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ORIGINAL RESEARCH

Resuscitation

Emergency department initiated resuscitative endovascular balloon occlusion of the aorta (REBOA) for out-of-hospital cardiac arrest is feasible and associated with improvements in end-tidal carbon dioxide

James Daley MD, MPH[1,2] | Ryan Buckley MD, MPH[1,2] | Kathryn Cannon Kisken MS, MPH[2] | Douglas Barber BS[6] | Raj Ayyagari MD[1,3] | Charles Wira MD[1,2] | Ani Aydin MD[1,2] | Igor Latich MD[1,3] | Juan Carlos Perez Lozada MD[1,3] | Daniel Joseph MD[1,2] | Angelo Marino DO[1,3] | Hamid Mojibian MD[1,3] | Jeffrey Pollak MD[1,3] | Cassius Ochoa Chaar MD, MS[1,5] | James Bonz MD[1,2] | Justin Belsky MD[1,2] | Ryan Coughlin MD[1,2] | Rachel Liu MBBCh[1,2] | John Sather MD[1,2] | Reinier Van Tonder MD[1,2] | Rachel Beekman MD[1,4] | Elyse Fults MD[1,2] | Austin Johnson MD, PhD[7] | Christopher Moore MD[1,2]

[1]Department of Emergency Medicine, Yale New Haven Hospital, New Haven, Connecticut, USA

[2]Department of Emergency Medicine, Yale School of Medicine, New Haven, Connecticut, USA

[3]Department of Radiology and Biomedical Imaging, Yale School of Medicine, New Haven, Connecticut, USA

[4]Department of Neurology, Yale School of Medicine, New Haven, Connecticut, USA

[5]Department of Vascular Surgery, Yale School of Medicine, New Haven, Connecticut, USA

[6]Yale School of Medicine, New Haven, Connecticut, USA

[7]Department of Surgery, Division of Emergency Medicine, The University of Utah, Salt Lake City, Utah, USA

Correspondence
James Daley, Department of Emergency Medicine, Yale New Haven Hospital, New Haven, 464 Congress Avenue, New Haven, CT 06519, USA.
Email: james.i.daley@yale.edu

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Abstract

Objectives: Out-of-hospital cardiac arrest (OHCA) claims the lives of approximately 350,000 people in the United States each year. Resuscitative endovascular balloon occlusion of the aorta (REBOA) when used as an adjunct to advanced cardiac life support may improve cardio-cerebral perfusion. Our primary research objective was to determine the feasibility of emergency department (ED)-initiated REBOA for OHCA patients in an academic urban ED.

Methods: This was a single-center, single-arm, early feasibility trial that used REBOA as an adjunct to advanced cardiac life support (ACLS) in OHCA. Subjects under 80 years

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with witnessed OHCA and who received cardiopulmonary rescuitation (CPR) within 6 minutes were eligible.

Results: Five patients were enrolled between February 2020 and April 2021. The procedure was successful in all patients and 4 of 5 (80%) patients had transient return of spontaneous circulation (ROSC) after aortic occlusion. Unfortunately, all patients re-arrested soon after intra-aortic balloon deflation and none survived to hospital admission. At 30 seconds post-aortic occlusion, investigators noted a statistically significant increase in end tidal carbon dioxide of 26% (95% confidence interval, 10%, 44%).

Conclusion: Initiating REBOA for OHCA patients in an academic urban ED setting is feasible. Aortic occlusion during chest compressions is temporally associated with improvements in end tidal carbon dioxide 30 seconds after aortic occlusion. Four of 5 patients achieved ROSC after aortic occlusion; however, deflation of the intra-aortic balloon quickly led to re-arrest and death in all patients. Future research should focus on the utilization of partial-REBOA to prevent re-arrest after ROSC, as well as the optimal way to incorporate this technique with other endovascular reperfusion strategies.

