European Journal of Medical and Health Sciences
www.ejmed.org

A Randomized, Clinical Trial Comparing the Efficacy of a Fascia Release Technique for the Treatment of Acute Ankle Sprains

David Salo, Anna Beth Johnson, Devansh Pandey, Jonathan Pierce, Barnet Eskin, Michael Silverman, and Lev Paley

ABSTRACT

Acute ankle sprains are treated with ice, elevation, immobilization, and non-steroidal anti-inflammatory drugs. Resolution typically takes days. Osteopathic physicians utilize manipulation for a variety of joint disorders and injuries. Few have been studied in randomized controlled trials and many allopathic physicians are unaware of their utility. One manipulation, a modified muscle energy release technique, appears to offer promise for the treatment of acute ankle injuries, potentially returning patients to function more quickly than standard treatment alone. This study involved a comparison of a modified muscle energy release technique with standard treatment to standard treatment alone in the emergency department (ED) setting for patients with acute ankle injuries. This is an IRB approved, randomized single-blind sham-controlled study on a convenience sample of ED patients with pain from acute inversion injury. The study was set in a suburban ED with a 3-year Emergency Medicine Residency and an annual volume of 80,000. Inclusion criteria were patients aged 18-55 years; a Grade I or II acute ankle sprain less than 48 hours old; initial VAS scores ≥ 35; and being able to take 4 steps in the ED. We excluded fractures and Grade III injuries. The experimental manipulation technique involved placing the ankle into position of injury (inversion) for over 90 seconds and then bringing the ankle back to a neutral position over 90 seconds against mild hand resistance. The sham manipulation was similar but with plantar-flexion manipulation instead Patients were evaluated pre and 5 minutes after manipulation and 2 days later with a 100mm VAS pain scale completed by the patient after taking 4 steps. 17 patients were enrolled, 7 in the experimental (E) and 10 in the sham (S) group; 7 (41%) were female. There was no difference between groups for age (E=32; S=32 years p=0.9), gender (p=0.9), time from injury (E=7 vs S=11 hours; p=0.4) or initial VAS (E= 51 mm (SD 27); S= 57 mm (SD 20) (p=0.7). Both groups had similar distributions of pain (see schematic). There was no difference in mean pain relief between groups immediately after manipulation E=2.4mm (-11.0-15.88, 95%CI) vs S= 7.2mm (0.08-14.8, 95%CI) (p=0.4) or 2 days later E=29.1mm 1mm (8.5-49.7, 95%CI) S=26 (7.7 95%CI (p=0.8). Muscle energy release for acute ankle sprain does not improve pain immediately or in 2 days compared to standard treatment.

Keywords: Ankle Sprain, Holistic therapy, Osteopathic Manipulation, Myofascial Release.

Submitted: October 13, 2022

Published: August 31, 2023

ISSN: 2593-8339

DOI: 10.24018/ejmed.2023.5.4.1553

D. Salo
Morristown Medical Center, USA
(e-mail: ds1122@aol.com)
A. B. Johnson
Morristown Medical Center, USA
(e-mail: johnson.annabeth@gmail.com)
D. Pandey
Morristown Medical Center, USA
(e-mail: devansh.pandey2015@gmail.com)
J. Pierce
Morristown Medical Center, USA
B. Eskin
Morristown Medical Center, USA
(e-mail: phdmd@gmail.com)
M. Silverman
Morristown Medical Center, USA
(e-mail: msilvermanmd@gmail.com)
L. Paley
Morristown Medical Center, USA

.

Corresponding Author

I. Introduction

There are over 628,000 acute ankle injuries treated in emergency departments (ED) each year in the US and account for nearly 20% of injury related ED visits [1]. The current standard of care for acute ankle sprains includes rest, compression dressings, elevation, early mobilization, and analgesia. Analgesia typically includes nonsteroidal anti-inflammatory drugs and acetaminophen. Despite this current practice, 25% to 40% of ankle sprains are associated with recurrent injury or prolonged disability [2]. Some authors have postulated that such common complications are the result of inadequate treatment of the initial injury because insufficient consideration is given to the exact nature of the pathologic process in each patient.

