The Use of Resuscitative Endovascular Balloon Occlusion of the Aorta in Treating Hemorrhagic Shock from Severe Trauma

A guide to this innovative, less invasive technique.

ABSTRACT: Hemorrhage is the leading cause of preventable death in trauma patients. In recent years, technological innovations and research efforts aimed at preventing death from hemorrhagic shock have resulted in the emergence of resuscitative endovascular balloon occlusion of the aorta (REBOA). REBOA offers a less invasive option for emergent hemorrhage control in noncompressible areas of the body without the added risks and morbidities of an ED thoracotomy. This article outlines the procedure and device used, describes the procedure's evolution, and discusses various considerations, pitfalls, and nursing implications.

Keywords: aortic occlusion, hemorrhage, REBOA, shock, trauma

CASE STUDY

N. P., a woman in her mid-50s with a history of hypertension, presents to the ED after being hit by a truck. (This is a real case but identifying details have been changed.) On arrival, her Glasgow Coma Scale score is 14 (eye response, 4; verbal response, 4; motor response, 6). Her airway is patent and she has bilateral breath sounds. A manual blood pressure is obtained showing a systolic pressure in the 60s. Electrocardiogram testing reveals that she is tachycardic. Bilateral lower extremity deformities are clearly visible, including an actively bleeding open left femur fracture. Two large-bore IV catheters are inserted and two units of blood are transfused with a rapid infuser. A chest X-ray shows no acute pathology. A pelvic X-ray shows extensive fractures of the left hemipelvis. A bedside focused assessment with sonography for trauma (FAST) of

the abdomen is negative for any obvious intraabdominal bleeding.

A pelvic binder is placed on the patient in the ED. Her vital signs respond temporarily to the transfusion, but then her blood pressure quickly drops to 70/40 mmHg. What are the trauma team's options? The patient is clearly very unstable, and transport anywhere could be hazardous. Given the impending cardiovascular collapse, should the team proceed with an ED thoracotomy, cross-clamping the aorta to temporarily resolve bleeding? Should they wait, continue resuscitation in the trauma bay, and hope the patient responds enough to be taken for an exploratory laparotomy or an interventional radiology procedure? Her condition continues to deteriorate rapidly. The team decides to perform resuscitative endovascular balloon occlusion of the aorta (REBOA). They obtain femoral arterial access and insert a REBOA catheter. Upon occlusion of the aorta, the patient's blood pressure returns to normal and she is, for the moment, stabilized.

