Pre-hospital CPR and early REBOA in trauma patients - Results from the ABOTrauma Registry.

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Abstract

Background: Severely injured trauma patients suffering from traumatic cardiac arrest (TCA) and requiring cardiopulmonary resuscitation (CPR) rarely survive. The role of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) performed early after hospital admission in patients with TCA is not well-defined. As the use of REBOA increases, there is great interest in knowing if there is a survival benefit related to the early use of REBOA after TCA. Using data from the ABOTrauma Registry, we aimed to study the role of REBOA used early after hospital admission in trauma patients who required pre-hospital CPR.

Methods: Retrospective and prospective data on the use of REBOA were collected from the ABOTrauma Registry from 11 centers in seven countries globally between 2014 and 2019. In all patients with pre-hospital TCA, the predicted probability of survival, calculated with the Revised Injury Severity Classification II (RISC II), was compared with the observed survival rate.

Results: Of 213 patients in the ABOTrauma Registry, 26 patients (12.2%) who had received pre-hospital CPR were identified. The median (range) Injury Severity Score (ISS) was 45.5 (25-75). Fourteen patients (54%) had been admitted to hospital with ongoing CPR. Nine patients (35%) died within the first 24 hours, while seventeen patients (65%) survived post 24 hours. The survival rate to hospital discharge was 27% (n=7). The predicted mortality using the RISC II was 0.977 (25 out of 26). The observed mortality (19 out of 26) was significantly lower than the predicted mortality (p=0.049). Patients not responding to REBOA were more likely to die. Only one (10%) out of 10 non-responders survived. Survival rate in the 16 patients responding to REBOA was 37.5% (n=6). REBOA with a median (range) duration of 45
(8-70) minutes significantly increases blood pressure from median (range) 56.5 (0-147) to 90 (0-200) mmHg.

Conclusions: Mortality in patients suffering from TCA and receiving REBOA early after hospital admission is significantly lower than predicted by the RISC II. REBOA may improve survival after TCA. The use of REBOA in these patients should be further investigated. Keywords: REBOA, Cardiac Arrest, Trauma, CPR, Endovascular Resuscitation.

Background
Globally, trauma with massive bleeding is the second leading cause of death under the age of 40 years (1). Traumatic cardiac arrest (TCA) has an extremely high mortality especially in blunt trauma. Cardiopulmonary resuscitation (CPR) after trauma is considered to be of little benefit (2). CPR is initiated when the carotid pulse cannot be palpated in an unresponsive patient. However, this does not per se confirm “true” cardiac arrest but may represent a state of inadequate perfusion with impending cardiac arrest. The international resuscitation guidelines (ERC and AHA) advocate a consistent approach to CPR on the basis of up-to-date evidence and expert’s consensus opinions about the use of invasive measures, including resuscitative thoracotomy (RT), in order to eliminate reversible causes of cardiac arrest in trauma patients (2-5). One invasive measure to prevent patients from exsanguination in non-compressible torso hemorrhage, but not yet mentioned in the CPR guidelines, is Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) (6, 7). REBOA may have the potential to temporarily diminish exsanguination at the expense of ischemia (8). The role of early REBOA after hospital admission in patients with pre-hospital TCA and consecutive CPR, either
arriving with a return of spontaneous circulation (ROSC) or ongoing CPR, is not yet clear. The possible control of bleeding and the hemodynamic effect of REBOA with improvement in coronary and cerebral perfusion pressure may have a positive survival benefit (9, 10). On the other hand, REBOA serves as a bridge to definitive surgical bleeding control and treatment, and is therefore a procedure used to gain time and not for definitive care (11).

Surprisingly, recently published registry-based work by Joseph et al. did not find a positive survival benefit for patients who were treated with REBOA in the American College of Surgeons Trauma Quality Improvement Program data set (12). Using the ABOTrauma Registry, we aimed to study the role of early REBOA on arrival to the hospital in trauma patients who had received pre-hospital CPR due to TCA.

Patients and Methods

Data from the ABOTrauma Registry between 2014 and 2019 were analyzed. Trauma patients receiving REBOA for treatment of hemorrhagic shock at 11 centers from seven countries were included. The ABOTrauma Registry provides retrospective and prospective data for trauma patients in hemorrhagic shock in whom REBOA had been used. Center recruitment is ad hoc, with known REBOA-practicing institutions invited to participate directly. Centers can also register independently via the registry website after approval from the principle investigators. To capture clinically pragmatic data, there are no center-specific criteria such as minimum case volume or hospital size. The registry is funded and hosted by the Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden. Ethical approval for the registry was obtained from the regional committee (study number: 2014/210; Regionala Etikprövningsnämnden, Uppsala, Sweden). Patient data are
anonymized at the point of registration with a unique registry-generated ID number. No patient identifiable data (name, hospital number, date of birth) are held in the registry and all data are held on a secure electronic database. A secured password has been given to centers joining the registry to be able to enter data and the registry is in line with the current European data protection regulation. The need for ethical approval of the current study was waived by the ethical committee of the Medical Association Saxony-Anhalt Germany.

