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Intrauterine balloon tamponade for management of severe postpartum haemorrhage in a perinatal network: a prospective cohort study

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Objective To evaluate the effectiveness of intrauterine balloon tamponade (IUBT) for management of severe postpartum haemorrhage (PPH). To identify the factors predicting IUBT failure.

Design Prospective cohort study.

Setting Ten maternity units in a perinatal network.

Population Women treated by IUBT from July 2010 to March 2013.

Methods The global IUBT success rate was expressed as the number of women with severe PPH who were successfully treated by IUBT divided by the total number treated by IUBT. IUBT failure was defined as the need for arterial embolisation or surgery. Logistic regression analysis was used to estimate factors predicting IUBT failure.

Main outcome measures Global IUBT success rate. Factors associated with IUBT failure.

Results Intrauterine balloon tamponade was attempted in 226 women: 171 after vaginal delivery (VD) (75.7%) and 55 during or after caesarean delivery (CD) (24.3%). The global success rate was 83.2% (188/226) and was significantly higher after VD (152/171, 88.9%) than CD (36/55, 65.5%, $P < 0.01$). The percentage of CD was significantly higher in the failure group (50.0 versus 19.1%, $P < 0.01$), as was mean (SD) estimated blood loss before IUBT: 1508 ± 675 ml versus 1064 ± 476, $P < 0.01$. Coagulopathy was significantly more frequent in the failure group (50.0% versus 17.2%, $P < 0.01$). CD [Odds ratio (OR) 3.5; 95% CI 1.6–7.6], estimated blood loss before IUBT (OR 3.2; 95% CI 1.5–6.8) and coagulopathy (OR 5.6; 95% CI 2.5–13.0) were predictive of IUBT failure.

Conclusion Intrauterine balloon tamponade is an effective method for treating severe PPH. Early balloon deployment before the development of coagulopathy increases its success rate.

Keywords Bakri balloon, Belfort–Dildy Obstetrical Tamponade System, ebb balloon, intrauterine balloon tamponade, postpartum haemorrhage.

Tweetable abstract Intrauterine balloon tamponade is effective for achieving haemostasis in intractable postpartum haemorrhages.

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Introduction

Severe postpartum haemorrhage (PPH) affects 1–2% of deliveries in high-income countries and its frequency is increasing.[1–9] PPH is among the most common causes of pregnancy-related death in the USA and Europe and remains the leading cause of maternal death in France.[10–15] Postpartum hysterectomy is the most common and final procedure for achieving arrest of severe PPH.[16,17] Alternative procedures, such as uterine compression sutures, pelvic vessel ligation and arterial embolisation, can be attempted to avoid hysterectomy.[17–30] More recently, intrauterine balloon tamponade (IUBT) has emerged as a widely

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recommended technique for avoiding invasive procedures.[31,32] This non-invasive procedure is an effective tool for PPH management with a success rate 84–91.5%, according to two systematic reviews.[33,34] Nonetheless, the use of IUBT has been described mainly for small numbers of patients in case reports[35–47] and a few small retrospective and prospective series.[32,48–56] The three largest prospective studies included only 43, 48 and 51 women each.[32,55,56]

The objective of our study was to evaluate the effectiveness of this non-invasive technique in a large prospective cohort study set in a perinatal network including different levels of care. A second objective was to identify the factors predicting IUBT failure.

Methods

This prospective cohort study was conducted from July 2010 to March 2013 in a perinatal network of 10 maternity units with a total of around 19 000 deliveries per year.

Intrauterine balloon tamponade became standard practice in the tertiary university referral hospital in April 2008, and its efficacy and tolerability as an initial second-line treatment for severe PPH unresponsive to prostaglandins were evaluated after 2 years.[32] Encouraging results led to the progressive introduction of IUBT, beginning in July 2010, into the nine other public and private maternity units of the network. A two-part educational intervention took place in each maternity unit in the network. During the first phase, one of the co-authors (Dr Raynal) presented the key points of the IUBT protocol to the local clinicians (obstetricians and midwives) and discussed with them possible difficulties in its local implementation as well as potential solutions. During the second phase, all cases of severe PPH treated by IUBT were reviewed during a meeting of each medical team, with Dr Raynal present; the quality of care was critically analysed, and local staff received feedback on their practices.

