Life over Limb: Lower Extremity Ischemia in the Setting of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

PHILIP J. WASICEK, M.D., WILLIAM A. TEETER, M.D., M.S., SHIMING YANG, PH.D., PETER HU, PH.D., MELANIE R. HOEHN, M.D., DEBORAH M. STEIN, M.D., M.P.H., THOMAS M. SCALEA, M.D., MEGAN L. BRENNER, M.D., M.S.

From the Shock Trauma Center, University of Maryland Medical Center, Baltimore, Maryland

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a temporizing maneuver used to decrease hemorrhage, and thus perfusion, below the level of aortic occlusion (AO). We sought to investigate lower extremity ischemia in patients who received REBOA. Between February 2013 and September 2016 patients at a tertiary center that received REBOA and survived more than six hours were enrolled. Thirty-one patients were identified, the mean ISS was 40 ± 14 and inhospital mortality was 39 per cent. Twenty received REBOA in zone 1 (distal thoracic aorta). Three (15%) developed lower extremity compartment syndrome (LECS) after zone 1 REBOA. Injury of iliofemoral arteries and veins was each associated with calf fasciotomies (both $P = 0.005$). A longer duration of AO at zone 1 was associated with calf and thigh fasciotomy ($P = 0.046$ and $P = 0.048$, respectively). Iliofemoral arterial injury was associated with thigh fasciotomy ($P = 0.04$). Eleven patients received REBOA in zone 3 (distal abdominal aorta). Five (45%) patients underwent fasciotomy; four (36%) due to LECS. Femoral arterial injury was associated with calf fasciotomies ($P = 0.02$). There was no association with sheath size or laterality and need for fasciotomy. Neither groin access for REBOA or AO solely caused limb loss or LECS. The contribution to distal ischemia by REBOA remains unclear in patients with lower extremity injury.

RESUSCITATIVE ENDOVASCULAR BALLOON occlusion of the aorta (REBOA) is a temporizing maneuver used to decrease hemorrhage below the level of the aortic occlusion (AO) in the setting of exsanguinating hemorrhage. Decreased distal blood flow could potentially cause ischemia, particularly in the setting of prolonged occlusion times. The extremity ischemic burden of REBOA has not been well studied. Prior clinical studies have reported on REBOA-related and access site-related complications[1–5]; however, the detailed description of lower extremity ischemia in the setting of REBOA is lacking.

After an ischemic insult, progressive tissue swelling and microvascular damage occurs, which may lead to compartment syndrome and necrosis necessitating fasciotomy and/or amputation.[6, 7] The threshold for significant ischemia of the lower extremity has been defined as less than six hours.[6] However, this is mostly documented in patients with chronic disease not in hemorrhagic shock who have developed a healthy system of collateral circulation permitting several hours of ischemia. More contemporary investigation has focused on the ischemic threshold for functional limb recovery.[7] Large animal models estimate the ischemic threshold for functional limb recovery of lower extremities to be 4.7 hours,[8] and this decreases to less than three hours in the setting of hemorrhagic shock.[9] In the setting of additional derangements, such as soft tissue injury, skeletal injury, vascular injury, and potentially the presence of an introducer sheath, this threshold could be even less, as low as minutes to hours, which is potentially in the range of duration of AO with REBOA. In addition, this threshold may be affected by REBOA location, which is typically placed in descending thoracic aorta (Zone 1) for intra-abdominal hemorrhage or the distal abdominal aorta (Zone 3) for pelvic or junctional hemorrhage.

The objective of this study was to investigate lower extremity ischemia in patients who received REBOA.

Address correspondence and reprint requests to Philip J Wasicek, M.D., University of Maryland School of Medicine, 22 South Greene Street, Baltimore, MD 21201. E-mail: pwasicek@som.umaryland.edu.

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Methods

Demographics and hospital course data were collected prospectively on all trauma patients, age ≥18 years old, who underwent REBOA at the Shock Trauma Center. This database was approved by the Institutional Review Board of the University of Maryland, Baltimore. Patients admitted between February 2013 and September 2016 who received REBOA were included. Patients who did not survive greater than six hours into their hospitalization were excluded.

