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An Evaluation of the Efficacy of Condom Balloon Catheter in Utero for Controlling Non-traumatic Primary Postpartum Hemorrhage in Dhaka Medical College Hospital, Dhaka, Bangladesh

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Abstract		Original Research Article

Primary Postpartum Hemorrhage (PPH) still is one of the leading causes of maternal morbidity and mortality in both developed and developing countries. Globally, it is estimated that severe PPH occurs in about 11% of women who give a live birth. This was a prospective type of study undertaken with the objective to evaluate the efficacy of condom balloon catheter in Utero for controlling non traumatic Primary Postpartum Hemorrhage in Dhaka Medical College Hospital, Dhaka, Bangladesh during the period from February 2013 to July 2013. The study population was 50. Data was collected by structured oriented questionnaire. Fifty (50) cases with Primary Postpartum Hemorrhage fulfilled the inclusion and exclusion criteria were selected. The age of the patient ranged from 18 to 40 years. 58% had primary level of education, 62% were of lower socioeconomic status. 30 (60%) of respondents were multigravida and 52% had no or inadequate antenatal care. Forty two (84%) patients developed PPH in this hospital and other 16% were referred from outside. Normal vaginal delivery in 28 (56%) patients, assisted vaginal delivery in 1 (2%), LSCS in 21 (42%) patients. Time interval between delivery and onset of PPH, 40 (80%) patients had immediate onset and others 10 (20%) started to bleed within 24 hours. Among the cases more than half of the patients 28 (56%) had uterine height more than 20 weeks. In 40 (80%) cases condom introduce within 0-4 hours and in rest of the cases 10 (20%), it was introduced within 5-24 hours. Among twenty four cases (48%) condom was kept for 24 hours and in 26 (52%) it was kept for 48 hours. More than half of the patient required more than 1 unit of blood transfusion. Few patients 3 (6%) did not require blood transfusion. The mean duration of stay was 5.1 days, modal duration was 5 days, standard deviation was 2.16 and the total duration ranged from 2 to 12 days. In spite of the large range of stay, more than three- fourth 42 (84%) of the respondents were released from the hospital within 7 days of admission. Presence of risk factors for postpartum hemorrhage, there were PE or Eclampsia 19 (38%), multiple pregnancy 12 (24%), jaundice 11 (22%), retained placenta 7 (14%), APH 6 (12%), prolonged labour 4 (8%), obstructed labour 3 (6%), multigravida (>4) 3 (6%), previous C/S 3 (6%) and undetermined predisposing factor 1 (2%). Condom balloon catheter is an effective measure to control PPH. At times when PPH do not respond to pharmacologic measures, condom balloon catheter would be an emergency lifesaving procedure. It is simple, cheap, acts rapidly to poor country like Bangladesh with minimum resources and maintains natural contour of the uterus. It also helps to decide for surgical intervention and more importantly gives time till surgical help becomes available. It does not need special expertise, so can be used effectively even by people with limited medical expertise at remote corners of the country.
Key words: Condom Balloon Catheter, Utero, Non-traumatic, Postpartum Hemorrhage.

INRTODUCTION

Primary postpartum hemorrhage (PPH) remains a major complication of childbirth in worldwide as well as in Bangladesh. In Bangladesh it remains the number one killer of mother and contributes to 26% of all maternal deaths [1]. Primary postpartum hemorrhage (PPH) is defined as the loss of greater than 500 ml of blood from the genital tract in the first 24 hours following delivery [2]. This compares with 1000 ml of blood loss from caesarean section [3]. It is one of the leading causes of maternal morbidity and mortality [4]. There are 600,000 maternal deaths reported worldwide every year and 99% of these occur in

