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Fixed-Distance Model for Balloon Placement During Fluoroscopy-Free Resuscitative Endovascular Balloon Occlusion of the Aorta in a Civilian Population

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IMPORTANCE Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an innovative procedure in the treatment of noncompressible truncal hemorrhage. However, readily available fluoroscopy remains a limiting factor in its widespread implementation. Several methods have been proposed to perform REBOA without fluoroscopic guidance, and these methods were adapted predominantly from the military theater.

OBJECTIVE To develop a method for performing REBOA in a civilian population using a standardized distance from a set point of entry.

DESIGN, SETTING, AND PARTICIPANTS A retrospective study of whole-body computed tomographic (CT) scans from a cohort of 280 consecutive civilian trauma patients from University Hospitals of Lyon, France, was used to calculate the endovascular distances from both femoral arteries at the level of the upper border of the symphysis pubis to aortic zone I (descending thoracic aorta) and zone III (infrarenal aorta). These whole-body CT scans were performed between 2013 and 2015. Data were analyzed from July 16 to December 7, 2015.

MAIN OUTCOMES AND MEASURES Two segments (1 per zone) common to all CT scans were isolated, and their location, length, prevalence in the cohort, and predicted prevalence in the general population were calculated by inverting 99% certainty tolerance limits.

RESULTS Among the 280 trauma patients (140 men and 140 women) in this study, the mean (SD) height was 170.7 (8.7) cm, and the mean (SD) age was 38.8 (16.5) years. The common segment in zone I (414-474 mm) existed in all CT scans. The common segment in zone III (236-256 mm) existed in 99.6% and 97.9% of CT scans from the right and left femoral arteries, respectively. These segments are expected to exist in 98.7% (zone I) and 94.9% (zone III) of the general population.

CONCLUSIONS AND RELEVANCE Target distances for blind placement of REBOA exist with more than 94% prevalence in a civilian population. These findings support the expanded use of REBOA in emergency department and prehospital settings. Validation for safety and efficacy on cadaveric and clinical models is necessary.

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Hemorrhage is the most frequent cause of preventable deaths for both civilian and military trauma patients. During the recent conflicts in Iraq and Afghanistan, more than 80% of preventable deaths were attributed to hemorrhage.¹⁻⁴ Similarly, in the civilian setting, hemorrhage is responsible for 15% to 40% of preventable deaths.⁵⁻⁷

The most common source of bleeding leading to preventable deaths reported in the literature is noncompressible truncal hemorrhage,^{1,2,4,6} a recent concept^{8,9} rigorously defined as “hemorrhage arising from trauma to the torso vessels, pulmonary parenchyma, solid abdominal organs and disruption of the bony pelvis resulting in hypotension or shock.”^{10(p122)} This injury is extremely lethal, with mortality ranging from 18% to 45%.^{9,11,12}

Noncompressible truncal hemorrhage can be managed via external aortic clamping during resuscitative thoracotomy¹³⁻¹⁹ or laparotomy.^{20,21} However, these procedures are difficult to perform in the field, and they require significant equipment and trained physicians.²²⁻²⁵ They also expose the patient to the various complications of open surgery. Despite recent skepticism,¹⁸ another emerging technique in controlling noncompressible truncal hemorrhage is resuscitative endovascular balloon occlusion of the aorta (REBOA), which allows for endovascular occlusion of the aorta by inflating a balloon proximal to the focus of hemorrhage.^{21,22,26-28} Stannard et al²² divided the aorta into 3 zones: zone I (extending from the left subclavian artery to the celiac trunk), zone II (from the celiac trunk to the lower renal artery), and zone III (from the lower renal artery to the aortic bifurcation). The balloon is inflated in either zone I or zone III depending on the suspected focus of hemorrhage.²² Zone II is never occluded because it exposes the patient to the risks of zone I occlusion (visceral ischemia) without providing significant benefits compared with a zone III occlusion. Animal and human studies suggest that REBOA may be superior to aortic-cross clamping by thoracotomy.^{29,30} However, the need for fluoroscopic confirmation of balloon placement during REBOA remains a limiting factor in its use in the emergency prehospital setting.

