Time performance of scoop stretcher versus vacuum mattress for prehospital spinal stabilization: open-label simulation-based randomized controlled trial

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Abstract

Recent research has yielded conflicting results on the use of spinal stabilization in prehospital care, with some guidelines expressing concerns about its potential lack of benefit or harm. Transportation on a backboard can cause pain, discomfort, and pressure ulcers, whereas the log-roll technique can cause unnecessary movement and aggravate existing injuries. The scoop stretcher and vacuum mattress provide comparable or better immobilization and comfort than the backboard. Prehospital time is critical, and patients with life-threatening conditions should undergo rapid stabilization procedures. Despite this, some studies have overlooked the scoop stretcher as a spinal stabilization device. The primary goal was to compare the time required to achieve spinal stabilization using a scoop stretcher versus a vacuum mattress. This was a monocentric, parallel, randomized (sealed envelope), superiority, open-label, controlled simulation experiment. All student paramedics, registered paramedics, and EMTs who work in the participating EMS were eligible to participate in the study apart of the study team. The experimental group had to use a scoop stretcher, whereas the control group used a vacuum mattress. Fifteen participants were included. The scoop stretcher group required less time to complete the stabilization procedure (median [Q1; Q3]: 127 seconds [111;145] versus 212 [156;237], p=0.005). Using a scoop stretcher for spinal stabilization is more time-efficient than a vacuum mattress, making it a viable option for unstable trauma patients in the prehospital setting. More research is needed to determine its efficacy in actual clinical practice.

Introduction

Spinal stabilization for suspected injuries has become standard care in the prehospital setting. However, recent studies have presented divided opinions regarding the support and rejection of prehospital stabilization.[1,2] Guidelines now attribute less importance to stabilization procedures in trauma patients and even express concerns about their potential lack of benefit[3] or the harm they may cause.[4,5] Transportation on a backboard can lead to pain, discomfort, and pressure ulcers.[5-11] Additionally, due to differences in diameters between the head, shoulders, and pelvis, spinal movement is inherent in this technique. The log-roll technique generates more movement than readily available alternative techniques, such as scoop stretcher (SS) techniques, during both device placement and removal.[12-18] This maneuver can be harmful as it may cause unnecessary movement, fracture dislocation, pain, anxiety, clot disruption, and worsen hemorrhagic conditions, particularly in cases of pelvic fractures, long bone injuries, or internal injuries.[19-21]

The use of a rigid collar remains highly controversial[22,23] and may result in pain, reduced mouth opening due to mandible com-

pression, respiratory discomfort, difficulties in airway management, increased intracranial pressure due to pain or compression of the jugular veins, worsening of injuries, patient agitation, and non-compliance.[22-35] Furthermore, its effectiveness is questioned,[36] as well as how it is fitted.[37] Under certain circumstances, its use must be completely avoided, while in other cases it can be used intermittently (*e.g.*, during mobilization).

Immobilization and comfort levels achieved with the SS are comparable to or better than those achieved with the backboard.[12,17,38] The vacuum mattress (VM) offers a similar or even higher degree of immobilization compared to the backboard.[39-44] While the backboard is considered the standard in Anglo-American countries, the VM is widely used in Europe, particularly in Germany.[45] In Switzerland, three devices are standard equipment in type B/C ambulances: the VM, the backboard, and the SS. The choice of device depends on the patient's condition: in critical time conditions (life-threatening situations), the SS is used to achieve rapid and adequate spinal stabilization while minimizing on-site time and reducing harmful movements (minimal handling strategy). Otherwise, the VM is the preferred device as it allows for comfortable and personalized immobilization based on the patient's anatomy. The use of the backboard device has been banned in the participating EMS due to the mandatory log-roll movements required for placing the patient on it, as well as the discomfort it causes. The only exception is when it is used as an extraction device, where spinal stabilization can still be achieved with it. Prehospital time is associated with increased mortality and worse outcomes in various critically injured patients,[46-52] and the method used for spinal stabilization can significantly impact it. Different guidelines recommend minimal spinal stabilization in patients with critical ABCD-problems, respectively, a life-threatening time-critical condition.[4,5] Therefore, a rapid stabilization procedure is necessary in prehospital practice.

