

Analysis of procedural performance after a pilot course on endovascular training for resuscitative endovascular balloon occlusion of the aorta

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Purpose: As resuscitative endovascular balloon occlusion of the aorta (REBOA) is performed in an extremely emergent situation, achieving competent clinical practice is mandatory. Although there are several educational courses that teach the REBOA procedure, there have been no reports evaluating the impact of training on clinical practice. Therefore, this study is aimed to evaluate the effects of the course on procedural performance during resuscitation and on clinical outcomes.

Methods: Patients who were managed at a regional trauma center in Dankook University Hospital from August 2016 to February 2018 were included and were grouped as precourse (August 2016–August 2017, n=9) and postcourse (September 2017–February 2018, n=9). Variables regarding injury, parameters regarding REBOA procedure, morbidity, and mortality were prospectively collected and reviewed for comparison between the groups.

Results: Demographics and REBOA variables did not differ between groups. The time required from arterial puncture to balloon inflation was significantly shortened from 9.0 to 5.0 minutes (P=0.003). There were no complications associated with REBOA after the course. Mortality did not show any statistical difference before and after the course.

Conclusions: The endovascular training for REBOA pilot course, which uses a modified form of flipped learning, realistic simulation of ultrasound-guided catheter insertion and balloon manipulation, and competence assessment, significantly improved procedural performance during resuscitation of trauma patients.

Keywords: Wounds and injuries; Aorta; Balloon occlusion; Education; Outcome assessment

INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (RE-

BOA) is an alternative to resuscitative thoracotomy followed by aortic cross clamping in patients with hemorrhagic shock [1]. REBOA has recently gained wide acceptance as a potentially

life-saving procedure; however, implementation of REBOA remains limited, and the procedure is regarded as difficult for physicians who have had limited exposure to endovascular techniques. Proper training is mandatory for its successful usage, and the risk of an unsuccessful balloon location is higher in patients whose physicians have not completed training in REBOA [2].

There are several educational courses that teach the REBOA procedure; however, the best methods for training and ensuring competence are not clear [3]. The endovascular training for REBOA (ET-REBOA) course was developed and conducted in Korea [1]. The pilot course of ET-REBOA consists of a modified form of flipped learning, with ultrasound-guided femoral access training and a realistic sensation of balloon catheter manipulation. For the competence assessment, a 13-item procedure checklist, self-reported confidence score of precourse and postcourse, and time taken to complete the procedure were obtained. Although procedural time was substantially decreased among the participants during the course, there is no evidence that this results in proficient placement during clinical application. To the best of our knowledge, there have been no reports evaluating the impact of the REBOA training program in clinical practice. Therefore, this study aimed to evaluate the effects of ET-REBOA pilot course on clinical procedures and patient outcomes.

METHODS

This study was approved by the Institutional Review Board of Dankook University Hospital (No. DKUH 201902006). Written informed consent was waived.

Sixteen residents and 12 specialists from Dankook University Hospital with no prior experience in performing the REBOA procedure participated in the ET-REBOA pilot course in September 2017. For patient outcome analysis, patients who were treated by the participant practitioners at a regional trauma center in Dankook University Hospital from August 2016 to February 2018 were included. Patients were grouped as precourse (August 2016–August 2017, $n = 9$) and postcourse (September 2017–February 2018, $n = 9$).

Variables regarding injury such as Injury Severity Score, injury site, systolic blood pressure (SBP) before REBOA, and cardiopulmonary resuscitation before REBOA were collected for the analysis. Data regarding the size of the balloon, zone where the balloon was inflated, and method of occlusion (intermittent vs. partial) were also collected. To evaluate the effect of the ET-REBOA course on procedural performance, the time required to decide whether to perform REBOA was defined as the time from pa-

tient arrival to arterial puncture, and the time required for the REBOA procedure was defined as the time from arterial puncture to balloon inflation. All parameters were documented during the REBOA procedure using a REBOA recording sheet [4]. REBOA-related complications, 24-hour mortality, and in-hospital mortality were analyzed to evaluate patient outcomes.

