Final Study Protocol (retrospective documentation)

Official title	Time performance of scoop stretcher versus vacuum mattress for prehospital spinal stabilization: open-label simulation-based randomized controlled trial
NCT Number	NCT04904770
Document type	Final Study Protocol (retrospective documentation)
Document version	Version 1.0 (Retrospective)
Document date	February 15, 2026
Sponsor	Genève TEAM Ambulances
Responsible party	Stuby Loric

Transparency statement

This document was created retrospectively to describe the study design and statistical analysis used in the trial identified as NCT04904770. A single, formally finalized study protocol did not exist prior to study initiation. The contents of this document reflect the methods actually used and reported in the final published article (Stuby et al, Emergency Care Journal, 2024).

Background and Rationale

Prehospital stabilization of patients' head and spine is discussed to prevent secondary injury during patient transport. Various stabilization methods exist, including the traditional Scoop Stretcher (SS) with straps and blankets and vacuum mattresses (VM). Each method has practical and safety considerations, including ease of use, time to application, hygiene, and stability. There is limited evidence comparing these methods. This study was conducted to evaluate and compare the time needed to perform head and spine stabilization using SS versus VM in a standardized simulation setting.

Study Objective

To compare the time efficiency of head and spine stabilization using the Scoop Stretcher versus the Vacuum Mattress in a simulated prehospital environment.

Study Design

- Type of study: Monocentric, parallel, randomized, superiority, controlled simulation study
- Design guidelines: SPIRIT-compliant; results reported according to CONSORT standards
- Setting: Training room of Genève TEAM Ambulances EMS, simulating prehospital conditions on level hard ground
- Randomization: Participants assigned randomly to stabilization method groups
- Duration: Single session per participant during scheduled EMS continuing education sessions (second half of 2021)

Participants

Population

- Inclusion Criteria: Student paramedics, registered paramedics, and EMTs actively working in the participating EMS.
- Exclusion Criteria: Being a study investigator.

- Recruitment: Participants recruited by email; participation voluntary; no incentives provided.
- Sample Size: Enrollment accepted after predetermined sample size achieved considering the absence of risk to the participants.

Interventions

Randomization in one of the two arms:

- A) Scoop Stretcher (SS) Stabilization: Model: Ferno Scoop Stretcher 65-EXL (Ferno-Washington, Inc., Wilmington, OH, USA), Head stabilization: Single-use taped blanket secured with duct tape

- B) Vacuum Mattress (VM) Stabilization: Model: RedVac Vacuum Mattress VM6000X01 (Kohlbrat & Bunz GmbH, Radstadt, Austria), Vacuum generated using ACCUVAC Pro suction pump.

Baseline Configuration: Simulation conducted on hard, level floor, SS and VM prepared with standard setup, video recording of all stabilization attempts.

Outcomes

Primary outcome

Time needed to complete the stabilization procedure. The timer was started as soon as the team leader 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

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. 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”.

Statistical Analysis

Population analyzed: All participants randomized and completing the assigned stabilization task.

Methods applied: 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).

Analysis reflects actual procedures and outcomes collected; no separate pre-specified statistical analysis plan existed.

Ethics and approvals

The study was conducted according to Good Clinical Practice. Swiss Federal Law on Human Research does not apply (no health outcomes assessed). This study was considered as falling outside of the scope of the Swiss legislation regulating research on human subjects so the need for local ethics committee approval was waived (CCER—Commission Cantonale d’Ethique de la Recherche sur l’être humain, Geneva, Switzerland, Req-2021-0053). All participants provided informed consent.

Data management

- Data collected automatically from SS and VM sensors; video recordings used for review

- Data exported to CSV and analyzed in Stata
- All authors had access to the database
- Curated dataset publicly available on Yareta

Publication

Stuby, L. Thurre, D. Time performance of scoop stretcher versus vacuum mattress for prehospital spinal stabilization: open-label simulation-based randomized controlled trial. (2024). *Emergency Care Journal*, *20*(1). https://doi.org/10.4081/ecj.2024.12226