

Study on Intrauterine Hydrostatic Ballooning by Condom as a Method of Controlling Post Partum Hemorrhage.

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Abstract:

Objectives: The aim of the study was to find out the effectiveness of intrauterine hydrostatic balloon for the management of Post Partum Hemorrhage (PPH). **Materials and Methods:** This prospective study was conducted in the department of obstetrics and gynaecology of Dhaka Medical College Hospital during the period of July, 2016 to December, 2016. Thirty five patients, admitted in the obstetrics ward having PPH included for this study. A questionnaire was used to collect information on age, parity, gestational week, antenatal care, mode of delivery, time interval of PPH. Medical management to control PPH was taken initially. If failed, hydrostatic ballooning by condom was done before proceeding for major surgical methods. The outcome measures by collecting information of time interval of condom introduction and PPH, duration of keeping condom, other management of PPH and days of hospital stay. **Results:** It was found that all the patients had one or multiple risk factors or complicating factors in the antenatal period which ended in early or late postpartum hemorrhage. Out of 35 patients 18 (51.43%) develop PPH immediately, 13(37.14) within 1-24 hours, 3 (8.57) within 25-72 hrs and 1 (2.86%) within 4 days to 2 weeks. In 28 (80%) cases condom introduced within 4 hours of PPH development and in rest 7 (20%) cases introduced within 5-24 hours. In 16(45.7%) cases it was kept for 24 hours and in 19(54.28%) cases was kept for 48 hours. There were no serious morbidity and bleeding was controlled effectively in all the cases.

Conclusion: This procedure is very safe, easy, does not require anesthesia, any logistic support and cheap. It can be given by primary health care provider at gross root level without referring to higher center and losing much blood. Uteri of young women can save to conserve their reproductive capacity.

Key-Words: Post partum hemorrhage, Hydrostatic ballooning, Condom, Outcome measures

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Introduction:

Post partum hemorrhage (PPH)¹ may be defined clinically as more than 1000 ml of blood loss from or within the genital tract, which will alter the general condition of the patient e.g. decrease in blood pressure and increase in pulse rate. Quantitatively it is defined as blood loss of more than 500 ml after vaginal

delivery or more than 1000 ml after caesarian section. PPH remains a major complication of childbirth, worldwide, as well as in Bangladesh. It is also a leading cause of maternal death all over the world. It has been estimated that worldwide more than 125 thousand women die of PPH². Two to five percent of deliveries may lead to PPH, with a blood loss of

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more than 1000 ml within the first twenty four hours³. It showed in a population-based study conducted in eight developing countries that 28 percent of all maternal deaths are due to PPH⁴. In Bangladesh it contributes to 25 percent of maternal deaths.

Whatever may be the cause of PPH, mortality due to this is absolutely preventable and is largely dependent on timely interference. Avoidance of hemorrhage remains the principal rationale for active management of 3rd stage of labor⁵. Ecbolic drugs used as prophylaxis, to ensure the maintenance of a well-contracted uterus include oxytocin and ergometrine^{6,7}.

The modern management of an atonic PPH includes the use of prostaglandin in parenteral, oral and vaginal route.⁸ Each has its advantages and disadvantages in terms of efficacy, side effects, availability, cost, ability and ease of administration.

Bi-manual compression, uterine packing⁹, surgical interventions, like B-Lynch brace suture¹⁰, ligation of uterine artery¹¹, ovarian artery, internal iliac artery¹², and embolization, are also effective methods of controlling intractable hemorrhage. Hysterectomy is the last resort to save life in spite of parity of the patient. All these procedures may lead to trauma, sepsis and other morbidities. Above all a well equipped facilities, skilled manpower and standard logistic supports are essential to perform the above- mentioned procedures.

