Original Article

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# Comparison of Outcomes Relating to REBOA Inflation Zones: Report from the ABO Trauma Registry

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**Background:** Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a temporary management modality for non-compressible torso haemorrhage that can be deployed in the pre- and intrahospital setting. This study aimed to compare outcomes following balloon placement in the three aortic zones.
**Methods:** This is a retrospective study using data from the ABO Trauma Registry. Relevant entries from January 2014 to December 2019 were used and stratified into three groups: those who received Zone 1, 2, or 3 balloon placements.
**Results:** The study sample consisted of 237 patients: 63 (27%) women and 174 (73%) men, median age 35 years. The primary location of the REBOA balloon was in Zone 1 for 180 patients, while it was nine in Zone 2 and 48 in Zone 3. Complication rates and total durations did not differ significantly between inflation zones. Emergency department mortality rates for Zones 1 and 2 patients were significantly higher than for Zone 3 ($P = 0.04$), but there was no difference between groups in 24-hour and 30-day mortality rates.
**Conclusions:** REBOA is currently used in the emergency setting for temporary stabilisation of the bleeding patient. In this cohort, balloon placement occurred in all zones of the aorta for similar durations, with no difference in complication rates between zones. Inadvertent Zone 2 placement was not found to be associated with increased complication rates.

**Keywords:** *REBOA; Trauma; Inflation Zone; Acute Haemorrhage; Endovascular Intervention*

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## INTRODUCTION

Resuscitative endovascular occlusion of the aorta (REBOA) is a temporary management modality of non-compressible haemorrhage. It can be deployed at both pre and intrahospital settings, to temporarily stabilise a patient's haemodynamic status for the purpose of achieving imaging and definitive interventions, and it forms part of the endovascular resuscitation and trauma management concept [1,2].

REBOA is mostly used in the adult trauma setting to decrease bleeding and to maximise cerebral and

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cardiopulmonary circulation [3,4], but is also described in post-cardiopulmonary resuscitation (CPR), obstetrics, and even in the paediatric population for instances of traumatic and non-traumatic haemorrhage [5,6].

Although the insertion of the REBOA catheter has been simplified, enabling pre-hospital or limited setting insertion via the use of anatomical landmarks alone without ultrasonographic or fluoroscopic assistance, standardised training is needed prior to adequate utilisation of this device. A discrepancy in usage is noted between high and low-to-middle income countries [7–9].

Aortic zones have been described for REBOA balloon deployment; Zone 1 being between the left subclavian artery and celiac trunk, Zone 2 between the celiac trunk and inferior-most renal artery, and Zone 3 between said renal vessel and aortic bifurcation. Varying morbidity and mortality rates have been reported for corresponding zones [10]. Examples of local complications include haemorrhage at insertion site, failed cannulation of artery, haematoma, and pseudo-aneurysm formation, while systemic complications are related to ischaemia–reperfusion concerns including acute kidney injury [11].

Zone 1 balloon placement can be expected to be associated with more pronounced ischaemia–reperfusion-related complications compared with Zone 3. Zone 2 placement is generally avoided for fear of acute ischaemia to the solid and hollow viscera supplied by the celiac trunk and superior mesenteric artery. Nonetheless, inadvertent Zone 2 placement does occur.

This study aimed to compare outcomes relating to balloon placement in the three zones.

## METHODS

This is a retrospective study using data from the multi-national ABO Trauma Registry which captures the use of REBOA in selected centres. The ABO trauma registry was created to capture REBOA-specific data, prospectively and retrospectively, in patients in whom REBOA was used specifically in traumatic haemorrhagic shock. Data entered into the registry include: country of data collection, demographics (gender and age), anthropometric measurements (weight, height and body mass index (BMI)), pre-existing cardiovascular disease, mechanism of injury, type of injury sustained, presence of concomitant head injury, body temperature at injury site, lowest blood pressure on injury site, lowest blood pressure during transport, Glascow coma scale on site, CPR on site, presence of pneumothorax or haemothorax, injury severity score (ISS), lowest blood pressure on arrival to trauma centre, temperature on arrival, heart rate, occurrence of arrythmia or asystole, electrocardiographic changes on monitor, lowest saturation in the emergency room (ER), administration of supplemental oxygen, pupillary response, presence of dilated pupils, ongoing CPR on arrival, intubation in the ER, patient arrived intubated, problems with intubation, and performance of cricothyroidotomy. All entries from January 2014 to December 2019 were considered. Entries with insufficient data for analysis were excluded. Ethics approval was obtained from the regional committee (study number 2014/210, Uppsala, Sweden). Centres that participate in data collection obtained ethics approval via local committees. The data captured are anonymised and receive a generated registry ID. All data are held on a secure electronic database and are password protected.

