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Research Article

Analysis of Bakri Balloon Tamponade Procedure: A Case Series

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Abstract

Background: Bakri balloon tamponade (BBT) is known to be highly effective in controlling post-partum haemorrhage (PPH) to the tune of 80%, but failures do happen. We planned this study with the aim to investigate the risk factors and possible reasons behind BBT failures.

Materials and methods: We identified all the PPH cases in which BBT was used over a period of 3 years. BBT was used in a total of nineteen cases. Among these 3 patients were in irreversible shock at the time of presentation, so we excluded them from the analysis. Of the remaining 16 cases, there were 10 cases of success and 6 cases of BBT failure.

Results: We found no statistically significant difference between success and failure cases in terms of maternal age, parity, gestational age, onset of labour, mode of delivery, cause of PPH, pre-delivery hemoglobin levels. Mean time lapse between delivery and IUBT insertion in failure cases was 2.41±1.46 hours as compared to 1.28±1.74 hrs in successful cases which was statistically non- significant. Average time between BBT insertion and decision for third line procedure was found to be 1.5 hours which was unacceptably high.

Conclusion: The authors conclude that it is not possible to predict success or failure of the balloon tamponade based on risk factors. The authors suggest that it may be worthwhile to simultaneously shift the patient to operation theatre under the care of senior obstetrician immediately following insertion of BBT with full preparedness for optimal outcome.

Key words: bakri ballon tamponade; bbt failure; maternal near miss; maternal mortality; postpartum hemorrhage

Introduction

Postpartum hemorrhage is the leading cause of maternal mortality worldwide. Bakri balloon therapy (BBT) has emerged as the fertility sparing and minimally invasive second line therapy in cases of postpartum hemorrhage not responding to oxytocic.1 BBT is easy to use and is found to be highly effective in cases of uterine atony with minimal complication rates. High level evidence is lacking regarding the timing of insertion of BBT, protocol followed for insertion of BBT, its deflation and factors predicting failure. [1,2] It is important to anticipate failures in order to be prepared for advanced interventions to curtail maternal morbidity and even mortality. We planned this study with the aim to investigate the risk factors and possible reasons behind BBT success and failures.

Materials and methods

This study is a retrospective case series. We identified all the PPH cases in which BBT was used from the preformed proforma which was filled with the use of BBT over a period of 3 years (September,2019-2023) at our institution. Bakri balloon therapy is the second line intervention for postpartum hemorrhage following failed medical management. Medical and first line conservative management includes administration of oxytocic, tranexamic acid, bimanual uterine compression, removal of retained products of conception and repair of genital trauma. Decision for insertion of BBT and also procedure of insertion was based on duty consultant. Vaginal packing was not used and distal end catheter of BBT was taped to the woman's thigh without applying any weights. Gradual deflation of balloon was done after 24 hours once the women was stable with OT backup. All women were administered broad spectrum antibiotics and foley's catheter was kept in situ for urine output measurement. BBT failure cases were defined as the inability of BBT to control PPH and requiring further surgical intervention.

The inclusion criteria were:

- Failure of the first-line conservative treatment of PPH
- Usage of BBT
- Gestation age ≥28 weeks

BBT was used in a total of nineteen cases. Among these 3 patients were in irreversible shock at the time of presentation, so we excluded them from the analysis.

Of the remaining 16 cases, there were 10 cases of success and 6 cases of BBT failure. These cases were analysed in depth in terms of their demographic profile, parity, mode of delivery, risk factors for PPH, total blood loss and associated co-morbidities to predict the factors responsible for failure.

All data were analysed using SPSS version 23.0. Continuous variables were presented as mean ± standard deviation (SD). Categorical variables were expressed as numbers and percentages. Continuous variables were compared between women with BBT success vs BBT failure. Categorical variables between the two subgroups were compared using the Chi-square Test. In this study, a P-value of <0.05 was considered significant.

