Original Article

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Use of Intermittent Aortic Balloon Occlusion: Report from the ABO Trauma Registry

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Background: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a helpful adjunct in the management of hemorrhagic shock due to bleeding in the abdomen or pelvis. Ischemia distal to the occlusion is a concern; intermittent aortic balloon inflation (i-REBOA) is a novel way to achieve decreased ischemia time.
Methods: This study was conducted using data from the multinational ABO Trauma Registry. All patients entered between January 2016 and December 2019 were included.
Results: The sample consisted of 157 patients. There were 57 patients in the i-REBOA group (36%) and 100 in the REBOA group (64%). The groups were similar in gender ($P = 0.50$), age ($P = 0.17$), mechanism of injury ($P = 0.42$), and injury severity score ($P = 0.13$). The levels of international normalized ratio (INR) ($P < 0.01$), activated partial thromboplastin time (aPTT) ($P < 0.01$) and lactate ($P = 0.02$) were higher in the i-REBOA group. Total balloon inflation times were longer in the i-REBOA group ($P < 0.01$). Major complication rates did not differ between groups. Mortality rates between groups were similar in the Emergency Department (ED) (3.8% for i-REBOA vs 10.1%; $P = 0.17$), within 24 hours (43.4% for i-REBOA vs 38.2%; $P = 0.54$), and at 30 days (63.6% for i-REBOA vs 48.4%; $P = 0.07$).
Conclusions: The data from this registry show that i-REBOA is currently being used and may allow for longer total balloon inflation times without higher morbidity or mortality rates.

Keywords: *Intermittent REBOA; ABO Trauma Registry; Trauma Hemorrhage; Trauma*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an established adjunct to the management of hemorrhagic shock and is part of the endovascular resuscitation and trauma management concept [1,2]. Balloon placement in the aorta decreases blood loss distally while shunting blood proximally to the more vital neurologic and cardiorespiratory centers [3]. Advantages include minimally invasive access, use without intubation, quick access and hemorrhage control, and use in pre-theatre settings. Comparison of REBOA with resuscitative thoracotomy and aortic cross-clamping noted more rapid aortic occlusion in REBOA patients, with the additional benefits of the possibility of prehospital deployment and independence from sonographic or fluoroscopic techniques, requiring only external anatomic landmarks for prompt insertion [4–6].

Three aortic zones are described, with reference to balloon inflation: Zone 1: between the left subclavian artery and celiac trunk; Zone 2: from the celiac trunk to the lowest renal artery; Zone 3: from beyond the lowest renal

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artery to the aortic bifurcation. Zone 2 is generally avoided while balloon placement in Zone 1 versus Zone 3 is governed by specific indications, with their own impact on overall morbidity and mortality [7]. Due to the complexity of these cases the outcome is not only dependent on the use of REBOA. The level and the duration of balloon inflation both contribute to the increased potential for ischemia–reperfusion syndrome and multi-organ dysfunction [8,9]. This is especially true for Zone 1 occlusion.

Partial balloon inflation (p-REBOA), in which the aortic balloon is partially deflated, allowing a proportion of aortic flow distal to the balloon, and intermittent balloon inflation (i-REBOA) have been proposed as means to mitigate the risk of ischemia–reperfusion syndrome [8–12]. Although the optimal duration of intermittent balloon inflation has not been established, the need for careful, incremental deflation of the aortic balloon as well as expeditious definitive management of the bleeding source has been outlined clearly in recent international literature [13,14]. In this study we aimed to ascertain clinical use and outcomes related to the use of i-REBOA.

METHODS

The study was conducted using the ABO Trauma Registry. This multi-national registry captures patients who underwent REBOA placement secondary to traumatic hemorrhagic shock in selected centers using REBOA. The registry is funded and hosted by the Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden. Participating centers can register independently or by invitation and can use the data for scientific analysis. There are no center-specific criteria for joining. Centers that participate in data collection arrange ethics approval by their local committees. The data captured is anonymized and receives a generated registry ID.

We performed a retrospective analysis of registry data entered from January 2016 to December 2019. i-REBOA was defined as any patient in whom the aortic balloon was inflated and deflated periodically. Patients in whom it was not specified whether i-REBOA was used/not used were excluded. Entries missing more than 50% of the necessary data were excluded. Those that were included in the study but lacked certain information necessary for any specific analysis were excluded from the relevant analysis.

