Clinical Effectiveness of HALO Tourniquet in Achieving Arterial Occlusion

Curtiss J Smith MD, Maria Crespo DO

Abstract

Morbidity and mortality from extremity hemorrhage has been a significant epidemiological concern among combat and civilian populations for centuries. Tourniquet devices have been a time-honored remedy to mitigate life-threatening bleeding with a relatively low risk of secondary ischemic injury. We investigated the clinical effectiveness a new tourniquet device with a unique design that involves a lever for tightening as opposed to traditional models that utilize a windlass mechanism. We applied the HALO to extremities of 42 adult subjects and developed a novel protocol to assess for blood flow restriction utilizing point of care ultrasound (POCUS) vascular doppler functions. All 42 trials were favorable in achieving arterial blood flow occlusion.

Introduction

The use of tourniquet devices to combat life threatening extremity bleeding was documented since the late 1500s and likely had played a major role in much of those earlier times.[1] Despite the introduction of different tourniquet devices and stepwise Hemorrhage control modalities, extremity hemorrhage remains a significant cause of morbidity and mortality, both in the military arena and among civilians.[1,2]

In 2000, the World Health Organization (WHO) estimated that severe trauma resulted in more than 5 million deaths, with hemorrhage accounting for approximately 35% and up to half of those deaths occurred before patients could reach definitive care.[2] Extremity hemorrhage accounts for approximately 9% of military related deaths.[1] Likewise, the frequency of significant vascular injury from penetrating injury among military personnel has been reported at 6.6% by one Air Force hospital in Iraq. Of these cases, 79% involved vasculature of the extremities.[1] Importantly, massive extremity hemorrhage is recognized as the number one cause of potentially preventable deaths on the battlefield.[13] Although more rare, civilian deaths from isolated extremity hemorrhage have also been studied. Dorlac et al found that 57% of patients evaluated in their study died from hemorrhages that may have anatomically been amenable to tourniquet control.[15]

Tourniquets serve as a temporary measure to control life-threatening hemorrhaging from an extremity. Proper use of tourniquets has been shown to save lives under potentially fatal conditions with comparatively low risk of injury.[3]

By applying sustained pressure and tension to blood vessels proximal to a site of an injury, arterial and venous blood flow becomes occluded and prevents exsanguination.[5] Performance variability exists between designs and application methods and certain designs demonstrate mechanical advantages over others in applying the necessary force to provide optimal vessel occlusion.[3]

The HALO (Hemorrhage Arresting Lever Operated) Tourniquet was invented by a group of combat veterans, engineers, and orthopedic surgeons and granted patent in 2018. Most field tourniquet designs incorporate a non-elastic strap, some type of buckle allowing a 180° strap direction change (strap re-direct), a strap securing mechanism, and a tightening mechanism.[14] The HALO is the first of its kind to implement a lever device for tightening, as opposed to a windlass with a twisting mechanism. HALO's buckle permits quick length adjustments to accommodate different widths of extremities. (Figure A)

Figure A: Halo Tourniquet™

The HALO underwent intensive mechanical testing to establish safety parameters. Simulations were conducted on models that replicate an adult male thigh at the 95th percentile for circumference and diameter (28.13 in and 8.95 in, respectively). A standard 3-inch-wide surgical tourniquet was used to derive the maximum circumferential tension applied by the HALO. A maximum limb occlusion pressure of 350 mmHg was used in the simulation, which is below the threshold of pressure known to potentiate nerve damage.[14]

The aim of this study is to determine if the HALO Tourniquet is clinically effective at occluding blood flow to the extremities of human subjects. Traditionally, the testing of clinical effectiveness of combat tourniquets has been focused on time and ease of device application. We believe both to be important measures and plan to address them in a separate phase. Most studies conducted to date use two endpoints in detecting clinical effectiveness (or "effective placement") of tourniquets: loss of palpable distal pulse and loss of handheld doppler signal.[4]

Materials and Methods

We developed a new protocol which aims to utilize point of care ultrasonography (POCUS) to assess blood flow in healthy volunteers both before and after HALO Tourniquet placement. To our knowledge, this methodology has not been utilized to evaluate clinical effectiveness of combat-style tourniquets.