Recently, the study from Roessler *et al.*[45] has drawn attention, particularly the absence of consideration for the SS as a spinal stabilization device, despite it being a good compromise between the VM and the backboard.

Objectives

The primary objective was to assess the time needed to achieve spinal stabilization using an SS compared to a VM. The secondary objective was to assess the subjective feelings of the simulated patients (*e.g.*, anxiety, comfort, and dyspnoea/shortness of breath) of the two different methods.

Materials and Methods

Study design and setting

This was a monocentric, parallel, randomized, superiority, controlled simulation study designed following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[53] and conducted regarding Good Clinical Practice.[54] The study design is displayed in Figure 1. The results are reported following the Consolidated Standards of Reporting Trials (CONSORT) and its extension for abstracts (Figure 1).[55,56]

The prehospital health system where the study took place was previously described.[57,58] Participants were recruited from one of Geneva's emergency medical services (EMS), *Genève TEAM Ambulances*.

Inclusion and exclusion criteria, recruitment

All student paramedics, registered paramedics, and EMTs who

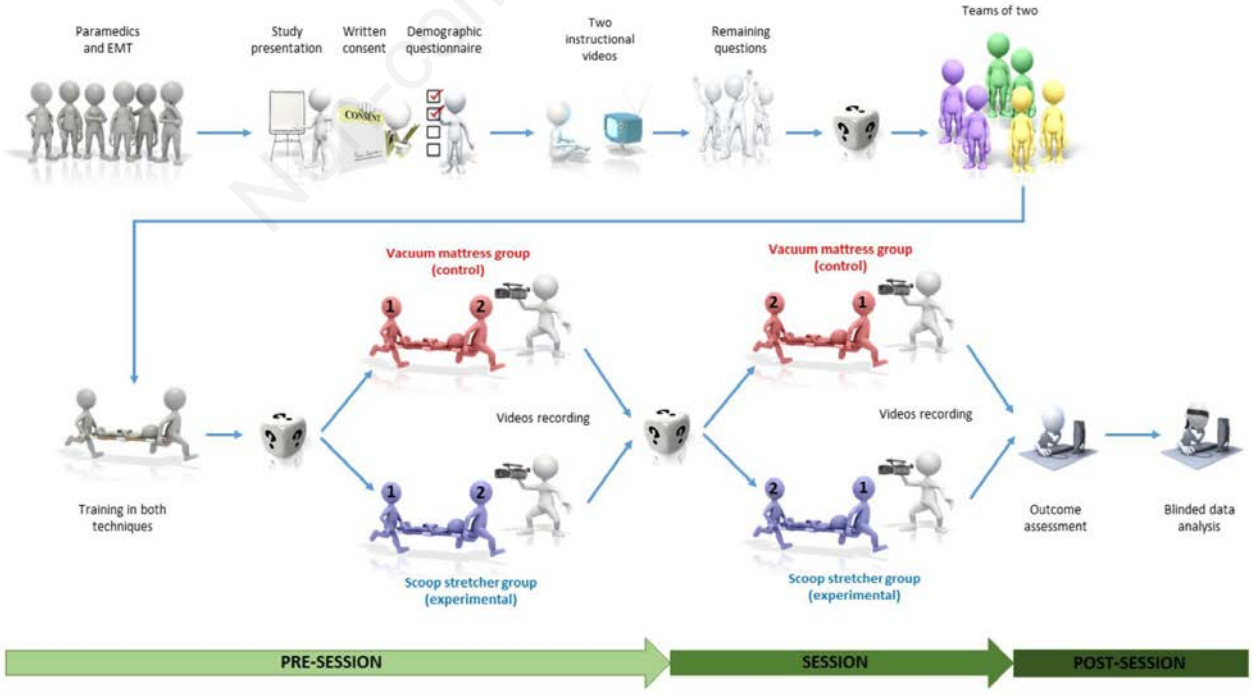

Figure 1. Study design.

actively work in the participating EMS were eligible for inclusion in the study. Being one of the study investigators was the only exclusion criterion. Participants were recruited by email. Participation was entirely voluntary. No incentives were provided. The study took place during two monthly continuing education sessions in the second half of 2021 and was stopped after the sample size was achieved.

