OBSTETRICS

Initial experience with a dual-balloon catheter for the management of postpartum hemorrhage

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OBJECTIVE: When uterotonics fail to cause sustained uterine contractions and satisfactory control of hemorrhage after delivery, tamponade of the uterus can be effective in decreasing hemorrhage secondary to uterine atony.

STUDY DESIGN: These data are from a postmarketing surveillance study of a novel dual-balloon catheter tamponade device, the Belfort-Dildy Obstetrical Tamponade System (ebb).

RESULTS: A total of 57 women were enrolled: 55 women had the diagnosis of postpartum hemorrhage, and 51 women had uterine balloon placement within the uterine cavity. This study reports the outcomes in the 51 women who had uterine balloon placement within the uterine cavity for treatment of postpartum hemorrhage, as defined by the "Instructions for Use." We further assessed 4 subgroups: uterine atony only (n = 28 women), placentation abnormalities (n = 8 women), both uterine atony and placentation abnormalities (n = 9 women), and neither uterine atony nor placentation abnormalities (n = 6 women). The median (range) time interval between delivery and balloon placement was 2.2 hours (0.3–210 hours) for the entire cohort (n = 51 women) and 1.3 hours (0.5–7.0 hours) for the uterine atony only group (n = 28 women). Bleeding decreased in 22/51 of cases (43%), stopped in 28/51 of cases (55%), thus decreased or stopped in 50/51 of the cases (98%) after balloon placement. Nearly one-half (23/51) of all women required uterine balloon volumes of >500 mL to control bleeding.

CONCLUSION: We conclude that uterine/vaginal balloon tamponade is very useful in the management of postpartum hemorrhage because of uterine atony and abnormal placentation.

Key words: abnormal placentation, balloon tamponade, postpartum hemorrhage, uterine atony

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Postpartum hemorrhage (PPH) remains one of the most common causes of maternal death and serious morbidity in both developed and developing nations.[1,2] Uterine atony, the most common cause of PPH, is managed initially by medical therapy with a variety of uterotonic agents. According to the 2006 American College of Obstetricians and Gynecologists *Postpartum Hemorrhage* Practice Bulletin, "When uterotonics fail to cause sustained uterine contractions and satisfactory control of hemorrhage after vaginal delivery, tamponade of the uterus can be effective in decreasing hemorrhage secondary to uterine atony."[3] The purpose of this report is to describe our initial clinical experience with a novel dual-balloon catheter tamponade device that was designed for the management of PPH in both vaginal and cesarean delivery.

Materials and Methods

In April of 2010, a dual-balloon tamponade catheter, the Belfort-Dildy Obstetrical Tamponade System (BD-OTS), trade-named "ebb" (Glenveigh Medical, LLC, Chattanooga, TN), received clearance by the Food and Drug Administration for use in the provision of temporary control or reduction of postpartum bleeding. The description of the device is summarized in the Figure.

This report is from a postmarketing surveillance study of BD-OTS cases from 20 clinical sites in the United States (Acknowledgments). A local study