The vascular function of the POCUS can provide useful information regarding the blood flow status in an extremity. This involves the use of high-resolution B-mode imaging to assess doppler color flow and pulsed doppler spectral waveform analysis.[6] These were the modalities utilized to draw conclusions about blood flow occlusion in our study.

Doppler color flow pattern (CFP) imaging uses different colors to differentiate the direction of blood flow according to doppler signal. Red indicates blood flowing away from the indicator, as in arterial flow, and blue indicates blood flowing towards the indicator, as in venous flow. Loss of or disrupted forwarded color flow is interpreted as decreased arterial flow.[7,8] (See figure 1A)

Spectral Waveforms represent the velocity pattern in a given vessel. Under normal circumstances, the waveform has a characteristic triphasic morphology.

There is an initial high-velocity, forward flow phase that results from cardiac systole. The peak of this waveform is referred to as "peak systolic velocity" (PSV). This is followed by a brief phase of reverse flow in early diastole and a final low-velocity, forward flow phase at the end of diastole. The average PSV of the Brachial and Femoral arteries is 57 ±22 cm/s and 91±14 cm/s[11]. The volume of blood in a given vessel at the end of this phase can be measured and is termed "end diastolic volume."[6]

The features of spectral waveforms immediately proximal to a vessel with arterial stenosis typically demonstrate decreased PSV, loss of triphasic waveforms (i.e., loss of reverse flow in early diastole) and broadening of the doppler signal. (See figure 1B). These findings can be demonstrated arterial occlusion between 50-100%.[7]

Another measure that can be considered in conditions of blood flow occlusion is the resistive index (RI). This is defined as the sum of the PSV and EDV divided by PSV. A higher resistive index implies increased resistance to flow.[6,9]

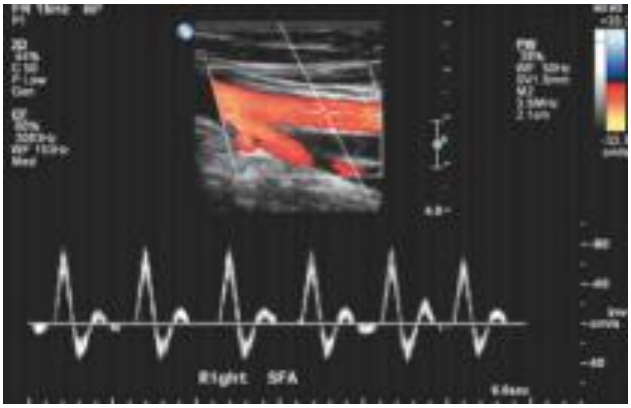


Figure 1A – Normal color flow pattern and doppler spectral waveforms.

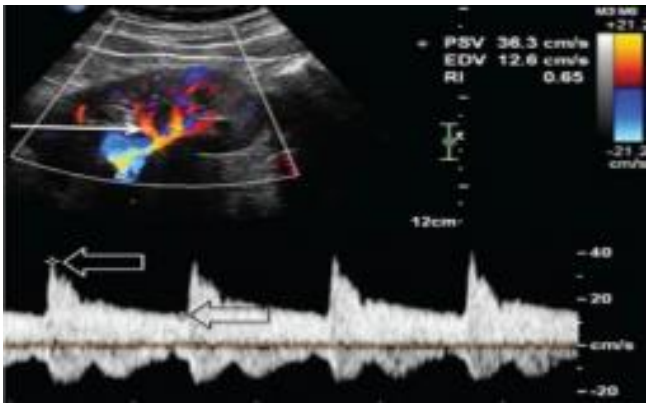


Figure 1B – Reduced blood flow in an artery demonstrated by spectral broadening and loss of triphasic waveforms

For our trials, these vascular dynamics were assessed and recorded as follows:

I. Assessment of distal perfusion
- Capillary refill
- Palpation of distal pulse

II. Assessment of color flow pattern (CFP)

III. Doppler spectral waveform analysis
- *Peak Systolic Velocity (PSV)*
  - Calculated by ultrasound
- *End Diastolic Volume (EDV)*
  - Variable normal values
- *Resistance Index Calculation:*
  - RI= PSV-EDV / PSV

  When PSV and EDV were unmeasurable, RI value was assumed to be 1.

