

## Pressure Balloon Therapy in Uncontrolled Obstetrical Hemorrhage

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**OBJECTIVE** – To study the effectiveness of pressure balloon pack in controlling severe uterovaginal bleeding in obstetrics. **METHODS** – A prospective study was conducted on 101 women with intractable obstetric hemorrhage over a period of 20 years. A specially designed pressure balloon pack (Shivkar Pack) was used to control the bleeding. **RESULTS** – Out of the 101 women, 75 showed complete cessation of bleeding; 20 showed partial response and 6 failed to respond needing other active surgical intervention. **CONCLUSION** – ‘Shivkar Pack’ is a simple, novel and effective life saving measure for arresting postpartum / postabortal obstetrical hemorrhage.

**Key words** : obstetric hemorrhage, pressure balloon, PPH

### Introduction

Obstetric haemorrhage is the leading cause of maternal mortality in India even today. Emergencies like postpartum haemorrhage and inversion of uterus are most unpredictable and can endanger a patient's life. Anemia, which is so rampant in our country, adds fuel to the fire. Saving every single drop of blood becomes extremely vital to tackle such emergencies. The obstetric disasters can occur in any setup, any time and in any patient. If such emergency occurs in a rural setup or any setup where adequate expertise and facilities are not available the patient has to be transferred to a tertiary care center. Most of the times the patient is totally exsanguinated by the time she reaches a tertiary centre. She may lose her life as she might have reached an irreversible state of shock. In tertiary care centre one may face a helpless situation as it is very risky to subject the women in a shocked state to any operative intervention. Hence the need for a simple, cheap, quick, safe, easily available non-operative yet effective method for immediate tamponade of uterine hemorrhage was felt. The principle author designed a simple device meeting all the above-mentioned requirements in 1981, mainly to tackle atonic PPH. The device utilized the principle of hydrostatic pressure using a simple condom and IV drip set with a IV bottle of saline. As it proved to be an efficient method, its use was further extended to other obstetrical and gynecological emergencies as well.

### Material and Methods

The articles required are : A condom (prewashed), a

disposable IV set, normal saline bottle, scissors, artery forceps and sterile roller gauze (Photograph 1).



Photograph - 1 : Assembled Shivkar Pack

### Technique of Pack Insertion

As shown in Photograph 1, the terminal portion of the IV set is passed through the condom and is fixed to the condom with a latex rubber band, 0.5 cm wide so as to make the condom airtight. This width of the band is used because whenever the intraballloon pressure exceeds safety limits, the band gives way and fluid starts leaking out from the side of the IV tubing, eliminating the risk of overstretching and injuring the uterus. This latex band is laced on to the condom at a distance equal to the approximate length of the uterine cavity from the fundus to the internal os. The IV set is connected to the IV bottle as usual and the bottle is hung up on the calibrated IV stand at 60 cm. After removing all the trapped air from the assembles condom, it is introduced inside the uterus so that the rubber band is placed at the level of the internal os. Neither anesthesia nor sedation is required. The IV flow controller is now released and fluid is allowed to run fast over 1-2 minutes

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from a 60 cm height above the abdominal level. Usually upto 300cc is required to fill up the dead space of the condom and also of the uterus. The IV bottle is then brought down to a 25 cm height from the abdomen. Usually this maintains the hemostasis. However the height of the bottle may be lowered or raised so as to achieve complete hemostasis with minimum possible pressure and volume. This is maintained for approximately 6-8 hours. A condom filled with fluid has a tendency to herniate into accessible spaces available; hence it is recommended that the vagina should be packed to prevent slipping of the condom. Total time taken for the entire assembly and achieving uterine tamponade is never more than 3 to 6 minutes.

The patient's vital parameters are closely monitored during therapy. Once they improve, and complete hemostasis is achieved, pack is removed usually at the end of 6-8 hours, by bringing the bottle down slowly by 5 cm every 15 minutes so that the uterus gradually contracts over the pack. In cases of coagulation failure, it may be necessary to maintain the condom pack for longer periods.

#### Mechanism of Action:

Atonic PPH occurs due to failure of 'living ligatures' of uterine muscles to compress the vessels. This condom pack acts by –

- i) directly compressing the bleeding vessels by hydrostatic pressure
- ii) improving the efficiency of failed live ligature by uterine muscle contractions
- and iii) by allowing sufficient time for resuscitation of the patient, which enables the severely anoxic uterine muscle to recover from tissue anoxia and contract.