KEYWORDS
aortic occlusion, cardiac arrest, endovascular, REBOA, reperfusion

1 | INTRODUCTION

1.1 | Background

Out-of-hospital cardiac arrest (OHCA) claims the lives of approximately 350,000 people in the United States each year.[1] Despite advances in technology and therapeutics, only 25% of patients have return of spontaneous circulation (ROSC) in the emergency department (ED) and 8.2% of patients survive to hospital discharge with a favorable neurologic outcome.[1] Over the past decade, approaches involving advanced endovascular reperfusion strategies have demonstrated promise in improving survival.[2,3] The most well-established endovascular reperfusion therapy for OHCA is the use of extra corporeal membranous oxygenation (ECMO) during cardiopulmonary resuscitation (CPR) and extracorporeal cardiopulmonary resuscitation (ECPR).[4] The ARREST trial[3] demonstrated improvements in survival with ECPR in the cardiac catheterization laboratory, although this can be a resource-intensive strategy and not easily replicated at other hospitals.

1.2 | Importance

Utilizing Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an adjunct to traditional ACLS (RCPR) is a potentially less resource-intensive and more generalizable endovascular reperfusion strategy. REBOA involves the placement of an intra-aortic balloon via a common femoral arterial (CFA) access site and then inflating the balloon to occlude the aorta, resulting in augmented blood flow to the heart and brain (Figure 1).[5] REBOA was initially developed as a means of temporizing traumatic intra-abdominal hemorrhage before obtaining definitive hemorrhage control in the operating room or interventional suite.[6] REBOA placement does not require an endovascular specialist (ES) and may be performed by an appropriately trained emergency physician, intensivist, or surgeon.[7–11] REBOA requires minimal equipment and can be used in the pre-hospital setting.[8]

Three recent European trials have demonstrated that RCPR by trained intensivists is feasible and noted statistically significant improvements in end tidal carbon dioxide ($ETCO_2$) after aortic occlusion, although none were able to measure real-time blood pressure.[8–10] The 3 pilot trials enrolled a total of 36 patients, with 1 patient surviving with a favorable neurological outcome and 2 others surviving to organ donation. Although the survival rate is quite low, these trials were noncontrolled and not designed to test efficacy. In the Norwegian trial, patients had prolonged arrest times before REBOA in the field, whereas in the Swiss trial, the 15 patients enrolled were not eligible for ECPR due to their high rate of comorbid conditions and poor prognosis. The feasibility of RCPR in United States EDs has not yet been established.

1.3 | Goals of this investigation

Our primary research objectives were to determine the feasibility and safety of RCPR as an adjunct to traditional ACLS for OHCA patients

