Intrauterine balloon tamponade in the management of severe postpartum haemorrhage after vaginal delivery: Is the failure early predictable?

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ABSTRACT

Postpartum haemorrhage (PPH) is one of the leading causes of maternal morbidity and mortality world-wide. The arrival of intrauterine balloon devices has revolutionised PPH management. However, it seems interesting to know the situations of failure to improve the management. The objective is to define the factors related to failure of intrauterine balloon tamponade (IUBT) in women with a postpartum haemorrhage (PPH) after vaginal delivery, and especially blood loss after placement to avoid delaying management.

Retrospective cohort study was conducted in 2 centers. All PPH after vaginal deliveries treated by IUBT were included. Two groups were defined (successes and failures) and compared. Failure was defined as the need of invasive procedure. Calculated area under receiver operating characteristic (ROC) curves and thresholds of bleeding at 10 minutes were also calculated for prediction of failure.

127 women were included. The overall success rate was 78.0% (95% CI 70.7–85.1%). Blood loss at 10 minutes was factor prognostic of early IUBT failure. The ROC curve of blood loss at 10 minutes for prediction of failure of IUBT had an area under the curve of 0.876 (95% CI 0.782–0.970). The predictive positive value of blood loss at 10 minutes were respectively 0.53, 0.8 and 0.94 for blood loss of 100, 200 and 250 ml.

Physicians should be alerted if blood loss are more than 200 ml at 10 minutes after placement of IUBT and considered invasive procedure if more than 250 ml to avoid delaying management of PPH.

KEYWORDS

Postpartum haemorrhage, sulprostone, balloon tamponade, delivery

TEXT

1.Introduction

Postpartum haemorrhage (PPH) is one of the leading causes of maternal morbidity and mortality world-wide (1). It complicates 5 to 10% of births, with severe haemorrhage (loss greater than 1000 ml) affecting 2% (2). In France, as in other developed countries, it is the leading cause of maternal death (16–22%) (3–5).

PPH management is well-described. In the first stage, simple obstetric procedures (such as manual uterine examination, manual removal of the placenta, careful visual assessment of the lower genital tract, and uterine massage) are performed at the same time as medical treatment is provided to improve uterine contraction (most often, oxytocin administration, followed by prostaglandins treatment should the haemorrhage persist) (6). Until the beginning of this century, the failure of this first stage of treatment led to second-line, that is, invasive treatment by uterine artery embolization (7–9) and/or by surgery, depending on the woman's haemodynamic status (10–16). The arrival of intrauterine balloon devices has revolutionised PPH management. Described for the first time in 2001, they have been used in France for more than a decade when sulprostone (E2 prostaglandin) treatment fails (17). Their overall success rate has been estimated between 69 and 91% (18–22). Several comparative studies have showed that intrauterine balloon tamponade (IUBT) enables a significant reduction in the number of invasive treatments (23–26). Different mechanisms may explain this success: direct tamponade of the uterine vessels, especially those of the lower segment, a reduction in the flow level of the uterine arteries because of the balloon's hydrostatic pressure and the uterine response — muscle contraction secondary to inflation of the balloon (27–29). However, the primary predictive factors of an IUBT failure that have been identified to date are coagulopathy, estimated blood loss at balloon insertion, and total blood loss (19,20,30,31). It seems essential to further identify early failure factors of IUBT to avoid delaying invasive treatments that would inevitably result in an increase blood loss. No study has yet clarified the early delay and the volume of blood loss after the insertion of the device in order to consider the IUBT failure.

As a result, the objective of the study was to define the volume of blood loss at 10 mn after the balloon insertion which predicts the IUBT failure after vaginal delivery.

2. Material and methods

2.1Methods

We conducted a retrospective two-centre study (Lille university hospital and Valenciennes hospital) from 1 January 2013 to 30 June 2018.

The study subjects were all women with a PPH after vaginal delivery who had a balloon placed. The study excluded women with caesarean deliveries and those transferred secondarily from other hospitals.