Even though there have been reported uses of REBOA without radiographic guidance,³¹⁻³⁴ the search for developing an effective fluoroscopy-free REBOA method is ongoing.^{10,35-37} Several methods have already been proposed. However, they were either performed on a male combatant population³⁵ (which is not representative of the general population) or needed morphometric and medical background data,³⁷ information that is usually unavailable in the acute setting. Thus, a simple model proposing the same distance for all patients in a civilian population is needed to make REBOA accessible to emergency prehospital and hospital settings where fluoroscopy and/or medical records are not immediately available. The aim of this study was to develop a fixed-distance model by determining whether there are specific portions within zone I and zone III of the aorta that are at a reliable and reproducible distance from a standardized point of entry and that could be used as targets for the positioning of the balloon during REBOA in a civilian population.

Key Points

Question When implementing resuscitative endovascular balloon occlusion of the aorta (REBOA), is the distance from the point of entry of the catheter to the balloon position in zones I and III the same for the entire general population?

Findings In this cohort study performed using 280 computed tomographic scans, the same distances were recorded in 97% of the sample population. These distances are expected to exist in more than 94% of the general population.

Meaning By marking these 2 distances on the catheter, we found that REBOA could be implemented without fluoroscopy, in emergency prehospital and hospital settings and for every patient regardless of morphometric and medical background data.

Methods

Study Population

A series of 280 anonymized contrast-enhanced whole-body computed tomographic (CT) scans of trauma patients (140 men and 140 women) hospitalized between January 1, 2013, and October 7, 2015, were selected at random from the Picture Archiving and Communication System of the University Hospitals of Lyon, France. Demographic data of the study population are presented in **Table 1**. We then performed a retrospective study of the distance from 2 standardized points of entry (the right and left femoral arteries) to zones I and III of the aorta. No approval from an ethics committee was necessary because this study was noninterventional, and the data were anonymized.

Study Protocol

Reconstructed images of each CT scan (OsiriX; Pixmeo) were used to measure the distances between the vessel origins within 0.1 mm. The superior border of the symphysis pubis, an easily identified external landmark, was chosen as a reference point (RP) from which all distances were measured. Entry RPs were defined as the position within the femoral arteries at the level of the superior border of the symphysis pubis. The central axis of the femoral arteries, the iliac arteries, and the aorta were then plotted using the CT scans (eFigure in the **Supplement**). All distances were calculated along this central axis relative to the RPs. The aortic bifurcation (inferior boundary of zone III) and the lower renal artery (superior boundary of zone III and inferior boundary of zone II), the celiac trunk (superior boundary of zone II and inferior boundary of zone I), and the left subclavian artery (superior boundary of zone I) were identified, and their distances from both RPs were calculated to determine the boundaries and lengths of the 3 aortic zones. Finally, the depth of the femoral artery, defined as the vertical distance from the skin to the femoral artery at the left RP, was measured on each CT scan, and its correlation with body mass index was calculated.

Data Analysis

All measurements were collected in an Excel spreadsheet (Microsoft), and data were analyzed with R version 3.1.3 for

Table 1. Clinical Characteristics of the Study Population

Characteristic	Mean (SD)	Minimum	25th Percentile	Median	75th Percentile	Maximum	P Value ^a
Men (n = 140)							
Age, y	37.8 (15.5)	17	24	36	48	88	NA
Height, cm	176.6 (6.9)	160	172	177	180	198	NA
BMI	24.47 (4.1)	16.0	22.0	23.7	26.2	36.7	NA
Women (n = 140)							
Age, y	39.8 (17.3)	16	25	37	51	90	NA
Height, cm	164.9 (5.9)	150	160	165	169	183	NA
BMI	23.50 (4.9)	15.6	20.4	21.9	25.9	45.2	NA
Total (N = 280)							
Age, y	38.8 (16.5)	16	24	36	50	90	.15
Height, cm	170.7 (8.7)	150	165	170	177	198	<.001
BMI	23.98 (4.5)	15.6	21.0	23.0	26.1	45.2	.04

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); NA, not applicable.

