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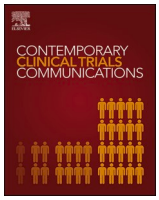

Personalized tourniquet pressure versus uniform tourniquet pressure in orthopedic trauma surgery of extremities: A prospective randomized controlled study protocol

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ABSTRACT

Background: In the field of orthopedic surgery, tourniquets are often used to achieve a clear operative field, expedite operations, and minimize hemorrhagic events. However, determining the optimal tourniquet inflation pressure is a topic of debate. The current approach involves using a constant tourniquet pressure, although this is associated with the potential to augment the risk of tourniquet-associated complications. The Association of Surgical Technologists recommends a tourniquet pressure of systolic blood pressure plus 50 mm Hg for the upper limb and 100 mm Hg for the lower limb. Nevertheless, this method lacks robust support from high-quality medical literature. Therefore, the study aimed to compare the hemostatic efficacy and disparities in tourniquet pressure settings based on systolic blood pressure versus those using the constant-pressure method. The findings might outline the theoretical framework necessary for advocating for tourniquet pressure setups guided by systolic blood pressure.

Methods/design: This randomized controlled study classified the tourniquet pressure regimen into two groups: one based on the patient's systolic blood pressure (the study group) and the other using a constant pressure (the control group). The study included patients aged between 16 and 70 who presented with fresh fractures (less than 3 weeks) of the lower and upper limbs. All the included patients required surgical treatment involving the intraoperative use of a tourniquet and had no contraindications to this surgery. Our primary outcome was to assess the surgeon's satisfaction with the hemostasis achieved in the operative field. We also examined the changes in the circumference of the limb where the tourniquet was applied and tracked any postoperative complications and their incidence. The study ultimately encompassed 144 patients.

Discussion: Despite the prevalent use of tourniquets in surgical operations related to limb fractures, conflicting viewpoints persist concerning the adjustments in pressure and other elements. The study aimed to compare the hemostatic efficacy and disparities in tourniquet pressure settings based on systolic blood pressure versus those using the constant-pressure method.

Study registration: The study was duly recorded in the Chinese Clinical Trial Registry on May 13, 2022 (Registration number: ChiCTR2200059867).

Registration website: https://www.chictr.org.cn/showproj.aspx?proj=162504.

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1. Introduction

Tourniquets are often leveraged to provide a clear operative field, expedite operations, and minimize hemorrhagic events. Simultaneously, improper use of a tourniquet can lead to complications in patients, including nerve damage, skin damage, and thrombosis, among others [1–3]. Tourniquet pressure adjustment is a complex process influenced by numerous factors, and a universally satisfactory setting protocol is still not available. An excessively inflated tourniquet increases the potential for postoperative complications. Conversely, insufficient pressure may not effectively halt bleeding, potentially interfering with surgical operations or even precipitating an increase in bleeding due to the compression of the veins in the limb without complete occlusion of arteries.

The optimum tourniquet pressure is the least possible pressure inhibiting arterial blood circulation to the extremity, referred to as limb occlusion pressure (LOP). The parameters affecting LOP include the patient's systolic blood pressure, circumference and profile of the limb, tourniquet cuff's width and design, thickness of the liner, and patient-specific soft tissue and vascular attributes [4–6]. Tuncali et al. [7] conducted research that led to LOP = (systolic blood pressure + 10 mm Hg)/*K*. In this formula, *K* represents the tissue padding coefficient. This is primarily associated with the shape and circumference of the limb. Despite this, the efficacy of this method is inconclusive and lacks concrete clinical corroboration in tangible clinical scenarios. This is predominantly due to the challenges associated with maintaining a steady systolic blood pressure intraoperatively and variables such as the placement of the cuff and distinct patient vascular conditions, for instance, atherosclerosis. Graham et al. [8] found that an increase in the ratio of tourniquet width to the patient's limb circumference correlated with a decrease in the LOP. Pedowitz et al. [9] found that a curved cuff necessitated a lower LOP compared with straight cuffs.