Both hospitals applied the same protocol for PPH management, based upon the Clinical Practice Guidelines issued by the French National College of Gynaecologists and Obstetricians (CNGOF) in 2014 (6). PPH was defined by blood loss more than 500 ml in the first 24 hours. Active management of the third stage of labour by intravenous injection of 5 IU of oxytocin was routinely recommended after each birth, together with the placement of a collection bag to enable accurate quantification of each woman's blood loss. Once PPH was diagnosed, the first actions (manual removal of the placenta, manual uterine examination, and careful visual assessment of the lower genital tract) were taken at the same time as a blood test to assess haemostatic indicators. At the same time, oxytocin was administered at a maximum dose of 35 IU. If bleeding persisted, sulprostone was administered at a dose of 250 micrograms/20 minutes and then 250 micrograms/40 minutes.

The failure of this first stage led to placement of the balloon (Bakri balloon®, Cook Medical, Bloomington, IN, USA and since 2018 in 1 centre, the BTC ESY®, Utah Medical Products, Utah, USA), inflated to 300–500 ml with its position verified by ultrasound. If bleeding continued through the balloon drainage channel after 30 minutes, then the IUBT was considered a failure and either a uterine artery embolisation or a surgical treatment (triple ligation, compression suture or hysterectomy) was immediately performed based on the woman's haemodynamic status.

During the study period and whatever the stage procedure, PPH was considered as controlled if bleeding was less than 50 ml during 10 minutes, active if bleeding was between 50 and 150 ml, and severe if superior than 150 ml.

Two groups of women were defined and compared according to whether the IUBT succeeded or failed. For each group, we collected the characteristics of the women, their labour, delivery, and PPH: blood loss from birth to the start of sulprostone administration and to balloon placement, and the time of those intervals (minutes), total blood loss, nadir haemoglobin level in the 24 hours after delivery, the change (delta) in haemoglobin between the last measurement before delivery and that on D1 or D2, the number of days of postpartum hospitalisation, admission to the intensive care unit, the number of packed red blood cell units transfused, and the doses of

tranexamic acid and fibrinogen administered. The presence of a coagulopathy at balloon placement was defined by prolongation of the APTT, a decrease in PT or fibrinogen, or by thrombocytopenia in the blood samples taken closest to balloon placement.

2.2 Statistics

The quantitative variables were described by their means and standard deviations or by their medians and interquartile intervals. The normality of the distributions was checked graphically as well as by a Shapiro-Wilk test. The categorical variables were described by their frequencies and percentages, and were compared between the two groups using the Chi-square test or the Fisher's exact test if the expected cell frequency was <5. Quantitative variables were compared using Student's t test, or Mann-Whitney U test when the data were not normally distributed.

ROC curve for blood loss 10 mn after IUBT placement was performed to assess the discrimination and to identify a cut-off maximizing positive predictive value (proportion of failures of IUBT when blood loss continued).

Significance was set at 0.05. The statistical analyses were performed with SAS software (version 9.4, SAS Institute, Inc, Cary, NC, USA).

2.3 Details of Ethics Approval

The local committee of the National Data Protection Authority approved this study (CNIL DEC 16-193).

3.Results

During the study period, the two hospitals had 48 890 deliveries: 39 625 (81%) by vaginal delivery and 9265 (19%) by caesarean. The frequency of PPH after vaginal delivery was 8.1% (n=3190 women). The study included 127 (0.3%) women: 82 (64.6%) at centre 1 (Lille) and 45 (35.4%) at centre 2 (Valenciennes) with 123 Bakri balloons and 4 BTC-ESY.

The overall success rate of IUBT was 78.0% (95% CI, 70.7–85.1). Four (3.1%) of the women whose IUBT failed were treated by embolisation, and 24 (18.9%) surgically. Five of the latter finally required an emergency hysterectomy (3.9%) (Figure 1).

There were no significant differences in the characteristics of the mothers and the course of labour (Table 1) between the groups with successful and failed IUBT.

