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Original Research Article

Non-pneumatic anti-shock garment (NASG) and balloon tamponade decrease maternal mortality and morbidity from Obstetrics Haemorrhage: A prospective observational study

Ashish Zarariya[1]*, Arya Chaubey[1], Disha Rama Harikanth[1]

[1]*Dept. of Obstetrics and Gynaecology, Government Medical College, Nagpur, Maharashtra, India*

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ABSTRACT

Background: Obstetric haemorrhage is the leading cause of maternal mortality and morbidity worldwide.
Materials and Methods: A prospective observational study was conducted among 132 women admitted, booked/referred, at tertiary care centre with Obstetric Haemorrhage for 2 years period. Of these 71 patients had received Non-pneumatic antishock garment and / or Uterine Balloon Tamponade (Group 1) and 61 didn't receive any (Group 2). Both groups were observed for its outcome.
Results: The socio-demographic parameters and obstetric characteristics among both groups were comparable. However, there were differences in their outcomes and complications. Surgical interventions were more among group 2 as compared to group 1, B-lynch/Modified B-lynch (8.4% vs. 1.6%), Stepwise devascularisation (2.8% vs. 1.6%) and Obstetric hysterectomy (7.0% vs. 3.2%). There was significantly more blood loss in Group 2 than group 1. Duration of hospital stay was significantly shorter (9.8±2.7 days) in Group 1 as compared to Group 2 (12.7±3.6). The shock index after intervention was significantly smaller (0.7±0.1) in Group 1 in comparison to Group 2 (0.8±0.1) and Group 1 required significantly less number of blood and blood products as compared to group 2. 19.7% required ICU admission in group 1 and 24.6% in Group 2. There was no mortality in group 1 and 3 patients died in group 2.
Conclusion: NASG and UBT is both life-saving and cost effective and can become the first defence against Obstetric Haemorrhage.

1. Introduction

Obstetric haemorrhage is the leading cause of maternal mortality and morbidity worldwide and is responsible for nearly one–quarter of all maternal deaths. It can occur in form of antepartum bleeding (placenta previa or placental abruption), intrapartum bleeding (rupture of uterus) or postpartum haemorrhage (because of atony of uterus, trauma to genital tract, associated with disseminated intravascular coagulation).

Uncontrolled haemorrhage can lead to irreversible hypovolemic shock, dilutional coagulopathy, multiple organ dysfunction syndrome, and mortality. However, even under randomized trial conditions, uterotonics can only reduce PPH by 24% to 60%.[1,2]

1.1. The need of NASG and Uterine balloon tamponade

Blood transfusions and surgery are sometimes the only definitive treatment for severe PPH and hypovolemic shock. 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 reduce adverse

* *Corresponding author*.
E-mail address: arya19960919@gmail.com (A. Zarariya).

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outcomes by helping women survive delays in receiving adequate emergency obstetric care.

Uterine balloon tamponade (UBT) is an approach recommended by the WHO and the International Federation of Gynaecologists and Obstetricians (FIGO) for the management of refractory PPH.[3,4]

After exclusion of a genital tract laceration, these procedures can be considered for control of obstetric haemorrhage secondary to uterine atony, placenta accreta and placenta previa.

This study was conducted to evaluate whether NASG application and uterine balloon tamponade insertion would result in reduced maternal morbidity and mortality for women with hypovolemic shock secondary to Obstetric haemorrhage, reduced time to shock recovery and the cost effectiveness of uterine balloon tamponade and NASG in terms of blood and blood products transfused for being used in low resource settings.

2. Aims and Objective

1. To compare the outcome in patients with postpartum haemorrhage with and without use of non-pneumatic antishock garment and balloon tamponade
2. To study the cost-effectiveness of non-pneumatic anti shock garment and balloon tamponade.

3. Materials and Methods

This was a prospective observational study conducted among the women admitted at the hospital with obstetric haemorrhage, antenatal as well as postnatal, booked as well as referred cases, managed with or without NASG & balloon tamponade as per standard management protocols for a period of 2 years from 2020-2022. Both arms were studied with respect to sociodemographic variables, obstetric characteristics & outcomes among 132 women which was calculated considering the Incidence of obstetric haemorrhage as 4%, absolute precision as 4%, Desired confidence level (1-a) as 95 and required sample size of 120. However, the final sample size was estimated as 132 (120+10) considering 10% dropout / non reference.