Patient variables such as age; gender; Injury Severity Score (ISS); Abbreviated Injury Score (AIS); location of REBOA placement; specific injuries including level of pelvic or lower extremity arterial; venous, soft tissue, and bony injuries; laboratory values; and blood product transfusion data were recorded. Vital signs including heart rate and systolic blood pressure were recorded before and after AO from a continuous (0.5 Hz) vital sign–monitoring system using a network of GE-Marquette-Solar-7000/8000® (General Electric, Fairfield, CT) patient vital signs monitors as previously described.[10] Primary outcomes included the development of lower extremity compartment syndrome (LECS), fasciotomy, and amputation. Secondary outcomes were defined as ICULOS, HLOS, and inhospital mortality. Amputations, fasciotomies, and indications for either were grouped according to time of procedure relative to REBOA. Level of compartment syndrome (calf, thigh, and gluteal) and level of amputations were documented. During the study period, REBOA was initially performed using a 12-French (Fr) sheath and the CODA® catheter (Cook Medical, Bloomington, IN). There was a transition to using a smaller 7–Fr sheath with the FDA approval of a novel, smaller profile catheter, ER-REBOA™ (Prytime Medical, Boerne, TX), which occurred in February 2016. Of note, the 12-Fr introducer sheath requires open common femoral artery exploration and repair for removal, whereas the 7-Fr introducer sheath can be removed percutaneously with manual pressure. REBOA sheath size, laterality, method of sheath removal, and sheath-related complications were recorded and categorized as additional secondary outcomes. REBOA-specific procedural timing metrics were recorded by available time-stamped videography in the resuscitation areas and operating rooms.

Patients were divided into two groups; Zone 1 and Zone 3 REBOA. Patients who underwent fasciotomy and/or amputation were compared to those who did not for differences in demographics, clinical data, and outcomes. Unpaired two-sample t test was used for mean comparison and Fisher's exact test for proportion comparison. Statistical significance was defined as a P value of 0.05 or less. Statistical analysis was performed using R Software (version 3.3.0; R Development Core Team, Vienna, Austria).

Results

Patient Demographics and Characteristics

A total of 31 consecutive patients were identified who underwent REBOA and survived six hours or greater into their hospitalization. Twenty had AO in Zone 1, and 11 had AO at Zone 3. Patient demographic characteristics are depicted in Table 1. Both groups were predominantly male. Zone 3 REBOA patients were older, sustained more blunt injury, had a higher lower extremity AIS, and had a higher incidence of pelvic fracture than zone 1 REBOA patients. All patients received packed red blood cell (pRBC) transfusions, and the mean number of pRBC was higher in the Zone 1 group compared with the Zone 3 group

TABLE 1. *Demographics and Incidence of Concomitant Injuries*

	Zone 1 (n = 20)	Zone 3 (n = 11)	P Value
Gender (% male)	90%	100%	1.00
Age (years old, ±SD)	33 ± 10	51 ± 16	0.0005
Mechanism of injury (% Blunt)	40%	91%	0.008
ISS	41 ± 14	39 ± 15	0.75
Lower extremity AIS	2.00 ± 1.59	3.36 ± 0.92	0.01
Iliac/femoral arterial injury	25%	45%	0.42
Iliac/femoral venous injury	25%	27%	1.00
Lower extremity fracture	35%	45%	0.71
Pelvic fracture	30%	91%	0.002
Isolated lower extremity soft tissue injury	25%	18%	1.00
% Patients in cardiac arrest at time of REBOA	35%	18%	0.43
Mean systolic blood pressure before AO	49 ± 35	57 ± 31	0.52
Mean systolic blood pressure after AO	140 ± 36	118 ± 15	0.07
Initial hemoglobin laboratory value	10.8 ± 2.2	10.8 ± 2.4	0.98
Lowest hemoglobin laboratory value within first 24 hours of admission	8.3 ± 2.0	8.8 ± 2.3	0.50
Number of units of pRBC transfused within first 24 hours of admission	30 ± 28	18 ± 16	0.20
AO duration	63 ± 55 minutes	87 ± 46 minutes	0.23

(30 ± 28 *vs* 18 ± 16 units). Mean AO time among Zone 1 and Zone 3 groups were similar, 63 ± 55 *versus* 87 ± 46 minutes ($P = 0.23$).

