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Clinical Research

Feasibility and Clinical Outcomes of Resuscitative Endovascular Balloon Occlusion of the Aorta in Patients with Traumatic Shock: A Single-Center 5-Year Experience

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) has recently gained popularity as an adjunct to resuscitation of patients with traumatic shock. However, the effectiveness of REBOA is still debated because of inconsistent indications across centers and the lack of medical records. The purpose of this study was to investigate the effectiveness and feasibility of REBOA by analyzing clinical results from a single center.
Methods: This study included 96 patients who underwent REBOA between August 2016 and September 2021 at a regional trauma center according to the center's treatment algorithm for traumatic shock. Medical records, including the time of the decision to conduct the REBOA procedure, time of operation, type of aortic occlusion, and clinical outcomes, were collected prospectively and analyzed retrospectively. Patients were classified by REBOA protocol (group 1, 2, or 3) and survival status (survivor or non-survivor) for analysis.
Results: The overall success rate of the procedure was 97.9%, and the survival rate was 32.6%. In survivors, blood pressure was higher than in non-survivors both before the REBOA procedure (p=0.002) and after aortic occlusion (p=0.03). The total aortic occlusion time was significantly shorter (p=0.001) and the proportion of partial aortic occlusion was significantly higher (p=0.014) among the survivors. The non-survivors had more acidosis (p<0.001) and higher lactate concentrations (p<0.001) than the survivors.
Conclusion: REBOA may be a feasible bridge therapy for resuscitation of patients with traumatic shock. Prompt and accurate decision-making to perform REBOA followed by damage control surgery could improve survival rates and clinical outcomes.

Keywords: Resuscitation, Traumatic shock, Balloon occlusion, Mortality, Complication

Introduction

A primary survey with simultaneous damage control resuscitation can reduce the preventable trauma death rate in patients [1]. Among the various types of damage control resuscitation methods, resuscitative thoracotomy followed by aortic cross-clamping (RT-ACC) has been performed in patients with profound refractory shock or traumatic cardiac arrest [1-3]. However, RT-ACC is an invasive procedure that can cause various complications, limiting its application [2,4]. With recent advancements in endovascular treatment techniques, resuscitative endovascular balloon occlusion of the aorta (REBOA) has been globally accepted as an adjunct to resuscitation in patients with hemorrhagic shock, and many studies have been published on this subject [2,5-8]. Despite these efforts, debate continues regarding the validity of REBOA due to inconsistent indications across centers and the lack of medical records. This study was conducted to investigate the effectiveness and feasibility of REBOA by analyzing the clinical outcomes of REBOA in patients with traumatic shock using prospectively collected medical records from a single center over 5 years.

Methods

Procedure and indications

During the 5 years from August 2016 to September 2021, 96 patients underwent REBOA according to the institution's protocol (Fig. 1). A 7F RESCUE balloon catheter (Tokai Medical Products, Kasugai, Japan) was inserted through the femoral artery for aortic occlusion. The indications for REBOA were profound traumatic hemorrhagic shock with a systolic blood pressure of less than 90 mm Hg, absence of cardiac tamponade or thoracic aortic injury on a chest X-ray, and partial or no response to resuscitation after transfusion of 3 units of red blood cells and 3 units of fresh frozen plasma.

Patient groups

Patients were classified into 3 groups (Fig. 1). Group 1 consisted of patients with traumatic shock with no signs of fluid collection in the abdomen as determined by focused assessment with sonography for trauma (FAST) and with no unstable pelvic fracture on radiography. Group 2 consisted of patients with no findings of intra-abdominal bleeding as determined by FAST and signs of unstable pelvic fracture on radiography. Group 3 consisted of patients with shock who were suspected of having intra-abdominal bleeding as indicated by FAST.

Definitions

Aortic occlusion zone and inflation

Regarding aortic occlusion, zone I extends from below the origin of the left subclavian artery to above the celiac artery, zone II extends from the celiac artery to the lowest renal artery, and zone III extends below the lowest renal artery and above the aortic bifurcation [2,3]. The final position of the catheter was confirmed by a serial chest X-ray. The lower tip of the balloon was adjusted to be above the diaphragm in zone I and overlying the lower margin of the third lumbar vertebra in zone III. Inflation was conducted with the goal of maintaining a target blood pressure. If the operator felt no resistance between the aorta and balloon during inflation, this was generally considered partial occlusion of the aorta. If the inflated resistance of the syringe was felt, the aorta was determined to be totally occluded.

