Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

Evaluating time until ligation in a novel tourniquet – A crossover randomized-controlled trial☆

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1. Introduction

*Exsanguination is one of the primary reasons for early death in trauma patients .

*Simple measures of hemostasis, such as direct pressure or the application of a tourniquet, can be lifesaving, it stops the blood flow to the respective limb when applied correctly, improving the chances of survival , this is supported by several societies and initiatives that raise awareness for early hemorrhage control .

*Although emergency medical service (EMS) teams are trained in applying a tourniquet, they usually arrive up to ten minutes after an incident on scene.

*Therefore, laypersons are a crucial link in the chain of survival for injured patients with massive external hemorrhage

*it has been shown in volunteer studies that the application is already possible after a short training period . However, complete ligation couldn't be achieved in every case .

Objectif

To investigate the effect of a novel tourniquet with 90-degree fixation (PAX Tourniquet) on application time compared to two established tourniquets with 180-degree fixation (CAT and SAM Tourniquet), this crossover randomized controlled (RCT) trial was conducted at the Department of Anesthesiology, Heidelberg University Hospital.

2. Materials and methods

2.2. Participants :

Participants were voluntary medical professionals above the age of 18 years without prior experience in the application of a tourniquet

**** Prior experience was defined*** as (i) having placed a tourniquet in real life, (ii) having undergone any trauma-, or emergency medicine course, (iii)being or was an instructor in a trauma-,or emergency medicine course.

All participants received a short, below1-min visual introduction using images on how to apply a tourniquet These were based on the four-step approach: “wrap,” “wind,” “secure,” and “time.” (according to the recommendation by the American College of Surgeons).

No practical demonstration was allowed before the first try

2. Materials and methods

2.3. Randomization and crossover :

Participants were 1:1 randomized to **the intervention group (the newly PAX tourniquet)** or the **control group (SAM or CAT tourniquet).**

In the control group, participants underwent another randomization to either the SAM or CAT tourniquet without a predefined allocation ratio as those were field-proven products and previously recommended by the Committee on Tactical Combat Casualty Care as limb tourniquets .

Each tourniquet was used only once as those are single-use products.

After a wash-out phase of 15 min, participants crossed over to the other group (Fig. 1).

