mortality. The normal SI range for healthy euvolaemic patients is between 0.5-0.7 (Birkhahn et al. 2005). Due to physiological changes in pregnancy and the higher blood plasma volume of pregnant women (Brown and Crumbleholme 1993, Gordon 2002), an SI value of ≤ 0.9 was used to indicate recovery in this study.

For time to recovery of SI while controlling for start of blood transfusions, a variable was created and coded '1' if the woman received a blood transfusion for resuscitation before recovery of SI (or by the end of the observation if her SI did not reach a recovery level during the observation) and '0' if she did not receive a blood transfusion before SI recovery/end of the observation. For IV fluids, a variable was created and coded '1' if the woman received more than 1000 mL of fluids during the first hour after study admission and '0' if she received ≤ 1000 mL during that first hour (an amount deemed minimal for resuscitation).

Analytic methods

Statistical analyses were conducted using SPSS 13.0 for Windows (release 13.0, 1 September 2004, copyright © SPSS, Inc). Analyses of the effects of the NASG on volume of blood loss after study admission while controlling for the dose of uterotonics received were conducted using Two-Way Analysis of Variance (ANOVA) and linear regression. Comparisons of pulse and SI recovery times for pre-intervention women compared to NASG women were conducted using 'survival analysis' for time-to-event data with censoring, when there is loss-tofollow up and/or not all women recover by the end of the observation period (Swinscow and Campbell 1997). Kaplan-Meier survival analysis was used to make simple between-group comparisons and Cox Regression (Campbell 2001) was used to compare the groups while controlling for covariates, including pulse or SI at admission (as a measure of severity of clinical condition), whether or not the woman received a blood transfusion during resuscitation, and whether or not the woman received more than 1000 mL of IV fluids during the first hour after admission to the study. When recovery of pulse or SI occurred at a time when measurements were being taken less frequently (every 4 hours), the midpoint of the interval was used. Tests of the hazard rates with and without the proportional hazard assumption revealed that the assumption was not violated and Cox Regression could be used.

Results

Blood loss controlling for uterotonics

Previous analyses of the Egyptian data presented elsewhere (Miller et al. 2006a) revealed that severe obstetric haemorrhage patients treated with the NASG had

significantly less measured blood loss after admission to the study than similar patients who did not have the NASG. However, a question remained for women with a diagnosis of PPH from uterine atony: 'Does the NASG have significant effects on blood loss, above the effects of oxytocin given to contract the uterus?' For women diagnosed with PPH due to uterine atony (69 pre and 76 NASG cases), we examined whether or not the NASG had a significant effect on blood loss independent of oxytocin. Although women in the NASG with uterine atony received significantly more units of oxytocin compared to pre-intervention phase women over the course of their hospital stay (39.5 units vs. 33.0 units, t = -2.31, p = .023), the difference for the first 6 hours of treatment was not statistically significant (32.0 units vs. 30.7 units, t = -.39, p = .698). Multivariate analyses controlling for the total dose of oxytocin received, reveal that the NASG has a significant effect on blood loss for women with uterine atony while controlling for dose of oxytocin given. When these variables are included in a two-way ANOVA, both treatment group (p = 0.00) and dose of oxytocin (p = 0.02) have significant effects on measured blood loss. Including these variables in a regression analysis (F=13.14, p=.000) reveals that women in the NASG group had 303 mL less blood loss (299 mL) than women in the pre-intervention group (602 mL), when the dose of oxytocin received is statistically controlled.

Time to recovery

Data on time from study entry to recovery of pulse (first pulse <100 BPM), and shock index (first SI \leq 0.9) were available for three of the four study hospitals (N = 272). Initial pulses at study admission ranged from 80 to 150 BPM, while initial shock indices ranged from 0.67 to 2.80. Of these 272 women in the three hospitals, only women who had non-missing data on pulse or SI recovery time (or length of observation if no recovery), and an initial pulse of greater than 100 BPM (N = 251), and/or an initial shock index >0.9 (N = 249) were included in these recovery time analyses.

