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A non-inflatable anti-shock garment for obstetric hemorrhage

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ABSTRACT

Objectives: Maternal death from hemorrhage in low resource settings is frequently due to long delays in transportation to referral centers and/or in obtaining blood and surgical interventions. This case series was designed to demonstrate the feasibility, efficacy and safety of the non-inflatable anti-shock garment (NI-ASG) for resuscitation and hemostasis in the initial management of obstetric hemorrhage and shock. *Methods:* Fourteen cases of obstetric hemorrhage and hypovolemic shock at Memorial Christian Hospital, Sialkot, Pakistan were managed with a specific clinical protocol based on using NI-ASG as the primary intervention. *Results:* The NI-ASG was used to resuscitate and stabilize women with hypovolemic shock from 18 to 57 h. Thirteen patients survived without evidence of morbidity, but one had prolonged shock followed by multiple organ failure and death. *Conclusions:* This study confirmed that the NI-ASG quickly restored the vital signs of most women in severe hemorrhagic shock and stabilized them while awaiting blood transfusion. © 2004 International Federation of Gynecology and Obstetrics. Published by

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1. Introduction

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Obstetric hemorrhage in excess of 1000 ml occurs in about 1% of deliveries and in an even smaller proportion of spontaneous or induced abortions [1-3]. These events may become life threatening for the

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woman, particularly in low resource settings, and can certainly cause anxiety and despair for the caregivers. Active management of the third stage of labor, administration of uterotonics when needed, prompt suturing of accessible lacerations and rapid infusion of intravenous saline will often arrest the blood loss and resuscitate the woman with postpartum hemorrhage. However, when these basic measures fail to stop the hemorrhage, the patient may require blood transfusion and, in some cases, laparotomy for surgical interventions to stop the bleeding. Many delivery facilities in South Asia have no blood bank and the limited availability of anesthesiologists, surgeons, nursing services and operating rooms may cause further delay in needed surgical interventions. During this waiting period, giving excessive saline infusion may restore the blood pressure but has the adverse effect of simultaneously augmenting hemorrhage. The generally recommended strategy for resuscitation and stabilization of severe hemorrhagic shock with uncontrolled bleeding is to give limited intravenous saline infusion, so as to maintain a state of hypovolemia and mild hypotension [4,5]. Since continuous cardiac and pressure monitors are not likely to be available, management while awaiting blood for transfusion is technically difficult particularly with regard to the rate of crystalloid infusion.

A new innovation in managing obstetric hemorrhage is a lower body counterpressure device, the non-inflatable anti-shock garment (NI-ASG). The trade name of this device is Zoex and it is distributed by Zoex, P.O. Box 435, Ashland, OR 97520 USA. The NI-ASG consists of a body suit of neoprene, cut in panels, with Velcro fasteners (Fig. 1). It is inexpensive, reusable, and easy to apply. This simple device has no pumps, tubes, valves or gauges and its pressure is developed solely by the elasticity of the neoprene garment material and a pliable sphere incorporated into the abdominal panel. This report concerns the use of the NI-ASG to resuscitate women with obstetric hemorrhage and hypovolemic shock and to stabilize them for the time required for definitive treatment.

During the last 3 years, the NI-ASG has been used for the management of about 150 women who experienced severe hemorrhage and shock at the Memorial Christian Hospital (MCH), Sialkot, Pakistan. Early in this experience, a series of six patients concerning the efficacy and safety of the NI-ASG was published [6]. Data have not been continuously collected over the 3 years of experience due to budgetary and staffing constraints on this busy obstetrics service which has about 8500 deliveries per year. However, the present paper



Figure 1 NI-ASG ready to apply. Panel 1 is not used when the subject is of short stature as is the case with this model. The panels are applied from the ankles upward, and number 5 contains a soft sphere which is placed over the navel and then compressed by panel number 6.

documents a series of 14 women with acute and severe obstetric hemorrhage which includes all consecutive cases resuscitated and stabilized with the NI-ASG at MCH during August through November 2003.