Adult volunteers were eligible to participate in the study and signed consent forms. Exclusion criteria included medical history of any of the following: currently pregnant, venous thromboembolism**,** arterial insufficiency, arterio-venous malformation**,** current use of anticoagulant or antiplatelet agents**,** trauma to the tested extremity in the last 4 months**,** and overlying cellulitis to the tested extremity.[4] Study investigators followed up with the subjects to assess for any adverse reactions as a result of the tourniquet application. As a safety measure, no tourniquet was left on a limb for longer than 4 minutes without a break period of at least 1 minute.[10] Standard infection control procedures were implemented: surgical masks were worn by both the investigator and subject and ultrasound machines were cleaned with 70% alcohol solution before and after each trial.

Following medical screening, qualified subjects were randomized to four groups according to extremity using block randomization. Each subject recorded their age as well as height and weight. Body Mass Index (BMI) was calculated for each subject. Group A underwent the study procedure on the left upper extremity, Group B on the right upper extremity, Group C on the left lower extremity and Group D on the right lower extremity. There was a total of 42 subjects evaluated in this phase. Rationale for this sample size was in accordance with similar studies performed in the field tourniquet evaluation as well as epidemiological calculations.

For each ultrasound exam: The linear probe was used with both B-mode and color Doppler functions. The arteries were assessed in the longitudinal plane with the probe directed perpendicular to the vessel of interest. [9,12]There were two models of ultrasound machines used in the trials: Sonosite and Butterfly.

Each study arm underwent the following three step procedure:

1. Evaluation of the upper and lower extremities by Point of Care Ultrasound (POCUS) before HALO tourniquet application at reference circulation points.
   - <u>For the upper extremity:</u> The brachial artery (BA) was identified with POCUS, 4-8 cm above the antecubital fossa with the arm in slight external rotation.
   - <u>For the lower extremity:</u> The superficial fe moral artery (SFA) was identified with POCUS at the midpoint of the thigh, with the leg in slight external rotation
2. Application of the Halo Tourniquet to the tested extremity by the study investigator
3. After the tourniquet was applied, the reference circulation points from step 1 were reassessed for signs of vessel occlusion.

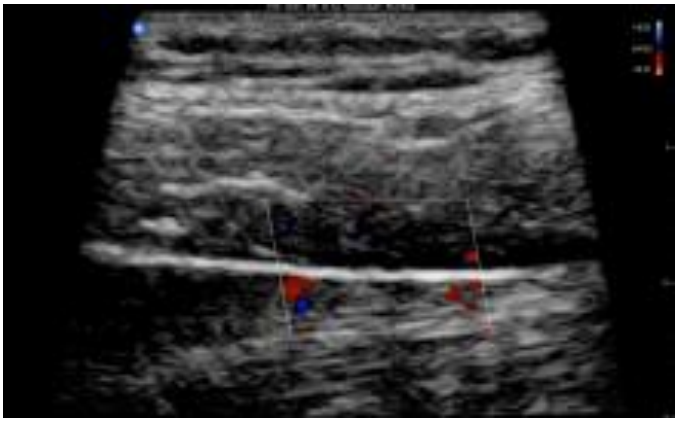


Figure 2: Example of loss of doppler color flow after tourniquet application

The following 3 parameters served as our end-point variables for determining clinical effectiveness. Each were recorded as positive of negative after a given trial.