### *Ethical Approval and Informed Consent*

Ethics approval was obtained from the regional committee (study number 2014/210; Uppsala, Sweden).

### *Statistical analysis*

Microsoft Excel 365, IBM SPSS Statistics for Windows, versions 25.0 and R 4.1.1, were used for data analysis. Standard descriptive and inferential statistics were analysed and non-parametric tests in the form of Wilcoxon matched-pair tests and Mann–Whitney U tests were performed. Statistics with $P$ values of less than 0.05 calculated by Kruskal–Wallis one-way analysis were deemed significant.

## RESULTS

From a total of 253 patients, 16 were excluded (insufficient data regarding inflation zone), resulting in a study population of 237 patients. The median age was 35 years (standard deviation (SD) 20.3 years; range 4–96 years), with 63 (27%) women and 174 (73%) men. Comorbidities were identified in 64 (31%) patients. The primary location of the balloon was in Zone 1 of the aorta in the majority of patients 180 (76%), with nine (4%) in Zone 2 and 48 (20%) in Zone 3. The groups of patients in whom the balloon was inflated in Zones 1, 2, and 3 of the aorta were similar in genders ($P$ = 0.70), age ($P$ = 0.96), BMI ($P$ = 0.11), and injury severity score ($P$ = 0.90). Patients in whom the balloon was inflated in Zone 3 (16%) were significantly less likely to have comorbidities ($P$ = 0.04) than those in whom the balloon was inflated in Zones 1 (35%) or 2 (38%). The mechanism of injury – that is, blunt, penetrating or mixed – varied significantly ($P$ = 0.03) among locations of the balloon, see Table 1.

There were no significant differences between the haemoglobin, platelet levels, blood pH, international normalised ratio, activated partial thromboplastin time or lactate levels of patients in whom the balloon was inflated in Zones 1, 2, or 3. The total duration of balloon inflation did not differ significantly between locations of the balloon ($P$ = 0.33), see Figure 1.

***Table 1*** Mechanism of injury and zone of REBOA placement.

| | *Zone 1* | *Zone 2* | *Zone 3* | *Total* |
|---|---|---|---|---|
| Blunt | 126 (72%) | 5 (3%) | 44 (25%) | 175 (74%) |
| Penetrating | 49 (89%) | 3 (5%) | 3 (5%) | 55 (23%) |
| Combined | 4 (80%) | 0 (0%) | 1 (20%) | 5 (2%) |
| Unspecified | 1 (50%) | 1 (50%) | 0 (0%) | 2 (1%) |

*REBOA: Resuscitative endovascular occlusion of the aorta.*

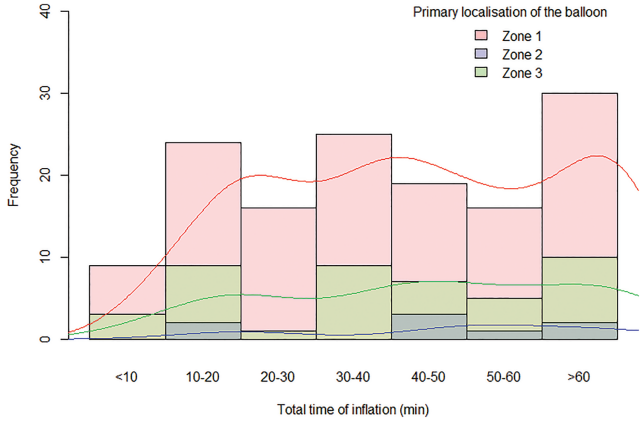


***Figure 1*** Total time of inflation in each zone.

The mean ± SD systolic blood pressure (SBP) recorded just prior to REBOA insertion was significantly lower in patients with Zone 1 balloon placement compared with those with Zones 2 and 3 placement ($P = 0.05$), whereas just after REBOA insertion this was significantly higher in Zones 1 and 2 patients compared with Zone 3 ($P < 0.01$), see Figure 2.