Outcomes—Incidence of Fasciotomy and Amputation, and length of stay (LOS)/Mortality

Primary and secondary outcomes are given in Table 2. Inhospital mortality and overall LOS were similar between Zone 1 and Zone 3 groups. Among the zone 1 group, two patients presented with extremely mangled extremities (as well as abdominal and pelvic injuries), and completion amputations were performed on both patients immediately after REBOA. One patient in the Zone 1 group underwent delayed amputation after attempted limb salvage for transection of the superficial femoral artery secondary to a gunshot wound, compared with two patients in the Zone 3 group, one of whom suffered a pelvic, tibia, and femur fracture as well as an open subtalar joint dislocation and the other sustained a complex pelvic fracture including a highly comminuted iliac wing, open femur fracture, as well as common femoral artery and external iliac vein injuries (Table 3). All three patients who underwent fasciotomy in the Zone 1 group ultimately developed LECS compared with four out of five patients in the Zone 3 group (one patient underwent prophylactic unilateral calf fasciotomy and did not develop compartment syndrome in any other compartments), but this was not statistically significant. Forty per cent of fasciotomies were performed at the index operation, and the remaining 60 per cent of fasciotomies were performed during the first 72 hours of admission.

Comparison of Incidence of Fasciotomy with Concomitant Injuries, Degree of Hemorrhagic Shock and pRBC Transfusion, and Duration of AO

Concomitant injuries were compared with the incidence of calf and thigh fasciotomies. All of the patients who underwent fasciotomy had a concomitant vascular and/or skeletal injury to the involved limb. For Zone 1 patients, iliofemoral artery and venous injury were both associated with calf fasciotomy (both $P = 0.005$). Iliofemoral arterial injury was also significantly associated with thigh fasciotomy ($P = 0.04$). Femoral arterial injury was associated with calf fasciotomy for patients undergoing Zone 3 AO ($P = 0.02$). Pelvic and lower extremity fracture rates were not significantly different when comparing those patients with and without fasciotomies.

Longer AO times were associated with calf ($P = 0.046$) and thigh fasciotomies ($P = 0.048$) in the Zone 1 REBOA group, as shown in Figure 1. Mean AO times were similar among patients in the Zone 3 REBOA group who underwent calf fasciotomy and those who did not. Mean AO time was not significantly longer

Table 2. *Primary and Secondary Outcomes*

	Zone 1 (n = 20)	Zone 3 (n = 11)	*P* Value
LOS ± SD, (range)	25.0 ± 27.8 days (1–102)	27.5 ± 27.5 days (1–86)	0.81
ICU LOS	14.7 ± 16.5 days (1–56)	25.3 ± 26.7 days (1–86)	0.18
Inhospital mortality	40%	36%	1.00
Fasciotomy (calf)	15%	45%	0.09
Fasciotomy (thigh)	10%	27%	0.32
Fasciotomy (gluteal)	0%	9%	0.35
Amputation (immediate)	10%	0%	0.53
Amputation (delayed)	5%	10%	0.28

