ORIGINAL RESEARCH

Precise Limb Tourniquet Arterial Occlusion Pressure Determination using Real-Time Ultrasonography and a Capacitive-Based Force Sensor

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Conflicts of interest/financial disclosure: The authors have indicated they have no financial relationships relevant to this article to disclose. No funding was received for this work. No conflicts of interest declared.

Keywords: force; hemorrhage; pressure; tourniquet; windlass

Abbreviations:
AOP: arterial occlusion pressure
BP: blood pressure
CAT7: Combat Application Tourniquet Generation 7
N: Newton
SBP: systolic blood pressure
TQ: tourniquet
US: ultrasound

Received: August 9, 2022
Revised: September 8, 2022
Accepted: September 16, 2022

doi:10.1017/S1049023X2200142X

Abstract

Background: Hemorrhage control prior to shock onset is increasingly recognized as a time-critical intervention. Although tourniquets (TQs) have been demonstrated to save lives, less is known about the physiologic parameters underlying successful TQ application beyond palpation of distal pulses. The current study directly visualized distal arterial occlusion via ultrasonography and measured associated pressure and contact force.

Methods: Fifteen tactical officers participated as live models for the study. Arterial occlusion was performed using a standard adult blood pressure (BP) cuff and a Combat Application Tourniquet Generation 7 (CAT7) TQ, applied sequentially to the left mid-bicep. Arterial flow cessation was determined by radial artery palpation and brachial artery pulsed wave doppler ultrasound (US) evaluation. Steady state maximal generated force was measured using a thin-film force sensor.

Results: The mean (95% CI) systolic blood pressure (SBP) required to occlude palpable distal pulse was 112.9mmHg (109-117); contact force was 23.8N [Newton] (22.0-25.6). Arterial flow was visible via US in 100% of subjects despite lack of palpable pulse. The mean (95% CI) SBP and contact force to eliminate US flow were 132mmHg (127-137) and 27.7N (25.1-30.3). The mean (95% CI) number of windlass turns to eliminate a palpable pulse was 1.3 (1.0-1.6) while 1.6 (1.2-1.9) turns were required to eliminate US flow.

Conclusions: Loss of distal radial pulse does not indicate lack of arterial flow distal to upper extremity TQ. On average, an additional one-quarter windlass turn was required to eliminate distal flow. Blood pressure and force measurements derived in this study may provide data to guide future TQ designs and inexpensive, physiologically accurate TQ training models.

Wood JN, Krippendorf BS, Blakeney CA, Kummer T, Hooke AW, Mullan AF, Sztajnkrycer MD. Precise limb tourniquet arterial occlusion pressure determination using real-time ultrasonography and a capacitive-based force sensor. ***Prehosp Disaster Med.*** **2022;37(6):772–777.**

Introduction

Uncontrolled hemorrhage is responsible for approximately 35% of civilian prehospital trauma deaths and 40% of trauma deaths within the first 24 hours post-injury.[1] Analysis of combat fatalities suggests that more than 90% of potentially survivable combat deaths are due to exsanguinating hemorrhage.[2] Hemorrhage control before shock onset is increasingly recognized as a time-critical intervention. Tourniquets (TQs) have become the prehospital intervention of choice in both military and civilian trauma settings for treating exsanguinating extremity hemorrhage.[3–8] Delays in TQ applications have been associated with lower blood pressure (BP), greater need for blood transfusion, and a 4.5-fold increase in mortality.[4,9]

Rapid, successful TQ application requires repeated practice, ideally with physiologically appropriate task trainers. Even amongst trained providers, 27% of prehospital TQ applications are inappropriate.[10] Training programs have been developed to train lay care providers to manage bleeding.[7,8] Despite the relatively simple design of modern commercial TQs,

novice providers successfully apply TQs only 16.9% of the time.[11] Even with training, only 54.5% retain this skill at nine months.[12] Three training sessions results in improved skill retention compared with only a single session.[10–14] Experience with civilian mass-casualty terror events has demonstrated the use of improvised TQs, and therefore the need to explore optimal designs for non-commercial TQs.[15,16]

Several knowledge gaps exist in terms of TQ training and design. Physiological parameters for successful TQ design remain opaque. United States Food and Drug Administration (FDA; Silver Spring, Maryland USA) requirements focus more on labeling and adverse event reporting than on design specifics. Early military studies emphasized loss of peripheral pulse, as determined by palpation or doppler flow, rather than providing physiological data. Subsequent studies used expensive manikin devices with unclear physiological validity or used indirect pressure measurement without direct visualization. The lack of an available, inexpensive, physiologically validated training tool both impacts the ability to evaluate improvised TQ designs and to consistently train both lay providers and medical personnel.

