

Pitfalls, Complications, and Necessity of Education about REBOA: A Single Regional Trauma Center Study

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Purpose: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an emergency procedure and extremely time-dependent, and the proficiency of the physician is important. Due to a lack of REBOA education programs in Republic of Korea, few physicians have been trained in the procedure. In this study, we examined how REBOA education affects clinical outcomes in a single center.

Methods: A retrospective study conducted from February 2017 to June 2020 at a regional trauma center. We collected data of patients who underwent REBOA and analyzed the factors that influenced the outcome. The patients were divided into the educated and non-educated groups (based on REBOA training received by their physicians), and the success and failure groups.

Results: A total of 24 patients underwent REBOA during the study. There were eight patients in the success group and 16 patients in the failure group. There are no significant differences between the educated and non-educated groups in sex, age, ISS, shock, injury-to-REBOA time, injury mechanism, injury sites, arrest, access site, type of catheter, type of REBOA, target Zone, mortality, and the result of REBOA. The non-educated group had a higher risk for failure compared to the educated group in multivariate analysis (odds ratio [OR] 154.64, 95% confidence interval [CI] 1.11-22.60).

Conclusions: Failure in REBOA is harmful to patients. The risk of failure is increased in the non-educated group. Physicians working in the trauma center or emergency department need to complete the REBOA education program.

Keywords: Balloon occlusion; Aorta; Trauma centers

INTRODUCTION

Non-compressible torso hemorrhage is one of the leading causes of potentially preventable trauma deaths [1-3]. Approximately, 30-40% of traumatic patients die from hemorrhage [4]. Globally, 1,481,700 people die from traumatic hemorrhage each year, and the years of life lost from traumatic hemorrhage amount to 74,568,000 years [5]. Consequently, hemostasis is the most important strategy in the care of patients with severe trauma [6]. Open aortic cross-clamping (OACC) has been used for trauma patients with torso hemorrhage [7]. In recent years, it has been argued that resuscitative endovascular balloon occlusion of the aorta (REBOA) can replace OACC in selective cases [8,9]. In Republic of Korea, most trauma patients are affected by blunt traumas (90.8% of reported patients). In particular, REBOA plays an important role in patients with hemorrhagic shock [10].

REBOA involves temporary placement of a balloon in the aorta to block the proximal portion of the bleeding site [3,11-13]. REBOA is less invasive compared to OACC and may provide similar physiological results [14]. Despite these benefits, REBOA is not widely used, due to lack of understanding of the procedure, lack of skills, and potential complications associated with the procedure [3,11,12]. Some of the known complications of REBOA include aortic occlusion, postoperative thrombosis, and limb amputation [15].

Since REBOA is an emergency procedure and extremely time-dependent [3], the proficiency of the physician is important. However, only a few have been trained in REBOA because of the lack of education programs for REBOA in Republic of Korea.

In this study, we examined how education for REBOA affects the outcomes in a single center. Patients who received REBOA in a single institution were targeted. The survey focused on the clinical outcomes, categorized by physicians who were educated in REBOA and those who were not. We hypothesized that there would be fewer complications in physicians trained in REBOA.

Endovascular training for REBOA (ET-REBOA)

Endovascular training for REBOA (ET-REBOA) is a training program for REBOA in Republic of Korea. In

the early period, REBOA was limited due to the lack of 7 Fr catheters, and there was no choice but to use a 14 Fr sheath or a 12 Fr hard balloon. In recent years, clinical applications of the 7 Fr catheters have increased, and good results for patient survival have been reported [16,17]. Therefore, ET-REBOA was created by Group for Resuscitative Endovascular and Advanced Treatment on Trauma (GREAT) for REBOA education. ET-REBOA was first started in May 2018 and is currently being implemented as a Korean Association for Research, Procedures, and Education on Trauma (KARPET) education program (<http://karpet.or.kr>).