Examination of the management of PPH showed a significantly shorter interval between birth and sulprostone in the failure group (36.5 minutes, IQR 22.0 to 48.0 versus 43.0 min, IQR 30.0 to 70.0; P = 0.041), as well as between birth and balloon placement (60.5 min, IQR 46.5 to 97.5 versus 72.0 min, IQR 50.0 to 137.0; P =0.047). Blood loss at balloon placement was higher, in the failure group but did not reach the significance (1834 ml +/- 541 versus 1661 ml ± 456, P = 0.092) At 10 minutes after balloon placement, estimated blood loss was significantly higher in the failure group (respectively, 293 ml ± 213 versus 47 ml ± 60, P=<0.001) (Table 2). Estimated blood loss at balloon placement was significantly correlated with the total volume of bleeding (Spearman's correlation = 0.78, P<0.001) (Figure 2). We also observed a higher rate of coagulopathy among women who finally received invasive treatments (64.3% versus 21.6%, P = <0.001).

The total volume of bleeding was higher among the women with IUBT failure (3595 ml ± 1425 versus 1917 ml ± 547, P<0.001); they had more units of packed red blood cells transfused (5.0 units, IQR 4.0 to 8.0 versus 2.0 units, IQR 2.0 to 3.0, P<0.001), and a higher dose of fibrinogen (6.0 g, IQR 4.5 to 6.0 versus 3.0 g, IQR 3.0 to 3.0, P<0.001). The rate of ICU transfer was significantly higher among the women for whom IUBT failed (92.9% versus 49.5%, P<0.001) and the total duration of hospitalisation was longer for them (8.0 days, IQR 5.5 to 10.0 versus 5.0 days, IQR 4.0 to 6.0, P<0.001) (Table 3).

The ROC curve of blood loss within 10 minutes to predict the failure of IUBT respectively had an area under the curve of 0.876 (95% CI, 0.782 to 0.970) (figure 3). We tried to define thresholds of blood loss at 10 minutes (table 4); the predictive positive values were respectively 0.53, 0.80 and 0.94 for blood loss of 100, 200 and 250 ml.

4. Discussion

IUBT has revolutionised the management of PPH and reduced the number of invasive procedures. Our cohort confirms the effectiveness of IUBT in the management of PPH, with an overall success rate of 78.0%. The main learning from the study is that clinicians could predict the failure of IUBT in the first 10 minutes after the placement and avoid delaying invasive procedures. A threshold of 200 ml has a positive predictive value of 0.80 and 250ml, one of 0.94. Further to this, the correlation we showed between the estimated blood loss at balloon placement and the total volume of bleeding suggests that the balloon should perhaps be used at an earlier stage.

First, we showed that the extent of bleeding at 10 minutes after balloon insertion made it possible to predict the failure of the IUBT. Wang et al. found greater blood loss after placement in the failure group (1209.58 ml ± 1139.72 ml versus 266.57 ± 361.60; P<0.001) (30). Similarly, Revert et al. showed that bleeding stopped or diminished very strongly 15 minutes after placement in 98.2% of the successful treatments compared with 15.3%

of the failures (P<0.01) (31). The study by CW Kong et al showed that a blood volume <50 ml at 30 minutes after placement was predictive of IUBT success (OR 0.975, 95% CI 0.952–0.998), P=0.034).(20) This factor seems essential for a rapid assessment of the effectiveness of IUBT and an early diagnosis of its failure. That is, it is reasonable to wonder whether balloon insertion delays the decision for invasive treatment in the case of failure by adding a new stage to PPH management that inevitably involves an increase in blood loss. Nonetheless, even when IUBT fails, as Dildy et al. showed, it enables a reduction of blood flow in 98% of cases while awaiting embolisation or surgical treatment (32).