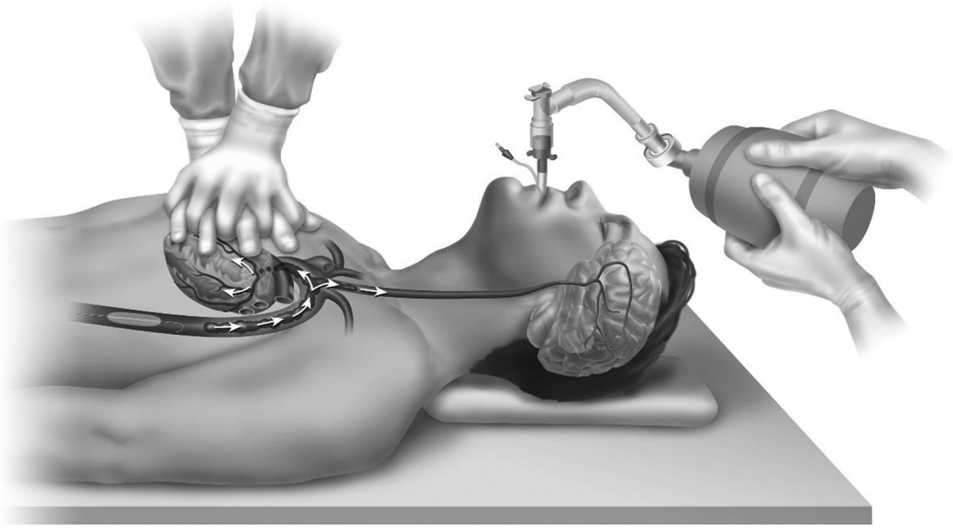

FIGURE 1 Thoracic aortic balloon occlusion as adjunct to ACLS. Thoracic aortic balloon occlusion during cardiac arrest with bag-valve mask ventilation and manual chest compressions. Arrows depict redirected blood flow to the heart and brain. ACLS, advanced cardiac life support. Note. From "A Research Protocol and Case Report of Emergency. Department Endovascular Aortic Occlusion (REBOA) in Non-traumatic Cardiac Arrest," by Daley, J., Cannon, K., Buckley, R., Aydin, A., Latich, I., Perez Lozada, J.C., Bonz, J., Joseph, D., Coughlin, R., Belsky, J., Van Tonder, R., Sather, J., Wira, C., Liu, R., Johnson, A., Moore, C., 2020, Journal of Endovascular Resuscitation and Trauma Management, 4, p. 89. Copyright 2020 by the EVTM research group at the Örebro University Hospital. Reprinted [or adapted] with permission. Note. From "The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) for non-traumatic cardiac arrest: A review" by Nowadly, C. D., Johnson, M. A., Hoareau, G. L., Manning, J. E., & Daley, J. I., 2020, Journal of the American College of Emergency Physicians Open, 1, p. 738. Copyright 2020 by Wiley Periodicals LLC. Reprinted [or adapted] with permission.

The Bottom Line

In this case series, a resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter was successfully placed in the emergency department of an academic medical center in 5 cases of out-of-hospital cardiac arrest. However, re-arrest was common after balloon deflation, and no patients survived.

presenting to the ED in the United States. When designing the trial, we had initially planned for feasibility to be the sole primary outcome. The Food and Drug Administration (FDA) requested that we include safety as a second primary outcome and limited enrollment in the trial to 5 participants. Given this limitation, the trial was not powered to determine safety with statistical significance, instead assessing safety on a qualitative case-by-case basis.

Our secondary objectives were to collect data related to procedural feasibility (eg, time to intra-aortic balloon inflation), to observe the effects of aortic occlusion on $ETCO_2$ and mean arterial blood pressure (MAP), as well as to measure rates of ROSC and patient survival. We hypothesized that an ED-initiated approach to RCPR would be feasible, and aortic occlusion would be associated with improvements in $ETCO_2$ and MAP.

2 | METHODS

2.1 | Study design and setting

This was a single-center, single-arm, early feasibility trial of an ED-based resuscitation protocol that used REBOA as an adjunct to traditional ACLS. At the time of the trial's inception, RCPR had not yet been studied in human subjects. This trial was supported by grants from the American Heart Association and Prytime Inc. (Boerne, TX), the makers of the ER-REBOA catheter used in the trial. Neither funding organization had a role in the design, conduct, nor reporting of the research. This trial took place at a tertiary urban academic medical center and used a convenience sample of 5 patients.

2.2 | Selection of participants

The trial qualified for exception from informed consent (EFIC) under emergency circumstances (21 Code of Federal Regulations 50.24), with oversight by the FDA, an investigational device exemption, approval by the local IRB, monitoring by a Data and Safety Monitoring Board and clinical events committee, and was registered on clinicaltrials.org (NCT03703453). EFIC activities included 5 community meetings before beginning trial enrollment and 3 meetings post-enrollment. Fliers were distributed throughout the city before enrollment began, as well as mass-email campaigns targeting approximately 50,000

individuals in the anticipated enrollment demographic. All patients were enrolled under EFIC in a manner consistent with federal regulations and their legally authorized representatives were notified of their participation post-enrollment.