Equipment

The SS used was the Ferno Scoop Stretcher, Model 65-EXL (Ferno-Washington, Inc., Wilmington, OH, United States), along with corresponding restraint straps. Head stabilization was achieved by using a single-use taped blanket (Figure 2) and then fixed around the head with duct tape (Figure 3). The rationale behind this choice, which is certainly one of the oldest methods, is multiple: i) it is applied more quickly and easily than commercial systems, ii) it entirely respects the head stabilization principle, *i.e.*, firmly connected at the bottom and shaped to fit the SS, the duct tape allowing the closing of the top, iii) hygienic since single-patient used (blanket replaced at the hospital, cleaned and returned to service), and iv) it is cost-effective. The VM used was the RedVac Vacuum Mattress, Model VM6000X01 (Kohlbrat & Bunz Gmbh, Radstadt, Austria). Vacuum pressure was generated using an ACCUVAC Pro suction pump (Weinmann Emergency Technology Gmbh & Co., KG, Hamburg, Germany). The same SS used for stabilization was employed to position the participant on the VM. These are the current procedures of the participating EMS. The procedures were video recorded with a HERO4 GoPro (GoPro Inc., San Mateo, California, USA).

Baseline configuration

The baseline configuration (Figure 4) was defined to be similar to a previous study (Roessler M., personal communication, April 2021). The same "ideal conditions" were applied, which involved conducting the study in a training room with the simulated patient placed on a completely level ground (hard floor) and the backboard ready with straps attached. For stabilization using the VM, the setup involved placing the VM near the participant with the SS on top, without straps. The VM was "inflated," meaning there was no need to allow air intake before the participants used it. The SS was adjusted to its "normal" length.

Stabilization procedures

Four individuals were required to complete the entire exercise. A team consisting of two paramedics and a "bystander" conducted the stabilization process, while the fourth individual took the patient's position. The team leader (TL) positioned him/herself alongside the patient to carry out the spinal stabilization procedure, while the other team member (TM) provided manual in-line head stabilization. The "bystander" was solely involved in assisting with the placement of the SS.

The experimental group had to follow this procedure: First, the TM positioned the head immobilizer before placing the SS under the patient. During this process, the TL held the head from the front until the TM took over and provided manual in-line head stabilization. Afterward, the TL rotated the patient approximately 15 degrees to facilitate the placement of the first half of the SS by a layperson. This maneuver was then repeated on the other side of the patient. The straps were then connected in an X shape on the chest and in two straight lines on the pelvis and femur (Figure 5). Finally, the head was secured using duct tape (only one on the forehead, none on the mandible) (Figure 3).

The control group was instructed to follow the same procedure as the experimental group, with a few exceptions. Firstly, the control group did not need to place a head immobilizer beforehand. Additionally, they did not use straps in conjunction with the SS. Instead, after placing the SS, the patient was positioned onto the closely positioned VM. The VM was then shaped and the straps were fastened following an X shape on the chest and in two straight lines on the pelvis and femurs (similar to what was done with the SS in Figure 5). Finally, the head was secured using an appropriate strip (only one on the forehead, none on the mandible).

Figure 2. Head immobilizer.

Figure 3. Head's fixation with duct tape folded on itself. The subject of the photos gave approval for the publication of these images.

Figure 4. Vacuum mattress (left) and scoop stretcher (right) baseline configuration.