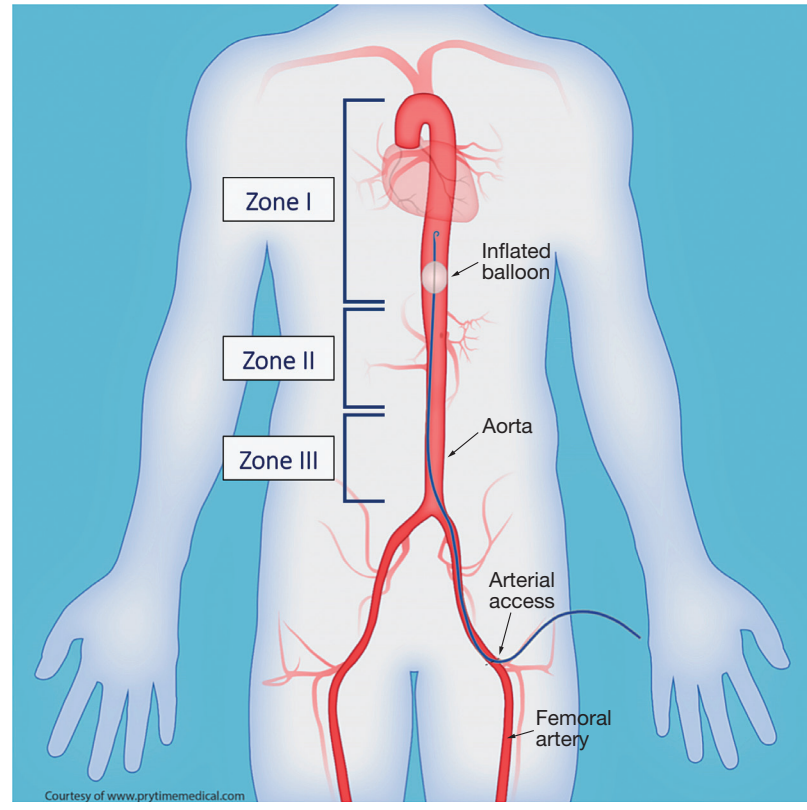

Figure 1. There are three aortic zones to be considered when performing REBOA: Zone I, from the origin of the left subclavian artery to the celiac artery; Zone II, from the celiac artery to the lowest renal artery; and Zone III, which includes the infrarenal abdominal aorta from the lowest renal artery to the aortic bifurcation. Adapted with permission from Prytime Medical, Inc., www.prytimemedical.com.

HISTORY AND SUPPORT FOR USE

Noncompressible torso hemorrhage (NCTH), which involves bleeding into the chest, abdominal cavity, pelvis, or a combination thereof, is a major component of potentially survivable injuries.[1] It carries a mortality rate in the civilian population as high as 45%.[2] Currently, the treatment of refractory shock or early traumatic cardiac arrest due to NCTH involves performing an ED thoracotomy to assist with ongoing resuscitative efforts (such as performing internal cardiac massage, controlling chest hemorrhage, or cross-clamping the aorta), followed by quick transfer to the operating room if the patient regains vital signs. Although ED thoracotomy can be useful, survival rates remain very low (8% to 31%).[1,3]

During the Korean War, intraaortic balloon occlusion (IABO) emerged as a less invasive possible alternative to ED thoracotomy. The technique involves inserting a transfemoral balloon catheter into the aorta in a retrograde fashion, providing inflow control and supporting blood pressure until hemostasis can be achieved. It was first used clinically under fluoroscopic guidance on two combat casualties in 1954, but neither patient survived.[4]

During the 1980s, refinements to IABO led to slight improvements in survival rates (13% to 33%).[1] During the 1990s, studies conducted among dogs and swine yielded promising findings; most recently, a pig study demonstrated that endovascular balloon occlusion resulted in decreased resuscitative fluid and vasopressor requirements and less acidosis.[5] But despite rapid advancements in the use of endovascular technology for cardiovascular disease, its use in trauma surgery has not kept pace. This has been attributed to both a lack of experience with this technology among trauma surgeons and a lack of trauma-specific device innovations.[1,6] Recently, the wars in Afghanistan and Iraq have resulted in large numbers of deaths from potentially survivable injuries, prompting renewed interest in the use of IABO in trauma surgery.[1,7,8]

In 2011, Stannard and colleagues published a detailed description of the REBOA technique, which is a form of IABO.[9] Three zones of the aorta were defined (see Figure 1) and a five-step technique for endovascular deployment was described: arterial access,

balloon selection and positioning, balloon inflation, balloon deflation, and sheath removal. Zone I includes the descending thoracic aorta; occlusion here resembles traditional aortic cross-clamping during a thoracotomy. Zone II includes the paravisceral aorta and is not a desirable occlusion site because of the presence of the mesenteric and renal vessels. Zone III includes the infrarenal abdominal aorta; occlusion here is optimal for controlling pelvic and lower extremity hemorrhage. REBOA has been shown to increase central and proximal perfusion, restore hemodynamic stability, and provide more time for operative preparation and planning for hemorrhage control.[5, 10] These results are essentially the same as those seen with ED thoracotomy with aortic cross-clamping, but through a less invasive, endovascular approach.