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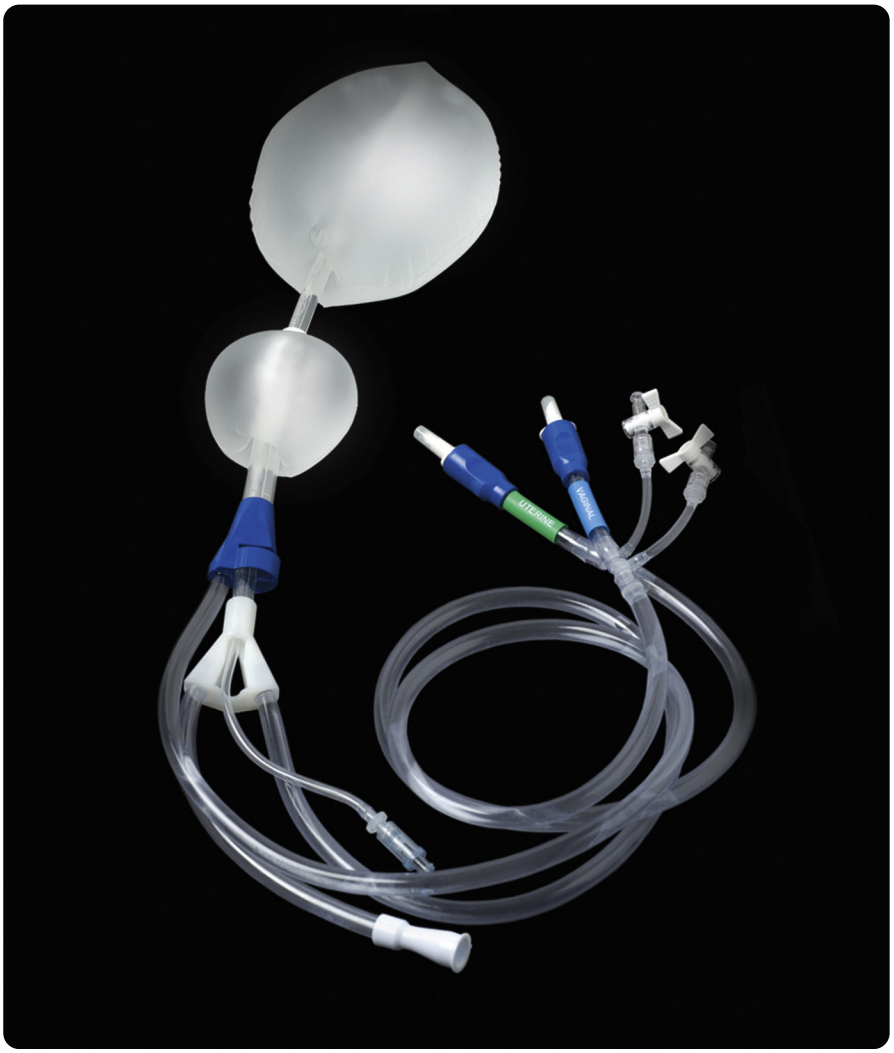
FIGURE
The Belfort-Dildy Obstetrical Tamponade System



The sterile single-use dual-balloon tamponade catheter trade-named "ebb" (Glenveigh Medical, Chattanooga, TN), also referred to as the Belfort-Dildy Obstetrical Tamponade System, features an upper uterine balloon (maximum recommended fill volume 750 mL) and a lower vaginal balloon (maximum recommended fill volume 300 mL). Each balloon can be filled easily by attaching an intravenous fluid bag to the in-line "spike" and manually filling the balloon by squeezing the intravenous bag that contains isotonic solution in increments that start at 250 mL; the volume is increased gradually until tamponade is achieved. Each balloon can be moved independently of each other to accommodate maternal anatomy properly. A third port allows for irrigation above the uterine balloon, and a central drain allows for monitoring of possible ongoing or recurrent hemorrhage from above the uterine balloon. Each balloon can be rapidly or gradually deflated in an independent fashion. Image provided by Glenveigh Medical.

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coordinator completed a case report form after each case was concluded. Data were obtained from the hospital medical record and by interview with the involved clinicians. All case report form data that included questions regarding efficacy were addressed by the local study coordinators (and not by the manufacturer).

The study protocol was approved by an investigational review board at each site. The study was registered with ClinicalTrials.gov (NCT01198652), and informed consent requirements (eg, written, verbal) from each of the respective investigational review boards were satisfied for all subjects. The purpose of the study was to assess the overall benefit and safety of the BD-OTS in actual clinical practice. Distribution data are reported as median (range) values and proportions; statistical calculations were performed with SAS software (version 9.2; SAS Institute Inc, Cary, NC).

RESULTS

The study was initiated in September 2010 and was discontinued in October 2012 after enrollment of 57 cases. Case data were collected and submitted by 11 of the participating 20 sites. Of the 57 women enrolled, 55 women had the diagnosis of PPH, and 2 women had other diagnoses and indications (1 catheter was used as PPH prophylaxis in a patient who received anticoagulation; 1 catheter was used for a vaginal cuff surgical procedure in a 59-year-old woman 30 days after hysterectomy with placement via a colpotomy). Of the 55 women with PPH, the uterine balloon was placed within the uterine cavity in 51 cases and was not inserted in the uterus in 4 cases (1 case was a catheter that was placed as a pelvic pressure pack after hysterectomy for PPH; 1 case was a failed insertion in a 16-year-old patient with PPH 12 hours after delivery; 1 case was a vaginal placement of the uterine balloon after hysterectomy for PPH to facilitate vaginal cuff repair; and 1 case was for PPH from vaginal lacerations whereby the uterine balloon was inflated in the vagina and the vaginal balloon was inflated externally).

