Acute lateral ankle sprains: from functional treatment to prevention

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Acute lateral ankle sprains: from functional treatment to prevention

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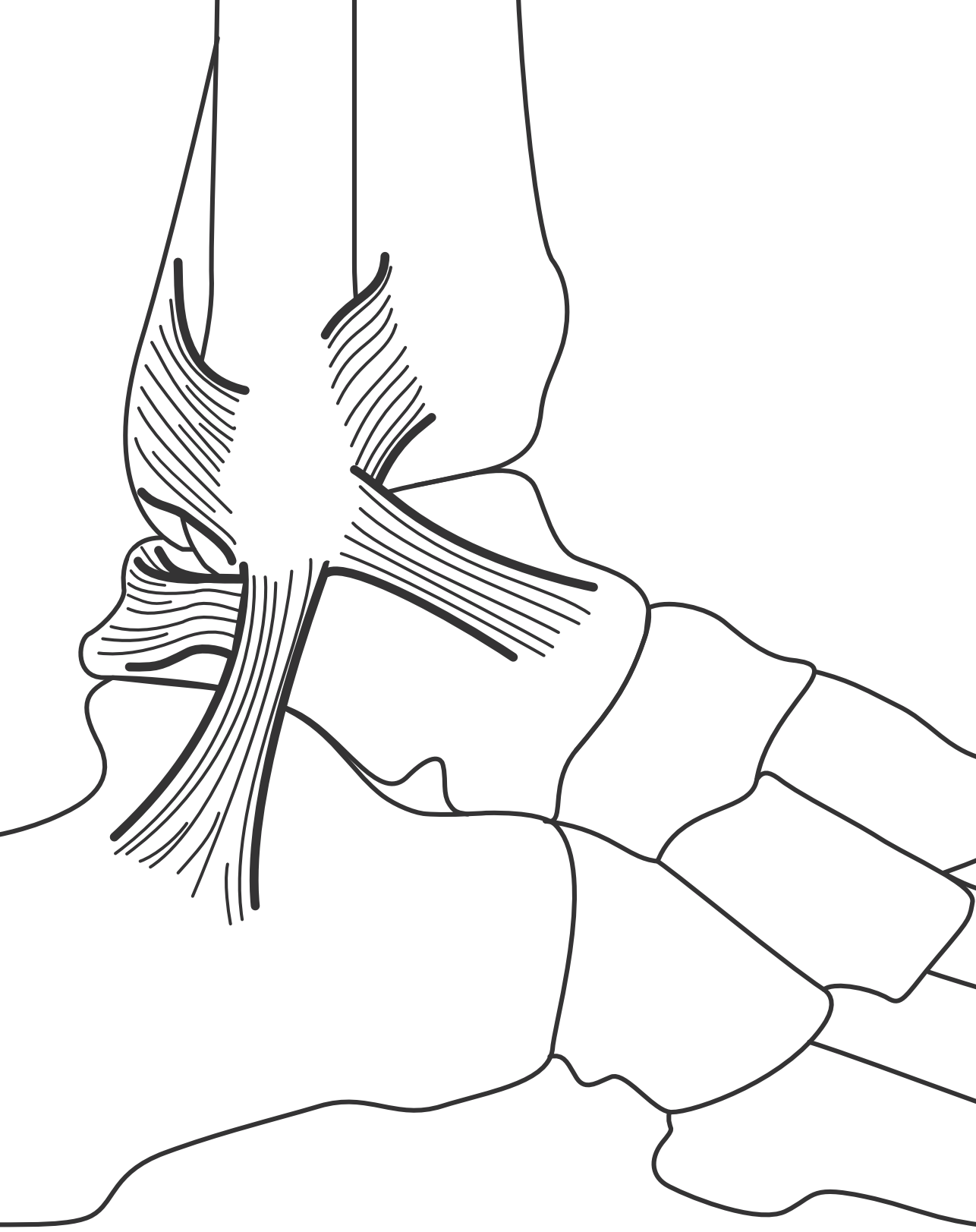
Contents