The last few years have produced tremendous advancements in endovascular aortic occlusion. In 2006, two military vascular surgeons (Eliason and Rasmussen) began developing a smaller version of the intraaortic balloon catheter, one that could be placed quickly without X-ray guidance.[11] Their device, known as the ER-REBOA catheter (Prytime Medical Devices, Boerne, TX), was first used in U.S civilian trauma centers in 2012.[12] (The letters "ER" stand for Eliason and Rasmussen.) In 2014, its first use in the civilian prehospital setting was performed in the United Kingdom.[13] The ER-REBOA approach represents a paradigm shift in trauma resuscitation because it simplifies aortic occlusion balloon deployment through easy-to-follow steps without the need for fluoroscopic guidance or cumbersome vascular wires.[14, 15] The Food and Drug Administration (FDA) approved the device in 2015.[16]

In the United States, the American Association for the Surgery of Trauma has created a multicenter REBOA registry to assess the safety and efficacy of the device prospectively.[17] As of March 2017, a total of 47 patients had been treated with the ER-REBOA catheter, with successful aortic occlusion achieved in 96% of cases. Seventy-seven percent of these patients showed hemodynamic improvements with its use, and the survival rate was 35% at time of discharge. An additional report of four patients with NCTH managed using the ER-REBOA catheter in a prehospital combat casualty care setting was recently published.[18] The four patients presented with torso gunshot or fragmentation wounds, hemoperitoneum, and class IV hemorrhagic shock. REBOA resulted in immediate normalization of blood pressure and facilitated resuscitation and surgical damage control of NCTH in all cases. All patients survived for transport to the next level of care. Clearly, early control of hemorrhage is critical to survival.

HOW TO USE REBOA

REBOA first requires arterial access. This can be accomplished using a percutaneous "femoral stick" and should be done under ultrasound guidance when feasible.[19] This method allows safer vascular access, as it affords more precise entry and the recognition of variant anatomy; it can also help in obtaining access via pulseless arteries. If ultrasound is unavailable, initial access can be gained using external landmarks and palpation. A femoral cutdown approach is no longer necessary but remains another option for access.

After access is obtained in either groin, a guide wire is then inserted to allow introduction of a 7 Fr vascular access sheath.[17] An ER-REBOA catheter can be floated directly through the sheath (see Figure 2). If an ER-REBOA catheter isn't available, a Coda balloon

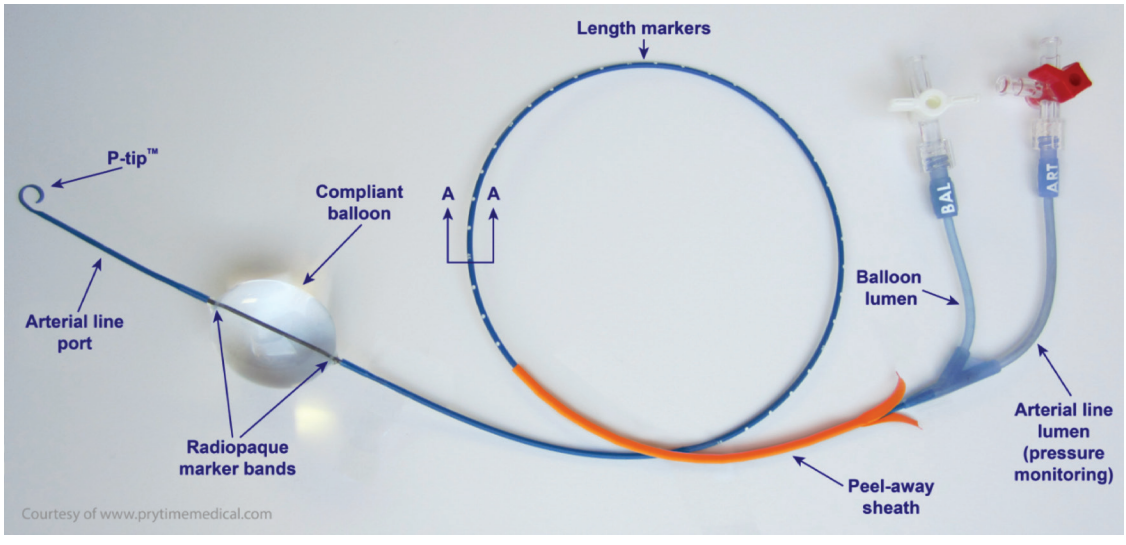

Figure 2. An example of an ER-REBOA catheter and balloon. Image courtesy of Prytime Medical, Inc., www.prytimemedical.com.