Abbreviated Injury Scale

For the Abbreviated Injury Scale (AIS), the body is anatomically classified into 9 compartments (head, face, neck, chest, abdomen, pelvis, spine, extremities, and external injuries including burns). Injury severity is graded on a 6-point scale, ranging from mild (1 point) to non-viable (6 points) [9,10].

Injury Severity Score

For the Injury Severity Score (ISS), the body is reclassified into 6 compartments (head and neck, face, chest, abdomen and pelvic cavity, pelvis and extremities, and external). The AIS severity code is taken for each of the 3 most severely injured body compartments, those 3 AIS codes are

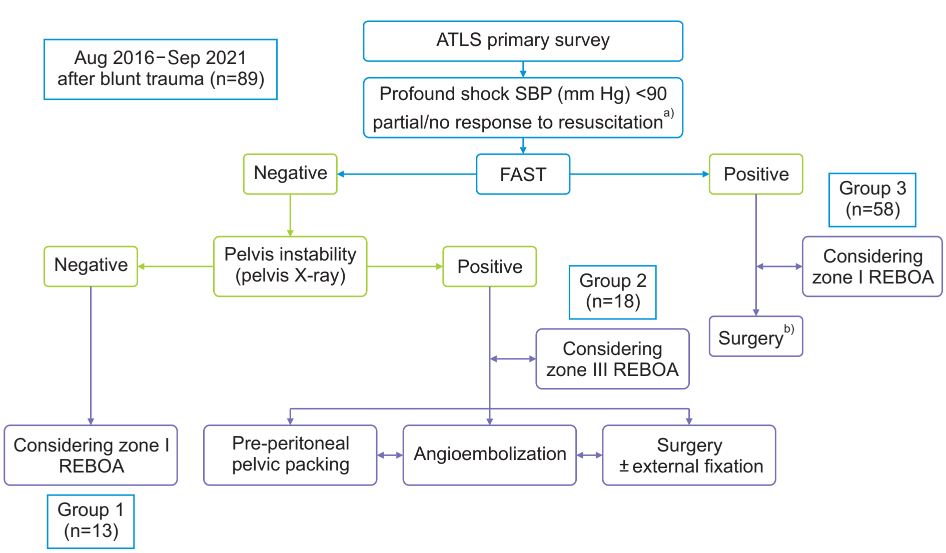

Fig. 1. Dankook University Hospital trauma center algorithm for resuscitative endovascular balloon occlusion of the aorta (REBOA) [2]. ATLS, advanced trauma life support; SBP, systolic blood pressure; FAST, focused assessment with sonography for trauma. a)Early transfusion in resuscitation room and no possible aortic injury as determined by chest radiography. b)Door-to incision time less than 30 minutes.

squared, and the 3 resulting values are added to yield the ISS. Severe trauma is generally defined as an ISS >15 [9,10].

Revised Trauma Score

The Revised Trauma Score (RTS) combines physiological data obtained upon patient arrival. The score is calculated based on the Glasgow Coma Scale, systolic blood pressure, and respiratory rate [9,10]. The RTS ranges from severe (0 points) to normal (7.8408 points).

Data source

Patient data were collected prospectively, and medical records were analyzed retrospectively. This study was approved by the Institutional Review Board of Dankook University Hospital, which waived the requirement for informed consent (IRB approval no., Dankook University Hospital 2022-06-048).

