

Resuscitative endovascular balloon occlusion of the aorta in Canada: a context-specific position paper from the Canadian Collaborative for Urgent Care Surgery (CANUCS)

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SUMMARY

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a well-described intervention for noncompressible torso hemorrhage. Several Canadian centres have included REBOA in their hemorrhagic shock protocols. However, REBOA has known complications and equipoise regarding its use persists. The Canadian Collaborative on Urgent Care Surgery (CANUCS) comprises surgeons who provide acute trauma care and leadership in Canada, with experience in REBOA implementation, use, education and research. Our goal is to provide evidence- and experience-based recommendations regarding institutional implementation of a REBOA program, including multidisciplinary educational programs, attention to device and care pathway logistics, and a robust quality assurance program. This will allow Canadian trauma centres to maximize patient benefits and minimize risks of this potentially life-saving technology.

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a well-described intervention for noncompressible torso hemorrhage.¹⁻⁴ International literature has described the indications, technique and outcomes of 7- to 12-French REBOA devices.^{2,4,5} Several Canadian centres have included REBOA in local hemorrhagic shock protocols.^{6,7} Since Health Canada approved the 7-French ER-REBOA catheter in October 2017 and Canadian sites began offering the Basic Endovascular Surgical Techniques (BEST) Course developed by the American College of Surgeons, Canadian interest in REBOA has increased.

Despite national interest, REBOA has known complications and there is equipoise regarding its use in patients with trauma.^{2,8} Clinical position statements and practice guidelines regarding REBOA have been published by other organizations to help standardize care.^{3,9-13} However, these documents are not generalizable to the Canadian setting and the role of REBOA in Canadian trauma systems remains unclear. Although there is a growing body of international literature (with most reports coming from the United States, South America and Japan), limited Canadian publications are available to guide national recommendations.^{6,7,14,15}

The Canadian Collaborative for Urgent Care Surgery (CANUCS) comprises surgeons who provide acute trauma care, including direct experience with REBOA, and leadership in trauma care across Canada. The objective of this paper is to provide context-specific consensus recommendations (consistent with the consensus process of the *Canadian Journal of Surgery*) to Canadian centres that are considering implementing a REBOA program to assist in optimizing patient safety, as well as quality assurance and improvement. These recommendations are informed by evidence, where available, or by expert opinion, where evidence is not available.

DEVELOPMENT OF STATEMENTS AND RECOMMENDATIONS

We created statements and recommendations for use of REBOA in Canadian centres in stages. First, 1 investigator (N.L.B.) searched MEDLINE and PubMed for articles mentioning use of REBOA in their title or abstract, including relevant REBOA primary studies, systematic reviews and clinical practice statements or guidelines. Searches used the keywords “resuscitative balloon occlusion of the aorta” or “REBOA” as relevant Medical Subject Heading indexing terms are not yet available. We also reviewed bibliographies of studies and asked CANUCS members for other studies, unpublished documents or data (e.g., unpublished provincial or hospital-based data, such as the number of REBOA deployments since implementing a REBOA program), or society or college statements relevant to the creation of recommendations specific to the Canadian context. With the assistance of a CANUCS member who had fellowship training in vascular and endovascular surgery (D.J.R.), we also conducted secondary literature searches from related surgical or interventional disciplines if we could not identify any studies that included our target patient population of trauma patients (e.g., safe vascular access techniques in vascular surgery and interventional radiology).

We then shared identified studies with members of the CANUCS and held several iterative virtual meetings (Zoom Video Communications) and group email threads to discuss potential issues relevant to the implementation of REBOA in Canadian trauma centres. Numerous co-authors have direct experience with REBOA insertion, use and education in Canada, the US and Africa. During these meetings, members discussed the existing literature and clinical practice statements or guidelines identified by the search.

