Life over limb: Arterial access-related limb ischemic complications in 48-hour REBOA survivors

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BACKGROUND: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is increasingly used in some trauma settings. Arterial access-related limb ischemic complications (ARLICs) resulting from the femoral arterial access required for REBOA are largely under reported. We sought to describe the incidence of these complications and the clinical, technical, and device factors associated with their development.

METHODS: This was a retrospective cohort study of records of adult trauma patients from the American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute care surgery registry between October 2013 and September 2020 who had REBOA and survived at least 48 hours. The primary outcome was ARLIC, defined as clinically relevant extremity ischemia or distal embolization. Relevant factors associated with ARLIC were also analyzed.

RESULTS: Of 418 identified patients, 36 (8.6%) sustained at least one ARLIC; 22 with extremity ischemia, 25 with distal embolism, 11 with both. Patient demographics and injury characteristics were similar between ARLIC and no ARLIC groups. Access-related limb ischemic complication was associated with larger profile devices ($p = 0.009$), cutdown access technique ($p = 0.02$), and the presence of a pelvic external fixator/binder ($p = 0.01$). Patients with ARLIC had higher base deficit ($p = 0.03$) and lactate ($p = 0.006$). One hundred fifty-six patients received tranexamic acid (TXA), with 22 (14%) ARLICs. The rate of TXA use among ARLIC patients was 61% (vs. 35% TXA for non-ARLIC patients, $p = 0.002$). Access-related limb ischemic complication did not result in additional in-hospital mortality, however, ARLIC had prolonged hospital LOS (31 vs. 24 days, $p = 0.02$). Five ARLIC required surgical intervention, three patch angioplasty (and two with associated bypass), and four ARLIC limbs were amputated.

CONCLUSION: Femoral artery REBOA access carries a risk of ARLIC, which is associated with unstable pelvis fractures, severe shock, and strongly with the administration of TXA. Use of lower-profile devices and close surveillance for these complications is warranted in these settings and caution should be exercised when using TXA in conjunction with REBOA. (*J Trauma Acute Care Surg.* 2022;92: 723–728. Copyright © 2021 American Association for the Surgery of Trauma.)

LEVEL OF EVIDENCE: Prognostic and Epidemiologic, Level III

KEY WORDS: Trauma; limb complications; resuscitative endovascular balloon occlusion of the aorta; REBOA; TXA.

With origins dating back to the Korean War, the use of an endovascular balloon for aortic occlusion during resuscitation has emerged as an adjunct to modern trauma resuscitation in selected cases. The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in the setting of traumatic noncompressible torso hemorrhage has grown in recent years.[1] Factors contributing to increased utilization include the development of lower-profile sheath delivery systems, more widespread availability of the devices, and some evidence of efficacy.[2,3] Even with growing comfort with the technique, the arterial access required to deploy REBOA devices in the setting of severe hemorrhagic shock remains difficult and can result in arterial access-related limb ischemic complications (ARLIC).[4] The ischemia and reperfusion induced by REBOA, as well as concomitant patient injuries, inexperience of providers placing these devices, and the prothrombotic state induced by the use of tranexamic acid (TXA) may predispose REBOA access sites to ARLIC also contribute to the development of ARLIC.[5] We sought to assess the incidence of these complications and the clinical, device, and technical factors associated with them.

METHODS

This was a retrospective cohort study performed in accordance with the STROBE guidelines (Supplemental Digital Content, http://links.lww.com/TA/C233). The study used REBOA records from the Aortic Occlusion for Resuscitation in Trauma and Acute care surgery registry, sponsored by the American Association for the Surgery of Trauma (AAST). After obtaining local IRB approval for data collection on all adult patients undergoing aortic occlusion, enrolled centers in the United States submit data directly to the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study via an AAST portal. Approval for this analysis was granted by the AORTA review panel, and deidentified data for admissions between October 2013 and September 2020 were compiled. Data points analyzed included patient demographics and injury characteristics, device and procedural technical aspects, and in-hospital outcomes.

