Interventional Radiologists Should Take the Lead in Revising REBOA

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"Necessity is the mother of invention" is a silly proverb. Necessity is the mother of futile dodges is much closer to the truth. The basis of growth of modern invention is science, and science is almost wholly the outgrowth of pleasurable intellectual curiosity.

—Alfred North Whitehead (1861–1947)

Circulatory collapse following massive exsanguination is the leading cause of mortality in trauma patients; 90% of these patients die before the bleeding can be controlled.¹

The desire to drastically reduce this mortality rate has led to decades of research in improving the surgical, medical, and interventional radiologic techniques used in trauma patient management.

One device created with that intent is the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) catheter, which was developed by Prytime Medical in Boerne, TX.

A Landmark Achievement, But...

The REBOA device is constructed with a compliant balloon mounted to a catheter, which is then advanced through a short sheath without a guidewire. The concept of REBOA, which was first utilized by a surgeon in the Korean War, is universally accepted as a landmark achievement toward developing a percutaneous means of controlling massive truncal and pelvic hemorrhage.²

But while I acknowledge the ingenuity of the device's use on the battlefield, I would argue that much of the credit for its development can and should be attributed to Charles Dotter, MD. Dr. Dotter, the "father of interventional radiology" who pioneered the use of balloon catheters, created the materials from which they are made. Dr. Dotter also developed the techniques used to direct these balloons to specific areas of the body.³

One might then reasonably think that 65 years after the REBOA catheter was first used, interventional radiologists

would be recruited to implement their knowledge and expertise to help modify, and ultimately perfect, the REBOA catheter.

Think again.

Instead, surgeons have predominated with respect to working on improving the design of the catheter. And while I respect trauma surgeons' skills, mental strength, and fortitude to deal with patients enduring the most horrific of circumstances, I also know this: trauma surgeons do not have a sufficient level of understanding of catheters, wires, and balloons required to utilize these devices, much less improve upon them. Nor have they undergone formal training in their use by physicians who possess the experience and skills to use these devices daily.

The time is long overdue for interventional radiologists to engage in the revision of the REBOA—a catheter that no IR physician would ever create or use.

What We Know

Numerous systematic reviews have been conducted on the use of REBOA catheters, as have many meta-analyses of the data. 4,5,6,7,8

Here are five facts revealed by the literature that relate to the use of these catheters:

- 1. When inflated, REBOA catheters result in an increase in cardiac afterload, proximal aortic blood pressure, and myocardial and cerebral perfusion.²
- 2. Most of these studies put the complication rate at under 6%.⁵
- 3. Animal studies reveal that ischemic complications result when inflation times exceed 30 minutes. ⁹
- 4. No strong evidence exists for a statistically significant difference in mortality rate either with or without the use of the REBOA catheter.⁵
- 5. The sequelae of shock circulation are a major contributor to fatal outcomes in trauma patients. 10

What We Can Do Today

Changes can be easily implemented to address the three most commonly encountered problems with REBOA: iatrogenic complications, inadequate training, and ischemia time. These changes consist of:

- 1. Lengthening the introducer sheath. The most common iatrogenic complication with the current REBOA device is dissection of the vessel upon the catheter's introduction. If the sheath (which is advanced over a wire) can be made long enough to terminate in the distal aorta, just above its bifurcation, then the REBOA can be advanced atraumatically through the iliac arteries. The pigtail catheter would easily form in the significantly larger aorta.
- Mandatory training. The makers of REBOA should require training and completion of a course by surgeons supervised by interventional radiologists, similar to how companies that made aortic stent grafts originally mandated training of vascular surgeons and interventional radiologists.
- 3. Establishing an inflation and deflation protocol. Other than on the battlefield or in a remote location, there is no indication for continuous inflation times to reach 60 minutes. If an occlusion time of up to 30 minutes is deemed safe, then the process should be initiated with 15 minutes up, 1 minute down. Controlling the balloon is a simple maneuver that can be assigned to ancillary staff. This would be a reasonable approach to take until sufficient data can be gathered from prospective studies.

If one believes that the concept behind REBOA is a good one (and at least intuitively it is), then one must ask the question: with all the advances made in trauma and vascular surgery, cardiology and interventional radiology over the past 40 years, why have similar techniques, technologies, and training protocols not benefited the trauma patient?

My jaded conjecture is money. Between the cost of bringing new devices to market and the poor reimbursement levels of these procedures (commonly required by the under-privileged and under-served populations), the financial loss is simply too great.

That said, these proposed solutions would cost our healthcare institutions nothing. The little costs associated with training and prospective studies could and should be borne by industry.

In my view, the ultimate in expeditious and effective care will be realized when all Level I trauma centers require an emergency department hybrid room that can not only function as an operating room but is also equipped with a 4D CT scanner.

Until then, interventional radiologists should step up and lead the charge toward achieving the very reachable goal of significantly reducing the mortality rate among trauma patients with massive hemorrhage.

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