Pulse recovery

Median pulse recovery times were 90 minutes for the NASG group compared to 180 minutes for the pre-intervention group (log rank test = 17.92, p = 0.000). However in these analyses it is necessary to control for the woman's pulse at admission, as recovery time is related to pulse at admission, pulse being an indicator of severity of shock². As shown in Table 1 below, median pulse recovery times were significantly shorter for NASG compared to pre-intervention cases, at two different levels of severity at admission: pulse at admission ≥ 120 BPM (severe shock) and pulse at admission < 120 BPM (moderate shock). A log rank test conducted after adjustment for pulse at admission indicates that the time to pulse recovery curves for the NASG and pre-intervention groups are significantly different.

Figure 1 presents the time to pulse recovery curves for the pre-intervention and NASG groups, controlling for pulse at admission as a continuous variable. Both

	Time from study entry <100 in minutes (95% co	Log rank test, adjusted for pulse at	
	Pre-intervention $(n = 106)$	NASG $(n = 145)$	admission
Pulse at admission <120	150 minutes (117-183 min) (n = 62)	45 minutes (36–54 min) (<i>n</i> = 86)	21.20, <i>p</i> = 0.000
Pulse at admission ≥ 120	240 minutes (161-319 min) (n = 44)	170 minutes (120-220 min) (n = 59)	

Table 1. Median pulse recovery times from Kaplan-Meier survival analysis

study group (pre-intervention vs. NASG) and pulse at admission are statistically significant (p = 0.000) in the model which includes both variables.

Shock index (SI) recovery

Median recovery times were 75 minutes for the NASG group compared to 120 minutes for the pre-intervention group (log rank test = 8.99, p = 0.003). A stratified analysis was then conducted by classifying women according to whether their SI at admission was above or below the median SI at the time of study admission, 1.22. As shown in Table 2 below, median SI recovery times were significantly shorter for NASG compared to pre-intervention cases, at two different levels of severity at admission: SI ≤ 1.22 and SI > 1.22. A log rank test conducted after adjustment for SI at admission indicates that the curves for the NASG and pre-intervention groups are significantly different. Figure 2 presents the time to SI recovery curves for the pre-intervention and NASG groups, controlling for SI at admission.

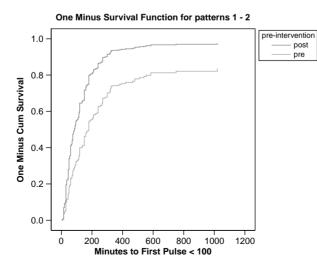


Figure 1. Time to pulse recovery curves from Cox Regression comparing pre-intervention and post-intervention (NASG) cases, controlling for pulse at admission

	Time from study entry to first SI \leq 0.9 in minutes (95% confidence interval)		Log rank test, adjusted for pulse at
	Pre-intervention $(n = 104)$	NASG $(n = 145)$	admission
SI at admission ≤ 1.22	90 minutes (71-109 min) (n = 61)	45 minutes (43-47 min) (n = 70)	15.13, <i>p</i> = 0.000
SI at admission >1.22	240 minutes (196–284 min) (n = 43)	120 minutes (84–155 min) (<i>n</i> = 75)	

Table 2. Median Shock Index (SI) recovery times from Kaplan-Meier survival analysis

As shown in Table 3 below, the Cox Regression results indicate that the NASG significantly reduces time to SI recovery, while controlling for both initial SI and whether or not the woman had a blood transfusion for resuscitation or receipt of > 1000 mL of IV fluids in the first hour. In the top panel of Table 3, it can be seen that both the NASG and blood transfusion decrease predicted recovery times, while increasing values of initial SI increase predicted recovery times. Results while controlling for the receipt of > 1000 mL of IV fluids in the first hour after study admission in a separate analysis are shown in the bottom panel of Table 3. NASG and initial SI value remain significant determinants of recovery time, while receipt of > 1000 mL of IV fluids was not significant in the final model.

