Hospitalists Serve a Vital Role in Implementing Life-saving Device
A Protocol for Patient Safety: The Ebb Balloon Trial at North Austin Medical Center

Written and contributed by Brian Monks, MD, Medical Director of Practice Development with Ob Hospitalist Group

In 2011, the Women's Center of Texas within the North Austin Medical Center (NAMC) in Austin, TX, adopted a new postpartum hemorrhage (PPH) protocol to increase patient safety for OB patients with this life-threatening complication. The protocol required the clinical intervention of both Ob Hospitalist Group (OBHG) hospitalists and Maternal Fetal Medicine physicians in cases of severe PPH (>1500 cc for OBHG hospitalists and >2000 cc for MFMs). A component of the protocol also called for the consideration of non-medicinal/non-surgical methods to control the bleeding in properly selected patients. One such method was the Ebb intrauterine tamponade balloon. This device had been recently designed and manufactured by Glenveigh Medical® and it was being evaluated as an alternative to the Bakri and Utah balloons for non-surgical management of PPH not successfully resolved by medication alone.

NAMC chose to utilize the Ebb balloon after careful consideration of its pros/cons and potential benefits over the Bakri and Utah balloons. The decision to use this device was made jointly by the chief perinatologist, the OBHG hospitalist team, members of the OB staff, the L&D nurse educator/manager, and the hospital's CMO. Since the device was new, NAMC opted to participate in an Institutional Review Board (IRB) study with the balloon as part of its PPH protocol.

The results of the study confirmed the Ebb balloon is very effective in managing PPH and NAMC actually inserted more balloons than any of the other participating centers during the trial. In fact, the Ebb balloon was so successful that NAMC's OB staff continued to use it after the IRB trial was completed. The use of the Ebb balloon began in 2011 and is still ongoing. To date, about 25 balloons have been inserted to remedy PPH at NAMC. A stipulation of the NAMC's PPH protocol was that a member of the OBHG Hospitalist team had to either insert/manage the balloon or be present to supervise its insertion/management in all cases.

This stipulation was included in the protocol because the OBHG hospitalists were the only physicians who were officially trained by Glenveigh in the use of the Ebb balloon prior to its implementation at NAMC. This training included a review of educational materials pertaining to the Ebb balloon itself as well as simulations of its insertion and use. The training culminated with each member of the OBHG hospitalist team being proctored during an actual insertion of the device and supervised during its use as well as removal by one of Glenveigh’s representatives. This portion of the training necessitated OB patients who had recently delivered, voluntarily allowing the device to be inserted as part of the training process. After demonstrating adequate proficiency with the Ebb balloon, the OBHG hospitalists were then assigned the task of mentoring other members of the OB staff with regards to its use. The mentoring process included educational materials about the device that were distributed to the staff OBs as well as proctoring/assistance with its insertion and supervision/co-management of the balloon while it was being used and removed. In some cases, more than one staff OB and/or a perinatologist were present during the didactic sessions. The balloon was only used when it was clinically...
indicated and OB staff members were essentially certified by the OBHG hospitalists after adequate proficiency with the device was demonstrated.

This approach turned out to be very beneficial in a number of different ways:

- It enabled Glenveigh Medical to utilize its physician representatives very efficiently. The training of the OBHG hospitalist team took only a small fraction of the time and money that would have otherwise been necessary to train the entire OB staff of over thirty physicians.
- It enabled the team of OBHG hospitalists to become experts with regards to the Ebb balloon and give feedback to Glenveigh Medical about their experiences that contributed to future product developments.
- It reinforced the importance of the OBHG hospitalist’s role within the protocol for cases of severe PPH and allowed these physicians to assist their colleagues in a non-competitive and non-confrontational manner.
- It provided an easy and effective way to introduce this new medical device to the OB staff and promote its subsequent use in the future by the various members of the OB staff after the IRB trial completed.

Now, staff OBs who are experienced with the Ebb balloon can mentor their own partners who are less experienced with this device without the presence of an OBHG hospitalist. However, the PPH protocol still requires at least a second staff OB to be present to assist in all cases of blood loss estimated to be >1500 cc and an MFM to be present once the EBL is >2000 cc.

Interestingly, however, is the fact that an OBHG hospitalist is still almost always requested when severe PPH is occurring or an Ebb balloon is being placed. This continued reliance on the OBHG hospitalists, though not required, gives positive affirmation to the high level of comfort and confidence the staff OBs have in the skill and supportive nature of the OBHG hospitalist role and their recognized roles as physician leaders with regards to NAMC’s management of PPH. The successes of the PPH protocol and the Ebb balloon implementation program at NAMC have been phenomenal. This particular model in which the OBHG hospitalists play a pivotal role will undoubtedly be used again in the future when other medical devices become available for clinical use or trial requiring staff OB education and mentoring for proper implementation. In fact, NAMC’s model is now being considered as a prototype for introducing new medical devices (including the Ebb balloon) in all of OBHG's 50+ dedicated OB/GYN hospitalist programs in 20 different states.

The benefits of OB/GYN hospitalists are becoming increasingly apparent as more and more hospitals are choosing to utilize their services. The Ebb balloon IRB trial certainly demonstrates a potential benefit of OB/GYN hospitalists not yet widely publicized or recognized by the industry. Undoubtedly, manufacturers and vendors of medical devices will appreciate the value that a model such as the one at NAMC provides when introducing new products into the hospital setting. This benefit, obviously, is not limited only to the field of OB/GYN. The hospitalist movement is growing and hospitalists currently work within several different disciplines or fields of clinical practice. These physicians will most likely prove to be increasingly instrumental in facilitating the successful and efficient implementation of new medical products/devices in the future.

We invite you to discover more about OBHG and the advantages that our customized programs deliver to our partner hospitals, physicians and patients by visiting www.OBHG.com or contact an OBHG representative today via Programs@OBHG.com or 800.967.2289.

Written and published by OBHG Media. Copyright © 2014. Ob Hospitalist Group. All rights reserved.

Interested in linking to or reprinting this content? View our policies at http://www.obhg.com/media-room.