catheter (Cook Medical, Bloomington, IN) may be used instead, but the sheath would require further upsizing to a 12 Fr.[20] The balloon must be completely deflated before use. The arterial line setup and extension tubing should be connected, readying the device for blood pressure transduction distal to the balloon. The depth for REBOA advancement can be determined using radiography or external landmarks.[19,21] For Zone I deployment, using an external measurement from the sternal notch to the entry point of the sheath should reliably land the balloon in that zone. Zone III deployment can be accomplished by measuring from the level of the xiphoid process to the femoral access point.

Once correct positioning has been confirmed by standard X-ray, the balloon is inflated in a controlled fashion with contrast or saline. Although the FDA has approved the ER-REBOA catheter for deployment without X-ray, in a modern trauma center (especially one with digital portable technology), a simple X-ray should be obtained. The current recommendation is to inflate the balloon gradually, starting with 8 cc in Zone I and 2 cc in Zone III,[22] in order to avoid overinflation and possible balloon or vessel rupture. Whether occlusion of the aorta has been successful can be determined by monitoring blood pressure feedback via the device's arterial line—a gradual increase in systolic blood pressure should be seen. The catheter should be secured in place, either to the patient using sutures or to a central line holding device, to prevent device migration.

At this point, it's critical to move expeditiously to address the hemorrhagic source, as balloon inflation time is equivalent to aortic cross-clamp time; that is, perfusion to the abdominal viscera and lower extremities is halted until the balloon is deflated. Although consensus about duration of aortic occlusion is lacking, findings from animal studies have led some experts to recommend a maximum duration of 30 to 60 minutes in Zone I and perhaps up to 60 minutes in Zone III.[23-25] The provider may temporarily deflate the balloon and allow for transient reperfusion until definitive hemorrhagic control is achieved.

Once such control has been achieved, the balloon is deflated slowly and removed through the sheath. It is imperative to identify and prepare for potential ischemia and reperfusion injury in the lower extremities. If need be, an angiogram of distal extremities or Doppler assessment with frequent physical examination can be performed to check for limb perfusion. Finally, the sheath can be removed; manual pressure should be applied at the puncture site for at least 20 minutes before placing a pressure dressing. If the larger 12 Fr sheath was used for access, surgical repair will be required for adequate arterial closure.

INDICATIONS, PITFALLS, AND LIMITATIONS

Indications. REBOA is indicated in almost any case of intraabdominal hemorrhage with impending cardiovascular collapse, such as cases of ruptured abdominal aortic aneurysms, penetrating mechanism of injury to the abdomen or pelvis, blunt trauma without severe chest injury but with a positive FAST or a suspected pelvic fracture, and lower extremity trauma with impending cardiovascular collapse.[26-28] It may also be indicated in cases of complex retroperitoneal hemorrhage.[29] An algorithm has been proposed for cases of persistent shock (systolic blood pressure less than 90 mmHg with transient or no response to resuscitation efforts).[24] (See Figure 3.[24])

Pitfalls. Several potential pitfalls must be kept in mind. The timing of the decision to deploy REBOA is critical to survival; as Pasley and colleagues have noted, "Mortality is high after loss of pulses has occurred."[24] Since obtaining arterial access is the first step in REBOA placement, early femoral arterial line placement in the hypotensive trauma patient should always be considered.

