Development of Personalized Tourniquet Systems Using a New Technique for Measuring Limb Occlusion Pressure

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Abstract— **A new technique has been developed to facilitate safer personalized tourniquet systems for surgery, using a unique dual-purpose tourniquet cuff that enables automatic measurement of tourniquet Limb Occlusion Pressure (LOP), while overcoming limitations inherent in manual and automatic techniques of LOP measurement. A study was performed to determine the accuracy of this new technique compared to LOP measured using a gold standard Doppler ultrasound technique. 252 pairs of LOP measurements were taken from upper and lower limbs of 143 surgical patients, enrolled from three different surgical clinics, using the new technique and the Doppler technique. LOP difference was defined as new technique reading minus Doppler technique reading. The mean LOP difference (new-Doppler) ± SD mmHg was +0.56 ± 11.73 for all limbs (252 limbs), +0.99 ± 7.79 for upper limbs (134 upper), and +0.08 ± 15.03 for lower limbs (118 lower). Additional analysis was performed to further improve the performance of the new technique by noise detection and by development of rules allowing identification and removal of outlier data prior to completion of each LOP measurement. In this study, the additional analysis removed 3/252 pairs of LOP measurements and reduced the SD: mean LOP difference (new-Doppler) ± SD mmHg was improved to +0.30 ± 10.31 for all limbs (249 limbs), +0.99 ± 7.79 for upper limbs (134 upper), and -0.50 ± 12.62 for lower limbs (115 lower). We conclude that the new technique of LOP measurement has surgically acceptable accuracy comparable to LOP measurement by Doppler ultrasound. Additionally, the new technique may facilitate adoption of safer personalized tourniquet systems by incorporating inherent advancements over manual and automatic techniques of LOP measurement, including: elimination of a distal LOP sensor; reduced procedural complexity and surgical time; related improvements in the rate of success of LOP determination; and reduced direct and indirect costs.**

Keywords— **Tourniquet, Personalized, Safety, Surgery, Advancement.**

I. Introduction

It is well established that the optimal surgical tourniquet pressure setting for each patient is based on the Limb Occlusion Pressure (LOP) [1][2][3]. Evidence shows that higher tourniquet pressures are associated with higher probabilities of injuries [1], and lower tourniquet pressures can lead to breakthrough bleeding and other complications. LOP is defined as the minimum pressure required, at a specific time in a specific type of tourniquet cuff applied to a specific patient's limb at a specific location, to stop the flow of arterial blood into the limb distal to the cuff. The use of personalized tourniquet settings based on LOP has been limited by practical difficulties of manual LOP determination using Doppler ultrasound, and because of limitations inherent in the current technique of automatic LOP measurement. These limitations include: need for a distal bloodflow sensor, adding cost, complexity and affecting preparation of the sterile field; effect on perioperative workflow and time; and success rate of LOP measurement that is dependent on variables affecting measurement of low peripheral bloodflow. A new technique for measuring LOP has been developed in an effort to overcome these limitations, using a tourniquet cuff with continuous pneumatic passageway surrounding the limb as a dual-purpose patient sensor and pneumatic effector, and no distal sensor. The objective of this initial study was to determine the accuracy and reliability of the new technique by comparing the LOP measurements made using the new technique with LOP measurements made using a gold standard Doppler ultrasound technique [4].

II. Materials and Methods

A. Patients

The study enrolled 143 pre-surgical and post-surgical patients aged 17-86 (54 ± 15, mean ±SD) at three different surgical centers in Vancouver BC: Cambie Surgery Centre (80 patients); Complex Joint Clinic, Vancouver General Hospital (52 patients); and the Foot and Ankle Clinic, St. Paul's Hospital (11 patients). Table 1 lists the inclusion and exclusion criteria. Table 2 provides a summary of the patient data.