While few patients remained haemodynamically unchanged post-REBOA insertion, more patients in the Zones 2 and 3 groups gained complete haemodynamic stability than those in the Zone 1 group ($P < 0.01$), see Figure 3.

Aside from aorta/iliac artery perforation and haematoma over the access site, complications were not found to be different between the three groups (Table 2).

Death in the emergency department (ED) was significantly higher for Zones 1 and 2 patients, with post-hoc power analysis ($\alpha = 0.05$) showing adequate power (>0.8) for detecting significant differences between mortality rates in Zones 1 and 3 in the ED. The difference in mortality rates at 24 hours and at 30 days did not reach statistical significance between groups, see Tables 3 and 4.

## DISCUSSION

The mechanism of injury is one of the main determinants with regard to the zonal approach. In our study, the locations of REBOA balloon placement varied significantly, with Zone 1 most used for penetrating trauma and Zone 3 most used for blunt trauma; this observation is in keeping with other literature. Thrailkill and coworkers made a similar observation in their study, in which penetrating trauma favoured Zone 1 placement [12]. The authors also reported that Zone 1 placement with penetrating trauma is well justified as it efficiently and rapidly increases central and carotid flow.

In keeping with findings from the present study, a report by Beyer et al. [13] using data from the AORTA Registry demonstrated that Zone 1 REBOA balloon placement achieved significantly higher SBP as compared with Zone 3 (58 ± 4 mmHg vs. 41 ± 4 mmHg, $P = 0.008$).

Although some patients in this study remained haemodynamically unchanged post-REBOA insertion, a majority of Zone 2 patients (88%) and almost half of Zone 3 patients (47%) gained complete haemodynamic stability, in comparison to 27% for Zone 1 patients. One may postulate that the degree of shock was more severe in patients with penetrating injury and Zone 1 REBOA, with low SBP prior to insertion and thus a more profound response post-inflation. Indeed, although the ISS did not differ significantly between groups, Zone 3 patients (84%) were significantly more stable from a haemodynamic perspective than patients from Zone 1 (65%) or Zone 2 (63%).

In this patient population, the rates of complications in the form of vessel perforation and haematoma formation over the access site differed significantly among the three groups. Due to the fact that very few patients developed these complications, it is difficult to assess the accuracy of these associations. According to our research, the rates of all other complications did not differ significantly between patients independent of the zone of occlusion, further supported by Matsumoto et al., who noted that survival and complications were not related to a non-target Zone 2 placement [14]. It was conceded however, that Zone 2 placements must have negative effects on outcomes on the basis of predisposing Zone 2 placements to gastrointestinal ischaemia. An animal study performed by Tibbits et al. showed that the placement zones differed in terms of fluid requirements and metabolic complications [15]. Despite this, additional research is still needed to analyse the negative effects of Zone 2 REBOA placement.

Qasim and colleagueds reported that Zone 3 is arguably the least complicated of the three zones, and that consensus opinions indicate that Zone 3 generally allows for longer inflation times [16,17]. In the current