During the study period, all maternity units in the network followed the protocol for stepwise management of PPH, according to the national clinical guidelines then in effect for first-line therapy:[57] (i) active management of the third stage of labour; (ii) manual removal of the placenta, without delay in the case of haemorrhage or after 20 minutes in the absence of bleeding in vaginal births; (iii) in the case of excessive bleeding, administration of additional oxytocin (10 IU) after exploration of the genital tract for partially retained placental tissue or traumatic damage, uterine massage until adequate contraction occurs, emptying of the bladder, and search for and treatment of any obvious bleeding in any episiotomy or tear; (iv) if bleeding continues, intravenous infusion of sulprostone (PGE2 analogue), starting at a dose of 500 microgram per hour for 1 hour.

If bleeding continued despite the intravenous sulprostone infusion, the blood loss was reassessed and the network protocol required that an intrauterine balloon tamponade test be used as the initial second-line therapy, i.e. before any invasive procedure in immediate haemorrhages due to uterine atony or placenta praevia.

Insertion of the Bakri balloon (Cook Medical, Bloomington, IN, USA) or the Belfort–Dildy Obstetric Tamponade System, trade-named '*ebb*' (Glenveigh Medical, LLC, Chattanooga, TN, USA, currently marketed by Clinical Innovation, Salt Lake City, UT, USA) into the uterus and its intrauterine position were monitored by abdominal ultrasound scanning. When the balloon was inserted during a caesarean, the distal end of the balloon shaft was introduced through the cervical opening with an assistant pulling vaginally. Its position was checked and adjusted through the uterine incision, which was closed before the balloon was completely filled.

It was recommended that the balloon, once placed in the cavity, be inflated with 400–500 ml of sterile water. Only the upper uterine balloon was inflated when the ebb device was used. At this stage, if there was no bleeding through either the cervix or the balloon drainage channel after 15 minutes, the tamponade test was considered successful. After 12 hours, it was deflated to half its volume of water and was completely removed 12 hours later.

On the other hand, if bleeding continued, the tamponade test was considered a failure, and an emergency radiological or surgical invasive procedure was performed immediately after withdrawal of the balloon in the operating room.

All patients had a Foley catheter inserted into the bladder and received antibiotic prophylaxis (amoxicillin-clavulanate and gentamicin) for 48 hours.

For each case of PPH treated by IUBT, maternal and obstetrical data were collected, including the times of the different procedures/examinations, from the medical charts.

Severe PPH was defined by its unresponsiveness to first-line treatment. The failure of IUBT was defined as the need for any invasive procedure, including arterial embolisation, conservative surgical procedures (including uterine compression sutures or pelvic vessel ligation), and hysterectomy.

The primary outcome measure was the global success rate of IUBT, expressed as the number of women with severe PPH treated successfully, divided by the total number treated by IUBT. Other outcomes were IUBT success rates after vaginal and caesarean deliveries and factors associated with IUBT failure.

The prospective evaluation of the effectiveness of this emerging technique was supported by a grant from the Agence Régionale de la Santé d'Ile de France for a 3-year period.

Pearson chi-square or Fisher exact tests were used to compare categorical variables between the groups with successful and failed IUBT, and Student or Mann–Whitney tests to compare the continuous variables. Factors identified as associated with IUBT failure with a *P*-value <0.20 in these univariate analysis were included in multivariate logistic models. These models were constructed by backward stepwise regression, to estimate the relations between the baseline characteristics and the relevant clinical variable for the risk of IUBT failure. Adjusted odds ratios and their confidence intervals were calculated. All hypotheses were tested at the two-tailed 0.05 significance level. Co-linearity was tested before modelling. We performed a Hosmer–Lemeshow test, a statistical test for goodness of fit, to verify the validity of our model (if the *P*-value <0.05 then the model is not correctly specified).

SAS software 9.3 (SAS Institute, Cary, NC, USA) was used for the statistical analyses.

