The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: 1476-7058 (Print) 1476-4954 (Online) Journal homepage: http://www.tandfonline.com/loi/ijmf20

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To cite this article: Maria Escobar, Paula Fernández, Javier Carvajal, Juan Burgos, Adriana Messa, Maria Echavarria, Albaro Nieto, Daniela Montes, Suellen Miller & David Hurtado (2019): Impact of nonpneumatic antishock garment in the management of patients with hypoperfusion due to massive postpartum hemorrhage, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2019.1568982

To link to this article: https://doi.org/10.1080/14767058.2019.1568982

Accepted author version posted online: 11 Jan 2019.

Impact of non-pneumatic anti-shock garment in the management of patients with hypoperfusion due to massive postpartum hemorrhage

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Short title: Impact of NASG in postpartum hemorrhage

Key words: Postpartum hemorrhage; High risk pregnancy; Shock; Uterine atony; Hysterectomy

WORD COUNT:2980

ABSTRACT

Objective: The objective of this article was to compare hemodynamic and perfusion parameters as well as the clinical outcomes in critically ill patients with postpartum hemorrhage (PPH) who received treatment with a non-pneumatic anti-shock garment (NASG) as part of an intervention package, with a group of patients in similar conditions who did not receive a NASG.

Methods: This observational study analyzed a historic cohort of 154 patients with PPH, secondary hypovolemic shock and signs of hypoperfusion who were admitted in this institution from 2012 to 2015. Group 1 (n=77) was managed with NASG and Group 2 (n=77) received interventions other than NASG. Hypoperfusion markers and maternal outcomes were compared in both groups.

Results: Of 154 patients included in the analysis, 36.4% required total abdominal hysterectomy (TAH) to achieve hemorrhage control, 98.2% of whom belonged to Group 2 and 1.8% to Group 1 (p=0.001). The use of blood products was more common in Group 2 ($p<0.001$), as was the administration of vasoactive agents. The mean number of days of hospitalization at the Obstetric High Dependency Unit (OHDU) was significantly lower in Group 1 and reached a statistically significant p value. Only two cases of maternal death occurred in Group 2.

Discussion: The use of NASG in the management of PPH is a cost-effective strategy for patients with severe shock and signs of hypoperfusion and is optimal in a limited-resource scenario. In this study, the use of NASG was related to better outcomes in a statistically significant manner with better results regarding maternal outcomes such as uterine preservation and decreased transfusion requirements and hospital days.

Conclusion: NASG, associated with the use of uterotonic agents and other strategies for PPH control, is a safe tool that helps reduce morbimortality in critically ill patients with PPH.

Funding details: There were not funding sources.

Disclosure statement: The authors report no conflicts of interest

Main text

INTRODUCTION:

Every day, approximately 830 women worldwide die as a result of complications related to pregnancy, delivery and postpartum (1). The World Health Organization has shown that 73% of maternal deaths are secondary to direct obstetric causes including postpartum hemorrhage (PPH) in the first place (27.1% of total deaths) (2). This mortality is associated with a significant burden of maternal morbidity, need of transfusions, surgical interventions and health system costs (3).

The non-pneumatic anti-shock garment (NASG) is a first-line device for managing and stabilizing women with postpartum hemorrhage in hypovolemic shock by increasing venous return and cardiac output and mechanically controlling the bleeding (4-6). Several studies have shown its usefulness for transportation and initial management of patients with PPH in association with a 48% decrease in the mortality due to PPH, especially in low-income countries with limited management strategies (7). Currently, the Safe Motherhood and Newborn Health Committee of the International Federation of Gynecology and Obstetrics recommends the NASG for the initial management of PPH (8-11).

The High Obstetric Complexity Unit (HOCU) of Fundación Valle del Lili (FVL) in Cali, Colombia, is an obstetric critical care unit that has been established in our country as a referral center for patients with extreme maternal morbidity (EMM) (12). Since 2014, the standard use of NASG has been implemented for the management of PPH, even in severely ill patients, and the results of this process have shown NASG as an effective strategy for controlling hypovolemic shock with confirmed hypoperfusion (13).