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Scheduled for a visit to one of three surgical clinics in Vancouver, Canada
Agreed to participate in the study and provide informed consent
Exclusion criteria
Unable to give informed consent on their own behalf
Standard contraindications to tourniquet use
Vascular disease or circulation problems in the extremities
History or indication of deep vein thrombosis

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Table 2 Summary of anthropometric data from 143 pre-surgical or post-surgical adult patients (47 female, 96 male)

	Age [yr]	Mass [kg]	Height [cm]	Upper Limb Circ. [cm]	Lower Limb Circ. [cm]
Mean ±SD	54 ±15	83±17	173±9	32±3	55±5

B. Protocol

Each patient was asked to lie on a clinic bed and an appropriately sized dual-purpose tourniquet cuff with underlying matching limb protection sleeve was applied to non-surgical upper and lower limbs, on an upper arm and a thigh. A standard blood pressure cuff was applied to the other arm.

The patient was instructed to inform the operator if the cuff pressure became uncomfortable and measurements were discontinued if a patient requested the cuff to be deflated prior to completion of the measurement.

The patient's blood pressures were taken at the start and at the end of the measurement sequence. In between, two pairs of LOP measurements were taken, one pair on the upper limb and one pair on the lower limb for a total of 4 LOP measurements. Each pair of LOP measurements consisted of one measurement using the new technique and one measurement using the Doppler technique. The limit for maximum applied tourniquet pressure was 340 mmHg and measurements were taken in randomized order (either upper or lower limb first; and either new technique or Doppler technique first).

C. Measurements

a) Equipment:

Unique dual-purpose disposable tourniquet cuffs were used for all LOP measurements in the study. These tourniquet cuffs are designed to surround and conform closely to a range of underlying limb shapes, and have a stiffened two-layer design incorporating a continuous pneumatic passageway that completely surrounds the underlying limb after application. The cuffs are designed for the dual purpose of serving as a patient sensor for LOP measurement, and as a tourniquet effector to safely stop arterial blood flow during a time period suitably long for the performance of a surgical procedure. The cuffs are constructed generally as described in US Patent 8,425,551.

The manual technique estimated the LOP using a manual pressure regulator and an ultrasonic Doppler flowmeter (Kovan ES100x). The new technique estimated the LOP using a modified tourniquet instrument (Delfi PTSii).

Blood pressures were measured using a standard portable blood pressure monitor and cuff (GE Carescape V100).

b) Tourniquet measurements:

For upper limb measurements using the manual technique, an operator positioned the Doppler probe at the radial artery in the wrist to monitor arterial flow distal to the tourniquet. For lower limb measurements, the operator positioned the Doppler probe at either the dorsalis pedis artery or the posterior tibial artery on the foot to monitor arterial flow distal to the tourniquet. Once the operator positioned the Doppler probe and heard a clear distal pulse, a second operator continuously inflated the tourniquet cuff using the manual pressure regulator up to the pressure at which the distal pulse could no longer be detected by the operator of the ultrasound probe. This pressure was recorded as the estimated LOP. The ultrasound probe operator was blinded to the LOP measurements using the new technique.

For the new technique, the instrument increased the cuff pressure in 10 mmHg stepwise increments, analyzed the pneumatic pressure pulsations induced in the cuff bladder by the arterial pressure pulsations at each cuff pressure increment, and used characteristics of the pulsations as the cuff pressure was incremented to determine the LOP.

In both techniques, the cuff was immediately deflated after LOP was determined.

c) Data collection:

Patient anthropometric measurements, blood pressure readings, and manual Doppler LOP measurement results were recorded on a data collection sheet. Notes were also recorded on this sheet if there were any experiment or patient-related factors noticed during each measurement. For LOP measurements using the new technique, the pressures in the cuff bladder at each pressure increment, including the pneumatic pressure pulsations induced by arterial pressure pulsations were recorded in LabVIEW™. The data were collected at 100Hz and digitally filtered with a 2nd order Butterworth band-pass (0.5 – 7 Hz) filter.

D. Data analysis

Measurements that were discontinued due to patient-specific factors and measurements in which there was a data collection error were excluded from the analysis.