2. Methods

The MCH is a 340-bed general hospital, predominantly obstetrical, and during the four month study period there were 3579 deliveries. Nurse midwives under supervision of an obstetrician are the primary providers of labor and delivery services. Women in this study received 1:1 nursing care in labor and delivery until they were stable enough for transfer to the intensive care unit. MCH has 24 h/day clinical laboratory and anesthesia services. General surgeons and a medical intensivist are always available for consultations. However, there is no blood bank facility at MCH or elsewhere in Sialkot. When blood transfusion is required, family members and friends must be recruited as donors.

The NI-ASG was applied following a specific protocol. The intent was to apply the device as soon as there was clinical evidence of severe hemorrhage or shock. The inclusion criteria for

patients in this series included blood loss of \geq 750 ml, systolic blood pressure of ≤ 100 and pulse ≥ 100 . In some cases, there was delay and patients were in more profound shock due to pre-admission bleeding or completion of surgical interventions resulting in excessive hemorrhage before the NI-ASG was applied. As shown in Fig. 1, the panels of the NI-ASG are numbered from 1 to 6, and application begins with securing the panels at the ankles and progresses sequentially up to the abdomen. While using the NI-ASG vital signs were recorded every 15-30 min, oxygen saturation was obtained intermittently as clinically indicated, and a Foley catheter was placed to document urine output. General guidelines for fluid resuscitation and maintenance included rapid infusion of saline, 1.5 times the estimated volume of blood loss followed by maintenance saline infusion of 150 ml/h. When the blood pressure and pulse were returned to baseline and the hemoglobin was at least 7.0, the NI-ASG was removed in segments, beginning at the ankles and sequentially removing the panels upwards at 15-min intervals with observation for recurrent hypotension or tachycardia.

3. Results

Data are presented in Table 1 on 14 women who were managed with the NI-ASG during this 4-month period. Acute blood loss prior to NI-ASG placement was estimated at between 2000 and 4500 ml. Not shown in Table 1 is the mean time of 5 h required to obtain blood donors and initiate transfusion. The mean time for use of the device was 31 h with a range of 18-57 h. Patients were transfused with between one and six units of whole blood. Thirteen patients survived without evidence of morbidity and one patient died on day 19 following her acute hemorrhage. The large majority of patients managed with the NI-ASG over the past 3 years have survived without complications, even though many appeared to have terminal shock when the NI-ASG was placed. Brief presentations follow on the course of one typical case of successful management (Case #7 in Table 1), an unusual case in this series who signed out of hospital before the treatment protocol was completed (Case #12), as well as a summary of the one mortality (Case #9).

Case # 7 in Table 1. This is a 24-year-old Gravida 3 Para 3 with two living children. She had a home birth followed by postpartum hemorrhage. She was brought to MCH 3.5 h after delivery with continuing bleeding. Upon admission, she was unconscious, cold and clammy with a blood pressure 40/palpable and pulse >150. The estimated blood loss was 3000 ml and the admission hemoglobin 7.0 gm/dl. No lacerations were observed and bleeding was determined to be secondary to uterine atony. She was immediately placed in the NI-ASG and given intravenous saline with oxytocin. Within 5 min, her BP was 90/40, and at 10 min 120/80 with of pulse 136. There was no evidence of genital lacerations and she did not have further significant vaginal bleeding. She was in the NI-ASG for 27 h and could arrange only one unit of whole blood, as she was Rh negative. She maintained a hemoglobin level of 7.0 and after 27 h, the NI-ASG was removed, she had stable vital signs and was discharged home.

Another case which requires some explanation is #12. The patient had a spontaneous abortion and entered the hospital 4 days later with continued bleeding, and estimated blood loss of 3000 ml. Upon admission, she had BP of 70/40, pulse of 142 and initial hemoglobin 7.4 g/dl. She was placed in the NI-ASG and dilation and curettage yielded products of conception. After receiving 2 units of whole blood, her hemoglobin was 3.7 and shortly thereafter, she left the hospital against medical advise. Despite the fact that she did not comply with the protocol regarding restoration of hemoglobin level to 7.0, there were no known adverse sequelae of her early discharge from hospital.