The objective of this study is to provide better levels of evidence regarding the use and application of NASG in the management of PPH in critical conditions.

MATERIALS AND METHODS

This report corresponds to a quasi-experimental (before-and-after) study of a group of patients with hypovolemic shock secondary to PPH who received non-NASG management from December 2011 to December 2013, the results of which were compared with a group of patients receiving NASG for the same indication (hypovolemic shock due to PPH) from December 2014 to December 2015. Since the protocol for the management of NASG in PPH was adapted and implemented between January and November 2014, patients assisted during that period were not included in the analysis.

The criteria for inclusion were defined as follows: patients of any gestational age who had completed their pregnancy at the FVL in Cali, Colombia, and who developed PPH (blood loss of 500 or 1000 milliliters following vaginal delivery or cesarean section, respectively) with hemodynamic instability (hypovolemic shock) and clinical and biochemical hypoperfusion markers.

Hemodynamic instability was determined according to the results of the shock index (relation between heart rate/systolic blood pressure) upon diagnosis and 24 hours later. Values above 0.9 were considered abnormal. This index is directly related to the need of massive blood products transfusion and the development of coagulopathy in massive PPH (12, 13).

The degree of hypoperfusion was determined by lactic acid levels >2 mMol/L and base deficits <-5 mMol/L at the time of diagnosis of PPH and 24 hours later. The APACHE II (Acute Physiology and Chronic Health Evaluation II) score was used for assessing the critical status of patients within the first 24 hours after hemorrhage.

The criteria for exclusion included those patients who were admitted to the OHDU using a NASG from other institutions, with hemodynamic changes of a different origin, antepartum hemorrhage of obstetric etiology or with a previously documented coagulation disorder.

Regardless of the use of NASG, all patients received standard medical care. In this protocol, oxytocin was the first-choice medication at dosages of 80 up to 160 milliunits (μU). As a second-choice medication, methylergometrine was used at an initial dose of

0.2 milligrams (mg) given intramuscularly at the beginning, repeated 20 minutes after the first dose and every 4 hours up to a total of 5 doses, provided hypertension does not occur. The third choice, misoprostol 800 micrograms, is given sublingually or intrarectally if the sublingual route is contraindicated. In addition, since 2014, patients not responding to medical management underwent conservative management with hydrostatic balloons and/or hemostatic sutures if indicated.

The primary source for data search was the institutional OHDU registry as per the standards of the FVL Clinical Research Institute. The information was retrospectively collected and entered into an electronic database designed for that purpose.

For the analysis of the data, demographic variables and those related to the etiology, management and clinical outcomes were collected. The analysis of quantitative variables was performed using the Student's T-test or the Mann-Whitney U-test statistics depending on the distribution, and whether the data was presented as mean and median with standard deviation and interquartile range, respectively. The categorical variables were analyzed using the Chi-square statistic or Fisher's exact test statistic, and the data were presented as distributions of both absolute and relative frequencies.

The statistical analysis was performed using Stata® (Stata Corp, 2011, Stata 12 Base Reference Manual, College Station, TX, USA). The study was approved by the Fundación Valle del Lili Institutional Ethics Committee. All women and their family members were informed about the need for using the NASG technique, the benefits obtained and the safety of the device.

RESULTS

Between December 2011 and December 2013, a total of 77 patients with PPH, hypovolemic shock and hypoperfusion were identified and who received standard care not including the NASG; these corresponded to 2.8% of all women with PPH assisted at the OHDU during the same study period. Between December 2014 and December 2015,

a total of 77 patients with PPH, hypovolemic shock and hypoperfusion were identified and received the NASG as part of medical care; these corresponded to 6.6% of the total of patients with PPH assisted at this institution during the same study period.

The main characteristics of the patients are shown in **Table 1.**

The main causes of PPH identified in all 154 patients included: uterine atony (96.1%), retained placenta (9.7%), placental abruption (6.5%) and placenta previa (4.5%) and showed no statistically significant differences between groups. Similarly, no differences regarding the presentation of associated conditions were found in either group and there was a high incidence of pregnancy-related hypertensive disorders (35% of the total cases).