LOP can be accurately determined by applying a Doppler flowmeter along with pulse oximetry [10]. Considering that patients may exhibit intraoperative blood pressure fluctuations, the Association of periOperative Registered Nurses recommends that 40–50 mm Hg should be added for LOP below 130 mm Hg, 60–75 mm Hg for LOP between 131 and 190 mm Hg, and 80–100 mm Hg for LOP above 190 mm Hg as tourniquet pressure [11,12]. Despite its potential advantages, using LOP to determine tourniquet pressures is extremely low among practicing physicians. This is largely attributable to the complex technical proficiency and substantial time commitment required to accurately determine LOP. Moreover, it becomes impossible to ascertain LOP when patients exhibit inadequate pulse fluctuation signals [13]. Two studies among foot and ankle surgeons found that only 7 % and 9 %, respectively, would opt for LOP when setting tourniquet pressures [14,15]. Further corroborating this was a survey conducted among Irish orthopedic surgeons that reached a similar conclusion [16]. These findings implied that the implementation of this method was poorly operationalized in clinical practice.

In medical practice, the current approach is to use a constant tourniquet pressure. Typically, pressures for the upper extremities are set at 250 mm Hg, whereas the lower extremities are set at 300 mm Hg [5,17]. The primary advantage of employing this method is its straightforwardness in surgery. However, the disadvantage lies in the generally high–tourniquet pressure settings [9,13]. These elevated pressures increase the probability of tourniquet-associated complications in patients. Tejwani et al. [18] conducted a randomized survey among orthopedic surgeons. Their findings indicated that many surgeons still leaned toward using a constant-pressure setting, basing this decision primarily on their own individual experiences. This preference persists despite numerous studies cited in medical literature that warn against the potential negative implications of using excessively high tourniquet pressures [19]. An uncomplicated approach that involves using preoperative systolic blood pressure exists in determining the optimal tourniquet pressure. This method serves as a sound alternative to employing either LOP or constant pressure. The Association of Surgical Technologists recommends a tourniquet pressure of systolic blood pressure plus 50 mm Hg for the upper limb and 100 mm Hg for the lower limb [4]. Although research indicates a lack of linear correlation between LOP and systolic blood pressure, the fact that systolic blood pressure is the most significant determinant impacting LOP remains indisputable [7,20]. This, thus, provides a solid theoretical foundation to propose adding a degree of marginal blood pressure value to the systolic blood pressure to offset the impact of intraoperative blood pressure variability, tissue pressure diminution and the influences of factors beyond systolic blood pressure.

Determining tourniquet pressure based on systolic pressure is straightforward, feasible, and easier to apply universally than implementing LOP. It also results in a lower tourniquet pressure than a constant pressure. Nevertheless, this method lacks robust support from high-quality medical literature. Although these recommendations have been available for many years and used by several international peers, a review of the related literature fails to yield any high-quality studies for citation [17]. To what extent tourniquet pressure, when set according to systolic blood pressure, can effectively reduce overall pressure compared with constant pressure remains uncertain. Furthermore, the level of success these recommendations have in achieving hemostasis has yet to be definitively determined. Hence, this prospective randomized controlled study on tourniquet pressure reduction was conducted to authenticate its significance and feasibility when setting tourniquet pressure based on systolic blood pressure. The aim was to thereby provide a theoretical underpinning for the widespread application of this method.

2. Methods/design

2.1. Study objectives

This study aimed to compare the hemostatic efficacy and disparities in tourniquet pressure settings based on systolic blood pressure versus those using the constant-pressure method in fresh extremity fracture surgeries necessitating tourniquet usage. These findings might outline the theoretical framework necessary for advocating for tourniquet pressure setups guided by systolic blood pressure.