Inclusion criteria for the present study were pre-hospital CPR initiated due to TCA and having complete data to calculate the probability of survival using the revised injury severity classification II (RISC II), availability of outcome data (return of spontaneous circulation - ROSC, survival, death) and REBOA (including REBOA-Zone) performed early after admission. TCA was defined as non-palpable pulse on a large central artery (carotid or common femoral artery) with necessary CPR due to trauma. ROSC was defined as palpable pulse in the mentioned arteries with no further need for external cardiac compression.

Exclusion criteria were no pre-hospital CPR, and missing data regarding outcome or RISC II calculation.

The RISC score has been developed using data from the German Trauma Registry (13). The update of the Revised Injury Severity Classification score, the RISC II, has been developed using 30,866 patients and was validated with 21,918 patients (14). Our opinion is that it is the best trauma score for predicting outcome currently available. The following variables were used to predict survival: New Injury Severity Score (NISS), age, head injury, Glasgow Coma Scale (GCS), coagulation (partial thromboplastin time), base deficit, CPR (pre-hospital or after admission), number of indirect signs of bleeding (low hemoglobin, hypotension, massive transfusion). For
most variables, an algorithm for replacing missing values had been established. The RISC II includes several new predictors, such as pupil size and reactivity, but also an innovative type of management of missing values (14). The probability of survival is calculated using the logistic function:

\[ P(\text{survival}) = \frac{1}{1 + \exp(-X)} \]

Results

Of 213 patients reported in the ABOTrauma Registry during the study period, 26 patients (12.2%) who had received pre-hospital CPR due to TCA were identified. These 26 patients were treated at 11 centers in seven countries in Europe and Asia. None of the 26 patients received pre-hospital REBOA. The mechanism of injury in 21 patients (81%) was blunt trauma and in three patients (11.5%) penetrating trauma; data were missing for two patients (7.5%). The median (range) age of these 26 patients was 55 (8-79) years and 18 (69%) were male. Twelve patients (46%) had been admitted to the hospital with ROSC and 14 (54%) with ongoing CPR. Due to missing data we cannot give a time range of the duration of the TCA. Of the 12 patients admitted to the ER with ROSC, five patients (42%) survived (see Figure 1). In the group receiving ongoing CPR on admission, only two patients (14%) survived (see Figure 1). Figure 1 provides a flow-chart visualizing patients who received REBOA post-ROSC vs. pre-ROSC and the survivors in each group. The median (range) Injury Severity Score (ISS) was 45.5 (25-75) while the median (range) NISS was 46.5 (25-75). In all patients, data were sufficient to calculate the probability of survival using the RISC II. The RISC II predicted a mortality of 0.977 and therefore the
predicted mortality was 25 out of 26 patients (0.977 x 26 = 25.4 ≈ 25). Of the 26 patients, 17 (65%) survived post 24 hours and seven patients (27%) survived to hospital discharge. Mortality following early REBOA after hospital admission (19 out of 26) was significantly lower (p=0.049) than the predicted mortality (25 out of 26). Of the nine patients who died within the first 24 hours, six died in the ER and three died during emergency operation in the OR. Those who died after 24 hours (n=10) died after, median (range), 1.5 (1-6) days in the ICU. The SMR was 0.798, meaning that fewer patients died than predicted.

As expected, the investigated patient cohort had a pronounced trauma-induced coagulopathy (TIC) presented by a median (range) INR of 1.55 (1.08-9.96), a PTT of 66.8 (23.3-180) seconds and relatively low platelet count of 116.000 (12.000-335.000). Furthermore, the patients were in pronounced shock with a median (range) base excess of -16.5 (minus 4.3 – minus 28) and lactate of 11.7 (2.1-18.9) mmol/l.

