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Impact of condom balloon tamponade on the rate of obstetric hysterectomy: a ten-year study

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ABSTRACT

Background: The objective of this present study was to assess the efficacy of condom uterine balloon tamponade (C-UBT) in averting the obstetric hysterectomy (OH) in cases of major postpartum haemorrhage (PPH) over a period of 10 years.

Methods: A retrospective cohort study from January 2010 to December 2019. A historical cohort was drawn from a group of women who had OH for major PPH between Jan 2010 to December 2014 (Group 1) whereas those from January 2015 to December 2019 were designated as Group 2. Total 305 C-UBT were used in the later period. Women who had OH at <28 weeks were excluded from the study. Primary outcome was to determine the efficacy of C-UBT in averting the risk of OH. Secondary objective was to determine the success rate of C-UBT after five years of use

Results: Total 37463 births occurred from January 2010 to December 2014 and 38808 during January 2015 to December 2019. Cases of OH were 33 in the first five years period (Group 1) and 20 in the later (Group 2), $p < .05$, odds ratio=0.58 with 95% CI 0.335-1.019 favoring C-UBT. After exclusion of rupture uterus and placenta accreta syndrome, OH for uterine atony alone were 22 (66.6%) for Group 1 and 08 (40%) for Group 2, $P=0.01$ odds ratio=0.350 (95% CI 0.156-0.788). No OH was done in group 2 for placenta previa. Efficacy of C-UBT was 96%.

Conclusions: C-UBT is very safe, cheap and effective option for averting OH and associated physical, emotional and psychosocial morbidity.

Keywords: Caesarean delivery, Condom balloon tamponade, Obstetric hysterectomy, Post-partum haemorrhage, Uterine atony, Uterotonics, Vaginal delivery

INTRODUCTION

In spite of advances in the medical field, the postpartum haemorrhage (PPH) remains the leading direct cause of maternal mortality and morbidity globally and around 99% of these deaths occurring in low- and middle-income countries (LMICs).¹

Atony of the uterus is the commonest cause (70-80%) of PPH and as soon as PPH is diagnosed, massage of the uterus, emptying of urinary bladder, uterotonic agents along with resuscitative measures are the essential components of medical management. These measures along with injection tranexamic acid, ruling out retained

products, assessing coagulation defects and surgical correction of genital trauma (if any) are the first line intervention for the cause directed management approach.

Sometimes the first line measures are not effective or the uterotonics are not available in LMICs which often lack blood bank and surgical facilities also. Some of the uterotonic agents might be contraindicated in the given clinical situation. For such cases of major/severe PPH, it is imperative to use evidence-based guidelines issued by national and renowned world authorities which clearly recommend that while choosing the second line interventions, less invasive methods like uterine balloon tamponade (UBT) should always be used first

particularly in LMICs.²⁻¹⁰ If these methods fail, then more aggressive and invasive interventions including major surgery as a third line intervention may be resorted to save the life of the mother. The obstetric hysterectomy (OH) is the final step of the surgical recourse.

UBT involves insertion of a balloon into the uterine cavity followed by its inflation in order to achieve a tamponade effect and stop bleeding. The first published evidence dates back to 1983 when Goldrath inserted and inflated a Foley's catheter in the uterus to achieve tamponade. There are many variants of UBT, the most commonly used one is a commercially available purpose designed UBT "Bakri balloon®".¹¹⁻¹⁴ There is much evidence proving its efficacy.¹⁴⁻¹⁷ This device however is not a cost-effective option for LMICs.

Amongst the low-cost option of UBT, condom balloon tamponade (C-UBT) device is the most widely used. C-UBT was first generated and used in Bangladesh in 2001 by Akhter et al. In India, Shivkar et al prepared indigenous C-UBT named 'SHIVKAR's PACK'.¹⁸ Afterwards many reports established the efficacy of C-UBT across India.¹⁹⁻²³ Use of C-UBT has extended for uncontrolled PPH in hemodynamically unstable patients also.²⁴⁻²⁹ The only RCT comparing Bakri balloon® with C-UBT also reported no significant difference between the two in terms of success.³⁰

The advantages of C-UBT are many like being least invasive, cheapest, most rapid, safe, highly effective and need minimum training as well as clinical skill. The resources to assemble it are available in almost every labour room even in LMICs. In spite of all these advantages, the use of UBT is far less than desired in these countries and needs active motivation and training for its implementation.