The pressure in the capillary system is 21-48 mm of Hg or 28.5-65.5 cm of water. Pressure in intervillous space is 25mm of Hg or 33.9cm of water. Hence the pack stops most of the bleeding except for arteriolar spurters wherein the pack may fail or be less effective.

Fig. 1 shows the graphical representation of pressure and volume relationship of the pack, obtained after series of in vitro experiments. The graph has three limbs A, B, and C. These three limbs are observed even in vivo as well.

*1) Limb A* – As soon as the condom begins to fill up with saline, initially 100cc of volume is used up to fill in the dead space of the condom. Hence, hardly any pressure is built up in the balloon as shown in the graph part A.

*2) Limb B* – The next 200 cc now fill up the dead space of uterine cavity and start exerting pressure on the

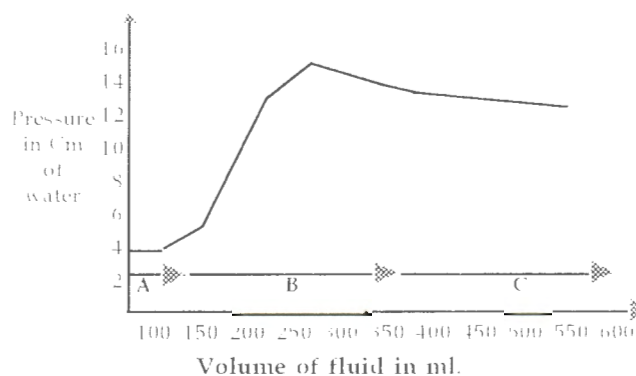


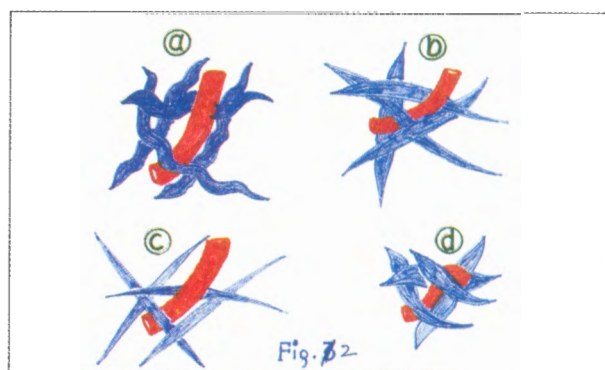
Fig. 1 : Pressure volume relationship of the pack

uterine wall. The distended condom closely applies to the exact contour of the uterine cavity leaving no dead space. In this phase, the intrauterine pressure is directly proportionate to the volume of saline.

*3) Limb C* - In this phase, the condom wall is subjected to further stretch. It gets overdistended and loses its elastic property or the fluid now starts leaking out through the side of the IV tubing, as latex rubber band gives way. Hence the intraballoon intrauterine pressure starts going down.

When the uterus is extremely flabby there is a small risk of overstretching the condom; hence care should be taken to limit the intraballoon volume to 350 to 400cc. The uterovaginal canal may be considered a complex multilayered elastic balloon, but its tone may show minimal variations from time to time and from patient to patient. Hence pressure and volume need to be individualized while the above mentioned criteria are only general guidelines.

Atonic uterine muscle fibres loosely surround the vessels which do not get effectively compressed. But when these loose muscle fibres are stretched with the condom pack, the folded loose fibres unfold to straighten out, bleeding vessels get nipped and bleeding decreases or stops. Photograph 2 (a) corresponds to limb (A) of Fig.1



Photograph 2 : Mechanism of Action - Improvement of Efficiency of Living Ligature of Uterine Muscle

(b) corresponds to limb (B) and (c) corresponds to limb (C). If the uterus is overstretched as in Photograph 2 (c), bleeding may restart. Photograph 2 (d) shows the effective living ligature when uterine contraction sets.

When patient is in a shocked state for a long time, there is tissue – anoxia of uterine muscle and all the measures to overcome atony fail. The pack by directly compressing the uterine wall decreases bleeding or stops the bleeding immediately. The resuscitation measures are now more effective and once oxygen carrying capacity of blood improves, muscle fibres gain the tone and the ability to contract. Since the pack is maintained in the utero for 6-8 hours, anoxic muscle gets time to recover and contract.