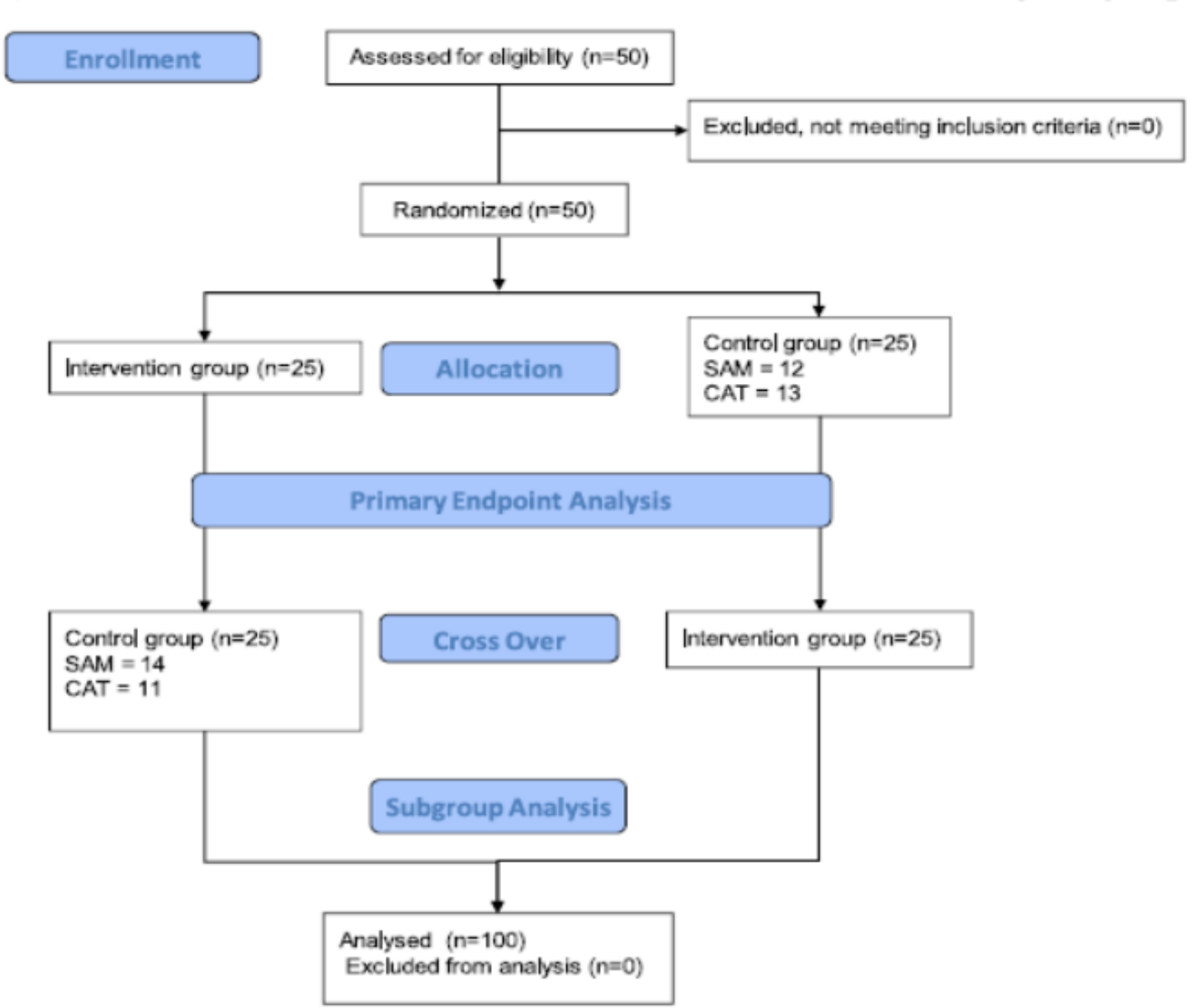

Fig. 1. Study flow diagram according to CONSORT guidelines [14]

2.5. Ultrasound and hyperspectral imaging

In both groups, the imagined scenario was a person with a massive hemorrhage due to an amputation of one arm. The person was cooperative and sitting in a chair.

To assess the application's success , Continuous color Doppler of the brachial artery was used on every try. When the color Doppler signal was extinguished, the participant was informed that the bleeding had stopped

Hyperspectral imaging (HSI), performed with the Tivita®Tissue System(Diaspective Vision, GmbH, AmSalzhaff, Germany),was used to assess skin perfusion as described previously

Three hyperspectral images were captured to assess microcirculation in a participant's hand: before tourniquet application, 30 seconds after tourniquet placement, and 30 seconds after tourniquet removal.

Hyperspectral Imaging (HSI) is a non-invasive technique for evaluating microcirculation. The imaging system used an integrated aiming system with two overlapping light points, and a green dot indicated optimal conditions.

RGB images and remission spectra from 500 to 1000 nm were collected. HSI parameters calculated from 640 × 480-pixel images include:

Tissue oxygenation (StO2) from 500–650 and 700–815 nm (percentage).

Near-infrared perfusion index (NIR) from 655–735 and 825–925 nm (arbitrary units).

Tissue hemoglobin index (THI) from 530–590 and 785–825 nm (arbitrary units).

Tissue water index (TWI) from 880–900 and 955–980 nm (arbitrary units).

Measurements were taken retrospectively from the palm of the ligated hand

2.6 Outcomes:

- ***The primary outcome*** of the study was the time taken to successfully apply a tourniquet, measured from the start of personal instructions to successful application.

- ***Secondary end points included:***

*Differences in hyperspectral measurements between groups at three specific time points.

*The learning effect, assessed through a crossover study design.

*Usability ratings for each tourniquet provided by the participants.

- Subgroup analyses compared individual tourniquets and examined differences based on gender and profession.

- To evaluate potential carry-over effects, time differences between the first and second attempts were analyzed across study groups.

- Participants were surveyed before randomization about their knowledge of tourniquet use and their confidence in applying one. After each session, they rated tourniquet-specific handling characteristics on a 1–5 Likert scale, with 1 indicating ease of handling or high confidence.

3. Results :

- Between July 2021 and November 2021, we recruited 50 volunteers to participate in this study, resulting in 50 first and 50 s attempts after crossover (Fig. 1).
- In total, 100 attempts were conducted, of which two failed. Resulting in a success rate of 98%.
- Both failed attempts were with the SAM tourniquet on the first attempt. Across both groups, a median ligation time of 50 s (IQR 39 to 65) was observed.

The study participants' characteristics are presented in Table 1.