For comparison, chi-square tests or Fisher exact tests were used. Statistical significance was set at $P < 0.05$. All statistical analyses were performed using IBM SPSS ver. 19.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Demographics and REBOA variables

Sex, median age, and body mass index showed no statistical difference between the precourse and postcourse groups. Median Injury Severity Score (29.0 ± 16.7 vs. 38.0 ± 10.8 , respectively), SBP before REBOA (56.0 ± 13.8 vs. 53.0 ± 18.3 mmHg, respectively), and the number of patients with cardiopulmonary resuscitation before REBOA were also similar among two groups. The size of the balloon used for REBOA, the zone where the balloon was inflated, percentage of partial occlusion, and SBP after REBOA did not show any difference (Table 1).

Performance change after ET-REBOA course

Median time required to decide whether to perform REBOA was shortened from 33.0 to 15.0 minutes after ET-REBOA course, although statistical significance was not shown ($P = 0.104$). The time required from arterial puncture to balloon inflation was significantly shortened from 9.0 to 5.0 minutes ($P = 0.003$) (Table 2).

Diversification of the operators

The number of operators who performed REBOA increased from two to four. For procedural assistance, five physicians, including the residents from the emergency department, were newly involved. A total of six physicians who had no previous experience with REBOA participated in clinical practice after the ET-REBOA course.

Patient outcome

There was one probable complication related to REBOA in the precourse patient group (one patient with skin necrosis of the right dorsum). There were no statistical differences in 24-hour mortality or in-hospital mortality rates for the precourse and postcourse patients.

Table 1. Comparison of characteristics regarding injury and REBOA procedure

Characteristic	Precourse (n=9)	Postcourse (n=9)	P-value
Male sex	6 (66.7)	6 (66.7)	>0.999
Age (yr)	48.0±19.1 (7.0–74.0)	52.0±19.5 (26.0–89.0)	0.285
Body mass index (kg/m ²)	24.7±3.0 (18.3–27.0)	24.1±2.7 (20.3–29.3)	0.487
Injury Severity Score	29.0±16.7 (17.0–75.0)	38.0±10.8 (16.0–50.0)	0.792
Injury site			NA
Pelvis	4 (44.4)	1 (11.1)	
Mesentery and spleen	3 (33.3)	1 (11.1)	
Liver	1 (11.1)	2 (22.2)	
Multiorgan	1 (11.1)	5 (55.6)	
SBP before REBOA (mmHg)	56.0±13.8 (40.0–85.0)	53.0±18.3 (0–60.0)	0.513
Preprocedure CPR	3 (33.3)	3 (33.3)	>0.999
Balloon size			NA
12F	1 (11.1)	0	
7F	8 (88.9)	9 (100)	
Zone			NA
I	6 (66.7)	7 (77.8)	
III	3 (33.3)	2 (22.2)	
REBOA			NA
Intermittent	4 (44.4)	3 (33.3)	
Partial	5 (55.6)	6 (66.7)	
SBP after REBOA (mmHg)	104.0±16.1 (66.0–129.0)	99.0±25.7 (75.0–168.0)	0.775

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

REBOA, resuscitative endovascular balloon occlusion of the aorta; NA, not applicable; CPR, cardiopulmonary resuscitation; SBP, systolic blood pressure.

Table 2. Comparison of procedural performance and patient outcome

Variable	Precourse (n = 9)	Postcourse (n = 9)	P-value
Time from arrival to arterial puncture (min)	33.0±84.1 (20–280)	15.0±24.8 (8–87)	0.104
Time from arterial puncture to balloon inflation (min)	9.0±2.6 (5–13)	5.0±1.9 (2–9)	0.003
Procedure-related complication	1 (11.1)	0	NA
24-Hour mortality	4 (44.4)	7 (77.7)	0.335
In-hospital mortality	6 (66.7)	8 (88.9)	0.576

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

DISCUSSION

As REBOA is performed in an extremely emergent clinical situation, competence is a prerequisite for the procedure. Evidence-based training and assessment of operator skills are essential for successful implementation and patient safety. However, there have been limited guidelines or consensus regarding the ideal modality for training, educational content, and validated assessment tools for REBOA until recently.