2.2. Study design

This single-center, prospective, randomized controlled study was conducted at Beijing Jishuitan Hospital. Patients admitted for surgical treatment will be detailed and asked if they wish to participate in this study, and applicants will then be screened according to inclusion and exclusion criteria and provided with consent form. Participants were categorized randomly into two distinct groups. The study group had the upper extremity tourniquet pressure set at a level equating to the systolic blood pressure plus 50 mm Hg, and the lower extremity tourniquet pressure was set at the systolic blood pressure plus 100 mm Hg. The upper and lower extremity tourniquet pressures were fixed in the control group at 250 and 300 mm Hg, respectively. We hypothesized that the hemostatic effect in the study group did not fall short of that in the control group. The flow chart of the research design is shown in Fig. 1, and the enrolment, intervention and assessment schedule is shown in Fig. 2.

2.3. Inclusion criteria

(1) Patients between the ages of 16 and 70 years, irrespective of sex
(2) Patients presenting with fresh fractures (less than 3 weeks) of the lower and upper limbs and involving the intraoperative use of a tourniquet
(3) Patients who signed informed consent

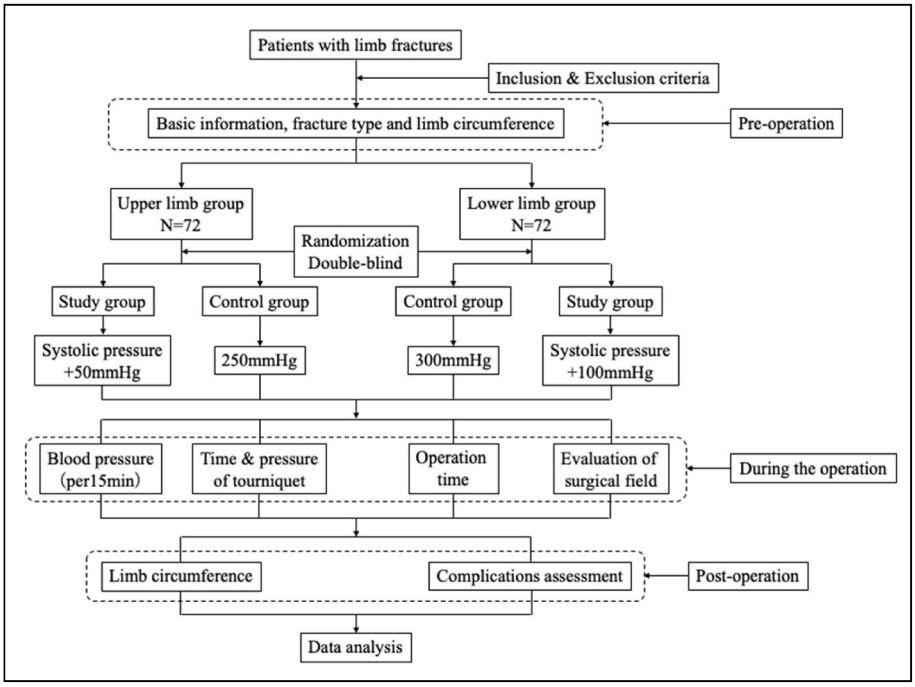

Fig. 1. Flow chart of the study.

	STUDY PERIOD							
	Enrolment		Allocation	Post-allocation				Close-out
TIMEPOINT	Day-1	Day0	Day0	Day0			Day1	Day2
				Pre-operation	During operation	Post-operation		
ENROLMENT								
Eligibility screen	X							
Informed consent		X						
Allocation			X					
INTERVENTIONS								
Study group					← →			
Control group					← →			
ASSESSMENTS								
Basic information				X				
Type of fracture				X				
Type of anesthesia					X			
Type of operation					X			
Duration of operation					X			
Extent of hemorrhage					X			
Tourniquet pressure					X			
Duration of tourniquet					X			
Blood pressure (every 15 min)					X			
Limb circumference				X		X	X	X
Adverse events				X	X	X	X	X

Fig. 2. SPIRIT figure showing the enrolment, intervention, and assessment schedule.