Discussion

This secondary analysis, including decreased time to recovery from shock and the independent blood loss-reducing effect of the NASG on patients with uterine

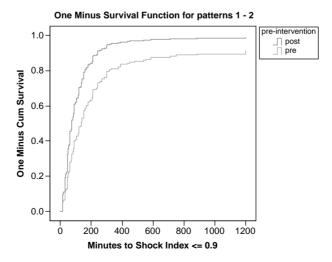


Figure 2. Time to SI recovery curves from Cox Regression for pre-intervention and postintervention (NASG) cases, controlling for SI at admission

	В	Wald	Sig.	Exp(B)	95.0% CI for Exp(B)			
					Lower	Upper		
Blood transfusion $(n = 222)$								
NASG	.651	19.337	.000	1.918	1.435	2.563		
Initial SI value	-1.199	15.809	.000	.301	.167	.544		
Blood transfusion for resuscitation	.856	26.131	.000	2.353	1.695	3.266		
Volume of IV fluids given in the first hour $(n = 196)$								
NASG	.454	8.519	.004	1.575	1.161	2.136		
Initial SI value	-1.841	37.367	.000	.159	.088	.286		
>1000 mL of IV fluids in first hour	.154	.829	.363	1.167	.837	1.625		

Table 3. Cox Regression results for the effects of study group on shock index recovery time, controlling for initial SI value and other resuscitative measures

B = beta (the estimated regression coefficient).

Wald = Wald statistic.

Sig = Significance of the Wald statistic.

EXP(B) = Predicted change in the hazard for a unit increase in the predictor.

atony who received uterotonics, further demonstrates the potential role of the NASG in the management of patients suffering from severe obstetric haemorrhage and hypovolaemic shock. Rapid recovery from shock is critical in the resuscitation and stabilization of women with severe obstetric haemorrhage, and it appears that the NASG was able to achieve this goal more efficiently than the standard protocol at the study hospitals. Unadjusted median recovery times were 1.6-2 times longer in the pre-intervention group than in the group treated with the NASG, and the differences were even greater when adjustments were made for severity of the woman's condition at admission to the study.

Although this study was conducted in CEmOC facilities, the implications for the use of this non-invasive, inexpensive, simple, and reusable device in lowresource settings are numerous. A first-aid device that could be applied at the community level that would decrease bleeding, restore vital signs, and keep the major organs, heart, lung, brain, and kidneys perfused with oxygen, might reduce maternal deaths due to haemorrhage. The NASG has the potential to 'buy time' and keep women alive as they overcome the delays that contribute to high rates of MMR among poor women in low-resource settings. For example, as part of a home-to-hospital continuum of emergency obstetric care system (de Graf-Johnson et al. 2005, Miller et al. 2006b)³, if community health workers, auxiliary nurse-midwives, or village health workers were trained to apply the NASG at home or at the primary health care level, women could be transported to a referral facility in the NASG. They might then arrive in better condition, with less loss of blood, perfusion of the core organs, and ready for surgery, if that is deemed necessary for definitive therapy. A woman with the NASG, who had recovered from shock before arriving at a CEmOC facility, might have a greater chance of survival without long-term morbidities than one who arrives without a pulse, without a blood pressure, and/or unconscious. If, on arrival at the referral facility, there was a delay in obtaining blood or in accessing the operating theatre, the NASG might enable the woman to survive these further delays.

Limitations

Limitations of this study include the unblinded, non-randomized, pre-post study design and the relatively small sample size. The study groups were similar in terms of demographic characteristics and diagnoses (Miller et al. 2006a), and initial differences in clinical condition between the groups were statistically controlled for. However, this does not rule out the possibility that other differences between the non-NASG and NASG groups are responsible for the statistically significant differences found in pulse and SI recovery times and blood loss controlling for oxytocin. Another clinically important limitation of the study is a possible upward bias in recovery times for both groups, because vital signs were measured only every 15 minutes in the initial recovery period. Thus, if a woman's pulse recovered at the 16th minute, it may have not been recorded until the 30th minute. Given that actual recovery times may be shorter for both groups, the large and significant differences in pulse and SI recovery time between NASG and non-NASG groups (e.g., 45 vs. 150 minutes to pulse recovery for women in less critical condition) are impressive.