Thereafter, using a modified Delphi process, we created a list of context-specific statements (which provided rationale for our recommendations and, in some cases, literature-based benchmarks for REBOA use) and recommendations for implementation of REBOA in Canada. During this process, we considered whether recommendations created to guide use of REBOA in other countries applied to the Canadian context. The goal of these meetings was to achieve consensus regarding recommendations. If consensus could not be reached, we did not provide a recommendation. We presented statements and recommendations, followed by a description of the literature supporting the statement and the rationale for creation of the statement (Box 1). We used this process instead of that recommended in the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) guidelines because insufficient literature yet exists to conduct a formal GRADE evaluation on implementation of a REBOA program.¹⁶

At the time of literature synthesis, we identified 1 report describing a single centre’s first year of their REBOA program, with a focus on system improvement,¹⁷ and 1 guideline for a multidisciplinary approach to institutional REBOA programs based on a panel of 6 trauma and vascular surgeons from Level 1 trauma centres in the US.¹⁰ We did not identify any published randomized controlled trials on REBOA in human participants; we look forward to the results of UK-REBOA to inform future recommendations. Most primary publications on REBOA use in humans consist of retrospective reviews, prospective observational studies and case series or case reports.² This is consistent with Level III or IV evidence, as per the Oxford Centre for Evidence-Based Medicine; expert opinion guidelines are Level V evidence.

A recent systematic review on REBOA for major exsanguination included 89 studies; 57 of 61 case series and cohort studies were at high risk of bias, as per the Cochrane Collaboration tool (not applied to 28 case reports).¹³ Current primary studies would have a moderate, serious or critical risk of bias as per the Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool, and were not designed to evaluate

Box 1: Clinical practice recommendations

REBOA placement

- Recommendation 1: Individual institutions should be responsible for credentialing REBOA providers and developing protocols to optimize patient care.
- Recommendation 2: Access for REBOA placement should be limited to the common femoral artery, directly over the femoral head.
- Recommendation 3: The position of the REBOA balloon should be confirmed before inflation.
- Recommendation 4: REBOA deployment should follow manufacturers’ instructions for use.
- Recommendation 5: Institutions must have physician resources to monitor the patient during balloon deployment.

Patient management after REBOA inflation

- Recommendation 6: Zone 1 aortic occlusion should be less than 30 minutes and should not be performed without a certified trauma, acute care or vascular surgeon present, with institutional capacity to meet these constraints.
- Recommendation 7: Zone 3 occlusion should be less than 60 minutes.
- Recommendation 8: Institutions transferring patients with zone 3 aortic occlusion to an interventional radiology suite must have in-suite capacity for resuscitative interventions.
- Recommendation 9: REBOA should be deployed only in sites with the capacity for definitive hemorrhage control.
- Recommendation 10: Institutional protocols for device removal and patient monitoring after REBOA are necessary and should be developed in conjunction with colleagues from vascular and endovascular surgery and from critical care medicine.

Quality assurance and quality improvement

- Recommendation 11: Institutions implementing REBOA should have multidisciplinary education, simulation, review and maintenance of skills programs.
- Recommendation 12: Institutions implementing REBOA should have a surgical REBOA coordinator.

REBOA = resuscitative endovascular balloon occlusion of the aorta.

processes of care within REBOA programs. We have interpreted the available information with these limitations in mind, driven by an understanding of both REBOA use and the Canadian health care system, to prioritize patient safety during implementation of REBOA programs. As the literature evolves, and the Canadian experience with REBOA grows, we expect to modify our recommendations accordingly.

CLINICAL PRACTICE STATEMENTS

Statement 1: *The busiest trauma centres in Canada may expect fewer than 15 trauma patients who could potentially benefit from REBOA per year*

Rationale: Although the Trauma Quality Improvement Program database recorded a median of 6 (interquartile range 4–7) REBOA cases per year in 2019,³ the busiest trauma centres in the US report up to 70 REBOA deployments annually.⁹ The frequency of REBOA use in Canada appears to be more consistent with reports from Japan (6 cases per year)^{18,19} and the United Kingdom (3–8 cases per year)²⁰ A recent gap analysis from 2 trauma centres in Alberta identified 30 patients who could have potentially benefitted from REBOA over a 2-year period.¹⁴ This is consistent with an estimate of up to 15 cases of REBOA use annually reported by the Vancouver General Hospital (N. Garraway, personal communication, 2020) and up to 6 cases by the Nova Scotia Trauma Program, based on an internal needs assessments (unpublished data). In the 2 years after the implementation of REBOA programs at Montreal General Hospital, Vancouver General Hospital and St. Michaels Hospital in Toronto in 2018, there have been 27, 5 and 4 REBOA deployments, respectively (unpublished data; N. Garraway, personal communications, 2021).