METHODS

Population

This study was a retrospective study conducted from February 2017 to June 2020 at a regional trauma center belonging to tertiary medical institutions in the Gangwon province, Republic of Korea. We collected data of patients who underwent REBOA using the registry of a Yonsei University Wonju Severance Christian Hospital. The patients were divided into two groups based on training received by their attending physicians (educated and non-educated) for comparative analysis. The educated group consisted of patients who received REBOA from trauma surgeons who completed training in REBOA, while the non-educated group included patients who received REBOA from physicians who did not complete training in REBOA. Demographic data, Injury Severity

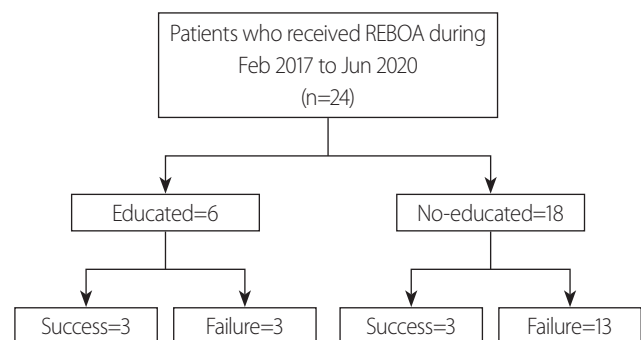


Fig. 1. Flowchart of this study. REBOA: resuscitative endovascular balloon occlusion of the aorta.

Table 1. Patient characteristics according to education status

	Total (n=24)	Educated (n=6)	Non-educated (n=18)	p-value
Sex				1.000
Male	12 (50.0)	3 (50.0)	9 (50.0)	
Female	12 (50.0)	3 (50.0)	9 (50.0)	
Age	52.8±17.6	62.3±14.3	49.6±17.8	0.127
ISS	29.7±18.9	35.2±26.4	27.9±16.2	0.425
Shock	20 (83.3)	5 (83.3)	15 (83.3)	1.000
Injury-to-REBOA time	173.9±114.9	217.2±142.1	159.4±105.1	0.297
Injury mechanism				0.204
Crush	1 (4.2)	0 (0.0)	1 (5.6)	
Fall	5 (20.8)	0 (0.0)	5 (27.8)	
In-car TA	7 (29.2)	2 (33.3)	5 (27.8)	
Motorcycle TA	3 (12.5)	0 (0.0)	3 (16.7)	
Pedestrian TA	7 (29.2)	4 (66.7)	3 (16.7)	
Not-trauma	1 (4.2)	0 (0.0)	1 (5.6)	
Injury sites ^a				
Multiple	6 (25.0)	1 (16.7)	5 (27.8)	1.000
Liver	5 (20.8)	0 (0.0)	5 (27.8)	0.384
Spleen	1 (4.2)	1 (16.7)	0 (0.0)	0.555
Kidney	2 (8.3)	0 (0.0)	2 (11.1)	1.000
Inferior vena cava	2 (8.3)	0 (0.0)	2 (11.1)	1.000
Mesentery	4 (16.7)	2 (33.3)	2 (11.1)	0.527
Artery ^b	3 (12.5)	0 (0.0)	3 (16.7)	0.546
Pelvis	11 (45.8)	4 (66.7)	7 (38.9)	0.478
Leg	2 (8.3)	0 (0.0)	2 (11.1)	1.000
Arrest	11 (45.8)	1 (16.7)	10 (55.6)	0.237
Access site				1.000
Right femoral artery	17 (70.8)	4 (66.7)	13 (72.2)	
Left femoral artery	7 (29.2)	2 (33.3)	5 (27.8)	
Type of catheter				0.088
12 Fr	9 (37.5)	0 (0.0)	9 (50.0)	
7 Fr	15 (62.5)	6 (100.0)	9 (50.0)	
Type of REBOA				0.339
Partial occlusion	10 (41.7)	4 (66.7)	6 (33.3)	
Total occlusion	14 (58.3)	2 (33.3)	12 (66.7)	
Target zone				0.637
1	12 (50.0)	4 (66.7)	8 (44.4)	
3	12 (50.0)	2 (33.3)	10 (55.6)	
Mortality	18 (75.0)	4 (66.7)	14 (77.8)	1.000
Result of REBOA				0.617
Success	8 (33.3)	3 (50.0)	5 (27.8)	
Fail	16 (66.7)	3 (50.0)	13 (72.2)	

Values are presented as mean±standard deviation or number (%).

ISS: injury severity score, REBOA: resuscitative endovascular balloon occlusion of the aorta, TA: traffic accident.

^aDuplicated.

^bAbdominal aorta injury, proper hepatic artery injury, iliac artery injury.

Score (ISS), shock (SBP <80 mmHg), injury-to-REBOA time, injury mechanism, injury sites, arrest, access site, type of catheter, type of REBOA (partial or total occlusion), target Zone, and mortality result of REBOA were obtained from the patients' electronic medical records. SBP was recorded as the moment when the trauma surgeon decided to perform REBOA. The mechanism of injury were classified as crush injuries, fall, in-car traffic accidents (TA), motorcycle TA, and pedestrian TA.