Results

The mode of delivery in the study group was vaginal in 87.5% (14/16; one was forceps vaginal delivery) and caesarean in 12.5% (2/16). The most common cause of PPH was uterine atony (68.8%) followed by secondary PPH (25%) and coagulopathy (6.2%). The success rate of BBT in our study was 62.5%. The BBT success and failure cases were compared in terms of demographic details, risk factors for PPH and post PPH outcomes as shown in table 1 and 2. We found no statistically significant difference between success and failure cases in terms of maternal age, parity, gestational age, onset of labour, mode of delivery, cause of PPH, pre-delivery hemoglobin levels and associated co- morbidities. Being unbooked or registered at any facility was found in 30% of success cases and 83% of failure cases and was found to be significant, p=0.0469. Among the post PPH outcomes, number of blood units transfused was found to be statistically significant, p= 0.0307; 5.5±6.20 and 21±19.17 in success and failure cases respectively. Average duration of hospital stay was 5.81±1.77 days in success cases and 11±6.92 days in failure cases and was statistically significant as well (p=0.0374).

PARAMETERS	SUCCESS CASES (10)	FAILURE CASES (6)	p value
Maternal age (years)	28.27±6.88	30.33±4.50	0.5165
Parity	2.36±1.28	2.5±1.8	0.8579
Unbooked at any facility	30%	83%	0.0469
Gestational age (weeks)	36.45±6.54	34.28±7.73	0.5572

Tables 1: Demographic profile details between success and failure cases

PARAMETERS	SUCCESS CASES (10)	FAILURE CASES (6)	p value
Multiple pregnancy	20%	17%	0.8857
Induction/augmentation of labour	40%	33%	0.7862
Mode of delivery(NVD)	90%	67%	0.2680
Pre-delivery haemoglobin (gm%)	9.6±1.4	8.8±2.0	0.3608
Pre-delivery thrombocytopenia (≤ 1 lakh/µl)	40%	83%	0.1042
Pregnancy induced hypertension	20%	67%	0.0689
Atonic PPH	80%	67%	0.5728
Hemoglobin drop post PPH (gm%)	1.4±1.8	3.3±1.6	0.0518
Mean time lapse between PPH and BBT insertion (hours)	1.28±1.74	2.41±1.46	0.2048
Estimated blood loss(ml)	1163.63±361.31	1433.33±314.11	0.1525
Blood transfusion (units)	5.5±6.20	21±19.17	0.0307
ICU/HDU stay (days)	3.31±2.62	7±7.53	0.1722
Total hospital stay	5.81±1.77	11±6.92	0.0374
Maternal mortality	20%	67%	0.0689

Table 2: Risk factors for PPH and Post-PPH outcomes.

Mean time lapse between delivery and IUBT insertion in failure cases was 2.41±1.46 hours as compared to 1.28±1.74 hrs in successful cases which was statistically non- significant.

Among the 6 failure cases, one underwent uterine artery embolization, one was managed with compression sutures and bilateral internal iliac artery ligation and 3 required hysterectomies i.e., 50% rate. One had cardiac arrest before proceeding to hysterectomy. Average time between BBT insertion and decision for third line procedure was found to be 1.5 hours which was unacceptably high. There were 66.6% (4/6) maternal mortalities in these failure cases as compared to 20% (2/10) in cases which were successful.

