

Tape versus semirigid versus lace-up ankle support in the treatment of acute lateral ankle ligament injury.

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The objective of this study is to compare tape versus semi rigid support versus lace up brace treatment for acute lateral ankle ligament injuries with regard to clinical outcome and cost effectiveness.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON33389

Source

ToetsingOnline

Brief title

Treatment of lateral ankle ligament injury.

Condition

- Tendon, ligament and cartilage disorders

Synonym

ankle sprain, lateral ankle ligament injury

Research involving

Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen

Source(s) of monetary or material Support: 2 bedrijven: Medi en Basko,Basko,Medi

Intervention

Keyword: Ankle ligament letsel, brace, conservatieve behandeling, tape

Outcome measures

Primary outcome

1. Karlsson scoring scale

The patients were asked to fill out a questionnaire regarding the function of the ankle joint. The score includes eight items based on a subjective evaluation of stability, pain, swelling and stiffness in relation to activities of everyday life, sports and recreational activities, running, stair climbing and working ability. The maximum score is 100 points. (Appendix B)

Excellent 90-100 points

Good 80-89 points

Fair 60-79 points

Poor ≤ 60 points

Secondary outcome

Secondary outcome measures:

2. Foot and Ankle Outcome Score. FAOS

- FAOS consists of 5 subscales; Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport Rec), and foot and ankle-related Quality of Life (QOL). The last week is taken into consideration when answering the questionnaire. Standardized answer options are given (% Likert boxes) and each question gets a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

The result can be plotted as an outcome profile.

- FAOS content is based on the Knee injury and Osteoarthritis Outcome Score (KOOS), content validity was confirmed by 213 patients with ankle instability.
- FAOS was developed to assess the patients* opinion about a variety of foot and ankle related problems. FAOS is patient-administered and takes about 10 minutes to fill out.

3. Return to work

- Time to return to work
- Work at level / below level / no return to work

4. Return to sports.

- Time to return to sports
- Sports at level / below level /no return to sports

5. Pain

- VAS score 0-10: 0 = no pain, 10 = unbearable pain

6. Objective instability

- Objective instability of the ankle is either measured during physical examination using the TTT (≥ 90 or ≥ 30 difference with uninjured ankle) Talar tilt test or inversion stress test is performed in the same position and a varus force is applied to the heel. In maximal dorsiflexion the contribution of the subtalar joint is minimised and the calcaneo-fibular ligament is taut. This is a test predominantly of the calcaneo-fibular ligament. The second test is the Anterior Drawer Test (ADT). The patient sits on a bench with the legs hanging downwards. The knee joint is flexed and the foot held in 150 plantar flexion. First the healthy ankle is examined. Examination is performed

according to van Dijk. 38 The examiner assigned one of the four predetermined numbers to each examined ankle joint, based on the estimated anterior displacement of the talus relative to the tibia.

o 0 = 0-2mm, 1 = 3-5mm, 2 = 6-10mm and 3 = 11-15mm.

- Because the manual ADT is of a subjective nature we measure the instability with the dynamic anterior ankle tester (DAAT). 39 The principle of the test is to apply a force impulse tot the calcaneus, within the muscle reflex time, and to measure anterior-posterior translation and mediolateral rotation. The highest and the lowest score were discarded and the mean of the three remaining scores counted as the result of the test.

7. Range of motion

- Degrees maximum dorsiflexion to plantarflexion
- Limited: yes / no (>5 degrees, compared to healthy side)

8. Recurrent inversion injury

- Yes/no
- Number of sprains per month

9. Complications / Adverse events

- Any event leading to discontinuation of study participation and temporary or permanent physical damage due to the treatment under investigation (Local skin irritations (contact dermatitis and folliculitis), sensory deficit, stiffness, muscle atrophy). Use of not allowed painkillers is also an adverse event.