The purpose of the current study was to define the physiologic parameters underlying successful TQ application, by directly visualizing cessation of arterial flow distal to the applied occlusion device, either BP cuff or TQ via point-of-care ultrasonography, and determining the associated contact force and arterial BP required to achieve this occlusion. The eventual goal of this study is to provide end-users with transparent data to develop simple, inexpensive models for both assessment of TQ design and to assist with hemorrhage control training.

Methods

Study Population and Design

Fifteen tactical officers participated as live models for the study. An unblinded study was conducted to measure the force necessary to achieve arterial occlusion of the upper extremity.

This study (ID 20-001643) was approved by the Mayo Clinic Institutional Review Board, Rochester, Minnesota USA.

Blood Pressure Cuff Model

Arterial occlusion was induced using a standard adult BP cuff (Welch Allyn; Skaneateles Falls, New York USA) placed at the mid-bicep level with the subject in an upright, seated position. The BP cuff was inflated until cessation of distal radial pulse was achieved. A single emergency physician evaluated pulse loss by palpation. Concomitant brachial artery flow was assessed using a Zonare ZS3 Ultrasound (Mindray Medical USA Corp; Mahwah, New Jersey USA), operated by an ultrasound (US)-trained emergency physician. The BP cuff was further inflated as required until loss of US-confirmed brachial artery flow was observed. Blood pressure (mmHg) was recorded both for loss of radial pulse and for loss of brachial artery flow. Generated force was measured with a capacitative-based force sensor (SingleTract, Pressure Profile Systems, Inc; Glasgow, Scotland UK). A single, pre-calibrated circular sensor (0.35mm in thickness, 15mm in diameter, 450N [Newton] maximum force) was placed between the skin and the BP cuff at a standardized location on the lateral aspect of the arm, centered under the BP cuff at the mid-width. Force was measured at 40Hz while the BP cuff was inflated to the desired endpoint. The steady-state maximal generated force (N) was maintained for 30 seconds. A single steady-state measurement was recorded, both for loss of radial pulse and for brachial artery flow.

Tourniquet Model

Arterial occlusion was induced using a Generation 7 Combat Application Tourniquet (CAT7; CAT Resources; Rock Hill, South Carolina USA) placed at the mid-bicep level with the subject in an upright, seated position. The CAT7 was applied and the windlass tightened until loss of distal radial pulse was achieved. A single emergency physician evaluated pulse loss by palpation. Concomitant brachial artery flow was monitored using a Zonare ZS3 Ultrasound (Mindray Medical USA Corp; Mahwah, New Jersey USA) operated by an US-trained emergency physician. The BP cuff was further inflated as required until loss of US-confirmed brachial artery flow was observed (Figure 1). Number of windlass turns was recorded both to achieve loss of radial pulse and for loss of brachial artery flow. Generated force was measured with a capacitative-based force sensor (SingleTract, Pressure Profile Systems, Inc; Glasgow, Scotland UK). A single, pre-calibrated circular sensor (0.35mm in thickness, 15mm in diameter, 450N maximum force) was placed between the skin and the BP cuff at a standardized location on the lateral aspect of the arm, centered under the CAT7 at the mid-width. Force was measured at 40Hz while the TQ was tightened to the desired endpoint. The steady-state maximal generated force (N) was maintained for 30 seconds. A single steady-state measurement was recorded, both for loss of radial pulse and for brachial artery flow.

Outcome Measures

The primary outcome was to determine the steady-state forces required to achieve radial artery pulse loss as determined by palpation and cessation of brachial artery flow as determined by point-of-care ultrasonography. The secondary outcome was determination of BP cuff pressure (mmHg) and windlass turns associated with loss of radial pulse and brachial artery flow.