3.1. Inclusion criteria

Those diagnosed of obstetric haemorrhage

1. Antepartum haemorrhage.
2. Postpartum haemorrhage including secondary haemorrhage.

3.2. Exclusion criteria

1. Patients referred with irreversible shock/sepsis/multiorgan dysfunction syndrome
2. Patients requiring ventilatory support
3. Gynecological bleeding
4. Ectopic pregnancy, post abortal and molar pregnancy bleeding

Sociodemographic data of each patient were collected and outcome was measured. The data was analysed using Independent t test and Chi square test among 2 groups. The patients in whom NASG and/or UBT was used were considered in group 1 and the remaining patients in whom NASG and/or UBT was not used were considered in Group 2. The p value$\leq$0.05 was considered as statistically significant.

Uterine balloon tamponade involves inserting a sterile balloon into the uterine cavity, then fill the balloon with warm water/ normal saline to make the additional pressure control the patient's haemorrhage. The Sengstaken-Blakemore tube, Foley catheter and Bakri balloon have the advantage of providing an outflow tract for the continuous bleeding. The non-pneumatic anti-shock garment (NASG), is a first-aid compression garment device made of neoprene and a hook-and-loop fastener comprising lower-extremity segments, a pelvic segment, and an abdominal segment, which includes a foam compression ball that goes over the uterus. The NASG reverses shock by compressing the lower-body vessels and, decreasing the container size of the body, so circulating blood is directed mainly to the core organs: the heart, lungs, and brain. It also compresses the diameter of pelvic blood vessels, thus decreasing blood flow.

4. Results and Observations

We found total 132 patients of Obstetric haemorrhage. Out of these 71 patients received Non-pneumatic antishock garment and or uterine balloon tamponade and 61 didn't receive Non-pneumatic antishock garment and or balloon tamponade. Both groups observed for its outcome. Of the 132 cases studies we found that the socio-demographic parameters and obstetric characteristics among both groups were comparable. (Tables 1, 2 and 3) However there were differences in their outcomes and complications. (Table 4) This study showed the following results.

There was significantly more blood loss in group 2 as compared to group 1. The blood loss was assessed by weighing the used mops & gauze pieces in dry and soaked state with a high accuracy digital weighing machine and also by measuring the amount of blood and clots in suction machine, kidney tray and Brasss V drape. The comparison of the post-delivery shock index (heart rate divided by systolic blood pressure) and the shock index after intervention between the groups showed that it was significantly lesser in Group 1 (1.5±0.1) and (0.7±0.1) in comparison to Group 2 (1.7±0.7) and (0.8±0.1) respectively. This study noted that Group 2 received more number of blood and blood products and also showed more complications as compared to group 1 and this difference was statistically significant. The mean hospital stay was

Table 1: Distribution of patients according to sociodemographic variables

Socio-demographic variables		Group 1 N (%)	Group 2 N (%)	P value
Mean age (years)		27.2 ± 1.6	24.6 ± 1.4	0.52
Education	Illiterate	14 (19.7)	18 (29.5)	0.345
	Primary	46 (64.8)	35 (57.4)	
	Secondary	9 (12.7)	8 (13.1)	
	Higher secondary	2 (2.8)	0 (0.0)	
Residence	Rural	48 (67.6)	43 (70.5)	0.720
	Urban	23 (32.4)	18 (29.5)	
Socioeconomic status	Upper middle	6 (8.5)	2 (3.3)	0.005*
	Lower middle	24 (33.8)	12 (19.7)	
	Upper lower	28 (39.4)	19 (31.1)	
	Lower	13 (18.3)	28 (45.9)	
Booking status	Booked	8 (11.3)	6 (9.8)	0.790
	Referred	63 (88.7)	55(90.2)	

Table 2: Distribution of patients according to obstetric characteristics

Obstetric characteristics		Group 1 N (%)	Group 2 N (%)	P value
Parity	Primi	28 (39.4)	22 (36.1)	0.079
	Para 1	29 (40.9)	27 (44.3)	
	Para 2	13 (18.3)	12 (19.6)	
	Para 3	1 (1.4)	0 (0.0)	
Gestational age	<28 weeks	5 (7.1)	3 (4.9)	0.493
	28-36 weeks	46 (64.8)	39 (63.9)	
	37-40 weeks	18 (25.3)	19 (31.2)	
	>40 weeks	2 (2.8)	0 (0.0)	
Past medical history	Anaemia	23 (32.3)	10 (16.4)	0.050*
	Essential hypertension	1 (1.4)	1 (1.6)	
	Diabetes	0 (0.0)	4 (6.5)	
	Splenomegaly	1 (1.4)	0 (0.0)	
	Platelet disorder	2 (2.8)	0 (0.0)	
Obstetric complications	APH	27 (38.0)	23 (37.7)	0.358
	Hypertensive disorders of pregnancy	13 (18.3)	9 (14.7)	
	Multiple pregnancy	4 (5.6)	7 (11.4)	
	Polyhydramnios	1 (1.4)	3 (4.9)	
	Previous LSCS	1 (1.4)	0 (0.0)	
	Rupture uterus	2 (2.8)	0 (0.0)	
	PROM	0 (0.0)	1 (1.6)	

significantly smaller (9.8±2.7) in Group 1 in comparison to Group 2 (12.7±3.6). (Table 4)

The comparison of ICU admission of the patients between the groups showed that, in the Group 1, 14(19.7%) required ICU admission and in the Group 2, 15 (24.6%) required ICU admission The comparison of maternal mortality of the patients between the groups showed that, in the Group 1 there was no mortality (0.0%) and in the Group 2, three patients (4.91%) died.