developing countries [4]. 25% of deaths in developing world are due to PPH, the prevalence is 34% in Pakistan [5-7]. PPH has many potential causes but the commonest is uterine atony, responsible for 80% of cases [8]. When uterus fails to contract, it leads to continuous blood loss from placental site. Risk factors for uterine atony are prolonged first and/or 2nd stage of labour, augmented labour, retained placenta, placenta accreta, multiple pregnancy, polyhydramnios and uterine fibroids. Multiparity and precipitated labour also promotes uterine atony [9]. Other causes of primary PPH include retained placental tissues, uterine rupture, lower genital tract trauma, uterine inversion and consumptive coagulopathy [10-12]. Prevention of uterine atony is the key to reducing the incidence of PPH [13, 14]. Management of PPH involves a stepwise approach which includes oxytocin, ergometrine, misoprostol, prostaglandin F2α. If these attempts prove to be unsuccessful and the woman is not already having caesarean section, a laparotomy is considered. During this time, various surgical interventions may be used, like internal iliac artery ligation, B-Lynch suture, peripartum hysterectomy etc. Sterile gauze was invariably used for uterine packing but problems encountered in achieving a good packing were concealed bleeding, uterine trauma and infection [15]. Currently, the intrauterine balloon is believed to act by exerting inward to outward pressure that is greater than the systemic arterial pressure to prevent continual bleeding [16]. In its original description, after placement in the uterus, the condom is inflated with 250–500 ml normal saline according to need, and the outer end of the catheter was folded and tied with thread after bleeding had stopped [23]. Vaginal bleeding is observed and further inflation is stopped when bleeding has ceased. To keep the balloon *in situ*, the vaginal cavity is packed with roller gauze and sanitary pads. Success is gauged by the amount of blood loss per vaginum. Hemorrhage was arrested within 15 min [24].

Fig-1: Condom Balloon Catheter

Developed in Bangladesh by Akhter and Team. The Condom /Catheters Unit can be assembled in a few minutes and cost of components is ≤ U.S. $5.The Sengstaken-Blakemore tube[17], the Rusch hydrostatic urological balloon [18] and the SOS Bakri tamponade balloon catheter[19] have been described as methods for providing uterine tamponade. But Sengstaken Blackemore tube and other analogues devices are effective but expensive (approximately 140 UK pound)[20]. Condoms (latex) or plastic sheaths are used mainly as contraceptive devices and barriers against STDs. Recently obstetricians have given condoms a new image. A condom inflated with isotonic solution can be used to create the tamponade [21] to control PPH. This inflated condom has the same efficiency in controlling PPH as Rusch Urological hydrostatic balloon or Sengstaken Blackmore tube. The Millennium Development Goal of reducing the maternal mortality ratio by 75% by 2015 will remain beyond our reach unless we prioritize the prevention and treatment of PPH in low-resource areas [22]. In this context condom is almost inexpensive, easily available everywhere even in remote rural settings of Bangladesh. In uncontrollable PPH, it can be used to compress uterine sinuses efficiently, before proceeding to a major surgery. The procedure is very simple, efficient and can be used by grass root level health workers with minimum skill.

OBJECTIVES

General objective
To evaluate the efficacy of condom balloon catheter in Utero for Controlling non-traumatic Primary Postpartum Hemorrhage in a tertiary care hospital, Dhaka, Bangladesh

Specific Objectives
To identify the causes of Primary PPH
To observe the efficiency of Condom Balloon Catheter in controlling of Primary PPH
To evaluate the morbidity after the procedure
To calculate the cost effectiveness of the procedure

METHODOLOGY AND MATERIALS
An observational study was under taken with the objective to evaluate the efficacy of condom balloon catheter in Utero for controlling non-traumatic Primary Postpartum Hemorrhage in Dhaka Medical College Hospital, Dhaka, Bangladesh during the period from February 2013 to July 2013.We selected our study

participants purposively, who had developed primary PPH after vaginal delivery or LSCS or instrumental delivery and admitted in the selected hospital. All cases of Primary Postpartum Hemorrhage in the Obstetrics ward of the Dhaka Medical College Hospital, Dhaka, Bangladesh were selected maintaining following criteria:

Inclusion Criteria
- Patients having primary PPH after vaginal delivery/ caesarean section in the hospital or those referred from outside of the hospital.
- Patients who have failed to respond to usual medical treatment in controlling primary PPH.
- Clinical examination reveals no signs of sepsis.

Exclusion Criteria
- The patient with primary postpartum hemorrhage (PPH) with any one or more of the following conditions or complications.
  - Congenital bleeding disorder.
  - Patients on heparin / warfarin.
- Unwillingness to participate.