A final limitation of the study is that in order to obtain adequate sample sizes for statistical power, it was conducted in high volume CEmOC facilities. The true test of whether this device will indeed contribute to decreasing MMR will be to test its effectiveness at the community level. Studies are currently being conducted in Nigeria with longer delays in obtaining blood transfusions and IV fluids after reaching CEmOC facilities, and with the application of the NASG at the primary health care level.

Conclusions

Meeting the UN Millennium Development Goal to improve maternal health is a crucial step towards improving health and quality of life of everyone involved. Death related to childbirth and pregnancy is a leading cause of death among women of reproductive age, and addressing this problem demands multiple approaches across multiple sectors. Certainly, long-term strategies for decreasing maternal mortality, such as educating girls and women, raising the age of marriage, assuring access to family planning, decreasing unsafe abortion, building infrastructure (including roads, health care facilities), training of skilled attendants, and developing referral systems between home and hospital, are all necessary for progress towards achieving this MDG. However, short-term technological fixes can also play an important role while these longer-term strategies are being implemented. One such method would be the use of the NASG for immediate first-aid for obstetric haemorrhage. This secondary analysis of data from a comparative study of the NASG for treatment of obstetric

haemorrhage in tertiary care facilities in Egypt demonstrated that the NASG more rapidly reduced time to recovery from shock than standard management. This indicates that the NASG may prove useful in overcoming delays in receiving care at the facility level, the third delay. Can the NASG help women survive delays in arranging for transportation and during transport to referral facilities? Studies conducted at the community level with women being transported to referral level hospitals in the NASG are needed in order to answer this question.

Acknowledgements

Research for this paper was undertaken with support from the MacArthur Foundation and USAID Egypt. We thank Helen Cheng and Steve Shibosky of UCSF, WGHI for statistical consultation. Further, Amr Fathy, Ihab Nasshar, I Elshair, and the staff of El Galaa Teaching Hospital, Assiut University Teaching Hospital, El Minya University Teaching Hospital and Alexandria University Teaching Hospital are gratefully acknowledged. Dr. Turan's work on this article was also supported, in part, by grant # T32 MH-19105-17 from the National Institute of Mental Health (NIMH).

Notes

¹ Alexandria University Teaching Hospital, Alexandria, Egypt; Al Minya University Teaching Hospital, Al Minya, Egypt; Assiut University Teaching Hospital, Assiut, Egypt; and El Galaa Teaching Hospital, Cairo, Egypt.

 2 According to Creasy and Resnik (1994) Maternal and Fetal Medicine, moderate shock is indicated when the pulse is between 100–120 BPM, and severe shock when the pulse is above 120 BPM.

³ Early recognition of complication, first-aid emergency response, transport, and referral system.

References

- Bailey, P.E. and Paxton, A. (2002) Program Note. Using UN Process Indicators to Assess Needs in Emergency Obstetric Services. International Journal of Gynaecology and Obstetrics, 76, 299–305, discussion 306.
- Birkhahn, R.H., Gaeta, T.J., Terry, D., Bove, J.J. and Tloczkowsi, J. (2005) Shock Index in Diagnosing Early Acute Hypovolemia. *American Journal of Emergency Medicine*, 23, 323-326.
- Birkhahn, R.H., Gaeta, T.J., Van Deusen, S.K. and Tloczkowsi, J. (2003) The Ability of Traditional Vital Signs and Shock Index to Identify Ruptured Ectopic Pregnancy. *American Journal of Obstetrics and Gynecology*, 189, 1293–1296.
- Brees, C., Hensleigh, P., Miller, S. and Pelligra, R. (2004) A Non-inflatable Anti-shock Garment for Obstetric Hemorrhage. *International Journal of Gynaecology and Obstetrics*, 87, 119–124.
- Brown, J. and Crumbleholme, W. (eds) (1993) Handbook of Gynecology and Obstetrics (Norwalk: Appleton & Lange).
- Campbell, M.J. (2001) Survival Analysis. In Campbell M.J. (ed) Statistics at Square Two: Understanding Modern Statistical Applications in Medicine (London: BMJ, 59-73).
- Creasy, R.K. and Resnik, R. (eds) (1994) Maternal-Fetal Medicine: Principles and Practice (Philadelphia: WB Saunders).
- de Graf-Johnson, J., Daly, P., Otchere, S., Russell, N. and Bell, R. (2005) Household to Hospital Continuum of Maternal and Newborn Care. ACCESS Project (Baltimore: ACCESS).