2.4. Exclusion criteria

(1) Patients presenting preoperative peripheral vascular conditions including varicose veins and arterial occlusive vasculitis [21].
(2) Patients with preoperative deep vein thrombosis [22].
(3) Patients with hematologic disorders such as sickle cell anemia [23].
(4) Patients taking oral anticoagulants or antiplatelet drugs preoperatively
(5) Patients with open fractures [24].
(6) Other patients in whom the investigators believed tourniquet use was contraindicated

2.5. Interventions

Before the commencement of surgical anesthesia, we record the essential patient data upon authentication of informed consent. This included the patient's name, case number, age, sex, height, weight, body mass index, type of fracture, and the measurements of the circumference of the affected limb. For patients in the upper limb group, this circumference was measured 15 cm below the acromion along the lateral humerus of the arm. For the lower limb group, the circumference measurement was taken 15 cm above the upper edge of the patella, following the femur's length in the anterior aspect of the leg. The specific location for measurement was precisely identified and demarcated with a marker pen or other means. We measured the circumference of the limb in a vertical position using a flexible tape measure. The measure was used to encircle the limb at the identified measurement position without applying pressure, thus obtaining the limb circumference. Subsequently, the patients were indiscriminately allocated to either a study group or a control group.

We used constant tourniquet pressure in the control group. This encompassed 250 mm Hg for the upper limb group and 300 mm Hg for the lower limb group. In the study group, we set the tourniquet pressure in accordance with systolic blood pressure after the patients entered the operating room, which reflected an additional 50 mm Hg for the upper limb group and an extra 100 mm Hg for the lower limb group. The tourniquet was positioned on the upper third of the arm for the upper limb group, whereas the cuff was situated on the upper third of the thigh for the lower limb group. These measures were based on recommendations from pertinent guidelines [25,26].

The surgery was conducted by a board-certified traumatic orthopedic surgeon. Following the onset of the surgery, the investigator recorded the type of anesthesia, surgical operation, duration of the surgery, extent of hemorrhage, and tourniquet pressure and its duration, along with a regular 15-min interval check of intraoperative blood pressure. A comprehensive hemorrhage evaluation of the surgical field was conducted 15 min after the onset of the surgery. Throughout the intervention, the surgeon regulated tourniquet pressure if excessive bleeding within the site of the operation impeded the surgical operation.

After the surgical operation, the limb circumference at the specified position with the tourniquet was gauged on the first and second postoperative days. We consistently monitored for any complications arising from tourniquet use. To circumvent potential inconsistencies, both the preoperative and postoperative measurements of the patients' limb circumferences were executed by the same investigator.

2.6. Outcomes

The primary efficacy indicator in this study was the dissatisfaction rate, based on the surgeons' evaluation of the operative field. During the surgery, the operative field was rated on a four-level scale: Excellent, Good, Fair, and Poor. The category "Excellent" implied essentially no bleeding in the operative field, whereas "Good" indicated minimal bleeding that did not impact the surgeon's ability to carry out the surgery. "Fair" implied some bleeding within the operative area, but not to the extent that significantly impeded the surgery. Therefore, in the aforementioned cases, no tourniquet readjustments were required. A grade of "Poor" was given if excessive bleeding occurred within the operative field to the extent that it impeded surgical efficacy. Field evaluations were conducted 15 min after operation onset to mitigate the potential impact of residual venous blood at the extreme end of the limb due to incomplete blood expulsion, resulting in bleeding in the operative field that could skew judgment. This was done regardless of the prior evaluation throughout the entire operation if the surgical team perceived excessive bleeding in the field that substantially hindered the surgery and necessitated a tourniquet pressure readjustment. The dissatisfaction rate was calculated as the ratio of patients categorized as "Poor" and "Fair" to the total number of enrolled patients multiplied by 100 %.

Secondary efficacy indicators included the following:

1. Alterations in limb circumference: To determine this, the investigator measured the patient's limb circumference at the identical marking position before the surgery on the operation day, the first day following the surgery, and the second day after the surgery. This provided data to calculate any change in limb circumference.
2. Occurrence of postoperative complications: Follow-ups with patients were conducted on the day of surgery and the two subsequent days. The goal was to detect any complications related to the use of the tourniquet. Issues might encompass tourniquet discomfort, nerve injury presenting as limb movement paralysis or retardation, diminished or absent pain and thermal sensation in the affected innervated area [26], skin injuries such as indentation, petechiae, or blisters, and venous thromboembolism [17].
3. Complication frequency: The number of complicated cases in the study and control groups was documented according to the classification of various complications. The complication incidence rate within the individual groups, as well as the ratio of complicated cases to the total number of cases in the group, was also quantified.