RESULTS
This study was under taken with the objective to evaluate the efficacy of condom balloon catheter in Utero for controlling non traumatic Primary Postpartum Hemorrhage in Dhaka Medical College Hospital, Dhaka, Bangladesh. Study shows that mean age of the patient was 24.64 years with 5.21 standard deviation, median age was 25 years and range of age was 18-40 years. Patient ≤ 18 years was 12%, 19-35 years was 84% and ≥ 36 years was 4%. Study Illustrated that more than half of the patients 29 (58%) had primary level of education, about one-third 16 (32%) had no education. Around half of the study participants 31 (62 %%) were

of lower socio-economic status. Out of 50 cases, only 48% of the patients received antenatal care and 52% of the patient did not receive antenatal care. Study shows place of occurrence of postpartum haemorrhage. 42 (84%) patients developed PPH in this hospital and other 16% were referred from outside. Study shows normal vaginal delivery in 28 (56%) patients, assisted vaginal delivery in 1 (2%), LSCS in 21 (42%) patients. It shows the time interval between delivery and onset of PPH, 40 (80%) patients had immediate onset and others 10 (20%) started to bleed within 24 hours. Out of total 50 cases, per abdominal findings revealed more than half of the patients 28 (56%) had uterine height more than 20 weeks. Study shows that time interval of condom introduction after development of PPH. In 40 (80%) cases condom introduce within 0-4 hours and in rest of the cases 10 (20%), it was introduced within 5-24 hours. Table shows the duration of keeping condom in uterus. In 24 cases (48%) condom was kept for 24 hours and in 26 (52%), it was kept for 48 hours. Table shows number of unit of blood transfused during the management of PPH cases. More than half of the patient required more than 1 unit of blood transfusion. Few patients 3 (6%) did not require blood transfusion. Table elaborates the duration of hospital stay of the participants. The mean duration of stay was 5.1 days, modal duration was 5 days, standard deviation was 2.16 and the total duration ranged from 2 to 12 days. In spite of the large range of stay, more than three- fourth [42 (84%)] of the respondents were released from the hospital within 7 days of admission. Table illustrates the presence of risk factors for postpartum hemorrhage in the patients. These were PE or Eclampsia 19 (38%), multiple pregnancy 12 (24%), jaundice 11 (22%), retained placenta 7 (14%), APH 6 (12%), prolonged labour 4 (8%), obstructed labour 3 (6%), multigravida (>4) 3 (6%), previous C/S 3 (6%) and undetermined predisposing factor 1 (2%).

Table-I: Distribution of the cases by their age. (n=50)

Age	n	%
≤ 18 years	6	12
19 – 35 years	42	84
≥ 36 years	2	4
Total	50	100

Mean 24.64; Median 25; Mode 30; Standard Deviation 5.21; Range 18 - 40

Table-II: Distribution of the patient by their Education and Income.(n=50)

Indicators	n	%
Education		
Illiterate	16	32
Primary	29	58
Secondary	4	8
College/ University	1	2
Total	50	100
Income(monthly)		
Higher (>15,000 tk.)	3	6
Middle (5,000 -15,000 tk)	16	32
Lower (< 5,000 tk)	31	62
Total	50	100

Table-III: Distribution of the patients by their number of gravida, antenatal care, PPH started, mode of delivery and interval between delivery and PPH (n=50)

Health Status	n	%
Gravida		
Primigravida	20	40
Multigravida ≤ 4	27	54
Multigravida > 4	3	6
Total	50	100
Antenatal care		
Received	24	48
Not received	26	52
Total	50	100
PPH started		
In hospital	42	84
Outside hospital	8	16
Total	50	100
Mode of Delivery		
Normal vaginal	28	56
Assisted vaginal	1	2
LSCS	21	42
Total	50	100
Interval between delivery and PPH		
Immediate	40	80
1-24 hours	10	20
Total	50	100

Table-IV: Distribution of the respondents by their height of uterus.(n=50)

Height of uterus	N	%
≤ 20 wks	22	44
> 20 wks	28	56
Total	50	100

Table-V: Distribution of the respondents by their time interval of condom introduction after development of PPH (n=50)

Condom Introduction after (hours)	N	%
0-4	40	80
5-24	10	20
Total	50	100

Table-VI: Distribution of the patients by duration of keeping condom catheter in utero.(n=50)

Condom kept for (hours)	N	%
24	24	48
48	26	52
Total	50	100

Table-VII: Distribution of the respondents by blood transfusion required.(n=50)

Number of blood unit	N	%
Not required	3	6
1 Unit	16	32
More than 1 unit	31	62
Total	50	100