Variables, outcomes, and statistical analysis

Age, transport time, injury severity (as indicated by the AIS, ISS, and RTS), vital signs, laboratory findings, hemorrhage focus, damage control intervention and surgery, blood transfusion data, and details of the REBOA procedure including the aortic occlusion strategy were collected and analyzed to identify associations with mortality and complications. Continuous variables, presented as mean± standard deviation, were compared using the Student t-test. The Fisher exact test was used for discontinuous variables and to compare the mean values of the patient groups. Multivariate analysis was conducted using binary logistic regression, and statistical significance was determined to be indicated by p-values less than 0.05. IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Results

All REBOA procedures were performed in the trauma bay without real-time fluoroscopic guidance using C-arm or angiography. The procedure failed in 2 of the 96 patients (success rate, 97.9%). Two patients received cardiopulmonary resuscitation (CPR). In 1 of the 17 patients (17.7%) who received CPR before REBOA, vascular access to the femoral artery was obtained using the Seldinger technique; however, the catheter was inserted into the contralateral common iliac artery. Aortic occlusion failed in 1 of the 11 patients (10.6%) who received CPR during REBOA because the catheter was placed in the inferior vena cava through the femoral vein. In 5 of the 94 patients who successfully underwent REBOA (1 in group 3 and 4 in group 2), after the intra-aortic balloon catheter was placed, the hemodynamics of the patient stabilized; hence, the balloon was not inflated. As a result, a total of 89 patients were enrolled.

The survival rate of the 89 patients was 32.6% (Table 1). The survival rate was highest in group 3 (p=0.037), and no other endpoints showed statistically significant differences among the groups (Table 2).

The survivor group exhibited a low mean ISS (p=0.008) and a high mean RTS (p<0.001) relative to non-survivors (Table 3). All patients who underwent CPR before or during the REBOA procedure died. Blood pressures after aortic occlusion (p=0.03) and before REBOA (p=0.002) were higher in survivors than non-survivors. The total duration of aortic occlusion was significantly shorter (p=0.001) and the proportion of partial aortic occlusions was significantly higher (p=0.014) in survivors relative to the non-survivors. In non-survivors, we observed further progression of acidosis (p<0.001), higher mean lactate concentration (p<0.001), and significantly higher mean international normalized ratio (p=0.029) compared to the survivors. The mortality rate was higher in patients with multiple organ injuries than in those with a single organ injury (p=0.002). The non-survivor group received more packed red blood cell transfusions within 4 hours (p=0.001) and 24 hours (p=0.035) of hospital admission.

In the multivariate analysis, patients with a higher RTS had lower risk of mortality (p=0.007) than those with a higher ISS (Table 4). In contrast, patients with multiple organ bleeding (p=0.012), a long duration of aortic occlusion (p=0.001), and a high lactate concentration at arrival (p=0.04) were at relatively high risk.

Overall, 22 patients developed complications. A total of 16 patients required dialysis due to acute kidney injury, and 6 patients experienced procedure-related complications. However, no statistically significant differences were observed between the REBOA protocol-based or survival-based groups regarding complications. Bowel ischemia was observed in 2 patients from group 3, who underwent complete aortic occlusion, and toe ischemia was observed in 1 patient. In 3 patients, balloon migration from zone I to zone II after balloon inflation was observed on angiography or computed tomography.

Discussion

The treatment paradigm has shifted with advancements

Table 1. Patient demographics

Characteristic	Group 1 (n=13)	Group 2 (n=18)	Group 3 (n=58)	p-value
Age (yr)	56.46±20.79	61.22±22.98	51.59±19.51	0.152
Injury Severity Score	37.38±15.06	38.44±12.97	30.74±13.04	0.087
Head and neck (AIS >3)	6 (46.2)	5 (27.8)	14 (24.1)	0.28
Chest (AIS >3)	10 (76.9)	12 (66.7)	32 (55.2)	0.294
Abdomen and pelvic contents (AIS >3)	6 (46.2)	3 (16.7)	52 (89.7)	<0.001
Extremity and pelvic bone (AIS >3)	4 (30.8)	16 (88.9)	15 (25.9)	<0.001
Revised Trauma Score	2.56±2.41	4.62±2.44	4.03±2.59	0.082
Cardiopulmonary resuscitation in emergency room				0.658
Before REBOA	2 (15.4)	4 (22.2)	11 (19.0)	
During REBOA	3 (23.1)	2 (11.1)	6 (10.3)	
Initial laboratory data				
pH	7.13±0.23	7.20±0.21	7.18±0.19	0.561
Lactate (mmol/L)	8.00±4.21	10.01±6.29	8.61±4.53	0.703
International normalized ratio	1.48±0.58	1.47±0.40	2.15±3.28	0.738
Hemoglobin (g/dL)	10.99±2.65	9.91±2.65	10.25±2.76	0.553
Main bleeding focus				0.587
Single organ	6 (46.2)	12 (66.7)	37 (63.8)	
Multiple organs	6 (46.2)	6 (33.3)	20 (34.5)	
Mortality				
Overall mortality	12 (92.3)	14 (77.8)	34 (58.6)	0.037
Mortality due to hemorrhage	5 (38.5)	7 (38.9)	27 (46.6)	0.005
Complications				
Acute kidney injury	4 (30.8)	5 (27.8)	7 (12.1)	0.101
Procedure-related	1 (7.7)	0	5 (8.6)	0.470