**Transfusion requirements**

The median (range) hemoglobin value on admission was 6.1 (2.4-8.8) mmol/l or 9.8 (3.8-14.2) g/dl. In 20 patients, transfusion was documented and, median (range), 22 (4-58) packed red blood cells (pRBC), 20 (6-70) fresh frozen plasma (FFP) and 5 (1-80) platelet packs were transfused within the first 24 hours. In six patients, transfusion before aortic occlusion was documented. In these six patients, a median (range) of three (1-7) pRBC were given before REBOA, two out of the six patients received two FFP respectively and one patient received one platelet pack before aortic balloon occlusion.
Special considerations regarding REBOA

Access to the common femoral artery was blindly achieved in 20 cases (76.5%), by ultrasound in three cases (11.5%), by cut down in one case (4%) and was unknown in two cases (8%). Access was achieved by an emergency physician in 14 cases (54%), by a radiologist in four cases (15%), by a vascular surgeon and an anesthesiologist respectively in three cases (11.5%), and by a trauma and general surgeon in one case each (4%). REBOA resulted in a significant rise in systolic blood pressure (SBP), i.e. an increase in SBP ≥20 mmHg, as shown in Figure 2. Except for one patient, all survivors were responders to the initial REBOA attempt (87%), with a significant rise in SBP after aortic occlusion (see Table 1). After aortic occlusion, the median (range) SBP was raised from 57 (0-80) mmHg to 90 (0-136) mmHg in survivors (see Table 2). In patients who died, only 10 patients (53%) responded (increase in SBP ≥20 mmHg) to the initial REBOA attempt. In the group of non-survivors, the median (range) SBP was raised from 53 (0-147) mmHg to 90 (0-200) mmHg on average.

The median (range) duration of aortic occlusion was 45 (8-70) minutes and there was no difference in occlusion time between survivors and non-survivors (p=0.68). REBOA was deployed in Zone I in 21 patients and in Zone III in five patients. Three blunt trauma patients underwent resuscitative thoracotomy, performed by an EMS physician in the field, and they arrived at the hospital with ongoing CPR subsequently and died. One resuscitative thoracotomy (RT) was performed in the ER due to no measurable blood pressure followed by Zone I REBOA. This patient was one of the survivors.
Discussion

Our study has shown that the survival rate in patients having TCA and receiving REBOA early after hospital admission is significantly higher than predicted by the RISC II. Furthermore, REBOA significantly increases SBP. Patients responding to REBOA are more likely to survive compared with those not responding, although the results lack significance due to the low sample size.

Resuscitation of patients who sustain a TCA has been associated with a low rate of survival ranging between 0% – 35%, depending on the mechanism of injury (2, 5). The high survival rate in our study (27%), despite the majority of patients being subjected to blunt trauma, justifies resuscitation efforts with the use of REBOA in patients with TCA. Current guidelines recommend to take RT into consideration in patients with TCA if CPR duration is less than 15 minutes (3). The RT rate in our study is relatively low (11.5%) and we are unable to give a solid explanation for this. One possible explanation could be that the majority of patients included in this study presented with TCA after blunt trauma and RT in blunt trauma is disputed, since the survival rate is very low (5). Another explanation could be a difference in local skills and algorithms, concerning the implementation of RT.

Massive bleeding is a preventable cause of death in trauma patients (15, 16). The use of local compression, hemostatic agents and adjunct tourniquets are often sufficient to stop or reduce external bleeding in the pre-hospital setting (17, 18). Non-compressible torso hemorrhage in the abdomen or pelvis is difficult to control without surgery. REBOA may reduce bleeding below the occlusion zone, stabilizing the hemodynamics by increasing coronary and cerebral blood flow, improving oxygenation of the heart and brain during CPR, and is associated with a more
favorable acid-base status of circulating blood [5]. More than 60% of our patients responded to REBOA with an increased SBP of more than 20 mmHg.

The RISC II predicted median survival rate of 2.2% in our patients is similar to other studies describing a survival rate of less than 8% and survival rate for TCA is still lower than in medical out-of-hospital cardiac arrest (19–25). Interventions treating reversible causes of TCA may improve survival and neurological outcome. The survival rate in our study supports the use of REBOA in TCA. Access to the common femoral artery in our series was mainly blind. In contrast, other studies had a cut down rate of more than 50% (6, 26). This can be explained by the fact that REBOA accesses were performed mainly by emergency physicians, radiologists or anesthetists in our study.

Due to the necessary transfusion requirement, we assume the majority of our patients had massive bleeding and the application of early REBOA possibly prevented TCA. The median time of aortic occlusion in our study was 45 minutes in the patients who survived, 85% in Zone I. Occlusion time up to 30 minutes in Zone I is associated with lower risk of complications (8, 27). Nevertheless, the optimal occlusion time may depend on other factors such as presence of collaterals or an associated hemorrhage proximal to the level of occlusion.