Osteopathic manipulative treatment has only been studied once in the setting of acute sprain. It is a method of correcting the underlying somatic dysfunctions, restoring functional anatomy, and decreasing edema. A review of the literature suggests that more can be done in this area of research [3]. The primary objective of this study was to evaluate quantitatively the effect of manipulative treatment by a variety of ED providers on patients with acute ankle injuries. The specific aim of this study was to assess the immediate effects of a single session of manipulation when performed in the ED, as well as determine additional benefits several days

later in patients who are treated with manipulation added on to the current standard treatment of acute ankle sprains.

II. Methods

A. Study Setting and Population

The setting was a suburban emergency department (ED) with a three-year emergency medicine residency training program and an adult ED census of 65,000. The study was conducted from January 2008 to April 2011.

B. Study Protocol

This was a randomized single-blind sham-controlled study on a convenience sample of patients who presented to the ED with a chief complaint of ankle pain from an inversion type of injury. There were six ED providers including four attendings, one resident, and one PA who were trained in the modified muscle energy release technique and were responsible for enrolling patients.

Patients were screened by the provider at the time of presentation for grade I-II ankle sprains provided the injury occurred within the past 48 hours. Following an explanation of the study by the provider, eligible subjects were asked to provide informed, written consent.

TABLE I: Inclusion and Exclusion Criteria

Parameters	Inclusion	Exclusion
Injury Pattern	Grade I or II acute ankle sprain from inversion injury sustained <48 hours prior to presentation	>48 hours, Grade III ankle sprain, acute fractures, direct trauma to the ankle (ex. motor vehicle collision, fall), neurological deficits
Severity of Injury	Moderate severity, initial VAS ≥ 35	VAS<35
Age	Adults aged 18-55	Pediatrics and Geriatric Population
Medical History		Pregnancy, Fever, Diabetes, Uncontrolled Hypertension, Severe Peptic Ulcer Disease, Neoplastic Disease, Allergies to study drugs
Other		Patient refusal or not available for call back, patients whose employers have contracted with the hospital to provide emergency care and follow-up.

The healthcare provider recorded patient demographic and clinical variables on a standardized, data collection instrument. All patients enrolled were given pain medication at the discretion of the attending ED physician, at the initial assessment. Patients filled out a 100 mm VAS at the time of enrollment and pain mapping of the ankle was performed. Only those patients with maximum pain over the lateral ligaments were treated and enrolled.

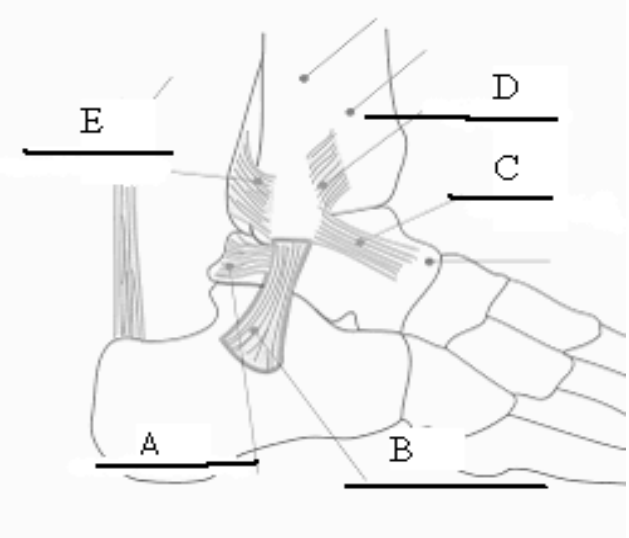

Fig. 1. Ankle diagram depicting ligament location.
A) calcaneofibular ligament; B) anterior talofibular ligament;
C) posterior talofibular ligament; D) anterior tibiofibular ligament;
E). posterior tibiofibular ligament.

After obtaining X-rays, patients were instructed to take 4 steps and then to complete the 100 mm VAS pain scale. This was followed by the experimental or sham manipulation. Patients were randomized via a random assignment list generated by a computer. The procedures performed in this study are those that would normally be done in the evaluation and treatment of acute ankle sprain except for the experimental and sham manipulations. For the experimental manipulation group patients were slowly placed into a position of injury (inversion) over a 90-second period. Patients were asked to rate their pain in 15-second intervals and inversion was halted when either pain increased by 1 point or full inversion had taken place. Inversion was held for 90 seconds. Following this, the patients were asked to slowly (over 90 seconds) bring their ankles to a neutral position against the manipulator's mild hand resistance. Sham (control group) manipulation consisted of plantar flexion over 90 seconds, withhold for 90 seconds, then back to normal positions over 90 seconds against the manipulator's hand. Patients were evaluated 5 minutes after treatment using a third post 4 step 100 mm VAS pain scale.