Values are presented as mean±standard deviation or number (%).
AIS, Abbreviated Injury Scale; REBOA, resuscitative endovascular balloon occlusion of the aorta.

Table 2. Comparison of REBOA data among groups

Variable	Group 1 (n=13)	Group 2 (n=18)	Group 3 (n=58)	p-value
Time (min)				
REBOA				
Door-to-puncture	35.54±21.62	44.0±67.65	25.71±20.20	0.126
Procedure completion	9.0±5.34	8.5±6.37	6.53±4.93	0.121
Total occlusion	110.85±46.79	140.0±134.79	161.53±206.29	0.993
Occlusion type				0.168
Only partial[a)]	10 (76.9)	11 (61.1)	48 (82.8)	
Including complete	3 (23.1)	7 (38.9)	10 (17.2)	
Systolic blood pressure (mm Hg)				
Before REBOA	57.15±26.69	53.28±22.76	49.52±21.04	0.606
After REBOA	94.85±39.60	98.72±26.85	95.59±34.07	0.805
Increasing gap	37.69±32.25	45.44±33.31	46.07±30.06	0.678

Values are presented as mean±standard deviation or number (%).
REBOA, resuscitative endovascular balloon occlusion of the aorta.
[a)]"Only partial group" is defined as "never resistance during inflation".

in endovascular treatment methods [11]. REBOA has recently been used as an alternative to RT-ACC in traumatic shock patients with subdiaphragmatic hemorrhage [8,10,12-14] as well as to treat hemorrhagic shock in non-trauma patients [15-17]. Furthermore, REBOA kits have been accepted as essential equipment in trauma bays and emergency rooms for the resuscitation of patients with traumatic shock [10]. In South Korea, however, the application of REBOA is limited because of a lack of knowledge and experience.

Table 3. Comparison between survivors and non-survivors

Variable	Non-survivors (n=60)	Survivors (n=29)	p-value
Age (yr)	54.4±21.79	53.93±18.12	0.92
Injury Severity Score	35.9±12.89	27.83±13.72	0.008
Head and neck (AIS >3)	21 (35.0)	19 (65.5)	0.037
Chest (AIS >3)	40 (66.7)	14 (48.3)	0.096
Abdomen and pelvic contents (AIS >3)	36 (60.0)	25 (86.2)	0.013
Extremity and pelvic bone (AIS >3)	25 (41.7)	10 (34.5)	0.516
Revised Trauma Score	2.94±2.38	5.99±1.58	<0.001
Cardiopulmonary resuscitation			NA
Before REBOA	17 (28.3)	0	
During REBOA	11 (18.3)	0	
Systolic blood pressure			
Before REBOA	47.37±24.86	59.72±11.74	0.002
After REBOA	91.82±37.76	105±18.77	0.03
Increasing gap	44.45±34.61	45.28±21.46	0.891
Time (min)			
REBOA			
Door-to-puncture	31.18±38.96	30.14±28.05	0.898
Procedure completion	7.35±5.46	7.17±5.19	0.884
Total occlusion	182.83±207.63	81.38±40.34	0.001
Door to damage control time			
Surgery/intervention	94.27±103.7	70.75±36.26	0.25
Occlusion type			0.014
Only partial[a]	42 (70.0)	27 (93.1)	
Including complete	18 (30.0)	2 (6.9)	
Occlusion zone			0.454
Zone I	48 (80.0)	25 (96.6)	
Zone III	12 (20.0)	4 (13.8)	
Initial laboratory data			
pH	7.12±0.19	7.29±0.18	<0.001
Lactate (mmol/L)	10.3±4.68	5.82±3.86	<0.001
International normalized ratio	2.25±3.23	1.26±0.33	0.029
Hemoglobin (g/dL)	10.18±2.9	10.52±2.31	0.578
Algorithm group			0.037
Group 1	12 (20.0)	1 (3.4)	
Group 2	14 (23.3)	4 (13.8)	
Group 3	34 (56.7)	24 (82.8)	
Prehospital time	106.55±200.23	107.03±83.3	0.99
Main bleeding focus			0.002
Single organ	30 (50.0)	25 (86.2)	
Multiple organs	28 (46.7)	4 (13.8)	
Transfusion			
PRBC required for 4 hr	18.12±12.03	12.17±4.55	0.001
PRBC required for additional 24 hr	7.77±11.51	3.38±7.64	0.036
Complications			
Acute kidney injury	14 (23.3)	2 (6.9)	0.078
Procedure-related	6 (10.0)	0	0.172