Statement 2: *In Canada, trauma team members and leaders have variable training and skill sets for accessing the common femoral artery percutaneously or via open surgical cutdown*

Rationale: Open surgical cutdowns were required in up to 50% of REBOA placements in the initial AORTA (Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery) registry.¹ More recent data indicated that 17%–24% of REBOA placements required surgical cutdown for access to the common femoral artery (CFA).^{4,21} A 6-year review of the International ABOTrauma Registry reported that the CFA was accessed percutaneously in 72% of cases, either by using anatomic landmarks (51%) or ultrasonography (21%), and was accessed by open surgical cutdown in 24% of cases.²¹ The impact of the newly developed COBRA system (using a 4-French sheath and balloon)

on procedure success and complications in trauma patients has not yet been explored in clinical settings.²² Patients in cardiac arrest are more likely to require surgical cutdown to facilitate REBOA placement.^{1,3,23} Having immediate skills available to appropriately access the CFA is predictive of both speed of REBOA deployment and lower rates of procedural complications.^{19,23}

Several trauma care models exist nationally, but many sites have trauma team leaders as a shared duty between surgeon and nonsurgeon trauma physicians. In addition, trauma team leaders are not always on site. As a result of this mixed provider model, experience with CFA access is more variable in Canada. Thus, advanced surgical techniques, such as open surgical cutdown for CFA access, may not be immediately available in many Canadian trauma centres. In addition, general surgery residency programs in Canada provide inconsistent training in vascular and endovascular surgery. Although general surgery trainees are often present early in trauma resuscitation, many have minimal surgical experience operating on the femoral artery or gaining CFA access for endovascular procedures. Conversely, with the Royal College of Canada's direct-entry vascular surgery program, current vascular surgery trainees have less experience managing multisystem trauma patients than previous general surgery fellows.

Statement 3: *In Canada, nearly one-quarter of the population lives more than a 1-hour drive from a level 1 or 2 trauma centre*

Rationale: Geographic data reveal that 22.5% of people in Canada live more than a 1-hour drive from a level 1 or 2 trauma centre.²⁴ The presenting physiology of trauma patients living in rural Canada may therefore be different than their urban counterparts. Even if patients ultimately reach an urban centre, transferred trauma patients have significantly higher risk-adjusted mortality than those who are admitted directly.²⁵ Thus, REBOA outcomes in trauma patients in Canada may differ from results reported elsewhere. These realities pose challenges to identifying appropriate patients and logically staffing a REBOA program at a Canadian trauma hospital; these realities must be considered before an institution initiates REBOA.

CLINICAL PRACTICE RECOMMENDATIONS

REBOA Placement

Recommendation 1: **Individual institutions should be responsible for credentialing REBOA providers and developing protocols to optimize patient care**

Rationale: We recommend that REBOA privileges be limited to providers with appropriate training and skills

to access the CFA percutaneously or via open surgical cutdown.^{4,10} Certification from a REBOA course should be part of the credentialing process. Although a course does not confer system success,¹⁷ it does provide a baseline from which to develop an institutional REBOA program.²⁶ Representatives from vascular and endovascular surgery, trauma and acute care surgery, emergency and critical care medicine, anesthesiology, interventional radiology, nursing and hospital administration must be involved in developing institutional REBOA protocols. Tracking and management of REBOA-related complications must be considered in these protocols.^{9,10,17,27}

Recommendation 2: Access for REBOA placement should be limited to the common femoral artery, directly over the femoral head

Rationale: Arterial access for REBOA should be limited to the CFA to allow the artery to be compressed against the underlying femoral head and to limit complications, including access site hematomas, pseudoaneurysm formation, retroperitoneal hemorrhage and limb loss.^{2,13,23}