Enrollment began in January 2020, was halted for 8 months at the start of the coronavirus disease 2019 (COVID-19) pandemic, and concluded in April 2021. Patients were included if they had a witnessed cardiac arrest of suspected medical etiology and had CPR initiation within 6 minutes of their arrest. In total, 42 patients were screened for inclusion, with the majority being excluded because their arrest was not witnessed or they did not receive CPR within 6 minutes. Study exclusion criteria were as follows: traumatic etiology of the cardiac arrest, active terminal illness, severe dementia, known aortic disease, age greater than 79 years, age less than 18 years, wards of the state, known or suspected pregnancy, total resuscitation time greater than 45 minutes, Do Not Resuscitate (DNR) order in place, and if the physician anticipated a difficult procedure for any reason. Baseline demographic characteristics of enrolled patients are found in Table 1.

TABLE 1 Baseline characteristics of patient population

Demographics	No. (%)
Mean age, years [range]	60.6 [50–77]
Gender	
Male	4 (80)
Female	1 (20)
Race/ethnicity	
White	1 (20)
Black	4 (80)
Hispanic	0 (0)
Cardiac rhythms	
Prehospital initial cardiac rhythm	
PEA	3 (60)
V-fib	1 (20)
Unknown	1 (20)
ED initial rhythm	
Asystole	2 (40)
PEA	2 (40)
A-fib	1 (20)
Medical history	
Papillary thyroid carcinoma	1 (20)
Congestive heart failure	2 (40)
Hypertension	5 (100)
Hypothyroidism	1 (20)
Hypercholesterolemia	1 (20)
Diabetes	1 (20)
Deep vein thrombosis	1 (20)
Current medications	
ACE inhibitor	1 (20)
Adenosine diphosphate antagonist	0 (0)
Aspirin	1 (20)
β blocker	4 (80)
Statin	1 (20)

Note: Data are n (%) or mean (SD).
Abbreviations: ACE, angiotensin converting enzyme; ED, emergency department; CI, confidence interval; PEA, pulseless electrical activity. V-fib, ventricular fibrillation; A-fib, atrial fibrillation.

2.3 | Interventions

The research team included a procedural physician, an emergency physician code leader, a research coordinator, ED nurses, and ED technicians. At the time of protocol development, RCPR had not been performed in the setting of nontraumatic cardiac arrest and the EP investigators lacked clinical experience with intra-aortic balloon catheters. As such, the FDA directed that emergency physicians may obtain CFA access, however, an ES must be present to advance and manipulate the REBOA catheter. There were 10 emergency physician investigators who underwent specialized REBOA training, including attending the Basic Endovascular Skills for Trauma course (University of Maryland, Baltimore, MD), followed by recurring practice sessions in our simulation laboratory at approximately 6-month intervals.[12] There were 12 ES investigators with specialty training in either interventional radiology or vascular surgery who underwent a simulation-based training session to familiarize themselves with the research protocol and the device.

Patients were screened for enrollment by the research coordinator on days that an emergency physician investigator was working clinically or on a dedicated research shift. When a patient met enrollment criteria, a "REBOA alert" was paged out to the ES investigators, whereas the ED code leader began an ACLS-based resuscitation and the emergency physician investigator started to obtain CFA access. The REBOA procedure has been described in depth previously.[6] Briefly, the emergency physician investigator would initiate the procedure by placing a 7 French introducer sheath using ultrasound guidance in the CFA while the patient underwent chest compressions. Arterial placement was confirmed with bedside ultrasound and if ambiguity remained, a blood gas was drawn and analyzed at the bedside.