The study and the database were approved by the National Data Protection Authority no. 1295794 (Commission Nationale de l'Informatique et des Libertés). Given that the data set contained no data enabling patient identification, the study was exempted from informed consent requirements.

Results

During the study period, 226 cases of severe PPH were managed with IUBT in the 10 network maternity units: 171 (75.7%) after vaginal delivery and 55 (24.3%) during or after caesareans. Nine of the cases of IUBT performed in the tertiary university referral hospital and reported in our previous publication[32] are also included in this study because they occurred during this study period, from July to December 2010. The Bakri balloon was used for 198 women (87.6%) and the ebb balloon for 27 (11.9%); one woman (0.4%) initially received a Bakri balloon that was expelled after placement and was immediately replaced by an ebb balloon.

Figure 1 reports the outcomes of all women managed with IUBT. The global success rate was 83.2% (188/226) and was significantly higher after vaginal deliveries (152/171, 88.9%) than caesareans (36/55, 65.5%, $P < 0.01$). Among the 55 women with caesareans, the intrauterine balloon was used during surgery in five cases, always successfully, and postoperatively for the other 50, that is, after transfer to the postnatal ward.

Among 38 failures, 19 embolisations were attempted; two of them failed, leading to two conservative surgical procedures. Another 14 IUBT failures were managed immediately by conservative surgical procedures; six finally required hysterectomies. Finally, five hysterectomies were performed immediately after IUBT failure.

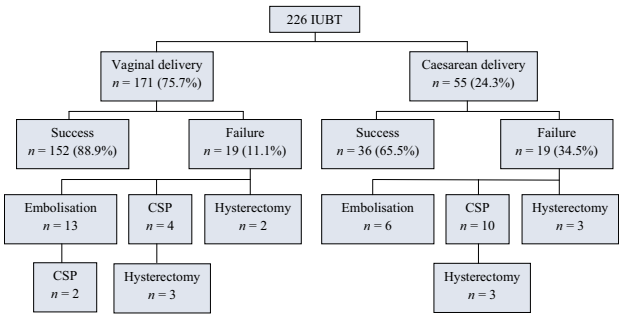

Figure 1. Flowchart. CSP, conservative surgical procedure; IUBT, intrauterine ballon tamponade.

Table 1. General and obstetric characteristics of the study population

	Success* *n* = 188	Failure** *n* = 38	*P*-value
Maternal age, year, mean ± SD	30.0 ± 5.4	31.8 ± 3.7	0.01
Ethnicity, *n*/total (%)			
White	139/181 (76.8)	31/36 (86.1)	0.54
Black	30/181 (16.6)	4/36 (11.1)	
Asian or other	12/181 (6.6)	1/36 (2.8)	
Body mass index, kg/m^2, mean ± SD	23.4 ± 4.2	22.8 ± 3.4	0.36
Primipara, *n* (%)	83/188 (44.1)	15/38 (39.5)	0.60
Prior caesarean delivery, n (%)	23/188 (12.2)	7/38 (18.4)	0.45
History of PPH, *n* (%)	18/188 (9.6)	4/38 (10.5)	0.77
Multiple gestation, *n* (%)	11/188 (5.9)	4/38 (10.5)	0.29
Gestational age at delivery, WG, mean SD	39.2 ± 2.0	38.5 ± 3.4	0.36
Mode of delivery, *n* (%)			
Vaginal delivery	152 (80.9)	19 (50.0)	<0.01
Caesarean delivery	36 (19.1)	19 (50.0)	
Birthweight, g, mean ± SD	3292 ± 673	3263 ± 717	0.81
Cause of haemorrhage, *n* (%)			
Uterine atony	155 (82.4)	28 (73.7)	0.34
Placenta praevia	25 (13.3)	8 (21.1)	
Others***	8 (4.3)	2 (5.3)	

PPH, postpartum haemorrhage; WG, weeks of gestation.
*Defined as severe postpartum haemorrhage stopped by the intrauterine balloon tamponade.
**Defined as the need for arterial embolisation or surgery after the intrauterine balloon tamponade test.
***Including two cases of uterine ruptures, six cases of thrombus, one case of intraoperative complications (extension of the low transverse uterine incision) and one case of placental abruption.