Table 3. *Detailed Description of Fasciotomies and Delayed Amputations*

	Description of Fasciotomies	Description of Delayed Amputation
Zone 1: patient #1	Bilateral calf and thigh fasciotomies for compartment syndrome	N/A
Zone 1: patient #2	Unilateral prophylactic calf fasciotomy, but then developed thigh compartment syndrome on same limb and underwent thigh fasciotomy	N/A
Zone 1: patient #3	Unilateral calf fasciotomy for compartment syndrome	Above-knee amputation
Zone 3: patient #1	Unilateral prophylactic calf fasciotomy	N/A
Zone 3: patient #2	Bilateral prophylactic calf fasciotomy but then developed unilateral thigh compartment syndrome and underwent thigh fasciotomy	N/A
Zone 3: patient #3	Unilateral calf and thigh fasciotomies for compartment syndrome	Hemipelvectomy
Zone 3: patient #4	Bilateral calf fasciotomy for compartment syndrome	Above-knee amputation
Zone 3: patient #5	Unilateral calf fasciotomy and bilateral thigh and gluteal fasciotomies for compartment syndrome	N/A

N/A, not applicable.

between those who underwent thigh fasciotomy and those that did not in the Zone 3 REBOA group.

The degree of anemia as measured by the initial hemoglobin, lowest hemoglobin values within the first 24 hours of admission, and number of pRBC transfused within the first 24 hours of admission were compared with the incidence of fasciotomy. Among Zone 1 patients, a lower initial hemoglobin level (8.0 ± 1.3 *vs* 11.3 ± 2.0 g/dL) was associated with fasciotomy ($P = 0.01$). Zone 3 patients who underwent fasciotomy a had significantly lower 24-hour hemoglobin nadir (7.2 ± 0.9 *vs* 10.2 ± 2.3 g/dL, $P = 0.002$) and higher pRBC transfusion requirement compared with Zone 3 patients who did not require fasciotomy (29 ± 19 *vs* 9 ± 3 units, $P = 0.03$).

Description of Sheath-Related Metrics and Comparison with Fasciotomy

There were 13 patients with 7-Fr sheaths placed and 18 patients with 12-Fr sheaths placed. All patients had sheath removal during the index operation. Mean indwelling sheath duration was 170 ± 125 minutes (maximum 482 minutes). Sheath placement and size compared with fasciotomy laterality is compared in Table 4. There was no association with the size or presence of the sheath and need for fasciotomy for Zone 1 or Zone 3. For Zone 1 patients, 14 patients underwent open sheath removal. There were two cases in which intraoperative thrombectomy was performed at time of sheath removal, without administration of systemic heparin, and neither patient required a fasciotomy or had further complications from limb ischemia. There were two patients who had arterial shunts placed instead of arteriotomy repair at the time of sheath removal, but expired before definitive interposition graft repairs could be performed (LOS was 11.2 and 29.1 hours for these patients). Neither suffered additional complications requiring fasciotomy or amputation after the index operation. There were two cases in which the sheath was placed in the superficial femoral artery, requiring patch angioplasty closure for the 12 Fr sheath, and primary repair for the 7 Fr sheath. The remaining six patients had percutaneous removal of 7 Fr sheaths without complication.