But in poor country like Bangladesh, with various constraints for logistic supports, equipped facilities and skilled manpower a cost-effective, simple alternative to control intractable PPH is a demand especially for rural and remote areas. Inflated stomach balloon of a Sengstaken Blackmore tube¹³ and Rusch Urological hydrostatic balloon catheter¹⁴ has been used for a long time in UK for compressing uterine sinuses for stopping bleeding, In atonic PPH. Sengstaken Blackmore tube and other analogues devices are effective but expensive (approximately 140 UK pounds).

In Dhaka Medical College an innovative device has been introduced since several years using a condom. An inflated condom has the same efficacy in controlling atonic PPH as Rusch, Urological hydrostatic balloon or Sengstaken Blackmore tube. 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 major surgery.

The procedure is very simple, efficient and can be used even by grass root level health workers with minimum skill.

This method can easily be applied to manage PPH of women at the remote corner of the country and by this minimum cost efforts maternal death due to PPH can be minimized. Present study has been designed to prove the efficacy and simplicity of the method.

Materials and Methods:

This prospective study was done in the department of Obstetrics and Gynecology, Dhaka Medical College Hospital (DMCH) during the period from July 2016 to December 2016. Total 35 patients having PPH either primary or secondary and who have failed to respond to usual medical treatment in controlling PPH were purposively selected.

At first all 35 patients urinary bladder was kept empty by indwelling catheter. A sterile rubber catheter was inserted within the condom and tied the mouth of the condom by a silk thread. At lithotomy position of the patient the condom was inserted within the uterine cavity inner end of the catheter remained within the condom and outer end of the catheter was connected with a saline set and the condom was inflated with 250 - 500 ml of running normal saline. Bleeding was observed; when it reduced considerable amount further inflation was stopped and outer end of the catheter was tied with thread. Then uterine condom catheter was kept for 24 to 48 hours depending blood

loss and was deflated gradually 15 minutes and removed.

Uterine contraction was maintained by giving oxytocin for minimum 6 hours after the procedure. Patients were under triple antibiotic coverage by amoxicillin, metronidazole and gentamycin, intravenous for 2 days and oral for 5 days.

A questionnaire was used to record information on age, parity, gestational weeks, antenatal care, interval between delivery and PPH, type of PPH, time interval of onset of PPH and introduction of condom and duration of retention of condom, associated complication for PPH and hospital stay.

Collected data were compiled and tabulated according to key variables and calculated by students't' test. Students't' Test were performed using software like SPSS and a P value <0.05 was considered significant.

Results:

During the study period, out of the 253 PPH cases 185 were managed medically, 19 were managed by cesarean hysterectomy and 35 cases were managed using hydrostatic ballooning by condom which was 13.83% of total PPH cases.

Table- 1 shows that mean (± SD) age of the patients was 27.68± 7.32, median was 29 and range of age was 18-40. Median parity was 1 and range was from 0-5. Mean Gestational age was 36.63 ± 2.82 weeks, median 37 weeks and range 32 to 41 weeks.

Table-1: Basic data of the patient (n=35)

Parameters	Mean ± SD	Median	Range
Age (years)	27.68 ±7.32	29.00	18.00-40.00
Parity		1.00	0.00-5.00
Gestation age (week)	36.63 ±2.82	37.00	32.00-41.00

Table 2 shows that 31.43% patient had antenatal care and 68.57% had no antenatal care and the difference was significant statistically. It also shows that normal

vaginal delivery in 25 (71.43%) patients, assisted vaginal delivery in 2 (5.71%), LSCS in 8 (22. 86%) patients. Primary PPH was in 30 (85.71%) cases and secondary PPH was in only 5(14.28%) patients (Table-2).