^a Determined by use of the *t* test (comparing men and women); significance was set at *P* = .05.

Windows. Analysis was performed for the entire cohort, as well as for male and female subgroups. All data regarding lengths are presented as mean (standard deviation) values.

Locating the Common Segments

Once this protocol had been performed on all CT scans, the following algorithm was used to find a common segment of at least 2 cm in each of zones I and III:

1. Find the minimum of the superior boundary of the zone (ie, the upper boundary of the common segment).
2. Find the maximum of the inferior boundary of the zone (ie, the lower boundary of the common segment).
3. If the upper boundary minus the lower boundary is 2 cm or more, then this is the common segment to all CT scans. If it is less than 2 cm, then for each CT scan, begin with the segment [superior boundary - 2 cm; superior boundary] and decrease the distance from each boundary to the RPs by 0.1 mm until reaching the segment [inferior boundary; inferior boundary + 2 cm]. The common segment is the one that is present in the maximum number of CT scans.

A length of 2 cm was arbitrarily chosen as the minimum length for the common segments, given the size of the balloons used for REBOA and the diameter of the aorta.³⁸⁻⁴¹

Normality Testing

For both zone I and zone III, separate distributions were generated for the superior and inferior boundaries. These 4 distributions were assessed for normality using quantile-quantile plots. Normality was quantified with the Shapiro-Wilk test. Statistical significance was set at *P* = .05.

Calculating the Probability of the Segments' Existence in the General Population

For each segment, each of its 2 boundaries was set as a 99% certainty 1-sided tolerance limit for the corresponding zone boundary distribution (ie, the upper boundary of the segment for the upper boundary of the zone). One-sided tolerance limits are single cutoff values above which (or below which) *x*% of the general population will fall with *y*%

certainty.⁴² Tolerance limits are calculated for a given proportion of the population. However, the equation can be solved to calculate the proportion of the population for a given tolerance limit. The proportion *z*_u% of the general population lying inferior to the superior boundary was calculated. Similarly, the proportion *z*_l% lying superior to the inferior boundary was calculated. The proportion of the population for which the segment is valid is the complement of the union of *z*_u% and *z*_l%.

Results

Normality Testing

The quantile-quantile plots for the 4 distributions of the zone boundaries closely follow the normal distribution, on both sides. The Shapiro-Wilk test *P* value was calculated for all distributions before and after the removal of the maximum value of each distribution (Table 2). Before the removal, on the right side, only the superior boundary of zone I and the inferior boundary of zone III follow a normal distribution. On the left side, only the superior boundary of zone I follows a normal distribution. After the removal, all distributions become normal, on both sides. The maximum values were removed as outliers, as evidenced by the quantile-quantile plots.

Common Segments

On the right side, zone I extended from 284 to 653 mm from the RP. On the left side, it extended from 274 to 649 mm. The mean (SD) length of zone I was 220 (21) mm.

On the right side, zone III extended from 160 to 363 mm from the RP. On the left side, it extended from 152 to 367 mm. The mean (SD) length of zone III was 97 (12) mm.

A segment common to 100% of CT scans on both sides exists in zone I extending from 414 to 474 mm from the RP (60 mm long). A segment common to 99.6% of CT scans on the right side and to 97.9% of CT scans on the left side exists in zone III extending from 236 to 256 mm from the RP (20 mm long) (Figure).