2.7. Randomization

Before beginning the project, a certified professional created a randomized control table. Sealed envelopes were also prepared, and both the study and control groups were randomly allocated in a 1:1 proportion. The sealed randomization envelopes were unsealed by investigator A before the inflation of the tourniquet pre-surgery, with tourniquet pressure being adjusted according to the instructions enclosed within the envelopes.

2.8. Blinding

Both the patient and the surgeon remain uninformed following the adjustment of pressure levels by investigator A. The surgeon then proceeded to assess the field of surgery, a process that was scrutinized and documented by investigator B. After the surgery, investigator B was also assigned to measure and gather the patient's postoperative data. The investigator A can't be involved in both data entry and data analysis. After all data entry, the unblinding will be conducted to determine whether the participants are assigned to the study or the control group.

2.9. Data collection and management

The investigator B will collect data using a paper case report form (CRF). The investigator C will check the quality of data collection and input these data into a secret online table managed by chief investigators. The data entered will be double checked to avoid error. If a participant does not want to continue with the study, the investigator will ask if it is possible to continue to collect the data and make every effort to complete the follow-up.

2.10. Sample size calculation and data analysis

In this study, we aimed to test the non-inferiority hypothesis. The hypothesis comprised two parts: H0: the "dissatisfaction rate" in the study group was lower than that in the control group; and H1: the "dissatisfaction rate" in the study group did not fall short of that in the control group. According to the results of our pilot study, the dissatisfaction rate in the study group was approximately 34 %, whereas the rate in the control group was about 18 %. We deemed the difference in dissatisfaction rates between the groups clinically significant if it exceeded or was equal to 10 %. The one-sided test was used with a Type I error probability of 0.025 and a Type II error probability of 0.2. The sample sizes in the study and control groups were equal, estimated to be 32 pairs using PASS (Power Analysis and Sample Size) 2008 software. Factoring in a potential 10 % loss rate, we could expand the sample size to 36 pairs per group.

Statistical analysis was calculated using SPSS (version 20.0, IBM, IL, USA). The quantitative data were outlined by mean, standard deviation, minimum and maximum values, median, and quartiles. Qualitative data and ordinal data were detailed using the total number of patients and corresponding percentages. The group *t*-test or the Wilcoxon rank-sum test for quantitative data was applied to assess the difference in baseline data between groups. For qualitative data, the chi-square test or exact probability test was used. The Wilcoxon rank-sum test was applied for ordinal data. For missing data, multiple imputation will be used.

We employed the chi-square test to evaluate the discrepancy in the "dissatisfaction rate" across the two groups to explore the primary indicator. The 95 % confidence intervals were calculated for the "dissatisfaction rate" and its difference between the two groups. Similarly, we analyzed the secondary efficacy indicators in line with the primary efficacy and baseline indicators. We leveraged one-sided 0.025 as the test level to ascertain the non-inferiority of the primary indicator. All additional tests were two sided, and any statistical significance was deemed to exist when $P > 0.05$.

2.11. Quality control

The study quality control committee will comprise one professor and three vice professors. The investigators will report the progress of the study to the quality control committee every two weeks for evaluation. Every investigators were well-trained and familiar with the progress and data collection with standard CRF before the start of the study. The chief investigators have access to the data and the study quality control committee will make the final decision to terminate the study.