REBOA

All patients received REBOA in-hospital. Most of the cases of REBOA were performed by the trauma surgeon on duty, but two cases were performed by an emergency physician. For the procedure, a 12 Fr or 7 Fr catheter was used. In all cases, the access site was the femoral artery, including both the left and right femoral arteries. The REBOA Zone was confirmed via X-ray or ultrasonography. Total or partial occlusion was performed depending on the patient's condition. The injury-to-REBOA time was defined as the time of the accident to the time when the REBOA balloon was first inflated. When the REBOA balloon was located outside the desired targeted Zone during

the first procedure, we recorded it as a failure. When an arrest occurred before REBOA was performed, we recorded it as an arrest.

Statistical analysis

All statistical analyses were performed using R Statistical Software (version 3.6.3; R Foundation for Statistical Computing, Vienna, Austria). The sample population followed a normal distribution, which was confirmed using the Shapiro-Wilk test. For the comparative analyses between the two groups, the Student t-test was used for continuous variables and the Fisher's exact test was used to compare categorical variables. A logistic regression analysis (LRA) model was used to determine whether the success of REBOA was a dependent variable. LRA was performed as univariate and multivariate analyses. The independent variables of the LRA model were sex, age, ISS, injury-to-REBOA time, arrest, access site, type of catheter, target Zone, and education. All results of LRA were expressed as odds ratios (ORs) and 95% confidence intervals (CIs). The LRA model for all statistical analyses, $p < 0.05$ was considered statistically significant.

Table 2. Description for failure of REBOA

No	Sex/age	Reason of REBOA	Education	Target zone	Result of REBOA	Mortality
1	M/58	Pseudoaneurysm of abdominal aorta	No	1	REBOA was not function	Death
2	F/54	Liver injury	No	1	Placed in Zone 2	Survival
3	F/70	IVC injury, mesentery injury	No	1	Placed in Zone 2	Death
4	M/18	Liver injury, proper hepatic artery injury	No	1	Placed in Zone 2	Death
5	F/53	IVC injury	No	1	Placed in Zone 2	Death
6	M/55	Liver injury, kidney injury	No	1	Placed in Zone 2	Death
7	F/73	Pelvic bone fracture, spleen injury	Yes	1	Placed in Zone 2	Death
8	M/70	Iliac artery injury	Yes	1	Placed outside the aorta	Death
9	F/16	Pelvic bone fracture	No	3	Placed in the right common carotid artery	Death
10	M/51	Pelvic bone fracture	No	3	Placed in Zone 2	Death
11	M/66	Pelvic bone fracture	Yes	3	Placed in Zone 2	Death
12	M/77	Pelvic bone fracture	No	3	Placed in Zone 2	Death
13	F/52	Pelvic bone fracture	No	3	Placed in Zone 2	Death
14	F/43	Pelvic bone fracture	No	3	Placed in below the iliac bifurcation	Survival
15	M/52	Both leg injury	No	3	Placed in below the iliac bifurcation	Survival
16	M/58	Pelvic bone fracture	No	3	Placed in inferior vena cava	Death

REBOA: resuscitative endovascular balloon occlusion of the aorta, IVC: inferior vena cava, M: male, F: female.

RESULTS

Patient selection and characteristics

A total of 24 patients underwent REBOA during the study. The patients were categorized into the success and failure groups. There were eight patients in the success group and 16 patients in the failure group. The patient flowchart is summarized in Fig. 1. The success of REBOA was not statistically different between the two groups (Fisher's exact test; $p=0.617$).

Other patient characteristics according to the education status are summarized in Table 1. There were no significant differences between the educated and non-educated groups in terms of patients' characteristics: sex ($p=1.000$), age ($p=0.127$), ISS ($p=0.425$), shock ($p=1.000$), injury-to-REBOA time ($p=0.297$), injury mechanism ($p=0.204$), arrest ($p=0.237$), access site ($p=1.000$), type of catheter ($p=0.088$), type of REBOA ($p=0.339$), target Zone ($p=0.637$), mortality ($p=1.000$), and result of REBOA ($p=0.617$). There was one case which involved a non-trauma patient. In this case, REBOA was performed during surgery due to a pseudoaneurysm of the abdominal aorta in the previously performed abdominal aortic graft.