Case # 9. This is a 30-year-old gravida 8 Para 7 with six living children. She presented to the labor room near term with 3 h of vaginal bleeding, hemoglobin of 4.0 and absent fetal heart tones. The clinical impression was placental abruption with fetal demise and severe anemia. Even though she met the criteria for NI-ASG use, the providers did not use it at this time. Blood donors were requested urgently, intravenous saline was given, but she continued bleeding with the total estimated at 4000 ml by 11 h post-admission. At that time, just before the first unit of blood became available for transfusion, she experienced cardiac arrest. By then she also appeared to have a mild coagulopathy with a slightly prolonged bleeding time and platelets of 156,000. After cardiac resuscitation, she was placed in the NI-ASG and received 3 units of blood transfusion over the next 3 h. She was then taken to the OR for cesarean hysterectomy. She got a fourth unit of whole blood transfusion in the immediate post-operative period, and the hemoglobin following this was 3.7. Two more units of blood were obtained and transfused at 19 and 24 h after surgery. She remained in the NI-ASG for 57 h, but during this time she developed a clinical picture of renal failure and labile blood pressure. At the time the NI-ASG was removed, she was having seizures,

Diagnoses	Degree of shock	Est. blood loss	Hb before ASG	Transfusions	Hours in ASG	Hb after ASG
#1 Hemorrhage post C/S	drowsy 80/40 p 120	3000 hyst+1000	10.6	3 units	33	8.2
#2 Third trimester placenta previa	70/40 p=93	4000	3.4	3, (2 post-ASG)	18	6.5
#3 Incomplete TAB uterine perforations sepsis	70/40 and tachy	3000	8.5	1 unit	30	9.1
#4 Post-C/S incision uterine atony ASG applied post TAH	90/50	3000	adm=11.5	3 units	27.5	5.6-6.2 at D/C
#5 Cervical laceration PPH	80/50 tachy	2000	7	2 units	39	6.2
#6 Term IUP placenta previa	70/P	2500	12.5	3	20	9.5
#7 PPH home del 3+h before uterine atony	unconscious cold/clammy 40/P	3000	7	1 Rh neg	27	7
#8 Placenta previa C/S w ASG postop	80/40 ketamine rx	3500	5.3-3.3	2	34.5	7.8-7.0 at D/C
#9 Abruption, cardiac arrst. fetal demise, C-Hyst	post-arrest, no obtainable BP	4500	4	6 units	57	4.2
#10 Occult uterine rupture Macrosomic, fetal demise	60/40 drowsy	2000	11.6	3	32.4	8
#11 Ruptured uterus fetal demise	80/P rapid thready pulse	3000	10.1	2	24.4	9.5
#12 Incomplete AB retained POC×4 days	70/40 P 142	3000	7.4	2	30.7	3.7
#13 C/S, fetal distress, fibroids intra-operative hemorrhage	80/40 (immediately postoperative)	2000	10.1	0	12.5	6.7
#14 Late postpartum hemorrhage, d. 6	90/40 <i>p</i> =120	2000	10->6.2	2	24.5	9

 Table 1
 Case summaries of obstetrical hemorrhage managed with the anti shock garment

tachycardia, and labile blood pressure. She expired on post-operative day 19 with continued severe anemia and creatinine of 9.0. The clinical impression was that there was inability to adequately replace the blood volume in time for effective surgical intervention. There appeared to be an unwarranted delay in use of the NI-ASG in this patient and by the time the device was placed (with the dead fetus still in-utero) the patient had severe shock, was post-resuscitation from cardiac arrest, and had early evidence of DIC. There has been limited experience with the use of the NI-ASG when there is abruption with the fetus in-utero. However, in the earlier report, one such case was successfully managed by early application of the NI-ASG with stabilization of the patient for several hours while blood replacement was arranged in preparation for hysterotomy [6].

4. Discussion

Earlier reports on lower body counterpressure for management of hypovolemic shock used pneumatic devices such as the MAST, medical (or military) anti-shock trousers [7-9] that had the inherent risk of over-inflation, which may lead to tissue ischemia. An important safeguard of the NI-ASG is that it does not produce excessive pressure, when properly applied by one person. When an individual health care provider uses full strength to apply the NI-ASG, the pressure obtained is in the range of 20-40 mm Hg. This amount of pressure applied to the lower extremities and the abdominal capacitance vessels results in increased return of blood from the lower body and auto transfusion to the central circulation [10]. The restoration of perfusion to the heart, lungs and brain are essential to resuscitation and the simultaneous tamponade to the abdomen and pelvis is responsible for marked decrease in further blood loss. When the NI-ASG is properly applied, the subject should not have any discomfort or dyspnea. If there is discomfort, individual panels should be adjusted and, if dyspnea or hypoxia cannot be relieved, the NI-ASG should be removed while the underlying disorder is identified and corrected.