Table 2. Data on Zone Boundary Distributions on Both Sides in the Study Population

Distribution	Zone Boundary, mm		P Value ^a
	Range	Mean (SD)	
Right side			
Superior boundary of zone I	474.1-652.6	549.8 (29)	.06
After removing maximum value	474.1-635.6	549.4 (28.5)	.23
Inferior boundary of zone I	284.0-414.1	329.4 (18.4)	.005
After removing maximum value	284.0-391.3	329.1 (17.7)	.76
Superior boundary of zone III	259.6-362.5	297.0 (17)	.03
After removing maximum value	259.6-354.0	296.7 (16.6)	.25
Inferior boundary of zone III	160.1-246.8	200.4 (16)	.40
After removing maximum value	160.1-235.6	200.2 (15.7)	.10
Left side			
Superior boundary of zone I	474.0-649.1	546.3 (29)	.12
After removing maximum value	474.0-628.9	546.0 (28.4)	.39
Inferior boundary of zone I	274.3-410.6	326.0 (18.6)	.003
After removing maximum value	274.3-394.0	325.6 (18)	.65
Superior boundary of zone III	249.0-366.5	293.5 (17.7)	.02
After removing maximum value	249.0-359.0	293.3 (17.2)	.61
Inferior boundary of zone III	151.6-279.0	197.0 (17)	.002
After removing maximum value	151.6-247.9	196.7 (16.3)	.69

^a Shapiro-Wilk test results. Normality was accepted if $P > .05$.

Predictably, on both sides, segment III was inferior to the inferior boundary of zone I in 100% of CT scans, and segment I was superior to the superior boundary of zone III in 100% of CT scans. This means that a balloon placed in the common segment in zone I will never appear in zone III and that a balloon placed in the common segment in zone III will never appear in zone I.

Frequency of Common Segments in the Study Population

Right-sided common segments I and III were calculated to exist in 98.99% and 95.97%, respectively, of the general population. From the left RP, common segments I and III exist in 98.67% and 94.90%, respectively, of the general population (Table 3).

Depth of the Femoral Artery

The mean (SD) depth of the femoral artery was 24 (10) mm and was directly proportional to the body mass index ($R^2 = 0.41$, $P < .001$).