The management strategies for both groups are summarized in **Table 2.**

At the time of diagnosis of PPH, the shock index was greater than, or equal to, 1 in 100% of patients in both groups, with a median of 1.05 (0.94-1.24) for the non-NASG group and 1.2 (1.1-1.4) for the NASG group, with no significant differences (11.7% vs. 6.5%; p=0.4). As for the perfusion parameters evaluated, no significant differences were found between the non-NASG group and the NASG group for lactic acid levels upon diagnosis of PPH (median of 2.3 and 2.6, respectively; p=0.5); for lactic acid levels 24 hours after PPH (median of 1.36 and 1.28, respectively; p=0.55); for base excess values upon diagnosis (median of -7.3 and -7, respectively; p=0.914); and 24 hours after management (median of -4.3 and -4.6, respectively; p=0.296).

With regard to fibrinogen values, a statistically significant difference was observed between the non-NASG group and the NASG group, with a median of 254 and 418, respectively; p=0.001.

There were two cases of maternal mortality in the non-NASG group (2; 2.59%), which corresponded to deaths due to consumption coagulopathy resulting in multiple organ failure.

DISCUSSION

A number of observational studies of major impact worldwide have shown that the NASG is a useful tool for transportation, stabilization and reduction in PPH-related morbidity (8-11). These results have allowed the adoption of NASG as a first-line management strategy to be used at OHDUs from 2014 onwards. The results of its implementation for the management of critically ill patients confirmed by hypoperfusion markers have previously been reported. These findings resulted in the need to compare the results with a group of patients with similar characteristics of PPH, hypoperfusion and shock who were not applied the NASG due to unavailability of the device in Colombia at that time. All patients received the same medical care scheme as described in the institutional protocol.

All patients included in the analysis showed shock index scores greater than 1 upon the identification of PPH; this parameter has shown direct relationship with hemodynamic instability secondary to hypovolemia and, with values above 1.1, up to 89% of the cases are associated with protocol requirements of massive transfusion (14-16). In our series, the results evidenced that the need of blood products was (statistically significantly) higher for the non-NASG group (85.7%), while only 39% of patients in the NASG group required some type of transfusion. In middle- or low-income countries where the mortality rate due to PPH is directly related to the availability of blood products, this finding may support the need to include the NASG in the PPH management kit at each medical care level.

Likewise, abdominal hysterectomy as a management strategy was more common in the standard care (non-NASG) cohort compared to the NASG group (98.2% vs. 1.8%). Systematic reviews and meta-analyses of the outcomes of peripartum hysterectomy for PPH worldwide, with 128 studies and 7858 patients, have shown that performing this procedure is associated with delayed management and high morbidity and mortality. In these reports, only 27% of the patients received some type of treatment prior to total abdominal hysterectomy, 47% required second surgery or reoperation, 72% developed

complications, 45% were admitted to the intensive care unit (ICU), the average bleeding was 3.7 liters and the reported mortality ranged from 5% to 59%. In this context, and being aware of the limitations regarding human resources, locations and economy in the countries of our region, timely and prompt management using NASG might be associated with decreased disease burden and, probably, better cost-effectiveness of PPH management (17).

In the group comparison, use of damage control surgery, use of vasoactive agents and hospital days were statistically significantly higher in the historical non-NASG cohort. The opportunity of access to highly complex management at obstetric intensive care units or hospitals with the necessary management resources is below the expected standards in low- and middle-income countries. Although reliable statistics regarding availability are not available, it can be indirectly assumed that only one third of cases of extreme maternal morbidity are admitted to these types of units in our country (18).

In the same way as the approaches above and considering the human and political development in developing countries to reach the standards of countries with universal access to beds at ICUs, implementing effective strategies such as the formalization and inclusion of NASG within an intervention package for PPH management may have enormous impact, even in critically ill patients such as those described in this series.

In the group of patients receiving NASG management, no NASG-related adverse events or maternal deaths occurred versus two patients who died due to coagulopathy in the non-NASG group of patients. Establishing a direct correlation of a single management strategy in the reduction of deaths due to PPH is very difficult, and its inclusion in a planned intervention package process along with the prompt application of NASG (20 minutes in average) is likely to be responsible for these findings (13). This study does not allow to establish such causality.