The comparison of surgical procedures between the groups showed that, in the Group 1, 1(1.6%) patient required Blynch/ Modified Blynch, 1(1.6%) patient required Stepwise devascularisation and 2 (3.2%) patients required Obstetric hysterectomy and in the Group 2, 6(8.4%) required Blynch/Modified Blynch, 2(2.8%) required Stepwise devascularisation and 5(7.0%) patients required Obstetric hysterectomy. The comparison of additional procedures between the groups showed that, in the Group 1, 9(12.6%) required massive obstetric transfusion, 4(5.2%) required intubation and 3(4.6%) required haemodialysis and in the Group 2, 7(11.4%) required massive obstetric transfusion, 2(3.3%) required intubation and 5(8.2%) required haemodialysis. However, the difference between the groups were not statistically significant (p>0.05).

5. Discussion

In India, Obstetric haemorrhage is the leading cause of maternal deaths (29.6%) with atonic PPH being the

Table 3: Distribution of patients according to types of delivery and PPH

Characteristics		Group 1 N (%)	Group 2 N (%)	P value
Mode of delivery	Vaginal	23 (32.4)	16 (26.2)	0.438
	LSCS	48 (67.6)	45 (73.8)	
Vaginal delivery	Spontaneous	17 (73.9)	11 (68.7)	0.449
	Induced	6 (26.1)	4 (25.0)	
	Instrumental	0 (0.0)	1 (6.3)	
AMTSL done	Yes	20 (86.9)	16 (100.0)	0.132
	No	3 (13.1)	0 (0.0)	
Birth weight	<2500 g	45 (63.4)	0.141 (49.2)	0.141
	2500-3500 g	25 (35.2)	31 (50.8)	
	>3500 g	1 (1.4)	0 (0.0)	
Place of delivery	Home	1 (1.4)	0 (0.0)	0.634
	Peripheral Centre	15 (21.1)	14 (22.9)	
	Tertiary care Centre	55 (77.5)	47 (77.1)	
Type of PPH	Atonic	47 (66.2)	38 (62.3)	0.230
	Traumatic	13 (18.3)	7 (11.5)	
	Mixed	11 (15.5)	16 (26.2)	

Table 4: Distribution of patients according to blood loss, outcome measures & complications

Complications		Group 1 N (%)	Group 2 N (%)	P value
Blood loss	<500 ml	1 (1.4)	0 (0.0)	<0.001*
	500-1000 ml	8 (11.3)	0 (0.0)	
	1000-2000 ml	53 (74.6)	16 (26.2)	
	>2000 ml	9 (12.7)	45 (73.8)	
Complications	AKI	9 (12.6)	14 (22.9)	0.997
	DIC	3 (4.2)	5 (8.2)	
	Pulmonary edema (PE)	2 (2.8)	3 (4.9)	
	AKI, DIC & P.edema	1 (1.4)	2 (3.3)	
Mean Hospital stay (days)		9.8±2.7	12..7±3.6	<0.001*
Mean Shock index	Post-delivery	1.5±0.1	1.7±0.7	0.368
	After intervention	0.7±0.1	0.8±0.1	0.002*
Mean Haemoglobin	Pre delivery	8.4±2.0	9.9±2.3	<0.001*
	Post delivery	6.9±1.6	6.6±1.2	0.172
Number of Blood and blood product transfusion				
Whole blood/PRC	1	3 (4.2)	0 (0)	<0.001*
	2	47 (66.2)	1 (1.6)	
	3 or more	21 (29.6)	60 (98.4)	
FFP	1	1 (1.4)	0 (0)	<0.001*
	2	42 (59.1)	18 (29.5)	
	3 or more	14 (19.7)	38 (62.3)	
Platelets	1	1 (1.4)	0 (0)	<0.001*
	2	22 (30.9)	10 (16.4)	
	3 or more	13 (18.3)	34 (55.7)	

major cause. PPH Bundle, AMTSL, uterine massage, IV fluids, tranexamic acid, uterotonics drugs are very much in use though still not practised as strict protocol basis at many centres. Management of PPH has undergone positive changes by using the bundle approach. Though 1^{st} bundle is used completely, use of 2^{nd} bundle for refractory PPH specially NASG and UBT is not always done because of individual choice of obstetrician, availability and clinical situation (like in caesarean-surgical options preferred). Women can succumb to death just within 1-2 hours after the onset of obstetric bleeding. So, the need comes for a simpler technique such as UBT or NASG application which can stop bleeding or at least stop bleeding temporarily to buy some time to tide over the crisis.