Comparison of the Male and Female Subgroups

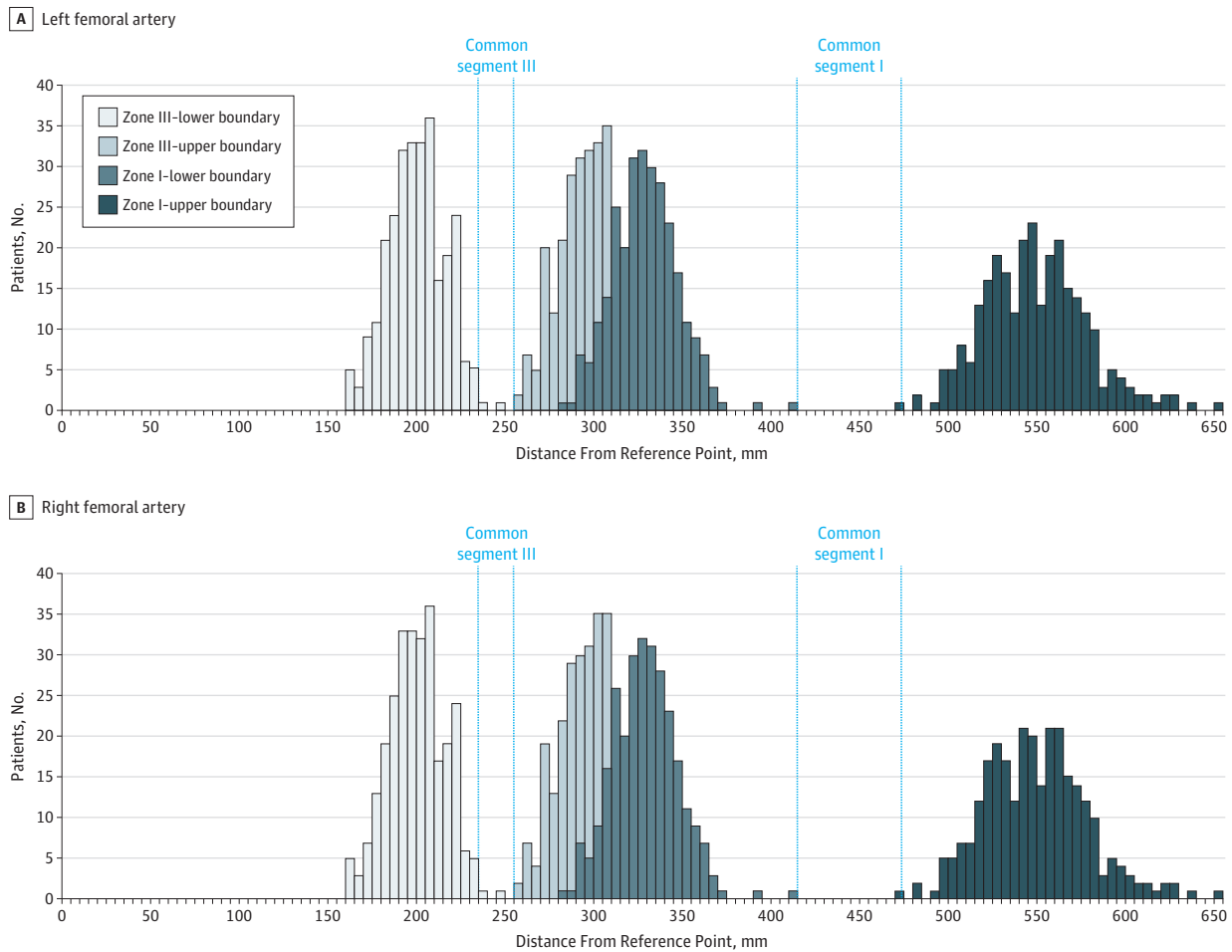
The differences between men and women regarding zone boundaries are presented in Table 4. The common segment in zone I was present in 100% of men and women in our sample, and there was no statistically significant difference between men and women for the common segment in zone III (men = 100% and women = 99.3% for the right side [$P = .16$]; men = 97.1% and women = 98.6% [$P = .21$] for the left side). Regarding the mean (SD) depth of the femoral artery, there was no difference between men (23 [9] mm) and women (24 [10] mm) ($P = .09$).

Discussion

Resuscitative endovascular balloon occlusion of the aorta is a promising technique for the control of noncompressible truncal hemorrhage. However, it cannot be currently used in the prehospital setting because of the need for fluoroscopic confirmation of balloon inflation in the correct aortic zone and because accidental inflation inside aortic branches, such as the renal arteries, must be avoided. Six different ways have been proposed to determine the correct wire length, so that the balloon will be inflated in the right position without fluoroscopy: (1) for zone III only, blind introduction of the balloon up to 50 cm, slow inflation with saline solution, withdrawal until wedged in the aortic bifurcation, and advancement of 5 cm upward³¹; (2) measuring the distance from the point of insertion to external landmarks corresponding to zones I and III^{10,21,36}; (3) a fixed-distance model (calculated on a male combatant population)³⁵; (4) a linear model calculating the expected locations of zones I and III given the torso height of the patient³⁵; (5) ultrasonographic guidance^{36,43,44}; and (6) a multivariate model using morphological and medical background data, recently proposed by MacTaggart et al.³⁷

If REBOA is to be used in the prehospital setting, it is important to develop a very simple method that requires as little information as possible and is applicable to every patient. Our study reports a fixed-distance model in a mixed civilian population that does not depend on any patient information. This model works in 97% of our cohort and is projected to succeed in 94% of the general population. The “general population” is defined as the population from which the sample is drawn, in our case the population of the Lyon area in France. However,

Figure. Distributions of the Distance of Zone I and Zone III Boundaries From the Reference Point in the Study Population



Zero corresponds to the reference point on each side. The blue dotted lines delineate the common segments. Bins are 5 mm in width.

