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Personalizing Tourniquet Pressures – SBP-Based Estimation Methods are Unsafe, Unreliable, and Inconsistent

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Abstract - **It is well established that unnecessarily high tourniquet pressures are associated with higher probability of patient injuries, and insufficient tourniquet pressures can lead to break-through bleeding and other complications. Measurement of a patient's limb occlusion pressure (LOP) through the use of an automatic personalized tourniquet system enables the simple and safe application of personalized tourniquet pressures, reducing the risk of tourniquet-related injuries. Doppler ultrasound may be used to measure LOP, however manual measurement of LOP by Doppler is time-consuming and error-prone if attempted by inadequately trained staff. Other methods based on systolic blood pressure (SBP) have been proposed in an attempt to indirectly estimate personalized tourniquet pressures. Such methods include: (1) setting tourniquet pressure as a function of the patient's SBP, (2) indirectly estimating LOP by using a formula based on SBP and a 'tissue padding coefficient'. Alternatively, non-personalized fixed tourniquet pressures are used, resulting in pressures that may be hazardously high or low. Data from a previous clinical study involving 143 patients was retrospectively analysed to compare the differences between measured LOP to the recommended pressures of the two SBP-based estimation methods. Results from method (1) using only SBP indicate a predicted bleed-through for 41% of patients, and results from method (2) using SBP and a coefficient indicate an estimated bleed-through rate for 62% of patients. Alternatively, using a non-personalized fixed pressure predicted no bleed-throughs, but resulted in unnecessarily high pressures that were on average 121 mmHg above LOP. This study demonstrates that indirect SBP-based estimation methods recommend unsafe, unreliable, and inconsistent tourniquet pressure settings when compared to the measurement and setting of tourniquet pressures by LOP. The next advances in tourniquet safety will come from widespread adoption of using personalized tourniquet systems to automatically measure LOP, and by personalizing safety margins to further reduce applied tourniquet pressure levels.**

Keywords – **Tourniquet, Personalized, LOP, Pressure, Safety**

I. Introduction

The use of tourniquets in clinical practice has evolved over the past 40 years resulting in more safe and effective technology and protocols that decrease the risk of tourniquet-related injury. Evidence shows that high tourniquet pressures are associated with higher probabilities of injuries, and insufficient tourniquet pressures can lead to break-through bleeding and other complications [1]. Historically, tourniquet pressures have been set at standard fixed pressures of 250-300 mmHg for upper limb surgeries and 300-550 mmHg for lower limb surgeries [2]. However, these fixed pressures do not take into account patient-specific variables such as limb shape and size, limb position, composition of tissue underlying the cuff, and SBP [2], resulting in unnecessarily high or low applied pressures leading to tourniquet-related injuries or break-through bleeding.

The development and implementation of personalized tourniquet systems reduces applied pressures and pressure gradients which influence the risk of nerve and tissue injury. Personalized pressures are centered around the concept of Limb Occlusion Pressure (LOP). Limb Occlusion Pressure 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 of the flow of arterial blood into the limb distal to the cuff [1]. LOP is determined through measurement, which can be achieved with an automatic personalized tourniquet system. Doppler Ultrasound may also be effectively employed by an adequately trained clinician to measure LOP, however manual measurement of LOP by Doppler is time-consuming and can be error-prone if attempted by inadequately trained staff [3]. Once LOP has been measured, tourniquet pressure is set by adding a safety margin to the LOP to account for physiologic changes and other intraoperative variations [4]. The addition of a safety margin ensures an effective bloodless surgical field while maintaining personalization of the applied tourniquet for each patient, reducing the risks of tourniquet-related injuries [4].