After placement of the introducer sheath, the ES investigator would then advance the ER-REBOA catheter (Prytime Inc.) to the 45 cm marker in all patients, as externally measuring the catheter length was not possible due to ongoing chest compressions. The catheter was connected to a Compass device (Centurion Medical Products Inc., Williamston, MI), which provides a digital readout of real-time MAP proximal to the intra-aortic balloon in the aortic arch. Investigators confirmed aortic catheter placement by examining the aorta and inferior vena cava using bedside ultrasound. Subsequently, the catheter's intra-aortic balloon was inflated with 8 mL of saline, and the contralateral femoral pulse was palpated to confirm aortic occlusion.

To minimize the possibility of ischemic damage, the total intra-aortic catheter inflation time was limited to no more than 15 minutes. If the

patient achieved ROSC after aortic occlusion with an aortic arch MAP of at least 60 mm Hg, the intra-aortic balloon was gradually deflated at the rate of 1 mL per minute. If the patient's MAP decreased below 60 mm Hg, intra-aortic balloon deflation was halted while investigators attempted to medically optimize the patient with vasopressor support. If the patient re-arrested during intra-aortic balloon deflation, the balloon was re-inflated and ACLS resumed. When a total of 15 minutes of full inflation time was exhausted, the intra-aortic balloon was deflated, and the resuscitation was ended. Investigators twice deviated from this aspect of the protocol because they determined that more time was needed to medically optimize the patient to prevent re-arrest on intra-aortic balloon deflation.

2.4 | Outcomes

The primary outcomes of this trial were feasibility and safety. Feasibility was defined by the successful inflation of the intra-aortic balloon above the level of the diaphragm in at least 70% of patients. This was based on the expert opinion of ES physicians experienced in the use of REBOA whom were consulted during trial development. Correct device placement was confirmed by visualization of the catheter in the aorta using ultrasound as well as lack of the catheter in visualized contra-lateral femoral artery and inferior vena cava. Two ultrasound windows were used; the abdominal aorta with visualization of the catheter continuing cranially out of view and the echocardiographic parasternal long window with catheter visualization in cross section in the descending aorta. Safety was defined as a composite prevalence of 5 pre-specified adverse events: vascular damage requiring intervention, arterial thromboembolism, lower extremity amputation, renal failure requiring nontemporary dialysis, and lower extremity paralysis. Secondary outcome measures are listed in Table 2.

A research associate manually collected data during the case and it was then entered into an electronic database after the case concluded. Patients with missing data were excluded from statistical analysis regarding that particular missing variable, however, they were not excluded from the entire analysis.

TABLE 2 Study primary and secondary outcomes

Outcomes
Primary
• Feasibility • Safety
Secondary

• Procedural
  ○ Time from first needle stick to sheath and balloon placement
  ○ No. of attempts required
• Hemodynamic
  ○ End-tidal carbon dioxide
  ○ Mean arterial pressure
• Patient-oriented
  ○ Return of spontaneous circulation
  ○ Neurologically favorable survival

2.5 | Analysis

The primary outcome of feasibility is reported as the proportion of patients who underwent successful REBOA placement whereas the primary outcome of safety is reported as a composite of 5 pre-specified events. A power calculation was not performed due to lack of any prior clinical data and the trial's early-feasibility status, which limited initial patient enrollment to 5 subjects. Changes in secondary hemodynamic outcomes ($ETCO_2$, MAP) after aortic occlusion were determined by using each patient's pre-occlusion measurement as a baseline and comparing it to their post-occlusion readings. We then calculated each hemodynamic variable's mean proportional change. Additional secondary outcomes are reported as a mean with standard deviation.

3 | RESULTS

Five patients were enrolled in the trial and the REBOA procedure was successful in all 5 cases. Patient demographics may be found in Table 1. CFA access was the most technically challenging aspect of the procedure with 2 (40%) patients requiring 1 attempt, 2 (40%) patients requiring 2 attempts, and 1 (20%) patient requiring 4 attempts. In 3 cases, common femoral access was obtained successfully by the emergency physician investigator, whereas in 2 cases it was by the ES investigator. The ES investigator advanced the REBOA catheter in all 5 cases without difficulty. Data regarding the time-to intra-aortic balloon inflation was recorded in the second and third patients as 25 and 11 minutes, respectively. Because of our limited resources and the logistically complex nature of patient enrollment during the COVID-19 pandemic, investigators were unable to consistently record data relating to some of the secondary outcomes, such as the time frame surrounding the procedure, oxygen saturation, coronary perfusion pressure, electrocardiogram rhythm analysis, $ETCO_2$, and MAP.