1. **Decreased distal perfusion**
   • Assessed by delayed capillary refill or loss of palpable distal pulse
2. **Decreased or absent doppler color flow pattern**

3. **At least 1 objective sign of disrupted doppler spectral waveforms:**

- Loss of triphasic waveform
- Increased spectral broadening
- Decreased PSV
- Increased Resistive Index

For a trial to be considered favorable (i.e.- clinically effective), a positive result must have been obtained in all 3 categories.

Since doppler spectral waveforms have not been studied in tourniquet trials, we analyzed additional data from this parameter. Using compiled data from all trials, we determined the overall incidence of spectral broadening and loss of triphasic waveforms after tourniquet application. Additionally, a paired t test was used to assess for differences in PSV and RI before and after tourniquet application.

The Primary study investigator in this phase is a senior emergency medicine resident physician with oversight from an ultrasound fellowship trained emergency medicine faculty member. All HALO tourniquets used in the trials were supplied by HALO LLC.

Results

For this study, 46 subjects were recruited and initially evaluated, but only 42 fully completed the trial. The average age of the subjects was 28 years. The average BMI was 27.05 with a range of 20.7-40.2 kg/m^2.

After tourniquet application, all of the 42 (100%) subjects had objective signs of decreased distal perfusio n (i.e. loss of peripheral pulse and/or increased capillary refill time) and there was a 100% incidence of loss of doppler color flow. (See figure 2).

The average incidence of spectral broadening was 38.2% (upper extremity = 36.4%; lower extremity= 40%). The average incidence rate of loss of triphasic waveforms was 61.2% (upper extremity = 55%; lower extremity = 68.2%). (See figure 3 & 4)

Finally, we found that after tourniquet application, there was a significant decrease in PSV and a significant increase in RI from baseline assessment. (See Table 1; Figure 6 and Table 2; Figure 7)

Based on our model for clinical effectiveness, all 42 trials met these criteria.

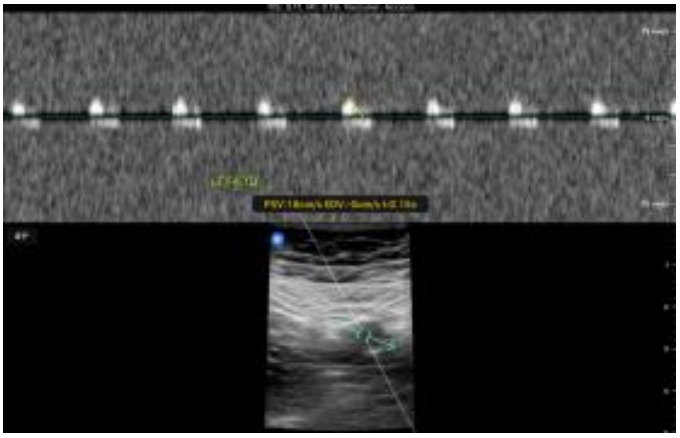


Figure 3: Loss of triphasic waveform in the left femoral artery after tourniquet application