Chapter 1

General Introduction

Although an ankle injury is a common sports injury, ankle injuries often occur during daily activities. After the occurrence of an ankle injury, the process of recovery begins immediately. This process will be different for each individual, e.g. depending on the type and severity of the injury, the treatment of choice and the physical and behavioral factors of the injured person. The process will end once he or she is able to resume the normal daily-life level of activities engaged in prior to the injury. For an athlete (i.e. anyone involved in sports), the recovery process mostly ends when he or she resumes the sporting activity. The main steps in the process can be summarized in the Injury Sequence model by Bol et al. (1991)[2]. This model integrates the stages of injury occurrence, diagnosis, treatment, and rehabilitation of an injury in relation to returning to daily activities. The model is applicable for both injuries in the general population and sports injuries.

Stage 1: Injury occurrence

The first stage of the Injury Sequence model is the stage of injury occurrence. Onset of injuries can be related to the activities and actions and physical constitution of the injured persons. The activities and actions are determined by, for example, the personal characteristics of the injured persons, personal goals, the type of sports or daily activities, the materials used during activities of daily living and sports activities, the rules of the game, weather conditions, domestic conditions (e.g. carpeting, obstacles in the house) and the quality of the sporting playground or accommodation. Knowledge about these potential causes of ankle injuries is, especially in sports, extensive and important from a prevention perspective, but etiology is not the main topic in this thesis. Ankle injuries, especially ankle sprains, are a common health problem, also in the Netherlands. For example, in 2010 there were 910,000 ankle injuries, of which 68% occurred in sports[18]. Approximately one fifth of all sports injuries are ankle injuries[30,32]. Of all the ankle injuries caused by sports activities, more than 70% are ankle sprains[9,33].

Research on incidence of ankle injuries, treatment and prevention of these injuries often specifically focuses on ankle sprains. The incidence of acute ankle sprains has, for example, been studied in several athletic cohorts[5,16,37]. These studies typically only included ankle injuries treated at emergency departments (ED). Information about ankle injury rates and their time trends in the population at large is scarcer, even though ankle injuries very often occur during daily activities not related to sports. Moreover, ED studies, although important, only represent the tip of the iceberg in

terms of the extent of acute ankle injuries. For example, in 2013 only 40% of the ankle injuries in the Netherlands were presented to healthcare professionals and of these only 3% were treated at EDs[33].

For the development of proper health care policies and prevention strategies, it is important not to underestimate the total extent of the ankle injury problem. Population-based incidence rates of medically and non-medically treated ankle injuries can give a more complete picture of the burden of ankle injuries. Examining time trends in the occurrence of ankle injury gives more information than incidence studies alone and can provide clues to guide ankle injury prevention. Analyzing long-term ankle injury trends also allows researchers to monitor the results of injury prevention and intervention strategies, and to discover new developments in injury occurrence. Long-term trends (> 5 years) in ankle injuries or ankle sprains are not available. Therefore, one of the aims of this thesis was to investigate the incidence and time trends (10-25 years) of ankle injuries and sprains in the population at large and presented at EDs. The results of this study are presented in **Chapter 2.**

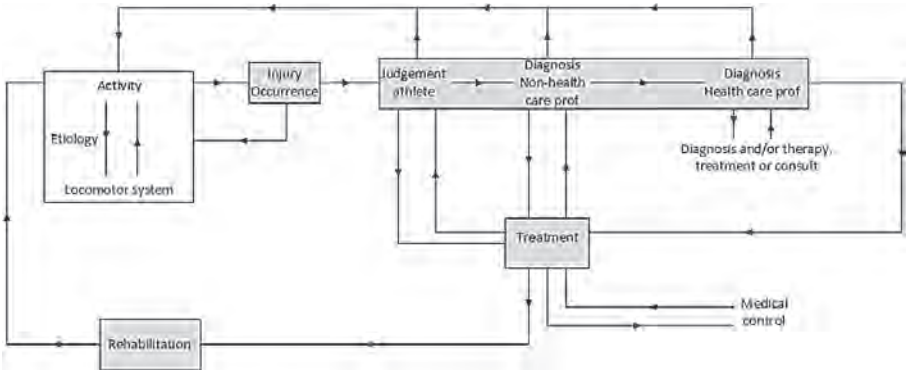


Figure 1: Injury Sequence model (Bol et al., 1991, translated from Dutch)

