

A Pilot Study of Proactive Team REBOA to Avoid Delays to Definitive Care

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As experience using resuscitative endovascular balloon occlusion of the aorta (REBOA) has expanded over the past few years, best practices for implementing a REBOA program have emerged. Early practice was single-surgeon focused, but we have learned that a team approach to REBOA practice is common in successful programs. Key components of our contemporary team approach are defining a patient selection algorithm, uniform acceptance of early CFA access, full team training, regular case reviews, and implementation of a process improvement program. This team approach to REBOA has resulted in numerous benefits for trauma patients with, most importantly, a significantly decreased time to definitive hemorrhage control. Here, we describe our experience and outcomes as a Level 1 Trauma Center implementing a REBOA program, shifting our hemorrhage control paradigm from reactive to proactive, and subsequently improving time to both temporary and definitive hemorrhage control maneuvers.

Keywords: REBOA; Process Improvement; Time to Intervention

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INTRODUCTION

The broad implementation of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in trauma has evolved rapidly in the past decade. Over-the-wire, 12 Fr occlusion balloons were initially used in a small number of centers to develop experience that was foundational to broader implementation when devices designed for trauma became available early in 2016 [1]. Devices specifically created for trauma were followed by procedural improvements which shifted REBOA use from solely being an alternative to a resuscitative thoracotomy to a procedure used proactively in noncompressible torso hemorrhage. Common femoral arterial (CFA) access shifted toward being ultrasound guided, and has been recognized as an independent intervention to guide resuscitation rather than as merely the first step in REBOA. These early devices were time limited to 30 min of occlusion in aortic Zone 1 secondary to the risks of increased ischemia as the only option was complete

aortic occlusion. More recently, a purpose-built partial REBOA catheter has enabled the routine implementation of partial occlusion to achieve further refinements such as reduced distal ischemia and prolonged safe partial occlusion time [2,3].

In the process of launching and sustaining a REBOA program, our center has continued to implement a process improvement initiative to maximize the utility and minimize the risks of endovascular aortic occlusion. In doing so we have observed a dramatic change in our REBOA use and team dynamics during this procedure. We have clearly differentiated between REBOA practiced as we first implemented it and our current use of endovascular hemorrhage control. We sought to quantify these differences to enumerate the change from reactive to proactive, and from REBOA that delayed definitive care to REBOA that was part of an efficient and effective trauma bay, which does not delay surgical or other resuscitative interventions. To quantify these changes and promulgate best practices, we reviewed trauma bay videos, direct observations, and operative records to compare our early experience with contemporary performance.

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METHODS

As part of an ongoing process improvement, we conducted a video review of procedures performed in the trauma bay and grouped them according to an early cohort and a contemporary cohort consisting of the first

10 cases and more recent 10 cases. We created a relative timeline with the start of the first procedure set as $T = 0$ and examined the following procedures: collection of belongings, attachment to monitors, measurement of blood pressure (BP), REBOA, thoracotomy, blood product transfusion, splinting/reduction, wound exploration, diagnostic peritoneal aspiration (DPA), chest tube placement, extended focused assessment with sonography for trauma (EFAST), pelvic x-ray, chest x-ray, blood draw, urine drug screen (UDS) sampling, urine pregnancy test, extremity imaging, common femoral artery percutaneous line placement, open exposure of the common femoral artery for placement of sheath access, intraosseous (IO) access, trauma line (large bore venous access), peripheral access, Foley catheter placement, rectal examination, spine/back examination, lower extremity examination, upper extremity examination, pelvis examination, chest and abdomen examination, head and neck examination, removal of patient clothing (exposure), Glasgow coma scale (GCS) assessment, circulation assessment, breathing assessment, airway assessment, transition of the patient from the emergency medical services (EMS) cart to the trauma evaluation cart, and EMS timeout. We examined time as an independent variable and time from arrival to initiation of REBOA, time from initiation of REBOA to completion of occlusion, number of concurrent procedures, and time to definitive control of hemorrhage as dependent variables.

RESULTS

We observed a significant improvement in our performance of the REBOA procedure, with overall efficiency improved in several key metrics. Key to these improvements was a focus not only on REBOA training and experience, but a shift in our approach to early CFA access. At our institution, early CFA access occurs when the initial non-invasive systolic blood pressure (SBP) reading is less than 90 mmHg, the patient has received ongoing blood product resuscitation to maintain an SBP > 90 mmHg, or the patient had a previous traumatic cardiac arrest prior to arrival and spontaneous circulation was achieved (Table 1). The majority of early CFA access cases do not progress to a REBOA placement. In the minority of cases where hypotension is confirmed and response to initial resuscitation is not satisfactory, time from arrival to initiation of REBOA decreased from a mean of 11.1 min to 7.5 min, a reduction of one third (32%) (Table 2). The improved speed in decision making contributed to improvements in proficiency in insertion of a 7 Fr sheath, preparation and insertion of a REBOA catheter, and balloon inflation which decreased by 48% overall (7.1 min to 3.7 min). These improvements reflect a successful process which were matched by other impactful benefits to the process of care, with the number of procedures performed concurrently with REBOA increased by 360% (from 3 to 11) (Figure 1). These incremental improvements in decision making,

Table 1: Trauma center CFA access guidelines and REBOA guidelines.