Data Collection

De-identified participant data were entered into a Microsoft Excel database (Microsoft Excel for Mac, v 14.57; Microsoft Corporation; Redmond, Washington USA). The output from the pressure system sensor system was collected per second, and an average steady-state generated force was calculated. Pressure (mmHg) required for loss of pulse and cessation of flow were recorded from the BP cuff. Similarly, number of CAT7 windlass turns were recorded.

Statistical Analysis

Data were analyzed utilizing descriptive statistics with 95% confidence intervals (CI). Student's T test was used to compare groups, with significance defined as 0.05. Systolic blood pressure (SBP), contact force, and contact pressure were recorded at the point of pulse loss and US occlusion. The association between SBP with contact force at pulse loss and US occlusion was evaluated using Pearson's correlation coefficient. Software used was R 3.6.2 (2019; R Foundation for Statistical Computing; Vienna, Austria).

Results

Fifteen tactical officers participated in the study. Mean participant age was 39.3 years (30-54 years). Body metrics included mean height 71.5" (range 68"-75"), mean weight 217.8 pounds (range 153 pounds-260 pounds), and biceps circumference mean 34.1" (range 30"-37.5"). Loss of radial artery pulse and cessation of brachial artery flow were achieved in all study participants, using the adult BP cuff and CAT7.

https://doi.org/10.1017/S1049023X2200142X Published online by Cambridge University Press

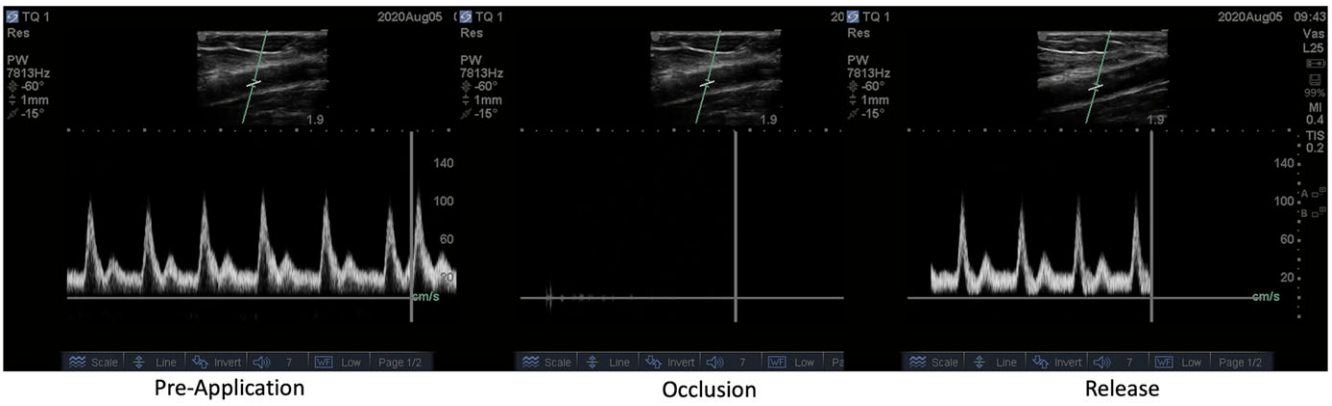

Figure 1. Ultrasound Flow Through the Brachial Artery.
Note: Using a CAT7 tourniquet and a Zonare ZS3 ultrasound, arterial flow waveform was noted to be present prior to windlass revolution, absent during the phase defining occlusion, and present again after release of windlass.