The study cohort consisted of trauma patients who had REBOA placed and survived at least 48 hours following the procedure. The primary outcome of this study was ARLIC, which was a composite of two variables in the registry: clinically relevant extremity ischemia or distal embolization. In the AORTA registry data collection tool, these variables are referred to as "Local access

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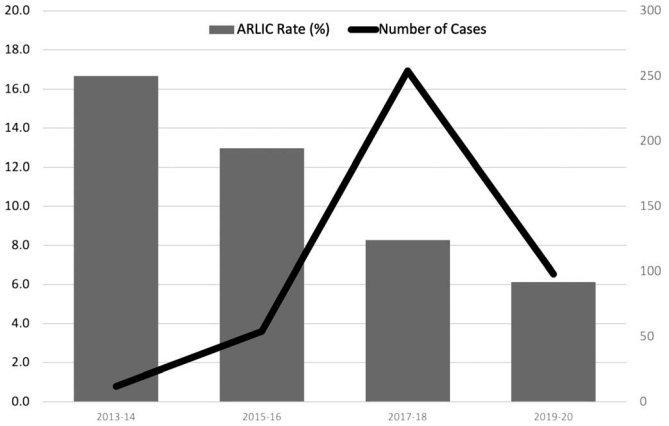

Figure 1. Biannual raw numbers of REBOA procedures and percentage with ARLIC. Complete reporting of all REBOA cases from all centers was unavailable for 2019 and 2020.

site complications" and are limited to include only those deemed "RELATED TO ENDOVASCULAR AO [aortic occlusion] ACCESS SITE ONLY." The AORTA data collection tool is available on the AAST website at: https://www.aast.org/Assets/5cf268d4-4a49-4c1f-9898-ac6b2b20b75f/635120800550300000/aorta-data-collection-tool-final-docx. Factors associated with ARLIC including access technique, operator, and the use of TXA during initial care were identified using χ^2 test or Fisher exact test and Student *t* test or Wilcoxon-Mann-Whitney test as appropriate. To reduce the effect of confounding, variables significantly ($p \leq 0.05$) associated with ARLIC on univariate analysis were entered into a multivariate logistic regression model to determine independent associations with the primary outcome. Statistical analysis was performed using SPSS Statistical Software version 24 (IBM, Armonk, NY). Statistical significance was defined at a p value less than 0.05.

RESULTS

Of 761 total REBOA records in AORTA, 418 (63%) were of patients surviving at least 48 hours, with 36 (8.6%) sustaining at least one ARLIC. Twenty-two patients had extremity ischemia, 25 had distal embolism, and 11 had both. The number of REBOA cases increased over time with a corresponding general numerical decrease in ARLIC rate (Fig. 1). There were 38 medical centers with cases in the cohort, with 27 contributing five or fewer cases. The seven highest reporting centers accounted for 78% of the cohort and 30 of the 36 (86%) of the ARLIC. The ARLIC rate at these centers ranged from 7.9% to 10.9%, with one center reporting a rate of 3.7% In the entire cohort, patient demographics, mechanism, Injury Severity Score (ISS), and hospital transfer status were similar between patients with and without ARLIC. Patients with ARLIC presented with a greater degree of shock than those without as evidenced by higher base deficit ($p = 0.03$) and lactate ($p = 0.006$) on admission, as well as a numerically lower systolic blood pressure ($p = 0.09$) and greater use of vasopressors during resuscitation ($p = 0.06$) (Table 1).

The duration of aortic occlusion was available for 313 (75%) of records and differed between those sustaining a ARLIC (median, 42 minutes; interquartile range [IQR], 19–92 minutes) and those without a ARLIC (36 minutes; IQR, 20–60 minutes), but the difference was not statistically significant ($p = 0.4$). Resuscitative endovascular balloon occlusion of the aorta placement in the emergency room was associated with the development of ARLIC ($p = 0.05$) over placement elsewhere; however, primary procedural performer specialty and training level were similar between the groups with and without ARLIC. The ER-REBOA (Prytime Medical Devices, Boerne, TX) was the most common REBOA device (78%), and its use was associated with a lower rate of ARLIC than other, larger-diameter devices ($p = 0.009$). Vascular access via surgical arterial cutdown was associated with a higher rate of ARLIC than was percutaneous arterial access ($p = 0.02$). Zone III REBOA was not associated with an increased risk of ARLIC over zone I ($p = 0.6$); however, the presence of a pelvic external fixator or binder was ($p = 0.01$). Tranexamic acid was used in conjunction with REBOA in 156 cases, with 22 developing a ARLIC (14%). Nearly two thirds (61%) of patients with a ARLIC had received TXA versus 35% TXA in the no ARLIC group ($p = 0.002$) (Table 2). Multivariate analysis revealed cutdown technique (odds ratio, 3.1; 95% confidence interval, 2.6–3.7; $p = 0.03$), TXA administration (2.5, 2.1–2.9, 0.01), and device other than ER-REBOA (2.3, 1.9–2.7, 0.04) as independent predictors of ARLIC.