Values are presented as mean±standard deviation or number (%).
AIS, Abbreviated Injury Scale; NA, not applicable; REBOA, resuscitative endovascular balloon occlusion of the aorta; PRBC, packed red blood cells.
[a])"Only partial group" is defined as "never resistance during inflation".

REBOA was performed at a regional trauma center at Dankook University Hospital in 2016, and a protocol for REBOA in trauma patients was established in 2017. After the creation of the protocol, medical records associated with the REBOA procedure were obtained prospectively. In addition, we have developed our own educational pro-

Table 4. Multivariable analysis for the risk of mortality

Variable	Univariate analysis			Multivariate analysis	
	Non-survivors (n=60)	Survivors (n=29)	p-value	OR (95% CI)	p-value
Injury Severity Score	35.9±12.89	27.83±13.72	0.008	1.041 (0.975–1.111)	0.229
Revised Trauma Score	2.94±2.38	5.99±1.58	<0.001	0.518 (0.321–0.837)	0.007
Total occlusion time (min)	182.83±207.63	81.38±40.34	0.001	1.029 (1.011–1.048)	0.001
Partial occlusion type	42 (70.0)	27 (93.1)	0.014	7.752 (0.313–191.761)	0.211
Multiple bleeding focus	28 (46.6)	4 (13.8)	0.002	9.765 (1.645–57.981)	0.012
SBP before REBOA	47.37±24.86	59.72±11.74	0.002	1.005 (0.952–1.061)	0.855
SBP after REBOA	91.82±37.76	105±18.77	0.03	0.993 (0.957–1.031)	0.723
Initial lab data					
pH	7.12±0.19	7.29±0.18	<0.001	0.382 (0.00–742.593)	0.803
Lactate	10.3±4.68	5.82±3.86	<0.001	1.237 (1.010–1.515)	0.04
International normalized ratio	2.25±3.23	1.26±0.33	0.029	0.9 (0.173–4.687)	0.9
PRBC required for 4 hr	18.12±12.03	12.17±4.55	0.001	1.01 (0.894–1.140)	0.877
PRBC required for additional 24 hr	7.77±11.51	3.38±7.64	0.036	1.049 (0.958–1.149)	0.3

Values are presented as mean±standard deviation or number (%), unless otherwise stated.
OR, odds ratio; CI, confidence interval; SBP, systolic blood pressure; REBOA, resuscitative endovascular balloon occlusion of the aorta; PRBC, packed red blood cells.

grams to facilitate consistent quality improvement [2,18-21]. This has produced an increased success rate and a decrease in complications [2,21-23].

The overall survival rate in this study was 32.6%, which was not higher than in other studies [2]. Among the patient groups defined by the Dankook University Hospital REBOA protocol, group 3 had the highest survival rate. One potential explanation is that relative to the other groups, group 3 included more patients with bleeding from a single-organ injury and fewer patients with head and neck injuries. Regarding the time taken to decide whether to perform REBOA and to perform subsequent damage control intervention including surgery (as indicated by the door-to-puncture and procedure times), group 3 exhibited the shortest times. This is because FAST enables rapid diagnosis and prompt treatment decisions for patients in shock. Although no statistically significant difference was observed, group 2 experienced a delay in diagnosis because it took longer to diagnose hemodynamically unstable pelvic fractures than to diagnose hemorrhagic shock using FAST. Moreover, group 1 included a higher percentage of patients with head and neck injuries than the other groups, delaying the decision to perform REBOA.

