

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.

Cite this article as: Dildy GA, Belfort MA, Adair CD, et al. Initial experience with a dual-balloon catheter for the management of postpartum hemorrhage. *Am J Obstet Gynecol* 2014;210:136.e1-6.

BACKGROUND AND OBJECTIVE

Postpartum hemorrhage (PPH) remains one of the most common causes of maternal death and serious morbidity in developed and developing nations. Uterine atony, the most common cause, is managed initially by medical therapy via uterotonic agents.

The purpose of this report was to describe our initial clinical experience

with a novel dual-balloon catheter tamponade device that was designed for the management of PPH in vaginal and cesarean delivery.

MATERIALS AND METHODS

In April 2010, a dual-balloon tamponade catheter, the Belfort-Dildy Obstetrical Tamponade System (BD-OTS; trade-named "ebb"; [Figure](#)), received Food and

Drug Administration clearance for use in the provision of temporary control of postpartum bleeding.

This report is from a postmarketing surveillance study of BD-OTS cases from 20 clinical sites in the United States. A local study coordinator completed a case report form after each case was concluded. Data were obtained from the hospital medical record and by interviewing the clinicians. All case report form data, including questions regarding efficacy, were addressed by local study coordinators.

RESULTS

Cases were submitted by 11 of the participating 20 sites. During the study period, September 2010 through October 2012, 57 cases were enrolled.

The study population included 51 women with PPH in whom the BD-OTS was placed according to the product label (ie, uterine balloon inflated in the uterus). Median (range) maternal age was 33 years (19–47 years). Of the 51 women, 15 (29%) were primigravid, and 12 (24%) had twin gestation. The estimated median gestational age at delivery was 38.4 weeks

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Supported by Glenveigh Medical.

G.A.D. and M.A.B. are the inventors and patent holders of the medical device described in this article. C.D.A. is Chairman and CSO of Glenveigh Medical, LLC, and its wholly owned subsidiary, Glenveigh Surgical, LLC (collectively, Glenveigh Medical), which is the manufacturer of the medical device described in this article. The remaining authors report no conflict of interest.

Presented at the 20th FIGO World Congress of Gynecology and Obstetrics, Rome, Italy, Oct. 7–12, 2012.

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(22.0–42.0 weeks); 23 women (45%) were delivered by cesarean section.

The most common causes of PPH were uterine atony (73%) and abnormal placentation (33%). Uterotonic agents were used in 50 cases (98%); 46 cases (90%) required ≥ 2 agents. Specific agents that were used included oxytocin 47 cases (94%), misoprostol 42 cases (84%), carboprost 36 cases (72%), and methylergonovine 22 cases (44%). Before BD-OTS insertion, 18 patients (35%) underwent surgical intervention.

The median time interval between delivery and balloon insertion was 2.2 hours (0.3-210 hours). Insertion under ultrasound guidance was performed in 42 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).

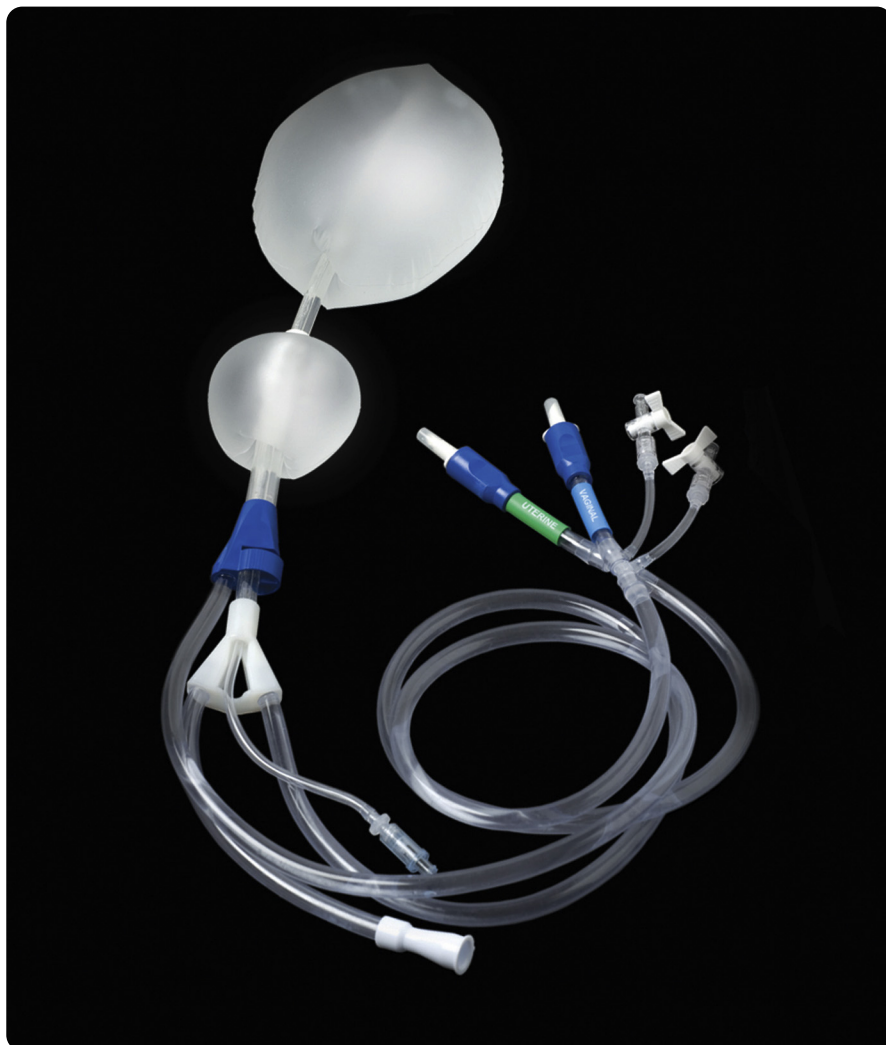
Bleeding was decreased in 22 cases (43%), stopped in 28 cases (55%), and thus decreased or stopped in 50 cases (98%). Median estimated blood loss was 2000 mL (855-8700 mL); 39 women (77%) received packed red blood cell transfusion of a median of 3 units (1-17 units). Intensive care unit admission was required in 12 cases (24%).