Table-2: Obstetrical history and type of PPH (n= 35)

	Number of patients	Percentage
Antenatal care		
Yes	11	31.43
No	24	68.57
Mode of Delivery		
Normal vaginal	25	71.43
Assisted vaginal	2	5.71
LSCS	8	22.86
Type of PPH		
Primary	30	80.66
Secondary	5	14.28

Table-3: Predisposing factors for PPH

Factor	Number of Patients	Percentage
Pregnancy Induced Hypertension	11	31.43
Jaundice	6	17.14
PROM	4	11.43
Multiple pregnancy	3	8.57
Obstructed Labour	3	8.57
Abruptio placenta	3	8.57
Placenta praevia	3	8.57
Secondary PPH following C/S	1	2.86
HELLP syndrome	1	2.86
Sepsis	1	2.86
Morbid adhesion	1	2.86
Retained product	1	2.86
Induction/augmentation of labor	13	37.14

Table- 3 shows predisposing/factors for PPH. These are pregnancy induced hypertension 11, (31.43%), Jaundice (17.14%) Premature rupture of membrane (PROM) 4 (11.43%), Multiple pregnancy 3(8.57%), obstructed labour 3(8.57%), Abruptio placenta 3 (8.57%), Placentas praevia 3(8.57%), Secondary PPH following C/S 1(2.86.%), HELLP Syndrome 1 (2.86%), sepsis 1 (2.86%), Morbid adhesion 1 (2.86%), retained product 1 (2.86%), Induction/ Augmentation of labour 13 (37.14%).

Regarding the interval between delivery and onset of PPH, 18 (51.43%) patients had immediate onset. Among others 13 (37.14%) started to bleed within 1-24 hours, 3(8.57%) started within 25-72 hours and another 1 (2.86%) started to bleed within 4 days to 2 weeks of delivery (.Table- 4).

Table-4: Interval between delivery and PPH (n=35)

Factors	Number of Patients	Percentage
Immediate	18	51.43
1 -24 hours	13	37.14
25-72 hours	3	8.57
4 days to 2 weeks	1	2.86

Table-5: Time interval of condom introduction after development of PPH" (n=35)

Condom Introduction (After hours)	Number of Patients	Percentage
0-4 hours	28	80
5-24 hours	7	20

Table-5 shows time interval of condom introduction after development of PPH. In 28 (80%) cases condom introduced within 0-4 hours and in rest of the cases 7(20%) it was introduced within 5-24 hours of development of PPH.

Table-6: Duration of keeping Condom (n=35)

Condom kept for (hours)	Number of Patients	Percentage
24 hours	16	45.71
48 hours	19	54.28

Table-6 shows the duration of keeping condom in uterus. In 16 cases (45.71%) condom was kept for 24 hours and in 19 (54.28%) it was kept for 48 hours.

Discussion:

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 lives¹⁵. Rectal or vaginal tablet misoprostal, although attractive for its cost, stability and ease of administration, but less effective and is not always available in our country, in addition it is associated with side effects like diarrhea, vomiting, fever, flushing, headache, hypertension and bronchospasm.

A variety of surgical techniques are used including uterine artery ligation, Ovarian artery ligation, internal iliac artery ligation and B-Lynch Brace suture^{10, 11, 12}. Each of these methods has their own benefits and risks or hazards. These procedures are attempted before proceeding for the last resort to save women's life that is hysterectomy. But each of the above techniques entails laparotomy and there is a potential risk of ligating external iliac vessels, Ureteric injury and more hemorrhage. Moreover skilled personnel and anesthetic support needed for the above mentioned procedures. B-Lynch Brace¹² suture compress the uterus without compromising major vessels. The advantage of the B-Lynch procedure is that the identification of specific blood vessels is not required, which is invariably a difficult part in ligation of arteries.

Although it is helpful during cesarean section, the B-Lynch procedure requires a laparotomy and therefore is not the first approach in cases of PPH followed by vaginal delivery and even where medical management of PPH has failed.

The control of uterine hemorrhage by the use of intracavitary packing has been described for over a century (Ramsbotham 1856) but fears of the concealment of continued bleeding. Uterine trauma and infection together with increasingly available effective medical and surgical measure to treat uterine atony have lead to its fall from favor.