Table-VIII: Distribution of the patients by their duration of hospital stay. (n=50)

Duration	N	%
< 7 days	42	84
7 – 14 days	8	16
Total	50	100

Mean 5.1; Median 5; Mode 5; Standard Deviation 2.16; Range 2- 12

Table-IX: Distribution of the patients by their presence of risk factors of PPH.(n=50)

Risk factors	N	%
Retained placenta	7	14
Previous C/S	3	6
Multigravida (>4)	3	6
APH	6	12
Jaundice	11	22
Multiple pregnancy	12	24
Instrumental	1	2
PE	16	32
Eclampsia	3	6
Prolonged labour	4	8
Obstructed labour	3	6
Unknown	1	2

DISCUSSION

Primary Postpartum Hemorrhage (PPH) still is a challenging problem for the Obstetricians. PPH remains a significant complication of childbirth in many developed and developing countries. Although most can be treated successfully with conservative measures such as medication, about 10% of the women with PPH require major surgical procedures and even hysterectomy to save their lives. In developing countries like Bangladesh PPH is one of the leading Obstetric causes of maternal mortality. In this study 50 cases were purposively selected with the objective to evaluate the efficacy of condom balloon catheter in Utero for controlling non traumatic Primary Postpartum Hemorrhage in Dhaka Medical College Hospital, Dhaka. Regarding this 50 cases, the medical management have failed to control PPH. Before preceding the major surgical methods, the packaging of uterine cavity by condom balloon catheter was done. The sample size of the study is small though the study showed that massive PPH was effectively controlled very quickly by this inflating condom balloon catheter. Distribution of the age of the patients from 18 to 40 years. In Table I shows that most of the patients belonged to '19-35 years' age group 42 (84%) with mean age 24.64 years ± 5.36 (SD). Humaira *et al.* shows Ages of patients ranged from 15-45 years, with a mean age of 30.10±5.81 years [25]. In Table II shows the educational status of the respondents. More than half of the patients 29 (58%) had primary level of education and about one-third 16 (32%) had no education. So PPH is more common in illiterate and less educated person because they are less conscious and unlighted about health problem. Female education is very much needed in creating awareness and they see medical care early before any complication arises. In this study Table II shows Distribution of the patients by their socioeconomic status. More than half of cases 31 (62%) were of lower socioeconomic status. Socioeconomic status reflects yearly income of the family. In our study PPH showed to be higher in lower socioeconomic group. Bibi S *et al.* carried out a retrospective study showed socioeconomic status was poor 55.1% & lower middle class 44.9% [26]. Table III shows more than half 27(54%) of respondents were multigravida and the remaining 20 (40%) were primigravida. Mumin *et al.* [27] mentioned a three-fold increased risk of PPH in grand multiparous patients as compared to non-grand multiparous patients. Zamman BS *et al.* conducted a descriptive study showed the frequency of postpartum haemorrhage, primipara was 24% and in multipara 76%. Thus the present study would tend to support multiparity as a risk factor for PPH. Table III also shows regarding the antenatal care of the 50 patients. Only 48% had antenatal care, rest 52% had no or inadequate antenatal care. The finding of present study was similar to Sayeba *et al.* regarding the antenatal care. In her study all 23 patients who had massive PPH associated with other complicating factors also did not had any antenatal care. In developing country like Bangladesh this statistics is very much significant [28]. So it can be recommended that proper antenatal care sometime identify the high risk patients and can prevent PPH by proper management in health care setup by skilled personnel. In this study Table III shows that for 42 patients (84%), PPH started in hospital and managed effectively. 8 cases (16%) developed PPH outside the hospital and were managed after admission. That means 84% cases that developed PPH after hospital delivery get adequate treatment immediately to reduce massive hemorrhage. Table III shows normal vaginal delivery occurred in 28 (56%) patient, assisted vaginal delivery in 1(2%) and 21 (42%) LSCS was followed by PPH. In this study Table shows out of 50 patients in 40 (80%) PPH developed immediately after delivery and in 10 (20%), it developed within 24 hrs. These findings of the study are consistent with the study of Sayeba *et al.* [24]. Table IV shows distributions of the respondents by their height of uterus. Out of total 50 cases, per abdominal findings revealed most of the cases (28, i.e. 56%) had a uterine height more than 20 weeks. Table V shows the time interval of condom introduction after development of PPH. In 40 patients (80%), it was introduced within 0-4 hrs and in 10 (20%) between 5-24 hrs. It indicates that in those patients where medical management failed, before going for surgical intervention this inflated