Stage 2: Injury diagnosis

The second stage of the Injury Sequence model is the stage of injury diagnosis. Although it seems logical that an injury is diagnosed by a healthcare professional, this is not always the case. In 2013, almost 60% of ankle injuries in the Netherlands were self-diagnosed by athletes or diagnosed by non-healthcare professionals[33]. Further, an injury is not always diagnosed directly after the occurrence. For example, an injured

person may initially deal with and/or treat the injury without consulting a healthcare professional (HCP), that is until after the complaints persist for 1 to 2 weeks. In the Netherlands, the person will typically go to his/her general practitioner (GP).
When a patient with an ankle injury visits the GP, the GP will take a detailed history from the patient and perform a physical examination of the ankle. Typically, the GP will ask the patient about the time of onset of the injury, the trauma that caused the injury, the ability to carry weight on the injured ankle, assess pain and other complaints and ask about prior history of ankle complaints and trauma.
During physical examination, the position of the foot in relation to the lower leg is inspected and the Ottawa Ankle Rules are applied. These rules will help the doctor to decide whether a patient with foot or ankle pain should be referred for an X-ray to diagnose or exclude a fracture[31].
If, according to the Ottawa Ankle Rules, there is no indication of a fracture, the GP has to assess the severity of the ankle injury in the first consultation or, in case of severe ankle swelling, after 4-7 days[6]. The injured ankle is examined for swelling, discoloration and tenderness in the malleolar zone. Manual anterolateral ankle tests (anterior drawer sign and talar tilt) are performed to measure ligament (in)stability. Based on the results of anamnesis and physical examination, the ankle injury is diagnosed as a distortion or ankle sprain.
Sprains are defined as injuries to the ligaments. Because most ligament ruptures occur when the foot is in plantar flexion, the anterior talofibular ligament is the most commonly injured ligament[23] (see Figure 2). A total rupture of the lateral ligamentous complex also involves the calcaneofibular and the posterior talofibular ligament[23]. Sprains to the lateral ligaments, and specifically the anterior talofibular ligament, are the main subject of this thesis.

Furthermore, it is known that the severity of acute lateral ankle sprains can vary widely. The severity can be classified in a number of ways. Grading can be based on anatomical damage, clinical presentation, mechanism of trauma, or a combination of these aspects[25]. The most frequently used terms to express severity are mild, moderate and severe, known respectively as Grade I, Grade II and Grade III[28]. In this thesis all ankle sprains, mild, moderate and severe, were included.

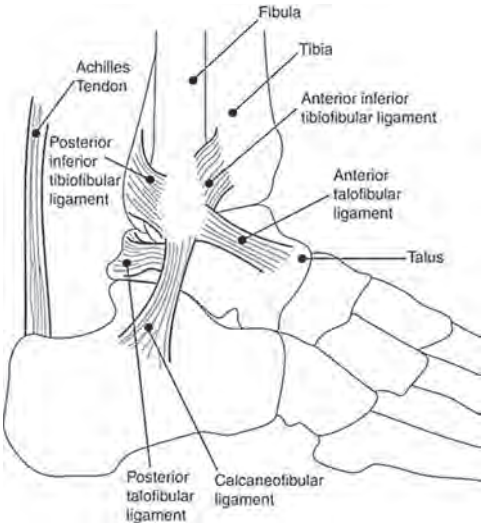


Figure 2: Lateral view of the ligaments in the ankle
Source image: National Institute of Arthritis and Musculoskeletal and Skin Diseases