When inflating the balloon, care must be taken to avoid overinflation, as this can result in balloon rupture and arterial injury. Always check lower extremity pulses after inserting the catheter and before leaving the operating room, as changes can indicate complications. Problems with femoral access, such as intimal flaps, acute thrombosis, and distal embolization, will present as a sudden change in the pulses, and constitute a surgical emergency.

There are concerns about the effects of REBOA during general anesthesia, in particular its effects on the cardiovascular system.[30] These include the sudden increase in afterload produced by aortic occlusion, which can lead to increased left ventricular work, ventricular dilation, and worsening myocardial ischemia.[30] Central hypertension may also exacerbate intracranial, thoracic, or upper extremity bleeding. It is therefore imperative to rule out any signs of chest trauma (for example, by chest X-ray) before considering catheter placement. Other major physiologic considerations include renal hypoperfusion, which can lead to renal failure; increased pulmonary vascular resistance and the potential for pulmonary edema; and prolonged intestinal or visceral ischemia.[30] Furthermore, reperfusion injury is a significant risk upon balloon deflation.[5,30] Reperfusion injury can manifest as profound hypotension, lactic acidosis, severe electrolyte derangements, cardiac arrhythmias, or rhabdomyolysis—any of which could easily lead to the patient's rapid demise.[30]

Limitations. REBOA requires a skilled operator and a team fully trained in the device to assist with setup and monitoring. Many providers will require additional training to become sufficiently familiar with the procedure. REBOA does not allow for internal cardiac massage in cases of traumatic cardiac arrest; it is simply an adjunct to other resuscitative efforts. Facility-specific issues may limit the usefulness of

REBOA. For example, trauma surgeons, vascular surgeons, interventional radiologists, and portable X-ray technologies and fluoroscopy equipment may not be readily available, but all are essential to a successful REBOA program. Lastly, prospective randomized controlled trials of REBOA, which are lacking, are needed to confirm and validate the early outcomes shown in single-center or registry data.

NURSING IMPLICATIONS

As with any endovascular technique, it's imperative to monitor the patient closely during the REBOA procedure. Areas with implications for nursing practice include maintenance of REBOA equipment, knowledge of the REBOA procedure, diligent and skillful assessment, accurate documentation, and the use of effective closed-loop communication throughout the procedure. (Closed-loop communication is a technique used to ensure accuracy and comprehension. After a message is spoken or sent, the recipient repeats it back for confirmation by the sender.)

Each facility should establish protocols that address the storage, location, and monitoring of the necessary equipment. As with most emergency procedures, having central locations for such equipment in both the ED and the operating room allows for expedited access if the procedure is needed. In addition to the ER-REBOA catheter, a REBOA pack should contain a regular femoral arterial line kit, two 7 Fr sheath kits, two 20 cc syringes, an arterial line transducer, a pressure bag, and an arterial line cable. Industry leaders are bundling all the necessary equipment together in REBOA kits. Nurses should check and maintain the supplies in the pack. They should also monitor the equipment for functionality and expiration on a weekly basis.