In survivors, the ISS and AIS scores for the head and neck were low, and the RTS was high. These results indicate that survivors had less anatomical damage, especially head and neck injury, and had a more stable Glasgow Coma Scale score, systemic blood pressure, and respiratory rate than non-survivors upon arrival. A comparison of the systemic blood pressure before REBOA and after aortic occlusion showed that survivors had a higher systemic blood pressure than non-survivors. According to the Eastern Association for the Surgery of Trauma guidelines [24], the survival rate of blunt trauma patients without signs of life is as low as 0.7% even after RT-ACC is performed. Additionally, none of the survivors received CPR in our study. This indicates that once a cardiac arrest occurs, it can have fatal consequences. Therefore, to increase the survival rate of patients with severe trauma, cardiac arrest must be prevented by performing damage control resuscitation as soon as possible in cases of impending cardiac arrest or profound shock [8,12,24,25].

The survivor group had proportionally more single-organ bleeding cases and required fewer early blood transfusions than non-survivors. Moreover, the total aortic occlusion time among the survivors was relatively short, and partial aortic occlusion was used in many cases. Based on these findings, the difference in the survival rate can be assumed to depend on the presence of severe multiple organ injuries, which necessitate more transfusions and result in unstable vital signs. Furthermore, the non-survivors often required complete aortic occlusion because of profound shock and massive hemorrhage in multiple organs, as well as a long anticipated duration of damage control surgery, which likely contributed to the longer aortic occlusion time. Therefore, complete occlusion and aortic occlusion time cannot be considered direct causes of mortality. Other studies have shown that maintaining an aortic occlusion time of within 60 minutes can improve the survival rate [2,3,6]. In this study, the average aortic occlusion time in survivors was 80 minutes; partial occlusion was used in most cases, and the procedure could be performed without fatal complications. Therefore, if partial aortic occlusion is applied, a longer aortic occlusion time may be possible without complications [2,12,23,26]. Regarding subsequent damage control intervention, the time required to perform damage control surgery was shorter in the survival group than the non-survival group; however, the difference was not statistically significant (p=0.25). Regardless, since prompt and appropriate damage control surgery after aortic occlusion can reduce complications and increase survival rates, damage control surgery should be performed as soon as possible after aortic occlusion [2,5,6, 12].

The results of the blood tests upon arrival showed that the survival group had relatively high pH, low lactate, and low international normalized ratio levels. This finding is statistically significantly related to metabolic acidosis and coagulopathy, 2 members of the fatal triad known as the main cause of traumatic death [1,10]. The difference in transport time to the hospital between survivors and non-survivors was not statistically significant (p=0.99). However, reducing fatal re-transfer and transport time delays in patients with massive hemorrhage can be critical for improving the trauma care system [1,10].

According to the multivariate analysis, RTS—which is based on physiological indicators rather than anatomical damage—was higher in survivors than among the non-survivors, with shorter aortic occlusion time and more single-organ than multi-organ damage. In non-survivors, lactate concentrations were higher, and, although not statistically significant, the metabolic acidosis level was lower. These results indicate that pH and lactate concentration can be used as prognostic factors during treatment and follow-up.

This study had a few limitations. First, despite the application of an algorithm, some patients were omitted from the study because of differences in application depending on the lead doctor of the trauma team. The use of complete versus partial occlusion techniques also depended on the doctor's individual discretion. Second, although the data were collected prospectively, some information was omitted from the retrospective review of the medical records. Third, the number of enrolled patients was insufficient for this single-center study. Nevertheless, the study could show meaningful clinical results because the records on REBOA performance were managed in greater detail than those used in other studies.

In conclusion, low RTS, high lactate level, long aortic occlusion time, and presence of multiple organ injuries were associated with mortality when performing REBOA in patients with hemorrhagic shock. In addition, prompt decision-making on the application of REBOA, partial aortic occlusion at the ideal occlusion level, and subsequent rapid damage control intervention (including surgery) could be critical for improving survival and clinical outcomes in patients with traumatic shock. Further studies are needed to investigate the feasibility of REBOA as a bridge therapy in traumatic shock.

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Conflict of interest

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