

Easy Balloon: The Easiest to Assemble Condom Balloon Uterine Tamponade for Primary Level of Health Care Centres

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Postpartum haemorrhage (PPH) is the major contributor to maternal mortality in the developing countries.

There is evidence of substandard care in most of deaths due to PPH mainly at the level of primary care in resource poor settings due to lack of facility for surgery or blood transfusions. Women with PPH are often referred to a higher centre in a critical state and many of them succumb on the way. These deaths are largely preventable.

As per WHO, the use of intrauterine balloon tamponade (UBT) is recommended for the treatment of PPH due to uterine atony if women do not respond to uterotonics or if uterotonics are not available [1]. The balloon tamponade is reported to be successful in 80–100% cases [2].

A simple condom balloon uterine tamponade (CBT) device which is assembled on the spot using basic minimum resources is the most feasible second-line intervention for management of PPH in low-resource settings [3].

Surprisingly, this potentially lifesaving simple intervention is not being used widely, most probably because of the inherent inconsistencies in assembling and use of conventional CBT.

The Conventional CBT

It is prepared by rolling a condom over the proximal one-third of any catheter followed by manually tying it with a suture material. It is then inserted into the uterine cavity and filled with saline till uterine bleeding stops or an arbitrary amount of 500 millilitres is instilled. Once haemostasis is achieved, the distal end of the catheter is occluded. Vagina is packed to prevent expulsion of balloon.

Disadvantages of the conventional CBT-

1. Tying the condom to catheter with a suture material have some disadvantages as follows-
 - (a) A very tight knot occludes the lumen of a soft catheter like Foley's and hinders inflation of balloon.
 - (b) A loose knot causes leakage of saline necessitating correction which causes delay in achieving the control of haemorrhage which may be life threatening.
 - (c) The string can cut through the condom material with consequent leakage of the distending fluid and resultant expulsion of the device which forfeits the whole purpose of using it. This is particularly common with suture material having sharp edges like *Polyglactin*.
 - (d) If thread is used to cut the cost, the sterilization may not be ensured in emergency predisposing infection.
2. The common methods for occlusion of the distal end of catheter have following disadvantages
 - (a) If a clamp is used for occlusion, it is inconvenient to the woman and the clamp is often not recovered by the original facility during the course of transfer.
 - (b) If the suture is tied for occlusion, it is difficult to further inflate or partially deflate the balloon in case the bleeding recurs or in severe spasmodic abdominal pain.
 - (c) When the catheter is knotted upon itself tight enough for occlusion, it is difficult to untie it later in case of need of further inflation or deflation .
3. Using a suture material like *Polyglactin* adds to the cost of device by 200–300 Rupees.

Effect on the health care system: Above-mentioned disadvantages are predominantly experienced by the first-line healthcare provider who is not an expert but is the first and often the only health care personnel available in the primary health care level. The inconsistencies in question may cause reluctance to use the method and deprive the critically bleeding women of an invaluable lifesaving non-operative treatment option. Use of CBT often arrests haemorrhage and even if the woman has to be shifted to higher centre, it reduces blood loss during the transfer.

To overcome these hassles, the authors propose an innovative approach in making of the device without any suture material thereby making it still cheaper, very easy to assemble, use and deflate but very consistent and is aptly named "Easy balloon".

It can be assembled and used confidently by the frontline healthcare providers. This has the potential to prevent maternal mortality and morbidity at this crucial level.

Easy Balloon

The assembly starts with rolling a condom over a Foley's catheter of any available size in a similar way as that of conventional CBT. This is followed by a different method of tying and is done by cutting two rings of approximately one millimetre width from the drainage port of Foley's catheter. First of these rings is used to tie the condom to the catheter by encircling twice over it. The method of device placement and insufflation is similar to conventional CBT. Another ring is used to occlude the distal end of balloon catheter once the balloon inflation is done and haemostasis is achieved. (Figure 1, Video1, 2) Occlusion of distal end of catheter with this ring is quick to perform, allows further inflation if needed as well as very easy deflation when planned for removal (usually 8–24 h later) and is done by simply pulling the two arms of the catheter in opposite directions. (Video 3).

A comparative evaluation of conventional CBT and Easy Balloon is depicted in Table 1.

Our Experience

We have been using this device for a research project as a second-line intervention with consistent efficacy since January 2016; it takes only few seconds to assemble it.