Stage 3: Treatment

Ankle injuries, e.g. ankle sprains, often result in persistent pain, limitations in movement, muscle weakness, swelling, stiffness, and absenteeism from work and/or sports participation[3,10,12,13,36,38,39]. To counteract the consequences of ankle sprains, a variety of treatments for ankle sprains have been used. Those treatments included surgical repair, plaster cast or splint immobilization and nowadays more functional treatment. Functional treatment consists of an early mobilization program frequently combined with the use of an elastic bandage or brace. Moppes and Van den Hoogenband (1982) were among the first to conclude that functional treatment should be the preferred method to treat complete lateral ankle ligament rupture[26]. Their findings have been corroborated by several other researchers[15,17,19]. Kerkhoffs et al. assessed the effectiveness of various (im)mobilization methods for acute ankle sprains[19]. They found statistically significant differences for return to sports, return to work, persistent swelling, objective instability, range of motion and patient satisfaction; all of these differences were in favor of functional treatment compared to cast immobilization. They concluded that functional treatment seems to be a more appropriate approach and should be encouraged. In 2002, Kerkhoffs et al. compared the effectiveness of various functional treatment strategies for acute lateral ankle ligament injuries in adults[20]. Their findings did not indicate the most effective treatment, although a lace-up brace or a semi-rigid brace yielded better results in

terms of reduction of swelling and speed of recovery than a bandage. We evaluated the effectiveness of ankle braces as a treatment for acute ankle sprains, compared to other types of functional treatment like ankle tape and elastic bandages. The results of this evaluation are presented in **Chapter 3.**

In cases where ankle braces are used in the early stage of ankle sprain treatment, mostly semi-rigid or lace-up braces are used. Those braces are called functional braces. Functional braces allow plantar and dorsiflexion (no loss of ankle function and performance) at the ankle while controlling for inversion and eversion. Semi-rigid braces are made of thermoplastic contoured lateral stirrups lined with foam pads for support of the medial and lateral malleoli. Lace-up braces are usually made of canvas. Semi-rigid stirrup braces restrict ankle inversion and eversion more than lace-up braces[4].
Another functional ankle brace is the soft brace. Although lace-up braces are sometimes called soft braces as well, in our definition the soft brace is an ankle brace based on the principles of functional ankle taping. The use of a soft brace in the early stage of ankle sprain treatment is not common. However, as ankle tape has been shown to be an effective treatment method, the use of a soft ankle brace based on the same principles, i.e. the principles of the Coumans tape bandage, seems a reasonable treatment option[26]. In **Chapter 4** the effectiveness of a four-week treatment with a soft ankle brace is compared to a four-week treatment of ankle taping. If the use of a soft ankle brace is comparable to treatment with ankle tape in terms of ankle sprain recurrences and residual complaints, differences in patient burden (braces are more easily applied) and cost are more important. The least expensive treatment method might become the leading choice of ankle sprain treatment. In a review of Lin et al. (2012), studies comparing the cost-effectiveness of ankle brace treatment with other treatments, such as compression bandage and a plaster cast, were critically assessed[22]. The number of the studies was limited and this, in combination with the heterogeneity of the studies, precluded any conclusion regarding the cost-effectiveness. **Chapter 5** describes the results of a cost analysis of soft bracing and taping and an economic evaluation of treatment.

Stage 4: Rehabilitation

After treatment of the ankle sprain, the rehabilitation stage begins. The rehabilitation stage ends with a return to daily life activity and/or sports. The long-term outcome after an ankle sprain is often unfavorable and some patients will not reach full

recovery after an ankle sprain. Recovery rates within three years after an ankle sprain range from 36% up to 85% of the patients[29]. Recurrent sprains and residual symptoms, such as pain, swelling, ankle instability, and impingement syndromes, after an acute lateral ankle sprain can have a large impact on a patient's life. Even after years, the discomfort and lack of trust in the injured ankle causes patients to make sacrifices, particularly in their sports performance level[21]. The current information about long-term consequences of an acute lateral ankle sprain is derived from studies comparing surgical and functional treatment to treatment involving immobilization. Nowadays functional treatment after acute lateral ankle sprains is recommended as the treatment of first choice. Information about long-term consequences of acute lateral ankle sprains derived from a study comparing different functional treatment methods is missing. Furthermore, no long-term information about patients from the population at large is available, as several studies with long-term follow-up included athletes only. **Chapter 6** gives more insight into the long-term consequences in terms of recurrent sprains and residual symptoms of functionally treated acute lateral ankle sprain in our population at large.