Study path and randomization

After being enrolled, the participants were provided with two instructional videos demonstrating stabilization techniques. They had the opportunity to ask questions, which were answered in a group setting. The participants were then randomly assigned into teams of two and given capital letter names using an online team generator.[59] Next, the stabilization techniques were demonstrated and practiced once. Any remaining questions from the participants were addressed. Following this, the teams entered a study room in alphabetical order based on the assigned capital letters. The TL was assigned to one of the study groups by opening a sequentially numbered, sealed envelope containing the designated stabilization technique. These envelopes were prepared based on a computer-generated list,[60] ensuring a 1:1 allocation ratio and block sizes of 2 and 4. It is important to note that the person responsible for creating the envelopes, DT, was not present during the study session. The equipment and materials were then reset to the initial configuration, and the team members changed their roles. Given that there was no anticipated risk to the participants, the small sample size, and the absence of potential adverse events due to the nature of the intervention and study design, no data safety monitoring board or interim analysis was necessary.

Outcomes, data collection, and data extraction

The primary outcome was defined as the time needed to complete the stabilization procedure. The timer was started as soon as the TL gave the command to start the stabilization maneuver and was halted once the person was fully stabilized and ready to be lifted off the ground. This time was subsequently assessed on the videos with the built-in stopwatch which provided precise measurements down to the second. Secondary outcomes were stabilization quality, levels of anxiety, comfort, and degree of induced dyspnoea or shortness of breath. The stabilization quality was assessed using a dichotomous variable (sufficient versus insufficient) and was checked according to the standard operating procedures (see Supplementary Materials). The levels of anxiety, comfort, and the degree of dyspnoea or shortness of breath were assessed using visual analog scales from 0 = "No anxiety at all" to 10 = "The worst anxiety imaginable", respectively from 0 = "Very, very comfortable" to 10 = "Very, very uncomfortable", and from 0 = "No dyspnoea or shortness of breath" to 10 = "The worst imaginable dyspnoea". These variables, along with height and weight measurements, were collected through a post-scenario questionnaire. Demographic data (age, gender, years of professional experience, professional title, baseline self-assessed ability to perform spinal stabilization) were gathered using a questionnaire To minimize copying or typing errors, all collected data were entered in duplicate using EpiData.[61] The consistency of the answers was then checked by merging the two files into a common variable where discrepancies were listed. After the discrepancies were resolved, the data were exported to a Stata DTA file.

Sample size calculation

The sample size calculation was based on existing data.[45] No useful data was identified in the literature, so, after conducting some pilot tests, it was assumed that the time required for stabilization on the SS would be equivalent to that on the backboard, under similar conditions. Standard deviations were calculated from confidence intervals using the formula: SD = √n x (upper limit – lower

Figure 5. Straps closures (X-I-I pattern) on the thorax, pelvis and femurs. The subject of the photo gave approval for the publication of this image.