All of our patients had pre-hospital TCA and pre-hospital REBOA may have been beneficial to some (28–30). This may improve blood pressure, reduce bleeding below the level of occlusion, and prevent true cardiac arrest (28–30). Nevertheless, it is important not to prolong ischemia time because it increases the risk of ischemia-reperfusion injury. Currently, no recommendation can be given regarding pre-hospital REBOA (31) since more evidence is required. The majority of our patients suffered from TIC which is multifactorial, including tissue injury and
hypoperfusion (32); this explains the high transfusion requirements in our patients despite the use of REBOA.

limitations

We have to acknowledge that our study has several limitations. First, our data have been retrieved from a partially retrospective registry and our sample size is small. Therefore, the results could be more an association than a cause-effect relationship. Second, the RISC II score has certain limitations, with age and injury severity as strong negative predictors of survival. This may underestimate the probability of survival in patients with reversible causes of TCA. Third, there were some missing values regarding transfusion requirements compared with data needed to compute RISC II, which were complete. Fourth, the ABOTrauma Registry was designed to capture REBOA-specific data and not evaluate the individual use of the technique. Accordingly, indications for and the efficacy of REBOA use are diverse. Fifth, the registry included patients who had REBOA deployed and established and not in those in whom REBOA failed and was not established, therefore we do not have a control group of patients with TCA and non-REBOA. Finally, this is an international study with limited control on the inclusion and exclusion criteria, and therefore having a risk of selection bias in the studied population.

conclusions

Our study has shown that mortality in patients suffering from TCA and receiving REBOA early after hospital admission is significantly lower than predicted by the RISC II. Early in-hospital REBOA may improve survival after TCA and pre-hospital CPR. These encouraging results should be followed by prospective studies with
larger numbers to define the exact role of REBOA in these critically ill patients.

abbreviations

ABO – Aortic Balloon Occlusion
AHA – American Heart Association
aPTT – activated Partial Thromboplastin Time
CPR – Cardio Pulmonary Resuscitation
ER – Emergency Room
ERC – European Resuscitation Council
FFP – Fresh Frozen Plasma
GCS – Glasgow Coma Scale
INR – International Normalized Ratio
ISS – Injury Severity Score
NISS – New Injury Severity Score
REBOA - Resuscitative Endovascular Balloon Occlusion of the Aorta
RISC – Revised Injury Severity Classification
ROSC – Return of Spontaneous Circulation
rPBC – reed Packed Blood Cells
RT – Resuscitative Thoracotomy
SBP – Systolic Blood Pressure
SMR – Standardized Mortality Ratio
TCA – Traumatic Cardiac Arrest
TIC – Trauma Induced Coagulopathy

declarations
Ethical approval statement

Ethical approval was obtained from the regional committee (study number: 2014/210; Regionala Etikprövningsnämnden, Uppsala, Sweden) for the ABOTrauma Registry. The ethical committee of the medical association of Saxony-Anhalt Germany waived the need for ethical approval for the current study (ethical committee number 70/19).

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to ownership by the Department of Cardiothoracic and Vascular Surgery, Faculty of Medicine and Health, Örebro University, Örebro, Sweden, but are available from the corresponding author on reasonable request.

Consent for publication

Not applicable

Competing interests

Authors P. Hibert-Carius, D. T. McGreevy, F. M. Abu-Zidan, and T. M. Hörer declare that there are no conflicts of interest that could inappropriately influence (bias) their work.

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Authors’ contributions
PH-C conceived the idea, formatted the data, wrote the manuscript, and approved its final version. DTMcG contributed to the idea, analyzed the data and supervised the writing process, repeatedly edited the manuscript and approved its final version. FMA-Z performed all the statistical calculations. TMH contributed to the idea, supervised the project, edited the manuscript and approved its final version. 

All other authors participated in the design of the registry, collected data, and approved the final version of the manuscript. PH-C and DTMcG contributed equally to this work.