Stage 5: Return to sports or daily life activity or full recovery → prevention

Once patients have fully recovered, they can restart the daily activities they were engaged in or return to sports. Regularly athletes start even sooner. To prevent the occurrence of a new ankle sprain, the use of injury-prevention measures is advisable. Evidence suggests that the preventive effect of measures like taping and bracing is especially strong in previously injured athletes[34]. A previous lateral ankle sprain is one of the most important risk factors for sustaining a new ankle sprain[1,7]. The identification of people who are more at risk for sustaining a recurrent sprain is useful because the occurrence of a recurrent ankle sprain has great impact on daily functioning and sports participation. Information about risk factors for recurrences would yield important input for directing recommendations and preventive strategies. Only two studies have identified risk factors for recurrent acute lateral ankle sprains. Pre-injury activity level[11] and the grade of initial injury[24] are both related to a higher risk for ankle sprain recurrences. In **Chapter 7** determinants of recurrent acute lateral ankle sprain are studied among our study population which includes athletes and non-athletes.

According to the guideline of the Dutch College of General Practitioners[27], sports participants are advised to use an ankle brace after recovery while engaging in sports to prevent recurrences. The use of an ankle brace is not the only known effective preventive measure. According to Verhagen and Bay (2010), taping and neuromuscular

training are also effective[34]. They concluded that (in theory) a combination of an external prophylactic measure (tape or brace) with neuromuscular training will achieve the best preventive outcomes with minimal burden for the athlete. In a recent study Janssen et al. (2014) evaluated the effectiveness of combined bracing and neuromuscular training, or bracing alone, against the use of neuromuscular training on recurrences of ankle sprain after usual care[14]. Bracing was better than neuromuscular training at reducing the incidence of recurrent ankle sprain (relative risk derived from Cox Regression 0.53; 95% CI 0.29 to 0.97) and also lower, but not significantly different for the combi group versus the training group (relative risk 0.71; 95% CI 0.41 to 1.23). No significant differences were found for time losses or costs due to ankle sprains between the intervention groups.

The availability of injury-prevention measures is usually not enough to convince athletes to use them[8,35]. To establish successful behavior modification in athletes, implementation of the effective preventive measures into sports practices is necessary. In **Chapter 8** the complete process of the development and implementation of an effective behavior-change intervention regarding ankle injury prevention is described.

Finally, **Chapter 9** contains the general discussion of this thesis, including recommendations for e.g. the injured person, the (non-)health care professional, the policy maker and the scientist as well as proposals for further research.