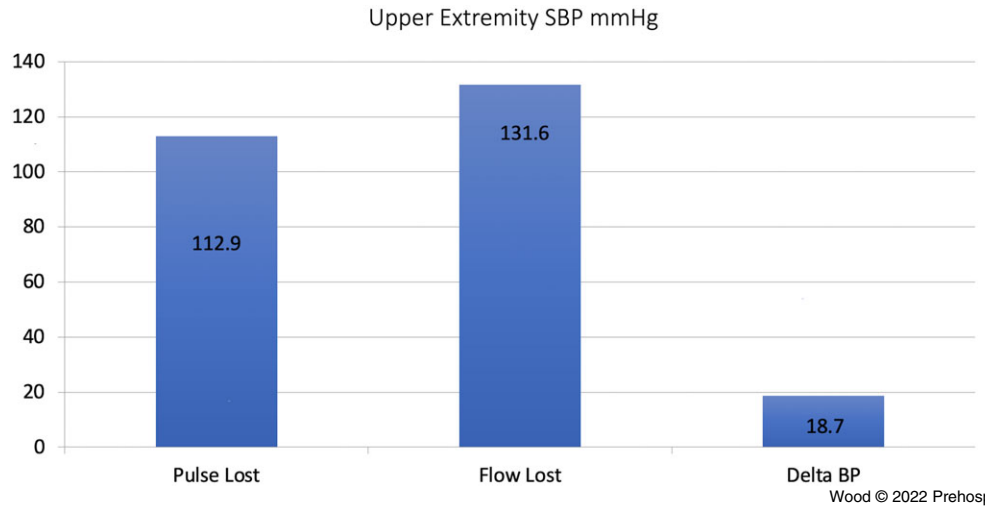

Figure 2. Upper Extremity Blood Pressure Measurements.
Note: Mean upper extremity BP, measured at the mid-bicep level, required for loss of palpable radial pulse and for loss of ultrasound-visualized brachial artery flow. Delta BP is the mean individual difference in the measured BP between loss of palpable pulse and cessation of blood flow visualized via ultrasound.
Abbreviations: BP, blood pressure; SBP, systolic blood pressure.

The mean (95% CI) SBP required to occlude a palpable distal pulse was 112.9mmHg (109-117; Figure 2) while the mean (95% CI) contact force was 23.8N (22.0-25.6; Figure 3). In all study participants, flow remained present in the brachial artery after loss of radial pulse. The mean (95% CI) SBP required to eliminate brachial artery flow as visualized by US was 131.6mmHg (127-137), while the mean (95% CI) contact force was 27.7N (25.2-30.2). The mean individual difference BP between loss of radial artery pulse and cessation of brachial artery flow was 18.7mmHg (15.0-22.3; P <.01), while the mean individual difference contact force was 3.9N (2.49-5.33; P <.01).

The mean (95% CI) contact force required to occlude a palpable distal pulse was 33.8N (31.7-35.9) while the mean (95% CI) contact force required to eliminate brachial artery flow was 41.9N (39.3-44.5). The mean (95% CI) number of windlass turns needed to lose the radial pulse was 1.3 (1.0-1.6; Figure 4). All study participants retained brachial artery flow at the time of radial artery pulse cessation. The mean (95% CI) number of turns to lose brachial artery flow as confirmed by US was 1.6 (1.3-1.9). The mean difference in windlass turns (95% CI) between loss of radial pulse to loss of brachial artery flow was 0.23 turns (0.17-0.29; P <.01).

Contact force (N) generated by both BP cuff and CAT7 TQ are provided in Figure 5. No strong relationship (R value) was noted between arterial BP (mmHg) and measured contact force (N).

Discussion

Increasing data demonstrate the life-saving potential of TQs in life-threatening extremity hemorrhage. To accomplish this, TQs must be rapidly and correctly applied to the correct cohort of patients. Data suggest application problems in novice providers, skill retention in trained providers, and application errors in operational use.[10–14] Unfortunately, inexpensive, physiologically accurate

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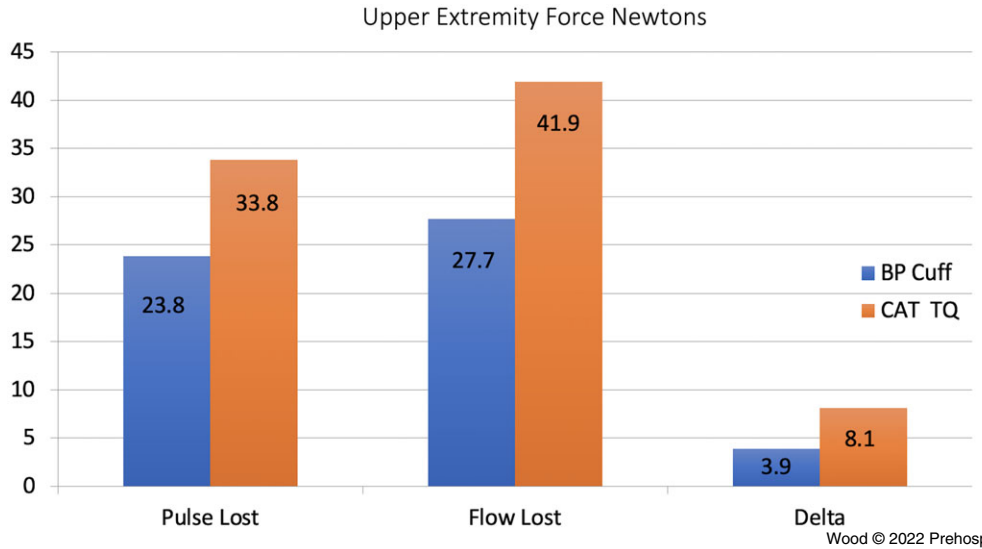