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, version 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

Of 253 registry entries, 96 were excluded, leaving a study population of 157 patients. The median age was 38.0 years (standard deviation (SD) 19.9 years; range 10–90 years), and 35 patients (22.3%) were women. Thirty-one patients (20.4%) had comorbidities. Two patient groups were identified: i-REBOA: 57 (36%) versus conventional REBOA with no intermittent inflation: 100 (64%). The groups were similar in gender (P = 0.50), age (P = 0.17), mechanism of injury, that is, blunt, penetrating or mixed (P = 0.42), injury severity score (ISS) (P = 0.13), and zone of inflation (P = 0.08); however, i-REBOA was used more frequently in patients with comorbidities than in those who were previously healthy (54.8% vs. 32.2%; P = 0.02).

There were no differences between groups in median values of systolic blood pressure just before REBOA insertion (P = 0.29), hemoglobin level (P = 0.27), blood pH (P = 0.87), or platelet count (P = 0.31); however, the median levels of international normalized ratio (INR) (P < 0.01), activated partial thromboplastin time (aPTT) (P < 0.01) and lactate (P = 0.02) were higher in the i-REBOA group. Total balloon inflation times were longer in the i-REBOA group (P < 0.01) (Figure 1).

Fewer patients in whom i-REBOA was used remained hemodynamically unstable (8.9% vs. 17.9%), although more patients in whom i-REBOA was not used (42.1%) gained complete hemodynamic stability (42.1% vs. 30.4%). These distributions differed significantly (P = 0.04) (Figure 2).

Balloon migration was more common with i-REBOA (8.8% vs. 2.1%; P = 0.05). Balloon rupture was more common with i-REBOA (5.3% vs. 1.0%) but this did not reach statistical significance (P = 0.11).

The rate of complications did not differ significantly between groups (Table 1). The mortality rate between groups was similar in the Emergency Department (ED) (3.8% for i-REBOA vs. 10.1%; P = 0.17), within 24 hours (43.4% for i-REBOA vs. 38.2%; P = 0.54), and at 30 days (63.6% for i-REBOA vs. 48.4%; P = 0.07; Table 2). There were no significant associations between the rate of complications and zone of inflation among patients who did and did not undergo i-REBOA (Table 3). While the mortality rate of patients with inflation in Zone 1 who underwent i-REBOA was significantly lower than those who did not in the ED (2.3% for i-REBOA vs. 14.0%; P = 0.04), the 30-day mortality rate of patients with inflation in Zone 1 who underwent i-REBOA was significantly higher than those who did not (66.7% for i-REBOA vs. 47.4%; P = 0.05; Table 4).

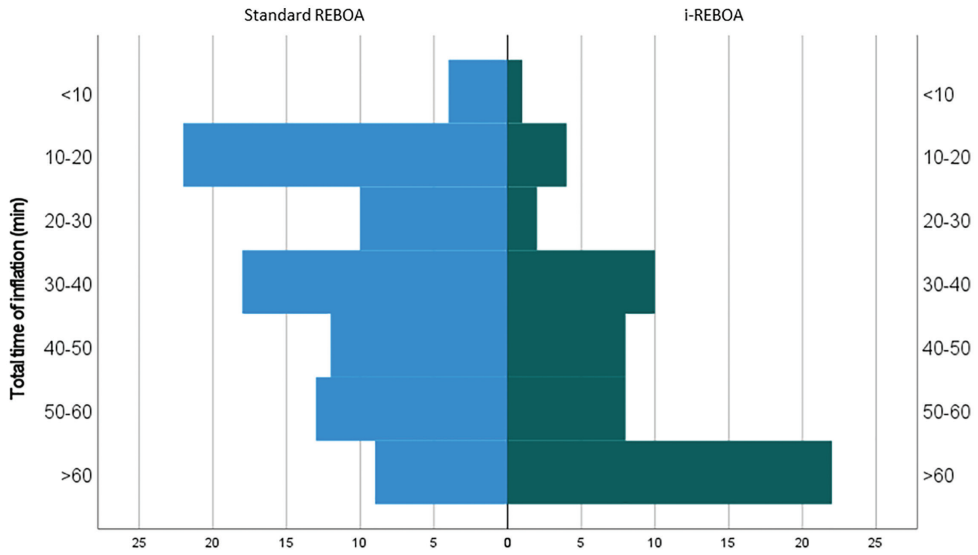

Figure 1 Comparison of total time of balloon inflation between i-REBOA and standard REBOA.