It has been an observation that UBT plays an important role in averting the need for third line interventions involving major surgery of which the most dreaded ultimate procedure is the obstetric hysterectomy (OH) which itself is associated with additional blood loss in substantial amount besides the need for skilled staff and facility for surgery. These resources are scarce in LMICs. Precise knowledge of the influence of UBT upon OH will inspire the healthcare providers and policy makers to promote its use and avert the maternal morbidity and mortality associated with it.

Very few studies from developed world have come out with the targeted data showing impact of UBT on decision to surgical intervention.³¹⁻³⁴ Studies from LMICs are particularly lacking in this regard. In our institute, we have started using C-UBT for last five years with a good success rate in terms of control of PPH but have yet to produce specific data regarding its role in avoiding OH as the primary outcome.^{35,36}

The present study was done with an objective to assess the efficacy of C-UBT in averting the obstetric hysterectomy in cases of major PPH by performing a before-and-after study in order to generate the evidence on the efficacy and safety of this intervention in a tertiary care centre in central India.

METHODS

Present retrospective cohort study was conducted in the Pt JNM Medical College and Dr BRAM Hospital, Raipur, Chhattisgarh. This is the largest and oldest hospital of the state where about 8000 women give birth annually and also the first teaching hospital to start using C-UBT in a research setting.

This research hypothesis was that the use C-UBT can avert OH related to PPH in a significant proportion.

Data for this study was collected for all women who had OH over a period of last 10 years i.e., from January 2010 to December 2019. As we have started using C-UBT in 2015, it was not possible to have had a concurrent comparison group which was therefore drawn from a historical cohort of women who were managed for major PPH for an equivalent period of time frame of five years preceding the use of C-UBT so that the quality of care received by the pregnant women during this period can be ascertained to be similar with the only difference of use of C-UBT. The group of women who had OH during the time span from Jan 2010 to December 2014 was designated as PreC-UBT group (Group 1) whereas that from January 2015 to December 2019 was termed as post C-UBT group (Group 2).

As per records, once PPH was diagnosed, the first line treatment of both the group was almost similar and included massage of the uterus and resuscitative measures including fluid administration, catheterization, ruling out retained products in uterus and uterotonic agents in cases of atony and surgical correction of genital trauma in lower genital tract trauma as first line intervention for the cause directed management. All essential investigations were sent and arrangement for blood transfusion was made. Thereafter the management protocol differed in the two groups.

In the Group 1 period (2010-2014), whenever these first line interventions were not effective, women were taken for laparotomy which is the third line intervention because balloon tamponade was not in use at that time and facility for intervention radiology to get uterine artery embolization was also not available. During laparotomy, uterine conserving techniques like compression sutures and de-vascularization were tried first, failing which OH were resorted to. Similar approach was followed in women undergoing caesarean section.

In the Group 2 period (2015-2019), in cases not responding to initial treatment as above, second line

intervention in the form of three variants of C-UBT was employed. Those were C G balloon, easy balloon and conventional C-UBT (Figure 3) and in cases of negative tamponade test (failure to arrest haemorrhage after inflating the C-UBT with 500 mL of saline), women were taken for laparotomy and managed similarly as described above. However, in women undergoing caesarean section, the decision of using C-UBT as a second line intervention or going straight to surgical treatment of PPH was taken by the operating team and subsequent to conservative surgical measures, OH was done as a life-saving option.

Baseline demographic data was then reviewed manually for maternal age, parity, mode of delivery, birth weight of baby, indication of OH, number and types of C-UBT used and blood transfusions. The data so gathered was entered in a proforma prepared for the purpose.