Procedure	Indications
CFA access	<ul style="list-style-type: none"> Cuff SBP < 90 mmHg, or Transient responder to transfusion, or Profound, refractory shock, or
REBOA	<ul style="list-style-type: none"> OHCA with ROSC Blunt or penetrating injury, and SBP < 90 mmHg, and Transient responder to 1–2 units whole blood or <ul style="list-style-type: none"> Profound hypotension or <ul style="list-style-type: none"> Arrested but not beyond salvage (ATLS Guidelines)

CFA: common femoral access, SBP: systolic blood pressure, mmHg: millimeter of mercury, OHCA: out of hospital cardiac arrest, REBOA: resuscitative endovascular balloon occlusion of the aorta, ROSC: return of spontaneous circulation, ATLS: advanced trauma life support.

Table 2: Comparison between early and experienced REBOA cases.

	First 10 REBOAs	Last 10 REBOAs	p Value
Initiation time (min)	11.1	7.5	0.032
REBOA time (min)	7.1	3.7	0.027
Concurrent procedures (n)	3	11	0.014
Time to OR/IR (min)	32.3	15.6	0.021

"Initiation time" is the time from patient presentation to start of the REBOA procedure. "REBOA time" is the length of time to perform the REBOA procedure. "Concurrent Procedures" is the number of overlapping procedures the team was performing during the REBOA procedure. "Time to OR/IR" is the time from patient presentation when the decision was made to proceed to definitive hemorrhage control.

REBOA technique, team organization, and performance combined to improve overall time to proceed to definitive control by 52% from 32.3 min to 15.6 min.

DISCUSSION

We observed significant changes in the use of REBOA at our institution as a result of deliberate process improvement and the intangible improvements inherent in the accumulation of experience over time. These improvements accumulated due to a team focused on improving efficiency of care, but are not the result of a single-minded focus on REBOA; the procedure remains relatively infrequent for an individual provider. We observed a striking improvement in the most important metric, time to definitive hemorrhage control. This metric has been previously shown to be impactful for survival [4]. This important metric reflects improvements