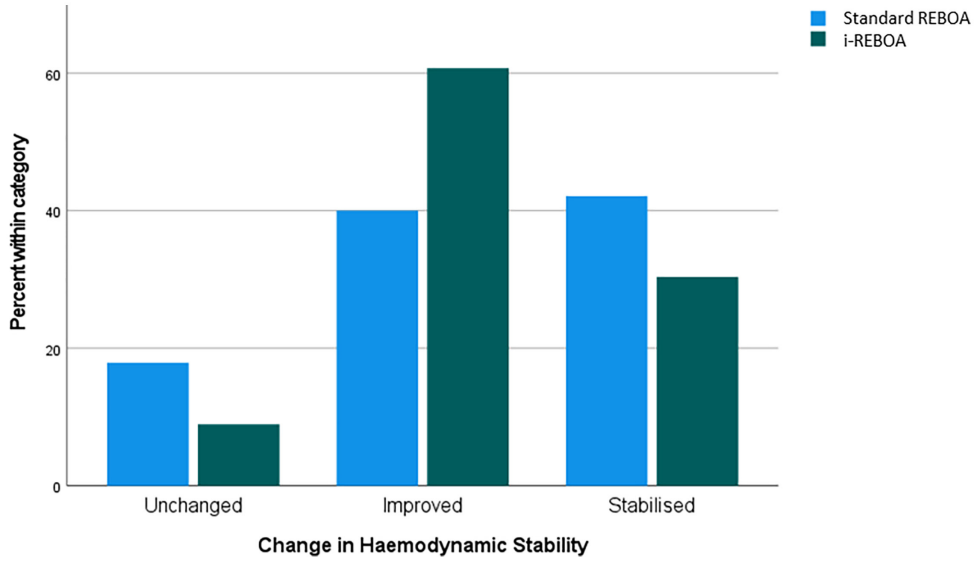

Figure 2 Change in hemodynamic stability with and without i-REBOA.

Table 1 Complication rates.

	i-REBOA	*Standard REBOA*	*P Value*
Pulmonary failure	7 (18.4%)	24 (30.8%)	0.16
New onset renal failure	10 (22.7%)	12 (14.0%)	0.21
Sepsis/SIRS	5 (12.8%)	15 (19.0%)	0.40
Extremity ischemia	5 (10.6%)	8 (10.1%)	0.93
Embolization/thrombus formation	3 (5.9%)	9 (10.2%)	0.38
Aorta/iliac perforation	1 (2.0%)	2 (2.2%)	0.91
Hematoma over access site	1 (2.2%)	1 (1.2%)	0.67
Major bleeding from access site	1 (2.0%)	1 (1.1%)	0.67
Intimal injury	0 (0.0%)	1 (1.1%)	0.45

Table 2 Mortality rates in ED, within 24 hours and after 30 days.

	i-REBOA	*Standard REBOA*	*P Value*
Death in ED	2 (3.8%)	9 (10.1%)	0.17
Death within 24 hours	23 (43.4%)	34 (38.2%)	0.54
Death within 30 days	35 (63.6%)	44 (48.4%)	0.07

Table 3 Complication rates in patients with Zone 1 inflation.

	i-REBOA	*Standard REBOA*	*P Value*
Pulmonary failure	6 (19.4%)	16 (32.7%)	0.19
Acute kidney injury	6 (17.6%)	9 (17.0%)	0.94
Sepsis/SIRS	3 (9.7%)	8 (16.3%)	0.40
Extremity ischemia	2 (5.1%)	4 (8.3%)	0.56
Embolization/thrombus formation	2 (4.9%)	3 (5.5%)	0.90
Aorta/iliac perforation	0 (0.0%)	0 (0.0%)	–
Hematoma over access site	1 (2.6%)	0 (0.0%)	0.25
Major bleeding from access site	1 (2.5%)	1 (1.8%)	0.82
Intimal injury	0 (0.0%)	1 (1.8%)	0.39

Table 4 Mortality rates in ED, within 24 hours and after 30 days in patients with Zone 1 inflation.

	i-REBOA	*Standard REBOA*	*P Value*
Death in ED	1 (2.3%)	8 (14.0%)	0.04
Death within 24 hours	22 (50.0%)	22 (38.6%)	0.25
Death within 30 days	30 (66.7%)	27 (47.4%)	0.05

DISCUSSION

It has been reported that prolonged ischemia after REBOA followed by reperfusion results in multiple organ failure and is more prominent with continuous balloon inflation [15–17]. Kuckelman et al. [18] reported that i-REBOA enabled extension of the occlusion time for Zone 1 without an overt increase in complications in an animal study.