Despite the safe, reliable, and consistent results of measuring LOP with an automatic personalized tourniquet system to set personalized tourniquet pressures, the use of

these systems has been limited in practical settings [5]. Other methods have been proposed in an attempt to indirectly estimate personalized tourniquet pressures. One such method is the setting of the tourniquet pressure by the patient's systolic blood pressure (SBP) plus 100 mmHg [6]. A method proposed by Tuncali et al. introduces an SBP-based formula to estimate limb occlusion pressure as a function of a patient's SBP and a 'tissue padding coefficient' [3]. These coefficients were experimentally determined using a single 11cm wide cylindrical cuff, attempting to account for limb circumference and some of the patient-specific and cuff-specific variables that influence a patient's LOP [3].

The objective of this analysis was to evaluate the safety and effectiveness of the above-described methods of setting tourniquet pressures by comparing the suggested tourniquet pressures for each patient with their LOP measurement.

II. Methods

Data from a previous study involving 143 patients performed by the authors in 2014 was retrospectively analysed [5]. The method used to perform the data collection is described in the respective publication [5]. Collected data includes: the lower limb measurements for systolic blood pressure, thigh circumference, and LOP measured with Doppler Ultrasound by adequately trained and experienced researchers.

A. Tourniquet Pressure (TP) Setting Methods

1) *Personalized Tourniquet Pressure* (PTP): TP is set by measurement of the patient's LOP, plus a safety margin. The current guidelines recommended by the Association of periOperative Registered Nurses (AORN) for a safety margin is to add 40 mmHg for LOP less than 130 mmHg, 60 mmHg for LOP between 131 mmHg and 190 mmHg, and 80 mmHg for LOP above 190 mmHg [4,7].

2) *SBP Estimation*: TP is set by measurement of the patient's systolic blood pressure, plus 100 mmHg.
$$TP = SBP + 100 \quad (1)$$

3) *SBP Formula Estimation*: tourniquet pressure is set by measurement of the patient's SBP and their limb circumference, looking up the corresponding tissue padding coefficient (K_{TP}) from a list determined by Tuncali et al. [3], and calculating the pressure setting with the following formula:
$$TP = \frac{SBP+10}{K_{TP}} + 20 \quad (2)$$

4) *Fixed*: Tourniquet pressure is set to 350 mmHg.

B. Data Analysis

To determine the effectiveness of the indirect SBP-based estimation methods, the data was applied to the two formulas and the differences between each method's suggested tourniquet pressure and LOP measurement for each patient was calculated. The differences for the PTP and Fixed pressure methods for each patient were also calculated. The mean of the differences, standard deviation and standard error of the mean were calculated for all four methods. The distribution of the differences for the indirect SBP-based estimation methods were graphed using a histogram. A calculated difference less than zero was interpreted to predict break-through bleeding.

To demonstrate the variability of LOP between similar patient profiles data from 3 patients is presented. For each patient's SBP, limb circumference and LOP measured in the clinical study, the recommended tourniquet pressures from the automatic personalized tourniquet system, the SBP method, the formula-estimation method, and fixed pressures were calculated.

III. Results

From the 143 patients enrolled in the study, usable data was collected and analysed from 118 lower limbs. Reasons for data exclusions are presented in the clinical study publication [5]. Pressure setting difference was defined as the suggested tourniquet pressure calculation minus the measured LOP reading. The means of the pressure setting differences for each of the evaluated methods are shown in Table 1. A histogram of the pressure setting differences for the SBP estimation and SBP-formula estimation methods are shown in Figures 1 and 2 respectively. Table 2 describes three similar patient profiles, and Figure 3 demonstrates the variability in tourniquet pressures recommended by the SBP-based estimation methods.