All 4 of 5 (80%) patients had transient ROSC in the ED after intra-aortic balloon inflation. Of the patients who had ROSC, 2 had a vigorous cardiac response, with post-ROSC bedside echocardiograms demonstrating a visually estimated ejection fraction greater than 45% and an aortic arch MAP of approximately 60 mmHg. Two patients who had ROSC had a less robust response, with post-ROSC bedside echocardiograms demonstrating severe ventricular dysfunction and global hypokinesis with ejection fractions less than 20% and an aortic arch MAP less than 60 mm Hg. All patients with ROSC subsequently re-arrested soon after investigators attempted to wean the intra-aortic balloon support. On re-inflation of the intra-aortic balloon, all 4 patients subsequently regained intrinsic cardiac function, although with a reduced ejection fraction each time this occurred. None of the patients had sustained ROSC and all 5 patients died in the emergency department. At 30 seconds post-aortic occlusion, investigators noted a

TABLE 3 Mean relative change in $ETCO_2$ and MAP after aortic occlusion

	Mean % change (95% CI)
$ETCO_2$	
30-s post-occlusion	26.5 (9.5, 43.5)
5-min post-occlusion	4.0 (−27.2, 35.2)
15-min post-occlusion	−0.6 (−32.2, 31.0)
MAP	
30-s post-occlusion	95.7 (−25.3, 216.7)
5-min post-occlusion	131.0 (−19.0, 281.0)
15-min post-occlusion	21.0 (−16.9, 58.9)

Abbreviations: CI, confidence interval; $ETCO_2$, end tidal carbon dioxide; MAP, mean arterial pressure.

statistically significant increase in $ETCO_2$ of 26% (95% CI, 10%, 44%), although none of the other changes in hemodynamic variables reached statistical significance (Table 3).

4 | LIMITATIONS

This trial had several limitations. First, it was conducted at a tertiary academic referral center and our feasibility findings are limited to similar institutions. Second, our sample size was small and underpowered to detect efficacy or safety. Third, this trial took place in the context of the COVID pandemic. Enrollment was halted a month after it began due to the onset of the pandemic and resumed 8 months later when the University lifted research restrictions. All 4 of 5 patients were enrolled during the COVID pandemic and it is possible that COVID infection could have contributed to the etiology of their arrest and their outcomes. COVID infection control procedures made enrollment logistically much more difficult and contributed significantly to our difficulties in collecting secondary outcome data. None of the patients were tested for COVID due to the scarcity of test availability at the time.

5 | DISCUSSION

This is the first trial in the emergency medicine literature to demonstrate that REBOA can feasibly be used in ED OHCA patients in the United States tertiary ED. Recent trials in Europe by critical care physicians have demonstrated similar results in terms of feasibility and improvements in $ETCO_2$ after aortic occlusion during chest compressions, although this was the first trial to measure changes in real-time blood pressure.[8–10] We found that the most challenging aspect of using REBOA during a cardiac arrest resuscitation was obtaining CFA access, whereas the actual advancement of the REBOA catheter was uncomplicated. Unfortunately, this trial was unable to determine the safety of REBOA because all patients died before safety outcomes could be assessed.

Establishing feasibility is an important step in assessing a new therapeutic intervention but the question remains, will this technique lead to improved patient outcomes? Our limited data suggest that using REBOA as an adjunct to traditional CPR leads to improvements in CPR quality and central perfusion, although it is unclear if this these improvements are clinically significant as none of the patients survived to hospital admission. In 3 of 4 patients with available data, we noted rapid and statistically significant increases in $ETCO_2$ after initiation of aortic occlusion, however, increases in $ETCO_2$ at 5 and 15 minutes were much smaller and not statistically significant.