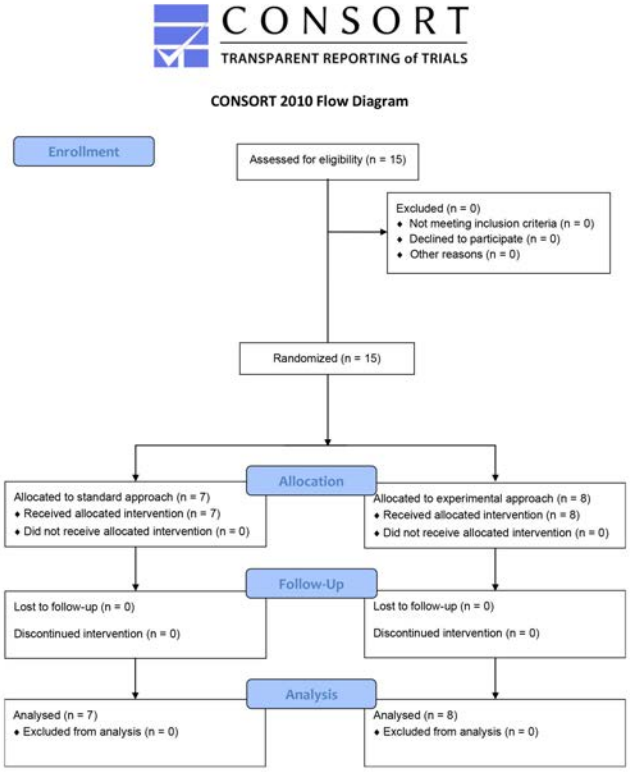

Figure 6. Study flowchart

limit) / divisor. The divisor was obtained from tables of the t-distribution with n-1 degrees of freedom since the confidence intervals were supposed to be calculated using a value from the t-distribution. The calculated standard deviation (reference mean) for time in seconds was 29 (83.4) for the backboard and 83.1 (254.4) for the VM. Based on these calculations, it was determined that 10 simulations would be necessary to have a 90% probability of detecting a statistically significant decrease in the primary outcome measure from 254.4 (83.1) in the control group to 83.4 (29.0) in the experimental group, at a significance level of 5%. Considering the absence of risk to participants, it was possible to accept a larger number of participants if desired.

Statistical analysis

The variables were described using the median [Q1; Q3] regardless of the distribution, due to the small sample size. Numeric data gathered through the visual analog scales were treated as continuous. Statistical analyses were all prespecified. Only a non-parametric test was applied *i.e.*, the Mann-Whitney U test was used to compare both groups. The Fisher's exact test was used to compare proportions. No subgroup analyses were performed. A two-sided p-value of 0.05 was considered significant. All statistical analyses were performed using Stata V15.1 (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

Results

Fifteen participants were enrolled in the study (Figure 6). Their characteristics are detailed in Table 1, and the characteristics of simulated patients are described in Table 2.

The time required to complete the stabilization procedure was shorter in the SS group (median [Q1; Q3] 127 seconds [111;145]

Table 1. Participants' characteristics.

	Vacuum mattress (n=7)	Scoop stretcher (n=8)
Age, years, median [Q1;Q3]	29 [27;34]	35 [31;39]
Gender, n (%)		
Woman	4 (57)	2 (25)
Man	3 (43)	5 (53)
Other	0 (0)	1 (13)
Professional title, n (%)		
Paramedic	7 (100)	6 (75)
EMT	0 (0)	1 (13)
Student	0 (0)	1 (13)
Professional experience, years, median [Q1;Q3]	5 [1;10]	7 [3;10]
Self-assessed ability to perform spinal stabilization, median [Q1;Q3]	8 [6;9]	8 [7;10]

Total may not be equal to 100% due to rounding.

Table 2. Simulated patients' characteristics.

	Vacuum mattress (n=7)	Scoop stretcher (n=8)
Age, years, median [Q1;Q3]	30 [29;40]	33 [29;37]
Gender, n (%)		
Woman	3 (43)	3 (38)
Man	3 (43)	5 (63)
Other	1 (14)	0 (0)
Weight, kg, median [Q1;Q3]	74.0 [56.3;82.4]	73.2 [68.0;91.5]
Height, cm, median [Q1;Q3]	173 [161;179]	174 [169;180]
Body Mass Index, median [Q1;Q3]	25.7 [20.7;26.2]	25.1 [22.9;27.6]

Total may not be equal to 100% due to rounding.

Table 3. Simulated patient's subjective feelings about the procedure.

	Vacuum mattress (n=7)	Scoop stretcher (n=8)	p
Anxiety level, median [Q1;Q3]	1 [0;3]	0 [0;0]	0.018
Comfort level, median [Q1;Q3]	7 [1;9]	1 [0;5]	0.18
Induced dyspnoea or shortness of breath, median [Q1;Q3]	0 [0;1]	0 [0;0]	0.18

versus 212 [156;237], p=0.005). All stabilizations (15/15) were of sufficient quality regarding the standard operating procedures. Secondary outcomes are displayed in Table 3.