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tables

Table 1: Comparison between REBOA responders and non-responders

|                        | Responders (n=16)                                                                 | Non-responders (n=10)                     | p-value |
|------------------------|----------------------------------------------------------------------------------|------------------------------------------|---------|
| Age (years)            | 40 (8-79)                                                                        | 62.5 (20-78)                             | 0.39    |
| Male:female            | 11:5                                                                             | 7:3                                      | 0.99    |
| Blunt: penetrating trauma* | 13:3                                                                            | 8:0                                      | 0.53    |
| ISS                    | 51 (25-75)                                                                       | 42 (25-75)                               | 0.52    |
| NISS                   | 51 (25-75)                                                                       | 43 (25-75)                               | 0.62    |
| SBP before REBOA (mmHg) | 56.5 (0-80)                                                                      | 40 (0-147)                               | 0.76    |
| SBP after REBOA (mmHg) | 95.5 (43-200)                                                                    | 40 (0-131)                               | 0.03    |
| partial-REBOA*         | 7/12 (58%)                                                                       | 3/6 (50%)                                | 0.49    |
| REBOA time (minutes)   | 45 (17-70)                                                                        | 28.5 (8-70)                              | 0.21    |
| RISC mortality         | 98.1 (57.4-100)                                                                  | 95.9 (63.2-99.8)                         | 0.34    |
| Survival               | 6/16 (37.5%)                                                                     | 1/10 (10%)                               | 0.19    |

Data are presented as median (range) or number as appropriate. ISS=Injury Severity Score; NISS=New Injury Severity Score; SBP=Systolic Blood Pressure; REBOA=Resuscitative Endovascular Balloon Occlusion of the Aorta; RISC=Revised
Injury Severity Classification.

P value= Mann Whitney U test or Fisher’s Exact test as appropriate.

*Numbers do not add up to 26 due to missing data.

**Indicates statistically significant difference.

Table 2: Comparison between survivors and non-survivors

| Variable                               | Survivors (n=7) | Non-survivors (n=19) | P value |
|----------------------------------------|-----------------|-----------------------|---------|
| Age                                    | 40 (30-78)      | 60 (8-79)             |         |
| Male: female                           | 3:4             | 15:4                  |         |
| CPR on arrival**                       | 2/6             | 12/17                 |         |
| Blunt: penetrating trauma**            | 7:0             | 14:3                  |         |
| Head injury                            | 3/7 (43%)       | 10/19 (53%)           |         |
| GCS at scene                           | 3 (3-10)        | 3 (3-14)              |         |
| ISS                                    | 41 (38-59)      | 50 (25-75)            |         |
| NISS                                    | 41 (38-59)      | 50 (25-75)            |         |
| RISC mortality                         | 94.3 (57.4-98.4)| 98.5 (63.2-100)       |         |
| REBOA Zone I: Zone III                 | 6:1             | 15:4                  |         |
| REBOA-responders                       | 6 (86%)         | 10 (53%)              |         |
| SBP before REBOA                       | 57 (0-80)       | 53 (0-147)            |         |
| SBP after REBOA                        | 90 (0-136)      | 90.5 (0-200)          |         |
| REBOA time (minutes)                   | 45 (17-65)      | 35 (8-70)             |         |
| pRBC*                                  | 24 (20-58)      | 15 (0-42)             |         |
| FFP*                                   | 28 (6-70)       | 18 (0-38)             |         |
| Platelets *                            | 30 (0-80)       | 2 (0-30)              |         |

Data are presented as median (range) or number as appropriate.

P value= Mann Whitney U test or Fisher’s Exact test as appropriate.

*Values refer to documented cases with transfusion; GCS=Glasgow Coma Scale; ISS=Injury Severity Score; NISS=New Injury Severity Score; RISC= Revised Injury Severity Classification; REBOA=Resuscitative Endovascular Balloon Occlusion of the Aorta; SBP=Systolic Blood Pressure; pRBC=packed Red Blood Cells; FFP= Fresh
Frozen Plasma.

**Numbers do not add up to 26 due to missing data.**

**Figures**

*Figure 1*

Flow-chart visualizing who received REBOA post-ROSC vs. pre-ROSC. TCA – traumatic cardiac arrest, ROSC – return of spontaneous circulation.
Results