Figure 3. Steady State Contact Force (N) Measurements.
Note: Steady state contact force (N), as determined using a capacitative-based force sensor, for both a standard adult BP cuff and CAT7 TQ, required to eliminate both distal radial pulse by palpation and distal brachial artery flow by ultrasonography. Delta represents the mean individual difference between loss of palpable pulse and cessation of blood flow visualized via ultrasound.
Abbreviations: BP, blood pressure; CAT7, Combat Application Tourniquet Generation 7; TQ, tourniquet.

task trainers are not readily available. Additionally, real-world events have repeatedly demonstrated the use of improvised TQs due to a lack of immediate availability of commercial TQs.[15,16] Limited data exist as to the best designs for improvised TQs, and the best methods to teach improvised TQ use. The purpose of the current study was to define the physiologic parameters underlying successful TQ application to provide end-users the tools to develop models for training and design development.

Although the focus of the study was development of physiological data for future model development, several practical realities with end-user implication became evident. Current TQ guidelines recommend assessing TQ efficacy not simply by cessation of active hemorrhage but also by loss of a palpable distal pulse. The rational for this is avoidance of development of a venous TQ and potential compartment syndrome by permitting arterial blood flow to continue while inhibiting venous return from the limb.

In all subjects, using both the BP cuff (Figure 2) and CAT7 TQ (Figure 3), flow through the brachial artery was observed using point-of-care US after loss of radial pulse (Figure 1). The BP cuff required, on average, 18.7mmHg above that required for distal radial pulse loss to eliminate brachial artery flow (Figure 2). Similarly, on average, an extra one-quarter windlass turn was required to eliminate brachial artery flow (Figure 4). This translated into an additional average force requirement of 3.9N (BP cuff) and 8.1N (CAT7; Figure 3). In terms of guidance for care providers, these results suggest that loss of radial pulse in itself is insufficient to preclude development of a venous TQ situation, and that an additional one-quarter windlass turn is required after loss of distal pulse.

Since the original studies by the US Army Institute of Surgical Research (USAISR; Fort Sam Houston, Texas USA), two different approaches have been used in TQ investigations.[17] The first is an indirect pressure measurement approach, in which the pressure under the TQ strap was measured using two #1 neonatal BP cuffs, each filled to 10-15mmHg above atmospheric pressure to avoid complete bladder collapse under TQ application.[18] The inflated bladders were connected to a gas pressure sensor, and the pressure was continuously displayed. Arterial occlusion pressure (AOP) was defined as the absence of either an audible arterial doppler pulse signal or a palpable pulse rather than direct flow visualization.[9,10] The second approach involved the use of a HapMed Leg Tourniquet Trainer (CHI Systems; Plymouth Meeting, Pennsylvania USA), a simulated right thigh above-the-knee amputation containing a pressure-sensing device. A series of 26 lights identify the degree of bleeding control based on a proprietary algorithm.[19–21]

Several concerns exist regarding these approaches. The first approach utilizes indirect pressure measurement with artificial interposition of a pressure bladder and far-distal measurement of arterial occlusion via either palpation or doppler flow. In addition to expense, the second approach utilizes a system with an opaque algorithm with unclear physiological validity.[20] This trainer is not currently in production. This study provides specific information about the amount of contact force required by a circumferential device to achieve complete loss of distal pulse and flow.