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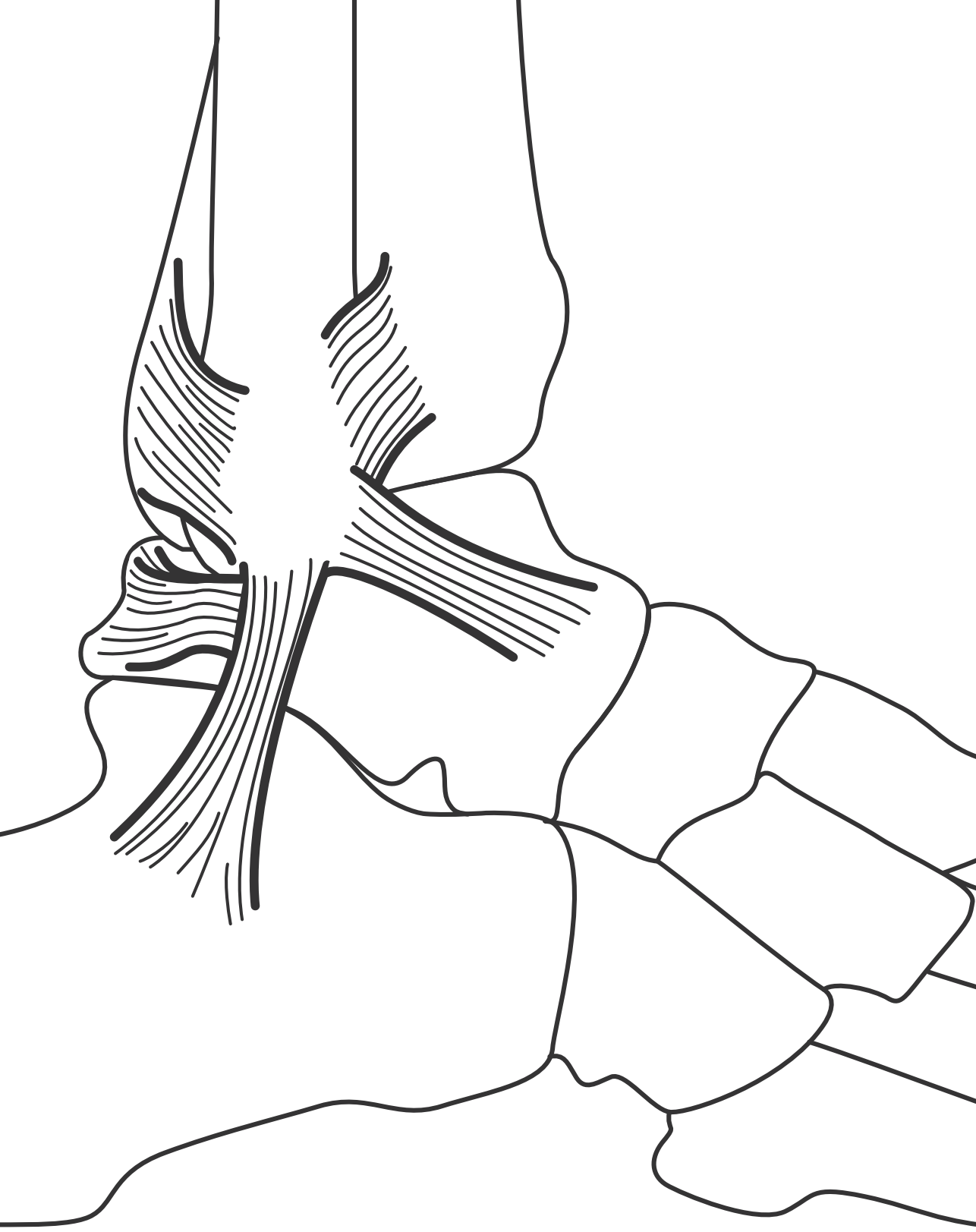

Chapter 2

Ankle injuries in the Netherlands: Trends over 10-25 years

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ABSTRACT

Ankle injuries are a common health problem; data on ankle injury rates and time trends in the population at large are scarce. Our aim was to investigate the incidence of and time trends in population-based and emergency department treated ankle injuries related to sports activities and other activities related to daily living.

Data were obtained from one national survey on accidents and injuries (2000–2010) and one based on emergency department data (1986–2010). Linear regression was used to determine linear trends in ankle injuries per 1,000 person-years.

The number of ankle injuries related to sports activities and other activities of daily living increased from 19.0 to 26.6 per 1,000 person-years ($p = 0.002$). The number of sports-related ankle injuries treated in emergency departments decreased from 4.2 to 1.5 per 1,000 person-years ($p < 0.001$), and from 3.2 to 2.1 per 1,000 person-years ($p < 0.001$) for other activities of daily living.

According to our data, the incidence rates of all ankle injuries are around 5.5 times higher than those registered at emergency departments. The high incidence rates of ankle injuries highlight the need for proper ankle injury treatment and prevention.