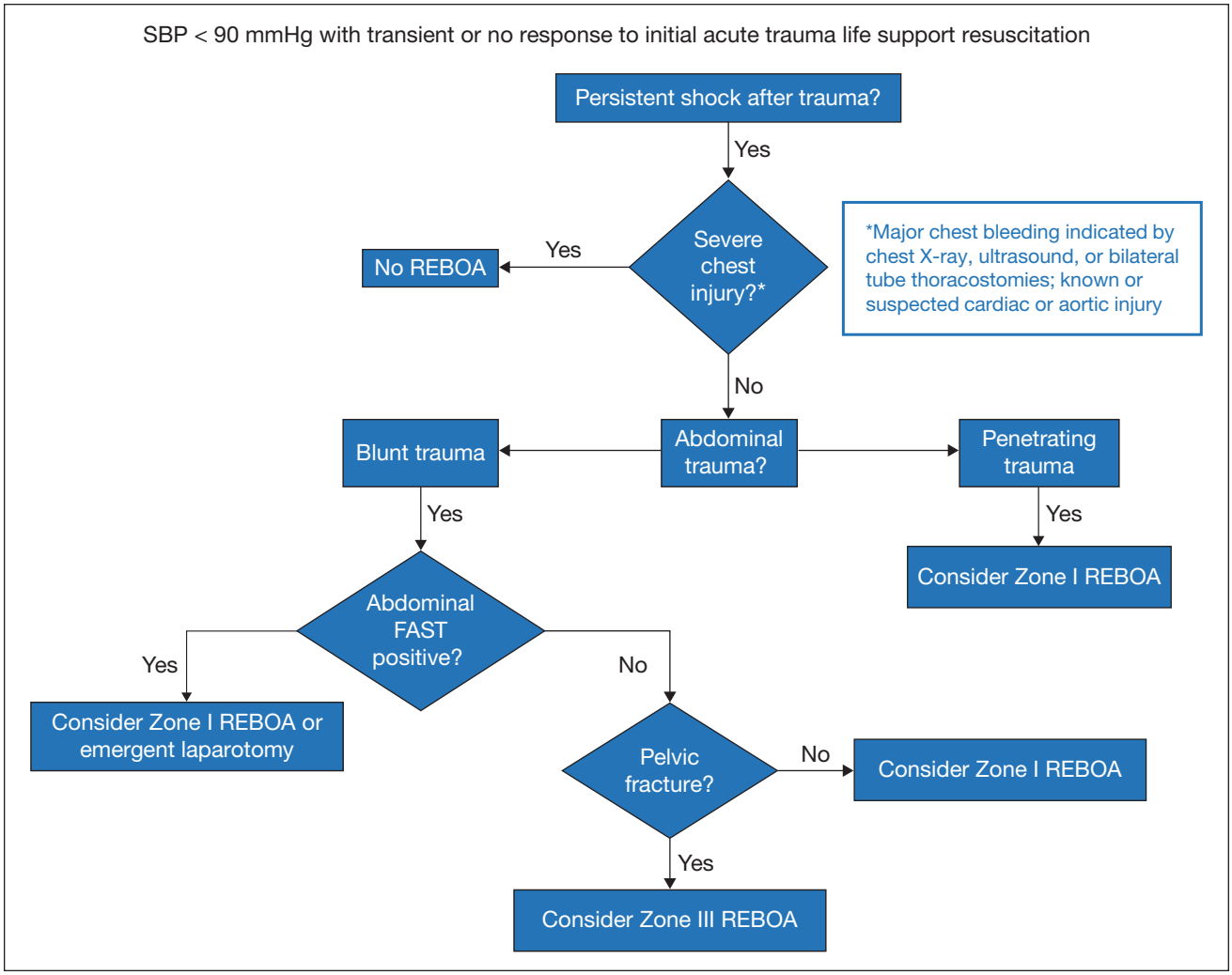

Figure 3. An algorithm for the use of REBOA for profound shock. FAST = focused assessment with sonography for trauma; SBP = systolic blood pressure. Adapted from Pasley J, et al.[24]

Nurses must be able to assess and recognize impending life-threatening conditions (such as ongoing bleeding, otherwise unexplained hypotension, respiratory distress, and altered mental status) revealed through subtle alterations in a patient's condition. Patient monitoring begins with the initial resuscitative phase and continues during and after the REBOA procedure. It should include monitoring of cardiopulmonary status, such as through continuous telemetry, pulse oximetry, and patient responsiveness. Once the decision to deploy REBOA has been made, preparation of the blood pressure transducing system should begin. To ensure accurate blood pressure monitoring, nurses should set up an arterial line and calibrate the monitor. During the REBOA procedure, recognition of arrhythmias, blood pressure irregularities, poor oxygen saturation, and any other abnormalities should be communicated immediately to the rest of the team. Precise documentation of the entire event, including "balloon-up" time (the clock time when the balloon was inflated) and total inflation time, should be captured in the electronic health record or as specified by facility protocol. It's essential that total aortic occlusion time be accurately recorded, as prolonged occlusion times are associated with higher morbidity and mortality.