One intent of the study was to identify parameters associated with successful TQ application. As most end-users do not have access to thin-film force sensors to ensure that developed models are physiologically accurate, this study attempted to determine a relationship between contact pressure (N) and BP (mmHg; Figure 5). Although linear relationships existed for both loss of pulse and occlusion of brachial artery, the derived R values demonstrated only weak relationships. This likely reflects the reality that multiple anatomic factors, including limb size, muscle mass, and adiposity, impact the required force and pressure. Tuncali, et al suggested that the AOP could be defined by the formula $AOP = [SBP + 10]/K^{tp}$, where K^{tp} is the tissue padding coefficient, reflecting the reality that arm circumference and width of the occluding device play a role in determining the pressure required to occlude flow.[22]

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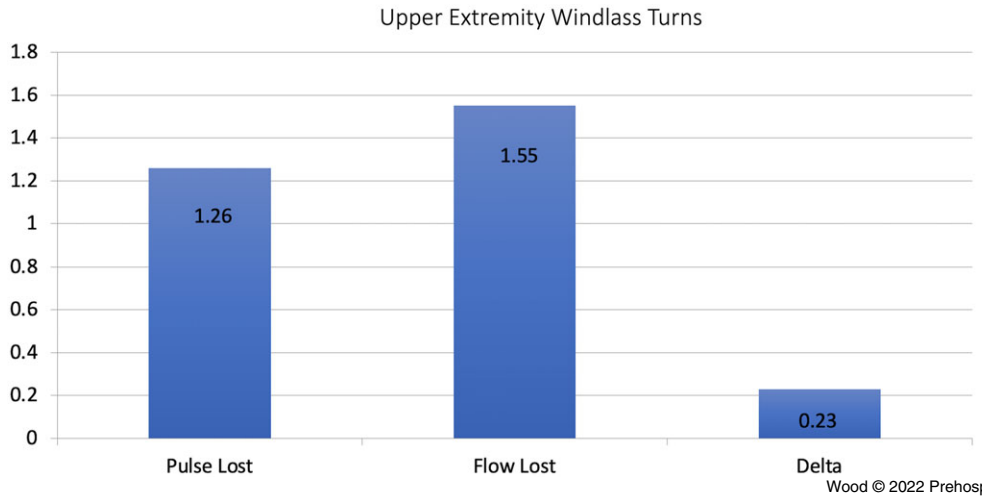

Figure 4. Upper Extremity TQ Application.
Note: Mean upper extremity windlass revolutions, measured using a CAT7 TQ at the mid-bicep level, required for loss of palpable radial pulse and for loss of ultrasound-visualized brachial artery flow. Delta represents the mean individual difference in the measured number of windlass turns between loss of palpable pulse and cessation of blood flow visualized via ultrasound.
Abbreviations: CAT7, Combat Application Tourniquet Generation 7; TQ, tourniquet.