In our series, coagulopathy was also a risk factor for IUBT failure. In a series of 137 cases where balloons were used exclusively in the management of PPH for placenta praevia, the success rate ranged from 20% with coagulopathy to 100% without it (33). Recently, the prospective French cohort of 226 women reported by Revert et al. showed that coagulopathy was a risk factor for IUBT failure, with an OR of 5.6 (95% CI 2.5–13.0)(31). Similarly, other studies have demonstrated that the prognosis for IUBT is poor among women who develop a coagulopathy during a PPH. A retrospective study of 46 women also showed that the fibrinogen level is a predictive factor of IUBT failure, with a predictive threshold of 172.5 mg/dl (P = 0.002) (34). Even if this information is interesting, it does not help clinicians during the management of PPH due to the delay of blood results.

This finding is associated with another prognostic factor well-known in the literature: estimated blood loss. That is, the risk of developing a coagulopathy increases with the volume of bleeding. We have shown that in the failure group the estimated blood loss was higher at balloon placement, although not significantly. The prospective cohort reported by Revert et al. showed that the blood loss estimated before balloon placement (>1500 ml) was a factor predicting failure (OR 3.2, 95% CI 1.5–6.8) (31). The retrospective Chinese study by CW Kong et al. also underlined the importance of early balloon insertion; a lower volume of bleeding at placement (<1400 ml) allowed a significant reduction in the risk of failure (OR 0.997, 95% CI 0.94–0.999)(20). Vintejoux et al. reported a success rate of 100% with early placement, defined by an estimated blood loss at balloon insertion < 1000 ml (19). In a retrospective series of 420 women, Howard et al. showed that the lower the blood loss estimated at balloon placement, the lower the maternal morbidity, with a higher haemoglobin nadir, and fewer units of packed red blood cells transfused, fewer NICU transfers, and fewer hysterectomies(35).

The study of other factors showed that the interval in minutes between birth and sulprostone administration and between birth and balloon placement were significantly shorter in the failure group. These data are discordant

with those in the literature. In the Chinese series reported by Wang et al., the time between birth and balloon placement was higher, albeit not significantly, in the failure group (55.34 ±45.24 versus 38.25 ± 40.63; P = 0.126), like the interval between the PPH diagnosis and balloon placement in the series by Revert et al. (1.7±2.0 versus 1.4 ± 1.2; P= 0.37)(30). Our results might be explained by probable massive haemorrhages with a substantial bleeding volume in a shorter interval in the failure group. These massive haemorrhages are often the most severe and associated with the early onset of coagulopathy.

Finally, concerning the overall success rate, we seem to be in agreement with the literature. Several series have found IUBT success rates ranging from 69% to 91.65% (Table 5) (19,21,30). The study of Georgiou et al. found that the effectiveness of different IUBT techniques for PPH management from 17 series with a total of 106 women; the global success rate was 91.5% (22). In the oldest review, based on 46 observational studies, Doumouchtsis et al. reported that effectiveness was 84% (95% CI 77.5–88.8) (18).

The main strength of the study is the data collection of the estimated blood loss at 10 minutes after balloon placement for PPH following vaginal deliveries. This information could help clinicians in the management of IUBT and avoid delaying invasive treatment that inevitably would involve an increase in blood loss. Moreover, this retrospective cohort came from two centres similar in terms of their practices and their application of the same PPH management protocol. This may nonetheless be a limitation because we were unable to compare these factors by centre because of the limited sample size. Another weakness is the obvious limitations of a retrospective study design in terms of accuracy of data collection, missing data and subtle changes in PPH management over the 5 years the study ran.

5. Conclusion

IUBT is essential and effective in the management of PPH with a global success rate of 77.95% in our cohort. Physicians should be alerted if blood loss are more than 200 ml at 10 minutes after placement of IUBT and considered invasive procedure if more than 250 ml to avoid delaying management of PPH after vaginal delivery. Our study also confirmed that rapid, massive haemorrhages associated with haemostatic disorders appear to predict IUBT failure and that early balloon placement may promote their control. Accordingly, a randomised study of the timing of balloon placement including patients with a PPH after vaginal delivery might be interesting to confirm our results.