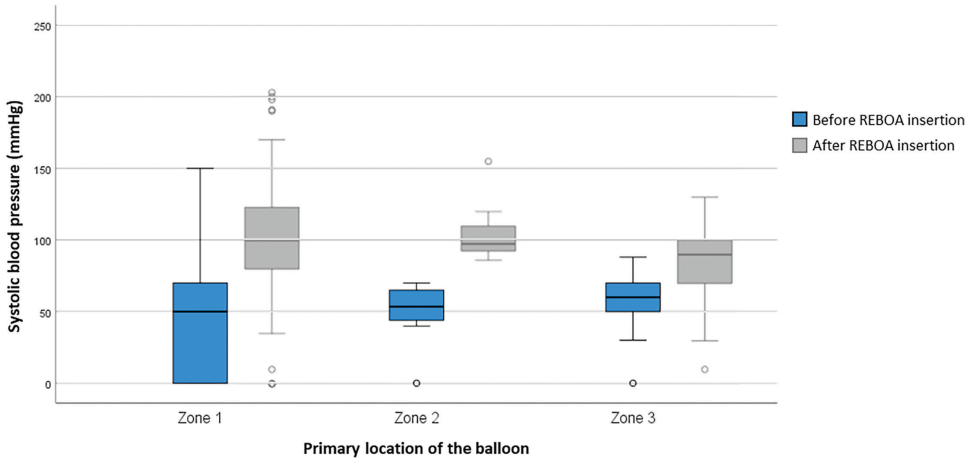


*Figure 2* Systolic blood pressure before and after resuscitative endovascular occlusion of the aorta (REBOA) insertion.

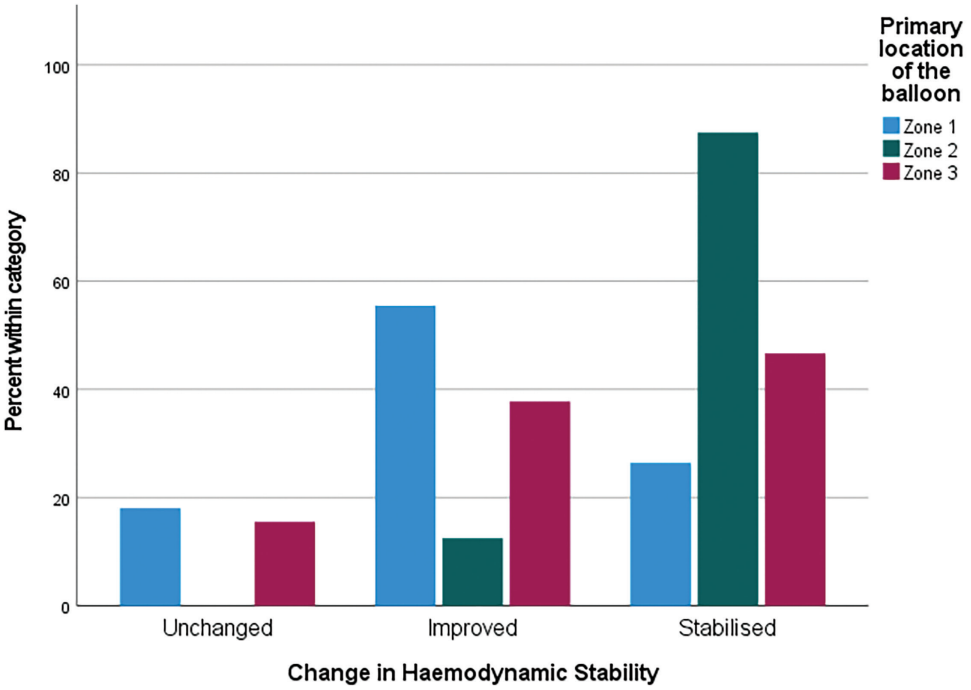


*Figure 3* Primary location of balloon inflation and change in haemodynamics.

study, the complication rate did not differ significantly between inflation zones while the total duration of balloon inflation did not differ significantly between balloon locations, with the median duration of inflation being 30–40 minutes, and the modal duration of inflation being greater than 60 minutes in both Zone 1 and Zone 3 locations.

The mortality rates in the ED of patients in which the balloon was inflated in Zones 1 and 2 of the aorta were significantly higher than that of patients in whom the balloon was inflated in Zone 3. This observation correlates with our previous postulation that a greater degree of shock was present during insertion; however, the 24-hour and 30-day mortality rates did not differ significantly. Perkins and colleaguesd reported a similar survival rate to our patient population with the Zone 1 survival rate at 39.4% and the Zone 3 survival rate at 54% [12,18].