Table 1
Baseline Characteristics. Data is presented as counts (%) or mean (SD)

Parameter	Intervention (n = 25)	Control (n = 25)	*p*-value
Age	26 (3.8)	26 (3.2)	0.664
Sex, female	13 (52%)	9 (36%)	0.401
Physician	6 (24%)	7 (28%)	0.713
EMT	–	1 (4%)	
Nurse	3 (12%)	3 (12%)	
Medical Student	16 (64%)	13 (52%)	
Profession not stated	–	1 (4%)	

EMT = Emergency Medical Technician.

3.1. Primary Endpoint

The time to successful tourniquet application was 49 seconds (IQR 40 to 62) in the intervention group and 56 seconds (IQR 43 to 77) in the control group, resulting in a difference of -7 seconds (95% CI -18 to 3; p = 0.572). After crossover, no significant difference was observed in the second session, with a difference of -0.2 seconds (95% CI -9 to 7; p = 1.000). (Figr2)

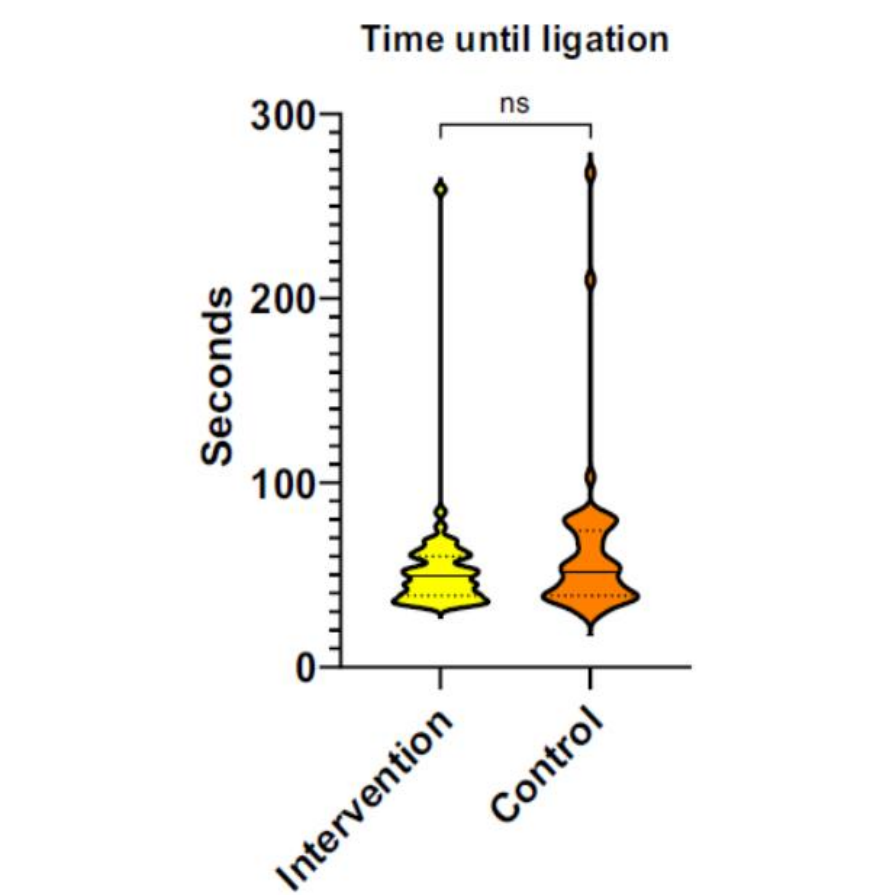

Fig. 2. Violin Plot of the primary outcome between the intervention and control groups. $n = 25$, each group. ns = not significant.