Despite improvements in hemodynamics and ROSC, each patient suffered a re-arrest when we attempted to wean them from the intra-aortic balloon, and none survived. Subsequent re-inflations would lead to a resumption of ROSC, followed by yet another re-arrest at the next attempt to wean, despite efforts to maximize medical support.

We hypothesize that this phenomenon of re-arrest, which was also noted in the aforementioned Norwegian trial, is related to the ER-REBOA catheter's inability to provide true partial-REBOA support. The ER-REBOA catheter may be thought of as an on/off switch without a dimmer function; it performs as designed when fully occluding the aorta but has a very limited ability to titrate any partial blood flow distal to the balloon. Removal of a small amount of saline from the intra-aortic balloon quickly results in a disproportionately large amount of aortic flow distal to the balloon, leading to rapid hemodynamic collapse and re-arrest.[13] The recent FDA approval of novel partial-REBOA devices that are able to finely titrate partial flow beyond the aortic balloon may help to address this problem.[14,15]

In summary, our data suggest that using a protocol involving RCPR for OHCA patients in a tertiary academic ED is feasible and that aortic occlusion during chest compressions is temporally associated with a transient improvement in $ETCO_2$. Although using RCPR as an adjunct to traditional ACLS is possible, the technique remains in its infancy and its efficacy is uncertain. Future research should focus on several areas: detailing the hemodynamic effects of aortic occlusion, determining if new partial-REBOA-capable devices help to prevent re-arrest after ROSC, examining the potential to use this technique as a bridge to more resource-intensive interventions such as ECPR and coronary reperfusion, and how to safely adapt this approach for institutions with more limited resources.

AUTHOR CONTRIBUTIONS

James Daley conceived the study, designed the trial, and obtained funding. Austin Johnson and Christopher Moore supervised the conduct of the trial and data collections. Charles Wira, Ani Aydin, Daniel Joseph, James Bonz, Justin Belsky, Ryan Coughlin, Rachel Liu, John Sather, Reinier Van Tonder, Rachel Beekman, Elyse Fults, Raj Ayyagari, Igor Latich, Juan Carlos Perez Lozada, Angelo Marino, Hamid Mojibian, Jeffrey Pollak, and Cassius Ochoa Chaar provided advice and guidance on study protocol design and procedure implementation as well as were present to assist with patient enrollment. Kathryn Cannon Kisken and Douglas Barber undertook recruitment of participants and data collection. Kathryn Cannon Kisken managed the study coordination efforts. James Daley, Rachel Beekman, and Kathryn Cannon Kisken drafted the

manuscript, and all authors contributed substantially to its revision. Austin Johnson and Christopher Moore should be considered joint senior authors. James Daley takes responsibility for the article.

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CONFLICTS OF INTEREST

James Daley would like to declare a potential conflict of interest. He received funding in the form of a research grant from Prytime Inc, the manufacturer of the ER-REBOA catheter used in this trial. He has no other financial relationship with the company and does not personally receive payments of any kind. Prytime Inc has not viewed this manuscript and had no part in its preparation or the design of the trial.

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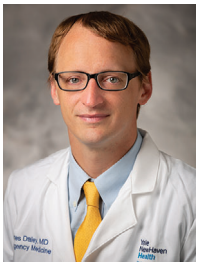

James Daley, MD, MPH, is an Assistant Professor of Emergency Medicine at Yale School of Medicine in New Haven, Connecticut. He is fellowship-trained in emergency ultrasound and research. His research interests are in resuscitation and diagnostic testing, particularly the use of point-of-care echocardiogram in critically ill patients as well as novel endovascular interventions for resuscitation.

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