Of 213 patients reported in the ABOTrauma Registry during the study period, 26 patients (12.2%) who had received pre-hospital CPR due to TCA were identified. These 26 patients were treated at 11 centers in seven countries in Europe and Asia. None of the 26 patients received pre-hospital REBOA. The mechanism of injury in 21 patients (81%) was blunt trauma and in three patients (11.5%) penetrating trauma; data were missing for two patients (7.5%). The median (range) age of these 26 patients was 55 (8-79) years and 18 (69%) were male. Twelve patients (46%) had been admitted to the hospital with ROSC and 14 (54%) with ongoing CPR. Due to missing data we cannot give a time range of the duration of the TCA. Of the 12 patients...
admitted to the ER with ROSC, five patients (42%) survived (see Figure 1). In the group receiving ongoing CPR on admission, only two patients (14%) survived (see Figure 1). Figure 1 provides a flow-chart visualizing patients who received REBOA post-ROSC vs. pre-ROSC and the survivors in each group. The median (range) Injury Severity Score (ISS) was 45.5 (25-75) while the median (range) NISS was 46.5 (25-75). In all patients, data were sufficient to calculate the probability of survival using the RISC II. The RISC II predicted a mortality of 0.977 and therefore the predicted mortality was 25 out of 26 patients (0.977 x 26 = 25.4 ≈ 25). Of the 26 patients, 17 (65%) survived post 24 hours and seven patients (27%) survived to hospital discharge. Mortality following early REBOA after hospital admission (19 out of 26) was significantly lower (p=0.049) than the predicted mortality (25 out of 26). Of the nine patients who died within the first 24 hours, six died in the ER and three died during emergency operation in the OR. Those who died after 24 hours (n=10) died after, median (range), 1.5 (1-6) days in the ICU. The SMR was 0.798, meaning that fewer patients died than predicted.

As expected, the investigated patient cohort had a pronounced trauma-induced coagulopathy (TIC) presented by a median (range) INR of 1.55 (1.08-9.96), a PTT of 66.8 (23.3-180) seconds and relatively low platelet count of 116.000 (12.000-335.000). Furthermore, the patients were in pronounced shock with a median (range) base excess of -16.5 (minus 4.3 – minus 28) and lactate of 11.7 (2.1-18.9) mmol/l.

Transfusion requirements

The median (range) hemoglobin value on admission was 6.1 (2.4-8.8) mmol/l or 9.8 (3.8-14.2) g/dl. In 20 patients, transfusion was documented and, median (range), 22 (4-58) packed red blood cells (pRBC), 20 (6-70) fresh frozen plasma (FFP) and 5 (1-80) platelet packs were transfused within the first 24 hours. In six patients, transfusion before aortic occlusion was documented. In these six patients, a median (range) of three (1-7) pRBC were given before
REBOA, two out of the six patients received two FFP respectively and one patient received one platelet pack before aortic balloon occlusion.

**Special considerations regarding REBOA**

Access to the common femoral artery was blindly achieved in 20 cases (76.5%), by ultrasound in three cases (11.5%), by cut down in one case (4%) and was unknown in two cases (8%). Access was achieved by an emergency physician in 14 cases (54%), by a radiologist in four cases (15%), by a vascular surgeon and an anesthesiologist respectively in three cases (11.5%), and by a trauma and general surgeon in one case each (4%). REBOA resulted in a significant rise in systolic blood pressure (SBP), i.e. an increase in SBP ≥20 mmHg, as shown in Figure 2.

Except for one patient, all survivors were responders to the initial REBOA attempt (87%), with a significant rise in SBP after aortic occlusion (see Table 1). After aortic occlusion, the median (range) SBP was raised from 57 (0-80) mmHg to 90 (0-136) mmHg in survivors (see Table 2). In patients who died, only 10 patients (53%) responded (increase in SBP ≥20 mmHg) to the initial REBOA attempt. In the group of non-survivors, the median (range) SBP was raised from 53 (0-147) mmHg to 90 (0-200) mmHg on average.

The median (range) duration of aortic occlusion was 45 (8-70) minutes and there was no difference in occlusion time between survivors and non-survivors (p=0.68). REBOA was deployed in Zone I in 21 patients and in Zone III in five patients. Three blunt trauma patients underwent resuscitative thoracotomy, performed by an EMS physician in the field, and they arrived at the hospital with ongoing CPR subsequently and died. One resuscitative thoracotomy (RT) was performed in the ER due to no measurable blood pressure followed by Zone I REBOA. This patient was one of the survivors.
Discussion

Our study has shown that the survival rate in patients having TCA and receiving REBOA early after hospital admission is significantly higher than predicted by the RISC II. Furthermore, REBOA significantly increases SBP. Patients responding to REBOA are more likely to survive compared with those not responding, although the results lack significance due to the low sample size.

Resuscitation of patients who sustain a TCA has been associated with a low rate of survival ranging between 0% – 35%, depending on the mechanism of injury (2, 5). The high survival rate in our study (27%), despite the majority of patients being subjected to blunt trauma, justifies resuscitation efforts with the use of REBOA in patients with TCA. Current guidelines recommend to take RT into consideration in patients with TCA if CPR duration is less than 15 minutes (3). The RT rate in our study is relatively low (11.5%) and we are unable to give a solid explanation for this. One possible explanation could be that the majority of patients included in this study presented with TCA after blunt trauma and RT in blunt trauma is disputed, since the survival rate is very low (5). Another explanation could be a difference in local skills and algorithms, concerning the implementation of RT.