When using i-REBOA, two options have been described, namely time-based and pressure-based techniques. The pressure-based technique employs mean arterial pressure (MAP) < 40 during deflation with 10-minute inflation increments, while the time-based technique employs 3-minute deflation periods, irrespective of MAP, with 10-minute inflation periods. In their swine model, Kuckelman and co-workers reported that the time-based technique had a superior survival benefit [18]. In the present study the emphasis was not on choice of technique and therefore this comparison was not made.

Intermittent inflation may prompt concerns as to the effectiveness of REBOA to bring about hemodynamic stability. The use of i-REBOA in this study resulted in a more pronounced initial improvement of hemodynamic status, but it was less likely to result in ultimate stabilization. This can be explained by the greater degree of coagulopathy and shock in the i-REBOA group, as reflected by higher levels of INR, aPTT, and lactate.

In this study, although the i-REBOA group had worse shock parameters and the duration of balloon inflation was on average three times longer, there were no differences in morbidity and mortality rates between groups. This implies that i-REBOA may be instrumental in allowing an extended overall duration of balloon inflation to facilitate referral and transport of a patient to appropriate facilities for definitive care, without additional morbidity or mortality.

Repetitive manipulation of the balloon during the use of i-REBOA carries inherent technical concerns. Balloon migration in this study was significantly more common with i-REBOA than without. Repeated re-inflation and manipulation of the catheter with longer inflation times could be responsible for this finding. The risk of balloon migration can be minimized by securing the catheter once proper positioning is achieved. With i-REBOA the catheter position is of utmost importance, as the lack of apposition to the aortic wall can cause downstream migration [19–21]. Inflation of the balloon during REBOA is usually performed blindly and is ceased when distal pulses disappear or when there is resistance during inflation [22,23]. Experience with the procedure can help with procurement of the necessary

tactile feedback of adequate inflation. Johnson and coworkers [21] reported that the distal arterial waveform may be measured and is a useful adjunct to determine complete aortic occlusion during balloon inflation. Over-inflation could lead to balloon or arterial rupture, arterial dissection and intimal injuries [22–24]. Balloon rupture in this study was more frequently encountered with i-REBOA than with standard REBOA, although this did not reach statistical significance. There were also no significant differences between groups in terms of intimal injuries or arterial ruptures, and the same held for distal ischemia, embolization, and renal failure.

This study has several limitations. The ABO Trauma Registry is an international registry and the indications, technical application, and efficacy of REBOA differ across the various contributing facilities. Furthermore, this database does not take into account the failed attempts at REBOA deployment, while non-reporting also needs to be considered. Finally, a major limitation is the absence of a control group.

CONCLUSIONS

It appears that i-REBOA can be employed with longer total balloon inflation times without higher morbidity or mortality rates, thereby alleviating some of the time-associated concerns related to aortic occlusion. The technique may be of value in severely shocked patients in whom resuscitation is ongoing and transport is required. Attention to balloon position, monitoring and security are of utmost importance and can prevent adverse events related to repetitive manipulation.

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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 that Tal Hörer has a conflict of interest due to his affiliation as editor in chief of the *Journal of Endovascular Resuscitation and Trauma Management*. The remaining authors declare that they have no conflicts of interest.

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Author Contributions

J Buitendag: Principal investigator; S Variawa S: Data preparation, data analysis, manuscript preparation; A Diayar: Data preparation, data analysis, manuscript preparation; P Snyders: Data preparation, data analysis, manuscript preparation; P Rademan P: Data preparation, data analysis, manuscript preparation; N Allopi: Data preparation, writing, data analysis, manuscript preparation; B Kessel B: Data collection, data preparation, manuscript revision; D McGreevy D: Data collection, data preparation, manuscript revision; T Hörer: Data Collection, data preparation, manuscript revision; G Oosthuizen: Critical revision and overall supervision.

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