The study population described herein includes the 51 women with a diagnosis of PPH who had the BD-OTS placed according to product labeling (ie, uterine balloon inflated in the uterus) and is summarized in the Table. Median (range) maternal age was 33 years (19–47 years); 15 women (29%) were primigravid; 12 pregnancies (24%) were twin gestations; the estimated median gestational age at delivery was 38.4 weeks (22.0-42.0 weeks), and 23 pregnancies (45%) were delivered by cesarean section. The most common causes of PPH were uterine atony (73%) and abnormal placentation

TABLE

Demographic and clinical characteristics of the complete study population (n = 51)

Variable	All (n = 51)	Uterine atony (n = 28)	Placentation (n = 8)	Both atony and placentation (n = 9)	Neither atony nor placentation (n = 6)
Maternal age, y[a]	33 (19–47)	33 (19–47)	32 (24–39)	33 (22–45)	34 (23–40)
Primigravid, n (%)	15 (29)	8 (29)	2 (25)	4 (44)	1 (17)
Twins, n (%)	12 (24)	7 (25)	1 (13)	3 (33)	1 (17)
Estimated gestational age at delivery, wk[a]	38.4 (22.0–42.0)	38.8 (34.9–40.7)	36.7 (22.0–42.0)	37.3 (34.7–42.0)	38.8 (36.4–40.0)
Cesarean delivery, n (%)	23 (45)	14 (50)	3 (38)	4 (44)	2 (33)
≥2 uterotonic agents, n (%)	46 (90)	27 (96)	6 (75)	7 (78)	6 (100)
Time from delivery to balloon insertion, h[a]	2.2 (0.3–210)	1.3 (0.5–7.0)	3.0 (0.3–210)	3.0 (1.1–168)	1.5 (0.8–4.1)
Ultrasound-guided balloon placement, n (%)	42 (82)	26 (93)	4 (50)	8 (89)	4 (67)
Vaginal balloon inflated, n (%)	46 (90)	26 (93)	6 (75)	8 (89)	6 (100)
Uterine balloon volume, mL[a]	500 (180–800)	500 (180–750)	675 (400–800)	640 (450–750)	488 (280–500)
Vaginal balloon volume, mL[a]	200 (100–400)	200 (100–400)	263 (150–300)	200 (100–300)	195 (150–300)
Duration of balloon use, h[a]	20.3 (0.3–35)	18.8 (1.0–35.0)	16.6 (0.3–27.0)	24.0 (5.8–30.7)	12.6 (2.0–22.8)
Bleeding stopped after balloon insertion, n (%)	28 (55)	16 (57)	4 (50)	2 (22)	6 (100)
Bleeding decreased or stopped after balloon insertion, n (%)	50 (98)	28 (100)	7 (88)	9 (100)	6 (100)
Surgical procedures before balloon insertion, n	19	7	4	7	1
Surgical procedures after balloon insertion, n	11	7	2	2	0
Hysterectomy after balloon insertion, n (%)	4 (8)	2 (7)	1 (13)	1 (11)	0 (0)
Estimated blood loss, mL[a]	2000 (855–8700)	2000 (855–8700)	2375 (1000–4500)	2300 (1500–3540)	1500 (1200–1950)
Red blood cell transfusion, n (%)	39 (77)	19 (68)	8 (100)	9 (100)	3 (50)
Red blood cell units transfused, n[a]	3 (1–17)	3 (2–17)	3 (2–12)	3 (1–6)	2 (2–4)
Intensive care unit admission, n (%)	12 (24)	6 (21)	4 (50)	1 (11)	1 (17)

Includes the 4 sub-groups of patients experiencing severe postpartum hemorrhage managed with a double balloon catheter.

[a] Data are presented as median (range).