Table 3. Projection of Existence of the Common Segments in the General Population

Common Segment Boundary	Right Side		Left Side	
	% of Population Above Upper or Below Lower Boundary ^a	% of Population With Free Common Segment ^b	% of Population Above Upper or Below Lower Boundary ^a	% of Population With Free Common Segment ^b
Zone I				
Upper boundary (474 mm)	1.01		1.33	
Lower boundary (414 mm)	0.002		0.001	
Sum	1.01	98.99	1.33	98.67
Zone III				
Upper boundary (256 mm)	1.65		3.03	
Lower boundary (236 mm)	2.38		2.07	
Sum	4.03	95.97	5.10	94.90

^a Calculated from 99% certainty 1-sided tolerance limit.

^b Calculated as the complement of the population lying outside of the segment.

this group may not be representative of broader populations. Fortunately, aortic morphometry seems to be more influenced by height⁴⁵ and/or torso length³⁹ than ethnic back-

ground. This means that we can interpret the general population from a height and/or torso length point of view, and given our cohort's diversity (height ranged from 150 to 198 cm), it is

Table 4. Comparison of the Distances From the Reference Points to Zone I and Zone III Boundaries Between Men and Women

Boundary	Mean (SD) Distance, mm		P Value ^a
	Men	Women	
Zone I	231 (18)	210 (17)	<.001
Upper boundary			
Right	560 (28)	540 (27)	<.001
Left	556 (28)	537 (27)	<.001
Lower boundary			
Right	329 (19)	330 (18)	.31
Left	325 (19)	327 (18)	.16
Zone II	33 (9)	31 (9)	.03
Zone III	98 (11)	96 (13)	.08
Upper boundary			
Right	295 (17)	299 (17)	.06
Left	291 (17)	296 (18)	.02
Lower boundary			
Right	198 (16)	203 (15)	.003
Left	194 (17)	200 (17)	.001

^a Determined by use of the t test (significance set at $P = .05$).

reasonable to believe that our results are applicable to patients with the same demographic characteristics as our cohort, regardless of their ethnic background.

Our study also presents data on the comparison of zone boundaries between men and women for the implementation of REBOA. Despite some statistically significant differences, it is important to note that the common segments apply to everybody, regardless of sex.

The fixed-distance model herein proposed is designed to be applied as a blind placement method. An important point concerning the applicability of such a method is its safety. In 3 small series,³¹⁻³³ in which a blind method was successfully applied, the complications reported included inflation inside the iliac artery (2 of 13 cases³¹) and aortic rupture requiring operative repair (1 of 6 cases³²). Both of these complications were prospectively addressed (feeling for the disappearance of the femoral artery pulse and repositioning³¹ and cautiously inflating the balloon,³² respectively). Owing to the possibility of such complications in any blind model, our results must be validated for safety and efficacy on cadaveric and clinical models, with the use of balloons that will already have landmarks for zone I and zone III marked on the catheter (at 444 and 246 mm, respectively [common segment centers], from the middle of the balloon).

One issue that has to be taken into account is the percentage of the general population for whom the model does not work. Unfortunately, there seems to be no way of detecting these patients before the model is actually implemented. For zone I, the model is predicted to fail in 1% of the general population on the right and 1.3% of the general population on the left side (Table 3), with the upper boundary (474 mm from the RP) being more prone to fallibility. Therefore, the closer the balloon is to the lower boundary, herein proposed at 414 mm, the more negligible chances of failure become.

When occluding zone III, however, the probability of incorrect balloon positioning (zone II or iliac artery occlusion)

is 5.1% (Table 3). Zone II occlusion (3%) is not an issue in an exsanguinating patient, because the priority is to stop the bleeding, and the balloon can be repositioned under fluoroscopic guidance when available. An iliac artery occlusion (2.4%) is suspected if the patient does not improve despite adequate resuscitation and is confirmed if a contralateral femoral artery pulse remains present. In that case, the balloon is deflated, pushed upstream, and reinflated, if fluoroscopy is not immediately available.³¹

Ultrasonographic devices are portable and, indeed, easy to use in a prehospital setting, and potentially attractive tools in performing REBOA without fluoroscopy while minimizing complications of a blind technique. However, the inability to visualize the abdominal aorta in certain patients (eg, obese patients or patients with a lot of air in the bowel)³⁶ can necessitate a completely blind model, such as the one we propose. Specifically, 25% of our population had a body mass index ranging from 26 to 45 (Table 1); ultrasonography might not be an option for these patients.