condom was introduced within short time. Only in 23.31% where medical management failed after 5-24 hrs, where they were managed by this tamponade [23]. Table VI shows that in 24 patients (48%), the condom was kept for 24 hrs and in other 26 (52%), it was kept for 48 hrs. The time to keep the balloon in situ was decided upon the amount of PPH and the time required controlling the hemorrhage after introduction. It was decided that in the respondents where the PPH was controlled immediately, they had this balloon for 24 hrs and those who had slightest trickling even after introduction was kept for 48 hrs. The results of the study co-related with the study of Sayeba *et al*. Table VII shows most of the patients were haemodynamicaly unstable so needed blood transfusion. They received 0-18 units of blood transfusion. Immediate blood loss prevented by this technique and reduced the amount of blood transfusion. These patients became haemodynamicaly stable very soon after using the technique. This result is also consistent with the study of Sayeba *et al*. [23]. Stones *et al*. retrospectively reviewed that the commonest reason for blood transfusion was retained placenta and/or membranes (49%) with low postnatal hemoglobin (29.6%) and uterine atony (11.7%) being the next most frequent indications [32] Humaira *et al.* study showed 68% responders were given blood transfusion[25]. In Table VIII shows the distribution of the patients by their duration of hospital stay. The mean duration of stay was 5.1 days, modal duration was 5 days, standard deviation was 2.16 and the total duration ranged from 2 to 12 days. This great variation is due to some other complications like some of the patients with pregnancy induced hypertension had pulmonary edema or it took time to control their severe hypertension or the patient with jaundice remained in the hospital to reduce their billirubin level. In spite of the large range of stay, more than three- fourth 42 (84%) of the respondents were released from the hospital within 7 days of admission with complete recovery. Their postnatal follow up was quite satisfactory. None of the patients had any complication due to introduction of inflated condom like sepsis. This finding is also in accordance with the finding of Sayeba *et al*. [24]. Regarding the risk factors for PPH table IX shows out of 50 cases 16 (32%) had PE or Eclampsia, 3 (6%) over distension of uterus due to multiple pregnancy or polyhydromnios, 12 (24%) pregnancy with jaundice, 11(22%) retained placenta, 7 (14%) APH, 6 (12%) prolonged labour, 4(8%) obstructed labour, 3 (6%) multigravida (>4), 3 (6%) previous C/S, 3(6%) and 1 (2%) undetermined predisposing factor [24]. Nahar *et al.* study showed about 75-90% of those were from primary PPH, a condition in which the uterus failed to contract after delivery of the fetus and / or placenta [29]. In international studies uterine atony was the most common cause of non-traumatic primary PPH, ranging from 50% [30] to 76% [31] of cases.

LIMITATIONS OF THE STUDY

It was a cross-sectional study with small sample size, which doesn't reflect the scenario of the whole country.

CONCLUSION AND RECOMMENDATIONS

Primary postpartum hemorrhage is an obstetric emergency.. Uterine atony is to be the major case of non-traumatic primary postpartum hemorrhage along with mismanaged third stage of labour. Use of condom balloon catheter can control PPH quickly and effectively. It is simple to use, inexpensive, and safe. The cost of the technique is very minimum like < US $ 5 in comparison to Sengstaken-blackmore tube or Rush urologic hydrostatic balloon catheter which are also not available in this country. It can be applied in many situations without very skilled personnel or specialists to save valuable life and make the motherhood safer. It can also save the uterus of many young women to conserve their reproductive capacity. As this procedure is very safe and easy and does not require anesthesia or many logistic supports, so it can be introduced in grass root level by health care providers or other health workers from where communication to the hospital is difficult and time consuming for a PPH patient's life to be saved. So it is expected that use of condom balloon catheter in utero needs consideration if medical treatment fails and hysterectomy should be performed as last resort. Health providers involved in safe delivery practice including the paramedics can be easily trained in this procedure and can reduce maternal mortality to a great extent. If a ready-made device with condom and plain rubber catheter can be made available in sterile packs (which should be cost effective) it would have been more applicable in all levels of health sector.

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