There were a total of 16 failed cases (Table 2). Most of the cases were placed in Zone 2. There were a total of six cases of unique failure. In the education group, three cases failed. Two of them were cases that were placed in Zone 2, and the other involved the catheter balloon coming out of the artery due to an iliac artery injury.

Logistic regression analysis model

Univariate and multivariate LRA was performed to determine success vs. failure. Sex (males vs. females) was not statistically significant in both univariate (OR 2.14, 95% CI 0.39-13.61) and multivariate (OR 1.48, 95% CI 0.11-23.68) analyses. Age was also not statistically significant (univariate analysis: OR 1.01, 95% CI 0.96-1.07; multivariate analysis: OR 1.09, 95% CI 0.98-1.30). ISS was not statistically significant in both univariate (OR 0.98, 95% CI 0.93-1.02), and multivariate (OR 0.98, 95% CI 0.91-1.05) analyses. Injury-to-REBOA time was not statistically significant in both univariate (OR 1.00, 95% CI 0.99-1.00) and multivariate (OR 1.00, 95% CI 0.99-1.02) analyses. The arrest group was not statistically significant compared

to the non-arrest group in both univariate (OR 3.86, 95% CI 0.65-32.36), and multivariate (OR 3.31, 95% CI 0.14-183). There is no statistically significant in the right femoral artery accessed group compared to the left femoral artery accessed group in both univariate (OR 0.56, 95% CI 0.09-3.68) and multivariate (OR 1.29, 95% CI 0.07-42.14) analysis. The 7 Fr catheter tended to be more successful than the 12 Fr catheter according to the multivariate analysis (OR 0.01, 95% CI 0.00-0.68), but not in univariate analysis (OR 0.45, 95% CI 0.07-2.63). The group with a target Zone of 3 was also not statistically significant compared to the group with a target Zone of 1 in both

Table 3. The logistic regression analysis model with procedural failure

	Univariate	Multivariate
Sex		
Female	Ref	Ref
Male	2.14 (0.39-13.61)	1.48 (0.11-23.68)
Age	1.01 (0.96-1.07)	1.09 (0.98-1.3)
ISS	0.98 (0.93-1.02)	0.98 (0.91-1.05)
Injury to REBOA time	1 (0.99-1)	1 (0.99-1.02)
Arrest		
No	Ref	Ref
Yes	3.86 (0.65-32.36)	3.31 (0.14-183)
Access site		
Right femoral artery	Ref	Ref
Left femoral artery	0.56 (0.09-3.68)	1.29 (0.07-42.14)
Type of catheter		
7 Fr	Ref	Ref
12 Fr	0.45 (0.07-2.63)	0.01 (0.00-0.68)
Target zone		
1	Ref	Ref
3	1 (0.18-5.65)	0.68 (0.06-7.62)
Education		
Educated	Ref	Ref
Non-educated	2.6 (0.37-18.88)	154.64 (1.11-22.60)
Hosmer & Lemeshow goodness of fit test		0.941
AUC		0.836

ISS: injury severity score, REBOA: resuscitative endovascular balloon occlusion of the aorta, AUC: area under the receiver operating characteristic curve.

univariate (OR 1.00, 95% CI 0.18-5.65), and multivariate (OR 0.68, 95% CI 0.06-7.62) analysis. Finally, the non-education group had a higher risk of failure compared to the education group in the multivariate analysis (OR 154.64, 95% CI 1.11-22.60) but not in the univariate analysis (OR 2.60, 95% CI 0.37-18.88). The *p*-value of the Hosmer and Lemeshow goodness of fit test for this model was 0.941, and the area under the receiver operating characteristic curve was 0.836, meaning that this LRA model adequately explains the data of this study (Table 3).

DISCUSSION

The main reason for REBOA in this study was intra-abdominal injury (54.2%). However, pelvic bone fracture (45.8%) and liver injury (20.8%) were the first and second most common reasons for REBOA when single organs were considered, respectively. Six patients (25.0%) had multiple injuries, and there was no significant difference between the educated and non-educated groups (*p*=1.000). Ordoñez et al. [18], in their seven-case series report, suggested that the combination of REBOA and emergent resuscitative thoracotomy could be useful in pa-

tients with non-compressible torso hemorrhage secondary to penetrating chest trauma. However, we performed REBOA only in patients with an injury below the diaphragm because REBOA is usually indicated in patients with injuries below the diaphragm [19], and performing REBOA in thoracic trauma patients with or without other torso injuries is debated [11].