TABLE 1. Patient Demographics and Admission Physiology

Variables	Reported, n	No ARLIC (n = 382)	Reported, n	ARLIC (n = 36)	*p*
Age: median (IQR), y	382	44 (30)	36	35 (25)	0.12
Male, n (%)	379	300 (79)	36	25 (69)	0.18
History of PVD	382	16 (4)	36	0 (0)	0.21
Injury mechanism					0.82
Blunt, n (%)	357	273 (76)	36	27 (75)	
Penetrating, n (%)	357	81 (23)	36	9 (25)	
ISS, median (IQR)	308	29 (22)	35	33 (12)	0.29
Transfer from alternate facility	382	54 (14)	36	3 (8)	0.33
Admission base deficit: median (IQR), mEq/L	281	9.5 (9)	29	10 (10.5)	0.032
Admission lactate: median (IQR), mmol/L	288	5.5 (5.2)	31	7 (11.9)	0.006
REBOA initiation SBP: median (IQR), mm Hg	319	70 (31)	**35**	62 (34)	0.088
Vasopressors/Inotropes required, n (%)	382	182 (48)	36	23 (64)	0.06

PVD, peripheral vascular disease; AO, aortic occlusion.

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TABLE 2. REBOA Procedural and Technical Characteristics

Variable	Reported, n	No ARLIC (n = 382)	Reported, n	ARLIC (n = 36)	*p*
Zone I REBOA	362	201 (55)	36	18 (50)	0.6
TXA given, n (%)	382	134 (35)	36	22 (61)	0.002
Pelvic stabilization, n (%)	382	103 (27)	36	17 (47)	0.01
Pelvic embolization, n (%)	382	55 (14)	36	6 (17)	0.71
Location of initial REBOA attempt					0.05
ED, n (%)	382	246 (64)	36	29 (81)	
Outside the ED, n (%)	382	136 (36)	36	7 (19)	
Arterial access technique					0.02
Percutaneous, n (%)	361	337 (93)	35	29 (83)	
Cutdown, n (%)	361	24 (7)	35	6 (17)	
Device type					0.009
ER-REBOA, n (%)	352	301 (85)	35	24 (69)	
Other (Coda, Reliant), n (%)	352	51 (14)	35	11 (31)	
Primary performer					0.67
Trauma surgeon, n (%)	356	301 (85)	36	31 (86)	
Fellow, n (%)	356	36 (10)	36	5 (14)	
Other, n (%)	356	19 (5)	36	0 (0)	
HLOS: median (IQR), d	382	24 (26)	36	31 (32)	0.02

ED, emergency department; SBP, systolic blood pressure; HLOS, hospital length of stay.

Mortality for the entire cohort was 21% and the rate did not differ between those with and without ARLIC. Among those surviving to discharge, ARLIC was associated with a median of seven additional hospital days ($p = 0.02$). Five (14%) of ARLIC underwent a surgical intervention: three underwent patch angioplasty (two with associated bypass), and a total of four (11%) limbs with ARLIC were amputated. Surgical thrombectomy/embolectomy is not a distinct AORTA variable.

DISCUSSION

This analysis of data from the largest United States registry of REBOA use revealed an 8.6% ARLIC rate among individuals surviving at least 48 hours following traumatic injury. The ARLIC rate in the cohort was driven primarily by the centers reporting the highest number of cases to the registry. The high-reporting centers had similar rates, suggesting a consistently observed rate of ARLIC despite center-based differences in practice and/or reporting. Although ARLIC are not widely reported in the REBOA literature, our observed rate is higher than those previously reported, which range from 0% to 6%.[6–8] An early review of data from the AORTA registry from 2012 to 2015 reported one pseudoaneurysm at the arterial access site and two distal embolizations but no cases of limb ischemia or surgical intervention/amputation.[6] A later report of cumulative data (2013–2017) from the AORTA registry cited limb ischemia in 1.2% of cases and embolization in 4.8%. The amputation rate was comparable to ours at 1.2%.[9] Both of these AORTA reports included data from patients who eventually died, with the median time to death 1 day in each and mortality rates between 70% and 90%. A case series of six patients who underwent REBOA placement reported no REBOA-related complications.[2] A retrospective review of REBOA-related arterial access complications following use of a device with a lower profile (7 French) sheath also reported no complications.[10] A meta-analysis conducted in 2018 of the incidence of limb complications following REBOA use reported an overall rate of 5.6% related to groin access.[8] We chose to limit our AORTA analysis to those records of patients who survived at least 48 hours because ARLIC may take time to develop and are not clinically relevant if they occur in patients who die shortly thereafter. Our unique smaller cohort size, selecting for 48-hour survivors, may serve to partially explain the higher ARLIC and subsequent intervention rates we discovered.