In Japan, guidelines published by Sato et al. depicted that Zone 1 REBOA should be employed irrespective of injury location. In a case series conducted on 24 patients in which REBOA was placed in four Japanese emergency departments that did not have immediate access to a trauma surgeon, the median balloon inflation time was 65 minutes in Zone 1, with a 50% mortality rate at 24 hours [19,20]. The median time of inflation is higher than with

***Table 2*** Complication rates according to inflation zones.

| | *Zone 1* | *Zone 2* | *Zone 3* | *P value* |
|---|---|---|---|---|
| Pulmonary failure | 28 (16%) | 2 (22%) | 10 (21%) | 0.85 |
| Sepsis/SIRS | 15 (8%) | 3 (33%)) | 9 (19%) | 0.08 |
| Acute kidney injury | 16 (9%) | 1 (11%) | 7 (15%) | 0.99 |
| Extremity ischaemia | 9 (5%) | 1 (11%) | 6 (13%) | 0.11 |
| Embolisation/thrombus formation | 7 (4%) | 1 (11%) | 6 (13%) | 0.12 |
| Compartment syndrome | 6 (3%) | 0 (0%) | 5 (10%) | 0.28 |
| Balloon migration | 6 (3%) | 0 (0%) | 1 (2%) | 0.78 |
| Balloon rupture | 4 (2%) | 0 (0%) | 1 (2%) | 0.93 |
| Aorta/iliac perforation | 1 (1%) | 1 (11%) | 2 (4%) | 0.03 |
| Haematoma over access site | 1 (1%) | 1 (11%) | 0 (0%) | <0.01 |
| Intima injury | 2 (1%) | 0 (0%) | 0 (0%) | 0.68 |
| Major bleeding from access site | 2 (1%) | 0 (0%) | 0 (0%) | 0.68 |

*SIRS: Systemic inflammatory response syndrome.*

***Table 3*** Mortality rates by zone of inflation and time of death.

| | *Zone 1* | *Zone 2* | *Zone 3* | *P value* |
|---|---|---|---|---|
| Death in ED | 31 (18%) | 1 (14%) | 1 (2%) | 0.04 |
| Death within 24 hours | 74/172 (43%) | 1/6 (17%) | 11/43 (26%) | 0.06 |
| Death within 30 days | 103/174 (59%) | 2/7 (29%) | 19/44 (43%) | 0.06 |

*ED: Emergency department.*

***Table 4*** Post-hoc power for detecting significant differences in mortality rates.

| | *Zone 1 vs. Zone 2* | *Zone 1 vs. Zone 3* | *Zone 2 vs. Zone 3* |
|---|---|---|---|
| Death in ED | 0.03 | 0.83 | 0.38 |
| Death within 24 hours | 0.19 | 0.56 | 0.05 |
| Death within 30 days | 0.35 | 0.48 | 0.09 |

*ED: Emergency department.*

the present study but the mortality rate within the first 24 hours in this study is very similar at 43%. In comparison, the 24-hour mortality rate in the present patient population was 17% for Zone 2 and 26% for Zone 3.

Several limitations exist for this study. The ABO Trauma Registry is an international registry and the indications, use of and efficacy of REBOA are diverse and differ from facility to facility. This database also does not take into account the failed attempts at REBOA deployment. Due to the limited control of data entries and participation criteria there might be selection bias. Finally, there were missing data variables in the registry that caused the exclusion of 16 patients to this study.

## CONCLUSIONS

REBOA is currently being used in the emergency setting for temporary stabilisation of the haemorrhagic patient. In the studied cohort REBOA was used in all zones of the aorta with no significant difference in total duration and complication rates between the three zones. Non-targeted Zone 2 placement did not increase complication rates, with ischaemic time kept to a median of 30–40 minutes in this cohort. It should, however, be emphasised that 76% (180 patients) of the sample was represented by those undergoing REBOA with Zone 1 inflation, 20% (48 patients) Zone 3 and only 4% (nine patients) in Zone 2. In light of the small number of patients in the Zone 2 group, the results may not be an accurate reflection of the true incidence of Zone 2 inflation time and complication rates and should therefore be interpreted with reserve.

## Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.
(2) The authors declare that they have read and abided by the JEVTM statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

## Conflicts of Interest

The authors declare a conflict of interest as Tal Martin Hörer, the editor in chief of the *Journal of Endovascular Resuscitation and Trauma Management*, is one of the researchers. The remaining authors declare that they have no conflicts of interest.

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## Author Contributions

JB was the principal investigator. SV, AD, PS, PR, and NA were responsible for data preparation, data analysis, and manuscript preparation. BK and DTM were responsible for data collection, data preparation, and manuscript revision. TMH was responsible for data collection and manuscript revision. GO was responsible for critical revision and overall supervision.

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