2.12. Ethics

This study adhered to the principles of the Declaration of Helsinki's 2013 edition as well as the Chinese Good Clinical Practice of 2020. The study design was inherently advantageous for the patients involved. Each participant was comprehensively briefed about the study's objective, process, and potential risks before providing their signed informed consent. Throughout this clinical study, the researchers meticulously documented any adverse events that transpired, preparing for such contingencies in the process. The investigator aimed to provide immediate treatment for any adverse event, irrespective of its connection or otherwise to the study at hand. In the event of a significant adverse event, the investigator had the responsibility to promptly notify the relevant regulatory bodies while simultaneously administering the appropriate treatment. As part of this study, potential risks included, but were not limited to, the following [17]:

1. Suboptimal intraoperative hemostasis: This was determined by the surgeon. If the hemostatic control was significantly compromised to the point that it disrupted the surgical operation, the tourniquet could be adjusted and the pressure could be reevaluated by the surgeon in charge of the application. In an extraordinary scenario of intraoperative massive hemorrhage at the surgical area, the tourniquet pressure was promptly elevated to halt the bleeding. Concurrently, the cause was identified, and hemostasis, rehydration, and intraoperative blood transfusion were conducted if necessary [21].
2. Dermatological trauma: The clinical presentations such as edema, contusions, blisters, indentation, and so forth were more prevalent. In more severe cases, skin burns were a possibility. The primary causative factors of skin damage were generally an inappropriate cuff or liner, high cuff pressure, a prolonged period of application, and accumulation of disinfectants in the cuff, causing chemical burns. Patients with fractures from trauma or other reasons were more prone to a combination of skin injuries, and the use of tourniquets might further escalate these injuries. Mild traumas, such as edema, might be addressed temporarily through managing symptoms by applying cold compresses, elevating the affected extremity, and locally applying anti-edematous medications. Severe skin burns heavily relied on preventive measures, for instance, the standard usage of tourniquets and safeguarding the skin with ointments, dressings, plasters, and padding. If the occurrence of a skin burn was already evident, a consultation with the burn care unit was mandatory to guide the treatment process while working toward infection prevention [21].
3. Deep vein thrombosis (DVT): DVT in the lower extremities is a routine postoperative complication in orthopedic surgeries, irrespective of the application of a tourniquet. Parmet et al. [27] reported an increased risk of macrothrombosis when a tourniquet was employed during knee arthroplasty surgeries. A potential risk of thrombus displacement existed, resulting in pulmonary embolism. Additionally, fat emboli generated during certain surgeries that penetrated the bone marrow cavity entered the circulatory system at the time the tourniquet was released, leading to pulmonary embolism [28]. The likelihood of a pulmonary embolism was contingent upon the duration of the tourniquet application and the level of invasive intervention in the bone marrow cavity [29]. For high-risk patients, applying preventive anticoagulants such as low-molecular-weight heparin could mitigate the risk of thrombosis. Postoperative monitoring of associated signs, supplemented with venous ultrasound or consultation with a vascular surgeon, could benefit diagnosis and necessary treatment [30,31].

The study was approved by the ethics committee of Beijing Jishuitan Hospital on February 22, 2022 and the approval number is No.202111-13-02. Prior to its commencement, the study was duly recorded in the Chinese Clinical Trial Registry on May 13, 2022 (Registration number: ChiCTR2200059867).

2.13. Dissemination policy

The results of study will be published in peer-reviewed journals and communicated to the participants, health care professionals, and other relevant groups. All investigators and other researchers who will participate in this study will become co-authors depended on their contributions.

3. Discussion

This study was conducted solely at Beijing Jishuitan Hospital due to study constraints and budget, making it a single-center study. It might not, therefore, be fully representative of the wider population.

Moreover, this study examines the hemostatic effects of the tourniquet, as indicated by the clarity of the surgical field and the presence of any ongoing bleeding. The primary indicator used for this study, the surgeon's "dissatisfaction rate" with the operative field, was inherently subjective and thus lacked a more objective standard. Though blinding and training of the assessment of the primary efficacy indicator was

implemented, this still generated variability among different operators and, as such, resulted in inconsistencies within the assessment outcomes.

Additionally, in the study group, the tourniquet pressure was set based on the patient's blood pressure taken upon entering the operation room. This blood pressure might fluctuate due to various factors, including the patient's age, any intraoperative bleeding, anesthesia application, psychological impact of the surgery, and patient's mental state during nongeneral anesthesia surgery. These variables could influence the effectiveness of the hemostatic function of the tourniquet. Consequently, anesthesiologists played a critical role in mitigating intraoperative blood pressure fluctuations [10,19,32,33]. This was yet another challenge that must be addressed to ensure the successful implementation of the systolic blood pressure-related tourniquet pressure methodology.