- El-Refaey, H. and Rodeck, C. (2003) Post-partum Haemorrhage: Definitions, Medical and Surgical Management. A Time for Change. *British Medical Bulletin*, 67, 205–217.
- Fortney, J.A. and Smith, J.B. (1996) The Base of the Iceberg: Prevalence and Perceptions of Maternal Morbidity in Four Developing Nations (Research Triangle Park: Family Health International).
- Geller, S.E., Adams, M.G., Kelly, P.G., Kodkany, P.S. and Derman, R.J. (2006) Postpartum Hemorrhage in Resource-poor Settings. *International Journal of Gynaecology and Obstetrics*, 92, 202–211.
- Gordon, M. (2002) Maternal physiology in pregnancy. In S.G. Gabbe and Simpson, J.L. (eds) *Obstetrics: Normal and Problem Pregnancies* (Edinburgh: Churchill Livingstone, 63–91).
- Gülmezoglu, A., Villar, J., Ngoc, N., Piaggio, G., Carroli, G., Adetoro, L., *et al.* (2001) WHO Multicentre Randomised Trial of Misoprostol in the Management of the Third Stage of Labour. *Lancet*, 358, 689–695.
- Hensleigh, P.A. (2002) Anti-shock Garment Provides Resuscitation and Haemostasis for Obstetric Haemorrhage. *British Journal of Obstetrics and Gynaecology*, 109, 1377–1384.
- Hofmeyr, G.J. and Molala, B.K.F. (2001) Hypovolemic shock. Best Practice & Research Clinical Obstetrics Gynaecology, 154, 645-662.
- Hofmeyr, G.J., Walraven, G., Gulmezoglu, A.M., Maholwana, B., Alfirevic, Z. and Villar, J. (2005) Misoprostol to Treat PPH: A Systematic Review. *British Journal of Obstetrics and Gynaecology*, 112, 547–553.
- ICM/FIGO (2003) Joint Statement: Management of the Third Stage of Labour to Prevent Postpartum Haemorrhage. Accessed 28 March 2006, available at http://www.internationalmidwives.org/modules/ContentExpress/img_repository/final%20joint%20statement%20active%20management-eng%20with%20logo.pdf
- Khan, K.S., Wojdyla, D., Say, L., Gulmezoglu, M. and Van Look, P.F. (2006) WHO Analysis of Causes of Maternal Death: A Systematic Review. *Lancet*, 367, 1066–1074.
- Koblinsky, M., Conroy, C., Kureshy, N., Stanton, M. and Jessop, S. (2000) Issues in Programming for Safe Motherhood (Arlington: John Snow Inc).
- Li, X.F., Fortney, J.A., Kotelchuck, M. and Glover, L.H. (1996) The Postpartum Period: The Key to Maternal Mortality. *International Journal of Gynaecology and Obstetrics*, 54, 1–10.
- McCormick, M.L., Sanghvi, H.C., Kinzie, B. and McIntosh, N. (2002) Preventing Postpartum Hemorrhage in Low-resource Settings. *International Journal of Gynaecology and Obstetrics*, 77, 267–275.
- McSwain, N.E., Jr. (1988) Pneumatic Anti-shock Garment: State of the Art 1988. Annals of Emergency Medicine, 17, 506-525.
- Miller, S., Lester, F. and Hensleigh, P. (2004) Prevention and Treatment of Postpartum Hemorrhage: New Advances for Low-resource Settings. *Journal of Midwifery and Women's Health*, 49, 283–292.
- Miller, S., Ojengbede, O., Bray, E., Lester, F., Fabamwo, A.O., Bello, M., et al. (2005) Ayorunbo: She who has been to heaven and returned. Near miss maternal mortality in Nigeria and Mexico. Abstract presented at the 134th annual APHA Conference in Philadelphia, USA (University of California, San Francisco).
- Miller, S., Hamza, S., Bray, E., Gipson, R., Nada, K., Fathalla, M.F., et al. (2006a) First Aid for Obstetrical Hemorrhage: The Pilot Study of the Non-pneumatic Anti-shock Garment (NASG) in Egypt. British Journal of Obstetrics and Gynaecology, 113, 424–429.
- Miller, S., Buffington, S.T., Beck, D., de Graf-Johnson, J., Daly, P., Otchere, S., et al. (2006b) Home and Community Based Health Care for Mothers and Newborns (Baltimore: ACCESS).
- Ornan, D., White, R., Pollak, J. and Tal, M. (2003) Pelvic Embolization for Intractable Postpartum Hemorrhage: Long-term Follow-up and Implications for Fertility. *Obstetrics and Gynecology*, 102, 904–910.
- Pearson, L. and Shoo, R. (2005) Availability and Use of Emergency Obstetric Services: Kenya, Rwanda, Southern Sudan, and Uganda. *International Journal of Gynaecology and Obstetrics*, 88, 208–215.
- Pelligra, R. (1994) Non-pneumatic Antishock Garment Use. Emergency, 26, 53-56.
- Prendiville, W.J., Elbourne, D. and McDonald, S. (2006) Active Versus Expectant Management in the Third Stage of Labor. *Cochrane Library*, 1, 1–27.
- Prual, A., Bouvier-Colle, M.H., De Bernis, L. and Breart, G. (2000) Severe Maternal Morbidity from Direct Obstetric Causes in West Africa: Incidence and Case Fatality Rates. *Bulletin of the World Health Organization*, 78, 593–602.