Concomitant use of the Bakri balloon and the NASG as first-line management of these patients was successful in 70% of cases. This finding has been described and confirmed by the literature in a previous report with a total of 54 cases (called “uterine sandwich”)

regarding PPH management (14). This routine implementation may provide the previously mentioned benefits of NASG in association with the internal compression and ability to objectively monitor bleeding provided by the Bakri balloon, which should be evaluated in studies designed for that purpose.

The perfusion parameters that were assessed reported similar hemodynamic compromise as reflected by hyperlactacidemia and base deficit at the moment of PPH diagnosis in both compared cohorts. The goals of hypovolemic shock reanimation could be reached in both groups, as assessed by the objective measurement of these perfusion parameters 24 hours after starting management; however, the group receiving standard care required the aforementioned increased number of invasive interventions as compared to the hemodynamic stabilization in the NASG group. This consideration should also be taken into account due to the direct impact of medical care costs on the health systems of patients with PPH.

This series is similar to others that have been reported regarding the effectiveness of NASG; however, this is the first time that results from the comparison of this strategy, as part of the reanimation processes in patients with PPH, hypovolemic shock and hypoperfusion, are obtained.

CONCLUSION

The use of NASG in critically ill patients within an intervention protocol for the management of PPH that was implemented at the FVL OHDU showed prompt recovery from hypoperfusion, thus preventing the use of invasive procedures that involve increased maternal morbidity and higher costs. This was evidenced when comparing the results with equally critically ill patients who were not given the chance to receive NASG management and achieve the same clinical objectives. Its implementation in management protocols at all healthcare levels, regardless of the degree of clinical compromise, should take part in processes for improving the obstetric services in middle- and low-income countries.

Conflicts of interest

All authors included in this article have no conflicts of interest

REFERENCES

1. Alkema L, Chou D, Hogan D, Zhang S, Moller AB, Gemmill A, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. Lancet. 2016; 387:462-474.

2. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller A-B, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014: 2:323–333.

3. Kerr R, Weeks A. Postpartum haemorrhage: a single definition is no longer enough. BJOG Int J Obstet Gynaecol. 2016:124; 723-726

4. Pierre M, Benhamou D. Management of postpartum haemorrhage WHO. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva Switzerland: World Health Organization Library; 2012: 48.

5. Abdul-Kadir R, McLintock C, Ducloy AS, El-Refaey H, England A, Federici AB, et al. Evaluation and management of postpartum hemorrhage: consensus from an international expert panel. Transfusion. 2014; 54:1756–1768.

6. Stenson AL, Miller S, Lester F. The mechanisms of action of the nonpneumatic anti-shock garment. Arulkumaran SS Karoshi M Keith LG Lalonde AB B-Lynch C Ed Compr Textb Postpartum Hemorrhage 2nd Ed USA Sapiens Publ. 2012; 331–340

7. Miller S[1], Bergel EF, El Ayadi AM, Gibbons L, Butrick EA, Magwali T, et al. Non-Pneumatic Anti-Shock Garment (NASG), a First-Aid Device to Decrease Maternal Mortality from Obstetric Hemorrhage: A Cluster Randomized Trial. PLOS ONE 2013;08:e76477

8. Pileggi-Castro C, Nogueira-Pileggi V, Tunçalp Ö, Oladapo OT, Vogel JP, Souza JP. Non-pneumatic anti-shock garment for improving maternal survival following severe postpartum haemorrhage: A systematic review. Reprod Health 2015; 12:28.

9. 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 2006; 113:424-429.

10. Miller S, Fathalla MM, Youssif MM, Turan J, Camlin C, Al-Hussaini TK, *et al.* A comparative study of the non-pneumatic anti-shock garment for the treatment of obstetric hemorrhage in Egypt. Int J Gynaecol Obstet 2010; 109:20-24.

11. Miller S, Ojengbede O, Turan JM, Morhason-Bello IO, Martin HB, Nsima D. A comparative study of the non-pneumatic anti-shock garment for the treatment of obstetric hemorrhage in Nigeria. Int J Gynaecol Obstet 2009; 107:121-125.