INTRODUCTION

Ankle injuries, especially ankle sprains, are a common health problem. The severity of acute ankle sprains can vary widely. They often result in persistent pain, limitations in movement, muscle weakness, swelling, stiffness, and absenteeism from work and/or sports participation[3,5,7,11,23,27,28]. Re-injuries and chronic ankle instability also can result from acute ankle sprains[17,24].
The incidence of acute ankle sprains has been studied in several athletic cohorts[4,9,13,15,25]. Information about ankle injury rates and their time trends in the general population is more scarce. A Danish emergency department (ED) study in the Hillerød County recorded an overall incidence of 7.0/1,000 ankle and foot sprains per person-years in 1994[10]. Nine years later an UK ED study estimated an incidence of only ankle sprains of 5.3/1,000 person-years[2]. An American ED study found an incidence of 2.2 ankle sprains per 1,000 person-years[26].

ED studies, while important, probably only represent the tip of the iceberg in terms of the impact of acute ankle injuries. Population-based incidence rates of medically and non-medically treated ankle injuries give a more complete picture. Examining changes over time gives more information than ED studies alone and can guide ankle injury prevention. By analyzing long-term ankle injury trends, it is possible to monitor the results of injury prevention and intervention strategies, or to discover new developments in injury trends. Population-based incidence rates of medically and non-medically treated ankle injuries are not available. Long-term trends (> 5 years) in ankle injuries or ankle sprains are neither available.

The purpose of this study was to investigate the incidence of and time trends in population-based and ED treated ankle injuries. The ankle injuries studied are related to sports activities and other activities in daily living.

METHODS AND MATERIALS

Surveys

Data were obtained from two national surveys, namely Injuries and Physical Activity in the Netherlands (IPAN), and the Dutch Injury Surveillance System (DISS).

Injuries and Physical Activity in the Netherlands

Injuries and Physical Activity in the Netherlands (IPAN) is a survey that registers data on both medically and non-medically treated injuries (Table 1), sports participation, and physical activity[18]. Medically treated injuries are injuries diagnosed and/or treated by any of the following persons involved in health care: general practitioner (GP), medical specialist, sports physician, dentist, physical therapist, occupational physician and ambulance personnel, or treatment in a hospital's ED. In case of non-medically treated injuries, patients did not seek medical or paramedical treatment for their injuries.

Over the period 2000–2010, data were registered on a daily basis throughout the year. A total of about 11,000 people were questioned each year. Between 2000 and 2006, respondents were interviewed by means of random digit dialing. A random number, based on the number of persons in a family, was chosen by a computer to select only one family member for the interview. Proxy interviews were held if the family members chosen were younger than 12 years.

Table 1: Characteristics of IPAN and DISS

Characteristic	*IPAN*	*DISS*
Injuries sustained during	Sports, other activities of daily living, Traffic participation*, Work*, Violence*	Sports, other activities of daily living, Traffic participation*, Work*, Violence*
Period	Between 2000 and 2011	Between 1986 and 2011
Target population	Dutch population (no age limitations)	Dutch population (no age limitations)
Recall period	3.5 months	None
Sample	Telephone and online interviews (n = ±11,000 per year)	Cases at emergency departments of 12 Dutch hospitals (n= ± 97,500 per year)
Subjective/objective data	Subjective	Objective
Healthcare professional	All	ED
Injury type	Medically and non-medically# treated injuries	Medically treated injuries (ED)

*Excluded from the analysis

Patients did not seek medical or paramedical treatment for their injuries

In 2006, all respondents were members of InterviewBase, a database containing the details of approximately 230,000 Dutch people who are willing to participate in research. New respondents are continuously recruited by means of either random digit dialing or the internet (invitation to join the InterviewBase in website banners which can be put on 70,000 different active websites). Children aged 0–11 years are interviewed by proxy; all information is gathered by interviewing their parents by telephone. Children aged 12–14 years and people aged 65 years or older are interviewed by telephone. Respondents aged 15–64 years are questioned online.