Of the total 132 cases of Obstetric haemorrhage, 71 patients received Non-pneumatic antishock garment and or uterine balloon tamponade and the remaining 61 didn't receive any. The sociodemographic and obstetric

characteristics of both the group were similar, but differed significantly in outcomes.

5.1. Reduction in blood loss

In our study majority of the intervention group (74.6%) had blood loss between 1000-2000ml and in non-intervention group majority (73.8%) had blood loss >2000 ml, which was statistically significant ($p \leq 0.05$). A study by S. miller et al. showed that Nonpneumatic antishock garment use resulted in statistically significant 64% reduction in median blood loss.[5] Another series of 11 cases using Sengstaken Blakemore tubes was published, in which mean blood loss was 2000ml and 81.8% success rate which is comparable to our study group.[6]

5.2. Reduction in shock index

In our study, the shock index in group 1 (With NASG or/ and UBT) was 0.7 ± 0.1 and in group 2 was 0.8 ± 0.1 (Statistically significant). A randomized clinical trial evaluating the effectiveness of NASG reported an improvement in recovery, as shown by a shorter time to a shock index below 0.98 and a systemic review of six eligible studies confirmed these findings.[7]

5.3. As a practical & affordable solution to PPH treatment

In the present study; In group-1(with NASG and or UBT) 66% patients required 2 units of WB/PRC whereas in group-2 almost all the patients (98.4%) required ≥ 3 units of WB/PRC. The cost effectivity was also measured in terms of mean days of hospitalisation which was significantly lower 9.8± 2.7 days in group 1 in comparison to 12.7±3.6 days in group 2. In a study of Sutherland et al for cost effectivity of NASG, the categories of cost included emergency hysterectomy, blood transfusions, uterotonics and provider training for the use of NASG and NASG itself. The study found that NASG is cost saving or highly cost effective.[8]

5.4. UBT and NASG reduces the need of surgical intervention

A study done by Emilie Gauchotte et al showed that there was reduction in need of surgical intervention with use of UBT from 28.4% to 6.6%.[9] This was comparable to our study where 13 of 61 women (21.3%) required surgical intervention (without NASG and UBT) and only 4 of 71 women (5.63%) required surgical intervention with the use of NASG and or UBT.[9]

5.5. Reduction in maternal mortality

In a study of El Ayadhi et al, there was 38% reduction in odds of death with application of NASG.[10] In our study, there has been no mortality in patients where NASG and/or UBT is used, whereas 3 mortality (4.91%) in patients where NASG / UBT was not used. With regards to the presence of any severe maternal complication as outcome of interest, our study showed beneficial effects associated with NASG/UBT use; In terms of decrease in ICU admissions (24.6% vs 19.7%), Acute kidney injury (22.9% vs 12.6%), Disseminated intravascular coagulation (8.2% vs 4.2%), Pulmonary edema (4.9% vs 2.8%) and Need of haemodialysis (8.2% vs 4.6%).

In developing countries where Placenta accrete spectrum is becoming more frequent causing higher blood loss and more requirement of transfusions, we suggest that the use of both these devices improves obstetric outcomes. These strategies can be implemented in high complexity obstetric units where they are available and provide time for definitive management. Also it can be used in some low-resource settings. However, the cost (especially of the Bakri Balloon) may be a limitation. In such settings, the hydrostatic balloon might be substituted for a low-cost simple balloon such as condom balloon with application of NASG providing a way to allow safe referral of a woman with hemodynamic instability to a higher-level facility.

6. Conclusion

Intrauterine balloon tamponade and NASG is an effective tool with a comparable success rate to other treatment modalities for managing massive PPH when standard uterotonic agents fail. UBT and/or NASG can not only be used in tertiary centres but also in limited-resource centres with little training, thereby earning time to prepare for another procedure by preventing massive bleeding or refer patient to another hospital. These cost effective techniques are both life-saving and fertility saving by avoiding laparotomy etc. and can become the first defence against atonic PPH.

7. Source of Funding

None.

8. Conflict of Interest

None.

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Author biography

Ashish Zarariya, Associate Proffessor

Arya Chaubey, Junior Resident https://orcid.org/0009-0008-1091-7409

Disha Rama Harikanth, Junior Resident https://orcid.org/0000-0002-6375-2635

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