We recommend using ultrasonography to guide access to the CFA whenever possible.³ As percutaneous access will not always be possible, all items required for percutaneous access and open surgical CFA cutdown should be immediately available in designated locations for REBOA cannulation.¹⁰ Further, a complete REBOA placement and securement kit should be assembled locally and simulated before use with patients.^{10,27}

Recommendation 3: The position of the REBOA balloon should be confirmed before inflation

Rationale: Current evidence supports plain radiography or fluoroscopy to confirm the position of the REBOA balloon in aortic zone I (located between the left subclavian and celiac artery) or zone III (located between the lowest renal artery and aortic bifurcation) before deployment.^{3,5,9} Ultrasonography can identify wire position within the aorta, but has not yet been validated to confirm balloon position.²⁸

Lack of radiologic confirmation of the balloon position should be limited to exceptional situations, such as patients receiving cardiopulmonary resuscitation; radiologic confirmation should then be obtained as soon as possible. Thus, radiologic technologists and imaging must be immediately available where REBOA will be deployed. We recommend using patient stretchers that permit radiography without turning patients with REBOA in situ.

Recommendation 4: REBOA deployment should follow the manufacturers' instructions for use

Rationale: Balloon inflation should follow manufacturers' instructions for use. An arterial line set-up that

connects to the REBOA catheter must be available to monitor blood pressure response to aortic occlusion. Overinflation may result in balloon or arterial rupture.^{3,9} Although some centres and providers have advocated partial balloon inflation,²⁹ partial REBOA has not yet been appropriately studied for use in civilian settings. A partially inflated balloon may migrate, causing intimal injury or iliac artery positioning.^{3,9} Based on currently available evidence, and the expected low volume of REBOA cases at Canadian institutions, we do not advocate for partial inflation as part of institutional protocols.

Recommendation 5: Institutions must have physician resources to monitor the patient during balloon deployment

Rationale: Increases in blood pressure after REBOA deployment can cause balloon migration or create flow around the balloon, precluding adequate occlusion.⁹ Institutions implementing REBOA must have resources to completely dedicate an appropriately trained physician to monitor balloon position and appropriate occlusion, and to manage the balloon until definitive hemorrhage control is achieved.

Patient management after REBOA inflation

Recommendation 6: Zone 1 aortic occlusion should be less than 30 minutes and should not be performed without a certified trauma, acute care or vascular surgeon present, with institutional capacity to meet these constraints

Rationale: A safe duration of zone 1 REBOA occlusion in trauma patients has not been defined by randomized controlled trials. Data from animal studies suggest that a balloon inflation time of up to 30 minutes is well tolerated, but 60 minutes results in an overwhelming physiologic insult that negates benefit.³⁰ A case series from Japan also reported a 50% mortality rate with a median balloon occlusion time of 65 minutes.¹⁸ Thus, the goal occlusion time in zone 1 is less than 30 minutes.^{3,11,13} To achieve this goal, zone 1 should not be occluded unless the hemorrhage control procedure can begin within 15 minutes of occlusion.⁹ Thus, zone 1 should not be occluded without a trauma or acute care surgeon present.⁹ In addition, zone 1 should not be occluded in institutions that cannot accommodate immediate operating room availability.

Recommendation 7: Zone 3 occlusion should be less than 60 minutes

Rationale: Definitive data on the safe duration of zone 3 aortic occlusion in trauma patients are not yet available. However, experts have suggested that zone 3 should only be occluded if the hemorrhage control procedure can begin within 30 minutes so that

hemorrhage control can be achieved in 60 minutes.^{2,3,11,13,30,31} Survival after longer zone 3 occlusion times has been reported, but is associated with serious complications.