It has been stated that ultrasound-guided percutaneous access to the common femoral artery along with surgical cutdown as

needed, sheath and device management, appropriate positioning of the catheter, management of inflation volumes, avoidance of catheter migration, decision making, and team training must be included in the REBOA skill training [5]. Acquiring femoral access can be a time-consuming step because the procedure is often performed in patients with profound hypotension. When combined with obesity, obtaining femoral access can become more challenging; however, this is not covered in all education courses [6,7]. The ET-REBOA course provided ultrasound-guided femoral access training and a realistic sensation of balloon catheter manipulation.

Assessment tools that have been previously used for REBOA training are pre-knowledge and post-knowledge tests, self-evaluated procedural confidence, procedure time, and performance rating. There are limitations to these tools; pre-knowledge and post-knowledge testing does not provide any evidence of procedural competence [3,8]. In addition, obtaining a confidence score from the trainee is not accurate, and it may overestimate the effect of the education as it compares "something" with "nothing." Several studies have adopted the time taken to complete the procedure for the educational outcome as an assessment tool, including the ET-REBOA course; however, improvement in speed does not guarantee the quality and safety of the procedure performed [8]. Reports of an internationally developed tool for assessing procedural competence has only been published recently [9,10].

In the ET-REBOA course a 13-item checklist was developed to assess competence. Participants were allowed repeated attempts to complete the checklist until they satisfied all items correctly. All participants fulfilled the checklist items on the second attempt, including seven participants who failed at the first attempt [1].

In addition to these efforts, procedural performance during clinical practice was compared before and after the course. The time required to decide whether to perform REBOA was decreased to 50%. Increased self-confidence and preparedness may have minimized hesitation, or the time required to gather proficient team members may have shortened. The time taken to perform the REBOA procedure was significantly decreased, suggesting that the competence of the participants, some of whom had no prior experience in endovascular procedures, improved after training. Residents from surgical and emergency departments who were trained also actively participated in the procedure, making the procedure more efficient. In the study, there was only one complication possibly related to REBOA, which occurred in the precourse group.

To the best of our knowledge, this is the first report evaluating the impact of the REBOA training program in actual clinical practice, however, there are several limitations. First, an internationally developed tool [9,10] was not available for assessing procedural competence in this course. Second, shortening of the procedural time may have been influenced by other factors in addition to the effectiveness of the education provided. Repetitive lectures regarding REBOA were given to various departments of the institute, including nurses and radiologic technicians. Accumulation of experience of the REBOA procedure itself may have influenced the time taken for the REBOA. Third, the number of

patients included in the study is relatively small. Lastly, since REBOA is rarely performed, a decline in proficiency level with time must be expected [3]. The results do not contain any information regarding REBOA skill retention. Training may start to wane at 6 months in the absence of clinical REBOA cases, but the study's results were based on a knowledge test and subjective comfort score [11]. Evaluation of the appropriate interval of the repetitive education is required based on the validated assessment tool for competence.

In conclusion, the ET-REBOA pilot course which uses a modified form of flipped learning, realistic simulation of ultrasound-guided catheter insertion and balloon manipulation, and competence assessment, might have significantly improved procedural performance in clinical practice. The ET-REBOA course could be an effective curriculum for the development of endovascular skills for performing REBOA.

NOTES

Ethical statements

This study was approved by the Institutional Review Board of Dankook University Hospital (No. DKUH 201902006). Written informed consent was waived.

Conflicts of interest

The authors have no conflicts of interest to declare.

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Author contributions

Conceptualization: SWC, YRC; Data curation: YRC, DHK, SWC; Formal analysis: YRC; Methodology: YRC, SWC; Project administration: all authors; Writing—original Draft: YRC, SWC; Writing—review & editing: all authors. All authors read and approved the final manuscript.

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