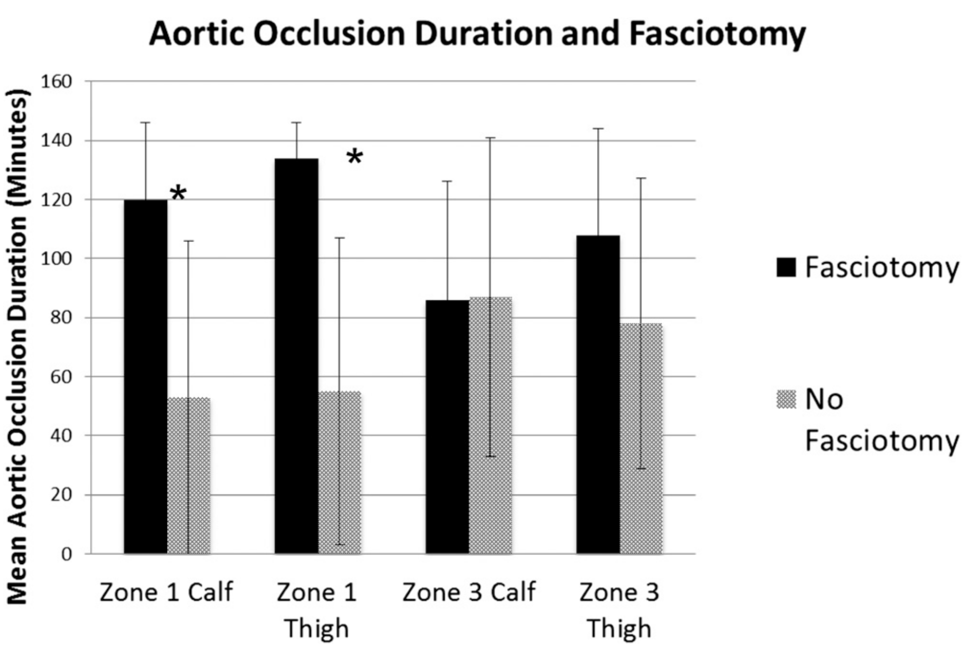

FIG. 1. Aortic occlusion duration and fasciotomy. *$P < 0.05$.

TABLE 4. *Incidence of Fasciotomy: Laterality of Sheath and Sheath Size*

	Fasciotomy Ipsilateral to Sheath	No Fasciotomy Ipsilateral to Sheath	Fasciotomy Contralateral to Sheath	No Fasciotomy Contralateral to Sheath
7-Fr Sheath Zone 1 (n = 10 patients)	1	9	1	9
12-Fr Sheath Zone 1 (n = 10 patients)	1	9	1	9
7-Fr Sheath Zone 3 (n = 3 patients)	2	1	2	1
12-Fr Sheath Zone 3 (n = 8 patients)	2	6	2	6

For Zone 3 patients, eight patients underwent open sheath removal. There was one instance of a 12 Fr cannulation at the bifurcation requiring reconstruction with interposition graft. This patient underwent a prophylactic calf fasciotomy on this extremity without further complication. There were three cases in which thrombectomy was performed at the time of sheath removal, and in one of these cases, calf fasciotomy was performed prophylactically. Systemic heparin was not administered during these cases and there were no related complications. The remaining three patients had removal of 7-Fr sheaths requiring only manual compression for hemostasis. Two of these three patients ultimately not only had fasciotomies on the ipsilateral side of sheath placement, but also had pelvic fractures and multiple long bone fractures of the same extremity and did not have complications from sheath placement as documented by arterial duplex within 72 hours after sheath removal.

Discussion

Comparison between Zone 1 versus Zone 3 REBOA

As shown in Table 1, the Zone 3 group was older, suffered more blunt injury, had a higher lower extremity AIS, and had a higher incidence of pelvic and lower extremity fractures, as well as iliofemoral arterial injury. Despite these differences, both groups were extremely critically ill, as evidenced by their high ISS, admission hemodynamics, incidence of cardiac arrest at the time of REBOA, transfusion requirements, hemoglobin values, and rate of inhospital mortality. Not surprisingly, the incidence of LECS, fasciotomy and amputation is high in patients receiving REBOA as they are some of the most physiologically devastated in our population. The hypothesis that AO decreases perfusion contributing to lower extremity ischemia is supported by the association of longer AO times with fasciotomy in Zone 1 patients. The finding of an association between longer AO times and fasciotomy in zone 1 as compared with zone 3 may suggest that AO in Zone 1 results in greater decreased perfusion to the lower extremities. Because perfusion is determined by a multitude of complex factors, it is likely not as simple as the level of AO.