Discussion

Postpartum hemorrhage is an unpredictable obstetric emergency. Most important is its timely detection and management by the treating obstetrician and her team. Management is etiology dependent. First line management of postpartum hemorrhage includes use of oxytocics and uterine massage, removal of retained products of conception, repair of genital tract laceration or correction of coagulopathy. Second line management includes use of non-invasive method i.e., balloon tamponade or invasive procedure like uterine compression sutures, step wise devascularisation, or emergency hysterectomy. Bakri balloon tamponade is a specially designed intrauterine balloon catheter which was first used in a five-case series of low-lying placenta or cervical pregnancies by Bakri et al. [3] Our case series described the use of BBT in management of PPH which continued despite administration of first line medical management. In cases of failure of conservative management of PPH, hysterectomy is warranted which has its associated morbidities and even mortalities. In a retrospective case series of 19 women conducted by Meliza GW Kong, the overall success rate of BBT was 79% (15/19); two underwent uterine artery embolization and two required hysterectomy.[4] In yet another series of 23 cases of PPH, balloon therapy failed in 3 cases due to improper placement of it owing to technical difficulty. In remaining cases, the success rate was 90%.[5] Our success rate is comparatively less as compared to that mentioned in the literature which could be explained of the fact that our institute is a tertiary referral centre. Majority women in our case series were not booked or registered at any health centre leading to poor antenatal and intranatal care. In a systematic review done by Doumouchtsis et al, the success rates of second line management in cases of PPH were analysed. Success rates of uterine artery embolization, balloon tamponade, uterine compression sutures and iliac artery ligation was 91%, 84%, 92% and 85% respectively.[6] The authors concluded that balloon tamponade was least invasive and most quickly implemented modality as the first step in the management of appropriate cases. Prognostic factors for intrauterine balloon tamponade were studied by Chai Wah Kong et al.[7] Placenta accreta and coagulopathy ($p = 0.048$) were considered adverse prognostic factors. Blood loss less than 1400 ml at the time of insertion of balloon tamponade and positive tamponade test (< 50 ml blood drained in tamponade bag within 30 minutes of insertion) were considered as good prognostic factors. The authors concluded that in presence of adverse prognostic factors or negative tamponade test, early resort to next line procedure should be promptly initiated. In our series, the estimated blood loss in success group was 1163.63±361.31 ml as compared to failure cases in which it was 1433.33 ± 314.11 ml although this was not found to be statistically significant. Average time between BBT insertion and decision for third line procedure was found to be 1.5 hours which was unacceptably high and prognostic factors should be taken care of while using BBT for postpartum haemorrhage. Chai Wah Kong et al, reported one maternal mortality in their study due to severe PPH. In our series, maternal mortality was unexpectedly high. In success group, two maternal deaths were there due to pulmonary embolism and puerperal sepsis. In failure cases, one had cardiac arrest prior to proceeding to hysterectomy. Two women who underwent hysterectomy, one died due to multiple organ dysfunction syndrome and one due to acute fatty liver of pregnancy (confirmed by post-mortem liver biopsy). One another case was the one who underwent uterine artery embolization, but succumbed on postpartum day [4] with a diagnosis of pulmonary embolism. As per the case series and systematic review done by Francisco Javier et al, various factors like maternal age, caesarean delivery, curettage before insertion of BBT and transfusion of > [7] red blood cell units were identified as significant and independent variables behind BBT failure. [8] We observed in our study as well that failure cases were associated with significantly more units of blood transfusion as compared to successful cases (blood units transfused was found to be statistically significant, $p= 0.0307$; 5.5±6.20 and 21±19.17 in success and failure cases respectively). This can be explained by the fact that if there is a delay in initiating management of PPH, loss of excessive blood may lead to coagulopathy which in turn can be the cause of BBT failure. There is strong evidence to suggest high possibility of BBT failure if mean time lapse between onset of hemorrhage to insertion of BBT is more.[9] We in our study found mean time lapse between onset of PPH to BBT insertion to be 1.28±1.74 hours for success group and 2.41±1.46 hours in failure group which was higher but was not statistically significant. Puerperal hysterectomy rates ranged from 6.5% by Francisco Javier et al to 50% by Danisman et al and in our series also in failure cases we retorted to hysterectomy in 50% cases. [8,10] The wide variation in hysterectomy rates is based on the availability of intervention radiology in the facility for uterine artery embolization.

Ours is one of its kind of study in which the success and failure cases of BBT are compared, although we were unable to come to a definitive conclusion regarding the prognostic factors for successful use of BBT owing to small sample size. The major limitation of our study is its retrospective nature and we plan to carry out prospective study in future.

Conclusion

The authors conclude that it is not possible to predict success or failure of the balloon tamponade based on risk factors. Also, precious time is wasted on moving to the next line of management after balloon tamponade failure which results in increased morbidity and mortality in these patients. The authors suggest that it may be worthwhile to simultaneously shift the patient to operation theatre under the care of senior obstetrician immediately following insertion of BBT with full preparedness. This will ensure optimal resuscitation of the patient as well as prompt action in case of earliest evidence of failure of BBT. However, more robust studies are needed before any recommendations may be made.

Conflict of interest: None

Research involving Human participants/animals- Quality improvement project

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