The attractiveness of uterine packing is that it does not require invasive surgery. Although there is a chance of intrauterine infection, but appropriate and aseptic packing techniques with prophylactic antibiotic therapy can minimize this complication⁹. A good packing technique involves careful layering of the ribbon gauze pack, but this may be easier in theory than in practice.

Keeping the technique of packing in controlling PPH by compressing the uterine sinuses, Sengstaken-Blackmore tube and Rusch Urological hydrostatic balloon catheter as well as inflated condom¹⁵, have been used by some researchers as well as by my supervisor to control intractable hemorrhage. The Sengstaken-Blackmore Tube is complex to use and expensive approximately 140 pound or \$225 (USD). The Rusch Urological hydrostatic balloon catheter, although simple and effective, is also expensive (20 pound or \$ 32 USD) and not available in our country. On the contrary a packet of condom and catheter is only Taka eleven which is equivalent to a few pence (and 19 cents US). Hydrostatic balloon conforms naturally to the contour of the uterus and compresses the open sinuses effectively and does not require complex packing technique and is easy to remove, and as condom is slippery there

is no chance of concealed bleeding. There is also a lower risk of infection, as there is no direct intrauterine manipulation. This intervention can be done easily, cost effectively and quickly and in addition it does not require skilled personnel.

In this study 35 patients were taken consecutively in whom the medical management have failed to control PPH. Before proceeding for major surgical methods the packing uterine cavity by hydrostatic balloon condom was done. The sample size of the study is small though the study showed that massive PPH was effectively controlled very quickly by this temponade of inflating condom. There are very few studies related to this present study.

The age range of respondents in our study was 18-40 years and in a separate study by Sayeba¹⁶ et al showed the range 19-40 years. Regarding the antenatal care of the 35 patients only 11 (31.43%) had antenatal care and rest 24 (68.57%) had no antenatal care at all. The p-value was >0.05 which was statistically significant. These findings of the present study were consistent with the study of Sayeba et al. In her study all 23 patients who had massive PPH associated with other complicating factors also did not had any antenatal care. 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 our study normal vaginal delivery occurred in 25(71.43%) PPH patients, assisted vaginal delivery is in 2(5.71%) and in 8 (22.86%) cases PPH followed cesarean section. Regarding interval between delivery and PPH in the respondents, Out of 35 patients 18 (51.43%) developed PPH immediately after delivery, in 13 (37.14%) patients, it developed within 24 hours, in 3(8.57%) developed within 25-72 hrs and lately, that is between 4 days to 2 weeks developed in 1 (2.86%) case. These findings of the study are consistent with the study of Sayeba et al.

In 28(80%) patients the time interval of condom introduction after development of PPH was within 0-4 hours and in 7(20 %) cases it introduced in between 5-24 hours. It indicates that in those patients where medical management failed, before going for surgical intervention this inflated condom was introduced within short time.

The frequency distribution of the respondents shows that in 16 patients (45.71%) the condom kept for 24 hours and in 19 patients (54.28%) it was kept for 48 hours. 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 hours and those who had slightest trickling even after introduction was kept for 48 hours. The results of the study co-related with the study of Sayeba et.al.

Summary and Conclusion:

PPH patients initially tried to manage medically, but who continued to bleed, were given intrauterine hydrostatic balloon by condom and normal saline. The intractable bleeding due to uterine atony, open sinuses in placental bed or in other causes was controlled very effectively by this intervention without proceeding for further intervention procedures like B-Lynch suture, uterine artery ligation or internal iliac artery ligation and there were no serious morbidity. The cost of this technique is very minimum like Taka 11.00 in comparison to Sengstaken-blackmore tube or Rush urologic hydrostatic balloon catheter which are also not available in this country. So in a country like Bangladesh where the maternal death rate from PPH is very high, this safe, inexpensive and easy procedure can be applied in many situations without requiring very skilled personnel or specialists to save the valuable life and make the motherhood safer.

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