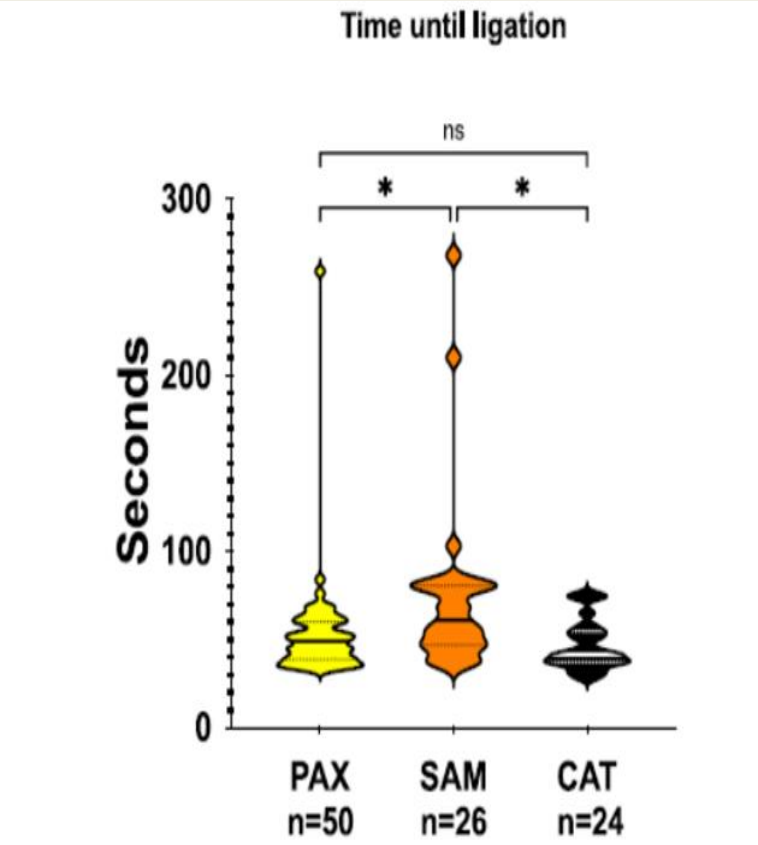

Fig. 3. Comparison between each Tourniquet. * $p < 0.05$; ns = not significant.

3.2. Secondary endpoints

- This analysis evaluates the time required for ligation using different types of tourniquets. Key findings include:

1. **PAX vs. SAM Tourniquet:** The PAX tourniquet performed significantly faster than the SAM, with an average ligation time of 54 seconds (SD 32) compared to 75 seconds (SD 52), showing a mean difference of −22 seconds (95% CI: −42 to −1; p=**0.037**) in favor of PAX. (Fig3)
2. **SAM vs. CAT Tourniquet:** A significant difference was also noted between SAM and CAT tourniquets, with SAM taking longer. The mean ligation time for SAM was 29 seconds slower than CAT (95% CI: 5 to 53; p=**0.015**).
3. **Gender Comparison:** No significant difference was found in ligation times between women (52 seconds, IQR 37–62) and men (49 seconds, IQR 40–64), with a DoM of −3 seconds (95% CI: −3 to 10; *p=0.284*).
4. **Learning Effect:** A significant improvement was observed in participants' second attempts, especially in the control group, with a decrease in ligation time of 9 seconds (95% CI: −21 to 0; p=0.**048**).
5. **Medical Students vs. Physicians:** There was no significant difference between medical students and physicians in terms of ligation time, with a median difference of 5 seconds (95% CI: −2 to 26; p=**0.08**).

- In summary, PAX and CAT tourniquets outperformed SAM in ligation speed, while no substantial differences were observed in terms of gender or experience level, although a learning effect was present.

6. Hyperspectral Imaging Results:

the findings on hyperspectral imaging and participant feedback on tourniquet use are as follows:

*StO2 (Tissue Oxygen Saturation) and NIR (Near-Infrared Imaging) : There was a significant decrease in StO2 and NIR during tourniquet application, with StO2 significantly increasing once the tourniquet was reopened compared to baseline.

*THI (Tissue Hemoglobin Index):THI significantly increased during ligation and remained slightly higher than baseline after the tourniquet was reopened.

*TWI (Tissue Water Index):No significant changes in TWI were observed during or after ligation (refer to Figures 4a–d and 5a–c for data visualization).