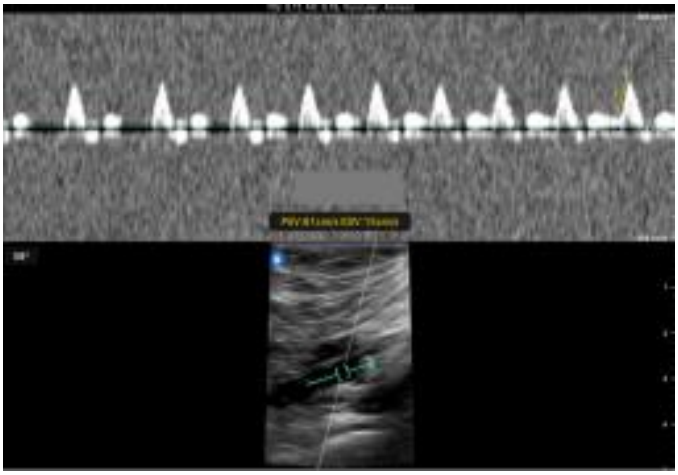
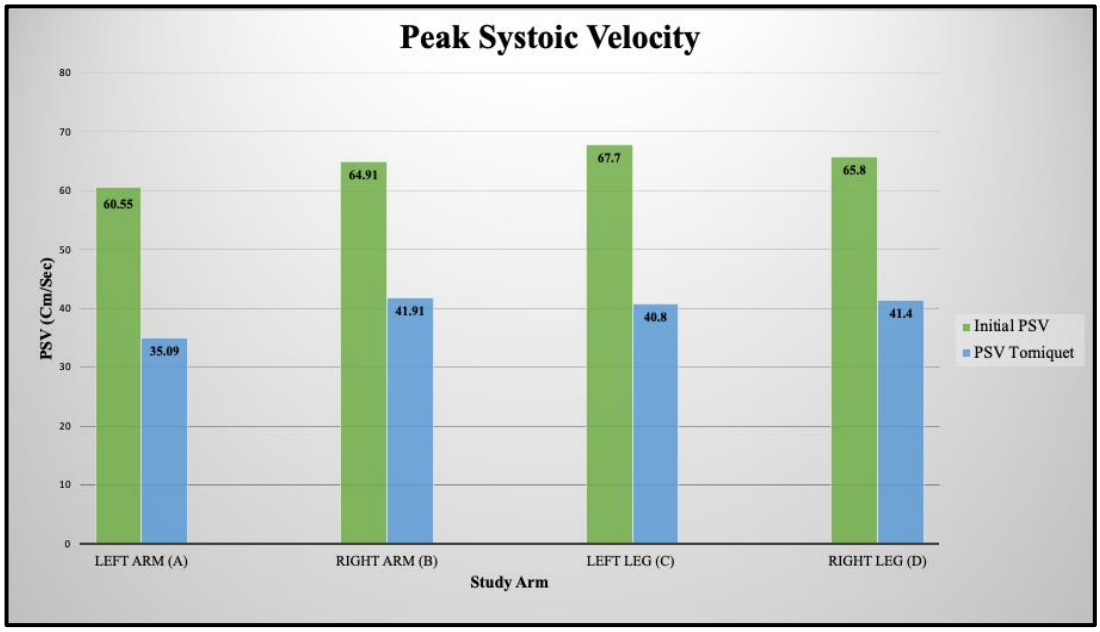


Figure 4: Spectral broadening after tourniquet application

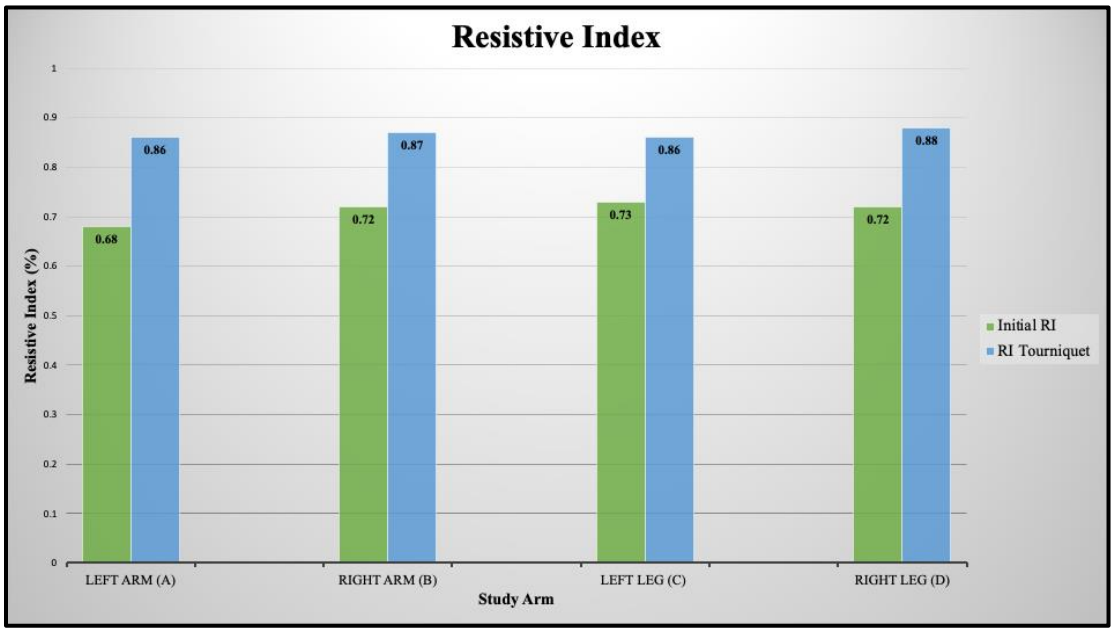
Peak Systolic Velocity								
	Initial PSV	PSV Torniquet	STDEV Initial	STDEV TQ	Mean Difference	Confidence Interval	Sample Size	P-Value: Paired T-test
Left Arm (A)	60.55	35.09	32.86	18.81	-25.45	2.98-47.92	11	0.0302
Right Arm (B)	64.91	41.91	21.19	19.92	-23	7.10-38.90	11	0.0091
Left Leg (C)	67.7	40.8	19.21	27.51	-26.9	12.70-41.10	10	0.002
Right Leg (D)	65.8	41.4	26.24	28.04	-24.4	7.29-41.51	10	0.0104