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Figure 1 : Flowchart:

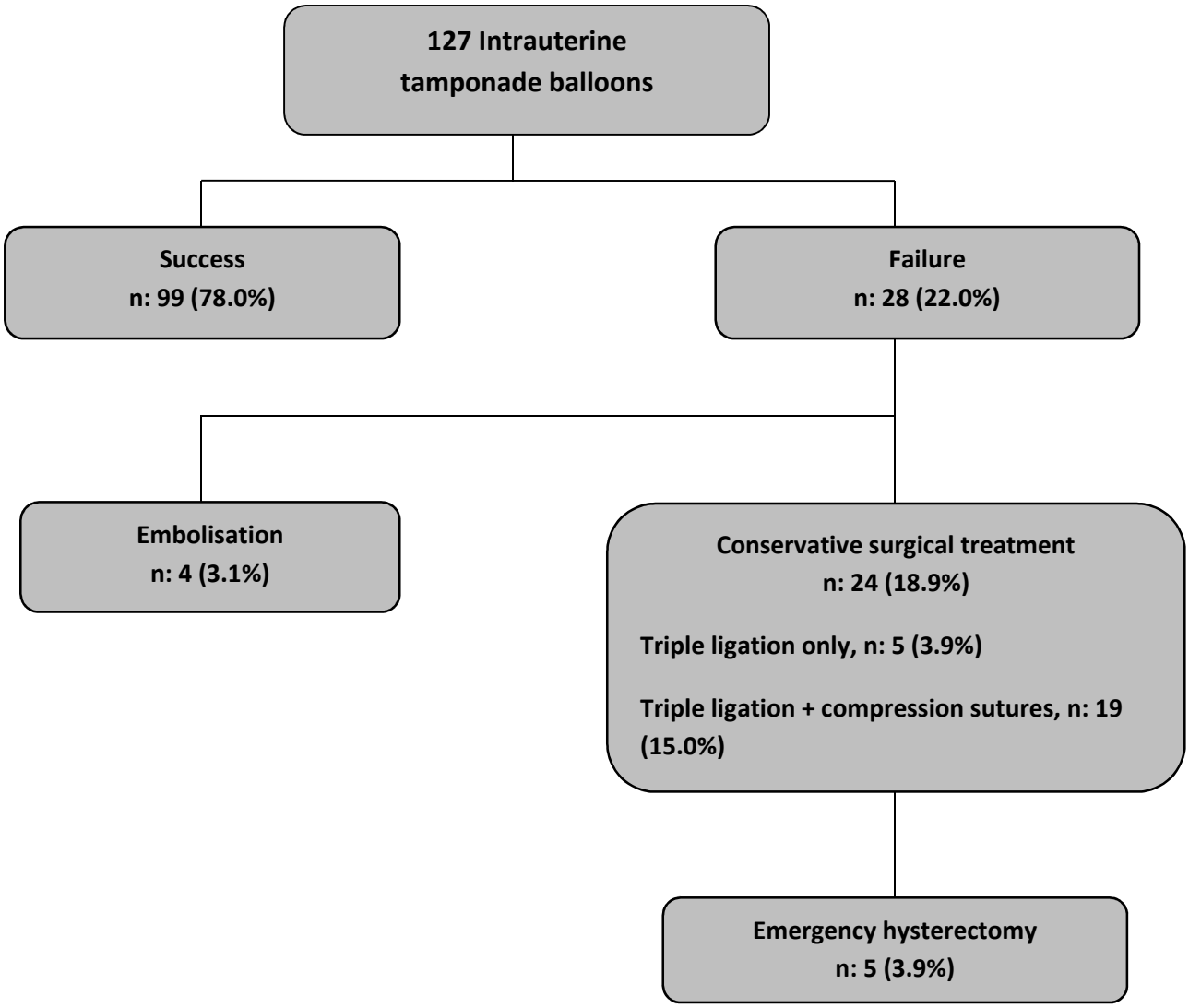

Figure 2 : Correlation between blood loss at balloon placement and total blood loss