Table 1 summarises the general and obstetric characteristics of the 226 women for whom IUBT was attempted. The success and failure groups were similar for ethnicity, body mass index (BMI), and percentages of primiparas, previous caesareans, previous PPH, and multiple gestations. Maternal age (mean ± standard deviation), however, was significantly higher in the failure group (31.8 ± 3.7 versus 30.0 ± 5.4 years old in the success group, $P = 0.01$).

Mean gestational age at delivery and mean birthweight were similar in both groups. On the other hand, the caesarean rate was significantly higher in the failure group (50.0 versus 19.1%, $P < 0.01$). Uterine atony was the most common cause of PPH (183/226, 81.0%), followed by placenta praevia (33/226, 14.6%). Interestingly, these rates were similar in both the success and failure groups, a finding that indicates that the cause of the severe PPH was not significantly associated with IUBT failure (Table 1). The IUBT success rate was 84.7% (155/183) for the women with uterine atony and 75.8% (25/33) for those with placenta praevia ($P = 0.70$). Two women with failed IUBT and no previous history of caesarean delivery or uterine surgery had undiagnosed uterine ruptures (Table 1).

The success and failure groups had similar rates of active management of the third stage of labour and of sulprostone treatment (Table 2). They also had similar estimated blood losses at PPH diagnosis, but the mean (standard deviation) estimated blood loss before IUBT was significantly higher in the failure group: 1508 ± 675 versus 1064 ± 476 ml, $P < 0.01$. Coagulopathy was also significantly higher in the failure group (50.0 versus 17.2%, $P < 0.01$). Conversely, bleeding that decreased dramatically or stopped within 15 minutes was associated with IUBT success (98.2 versus 15.9%, $P < 0.01$) (Table 2).

The IUBT success rate was similar for the reference hospital and the other maternity units [80.7% (71/88) versus 84.7% (117/138), respectively, $P = 0.53$]. It was also similar for both types of balloons: 83.3% (165/198) for the Bakri and 82.1% (23/28) for the ebb, $P = 0.79$.

Insertion failed for seven women (all with Bakri balloons). In three, bleeding nonetheless stopped without any additional procedures. The remaining four underwent embolisation and/or conservative surgical procedures.

No women died in this cohort study. One woman developed endometritis, which resolved favourably after antibiotic treatment. No other adverse outcome was observed to be associated with either IUBT or a delay of an invasive procedure associated with IUBT use.

The small number of IUBT failures ($n = 38$) required us to limit the multivariable model to three variables: maternal age, mode of delivery (vaginal delivery as reference) and estimated blood loss before IUBT (≤1500 ml as reference). Maternal age (OR 1.07; 95% CI 0.99–1.16) was not associated with IUBT failure. Caesarean delivery (OR 3.5; 95% CI 1.6–7.6) and estimated blood loss before IUBT (OR 3.2; 95% CI 1.5–6.8) were predictive of IUBT failure. The Hosmer–Lemeshow test, with its P-value of 0.41, validated the model's goodness of fit.

In a separate analysis, another model replaced estimated blood loss before IUBT by coagulopathy, as these two

Table 2. Medical management and clinical characteristics of postpartum haemorrhages in the study population

	Success* $n = 188$	Failure** $n = 38$	P-value
Prophylactic injection of 5 IU oxytocin, *n*/total (%)	164/188 (87.2)	35/38 (92.1)	0.58
Sulprostone, *n*/total (%)	180/188 (95.7)	38/38 (100.0)	0.36
Elapsed time between delivery and balloon insertion, h, mean ± SD	2.5 ± 2.0	2.5 ± 2.1	0.85
Elapsed time between diagnosis and balloon insertion, h, mean ± SD	1.4 ± 1.2	1.7 ± 2.0	0.37
Estimated blood loss at diagnosis, ml, mean ± SD	638 ± 353	731 ± 381	0.32
Estimated blood loss before IUBT, ml, mean ± SD	1064 ± 476	1508 ± 675	<0.01
Bleeding dramatically decreased or stopped after 15' balloon insertion, *n*/total (%)	162/165 (98.2)	6/38 (15.9)	<0.01
Coagulopathy, *n*/total (%)	32/186 (17.2)	19/38 (50.0)	<0.01
Uterine balloon volume, ml, mean ± SD	457 ± 140	473 ± 154	0.60
Red blood cell transfusion, *n*/total (%)	96/187 (51.3)	36/38 (94.7)	<0.01
Units of red blood cells transfused, mean ± SD	3.1 ± 1.5	7.2 ± 5.5	<0.01
Intensive care unit admission, *n*/total (%)	103/188 (54.8)	36/38 (94.8)	<0.01
Level care, *n*/total (%)			
Tertiary hospital	71/188 (37.8)	17/38 (44.7)	0.53
Other hospitals	117/188 (62.2)	21/38 (55.3)	