Failure of the procedure was defined as when the REBOA balloon was not located in the desired target Zone during the first procedure. Knowledge of the anatomy of the aorta is required for performing REBOA. To perform REBOA, the aorta is divided into three Zones. Zone 1 is defined as the part of the aorta from the left subclavian artery to the celiac trunk. Zone 2 is from the celiac trunk to the lowest renal artery. Zone 3 is the part of the lowest renal artery to the aortic bifurcation [12]. We decided Zone 1 occlusion for patients with cardiac arrest or hemorrhagic shock arising below the diaphragm. We tried to avoid Zone 2 because it is considered to be a non-occlusion Zone. Zone 3 occlusion was used for patients with pelvic bone fractures without evidence of intra-abdominal hemorrhage [20,21]. In our study, REBOA has often been in an unintended position and has even been destroyed (Fig. 2). Furthermore, we described other Zones, in ad-

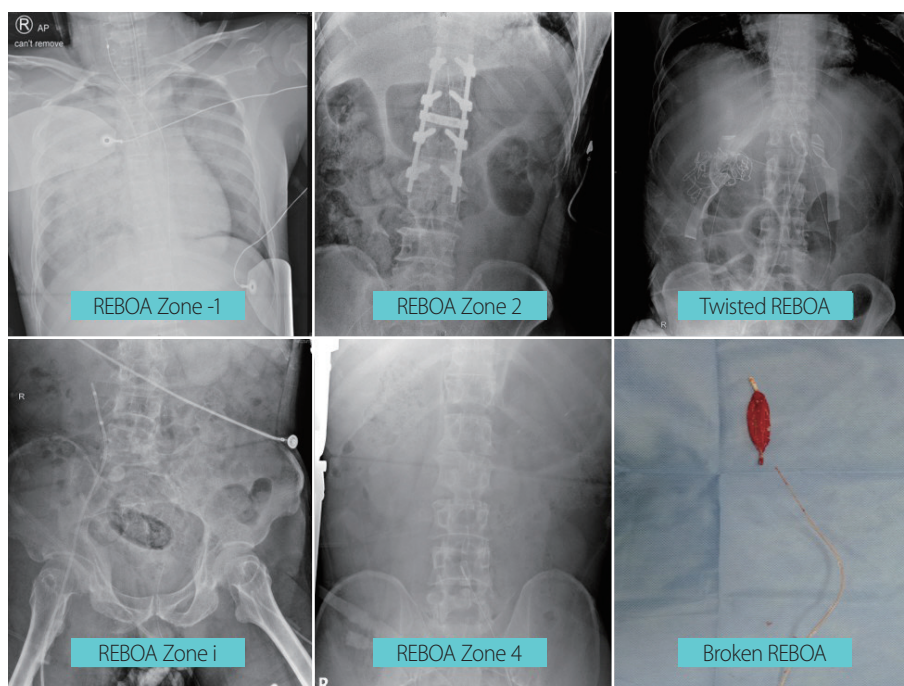


Fig. 2. REBOA in an unintended position and broken REBOA. REBOA: resuscitative endovascular balloon occlusion of the aorta.

dition to the previously known Zones. Depending on the anatomical structure, Zone 0, Zone -1, and Zone 4 were added and, if the inferior vena cava was entered, it was referred to as Zone i (Fig. 3).

As it is well known that a smaller diameter is associated with fewer access-related complications and therefore, safer [3,16,17], we used 7 Fr or 12 Fr catheters in REBOA. Many complications related to the REBOA catheter must be considered. These include femoral arterial complications (disruption, dissection, pseudoaneurysm, hematoma, and thromboembolism), extremity ischemia, aortoiliac complications (intimal tear, dissection, and rupture), and bowel ischemia [15,19]. These complications occur due to physical damage inflicted on the accessing vessel and ischemia with inflammation caused by blockage of downstream blood flow [15,22]. To date, there is a lack of studies on the correlation between catheter diameter and the risk of procedural failure.