Massive bleeding is a preventable cause of death in trauma patients (15, 16). The use of local compression, hemostatic agents and adjunct tourniquets are often sufficient to stop or reduce external bleeding in the pre-hospital setting (17, 18). Non-compressible torso hemorrhage in the abdomen or pelvis is difficult to control without surgery. REBOA may reduce bleeding below the occlusion zone, stabilizing the hemodynamics by increasing coronary and cerebral blood flow, improving oxygenation of the heart and brain during CPR, and is associated with a more favorable acid-base status of circulating blood [5]. More than 60% of our patients responded to REBOA with an increased SBP of more than 20 mmHg.
The RISC II predicted median survival rate of 2.2% in our patients is similar to other studies describing a survival rate of less than 8% and survival rate for TCA is still lower than in medical out-of-hospital cardiac arrest (19-25). Interventions treating reversible causes of TCA may improve survival and neurological outcome. The survival rate in our study supports the use of REBOA in TCA. Access to the common femoral artery in our series was mainly blind. In contrast, other studies had a cut down rate of more than 50% (6, 26). This can be explained by the fact that REBOA accesses were performed mainly by emergency physicians, radiologists or anesthetists in our study.

Due to the necessary transfusion requirement, we assume the majority of our patients had massive bleeding and the application of early REBOA possibly prevented TCA. The median time of aortic occlusion in our study was 45 minutes in the patients who survived, 85% in Zone I. Occlusion time up to 30 minutes in Zone I is associated with lower risk of complications (8, 27). Nevertheless, the optimal occlusion time may depend on other factors such as presence of collaterals or an associated hemorrhage proximal to the level of occlusion.

All of our patients had pre-hospital TCA and pre-hospital REBOA may have been beneficial to some (28-30). This may improve blood pressure, reduce bleeding below the level of occlusion, and prevent true cardiac arrest (28-30). Nevertheless, it is important not to prolong ischemia time because it increases the risk of ischemia-reperfusion injury. Currently, no recommendation can be given regarding pre-hospital REBOA (31) since more evidence is required. The majority of our patients suffered from TIC which is multifactorial, including tissue injury and hypoperfusion (32); this explains the high transfusion requirements in our patients despite the use of REBOA.

limitations

We have to acknowledge that our study has several limitations. First, our data have been
retrieved from a partially retrospective registry and our sample size is small. Therefore, the results could be more an association than a cause-effect relationship. Second, the RISC II score has certain limitations, with age and injury severity as strong negative predictors of survival. This may underestimate the probability of survival in patients with reversible causes of TCA. Third, there were some missing values regarding transfusion requirements compared with data needed to compute RISC II, which were complete. Fourth, the ABOTrauma Registry was designed to capture REBOA-specific data and not evaluate the individual use of the technique. Accordingly, indications for and the efficacy of REBOA use are diverse. Fifth, the registry included patients who had REBOA deployed and established and not in those in whom REBOA failed and was not established, therefore we do not have a control group of patients with TCA and non-REBOA. Finally, this is an international study with limited control on the inclusion and exclusion criteria, and therefore having a risk of selection bias in the studied population.

conclusions

Our study has shown that mortality in patients suffering from TCA and receiving REBOA early after hospital admission is significantly lower than predicted by the RISC II. Early in-hospital REBOA may improve survival after TCA and pre-hospital CPR. These encouraging results should be followed by prospective studies with larger numbers to define the exact role of REBOA in these critically ill patients.

abbreviations

ABO – Aortic Balloon Occlusion

AHA – American Heart Association

aPTT – activated Partial Thromboplastin Time
declarations

**Ethical approval statement**

Ethical approval was obtained from the regional committee (study number: 2014/210; Regionala Etikprövningsnämnden, Uppsala, Sweden) for the ABOTrauma Registry. The ethical committee of the medical association of Saxony-Anhalt Germany waived the need for ethical approval for the current study (ethical committee number 70/19).
Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to ownership by the Department of Cardiothoracic and Vascular Surgery, Faculty of Medicine and Health, Örebro University, Örebro, Sweden, but are available from the corresponding author on reasonable request.

Consent for publication

Not applicable

Competing interests

Authors P. Hibert-Carius, D. T. McGreevy, F. M. Abu-Zidan, and T. M. Hörer declare that there are no conflicts of interest that could inappropriately influence (bias) their work.