Recommendation 8: Institutions transferring patients with zone 3 aortic occlusion to an interventional radiology suite must have in-suite capacity for resuscitative interventions

Rationale: To ensure additional procedures can be performed if necessary, capacity includes supplies or processes (e.g., thoracostomy and central line kits, massive transfusion capability) and personnel (e.g., surgeons, anesthesiologists, respiratory therapists). Further, institutions implementing REBOA without a hybrid operating room suite should have a protocol for transfer from the operating room to interventional radiology and vice versa.³²

Recommendation 9: REBOA should only be deployed in sites with the capacity for definitive hemorrhage control

Rationale: Successful use of REBOA has been previously described in austere, prehospital, rural and transfer environments.^{33–37} However, Canadian paramedic and air ambulance services have variable provider models, resources and transfer times. In Canada, it is not feasible at this time to transfer a patient with in situ REBOA such that appropriately trained health care professionals can manage the REBOA and achieve the recommended timeline to the operating room and interventional radiology at the receiving site.

Recommendation 10: Institutional protocols for device removal and patient monitoring after REBOA are necessary and should be developed in conjunction with colleagues from vascular and endovascular surgery and from critical care medicine

Rationale: After hemorrhage control, the REBOA balloon must be deflated, and the catheter and sheath must be removed as soon as possible.^{3,9} An ankle-brachial index (ABI) should be recorded after balloon deflation and before leaving the operating room–interventional radiology suite. An ABI of 1.0–1.2 is considered normal in patients with compressible, non-calcified arteries. To continue invasive blood pressure monitoring, radial arterial access is recommended before removal of REBOA.

Institutional protocols for device removal and patient monitoring after REBOA are necessary. These protocols should be developed with vascular and endovascular surgery, as well as critical care medicine.^{10,27} If vascular and endovascular surgeons are not present for REBOA device removal, indications for consultation must be clearly defined. Vascular examinations of the lower

extremity and access site must be performed for at least 24 hours.¹⁰ Hourly neurovascular assessments should occur, as per local protocol. There should be a low threshold for computed angiographic assessment after an abnormal physical examination, including an ABI less than 0.9. In addition, assessment for pseudoaneurysm formation within 48 hours after percutaneous sheath removal is recommended.^{3,9}

Quality assurance and quality improvement

Recommendation 11: Institutions implementing REBOA should have multidisciplinary education, simulation, review and maintenance of skills programs

Rationale: Stakeholder education (including vascular and endovascular surgery, emergency medicine, nursing, interventional radiology, critical care, anesthesiology, trauma and acute care surgery) is necessary for institutions to prepare for introduction of a REBOA program.^{10,27} Multidisciplinary (including nurses, physicians, resident physicians, respiratory therapists, anesthesia assistants, radiologists), in situ simulation training is recommended before in vivo REBOA deployment.^{10,27}

Further, all REBOA deployments should be reviewed by a multispecialist panel to assess for appropriate indications.^{10,17,27} Ongoing competency and maintenance of skills is required and should follow institutional requirements. This would ideally include wet laboratories, task trainers, and multidisciplinary simulation.^{10,17} REBOA procedures should be coded using the classification from the *International Classification of Diseases, 10th edition* (ICD-10), namely REBOA ICD-10 04L03DZ. Canadian sites participating in REBOA deployment should contribute to a quality assurance or improvement registry (e.g., the AORTA registry).^{1,3}

Recommendation 12: Institutions implementing REBOA should have a surgical REBOA coordinator

Rationale: A REBOA site coordinator guides the process of deployment, dwell time and removal. The coordinator should be the primary contact with consulting services and leadership of the operating room, interventional radiology, emergency department and intensive care unit. Although different specialties have been successfully trained to insert and deploy REBOA^{3,21} in the Canadian context, the hospital REBOA coordinator should be a trauma or vascular and endovascular surgeon.¹⁰

CONCLUSION

Resuscitative endovascular balloon occlusion of the aorta is a well-described intervention for noncompressible

torso hemorrhage. However, REBOA has known complications and equipoise persists regarding its use. In Canada, case volumes, composition of trauma teams, experience with vascular access and geography create unique challenges for implementing and supporting REBOA programs. This context-specific position paper provides guidance for Canadian trauma centres regarding REBOA credentialing, multidisciplinary education, logistics and quality assurance to maximize patient benefits and minimize risks.

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