#### Advantages over the conventional pack

- (i) **Dynamicity of pack** – The moment the uterus starts contracting, the pressure in balloon increases and it pushes out the fluid allowing the uterus to continue contraction. This does not happen with the conventional pack. When the uterus relaxes, the fluid is drawn in, maintaining the pressure against the uterine wall and preventing reopening of capillary channels and bleeders.
- (ii) **Nonporous nature** – The conventional pack absorbs blood to some extent and hence exact amount of blood loss cannot be determined as against our pack which allows the amount of blood loss to be estimated accurately.
- (iii) **Infection risk in minimal**
- (iv) **Exact intrauterine pressure can be monitored and hence problems of too tight or too loose packing are avoided.**
- (v) **Even if the situation warrants a hysterectomy or internal iliac artery ligation, the pack can be used to minimize blood loss temporarily to buy time. Simplicity of the pack can allow a paramedical staff to use the pack even in remote places.**

**Indications** – Atonic PPH is a most important and common indication, however it is effective in PPH due to coagulation failure, inversion and in some cases of traumatic PPH.

**Contraindications** – The only contraindication is a suspected or diagnosed uterine rupture.

**Patient Selection** – Patients having atonic PPH with or without antecedent factors are selected for this method only when routine measures like bimanual massage, oxytocin, methergin, prostaglandin etc. have failed and

measures like obstetric hysterectomy or internal iliac ligation appear necessary. In cases of traumatic PPH, due to vaginal lacerations and of uterine inversion, the pack is inserted in the vagina with the latex rubber band at the introitus.

A majority of the women under study belonged to the age group of 20-25 years and there were more of multiparous women than primiparous (61 v/s 40). Out of 61 multiparas, 13 were grandmultiparas.

#### Results

Table I shows various indications in our series. Fortynine patients had atonic PPH and out of these, 34 achieved complete hemostasis, ten showed partial response and five failed to respond. Twelve cases had uterine inversion with PPH. In all the cases there was immediate control of hemorrhage as well as prompt correction of uterine inversion within few minutes to one hour. This avoided the need for anesthesia. Five women had bad vaginal lacerations which bled profusely and could not be effectively sutured. Bleeding was controlled in all of them. Intractable postabortal bleeding was successfully managed in 10 out of 11 cases.

**Table - I : Indications and Success Rates**

	Duration (In hours)	Cases	C	P	F
1. Atonic PPH					
Vaginal Delivery	6-8	43	30	10	3
LSCS	6-8	6	4	—	2
2. Uterine Inversion	4-6	12	12	—	-
3. Traumatic PPH (Vaginal laceration)	3-4	5	5	—	-
4. Coagulation Abnormally	12	24	18	6	-
5. Postabortal hemorrhage	2-4	11	6	4	1
Total		101	75	10	6

F – Failed                      C – Complete hemostasis,

P – Partial hemostasis

Table II shows the antecedent causes for atonic PPH. We had one mortality in our series. She had come as an emergency patient with 2 gm% Hb and PPH. She was transferred from a remote hospital in a state of shock. The pack was introduced, bleeding stopped but the

patient had cardiorespiratory arrest before blood could be made available.

**Table II: Antecedent Causes for atonic PPH**

Severe anemia	1
Accidental hemorrhage	14
Placenta accreta and failed MRP	3
Placenta previa accreta (LSCS)	2
Atonicity with no antecedent cause	29
	49

Out of 101 patients, 75 showed complete hemostasis (74.2%) and 20 showed partial hemostasis with considerably decreased bleeding though not instantaneously. Either minimum to moderate bleeding continued or it took more time for complete hemostasis. The method failed in only six cases where surgical intervention became necessary.

## Discussion

The present study is going on since 20 years. The simplicity and safety of the pack makes it an easily applicable method needing only minimal training. The method has proven to be extremely useful in saving the life of a patient avoiding the need for obstetric hysterectomy, which causes fertility loss and carries a high risk of mortality. One large series of 67 obstetric hysterectomies over 10 years reported mortality rate of 4.5%<sup>1</sup>. We had only one mortality in our series. On thorough review of literature, there was not a single study reported wherein condom pressure balloon was used. However one isolated case report was found. Riggs et al<sup>2</sup> used three Foley's balloons to provide tamponade of uterus for bleeding from placenta accreta and prevented obstetric hysterectomy.

## References

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