To determine the accuracy of the new technique of LOP measurement compared to the Doppler technique, data were analyzed for differences between each pair of LOP measurements. The mean of the LOP differences for each limb were calculated, as well as the standard deviations, standard errors and 95% confidence intervals of the means.

The distribution of the differences was graphed using a histogram and a Bland-Altman graph [5]. The Bland-Altman graph also shows the mean and standard deviation of the differences. Measurement pairs with LOP differences greater than two standard deviations from the mean were defined as outliers. Additional analysis was completed on the recorded pressure pulsation data in these measurements to identify any specific pulsation characteristics that were unique to outliers.

III. Results

From the 143 patients enrolled in the study, usable data were collected from 252 limbs consisting of 134 upper limbs and 118 lower limbs. Table 3 contains a list of factors leading to data collection errors or exclusions. LOP difference was defined as the new technique reading minus the Doppler technique reading. The means of the LOP differences between the new technique and the Doppler technique are shown in Table 4. Also shown in Table 4 are the standard deviations, standard errors, and the 95% confidence intervals of the means of the LOP differences. The LOP differences for all measurements is shown in Fig.1 and a histogram of the LOP differences is shown in Fig. 2.

Table 3 Data excluded from analysis

Patient-specific factor	**Upper Limb**	**Lower Limb**
Patient left for surgery before data collection started	1	1
Discomfort leading to discontinued measurement	0	9
LOP higher than permitted by protocol	0	10
Existing nerve sensitivity to higher cuff pressures	0	2
Patient movement causing loss of Doppler signal	1	0
Data collection error		
Tourniquet instrument error during measurement	2	0
Data collection software saving error	5	3
Total:	9	25

Table 4 LOP Difference (New-Doppler)

Limb	No. of Limbs	Diff. (mmHg, Mean ± SD)	Std. Error Mean (mmHg)	95% Confidence interval of the difference (mmHg)	
				Lower	Upper
Upper	134	0.99 ±7.79	0.67	-0.34	2.32
Lower	118	0.08 ±15.03	1.38	-2.66	2.82
Combined	252	0.56 ±11.73	0.74	-0.90	2.02

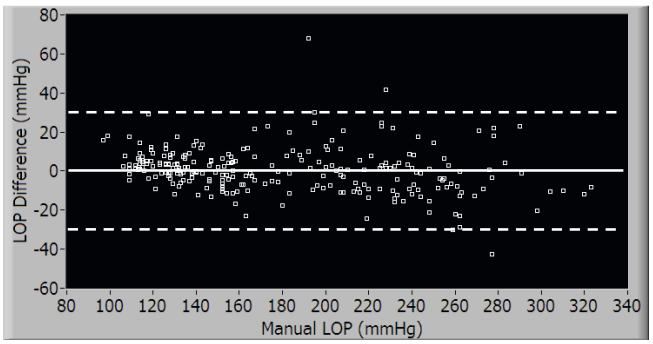

Fig. 1 LOP difference between new technique and manual Doppler technique for all limbs, graphed against the manual Doppler measurement. Mean difference is shown (solid line) plus or minus two standard deviations (dashed lines)

In one LOP measurement using the new technique, significant fluctuations in pressure pulsation data indicative of pneumatic noise were observed, indicating a need in future for better signal filtering and automatic noise detection and reduction.

The means and standard deviations listed in Table 4 were used to compare the accuracy of the new technique with the Doppler technique. The standard deviation of the lower limb LOP difference was highest (15.03 mmHg) and absolute LOP differences greater than two standard deviations of the lower limb mean LOP difference were defined as outliers (>30 mmHg). Three lower limb LOP measurements using the new technique had LOP differences greater than 30 mmHg and were classified as outliers.