Discussion

Our results were similar to those of the study from Roessler *et al.*,[45] indicates a faster procedure when using the SS compared to the VM. The time saved by using the SS is therefore particularly useful in cases of life-threatening injury, as it allows rapid spinal stabilization while complying with immobilization standards. The present study applied the same ideal conditions and setup. For instance, the straps were already attached to the device. Since the strap attachment was identical in the study of Roessler *et al.* on the backboard as in our study on the SS, there did not appear to be a time difference associated with this aspect in real-life scenarios between the two devices. Roessler *et al.* previously noted that the VM lacked sufficient stability for transporting a patient to the ambulance with only two individuals. However, by simply placing the SS beneath the VM, it becomes rigid enough to allow for transportation with just two people. It should be noted that when the patient is positioned other than supine, the closed SS can be used, functioning similarly to a backboard. This approach offers the supplemental advantage of avoiding detrimental movements, such as a log roll, during the removal process. Moreover, it has been proved that less misalignment occurs during placement on the scoop stretcher than on the spinal backboard.[62]

The log-roll maneuver has been suggested to be restricted or even abolished.[4] Consequently, choosing a SS for spinal stabilization in unstable trauma patients with life-threatening conditions can lead to significant time savings, without the drawbacks associated with a backboard. The main advantage of the SS over the backboard is that it eliminates the need to tilt the patient, which can cause pain and worsen injuries, especially in case of pelvic trauma, both during installation and removal processes. It is obvious that these patients must benefit from the placement of a pelvic binder, that is entirely compatible with the use of the SS, to offer an augmented control of the stabilization of the pelvis.

It must be taken into account that only one healthcare worker can carry all the equipment necessary for the stabilization with the SS. On the other hand, using the VM for stabilization requires at least two individuals or multiple trips to transport the equipment, which could potentially increase on-scene time or necessitate additional personnel.

Regarding the secondary subjective outcomes, comfort is superior in the VM group, although nonsignificative. This is not surprising considering the enhanced comfort offered by the device, including the softness and the individual body-shaped possibility. Then, no difference was observed in the induced dyspnoea/shortness of breath. It should be remembered that the subjects were healthy volunteers who were familiar with the subject. The only significant one was the level of anxiety which was lower in the SS group. This could be linked either to the fact that fewer manipulations are required when using only the SS, or that when using the VM, the subject is moved without straps from the ground to the VM, which can be distressing, for fear of a fall, or combination of the two phenomena.

Strengths and limitations

It is important to acknowledge that the reported times are applicable only when all the required equipment is readily available at the scene. Several factors should be taken into account when interpreting the results. The study's design was monocentric, and the participants involved healthy volunteers rather than actual patients. Additionally, the sample size was small, which may limit the generalizability of the findings. The presence of the "Hawthorne effect," wherein participants modify their behavior due to being observed, could also potentially influence the results, making them less reflective of real-world scenarios.[63,64] Furthermore, outcomes assessed in simulated patients may be subject to bias due to the open-label nature of the study design, and the subjective nature of the secondary outcomes.

The main strengths of the present trial are the registration of the trial, the randomized design, the assessment of stabilization quality, anxiety, and comfort levels and the degree of dyspnoea and shortness of breath, the sample size calculation, and the use of the same conditions as Roessler *et al.*

Conclusions

The use of a scoop stretcher for spinal stabilization was found to be more time-efficient compared to a vacuum mattress. This finding is significant considering the importance of minimizing prehospital time for unstable trauma patients. Stabilizing patients with a scoop stretcher could be a feasible and effective alternative that offers fewer inconveniences compared to the traditional backboard. However, further studies are required to evaluate its effectiveness in real clinical settings and actual practice.

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Online supplementary material:

Standard operating procedure – stabilisation du rachis avec la civière à aubes (original french version)

Standard operating procedure – scoop stretcher spinal stabilization (english translated version)

Standard operating procedure – stabilisation du rachis avec le matelas vacuum (original french version)

Standard operating procedure – vacuum mattress spinal stabilization (english translated version)