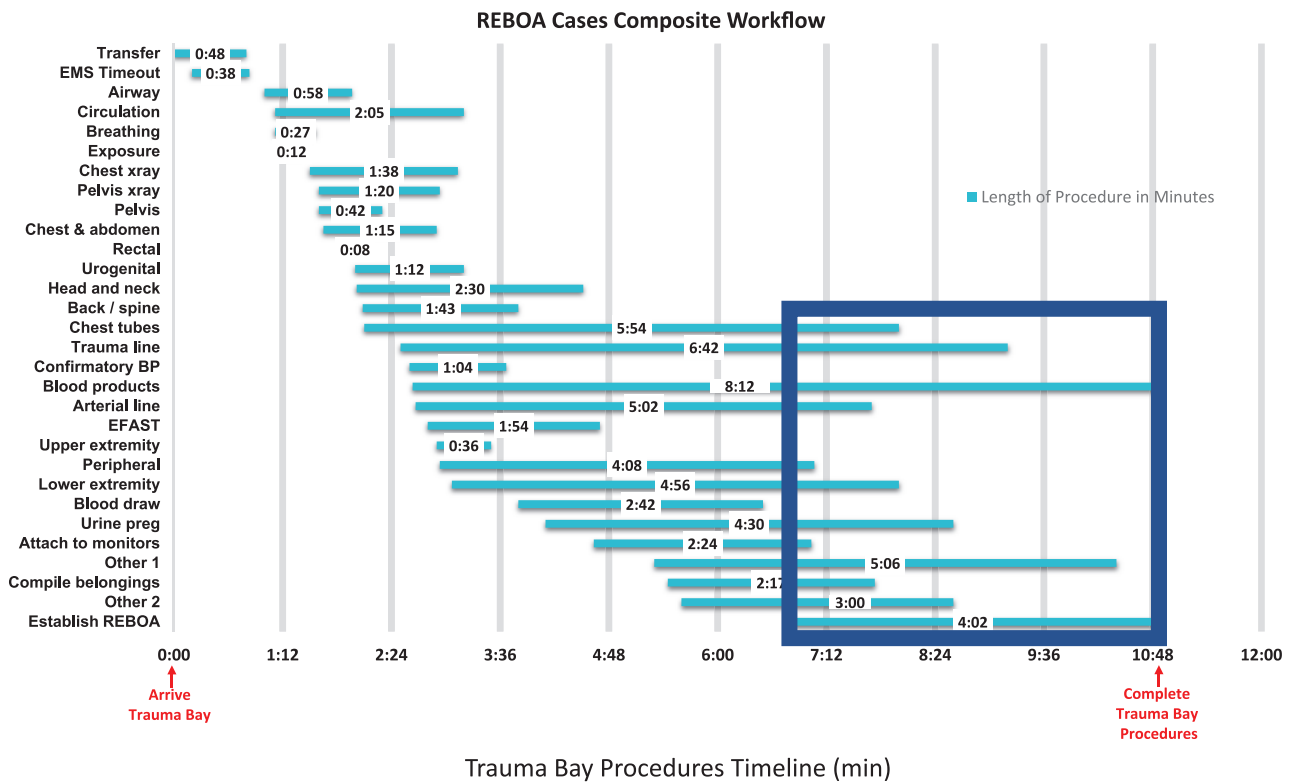


Figure 1 Trauma bay procedures in the 10 most recent cases where REBOA was performed. All procedure times are relative to the first trauma bay procedure. Procedures that were initiated or concluded within the period between REBOA initiation and REBOA completion were counted as concordant. This parallel performance of procedures reflects the development of improved proficiency and improved team coordination, which differs from the initial cases of REBOA where other procedures were delayed while REBOA was performed.

in several sub-steps which were measured in this process improvement review. These include faster initial decision to perform REBOA, procedural proficiency, and a dramatic increase in parallel treatment. Key to effective patient selection was our institution's development and adoption of a patient selection algorithm and uniform acceptance of early CFA access as a measure to assist in the treatment of patients presenting with traumatic hemorrhage. This transformation to CFA access and REBOA performed concurrently with other necessary diagnostic and resuscitative procedures is particularly noteworthy. In the early days of our REBOA program, the decision to perform the procedure was often followed by the trauma team lead becoming engrossed in CFA access and catheter manipulation while the rest of the team stopped to watch this novel procedure. Contemporary practice has access delegated to other members of the team (usually senior residents or advanced practice providers) while the rest of the team continues with their responsibilities and the trauma surgeon continues to lead and manage care.

Key to these improvements was gaining consensus on patient selection [5], and clinical adoption of this consensus. While patient selection guidelines vary, there is

broad consensus and ample evidence that following guidelines results in improved outcomes [6]. As has been widely noted, CFA access is a key to success, and provides actionable physiologic information independent of its use for REBOA. More recently, our institution joined a group of centers implementing a next-generation partial REBOA (pREBOA) catheter. This process of implementing the pREBOA-PRO was guided by the observations above. Namely, a consensus guideline was developed, key steps such as catheter preparation deployment and removal were rigorously trained, and reviews of each case were conducted to improve these processes. This process improvement program has now become institutional and has contributed to the rapid refinement of partial REBOA implementation through monthly multicenter case reviews. These multicenter process improvement efforts led to the rapid dissemination of best practices. The refinements in procedure evolved alongside refinements in device design and treatment guidelines. Key recommendations from these efforts can be applied by anyone seeking to implement a REBOA program: start with a consensus among providers regarding early CFA access and patient selection guidelines; develop and implement realistic simulation-based team

training along with arterial pressure monitoring and sheath management checklists to minimize avoidable complications; finally, conduct timely process improvements to yield improved outcomes.

Our observations are concordant with prior studies of the evolution of REBOA, with registry studies of REBOA in Japan [7] and the USA [8] both identifying better outcomes as REBOA procedures and devices continue to improve. Another consistent finding is the impact of case volume on success, with several studies documenting the value of moderate to high case volume [9,10]. We perform approximately two REBOA cases a month along with 10 CFA procedures, which we have found to be sufficient to enable meaningful process improvement. Our results provide insight into specific enhancements, which contribute to this broad improvement in REBOA, including better team dynamics evidenced by the increase in concurrent procedures and enhanced procedural capabilities evidenced by faster times to occlusion and faster times to definitive hemorrhage control.

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

M Chance Spalding is a member of the Prytime Medical Devices Speaker's Bureau and has received support for travel, food and beverage during speaking engagements. He does not have any financial interests or support from Prytime outside of the Speaker's Bureau.

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Author Contributions

MCS conceived of the original study idea. Both MCS and UP compiled and analyzed data and wrote the manuscript with support.

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