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(33%); some women had multiple causes. Uterotonic agents were used in 50 cases (98%), with 46 women (90%) requiring ≥2 agents. Specific agents that were used included oxytocin for 47 women (94%), misoprostol for 42 women (84%), carboprost for 36 women (72%), and methylergonovine for 22 women (44%). Before BD-OTS insertion, 18 women (35%) underwent surgical interventions that included occlusive suture (n = 1), surgical repair (n = 2), uterine artery embolization (n = 1), and other (n = 15), which predominantly constituted uterine curettage.

The median (range) time interval between delivery and balloon insertion was 2.2 hours (0.3−210 hours). Insertion under ultrasound guidance was performed in 42 of 51 cases (82%). The vaginal balloon was inflated in 46 cases (90%). The median fill volumes for the uterine balloon and vaginal balloon were 500 mL (180-800 mL) and 200 mL (100-400 mL), respectively. Uterine fill volume was <500 mL in 15 cases (30%), 500 mL in 13 cases (25%), and >500 mL in 23 cases (45%). Median duration of use was 20.3 hours (0.3-35 hours).

After resolution of the PPH, the clinical investigators were asked by the study coordinator whether, at the clinically optimal balloon volume, did bleeding increase, not change, decrease, or stop? The investigators judged bleeding to be decreased in 22 cases (43%), stopped in 28 cases (55%), and thus decreased or stopped in 50 cases (98%). The clinical investigators were able to monitor for ongoing bleeding by way of the drainage port located above the uterine balloon. After placement of the BD-OTS, 8 patients underwent surgical interventions that included hysterectomy (n = 4), surgical repair (n = 3), and uterine artery embolization (n = 4); some patients had multiple surgical procedures. Median estimated blood loss was 2000 mL (855-8700 mL); 39 women (77%) received packed red blood cell transfusion of a median of 3 units (1-17 units). Intensive care unit admission was required in 12 cases (24%).

No serious adverse events that potentially were attributable to the BD-OTS were reported. One uterine rupture was reported, but this event was not attributed by the clinical investigator to the BD-OTS because it was judged most likely to have been present before the use of the BD-OTS; furthermore, the BD-OTS was placed after unsuccessful placement of another commercially available tamponade balloon.

We also looked at demographic and outcome variables (Table) in the 4 subpopulations of our cohort: uterine atony alone (n = 28), abnormal placentation alone (n = 8), both uterine atony and abnormal placentation (n = 9), and neither uterine atony nor abnormal placentation (n = 6). The abnormal placentation group consisted of retained placenta, placenta previa, and placenta accreta. The "neither uterine atony nor abnormal placentation" group included several cases of genital tract lacerations, which we suspect was composed primarily of undocumented cases of uterine atony or abnormal placentation. Although group size was small for the latter 3 groups (which precluded meaningful statistical analysis), it is worth noting that the combination of uterine atony and abnormal placentation appears to be associated more with primigravidity, twins, a longer time interval between delivery and balloon insertion, a longer duration of balloon use, and a higher number of surgical procedures before balloon placement.

Comment

Contemporary Canadian,[4] British,[5] and American[3] obstetrics society guidelines recommend consideration of uterine tamponade before other surgical interventions in cases of PPH that are recalcitrant to medical therapy. Options for balloon tamponade include the Foley catheter,[6] Sengstaken-Blakemore tube,[7] Rusch urologic balloon,[8] Bakri Postpartum Balloon (Cook Medical, Spencer, IN),[9] condom catheter,[10] and the BT-Cath (Utah Medical Products Inc, Midvale, UT). The Bakri and BT-Cath single-balloon devices were designed for obstetrics use and have a maximum fill volume for the intrauterine balloon of 500 mL. In 25% of BD-OTS cases in this series, uterine balloon fill volume was 500 mL; in 45% of cases, the clinically effective uterine balloon fill volume exceeded 500 mL. The vaginal balloon, which was inflated in 90% of cases in our series, appears to be useful in anchoring the device such that the uterine balloon is not expelled and eliminates the need to introduce a vaginal pack to maintain intrauterine balloon placement. Furthermore, the integrated vaginal balloon mitigates the risk of foreign body retention and its attendant complications. Previous work with pulse Doppler ultrasound scanning during development of the BD-OTS showed that uterine artery diastolic blood flow was reversed at a uterine balloon fill volume of 1000 mL, which likely resulted in the reduction of perfusion at the distal uterine vascular tree.[11] Given that the predelivery uterine volume usually exceeds 500 mL by at least 1 order of magnitude, it is not surprising that a tamponade volume of >500 mL may be required to effect hemostasis, especially in an atonic uterus.

