



www.elsevier.com/locate/ijgo

# The pilot study of the non-pneumatic anti-shock garment (NASG) in women with severe obstetric hemorrhage: Combined results from Egypt and Nigeria

Suellen Miller<sup>a,\*</sup>, Janet Molzan Turan<sup>a</sup>, Aderinola Ojengbede<sup>a</sup>, Oladosu Ojengbede<sup>b</sup>, Mohamed Fathalla<sup>c</sup>, I. Oludare Morhason-Bello<sup>b</sup>, Mohammed Mourad Youssif<sup>d</sup>, Hadiza Galandanci<sup>e</sup>, Sabry Hamza<sup>f</sup>, Mohammed Awwal<sup>g</sup>, Akinwunmi Akinwuntan<sup>b</sup>, Aminu Isyaku Mohammed<sup>g</sup>, Lyndsay McDonough<sup>a</sup>, Kim Dau<sup>a</sup>, Elizabeth Butrick<sup>a</sup>, Paul Hensleigh<sup>h</sup>

<sup>a</sup> Women's Global Health Imperative, University of California, San Francisco, CA, USA

<sup>b</sup> University College Hospital, Ibadan, Nigeria

<sup>c</sup> Assiut University Teaching Hospital, Assiut, Egypt

<sup>d</sup> El Galaa Hospital, Cairo, Egypt

<sup>e</sup> Aminu Kano Teaching Hospital, Kano, Nigeria

<sup>f</sup> Abt Associates, Amman, Jordan

<sup>g</sup> Murtala Muhammad Specialist Hospital, Kano, Nigeria

<sup>h</sup> Stanford University Medical Center, Stanford, CA, USA

#### Introduction

The non-pneumatic anti-shock garment (NASG), a compression device comprising segments of neoprene that close tightly with Velcro, may decrease maternal mortality and severe morbidity among women in low resource settings who suffer from obstetric hemorrhage and hypovolemic shock [1].

# Methods

A pre-post study of the effects of the NASG added to a standard hemorrhage and shock protocol was conducted in 4 tertiary care hospitals in Egypt between May and December 2004 and in 6 tertiary care hospitals in Nigeria between March 2004 and April 2006. A sub-analysis of 263 women with severe hemorrhage (EBL on admission  $\geq$  1000 mL, pulse > 120) was conducted, n = 104 pre-intervention and 159 NASG. Analysis included chi-square tests and calculation of relative risks (RR) with 95% confidence intervals for categorical variables, and Student's t tests and me-

<sup>\*</sup> Corresponding author. Fax: +1 415 597-9300. *E-mail*: suellenmiller@hotmail.com (S. Miller).

<sup>0020-7292/\$ –</sup> see front matter © 2006 International Federation of Gynecology and Obstetrics. Published by Elsevier Ireland Ltd. All rights reserved.

dian differences with 95% confidence intervals for continuous variables.

#### Results

As shown in Table 1, there were no differences between the pre-intervention and NASG group by country or age; the pre-intervention group had more pregnancies and deliveries. There were a variety of diagnoses, mostly evenly distributed between the two groups, although there were significantly more NASG women with genital lacerations (20.1% vs. 10.6%), and more pre-intervention women with retained placental fragments. The leading cause of hemorrhage was uterine atony, approximately 33%. The patient's condition on study entry was statistically similar in the two groups.

The difference in median blood loss in the drape after treatment was statistically significant; those in the NASG lost 64% less, 250 mL vs. 700 mL (median difference 490 mL, 95% CI: 350–600). Neither mortality alone, 7 (6.7%) for pre vs. 3 (1.9%) for the NASG nor severe morbidity 5 (5.3%) vs. 2 (1.3%) were significantly different. However, a combined severe adverse outcome variable, a combination of mor-

 Table 1
 Demographic characteristics, diagnoses, condition on entry to study, and outcomes for pre-intervention and post-intervention (NASG) groups