IUBT, intrauterine balloon tamponade.
*Defined as severe postpartum haemorrhage stopped by the intrauterine balloon tamponade.
**Defined as the need for arterial embolisation or surgery after the intrauterine balloon tamponade test.

variables were correlated. The odds ratio for coagulopathy as a risk factor for IUBT failure was 5.6 (2.5–13.0).

Discussion

Main findings

This prospective cohort study showed the effectiveness of IUBT in our perinatal network. Mode of delivery, estimated blood loss before IUBT, and coagulopathy predicted IUBT failure. Bleeding not substantially responsive to IUBT within 15 minutes was also associated with failure.

Strengths and limitations

Our study is the largest prospective multicentre cohort study to assess the success rate of IUBT in treating severe PPH. The large number of patients allowed us to identify an important and modifiable factor of IUBT failure: the severity of blood loss before IUBT, which increases the probability of coagulopathy. Moreover, most of our cases involved severe PPH, as shown by the high rates of both transfusions of packed red blood cells and admissions to intensive care.

Another strength of our study was that all maternity units in the network followed a common protocol for stepwise management of PPH, with IUBT required as the initial second-line therapy. The study reported by Dildy et al.[56] included 51 patients, 19 of whom had undergone operative or embolisation procedures before balloon placement.

The main limitation of this prospective cohort study is the lack of a control group, which probably induces an overestimation of the efficacy of the IUBT. Insertion of the Bakri balloon in the uterine cavity failed in seven women. However, bleeding stopped for three of them without any additional procedure. Only a randomised clinical trial can assess the true efficacy of the IUBT.

Furthermore, we were interested in the study of an important factor potentially associated with IUBT: the estimated blood loss before IUBT. Exhaustive data were collected for maternal age, mode of delivery, and coagulopathy. Nonetheless, data about estimated blood loss before IUBT were missing in the files of 15.9% of the women, probably due to the life-threatening urgency of the situation. To overcome this limitation, we used several methods to deal with this missing information. The model we presented here had the narrowest confidence interval and thus probably the best accuracy of all the models tested, and we therefore consider it the most appropriate model.

Finally, we did not collect any data about difficulty in removing the placenta, which is suggestive of morbidly adherent placenta and is often associated with uterine atony. Therefore, some cases of PPH listed as uterine atony in our study are probably of mixed aetiology and secondary to a morbidly adherent placenta. However, even when the placenta is difficult to remove, the clinical diagnosis of morbidly adherent placenta remains inexact and imprecise.

Interpretation

Our results are consistent with the results of two reviews of much smaller studies, which report a success rate for balloon tamponade of 84–91.5%.[33,34] They also confirm the preliminary results of our previous evaluation of trends in the invasive procedure rate in our university hospital after IUBT was added as the initial second-line therapy to the protocol for management of severe PPH due to uterine atony unresponsive to sulprostone. The global IUBT success rate in that study of 31 women with vaginal deliveries and 12 with caesareans was 86% (37/43).[32]

Our results highlight one important and modifiable factor associated with IUBT failure: severity of blood loss before IUBT. Because the risk of coagulopathy increases rapidly with blood loss, early IUBT use may prevent its occurrence. This point may explain, at least in part, the better efficacy of the device in women with less severe blood loss before IUBT. Recently, Howard and Grobman also showed that women receiving IUBT at lower estimated blood loss quartiles had higher nadir haemoglobin, fewer transfusions of packed red blood cells, fewer intensive care unit admissions, and fewer hysterectomies.[55] These results and ours reinforce the conclusions of two previous studies that suggested IUBT be deployed earlier in the management of PPH:[32,56] used as a late first-line therapy, with prostaglandin administration, IUBT may be even more effective in preventing the need for blood transfusions, embolisation or a conservative surgical procedure and in avoiding the risks and costs associated with each of these. This hypothesis warrants a trial of its earlier use, especially as in our study no balloons were used prophylactically.