Our analysis of the AORTA registry also differs somewhat from that reported in a single-center series of 31 patients from 2013 to 2016.[11] This series of survivors of at least 6 hours did not report specifically on vascular access site complications, but focused on limb fasciotomy and amputation, with rates of 40% and 13%, respectively. Fasciotomy and amputations and were primarily related to preexisting limb injuries and not directly attributed to limb ischemia induced by REBOA, although longer occlusion times were associated with fasciotomy. These outcomes are supported by a recent analysis of REBOA data in survivors of at least 6 hours from the National Trauma Data Bank (2015–2017) in which the rate of amputation was 5% and primarily associated with severe lower extremity injuries, with less than 1% of amputations occurring in limbs without injuries.[12] Despite methodologic differences, both reports support our finding of a low REBOA-associated amputation rate.

Larger profile balloon devices used for REBOA such as the Coda (Cook Medical, Bloomington, IN) and Reliant (Medtronic, Minneapolis, MN) have recommended sheath diameters of 12 French and were primarily used for aortic occlusion prior to the purpose-made ER-REBOA with its 7 French sheath diameter. We noted that the shift to a lower-profile device was protective against ARLIC, which agrees with existing previous reviews of outcomes following REBOA use that have shown higher rates of ARLIC in periods prior to the availability of the ER-REBOA device; suggesting that lower profile devices may be safer.[7,10,13] Larger arterial access diameters often require open arterial repair

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following sheath removal if a "preclose" percutaneous closure technique is not used prior to sheath placement. In one single-center retrospective review, all 14-French sheath access sites required arteriotomy repair with 21% of patients requiring additional vascular procedures.[7] In contrast, patients with 7-French sheaths in this same review did not require any further vascular procedures upon removal. The "preclose" technique is not generally feasible for truly emergent bedside procedures, such as REBOA, in the setting of hemorrhagic shock. As evidenced by the association of arterial cutdown for access and ARLIC, the primary arteriotomy repair required for large sheath diameters and larger profile nature of these devices likely leaves the patient at an increased risk for ARLIC and the use of lower-profile devices is encouraged. New aortic balloon occlusion devices with profiles as low as 4 French have been approved and are coming to market in the United States, which may serve to limit the incidence of ARLIC moving forward.[14]

Unstable pelvic injuries can be associated with life threatening arterial hemorrhage and exsanguination without urgent intervention. These injuries are frequently stabilized with pelvic binders followed by external fixation during the initial phases of resuscitation and support has been growing for the use of zone III REBOA in the setting of these injuries. Asmar et al.[15] found patients with pelvic fractures who received REBOA had improved outcomes but also, as noted in our series, that ARLIC were associated with pelvic fixation. Prolonged use of REBOA in patients because of extremis, such as unstable pelvic injuries with hemorrhage, may have an increased risk of developing ARLIC.

Base deficit and lactate are both reliable measures of hypovolemic shock and global ischemia.[16] We observed that the development of ARLIC was associated with shock severity at the initial presentation as measured by significant metabolic acidosis. In addition, ARLIC was associated with lower blood pressure and greater use of vasopressors at the time of the REBOA procedure, likely resulting in minimally pulsatile and contracted/underfilled access arteries. These conditions make vascular access challenging and may predispose to the development of ARLIC. Given these results, we suggest consideration be given to establishing small-diameter arterial access earlier on in a patient's resuscitation such that, if needed, REBOA can be performed more safely following controlled upsizing of the initially established access.