Primary outcome of this study was to determine whether using C-UBT was associated with reduced rate of OH in cases of major PPH after adjusting for potential confounders.

Our secondary objectives were to determine the success rate of C-UBT after five years of use and whether the use of C-UBT was associated with reduced risk of OH across various indications.

Inclusion criteria

Authors included in this study all the women who have undergone emergency obstetric hysterectomy owing to refractory PPH after having delivered after gestational age of 28 weeks.

Exclusion criteria

Authors excluded women who had obstetric hysterectomy before 28 weeks of gestation.

Statistical analysis

The data was entered into excel 2016.sheet and analysed with SPSS version 20. Results were reported as mean, SD

or number percentage. Student’s unpaired t-test was used for analysis of continuous variables whereas the categorical variables were analysed by Chi square test with $p < 0.05$ considered as significant. Odds ratio (OR) and corresponding 95% confidence intervals (95% CI) were calculated for categorical data.

RESULTS

During the study period total 76,271 women gave birth in our department, of these 37,463 were in the first five years period from January 2010 to December 201 and 38,808 during January 2015 to December 2019.

Number of women who have undergone OH were 33 in the first five years period (Group 1) and 20 in the later (Group 2). The women of both the groups were comparable in terms of maternal age, parity, antenatal care booking status, mode of delivery, birth weight and rate of referral (Table 1). The total number of C-UBTs used were 305 in the time span of women belonging to Group 2 versus none in that of Group 1. The difference between the number of OH in the two groups was significant statistically ($p < 0.05$, Odds Ratio of hysterectomy with use of C-UBT was 0.58 with 95% CI 0.335-1.019) (Table 2).

The primary causes of OH in the two groups are depicted in Figure 1. After exclusion of rupture uterus and placenta accreta syndrome, uterine atony remains the predominating factor (66.6% for Group 1 and 40% for Group 2) the difference between the two groups was significant statistically ($p = 0.01$ (HS) odds ratio of having OH with use of C-UBT (Group 2) was=0.350 (95% CI 0.156-0.788). No OH was done in Group 2 for placenta previa. The mode of delivery of baby preceding OH is also shown in Table 2, significantly more women in Group 1 had to undergo OH after vaginal birth as compared to Group 2.

The year wise distribution of number of C-UBTs used and that of OH is shown in Table 3.

Figure 2 shows year wise distribution of OH due to atonic uterus and number of C-UBTs used in a graphic pattern and shows inverse proportion of the two.

Table 1: Demographic profile of women having undergone emergency obstetric hysterectomy in Group 1 and 2.

Characteristics	Group 1 (2010-2014) n=33 (mean+2SD)	Group 2 (2015-2019) (n=20) (mean+2SD)
Age (years)	29.5±0.752	30.6±0.628
Parity	2.8±0.252	2.7±0.244
Gestational age at delivery (weeks)	38.4±0.33	37.8±0.511
Baby weight (kg)	2.6±0.127	2.6±0.094
Blood transfusion	3.5±0.193	4.1±0.317

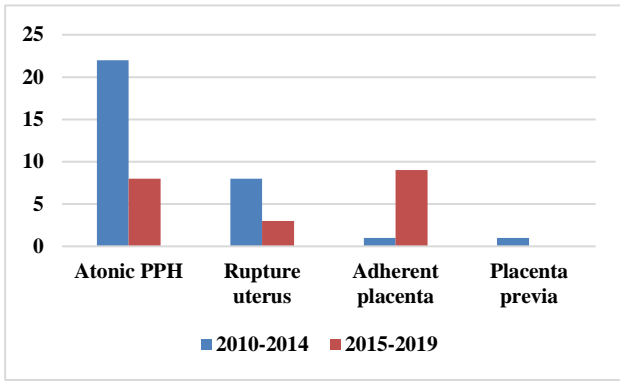


Figure 1: Indications of obstetric hysterectomies before and after C-UBT.