When applying our model, some practical issues must be taken into account. First, our model was calculated to a level of accuracy that cannot be achieved in a true prehospital trauma setting. However, given the potential error of a few millimeters, the common segments are large enough that any such error should be of little consequence. Second, the zone boundaries are calculated relative to the center of the lumen of the femoral arteries, thus ignoring the distance from the skin to the center of the vessel. This distance depends on the identification of external landmarks, the needle's angle, and the distance of the femoral artery from the skin, which in turn depends on subcutaneous fat thickness, but ultimately amounts to a variance of just a few millimeters, which we believe is mitigated by the comparatively large common segments. Finally, REBOA has to be implemented through the femoral artery proximal to the origin of the profunda owing to the large diameter of current devices.

While it is conceivable that the needle cannot be inserted at the standardized point of entry that we propose, the model can still be applied by positioning the marking on the catheter or wire at the level of the superior border of the symphysis pubis.

It is important to note that all blind placement methods, including ours, have different drawbacks. However, the aggregation of these approaches may result in a method that could make a blind implementation of REBOA in the prehospital setting a reality.

Conclusions

The current study, performed on a mixed civilian population, proposes a more than 94% accurate model for the correct positioning of a REBOA catheter for the management of noncompressible truncal hemorrhage without fluoroscopic guidance. This model allows for a standardized method using a simple external landmark (symphysis pubis) to facilitate the use of REBOA in the trauma bay, as well as in the prehospital setting.

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Invited Commentary

What Lengths Should We Go to for Fluoroscopy-Free Resuscitative Endovascular Balloon Occlusion of the Aorta?

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Noncompressible truncal hemorrhage remains the most common source of potentially preventable death following both civilian and military trauma.^{1,2} Efforts to teach how to “stop the bleed” at the point of injury are receiving increased emphasis



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in the trauma care and public health arenas.³ Although a variety of field-capable noninvasive modalities have been developed and studied, they remain site-specific and of variable efficacy. More invasive methods of hemorrhage control by direct aortic clamping via thoracotomy or laparotomy require instruments and surgical expertise that may not be readily available, especially in austere environments.

Resuscitative balloon occlusion of the aorta (REBOA) has recently emerged as a less invasive, yet similarly effective, alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage that does not involve a penetrating chest injury. The potential revolutionary advantages of the REBOA technique include its placement via percutaneous access, the ability to adjust or titrate aortic occlusion, and the potential for placement with or without radiographic guidance. An important challenge remaining in nonradiographic guided REBOA placement is to accurately estimate appropriate bal-

loon positioning in the peridiaphragmatic (zone I) or distal (zone III) aorta, avoiding the additional risks of direct mesenteric ischemia (zone II).

In this issue of *JAMA Surgery*, Pezy et al⁴ present their computed tomography-based aortic anatomy definitions to determine safe and effective fixed-distance REBOA placement in zones I and III. Using reconstructed images of computed tomographic scans from 280 randomly selected trauma patients at admission, the authors have determined common regions of aortic branch origins and defined boundaries of zones I to III from a fixed position at the superior border of the pubic symphysis. Imaging-based margins of safety for catheter placement in appropriate aortic zones led Pezy et al⁴ to recommend zone I placement to 444 mm and zone III placement to 246 mm from access point to the middle of the balloon. They have also determined the mean (SD) depth for percutaneous femoral artery access at 24 (10) mm and calculated the probability of successful extension of the resulting borders to at least 95% of the general population regardless of ethnicity or sex.

While the recommendations based on the computed tomographic determination of aortic zone measurement may prove to be more reliable for balloon placement than external