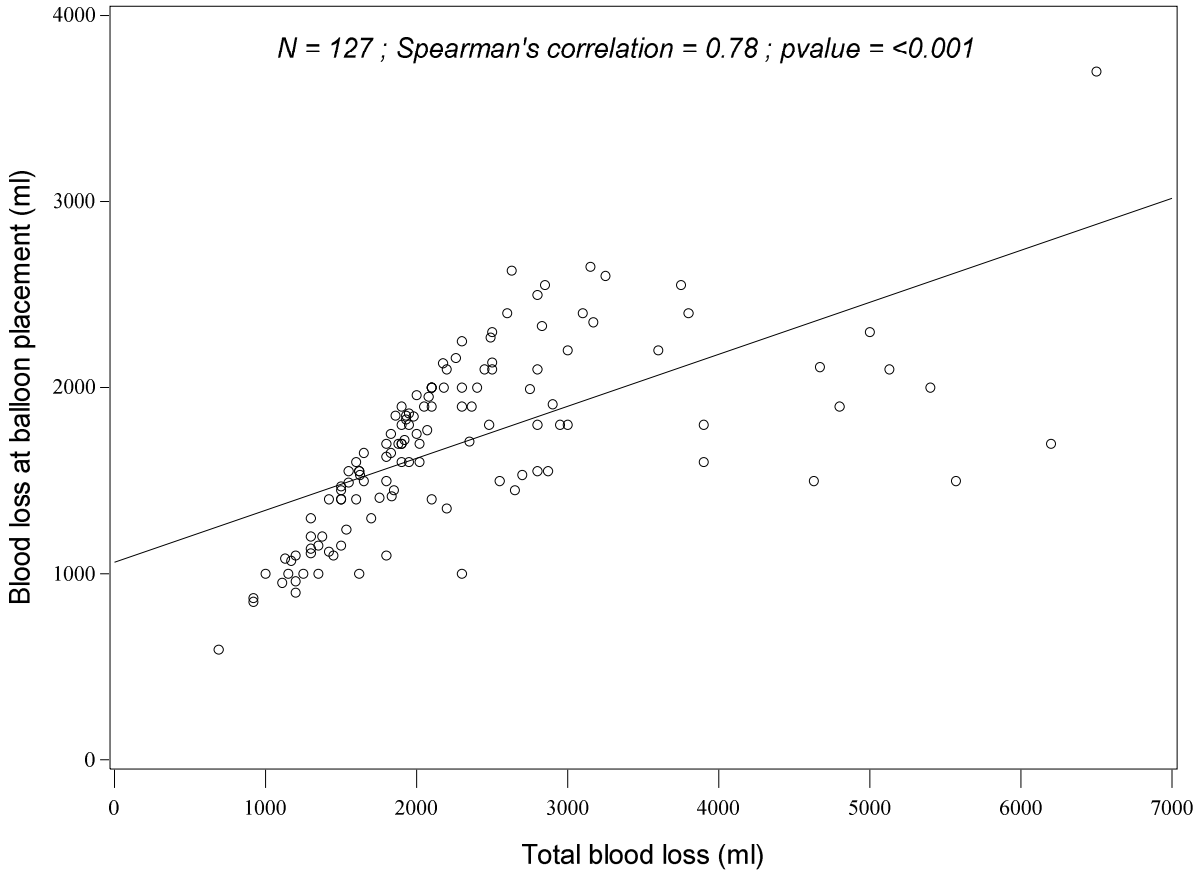

Figure 3 - ROC curve of predictions of blood loss at 10 minutes

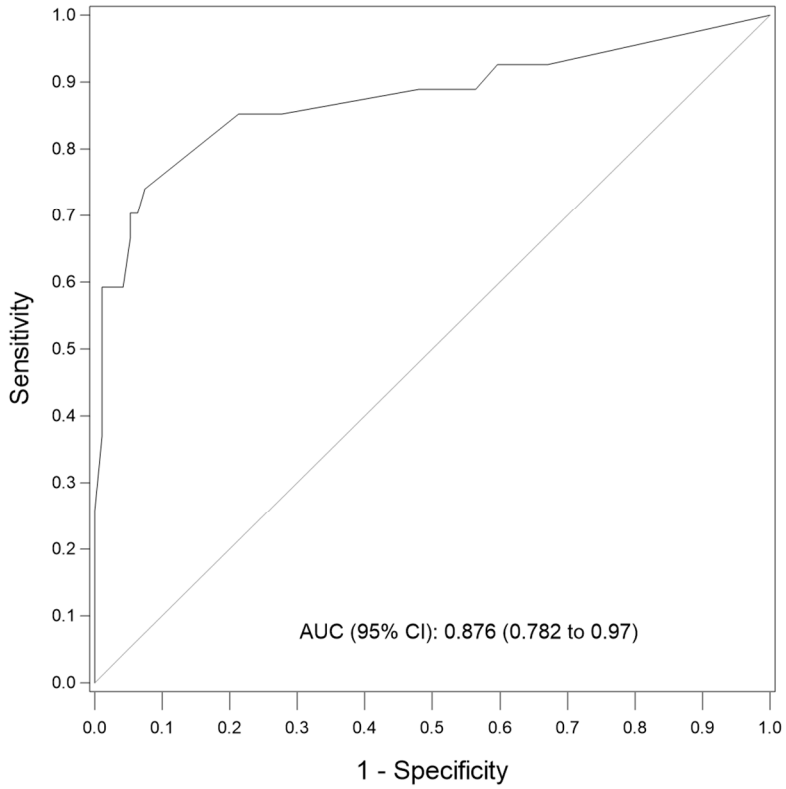

Table 1: Characteristics of patients

Parameters	Success of IUBT N=99	Failure of IUBT N=28	*P* value
Maternal age (years)	29.8 ± 5.3	29.0 ± 6.6	0.50
Body mass index (kg/m²)	23.0 (21.0 ; 27.0)	23.0 (20.5 ; 27.0)	0.80
Nulliparous	33 (33.3)	12 (42.9)	0.35
Gestational age (days)	276.0 (268.0 ; 285.0)	278.0 (268.0 ; 285.0)	0.80
Multiple pregnancy	10 (10.1)	5 (17.9)	0.32
History of PPH	22 (22.2)	4 (14.3)	0.36
Spontaneous labour	76 (76.8)	20 (71.4)	0.56
Oxytocin use during labour	51 (51.5)	13 (46.4)	0.63
Maximum oxytocin dose (mUI/min)	5.0 (2.5 ; 7.5)	7.5 (2.5 ; 7.5)	0.47
Total oxytocin dose (mUI)	975.0 (450.0 ; 2040)	1560 (1013 ; 2100)	0.35
Total duration of labour (minutes)	344.0 (185.0 ; 540.0)	409.5 (120 ; 539.5)	0.63
Duration of latent phase (minutes)	180.0 (60.0 ; 240.0)	150.0 (30.0 ; 300.0)	0.88
Duration of active phase (minutes)	141.0 (65.0 ; 233.0)	209.0 (76.0 ; 376.0)	0.21
Birthweight (grams)	3682 ± 832.2	3836 ± 1187	0.52
Active management of third stage of labour	93 (93.9)	24 (85.7)	0.23