Table 1 – Pressure Setting Differences (Method – LOP)

Method	Predicted Bleed Through	Diff. (mmHg, Mean ± SD)	Std. Error Mean (mmHg)
PTP	0%	77.78 ± 6.29	0.58
SBP Est.	41%	3.02 ± 27.87	2.58
SBP Formula Est.	62%	-10.44 ± 25.76	2.38
Fixed	0%	120.60 ± 34.94	3.23

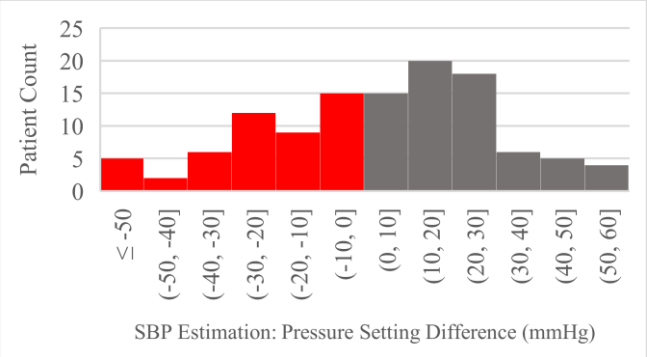

Fig. 1 Pressure setting differences for SBP Estimation method for all patients

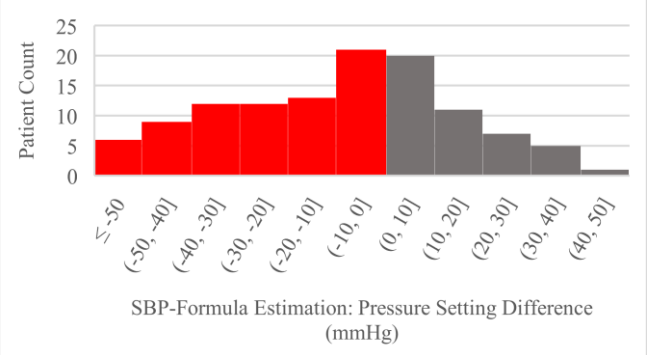

Fig. 2 Pressure setting differences for SBP Formula Estimation method for all patients

Table 2 – Case Study: Patient Profiles

Patient	Age	Height	Weight (lbs)	Thigh Circ. (in)	SBP (mmHg)
#9	43	5’ 10”	227	24.5	134
#14	43	5’ 9”	175	21.5	123
#132	64	6’ 1”	225	21.5	124

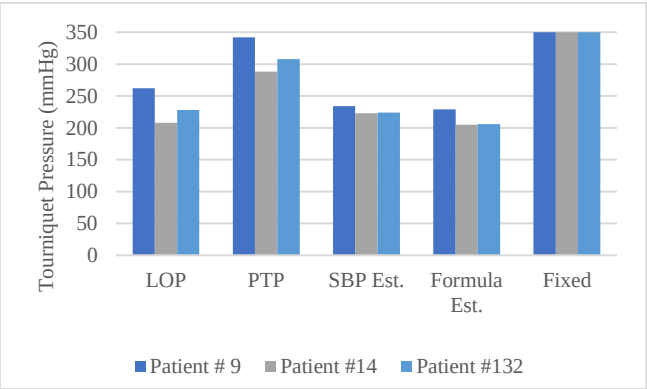

Fig. 3 Suggested tourniquet pressures for unique patient profiles

IV. Discussion

This analysis demonstrates that setting tourniquet pressures based on the measurement of a patient’s LOP is essential for setting safe, effective, and reliable tourniquet pressures during surgical procedures. SBP-based estimation methods do not account for enough patient-specific variables which influence LOP, resulting in unsafe, unreliable and inconsistent tourniquet pressure settings. The historic use of applying a fixed tourniquet pressure is usually effective for maintaining a bloodless field across many different patient profiles, however these fixed pressures are often hazardously high for the patient, increasing risk of tourniquet-related injury [8]. Health care professionals agree that tourniquet use is critical to saving the limbs and lives of both adult and pediatric patients, and urge for tourniquet pressure and time to be limited to the least amount possible to reduce risk of tourniquet-related injury [6,7,9].