Another important finding of this study is the association between IUBT failure and bleeding that is not at least very substantially responsive to IUBT after 15 minutes. A drawback to introducing an additional step in the management of severe PPH is that it may increase blood loss if it fails. Because the efficacy of IUBT can be assessed rapidly and readily, it has the advantage of avoiding a potential increase in maternal morbidity due to a delay in more invasive PPH management. Moreover, even when it fails to stop PPH, IUBT generally decreases bleeding while awaiting embolisation or surgery.[56]

The elapsed time between PPH diagnosis and balloon insertion, on the other hand, is not reliably associated with IUBT failure. Gradual, slow haemorrhages with a constant trickle of blood and/or bleeding that decreases but persists

because of incomplete response to uterotonic drugs probably explain this negative result.

Interestingly, the risk of IUBT failure was similar and low for the two main causes of PPH—atony and placenta praevia. We therefore think that IUBT should always be attempted in these two main causes of PPH.

We observed the misuse of IUBT in two cases of undiagnosed uterine rupture in women without any history of caesarean delivery; the misdiagnosis delayed appropriate emergency surgery and highlights the importance of careful exploration of the genital tract under anaesthesia for traumatic damage before any IUBT attempt. We do not think that these two cases of uterine ruptures can be attributed to the intrauterine balloon: the insertion of the Bakri balloon in the uterine cavity failed in the first patient and the other Bakri balloon was inflated with only 300 ml in the second patient. Furthermore, severe PPH preceded the IUBT in both women.

Most of the IUBTs in this study used the Bakri balloon because it was the only device specifically designed to manage postpartum uterine bleeding marketed in France in 2008. The ebb balloon became available in France only recently and was used only in the university hospital. In 2014, Dildy et al.[56] reported the data from a post-marketing surveillance study of the ebb device in the US: bleeding decreased or stopped in 50/51 of the women (98%) after balloon placement. Interestingly, nearly one-half (23/51) of those women required uterine balloon volumes of >500 ml to control bleeding. Accordingly, our use might have been suboptimal and resulted in an efficacy rate lower than that potentially possible. This point requires further investigation.

Our series included no women managed with a combination of IUBT and uterine compression sutures in a stepwise approach. Diemert et al.,[42] however, have reported using IUBT with or without B-Lynch sutures in 20 women with severe postpartum haemorrhage. Twelve of them were successfully treated with the balloon alone, and six more with the balloon and the B-Lynch suture. Therefore, a combination of IUBT and uterine compression sutures in a stepwise approach might be an effective option for avoiding postpartum hysterectomy.

Conclusion

In conclusion, we believe that IUBT should be a systematic part of the management protocol for PPH, used before any invasive procedure in PPH due to atony or placenta praevia unresponsive to medical therapy. However, although deployment of IUBT earlier in the management of PPH appears desirable, it is unknown whether it should be implemented as the initial second-line therapy when prostaglandin administration has failed, or even earlier, as the last first-line therapy, together with prostaglandin administration, transforming the vertical algorithm to a horizontal flow. We plan to address this important clinical question by conducting a clinical trial to assess earlier intervention (registered at ClinicalTrials.gov NCT02226731).

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

MR and JC analysed the data. MR and PRo drafted the manuscript. CQ and PRa participated in the interpretation of the results and made suggestions for revisions. EC collected the data. PRo and PRa contributed to the design of the study.

Details of ethics approval

The study and the database were approved by the National Data Protection Authority no. 1295794 (Commission Nationale de l'Informatique et des Libertés), 19 April 2010.

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