Besides, in order to establish consistent categories to minimize bias and enhance the surgeon's ability to assess bleeding, one of the inclusion criteria is "Patients presenting with fresh fractures (less than 3 weeks)". Fractures that are more than three weeks old can pose challenges for the surgeon in evaluating bleeding, as surrounding bruising and hematomas tend to have diminished over time. For this kind of fractures, further research is still needed.

Last, the secondary efficacy indicators did not specifically address tourniquet pain. In postoperative complications, more severe issues such as nerve injury and venous thrombosis were concentrated on particularly. Tourniquet pain is a prevalent clinical issue; however, its exact mechanisms remain incompletely understood. While there are established treatment methods for this pain, literature [34] indicates a notable correlation between the duration of tourniquet application and the occurrence of tourniquet pain. On the other hand, factors such as tourniquet pressure and the type of surgery performed—whether upper or lower limb—do not appear to significantly influence the incidence or severity of tourniquet pain. Meanwhile, related studies [35] have shown that the efficacy of estrogen-mediated limb ischemic preconditioning in preventing tourniquet ischemic inflammatory complications during orthopedic trauma interventions in postmenopausal women may be limited. Therefore, these variables, including the tourniquet pain and the menopausal or non-menopausal patients, were not included in the statistical analysis.

4. Conclusions

Despite the prevalent use of tourniquets in surgical operations related to limb fractures, conflicting viewpoints persist concerning the adjustments in pressure and other elements. With this randomized controlled study, we aimed to compare the hemostatic efficacy and disparities in tourniquet pressure settings based on systolic blood pressure versus those using the constant-pressure method. The findings might outline the theoretical framework necessary for advocating for tourniquet pressure setups guided by systolic blood pressure.

5. Trial status

The version number of this protocol is as follows: Version 2.0, date: 2022.1.11. The date of subject recruitment is as follows: June 13, 2022, and the last patient's data has been collected on January 22, 2024 and all research processes was completed. We did not plan to write and publish this study protocol at the beginning, but as the study progressed to a later stage, we felt that the overall design of the study was worthy of a systematic article and publication, and therefore the time of the submission of the manuscript is after the end of recruitment.

CRediT authorship contribution statement

Zhi-jian Sun: Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Chenghui Chen:** Writing – review & editing, Writing – original draft. **Zhe-lun Tan:** Methodology, Investigation. **Chang-run Li:** Methodology, Investigation. **Han Fei:** Methodology, Investigation. **Xiang Yu:** Methodology, Investigation. **Dong-chen Yao:** Methodology, Investigation. **Ting Li:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization.

Ethics approval and consent to participate

This study adhered to the principles of the Declaration of Helsinki's 2013 edition as well as the Chinese Good Clinical Practice of 2020. The study design was inherently advantageous for the patients involved. Each participant was comprehensively briefed about the study's objective, process, and potential risks before providing their signed informed consent. Before participation, all participants will be fully informed of the trial and sign the informed consent form. The participants will have the right to withdraw from the study at any time. This study was approved by the Ethics Committee of Beijing Jishuitan Hospital (No. 202111-13) on February 22, 2022. Additional file of model consent form and ethic approval document provides more details.

Consent for publication

Not applicable.

Availability of data and materials

In order to protect the privacy of participants, the data set generated or analyzed during this study will not be made public. However, it can be obtained from the corresponding author upon reasonable request.

Funding

This study was conducted with funding from Discipline Nova Project of Beijing Jishuitan Hospital (No.XKXX202102). Funding agency will not play any role in research design and data collection, analysis and interpretation, and manuscript writing. Additional file of funding documentation provides more details.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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We thank all researchers for their efforts to participate in this trial and to recruit and treat the participants.

Abbreviations

DVT	Deep vein thrombosis
LOP	Limb occlusion pressure
CRF	Case Report Form

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101376.

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