C. Data Analysis

We estimated a sample size of 8 per each treatment group to show a 50% improvement of post treatment VAS compared to initial VAS based on a SD of 5mm, alpha of 0.05, and delta of 15 mm (using sample size statistical calculator, which can be accessed at clincalc.com). A total of 18 patients were enrolled based on the assumption that up to 10% of patients may not be available for callback.

The primary endpoint of the study was improvement in pain between the two groups immediately after manipulation. Secondary endpoints were pain assessed at 48-hour callback when patients were asked to verbally rate their pain on a 10-point scale and to identify time to restore function as measured by discontinued use of immobilization aids/air cast and crutches. Following the study protocol patients were discharged based on the evaluation of the attending physician. Pain medication, use of casting or ankle supports and/or crutches, and appropriate outpatient follow-up were individualized according to the attending physician.

Appropriate parametric or nonparametric statistics were performed with a p value of 0.05 as significant. Data was entered into a Microsoft Excel 10 (Microsoft, Redmond, WA) database and analyzed using STATGRAPHICS Centurion XVI Version 16.1.11 (Statpoint Technologies, INC. The Plains, Virginia) and Analyze-It Software Version 2.24 Excel 12+ (Analyze-IT Software Ltd, Leeds, UK).

III. Results

Seventeen patients were enrolled based on the inclusion criteria. Seven patients were placed in the experimental group (E) and ten patients were placed in the sham group (S). Median age was 32 years. 41% were female. There was no difference in groups by age (E=32; S=32 years p=0.88), gender (p=0.91), time from injury (E=7 vs S=11 hours; p=0.43) or initial VAS (E= 51mm (SD 27); S= 57mm (SD 20) (p=0.7). Both groups had similar distributions of pain. There was no difference in mean pain relief between groups immediately after manipulation E=2mm (-11-16, 95%CI) vs S= 7mm (0-15, 95%CI) (p=0.4) or 2 days later E=29 mm 1mm (6-50, 95%CI) S=26 (8 95%CI (p=0.8).

TABLE II: Demographics of Selected Patients

Demographic Categories		E	S
Age	18-55 y/o	7	10
Gender	M	4	6
	F	3	4
Race	AA	2	1
	C	2	7
	O	1	0
	NA	0	0

Key: E – Experimental; S – Sham; M – Male; F – Female; AA – African American; C – Caucasian; O – Other; NA – Not Applicable.

TABLE III: VAS score comparisons for the experimental technique

Pre-Technique	VAS 82
Post-Technique	VAS 79
48 Hour Follow Up	VAS 64

TABLE IV: VAS score comparisons for the sham technique

Pre-Technique	VAS 87
Post-Technique	VAS 81
48 Hour Follow Up	VAS 66

TABLE V. Pain Level 1-10 by anatomical location

	A	B	C	D	E
Experimental	2	7	5	4	2
Sham	1	3	4	6	3

IV. Discussion

This was the first trial of a modified muscle energy release technique in patients with acute inversion-type ankle sprains presenting to an emergency department. Anecdotally, the technique showed great promise for immediate symptomatic pain relief in the ED. Six patients in this study did have significant relief with the technique, and perhaps there is a subgroup of patients that would benefit. Few studies exist that specifically study the use of manipulative medicine in the ED setting for acute ankle injury. A study published in 2003 in the Journal of Osteopathic Medicine studied the use of osteopathic manipulative medicine in the ED and found statistically significant benefits. This showed promise however it lacked a clear standardized technique as the author structured the study to allow techniques to vary at the discretion of the examiner. The study further fails to identify which technique was implemented in each case and the author does admit there was significant variability between patients. This makes external validity and reproducibility difficult [9]. Furthermore, one provider was called to perform all manipulations in that study. To this date, one simple technique, which can be used by both allopathic and osteopathic providers for all patients with ankle injury has not been proven. This does not necessarily show that the technique doesn't work, but that treating all ankle sprains with one technique and training a variety of healthcare providers to use one technique is not something we can recommend at this point. While this questions the use in the ED setting, its low adverse event profile, coupled with a possible delayed effect suggests further studies should be performed on the possibility of benefit from the technique.