This paper analyses the differences between the methods of setting tourniquet pressures and a patient’s measured LOP. The variables influencing safe tourniquet use are unique to each patient and tourniquet system, and thus simple comparisons of the average suggested tourniquet pressures is not strictly useful. The direct patient comparisons shown together in Table 2 and Figure 3 demonstrate the variability of LOP despite similar patient profiles of age, weight, height, limb circumference and SBP. Evaluation of the suggested tourniquet pressure setting for each patient with the four methods compared to the individual patient’s LOP demonstrates the unsafe and inconsistent suggested pressure settings of the SBP-based estimation methods.

As this was a retrospective study analysing previously collected data, there are some limitations when applying the raw data to the estimation formulas. One limitation is the limited scope of the SBP formula estimation method. The method proposed by Tuncali et al. was experimentally determined with a single cylindrical tourniquet cuff of 11cm width [3]. The estimated tissue padding coefficient accounts for some patient-specific and cuff-specific variables in addition to extremity circumference. However, with many types of cuffs on the market varying in shape, bladder width, stiffness and thickness, as well as variability of fit introduced with manual cuff application, the tissue padding coefficient may differ for each available cuff design [3]. The data analysed in this study was collected with a 2-layer cylindrical cuff, as described in US Patent 8425551. It is possible that the currently defined tissue padding coefficients are not applicable and accurate for any other cuff other than the one used to determine the coefficients.

Another limitation of this analysis is when the SBP and LOP measurements were taken. In this study, the data collection occurred in pre or post operative patients. In

clinical practice, these measurements are typically made after administration of anesthesia and before limb preparation and draping. The differences in setting and patient awareness may have an impact on the value of SBP and LOP measured.

The method of anesthetic management is of critical importance when evaluating the effectiveness of tourniquet pressure levels to provide a bloodless field. Significantly lower tourniquet pressure settings can be employed with controlled hypotension and active management of tourniquet pressure levels during interoperative hemodynamic fluctuations [10]. However, it is not always practical to rely on such controls in the surgical environment. Thus, safety margins must be sufficient to maintain an adequate bloodless field and simultaneously be minimized to reduce the applied tourniquet pressures, thereby reducing the risk of tourniquet-related injuries.

Despite the evidence in literature demonstrating that high tourniquet pressures are associated with higher risk for tourniquet-related injury, clinical protocols have been slow to adopt tourniquet settings based on LOP measurements [1,4,5]. It is cited that the use of Doppler Ultrasound to determine LOP can add equipment costs, is time consuming, and can be inaccurate if not performed by an adequately trained individual [1,3]. Recent advancements have seen automatic personalized tourniquet systems developed which automatically and accurately measure LOP [4,5]. The automatic system mitigates the concerns for the need of highly trained individuals, user error, and time-delays disrupting workflows.

Appropriate safety margins added to a measured LOP eliminate the need to actively maintain hypotension or manually adjust tourniquet pressure, while reducing effective tourniquet pressures. The current guidelines adopted by the AORN for LOP-based safety margins provides some personalization to the margins. Future advancements to reduce tourniquet pressures could be directed towards an automatic adaptive tourniquet that measures and adjusts in real-time to a patient's fluctuating LOP.

V. Conclusion

The effort to reduce applied tourniquet pressures to reduce the risk of tourniquet-related injuries must be balanced by the requirement to apply sufficient pressure to occlude blood flow distal to the cuff throughout the surgical procedure. SBP-based estimation methods and fixed standard pressures recommend unsafe, unreliable and inconsistent tourniquet pressures. Tourniquet pressures set by measuring LOP and including a personalized safety margin ensure the application of safer pressures while sufficiently occluding arterial flow throughout the duration of a surgical procedure. The next advances in tourniquet safety will come from the widespread use of automatic personalized tourniquet systems in clinical practice to measure LOP and set tourniquet pressure levels based on LOP, decreasing the incidence and severity of tourniquet-related injuries.

Conflict of interest

J. Kerr declares that she has no conflict of interest. J.A. McEwen has a financial interest in companies that develop and commercialize surgical tourniquet systems.

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