One of the largest studies to date examining LECS, fasciotomy, and amputation in trauma patients was performed by Branco et al.[11] and included more than 34,000 patients, 10,315 of whom sustained extremity injury. Among their findings, hypotension on admission, higher pRBC transfusion requirements, higher ISS, penetrating injury, open fractures, arterial, and venous injuries were all found to be associated with the need for fasciotomy after extremity trauma. The largest predictors (highest odds ratio) were found to be arterial injury, venous injury, followed by pRBC transfusion. Significant associations between the degree of hemorrhage, pRBC transfusion requirement, arterial and venous injuries were found between REBOA patients and fasciotomy, consistent with the findings by Branco et al.[11] Interestingly, Branco et al.[11] examined patients without extremity injury and found 14 patients who underwent lower extremity fasciotomy. On further examination, these patients were critically ill with significant injuries (all had major arterial and/or venous injuries), mean ISS 20 ± 10, and with a 36 per cent mortality rate. Although there were no REBOA patients who underwent fasciotomy without concomitant lower extremity injury, this finding by Branco et al.[11] suggests that it is a possibility. Because this population is similar to patients who meet indications for REBOA, constant assessment of lower extremity compartments in all REBOA patients is mandatory.

Sheath-Related Ischemia/Morbidity

Cases have been reported in the endovascular aneurysm repair,[12, 13] intra-aortic balloon pump,[14] and extracorporeal membrane oxygenation[15–17] literature describing lower extremity ischemia secondary to the placement of large introducer sheaths and cannulas in the common femoral artery (CFA), leading to obstruction and decreased flow. Although the introducer sheaths for REBOA are smaller (7 or 12 Fr in our series), there is still some degree of flow limitation, and in one patient it was noted that a 7-Fr sheath was completely occlusive in the CFA at time of removal. This patient was an 18-year-old female and in profound shock. Prolonged usage of the sheath after REBOA has been reported in Japan with the use of 7-Fr sheaths for up to 45 hours without any sheath-related complications[2]; however, there is description of a case of lower extremity ischemia secondary to prolonged usage (28 hours) of a larger 12-Fr sheath in a patient who underwent REBOA (25 minutes of occlusion time).[18] All patients in our series had sheath removal during the index operation. REBOA demands CFA access, and thus. a two-level hit to distal perfusion; one at the level of AO affecting both extremities, and one at the site of cannulation affecting the ipsilateral extremity. The degree to which the AO and sheath occlusion individually impact distal tissue perfusion are unknown. However, no statistical association was found between sheath laterality and incidence of fasciotomy. Given these findings, we submit that either CFA can be cannulated for REBOA regardless of concomitant lower extremity injury. Theoretically, placing the sheath on the contralateral side away from injury makes sense; however factors at the time of resuscitation may demand cannulation of the ipsilateral side, which seems acceptable given these results. It should be noted, however, that regardless of the side of access and presence or absence of distal injury, critical attention should be paid to timing of sheath removal; if the 7 Fr sheath must remain in place until coagulopathy is restored, assessing distal perfusion with an angiogram before leaving the operating room or angio suite is advised. If angiography, interpretation of angiography, or determination of distal ischemia in the setting of an indwelling sheath are not familiar skills, consultation with endovascular colleagues is mandatory.

Role of Prophylactic Fasciotomy in the Setting of REBOA

Studies have shown that early intervention with fasciotomy *versus* delayed fasciotomy is associated with a reduced amputation rate[19, 20] but the liberal use of routine prophylactic fasciotomy is limited by potential short and long-term morbidity associated with its use.[21, 22] Others have advocated for prophylactic fasciotomy in the setting of high-risk criteria (shock, ischemia time, and injury pattern).[23, 24] The value of prophylactic fasciotomy for REBOA patients is unclear, however, these patients certainly meet high-risk criteria described, and given their prognosis, the risk of the procedure outweighs any additional demise from LECS or amputation.

Conclusions

Patients undergoing REBOA are at increased risk of developing LECS and requiring fasciotomy at all levels. Increased duration of AO, worsening hemorrhagic shock, and concomitant vascular injuries are associated with the need for fasciotomy in the setting of REBOA. Neither groin access for REBOA or AO solely caused limb loss or the need for fasciotomy. The contribution to distal ischemia by both AO and an indwelling sheath remains unclear. Vigilant assessment of compartments and distal perfusion is warranted before, during, and after REBOA and use of a partially occlusive indwelling sheath.

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