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Authors’ contributions

PH-C conceived the idea, formatted the data, wrote the manuscript, and approved its final version. DTMcG contributed to the idea, analyzed the data and supervised the writing process, repeatedly edited the manuscript and approved its final version. FMA-Z performed all the statistical calculations. TMH contributed to the idea, supervised the project, edited the manuscript and approved its final version. All other authors participated in the design of the registry, collected data, and approved the final version of the manuscript. PH-C and DTMcG contributed equally to this work.
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tables

Table 1: Comparison between REBOA responders and non-responders
|                            | Responders (n=16) | Non-responders (n=10) | p-value |
|---------------------------|-------------------|-----------------------|---------|
| Age (years)               | 40 (8-79)         | 62.5 (20-78)          | 0.39    |
| Male:female               | 11:5              | 7:3                   | 0.99    |
| Blunt: penetrating trauma*| 13:3              | 8:0                   | 0.53    |
| ISS                       | 51 (25-75)        | 42 (25-75)            | 0.52    |
| NISS                      | 51 (25-75)        | 43 (25-75)            | 0.62    |
| SBP before REBOA (mmHg)   | 56.5 (0-80)       | 40 (0-147)            | 0.76    |
| SBP after REBOA (mmHg)    | 95.5 (43-200)     | 40 (0-131)            | 0.03    |
| partial-REBOA*            | 7/12 (58%)        | 3/6 (50%)             | 0.99    |
| REBOA time (minutes)      | 45 (17-70)        | 28.5 (8-70)           | 0.49    |
| RISC mortality            | 98.1 (57.4-100)   | 95.9 (63.2-99.8)      | 0.34    |
| Survival                  | 6/16 (37.5%)      | 1/10 (10%)            | 0.19    |

Data are presented as median (range) or number as appropriate. ISS=Injury Severity Score; NISS=New Injury Severity Score; SBP=Systolic Blood Pressure; REBOA=Resuscitative Endovascular Balloon Occlusion of the Aorta; RISC=Revised Injury Severity Classification.

P value= Mann Whitney U test or Fisher’s Exact test as appropriate.

*Numbers do not add up to 26 due to missing data.

**Table 2:** Comparison between survivors and non-survivors
| Variable | Survivors (n=7) | Non-survivors (n=19) | P value |
|----------|----------------|-----------------------|---------|
| Age      | 40 (30-78)     | 60 (8-79)             | 0.61    |
| Male: female | 3:4            | 15:4                 | 0.11    |
| CPR on arrival** | 2/6            | 12/17              | 0.11    |
| Blunt: penetrating trauma** | 7:0            | 14:3                | 0.51    |
| Head injury | 3/7 (43%)      | 10/19 (53%)          | 0.91    |
| GCS at scene | 3 (3-10)       | 3 (3-14)            | 0.61    |
| ISS      | 41 (38-59)     | 50 (25-75)           | 0.71    |
| NISS     | 41 (38-59)     | 50 (25-75)           | 0.4     |
| RISC mortality | 94.3 (57.4-98.4) | 98.5 (63.2-100) | 0.01    |
| REBOA Zone I: Zone III | 6:1            | 15:4                | 0.91    |
| REBOA-responders | 6 (86%)        | 10 (53%)            | 0.11    |
| SBP before REBOA | 57 (0-80)     | 53 (0-147)          | 0.81    |
| SBP after REBOA | 90 (0-136)     | 90.5 (0-200)        | 0.81    |
| REBOA time (minutes) | 45 (17-65)   | 35 (8-70)           | 0.61    |
| pRBC*   | 24 (20-58)     | 15 (0-42)            | 0.3     |
| FFP*    | 28 (6-70)      | 18 (0-38)            | 0.21    |
| Platelets * | 30 (0-80)      | 2 (0-30)            | 0.21    |

Data are presented as median (range) or number as appropriate.

P value= Mann Whitney U test or Fisher’s Exact test as appropriate.

*Values refer to documented cases with transfusion; GCS=Glasgow Coma Scale; ISS=Injury Severity Score; NISS=New Injury Severity Score; RISC= Revised Injury Severity Classification; REBOA=Resuscitative Endovascular Balloon Occlusion of the Aorta; SBP=Systolic Blood Pressure; pRBC=packed Red Blood Cells; FFP= Fresh Frozen Plasma.

**Numbers do not add up to 26 due to missing data.
Figures

Figure 1

Flow-chart visualizing who received REBOA post-ROSC vs. pre-ROSC. TCA - traumatic cardiac arrest.
Figure 2

Boxplot of Systolic Blood Pressure (mmHg) immediately before and after REBOA inflation for...