The quantitative data are presented with their means ± standard deviations or medians (1st quartile; 3rd quartile). The qualitative data are presented with N (%).

Table 2: Prognostic factors of IUBT failure

Parameter	Success of IUBT N=99	Failure of IUBT N=28	*P* value
Coagulopathy	21 (21.6)	18 (64.3)	**<0.001**
Interval from birth to sulprostone administration(minutes)	43.0 (30.0; 70.0)	36.5 (22.0 ; 48.0)	**0.041**
Blood loss at start of sulprostone administration(milliliters)	1150 ± 312.9	1281 ± 507.9	0.21
Interval from birth to balloon placement (minutes)	72.0 (50.0; 137.0)	60.5 (46.5; 97.5)	**0.047**
Interval from sulprostone administration to balloon placement (minutes)	24.0 (13.0; 43.0)	20.0 (15.0; 37.5)	0.67
Blood loss at balloon placement (milliliters)	1661 ± 456.2	1834 ± 541.2	0.092
Blood loss at 10 minutes after balloon placement (milliliters)	47.4 ± 60.2	292.8 ± 213.3	**<0.001**
Blood loss at 30 minutes after balloon placement (milliliters)	87.2 ± 128.0	449.3 ± 409.8	**<0.001**

The quantitative data are presented with their means ± standard deviations or medians (1st quartile; 3rd quartile). The qualitative data are presented with N (%).