Demographics/Diagnosis	Pre (n = 104)	NASG $(n = 159)$	Result of statistical test
Country, <i>n</i> (%)			
Nigeria	53 (51.0%)	67 (42.1%)	ns
Egypt	51 (49.0%)	92 (57.9%)	
Demographics			
Mean age ( $\pm$ SD) ( <i>N</i> = 261)	$\textbf{29.93} \pm \textbf{6.53}$	$\textbf{29.26} \pm \textbf{5.56}$	ns
Median parity (range) (N = 253)*	3 (0-12)	2 (0-9)	Median difference = 2, 95% CI: 1-2
Median gravidity (range) (N = 227)*	4 (1-13)	3 (1-12)	Median difference = 1, 95% CI: 1-2
Diagnosis, n (%) <sup>1</sup>			
Complications of abortion	11 (10.6%)	22 (13.8%)	ns
nverted Uterus	0	1 (0.6%)	ns
Retained placental fragments *	18 (17.3%)	11 (6.9%)	<i>p</i> = 0.014
Aolar pregnancy	1 (1.0%)	3 (1.9%)	ns
Placenta praevia	8 (7.7%)	8 (5.0%)	ns
Ectopic pregnancy	11 (10.6)	18 (11.3%)	ns
Abruption of the placenta	13 (12.5%)	15 (9.4%)	ns
Ruptured uterus	11 (10.6%)	7 (4.4%)	ns
Jterine atony	33 (31.7%)	55 (34.6%)	ns
Genital lacerations or trauma*	11 (10.6%)	32 (20.1%)	<i>p</i> = 0.042
Condition on study entry			
Median estimated blood loss (mL, range) (N = 253)	1500 (200-3000)	1500 (650-3000)	ns
Nean pulse (bpm $\pm$ SD) (N = 217) <sup>2</sup>	$123.01 \pm 12.27$	$\textbf{122.98} \pm \textbf{12.37}$	ns
Vomen with non palpable pulses, $n$ (%) *	10 (9.6%)	35 (22.2%)	<i>p</i> = 0.011
Nean systolic blood pressure (mmHg $\pm$ SD) (N = 230) <sup>3</sup>	$\textbf{85.91} \pm \textbf{21.33}$	$\textbf{81.26} \pm \textbf{17.63}$	ns
Nean diastolic blood pressure (mmHg $\pm$ SD) (N = 207) $^4$	$\textbf{52.80} \pm \textbf{16.16}$	$\textbf{52.67} \pm \textbf{12.33}$	ns
Dutcomes			
Median blood loss as measured in the drape (mL, range) (N = 231)*	700 (0-3500)	250 (0-880)	Median difference = 490 m CI: 350-600
Nortality, n (%) (N = 263)	7 (6.7%)	3 (1.9%)	RR = 0.28, 95% CI: 0.07-1.
Severe morbidity among survivors, $n$ (%) ( $N = 244$ ) <sup>5</sup>	5 (5.3%)	2 (1.3%)	RR = 0.26, 95% CI: 0.05-1.
Severe morbidity or mortality, $n$ (%) ( $N = 254$ )*	12 (11.8%)	5 (3.3%)	RR = 0.28, 95% CI: 0.10-0.

\* p < 0.05; \*\* p < 0.01.

<sup>1</sup> Woman could have multiple diagnoses, percentages add to more than 100%.

<sup>2</sup> Means for pulse are presented for women with palpable pulses, 10 women in the pre-intervention group and 35 women in the NASG group had non-palpable pulses at study admission.

<sup>3</sup> Means for systolic blood pressure are presented for women with palpable systolic BPs, 5 women in the pre-intervention group and 36 women in the NASG group had non-palpable systolic BPs at study admission.

<sup>4</sup> Means for diastolic blood pressure are presented for women with palpable diastolic BPs, 13 women in the pre-intervention group and 41 women in the NASG group had non-palpable systolic BPs at study admission.

<sup>5</sup> Among the women who survived, N = 253, minus 9 women with missing data on morbidity, resulting in N = 244.

tality or severe morbidity (renal failure, CNS damage, cardiac failure, or Adult Respiratory Distress Syndrome), was 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.

# Conclusions

The study examined not only PPH, but also all other forms of obstetrical hemorrhage. This combined analysis of data on the most severe cases from two very different settings continues to support the previously published findings that the NASG significantly decreases blood loss and may decrease morbidity and mortality for women experiencing severe obstetrical hemorrhage. Further rigorous research with a randomized design and a larger sample size will be necessary to demonstrate statistical reductions in mortality.

### Acknowledgments

We are grateful to the MacArthur Foundation and to USAID/Egypt for funding this project. We thank the staff at all facilities in Nigeria and Egypt and to JSI, Egypt's Healthy Mother/Healthy Child Program, particularly Reginald Gibson, Amr Fathy, and Khaled Nada.

## References

[1] Miller, S, Hamza S, Bray EH, Lester F, Nada K, Gibson R, et al. First Aid for obstetric haemorrhage: the pilot study of the non-pneumatic anti-shock garment in Egypt. Bjog 113(4):424–9.