COMMENT

Canadian, British, and American obstetrics society guidelines recommend consideration of uterine tamponade in cases of PPH recalcitrant to medical therapy before other surgical intervention is attempted. 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, which obviates the introduction of a vaginal pack to maintain intrauterine balloon placement. Furthermore, the integrated

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.

Dildy. Dual-balloon tamponade catheter for PPH. Am J Obstet Gynecol 2014.

vaginal balloon mitigates the risk of foreign body retention and attendant complications.

Practical lessons were learned from this initial experience: (1) In 45% of cases of PPH because of uterine atony or

abnormal placentation, uterine balloon volumes > 500 mL are required to achieve control of bleeding. (2) The vaginal balloon is useful in anchoring the uterine balloon in place; in several cases, clinicians preferred that the vaginal balloon

was inflated before the uterine balloon (contrary to “Instructions for Use”). (3) We believe that, in many cases, the use of the BD-OTS earlier in the course of PPH would have reduced the number of surgical interventions before balloon placement and the need for massive blood transfusion. Rather than using multiple agents and following expectant management, clinicians might consider moving the tamponade technique earlier in the treatment cascade.

This is the largest published series of a single type of uterine tamponade device for managing PPH. The use of the BD-OTS avoided hysterectomy in 47 of 51 cases (92%). Several other studies and systematic reviews of balloon tamponade have reported similarly high success rates.

In the overall study population, 23 patients (45%) delivered by cesarean section. The “Instructions for Use” provides recommendations for these

circumstances. The hysterotomy incision should be closed before the device is placed, and 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 preventable in most cases. Early recognition of bleeding and the prompt use of available resources are paramount to optimization of the outcome. We conclude that uterine tamponade is useful in the management of PPH caused by uterine atony and abnormal placentation. Future studies should look toward the implementation of this resource earlier in the management scheme of PPH, when initial uterotonic therapy is not immediately effective, or perhaps concurrently with the decision to administer any uterotonic agent beyond oxytocin.

CLINICAL IMPLICATIONS

- Success rates were high for balloon tamponade to control postpartum hemorrhage (PPH) because of uterine atony and abnormal placentation, thus avoiding hysterectomy.
- Uterine tamponade should be considered for PPH recalcitrant to medical therapy before any other surgical intervention is attempted.
- The vaginal balloon appears to be useful in anchoring the device such that the uterine balloon is not expelled, while it obviates the introduction of a vaginal pack to maintain intrauterine balloon placement.
- Intrauterine tamponade volume >500 mL may be required to effect hemostasis, especially in the atonic uterus.
- Future research should focus on the use of tamponade techniques earlier in the PPH treatment algorithm. ■

High-risk human papillomavirus at entry to prenatal care and risk of preeclampsia

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OBJECTIVE: To determine the association between high-risk human papillomavirus (HR-HPV) and preeclampsia.

METHODS: Retrospective cohort study of women with HR-HPV at entry to prenatal care compared with those with at least 2 normal pap smears. Preeclampsia was defined by clinical guidelines. Unadjusted and adjusted analyses were performed.

RESULTS: Three hundred fourteen women with HR-HPV matched with 628 women with normal pap smears. Exposed HR-HPV patients were younger, had lower body mass index, systolic and diastolic blood

pressure at entry to care, and more likely to be nulliparous and smokers. Exposed HR-HPV patients were more likely to develop preeclampsia (10.19% vs 4.94%; $P = .004$; adjusted odds ratio, 2.18; 95% confidence interval, 1.31–3.65). Women with HR-HPV were also more likely to deliver prematurely at less than 37 and less than 35 weeks.

CONCLUSION: HR-HPV is associated with an almost 2-fold increased risk of developing preeclampsia. This warrants a larger study, particularly when HPV infection can be prevented with vaccination.

Cite this article as: McDonnold M, Dunn H, Hester A, et al. High risk human papillomavirus at entry to prenatal care and risk of preeclampsia. *Am J Obstet Gynecol* 2014;210:138.e1-5.

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The authors report no conflict of interest.

Presented in oral format at the 33rd annual meeting of the Society for Maternal-Fetal Medicine, San Francisco, CA, Feb. 11-16, 2013.

0002-9378/free • © 2014 Mosby, Inc. All rights reserved. • <http://dx.doi.org/10.1016/j.ajog.2013.09.040>

BACKGROUND AND OBJECTIVE

Human papillomavirus (HPV) affects up to 80% of women in their lifetime. In pregnancy, infection of the placenta is possible and trophoblast cells appear to have the machinery for HPV replication.