Table 3 : PPH prognosis according to IUBT success or failure

Parameter	Success of IUBT N=99	Failure of IUBT N=28	*P* value
Total blood loss (milliliters)	1917 ± 547	3595 ± 1425	**<0.001**
Nadir Hb level in the 24 h after delivery (g/dl)	8.2 ± 1.6	7.6 ± 1.6	0.084
Delta Hb >2	70 (72.2)	19 (67.9)	0.55
Total duration of hospitalisation (days)	5.0 (4.0 ; 6.0)	8.0 (5.5 ; 10.0)	**<0.001**
Transfer to ICU	48 (48.5)	26 (92.9)	**<0.001**
Number of packed red blood cell units transfused (n)	2.0 (2.0 ; 3.0)	5.0 (4.0 ; 8.0)	**<0.001**
Dose of tranexamic acid administered (grams)	1.0 (1.0 ; 1.0)	1.0 (1.0 ; 2.0)	0.18
Dose of fibrinogen administered (grams)	3.0 (3.0 ; 3.0)	6.0 (4.5 ; 6.0)	**<0.001**

Delta Hb: difference between the last known Hb level before delivery and that at D1 or D2
The quantitative data are presented with their means ± standard deviations or medians (1st quartile; 3rd quartile). The qualitative data are presented with N (%).

Table 4 – Prediction of failure of IUBT 10 minutes after placement

Blood loss at 10 mn (ml)	Sensitivity	Specificity	PPV	NPV
50	0.89	0.52	0.35	0.94
100	0.85	0.78	0.53	0.95
200	0.59	0.96	0.80	0.89
250	**0.59**	**0.99**	**0.94**	**0.89**
300	0.52	0.99	0.93	0.88
400	0.37	0.99	0.91	0.86

PPV: positive predictive value, NPV: negative predictive value

References	Inclusion period	Global success rate	Success rate in the population of vaginal deliveries	Significant prognostic factors of failure/success
Revert et al	July 2010 – March 2013	83.2% n=226	*88.9% n=171*	Vaginal and caesarean: Factors predictive of failure - blood loss at 15 min after balloon placement *(univariate)* - Blood loss at balloon placement*(multivariate)* - Presence of a coagulopathy *(multivariate)*
C Kong et al	July 2012 – June 2017	72.8% n=81	*83.3% n= 24*	Vaginal and caesarean: Factors predictive of success - Blood loss < 1400 ml at balloon placement *(multivariate)* - Blood loss < 50 ml at 30 min after balloon placement *(multivariate)* Factors predictive of failure: - Presence of a coagulopathy *(multivariate)* - Placenta accreta *(multivariate)*
D.Wang et al	March 2015 – December 2015	91.65% n=407	*89,55% n=67*	Vaginal and caesarean: Factors predictive of failure: - Blood loss at balloon placement*(multivariate)* - Volume injected into the balloon *(univariate)* - Total blood loss after balloon placement *(univariate)*
Vintejoux et al	May 2010 – August 2011	69% n=36	*76.9% n=26*	Vaginal and caesarean: Factor predictive of success - PPH <1000 at balloon placement *(multivariate)*
J. Grange et al	January 2011- December 2015	74.1% n=108	*74.1% n= 108*	Vaginal only: Factors predictive of failure - Obesity with BMI > 30 (*multivariate*) - Total duration of labour (univariate) - Absence of tranexamic acid use *(univariate)* - Blood loss at balloon placement(univariate) - Blood loss >1500 ml at balloon placement (univariate) - Total blood loss after balloon placement *(univariate)*

Table 5: Principal articles in the literature assessing factors predictive of failure