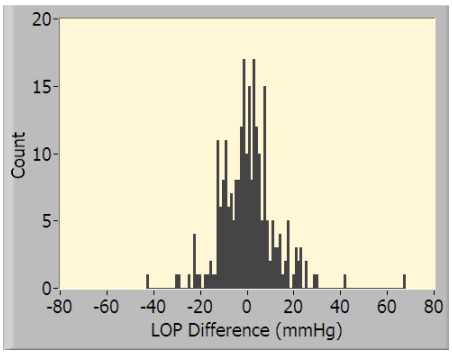

Fig. 2 Histogram of LOP difference between new technique and manual Doppler technique for all limbs

In further analysis of outlier data from three patients, a predictable difference was identified in the sets of pulsation characteristics at corresponding cuff pressure increments when compared to sets of pulsation characteristics at corresponding cuff pressure increments for non-outlier data. This difference could form the basis for adding rules to the new LOP measurement technique allowing automatic identification of outlier subject data prior to completion of LOP measurements.

Table 5 shows the results of the data with the outlier data from the three patients removed by application of these rules: the standard deviation of the lower limb measurement is reduced by 2.41 mmHg.

Table 5 LOP difference (New-Doppler) with outliers removed

Limb	No. of Limbs	Diff. (mmHg, Mean ± SD)	Std. Error Mean (mmHg)	95% Confidence interval of the difference (mmHg)	
				Lower	Upper
Upper	134	0.99 ±7.79	0.67	-0.34	2.32
Lower	115	-0.50 ±12.62	1.18	-2.83	1.83
Combined	249	0.30 ±10.31	0.65	-0.99	1.59

IV. Discussions and conclusions

A) Data variability

In this initial study, some differences in LOP between the new technique and the Doppler technique can be attributed to factors relating to the experimental methodology and possible procedural errors. These factors include patient physiological variation that may occur in the time period between the two measurements, measurement error in the Doppler technique, cuff shifting on the patient's limb during the measurements, or patient movement or muscle activity from discomfort during the measurements.

B) Limitations and next steps

As in all studies of this nature, the size of the study population is necessarily small compared to the overall patient population. Additionally, the clinical settings in which the study was conducted prevented repeated LOP measurements on patients due to time constraints.

A next phase of this study is planned for collection of repeated LOP measurements on non-surgical subjects in a lab setting, for collection of additional LOP measurement data on surgical patients, for testing of additional types and sizes of dual-purpose tourniquet cuffs, and for analysis of better noise detection and outlier identification rules.

A study is also planned to compare LOP measured using the new technique to LOP measured using an existing automatic technique in order to better understand the value of the advancements of the new technique relative to the existing distal-sensor-based technique of automatic LOP measurement.

Additional analysis will be carried out on existing and new data to further improve the new technique for LOP measurement by improved prevention, identification and removal of outlier data due to pneumatic noise, patient movement and other causes.

C) Conclusions

These initial results demonstrate that the new technique of LOP measurement has surgically acceptable accuracy that is comparable to LOP measurement by Doppler ultrasound, and that the new technique is feasible for incorporation into improved personalized tourniquet systems. Further, many limitations of present techniques of LOP measurement are overcome with the new technique, for example: no distal bloodflow sensor is required; the sterile field is unaffected; perioperative workflow and time is less affected as this technique allows measurement of the LOP while the limb is elevated and being prepared for surgery; and the success rate of LOP measurement should be substantially greater because the new technique is not dependent on variables affecting measurement of low bloodflow distal to the cuff such as cold digits or poor peripheral circulation.

The results of this study can be used to develop personalized tourniquet systems consisting of unique dual-purpose cuffs connected to instruments suitable for measuring tourniquet LOP with the new measurement technique. The simplicity, effectiveness, and accuracy of this technique should lead to broader clinical usage and acceptance of LOP measurement, thus leading to safer, personalized pressures in surgical tourniquet applications.

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This research was approved by the University of British Columbia Research Ethics Board (certificate H14–02048) and performed in accordance with the Helsinki Declaration of 1975, as revised in 2000 and 2008. All patients in the study provided informed consent prior to participation.

Conflict of Interest

B.A. Masri, B. Day, and A.S. Younger declare that they have no conflict of interest. J.A. McEwen has a financial interest in companies that develop and commercialize surgical tourniquet systems.

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