Table 1 & Figure 6: Initial and final PSV data for upper and lower extremities



Resistive Index								
	Initial RI	RI Tourniquet	STDEV-Initial	STDEV-TQ	Mean Difference	Confidence Interval	Sample Size	P-Value: Paired T-test
Left Arm (A)	0.68	0.86	0.11	0.12	-0.192	(-0.29)- (-0.092)	11	0.001
Right Arm (B)	0.72	0.87	0.11	0.11	-0.146	(-0.24) - (-0.056)	11	0.0047
Left Leg (C)	0.73	0.86	0.076	0.14	-0.129	(-0.24) - (-0.02)	10	0.0263
Right Leg (D)	0.72	0.88	0.08	0.11	-0.157	(-0.26) - (-0.05)	10	0.0072

Table 2 & Figure 7: Initial and final RI data for upper and lower extremities



Discussion

Life threatening extremity hemorrhage remains a significant risk for morbidity and mortality among both the military and civilian populations.[1,2] Massive extremity hemorrhage is recognized as the number one cause of potentially preventable death on the battlefield.[13] Tourniquets have been a time-honored remedy for temporization until definitive surgical intervention.

We evaluated the clinical effectiveness of the HALO tourniquet by establishing a new protocol which incorporates traditional methods of tourniquet evaluation (i.e. – loss of distal pulse) with the combined use of point of care ultrasound. Our method for determining clinical effectiveness stems from established standards of ultrasonographic features of vascular occlusion.[6,7,8]

Although all tourniquets serve to achieve the same goal of major vessel occlusion, they are not created equally. The mechanics of tourniquet designs are centered on their ability to exert enough force to halt blood flow, while also aiming to optimize ease and speed of application. The HALO tourniquet's wider strap is favorable in achieving occlusion at lower occlusion pressures, thus reducing the risk of ischemic injury.[14]

According to the inventors, the design of the HALO was centered on reducing application time and manual dexterity with its first-of-a-kind use of a lever instead of a windlass for tightening and its buckle design, which is intended for quick re-adjustments for differing limb widths The next stage of research for the HALO tourniquet should focus on time and ease device application, both of which are essential while under the duress of pot ential exsanguination from a life-threatening extremity hemorrhage.[13]

Conclusion

Our results indicate that the HALO tourniquet is clinically effective at occluding arterial blood flow. Applying the tourniquet under manufacturer instructions resulted in a 100% incidence of loss of distal pulse and decreased doppler color flow. Likewise, a statistically significant drop in peak systolic velocity and a significant increase in resistance index adds further objective evidence of the HALO tourniquet's clinical effectiveness.

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