- Yes / no
- Total number of complications per patient and per group

10. Tegner activity level

- Mean per group

11. EuroQol

The EuroQol (EQ5D) is a health related quality of life instrument that provides a single index of an individual's quality of life. It consists of 5 dimensions resulting in 243 possible health states.

12. Economic evaluation

- Main objective of the economic evaluation is to assess the cost effectiveness and cost-utility of brace and tape therapy of acute lateral ankle ligament injury. The economic evaluation will be performed from a societal perspective, implying that both direct health care and direct non-health care costs, as well as indirect costs will be used as economic indicators. Firstly, relevant categories of resource utilisation were identified. Secondly, the volume of each category was measured and multiplied by the resource costs.

13. Preference of the patient for treatment.

- (Tape / Semi rigid brace / Lace-up brace)

14. Compliance

- How many full days did you not wear the (semi rigid / lace-up) brace?
- Tape compliance is always 100% (except in cases of complications / adverse events)

Study description

Background summary

Injury to the anterolateral ligament complex of the ankle, or ankle sprain, is a common problem in acute care practice. Incidence numbers for casualty

departments in the Netherlands disclose that approximately 80.000 registered patients are treated each year for an acute ankle injury. The incidence is estimated at 1 per 10.000 people per day and ankle sprains form about a quarter of all sports injuries. Some sports (basketball, soccer and volleyball) have a particularly high incidence of ankle injuries. Ankle sprains may lead to persisting symptoms in 30-40% of all patients.

The lateral ankle ligament complex is formed by the anterior-talofibular, the calcaneal fibular and the posterior-talofibular ligaments (respectively ATFL, CFL, and PTFL).⁷ However, the number of ligaments injured does not affect the prognosis and is therefore not considered relevant for the treatment either. The most common mechanism of injury is supination and adduction (usually referred to as inversion) of the plantar-flexed foot.

Ankle inversion injuries are usually classified according to a 3-stage grading system: Grade I is a mild stretching of the ligament with no instability of the joint, grade II is a partial rupture of the ligament with mild instability of the joint, and grade III involves complete rupture of the ligaments with instability of the joint. Due to pain and swelling, classification of patients is often only possible after 4 to 5 days.

Primary treatment of inversion injuries is performed by different medical disciplines, varying from primary health care and emergency physicians to orthopaedic and trauma surgeons.⁵ The three main modalities of treatment for inversion injuries are: 1) operative treatment, 2) conservative treatment by immobilization with a plaster cast or splint and 3) functional conservative treatment.

Today, the majority of patients are initially treated functionally. A Cochrane Systematic Review about surgical versus conservative treatment for acute ankle ligament injuries was inconclusive due to insufficient evidence, but conservative treatment showed not be inferior either. A second Cochrane Systematic Review showed that functional treatment is superior to immobilization as conservative treatment for ankle ligament injuries. In combination with financial and practical consideration and the possibility for secondary reconstruction, initial functional treatment seems to be the best treatment option for most of the patients.

Functional treatment usually consists of early mobilisation with full weight bearing with external ankle support, e.g. tape, elastic bandage or a (lace-up) brace, often combined with coordination training. Based on the best evidence available, the Dutch CBO formulated the following consensus guideline about ankle ligament injuries. Patients with a distortion without a rupture of their lateral ankle ligament complex can be treated with a supporting elastic bandage for a few days. The patient is allowed to walk and bear weight with normal unwinding of their feet as soon as possible. When the patient has a rupture of their lateral ankle ligament complex the treatment has to be adjusted to the patient's individual demands. A disadvantage of using a brace is that the patient has to apply it by himself, whereas the advantage of taping is that the doctor is responsible for correct application of the tape. A disadvantage of taping is the potential risk of loosening of the tape and local skin irritations, such as contact dermatitis and folliculitis. The treatment period

should be 6 weeks.