- Serway, R.A. and Jewett, J.W. (eds) (2004) Fluids. In *Physics for Scientists and Engineers* (Belmont: Brooks Cole, 420–437).
- Swinscow, T. and Campbell, M. (eds) (1997) Survival Analysis. In *Statistics at Square One* (London: BMJ, 80-87).
- Thaddeus, S. and Maine, D. (1994) Too Far to Walk: Maternal Mortality in Context. Social Science & Medicine, 38, 1091–1110.
- Tsu, V.D. and Shane, B. (2004) New and Underutilized Technologies to Reduce Maternal Mortality: Call to Action from a Bellagio Workshop. *International Journal of Gynaecology and Obstetrics*, 85 Suppl 1, S83–S93.
- Tsu, V.D., Langer, A. and Aldrich, T. (2004) Postpartum Hemorrhage in Developing Countries: Is the Public Health Community using the Right Tools? *International Journal of Gynaecology and Obstetrics*. 85 Suppl, 1, S42–S51.
- UN (2000) United Nations Millennium Declaration (New York: UN).
- UN (2006) Resolution Adopted by the General Assembly: The Girl Child (New York: UN).
- UNFPA (2004a) State of the World Population 2004. The Cairo Consensus at Ten: Population, Reproductive Health and the Global Effort to End Poverty (New York: UNFPA).
- UNFPA (2004b) Programme Indicators, Part II: Indicators for Reducing Maternal Mortality. Accessed 29 March 2006, available at http://www.unfpa.org/monitoring/toolkit.html
- UNICEF, WHO and UNFPA (1997) Guidelines for Monitoring the Use and Availability of Obstetric Services (New York: UNICEF, WHO and UNFPA).
- Vivio, D. and Williams, D. (2004) Active Management of the Third Stage of Labor: Why is it Controversial? *Journal of Midwifery and Women's Health*, 49, 2–3.
- Walraven, G., Blum, J., Dampha, Y., Sowe, M., Morison, L., Winikoff, B., et al. (2005) Misoprostol in the Management of the Third Stage of Labour in the Home Delivery Setting in Rural Gambia: A Randomised Controlled Trial. British Journal of Obstetrics and Gynaecology, 112, 1277-1283.
- WHO, UNICEF and UNFPA (2004) Maternal mortality in 2000: Estimates developed by WHO, UNICEF and UNFPA. Accessed 29 March 2006, available at http://www.reliefweb.int/library/ documents/2003/who-saf-22oct.pdf