12. Escobar MF, Carvajal JA, Nieto AJ, Messa A, Burgos JM, Echavarría MP, Granados M. Model of obstetric attention based on critical care in Latin America. J Matern Fetal Neonatal Med. 2017; 17:1-8

13. Escobar MF, Füchtner CE, Carvajal JA, Nieto AJ, Messa A, Escobar SS, Monroy AM, Forero AM, Casallas JD, Granados M, Miller S. Experience in the use of non-pneumatic anti-shock garment (NASG) in the management of postpartum haemorrhage with hypovolemic shock in the Fundación Valle Del Lili, Cali, Colombia. Reprod Health. 2017; 12:14:58

14. Sohn CH, Kim WY, Kim SR, Seo DW, Ryoo SM, Lee YS, Lee JH, Oh BJ, Won HS, Shim JY, Lim KS. An increase in initial shock index is associated with the requirement for massive transfusion in emergency department patients with primary postpartum hemorrhage. Shock. 2013; 40(2):101–105.

15. Pacagnella RC, Souza JP, Durocher J, Perel P, Blum J, et al. A systematic review of the relationship between blood loss and clinical signs. PLOS ONE.

2013; 8(3), e57594.

16. Baskett PJ. ABC of major trauma. Management of hypovolemic shock. BMJ. 1990; 300(6737):1453–1457.

17. Van den Akker T, Brobbel C, Dekkers OM, Bloemenkamp KW. Prevalence, Indications, Risk Indicators, and Outcomes of Emergency Peripartum Hysterectomy Worldwide: A Systematic Review and Meta-analysis. Obstet Gynecol. 2016 Dec; 128(6):1281-1294

18. Senanayake H, Dias T, Jayawardena A. Maternal mortality and morbidity: epidemiology of intensive care admissions in pregnancy. Best Pract Res Clin Obstet Gynaecol. 2013 Dec; 27(6):811-820

Table 1.

Characteristics	**Non-NASG patients** **N: 77**	**NASG patients** **N: 77**	**p**
Age (Mean ± Standard Deviation)	28.2 ± 4	25.3 ± 7	**0.009**
Gestational age at admission (weeks) Median (Interquartile Range)	36 (32.6-38)	38 (34.5-39.6)	**0.003**
Parity at admission •Primigravida •Gravida 2 •Gravida 3 •More than Gravida 3	28 (36.36%) 26 (33.77%) 9 (11.69%) 13 (16.88%)	40 (51,95%) 27 (35,06%) 6 (7,79%) 4 (5,19%)	0.089
Vaginal delivery	20 (26%)	53 (68,8%)	**0.005**
Visual estimation of blood loss •<1000 •1000-1500	13 (16.9 %) 5 (6.5 %) 7 (9.1 %)	17 (22.1%) 22 (28.6%) 20 (26%)	**0.001**

•1501-2000 •>2000 •No data	18 (23.4%) 34 (44.2%)	8 (10.4%) 10 (13%)	
Hospital days (median)	10 (6-15)	4(3-7)	**0.001**
Hospital days at the Intensive Care Unit (ICU) (median)	4 (2-7)	3(2-3)	0.159
APACHE II score	11 (6-14)	8 (6-11)	**0.040**

Table 1. Clinical and demographic characteristics of NASG and non-NASG patients with PPH at the FVL, 2011 – 2016.

Table2.

Management strategy	**Non-NASG patients** **N: 77**	**NASG patients** **N: 77**	**P**
Use of blood products	66 (85.7)	30 (39)	**0.001**
Use of tranexamic acid	22 (28.6)	27 (35.1)	0.378
Use of vasoactive agents	9 (11.7)	5 (6.5)	0.401
Use of Bakri balloon	0 (0)	54 (70.1)	**<0,001**
Use of B-Lynch suture	6 (7.8)	8 (10.4)	0.575
Performance of total abdominal hysterectomy	55 (71.4)	1 (1.3)	**<0.001**
Performance of pelvic embolization	14 (18.2)	0 (0)	**<0.001**
Performance of vascular ligation	4 (5.2)	0 (0)	**<0.001**
Performance of damage control surgery	48 (62.3)	1 (1.3)	<0.001

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