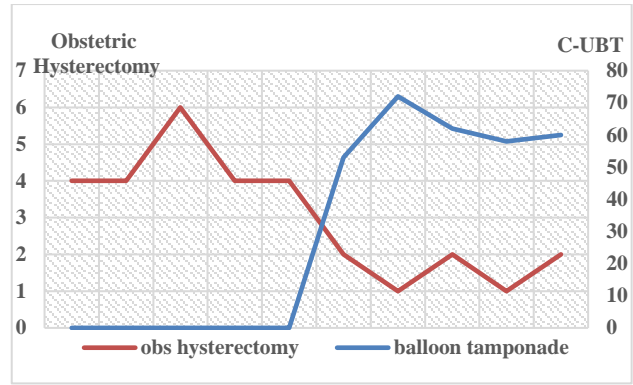


Figure 2: Relation of balloon tamponade and obstetric hysterectomy due to atonic PPH 2010-2019.

Table 2: Comparative data of obstetric hysterectomy (2010-2019) before and after C-UBT.

Characteristic	Group 1 2010-2014	Group 2 2015-2019	Effect size P, OR (95% CI)
Deliveries	37,463	38,808	
Balloon tamponade (C-UBT)	0	305	
Obstetric hysterectomies	33	20	P=<0.05, (S) OR=0.584 (95% CI 0.335-1.019) Favours use of c-UBT
Obstetric hysterectomies due to atonic PPH (excluding all other causes)	22	08	P=0.01 (HS) OR=0.350 (95% CI-0.156-0.788) Favours use of c-UBT
Mode of delivery preceding obstetric hysterectomy	n=33 Vaginal=18 (55%) LSCS=07 EL=08	n=20 Vaginal=07 (35%) LSCS=10 EL=03	P=0.004 (HS) OR=0.440 (95% CI-0.249-0.778) Favours use of c-UBT

S: significant, HS: Highly significant, OR: Odds ratio, 95% CI: Confidence interval.

Figure 3 shows the three types of C-UBTs, the frequency with which each of these were used as well as the indications. C G balloon was the commonest and used in 162cases (53%) followed by easy balloon in 102 (33%) and conventional C-UBT in 41 women. Out of all 305 C-UBTs, majority (87%) were used after vaginal delivery versus 13% women during caesarean section including 2 cases of “sandwich” surgery. In the former group, only 12 (4%) women required third line intervention with 07 managed by conservative surgical measures whereas 05 underwent OH. Remaining 03 OH cases in Group 2 were done for atony not amenable to conservative surgical measures during caesarean section but none of these women had C-UBT attempted prior to hysterectomy.

The success rate of balloon tamponade was 96% and the commonest indication was atonic PPH (81%). There was no complication in Group 2 which could be attributed to C-UBT.

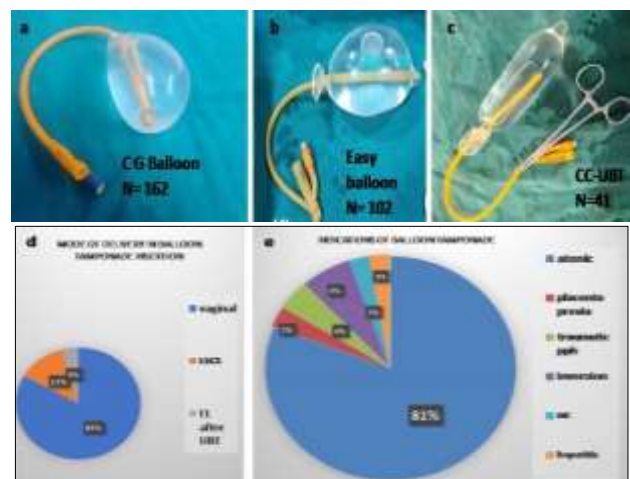


Figure 3: a-c, Types of C-UBT used (a) C G balloon n=162, (b) Easy balloon n=102, (c) Conventional C-UBT n=41. (d) Mode of delivery in all cases of C-UBT use n=305, (e) Indications of C-UBT in 305 cases.