Tranexamic acid is an antifibrinolytic agent that has been used to reduce hemorrhage across many specialties. The use of TXA has increased in trauma settings over the past decade because of the Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage trials, which generally favorable thrombotic complication profiles for the drug.[17,18] We, however, observed that the use of TXA in the setting of REBOA was strongly associated with the development of ARLIC. This is not surprising given that in one military study and in the prehospital STAAMP trial, TXA was associated with increased rates of deep venous thrombosis and pulmonary embolism, although arterial thromboembolism is not reported in these publications.[19,20] Similar findings to those we observed have also been demonstrated in the use of REBOA in controlling postpartum hemorrhage: a recent case study reported bilateral femoral arterial thrombi requiring surgical thrombectomy following the use of REBOA with concomitant use of TXA.[21] As the use of both REBOA and TXA as adjuncts to trauma resuscitation increase, a high index of suspicion for arterial access complications should be maintained if both REBOA and TXA are used, and we urge caution when deciding to use them concurrently.

In this analysis, ARLICs were not associated with additional mortality, but they were associated with an additional week of hospitalization. Overall injury severity as measured by ISS was similar between ARLIC and no ARLIC groups, making it possible that ARLIC played a role in the additional hospital days. Further analysis of the impact of ARLIC on patient outcomes is hindered by the limitations of the data available in the AORTA registry. It is not possible to define the true severity or clinical impact of the ARLIC we observed in this cohort. Although surgical procedures to repair ARLIC were rarely observed in this series, only patch angioplasty and surgical bypass are captured in the AORTA registry. Neither surgical thrombectomy/embolectomy nor localized primary arterial repairs are available in the data set. It is likely that these were required more frequently than in the 14% of ARLIC limbs undergoing patch angioplasty and/or bypass that were captured in this analysis. Amputation of the limb undergoing arterial access for REBOA is captured in the AORTA data set and was relatively rare among all patients undergoing REBOA but was performed in over 10% of ARLIC limbs. Although we cannot comment on the impact of non-iatrogenic limb injuries given the data available, there is a clear association between ARLIC and amputation and ARLIC should not be considered benign complications.

As the title of this article implies, the risk of REBOA-associated ARLIC and subsequent morbidity must be balanced against the potential mortality benefits of aortic occlusion as an adjunct to resuscitation. Resuscitative endovascular balloon occlusion of the aorta is most frequently and effectively employed as a salvage maneuver in patients exsanguinating from subdiaphragmatic sources as a bridge to allow for rapid transfusion and operative hemorrhage control. The potential for ARLIC should not discourage the use of REBOA if it may be lifesaving, but knowledge of the risk factors for ARLIC, especially when REBOA is used concurrently with TXA or in the presence of severe pelvic injuries, may assist clinicians in preparing to deal with complications that arise.

There are several limitations to this analysis. As noted, the AORTA registry data set does not contain sufficiently granular data points to perform detailed analyses of the impact of ARLIC on patient outcomes, particularly in the areas of the impact of limb injury severity and the use of surgical vascular repairs. More granular data on limb injuries are being collected moving forward in a revised AORTA data collection scheme, and further detailed analysis from one or more high-volume REBOA centers in warranted. Analyses of the AORTA registry are also limited by the retrospective nature of AORTA data collection at individual centers and the ensuing potential for recall and selection bias. There is a clear the delay in reporting as evidenced by the lag in available data from recent years. We cannot estimate the impact of the presumably pending REBOA cases on the results of our analysis. Finally, the nature and severity of extremity injuries were not collected in the AORTA registry at the time of this study (extremity abbreviated injury scores were added to new data collection in 2021). Therefore, we cannot assess the impact of these preexisting injuries on the development or outcomes of the ARLIC reported here.

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CONCLUSION

Arterial access-related limb ischemic complications related to vascular access for REBOA develop in nearly 10% of patients. Shock severity, surgical technique, device size, and pelvic fixation are risk factors for the development of these complications and percutaneous access is clearly preferable to surgical cutdown. The use of TXA and REBOA in conjunction presents additional risk for ARLIC and should be considered judiciously. During and following REBOA, close surveillance for ARLIC is warranted because they can result in amputation and confer a longer hospital stay.

AUTHORSHIP

D.S.K. conceived of the presented idea and designed the study. D.S.K., R.B.L., and S.E.M. performed the statistical analyses. All authors contributed to the writing and/or approval of the article.

DISCLOSURE

The authors declare no funding or conflicts of interest.
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