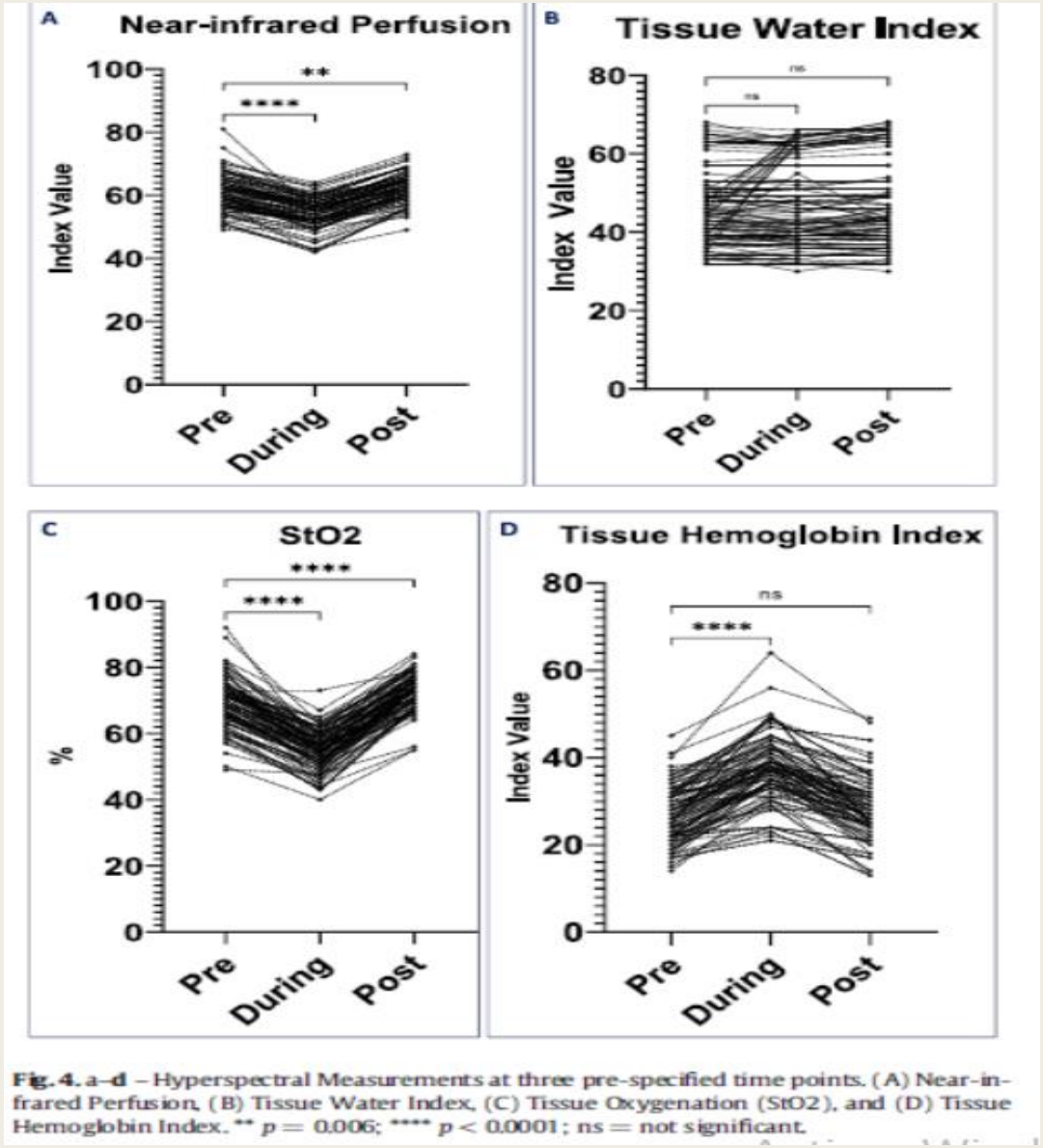

Fig. 4. a–d – Hyperspectral Measurements at three pre-specified time points. (A) Near-infrared Perfusion, (B) Tissue Water Index, (C) Tissue Oxygenation (StO2), and (D) Tissue Hemoglobin Index. ** $p = 0.006$; **** $p < 0.0001$; ns = not significant.

7. Reasons for Tourniquet Use:

88% (44 out of 50) of participants provided responses regarding tourniquet use, with some offering multiple answers.

The most common reasons for applying a tourniquet were: Major hemorrhage: 77.3% (n = 34)

5. Limitations of the Study:

- Lack of Realism: The simulation did not involve severe bleeding, which may limit the generalizability of the findings to real-life situations.
- Medical Background of Participants: All participants had medical training, which might have affected their performance and understanding of the need for tourniquet use. However, these individuals are likely to act as bystanders during mass casualty events.
- Observer Influence: The presence of the study team may have influenced participants' performance, potentially creating a more stressful but realistic environment.
- Ultrasound Operator Bias: The ultrasound operator was not blinded to the randomization group, which could introduce bias. However, as the same operator was used for all participants, the bias should be consistent across groups.

6. Future Research:

Further studies are needed to evaluate the clinical effectiveness of these tourniquets in real-life scenarios, especially with non-medically trained laypersons as users.

Conclusion

- In conclusion, the study demonstrates that the PAX and CAT tourniquets are easier to use, especially without prior training, while the SAM tourniquet may require additional hands-on practice. Despite some limitations, the study highlights the importance of easily applicable tourniquets and further research in real-world applications.
- This study showed that a novel tourniquet does not prolong the time until successful ligation when applied by medical personnel.
- Participants applied the tourniquet faster in the second try, showing an immediate

learning curve.