Table 3: Year wise distribution of number of C-UBT and obstetric hysterectomies.

Year	Group 1 (2010-2014)					Group 2 (2015-2019)				
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Deliveries	7203	7753	7141	7599	7767	7803	7759	7931	7956	7359
Balloon tamponade	0	0	0	0	0	53	72	62	58	60
Obstetric hysterectomy	07	07	07	06	06	04	02	06	03	05

DISCUSSION

“A stitch in time saves nine” is a reasonable argument but a more pragmatic approach will always be to avoid it if possible but at the same time ensuring favorable outcome. This becomes even more important in LMICs where necessary infrastructure for surgery is lacking. Another point is that even if the option of surgery is available, why to avail it if avoidable and thereby also avoiding the surgery related morbidity, complications and psychosocial trauma if any radical surgical measure like OH in these young women had to be resorted to. UBT is one such life-saving intervention which can potentially avert surgery. It is reported to have an overall pooled success rate of 85.9% according to the most recent meta-analysis published in 2020.³⁷ This study results endorse their observations with an efficacy of 96% and a potential benefit of averting OH with odds ratio (with use of C-UBT) of 0.58 with 95% CI 0.335-1.019. This observation is in accordance to others.³¹⁻³⁴

One important protocol which was followed in our institute was the threshold at which the UBT was used. It was when the woman was well within stage 2 of obstetric haemorrhage according to guidelines by the California maternal quality care collaborative or when the obstetric shock index (pulse rate/ systolic blood pressure) has just crossed 1 with the woman continuing to bleed in spite of first line intervention but before the OSI proceeds to 1.5.³⁵ Others have also observed the same fact that it is extremely effective and life-saving especially when placed before the advanced stages of shock.³⁸

The most common indication of use in our study was atonic uterus (81%). OH due to atony alone were also averted with the use of C-UBT and the difference was significant statistically, ($p=0.01$, HS) and OR=0.350 (95% CI 0.156-0.788). C-UBT also averted OH due to bleeding bed of placenta previa where the bleeding bed of placenta responded very well to tamponade effect.

The most preferred variant used in our study was C G Balloon by virtue of having a central drainage lumen and thereby enabling real time assessment of ongoing blood loss. It also enabled us to perform ‘Sandwich surgeries’ in cases where either UBT or compression suture applied as a lone intervention could have not averted OH.^{35,36} This fact is in agreement to the study demonstrating UBT combined to surgical treatment of PPH to be effective

strategy during caesarean section with decreased rate of OH.³⁹ The comparative efficacy of C G balloon was endorsed by others too.²³ Though various modifications of C-UBT differ in use including those balancing the hydrostatic pressure with uterine tone the efficacy of each is well established.^{37,40}

To the best of our knowledge, this is the first Indian study demonstrating the specific effect of use of UBT in averting the potential need of OH. This data may motivate clinicians across various level of facilities in LMICs like ours to attempt this cheap, easy to use and prepared at the point of care option before referring or contemplating surgical intervention. This is even more pragmatic in severely anaemic state as a result of uncontrolled haemorrhage superimposed on already anaemic antenatal status. Avoiding OH also avoids the psychosocial consequences of loss of uterus and fertility in young women.

Limitations of this study was retrospective nature of the study design. However, if it helps to create awareness and enhances use of UBT, it may well be worth. Further studies are needed to reinforce our observation.

CONCLUSION

There is a definite impact of condom balloon tamponade in decreasing the rate of obstetric hysterectomy in cases of postpartum haemorrhage. This study observation should encourage clinicians across all levels of healthcare facilities to attempt this conservative second line intervention of C-UBT, before proceeding with surgical intervention. C-UBT has the potential to avert the significant physical, emotional and psychosocial morbidity associated with OH. It is very safe and cost-effective option for LMICs.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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