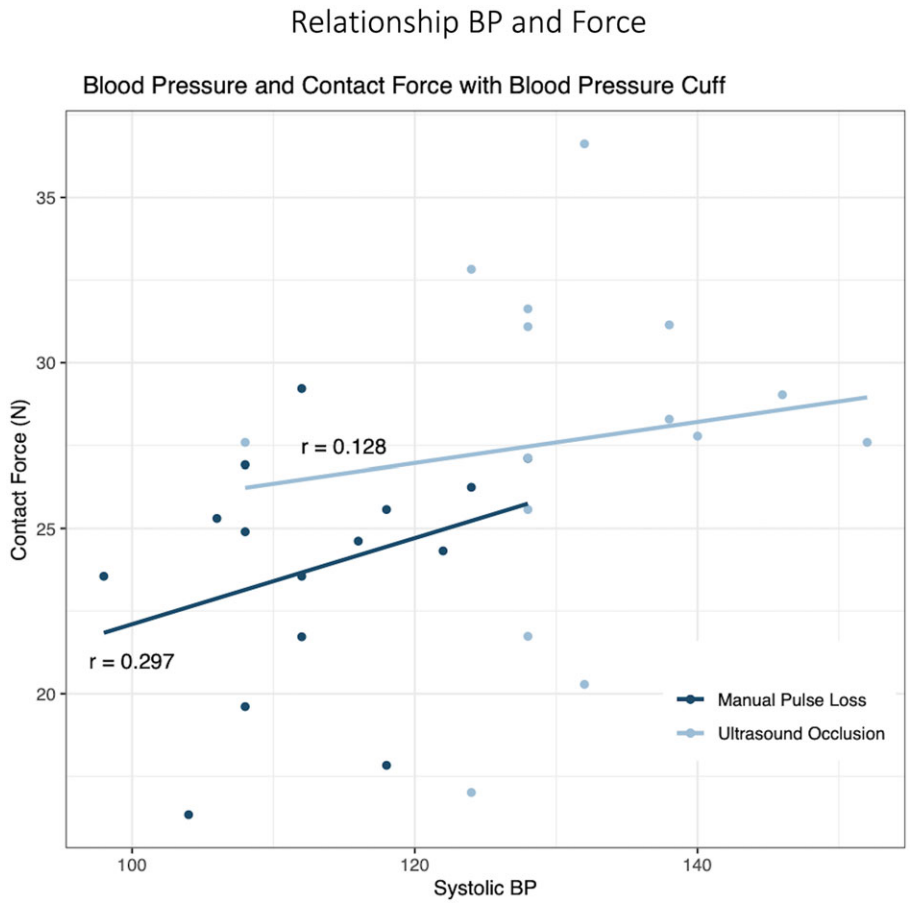

Figure 5. Relationship between Blood Pressure and Contact Force.
Note: The association between contact force (N) and systolic blood pressure (mmHg) determined for both loss of palpable radial pulse and loss of brachial artery flow as determined by ultrasonography.
Abbreviation: BP, blood pressure.

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Despite the lack of a strong force-pressure relationship, the data obtained from this study may still be applied to the development of a physiologically validated training model. One approach would be to design models requiring a force of 44.6N or an arterial BP of 137mmHg, equivalent to the upper 95% CI to occlude simulated blood vessels. This approach would provide an error margin accounting for 97.5% of similar individuals. Alternatively, analogous to the approach used in developing the acetaminophen toxicity treatment nomogram, a 25% "safety margin" above the mean could be used. This would lead to a force requirement equivalent to 52.4N or an arterial BP of 164.5mmHg. Either of these approaches could be used to design an affordable practice model using a collapsible tube with direct feedback achieved through the physiologically relevant cessation of flow.[23]

Limitations

This study has several limitations. Although unblinded, the individuals manipulating the BP cuff and CAT7 TQ and performing the pulse checks were unable to visualize the US screen or the thin film sensor results. The sample size was small and homogenous, consisting of fit males with reasonable muscular development. As such, these values may not apply to women, children, and all ethnic groups. However, the results likely reflect maximum forces above those required for these groups. This study did not solicit background health information and therefore did not specifically screen officers for peripheral vascular disease. Although not specifically evaluated, the US imaging did not demonstrate evidence of significant peripheral vascular disease. As a consequence, the values obtained in this study may not reflect forces required for individuals with peripheral vascular disease. The study only evaluated the upper extremity. It would be anticipated that lower extremity, particularly proximal lower extremity, TQs would require increased force to achieve vessel occlusion, due to increased circumference, muscle mass, and adiposity, and should be accounted for in training models. The CAT7 TQ was applied by a single individual well-versed in proper TQ application. Faulty application might result in greater force needs to achieve similar levels of occlusion. Lastly, although direct ultrasonographic visualization of the brachial artery was performed (Figure 1), there was no blood loss (real or simulated) to provide feedback of correct application. Moreover, blood loss would be anticipated to result in hypovolemia and decreased BP, which might impact the force required to occlude blood vessels. However, if this were the case, the physiological parameters identified in this study would reflect maximum required forces to achieve occlusion, and therefore still have validity in both testing of new TQ designs and training of providers in TQ application.

Conclusion

In a small sample of police officers, loss of distal radial pulse occurred despite on-going brachial artery flow. Providers should be aware of the risk of venous TQ despite loss of the radial pulse, and attempt to rotate the windlass an extra one-quarter turn after distal pulse loss. The BP and force measurements derived in this study may provide the data necessary to develop future economical and physiologically accurate TQ training models. Further study is needed to both develop such models as well as to evaluate lower extremity physiological requirements.

Author Contributions

MDS conceived the study concept. JNW, BSK, CAB, TK, AWH, and MDS collected the data. AWH, AFM, JNW, and MDS analyzed the data. JNW wrote the first draft, and all authors read and approved the final manuscript.

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