Once the catheter balloon has been deflated, postprocedure assessments should be conducted at regular, frequent intervals. These should include thorough cardiovascular assessment with continued evaluation for any early complications, with particular focus on the extremity where the catheter was placed. Monitoring of vital signs, as well as neurovascular assessment of the extremities, can provide indicators of poor perfusion or early signs of ischemia. Vital signs should be assessed every 15 minutes for the first two hours following the procedure, then every 30 minutes for the next two hours, then hourly once the patient has been transferred to a critical care setting. Neurovascular assessment should include determining capillary refill time; checking peripheral pulses, either through palpation and auscultation or by performing a bedside Doppler signal examination; and assessing for any sensory or motor neurologic deficits. Postprocedure assessment should also include examining the lower-extremity muscle compartments and groin area for bleeding. Asymmetry in the lower extremities could indicate early compartment syndrome and rhabdomyolysis resulting from reperfusion injury. Any dressings should be evaluated for evidence of significant bleeding, with any identified concerns reported to the team.

Nurses can provide crucial education and emotional support to patients and families, and nurses' role as patient advocate is also important. Since each trauma case is different, assessment of a patient's comprehension of the situation should begin as early as possible. Communication should be provided in a language the patient and family members understand. Involving family members or other caregivers in creating a broad support network is advised to help meet the patient's longer-term emotional needs. An approach that's supportive and nonjudgmental will promote healing and strengthen coping skills for the challenges ahead.

Lastly, as with any new intervention, it's essential to have proactive nursing leadership in implementing a REBOA program. Ensuring that nurses have the appropriate education and training in the use of arterial line technologies in the ED will be critical to such a program's success.

CASE REVISITED

N. P.'s blood pressure returns to normal upon inflation of the ER-REBOA catheter balloon in Zone III. The trauma team alerts the interventional radiology team, and the patient is immediately taken to the radiology suite. At the end of the REBOA procedure, the catheter balloon is slowly deflated, with continuous monitoring of the patient's vital signs. Total aortic occlusion time is 32 minutes. Over the next several minutes, diagnostic angiography reveals several vessels with active extravasation within the pelvis, and these are embolized. The patient continues to remain stable. The catheter is fully removed, and distal pulses are checked. N. P. is taken to the operating room and the orthopedic surgery team works to repair her pelvic and lower extremity injuries. After several weeks of intensive physical therapy, she has made progress toward recovery and is eventually discharged to a rehabilitation facility.

LOOKING AHEAD

REBOA has become an area of intense focus in trauma surgery. Several courses have been established to teach the endovascular skills necessary, allowing for broad adoption in the trauma community.[31,32] The development of the smaller ER-REBOA catheter was a major breakthrough in increasing ease of use, allowing for wider use of REBOA in cases of hemorrhagic shock. And further advancements in the management of hemorrhagic shock may be possible—perhaps combining REBOA with extracorporeal membrane oxygenation or hypothermic perfusion techniques. Such advancements could make REBOA more likely to be used in the prehospital care of patients with severe traumatic injury or even medical cardiac arrest. Partial REBOA, which allows for some distal limb perfusion during efforts to regain hemorrhagic control,[33] also appears promising, though more studies are needed.

The aforementioned multicenter REBOA registry may in time produce enough data to clarify REBOA's role and indications.[19] Although prospective Level I evidence (such as from a systematic review or meta-analysis of randomized controlled trials) is not yet

available, early retrospective data support the use of REBOA in controlling hemorrhagic shock. The effects of classic aortic occlusion on other organ systems have been extensively studied; whether REBOA has similar effects will require further examination. That said, given the increasing use and demonstrated efficacy of REBOA in controlling hemorrhagic shock, it is incumbent on all trauma team members to become familiar with the technique, the logistics of deployment, and the physiologic implications. ▼

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