Most cases in this study involved severe PPH, which was evidenced by a median estimated blood loss of 2000 mL, the use of multiple uterotonic medications in 46 of 51 cases (90%), transfusion of packed red blood cells in 39 cases (77%), and intensive care unit admission in 12 cases (24%). Nineteen operative/embolization procedures were performed before the insertion of the BD-OTS, which is further indicative of the severity of degree of PPH and the potential ultimately for more undesirable interventions such as hysterectomy.

Several practical lessons were learned from this initial experience: (1) in 45% of cases of PPH caused by uterine atony or abnormal placentation, uterine balloon volumes of >500 mL were required to achieve control of bleeding. (2) The vaginal balloon is useful in anchoring the uterine balloon in place; we noted that, in several cases, the vaginal balloon was inflated before the uterine balloon (contrary to the "Instructions for Use") and that some clinicians preferred this practice. (3) We believe that, in many of these cases, the use of the BD-OTS earlier in the course of PPH would have reduced the number of surgical interventions (which occurred before balloon placement) and a need for massive blood transfusion. These observations suggest

that, rather than using multiple agents and following expectant management, perhaps clinicians should consider moving the tamponade technique earlier into the treatment cascade. It is plausible that tamponade, when implemented at the time of prostaglandin administration (ie, as second line therapy, rather than as a third line therapy or "last ditch effort"), may result in a subsequent reduction in expensive operative therapies and blood transfusions and improve maternal outcomes. Supporting this concept, a large French before-and-after study (n = 23,863 deliveries) in which balloon tamponade was introduced into the PPH protocol concluded that, rather than saving balloon use for therapy later in the cascade of PPH management, its incorporation as a primary adjunctive therapy to uterotonics might further improve patient outcomes.[12] We have planned to address this important clinical question by conducting a clinical trial to assess earlier intervention.

This report on the BD-OTS is the largest published series to date of a single type of uterine tamponade device for the management of PPH. The 7th Annual Report of the Scottish Confidential Audit of Severe Maternal Morbidity[13] concluded that a variety of unspecified tamponade balloon devices successfully avoided hysterectomy in 50 of 57 cases (88%) of severe PPH during calendar year 2009. In our series of severe PPH cases, the use of the BD-OTS avoided hysterectomy in 47 of 51 cases (92%), which is quite similar to the Scottish national experience. The aforementioned French study reported the success rate for the Bakri balloon in 37 of 43 of severe PPH cases (86%).[12] Several systematic reviews of balloon tamponade report similarly high success rates (84% and 92%) for management of PPH.[14,15]

In our series of 51 cases of PPH in which the uterine balloon was inflated within the uterus, 17 of these cases involved abnormal placentation that was defined as placenta previa, retained placenta, or placenta accreta. Because this was a postmarketing surveillance study, we did not have access to further details regarding abnormal placentation and degree of suspected placental accretism. We suspect many of these cases involved focal accretas and do not know yet the appropriateness of this device for the management of more severe degrees of the morbidly adherent placenta. We do not advise the use of this device in lieu of hysterectomy when a large amount of placenta is adherent to the uterus.

In the overall study population, 23 of 51 patients (45%) experienced cesarean delivery. The "Instructions for Use" provide recommendations for these circumstances. Importantly, we know that the hysterotomy incision should be closed before the device is placed and that the device should be placed by ultrasound guidance if the abdomen is already closed or by direct visualization and palpation if it is placed during laparotomy.

Maternal death from PPH has been judged to be preventable in most cases.[1,16,17] Early recognition of bleeding and prompt use of available resources are paramount to the optimization of the outcome. We conclude that uterine tamponade is very useful in the management of PPH because of uterine atony and abnormal placentation. Future studies should look towards the implementation of this resource earlier in the management scheme of PPH, when initial uterotonic therapy is not immediately effective, or perhaps even concurrently with the decision to administer any uterotonic agent beyond oxytocin. ■

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