When we compared the educated and non-educated groups in the patients who underwent REBOA within our study, there were not many variables that showed signifi-

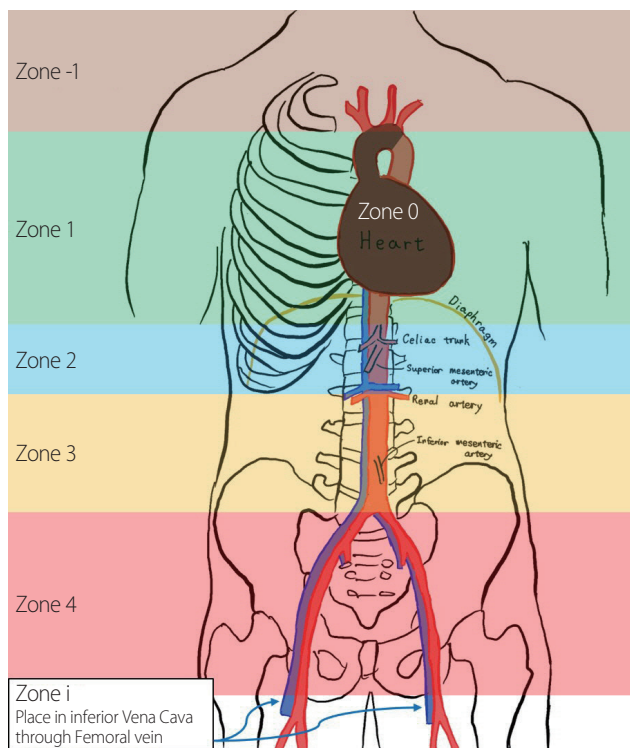


Fig. 3. New aortic Zones for resuscitative endovascular balloon occlusion of the aorta.

cant differences between the two groups according to the Student's *t*-test and Fisher's exact test. However, we noted that the non-educated group failed more frequently than the educated group in the LRA model in which the occurrence of failure as the dependent variable. This was not statistically significant in univariate analysis. However, in the multivariate analysis, it is statistically significant and its effect size is reinforced. In addition, there is a protective effect on procedural failure in the 12 Fr group compared to 7 Fr group in the multivariate analysis. However, it cannot be easily concluded that there is a greater risk of failure than the 12 Fr group. This finding is a contingency classified by education, the result of REBOA, and catheter type (Table 4). In the non-educated group, 8 of 9 cases (88.9%) failed when the 7 Fr catheter was used, and 5 of 9 cases (55.6%) failed with the 12 Fr catheter. Interesting, all REBOA-educated physicians used the 7 Fr catheter. There were 3 of 6 cases (50.0%) with failure using 7 Fr catheters in the education group. Fisher's exact test was performed, and there was no significant difference between the variables (catheter and result) in both the education and non-education groups. Considering the data size of this study, it is appropriate to defer the judgment on whether the catheter type affects the success of REBOA.

REBOA is a time-dependent procedure and is mostly used in emergencies. REBOA's role is to buy the time to allow for subsequent treatment, such as surgery or angiographic embolization. For patients with a high risk of death [3,23,24], it is very important to implement REBOA accurately and concisely, to reduce the patient's hemorrhagic burden even a little. Many studies have shown that a catheter with a smaller diameter is more favorable for patient safety compared to larger catheters [16,17]. If it is

Table 4. Contingency classified by education, the result of REBOA, type of catheter

	Education		Not-education		Total
	Success	Failure	Success	Fail	
12 Fr	0	0	4	5	9
7 Fr	3	3	1	8	15
Total	3	3	5	13	24
Fisher's exact test	$p=1.000$		$p=0.294$		

REBOA: resuscitative endovascular balloon occlusion of the aorta.

confirmed that the type of catheter affects the success rate of REBOA, education programs to increase REBOA success would become more important for every physician in the trauma center.

During the study period, the 7 Fr catheter was used after May 2018. Only one physician completed REBOA education. This study has limitations in that it does not consider the effects of inter-operator differences and it is a retrospective study in a single center. In addition, this study consists of a small number of patients, and no prior study has compared catheter diameter and procedural success rate. Therefore, further studies with more accumulated data are necessary.

CONCLUSION

REBOA is a technique for patients with life-threatening hemorrhagic shock. REBOA improves hemodynamic stability and enables treatment. It is useful in patients with blunt trauma. Therefore, REBOA is becoming important in Republic of Korea, where most trauma patients are affected by blunt trauma. However, the failure of REBOA is harmful to patients, and the risk of failure is increased when REBOA is performed by physicians without REBOA training. It is paramount that physicians in the trauma center or emergency department complete the REBOA education program.

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