Pakistan ranks third highest in number of maternal deaths worldwide with about 26,000 annual deaths [11]. Worldwide observations from similar settings show that about 25-30% of maternal deaths result from obstetric hemorrhage. This was the case at the MCH during the late 1990s when the institutional data showed that there was a maternal mortality ratio of approximately 500/100,000 births and 25% to 35% were primarily due to hemorrhage.

In 2001, the NI-ASG was introduced on the obstetrics service at MCH as a simple and effective means for the initial resuscitation with hypovolemic shock and for arrest of hemorrhage in women with acute obstetric hemorrhage. During the last 3 years, the NI-ASG has been used for the management of about 150 women who experienced severe hemorrhage and shock in this hospital. The medical staff at the MCH believe that lives are saved by the use of the NI-ASG, and that there has been a trend towards reduced maternal mortality due to hemorrhage. For example, in 2003 there were 43 maternal deaths among 8399 deliveries with 7 (16%) due to hemorrhage. Although the percent of maternal deaths due to hemorrhage appears lower in 2003, this project was not focused on maternal mortality per se and, in fact, no outside funds were available to support this clinical investigation. Also, with such infrequent events, several years of data and more intentional efforts towards identifying maternal deaths and attributing these events to specific causes are needed to interpret the full impact of interventions such as the NI-ASG. Identifying maternal mortalities and the direct causes of them is a worldwide problem with underreporting ranging from 17% to 63% in routine statistical systems of several developed countries [12]. Even more so in low resource settings. In 2003 when we made increased efforts to improve ascertainment, we found that four maternal deaths which were not recorded as such and two cases of deaths related to uterine rupture were not specifically attributed to hemorrhage. Without a larger study with contemporary controls, it is impossible to judge the effect of the NI-ASG on maternal morbidity and mortality resulting from hypovolemic shock secondary to postpartum hemorrhage. Two of

study. In July, 2003, maternal health specialists from around the world gathered in Bellagio, Italy to develop a list of proven and promising technologies appropriate for reduction of maternal mortality in low resource settings [13]. Among the priority technologies identified for improving outcomes with postpartum hemorrhage was the anti-shock garment. Important features of patient management with the NI-ASG are the ease and rapidity of application and the simplicity of care and monitoring of these patients while lower body counterpressure is applied. Contraindications include presence of a viable pregnancy and women with heart failure or history of mitral stenosis, as there is predictable and abrupt increased cardiac return when the NI-ASG is applied. It is also important to have 1:1 nursing care for these patients particularly when they are not fully conscious, however, none of these women have experienced vomiting or aspiration. Urine output should be constantly monitored and maintenance fluids adjusted to maintain at least 25 ml/h urine output. Adjunctive use of low dose dopamine intravenous drip may be used to stimulate renal function if necessary. Especially

the authors (PH and SM) continue to examine the effect of the NI-ASG in a larger, multi-country

during the initial management with the NI-ASG, respiration and oxygenation should be carefully evaluated. If there is dyspnea or any evidence of hypoxia, the abdominal segment of the garment should be loosened. If not corrected, the garment should be removed until normal ventilation can be established. The capability for continuous nurse monitoring that prevailed at MCH hospital may not always prevail in other low resource settings.

5. Conclusions

Use of the NI-ASG in most cases of obstetric hemorrhage at the MCH over the last 3 years has confirmed that the device was easy to use and appeared effective in resuscitation of women with symptoms of hypovolemic shock secondary to obstetric hemorrhage. Keys to successful outcome were early diagnosis and application of the NI-ASG, intensive monitoring of vital signs, renal function and oxygenation while using the device, and accurate diagnosis and definitive treatment of the source of hemorrhage. In those facilities where the interval between diagnosis of hypovolemic shock and the acquisition of blood and definitive surgical treatment is delayed, the use of the NI-ASG facilitates resuscitation and may prolong women's lives during this critical period.

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