V. Limitations

Our study was limited by several factors. First, the numbers enrolled were small, thus limiting our ability to detect small but potential clinically significant differences. In an over 3-year period in an ED with 65,000 annual visits, you might expect more patients to be available for the study. However, this may have been limited because the number of enrolling personnel was small because the efficacy of the technique likely depends on exactly how it is done, so we were concerned that the techniques among many enrollers might be different. Secondly, myofascial tissue manipulation relies on a clinician's subjective sense of tissue resistance, and it is difficult to fully standardize how different clinicians perform the manipulation, which makes external validity challenging. Also, investigators may have unintentionally influenced how the patient evaluated their pain on the VAS scale in the ED, since this was an unblinded study, by possibly asking leading questions regarding the patient's pain improvement.

VI. Conclusion

Our study was limited by several factors. First, the numbers enrolled were small, thus limiting our ability to detect small but potential clinically significant differences. In an over 3-year period in an ED with 65,000 annual visits, you might expect more patients to be available for the study. However, this may have been limited because the number of enrolling personnel was small because the efficacy of the technique likely depends on exactly how it is done, so we were concerned that the techniques among many enrollers might be different. Secondly, myofascial tissue manipulation relies on a clinician's subjective sense of tissue resistance, and it is difficult to fully standardize how different clinicians perform the manipulation, which makes external validity challenging. Also, investigators may have unintentionally influenced how the patient evaluated their pain on the VAS scale in the ED, since this was an unblinded study, by possibly asking leading questions regarding the patient's pain improvement.

REFERENCES

[1] Shah S, Thomas AC, Noone JM. Emergency department visits associated with ankle sprains in the United States. *Value in Health*. 2016;19(3). https://doi.org/10.1016/j.jval.2016.03.261.

[2] Hultman K, Fältström A, Öberg U. The effect of early physiotherapy after an acute ankle sprain. *Advances in Physiotherapy*. 2010;12(2):65-73. https://doi.org/10.3109/14038190903174262.

[3] Roberge RJ, Roberge MR. Overcoming barriers to the use of osteopathic manipulation techniques in the emergency department. *West J Emerg Med*. 2009;10(3):184-189.

[4] Wedmore IS, Charette J. Emergency department evaluation and treatment of ankle and foot injuries. *Emergency Medicine Clinics of North America*. 2000;18(1):85-113. https://doi.org/10.1016/s0733-8627(05)70109-7.

[5] Packer GJ, Goring CC, Gayner AD, Craxford AD. Audit of ankle injuries in an accident and emergency department. *BMJ*. 1991;302(6781):885-887. https://doi.org/10.1136/bmj.302.6781.885.

[6] Birrer RB, Fani-Salek MH, Totten VY, Herman LM, Politi V. Managing ankle injuries in the emergency department. *The Journal of Emergency Medicine*. 1999;17(4):651-660. https://doi.org/10.1016/s0736-4679(99)00060-8.

[7] Mascaro TB, Swanson LE. Rehabilitation of the foot and ankle. *Orthopedic Clinics of North America*. 1994;25(1):147-160. https://doi.org/10.1016/s0030-5898(20)31874-5.

[8] de Bie R, de Vet H, van den Wildenberg F, Lenssen T, Knipschild P. The prognosis of ankle sprains. *International Journal of Sports Medicine*. 1997;18(04):285-289. doi:10.1055/s-2007-972635.

[9] Eisenhart AW, Gaeta TJ, Yens DP. Osteopathic manipulative treatment in the emergency department for patients with acute ankle injuries. *J Am Osteopath Assoc*. 2003 Sep;103(9):417-21.

[10] Allee BA, Pollak MH Malnar KF Survey of osteopathic and allopathic residents' attitudes toward osteopathic manipulative treatment. *Journal of the American Osteopathic Association*. 2005 Dec;105(12):551-61.