There is no high level evidence, with regard to clinical or financial outcome, for the superiority of taping or bracing. According to the Cochrane Systematic Review concerning different functional treatment options (tape, semi rigid support, lace up support) for acute ankle ligament injuries *there is no most effective treatment both clinically and in costs based on currently available randomised trials. High quality, sufficiently powered randomised trials are warranted to compare the effectiveness of different functional strategies for treatment of an acute ankle sprain. An analysis of both direct and indirect costs of different functional therapies should be incorporated as costs may vary between strategies.

Two recent randomised trials show that the use of an ankle brace for the treatment of lateral ankle ligament sprains produces better short term results compared with standard management with an elastic support bandage.

Although most physicians probably consider the clinical result as most important outcome, the socio-economic consequences of ankle sprains in general are enormous. The costs for ankle injuries in the seventies were estimated at approximately 35 million US dollars per million people. A Harvard study from 1983 estimated the annual costs for ankle ligament injuries in the US at approximately 2 billion US dollars. Adjusted for inflation, today this would equal 3.65 billion US dollars. In 1995, Zeegers estimated the total socio-economic costs of ankle sprains in the Netherlands at approximately 1.3 billion Dutch guilders. Apart from direct cost (material, visits to emergency department, outpatient clinic and consultant fees), these estimates include indirect costs, like loss of income and incapacity to work during (part) of the rehabilitation period.

Study objective

The objective of this study is to compare tape versus semi rigid support versus lace up brace treatment for acute lateral ankle ligament injuries with regard to clinical outcome and cost effectiveness.

Study design

This study is designed as a single blind prospective randomized controlled trial to evaluate the difference in functional outcome after treatment with tape versus semi-rigid versus lace-up ankle support (brace) for grade II and III acute lateral ankle ligament injuries. The patients will be randomly allocated into one of the three groups. Randomization will be performed by computer. Blinding of patients is not possible, but the observer will be blinded at eight weeks and six months. Analysis of the data will be performed in a blinded fashion.

Intervention

Group 1 will be treated with adhesive non-elastic tape for six weeks. Group 2 will be treated with a semi-rigid brace for six weeks. Group 3 will be treated with a lace up ankle support. Use and application will be explained by the researcher using a standardised protocol. In case of complications another treatment will be started but the patient will be evaluated according to the intention to treat principle. Apart from the investigated treatment, patients will undergo the same rehabilitation program: active range of motion training, weight bearing as tolerated, and use of crutches until the pain subsides and full weight bearing is reached. The use of additional treatment (ultrasound, cryotherapy, laser, homeopathy and physiotherapy) will not be allowed. Analgesics are allowed, with the exclusion of non-steroidal anti-inflammatory drugs (NSAID*s) and morphine-mimetic drugs following the CBO guidelines.

Study burden and risks

The purpose and consequently the benefit of our study is to determine the optimal non-surgical treatment for acute lateral ankle ligament injury, tape, brace or lace-up brace treatment. To our knowledge there are no potential risks for the included patients, as both treatments have been described as being safe with little chance of complications. Only for tape, skin local irritations, such as contact dermatitis and folliculitis, were reported. These complications will resolve without any problem and can be reduced by practising proper technique. The tape bandage can be too tight.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients < 18 years
- Grade II or III ankle sprains
- Presentation < 72 hours after the acute injury

Exclusion criteria

- Patients with a history of chronic instability
- Who had a fracture on X-ray investigation
- Other injuries or disabilities on the same limb
- Alcoholism, serious psychiatric and neurological illness
- Patients with bilaterally sprained ankles
- Patients with previous surgery on the lateral ankle ligaments
- Skin diseases where taping is not practicable
- Patients who are unable to give informed consent
- Patients who are unable to fill out questionnaires
- Neuromuscular disorders of the lower extremities
- Active rheumatoid arthritis
- Gait disturbances

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2010
Enrollment:	182
Type:	Actual

Ethics review

Approved WMO	
Date:	05-01-2010
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL27757.041.09