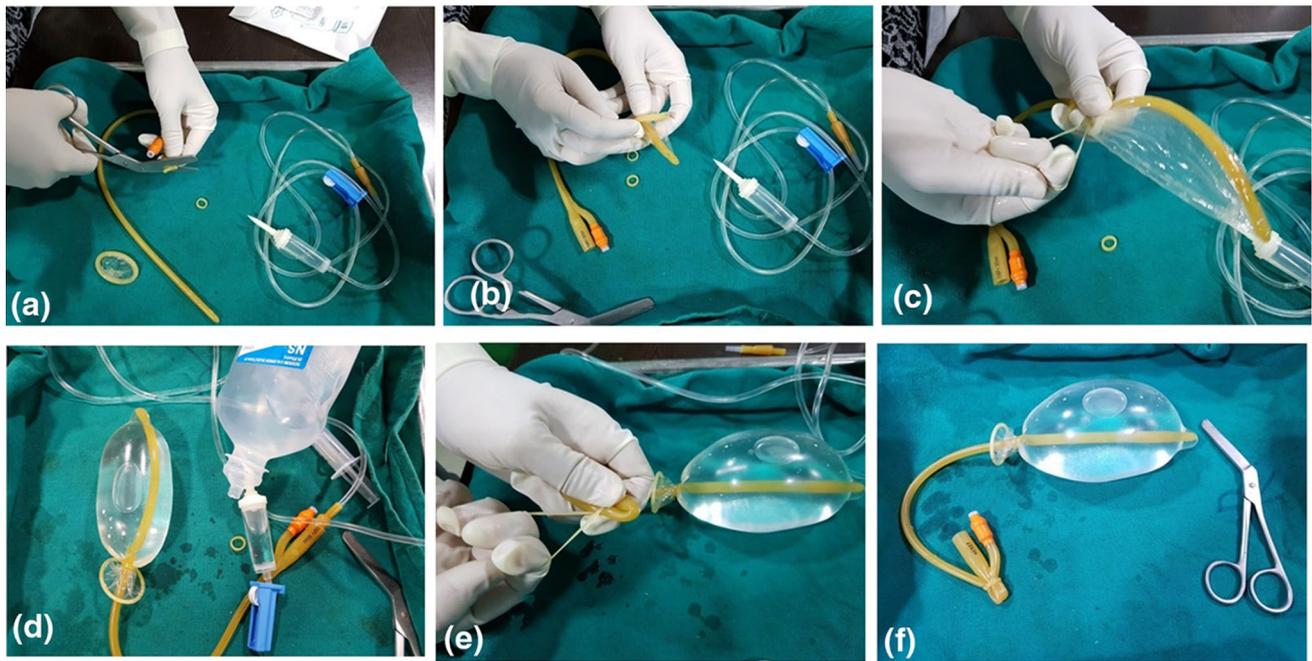


Fig. 1 Steps of assembling Easy Balloon. **a** Cutting two rings from Foley's catheter. **b** Unfolding the condom over proximal part of Foley's catheter. **c** Securing the condom over catheter with the ring by winding around twice. **d** Filling the balloon with normal saline by

connecting to an intravenous drip set after placing device in the uterus. **e** Occluding the distal end of catheter with the help of ring. **f** Complete Easy Balloon after inflation

Table 1 Comparisons between conventional condom balloon tamponade and Easy balloon

Conventional balloon	Easy balloon
1 Costs 200–400 Rupees (if suture material like Vicryl/silk is used)	Costs only 100 Rupees
2 Preparation time-consuming	quick to prepare (30–60 s)
3 Risk of improper sterilization In emergency if thread is used	Not required. Rings used are prepared from pre-sterilized packed Foley's catheter
4 Chance of leakage present If knot is loose or suture cuts through the condom material	No leakage, rings are always optimally tight
5 If the knot is too tight, it may prevent Inflation of saline by occluding catheter lumen	The tie is always of appropriate strength, does not occlude lumen
6 Distal ends needs occlusion using tying material, knot or clamp which needs removal of the same for deflation	No additional material or method is needed for distal end occlusion. Deflation is very easy

Saving time is invaluable when a very fast speed to create tamponade is needed. One such interesting case was of extensive vaginal laceration in a woman delivered at a primary health centre, her vagina was oedematous and any attempt to surgical treatment was causing increased bleeding leading to shock. The Easy Balloon was inserted, filled with one litre of saline within five minutes and the haemorrhage was controlled. A tight vulval pad was applied to prevent expulsion of the balloon. The woman

was kept under close monitoring. Balloon was deflated after 24 h, and woman made a smooth recovery.

Discussion

Although fundamentally designed for primary health care facilities, the device can successfully be used at all levels of the systems. For levels above the primary care, the

authors recommend using C.G. Balloon [4, 5] which works like commercially available uterine specific devices with the advantage of a drainage port to assess the ongoing haemorrhage in real time. The C.G. Balloon definitely entails a superior technology and function but for primary health care workers; Easy Balloon is recommended owing to its ease to prepare and use although with a disadvantage of not having a drainage port. Even then, it is better to use it than not using any CBT at all due to lack of consistency.

Although substituting the thread by rings cut out of Foley's catheter seems to be a very small change but can go a long way in building confidence of health care providers.

Another long-term benefit of using this device is saving money by-

- Reducing the cost by half to one-fourth by not using a pre-sterilized commercially available suture material like Polyglactin.
- Preventing any potential infection in case an inappropriately sterile string is used in order to save the cost.
- The need to transfer the women may be alleviated altogether in good number of cases due to remarkable consistency and efficacy of the device.

All these cost cutting measures can save a huge amount of financial resources over the years.

Conclusion

Easy Balloon is easiest to assemble and use as well as deflate, cheaper, faster, simpler, very effective and consistent device which can be assembled at primary health

care levels using only a Foley's catheter and condom without the need of any additional material for tying and thereby reducing the cost and potential infections.

This device can go a long way in achieving the triple advantage of being consistent, of lower cost (in comparison with conventional CBT using packaged Silk or Polyglactin) as well as reducing MMR in low-resource settings.

Compliance with ethical standards

Conflict of interest The Authors declares that they has no conflict of interest.

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