In IPAN, no definition of an injury was given to the respondents in advance. One question was used and had to be answered positively to identify reported injuries: "*Have you had any injuries in the past three months? Overuse injuries and less severe injuries should be taken into account*". In this study the incidence of and time trends in population-based ankle injuries related to sports activities and other activities of daily living were studied. The following question was used to identify sports injuries: "*Did you sustain this injury during sports participation?*" The self-reported sports injury data were checked by one of the researchers (EK) to establish whether they were in accordance with the following definition of a sports injury: "physical damage of a musculoskeletal nature as a result of a sudden event during a sports activity or as a result of a gradual process related to sports activity" (Schmikli et al., 2009); if so, they were included in the database. Injuries were classified as injuries resulting from other activities of daily living if they did not occur while participating in traffic, at work or during sports activities. Examples of accidents occurring in other activities of daily living are those that occur in and around the house, in public buildings, while playing or walking on pavements and streets (excludes participating in traffic), and while spending leisure time (excludes participating in sports). Injuries are considered ankle injuries when the body location "ankle" is indicated by the respondent. Ankle injuries can be sprains, fractures, muscular/tendon injuries, traumatic amputations, cartilage problems, overuse injuries, superficial injuries (scratches, bruises), open wounds or dislocations. An ankle sprain is defined as a rupture or stretching of the ankle ligament(s). Finally, to gain more insight into the sports participation, the total hours of sports participation per week are registered for every sports participant.

Information about the cause of injury, the injured body part(s), type of injury and sports participation is provided by the respondents themselves. Sampling has been done on the basis of social-demographic quota. To correct for different non-

response within these quota groups, the data is also synchronized with the Dutch population by weighting the survey data. Weighting has been done for age, gender, level of education, household size, employment, urbanity and living region, using the Random Iterative Method (RIM weighting method[19]).

Dutch Injury Surveillance System

Since 1986, the Dutch Injury Surveillance System (DISS) has registered injuries treated at the EDs of a representative sample of hospitals in the Netherlands (Table 1). The annual totals of registered patients range from approximately 71,000 (1986) to approximately 140,000 (1999), with an average of 97,500 per year. For this study, data from the period 1986–2010 were used.

At all times, a random representative sample of twelve general and university hospitals in the Netherlands participates in DISS. Both general and university hospitals have the same local referral function. In addition, university hospitals do have an education function and are sometimes more specialized in treatment of severe injuries like brain injuries, organ injuries and spinal cord injuries. The random sample can be used to make reliable estimates of the total number of cases treated in EDs throughout the Netherlands as a result of injuries.

Injury diagnoses and injury mechanisms are registered according to a modified version of the International Classification of Diseases of the World Health Organization (ICD 10th revision). The information is registered by an ED nurse or physician. In DISS, "sports" is defined as a physical activity in which performing is considered important. The definition of injuries resulting from other activities of daily living in DISS is the same as that used in IPAN.

The registration method of DISS and the definitions used have not changed since the first registration in 1986. Injuries are considered ankle injuries when the body location "ankle" is indicated by the ED nurse or physician. It is also possible to differentiate between several injury types, such as sprains and fractures. An ankle sprain is defined as a rupture or stretching of the ankle ligament(s). As the sprain is the most common ankle injury type, a sub-analysis with DISS data was made for this injury type when establishing the incidence rates.

Statistical Analysis

In IPAN, eleven one-year incidence rates were calculated for all ankle injuries related to sports activities and other activities of daily living treated by physiotherapists or GPs. Ankle injury rates according to gender or age were also calculated. Due to the change of the research method on 1 January 2006, injury rates in the Netherlands

according to IPAN increased considerably. To adjust for this, we estimated the gap in the trends between 2005 and 2006 by performing regression analyses on the annual rates. Two separate trend lines for the periods 2000–05 and 2006–10, and a dummy variable for the gap between 2005 and 2006 were used as model variables. The figures in 2000–05 were subsequently multiplied by a factor based on the estimated difference between the two separate trend lines.

In DISS, 25 one-year rates were calculated for all ankle injuries related to sports activities and other activities of daily living. Twenty-five one-year rates were calculated separately for ankle sprains.
Incidence rates per year are expressed as the number of ankle injuries per 1,000 person-years at risk and are calculated as the estimated number of ankle injuries in the Netherlands in one year divided by person-years at risk in the Netherlands at that time. By using incidence rates relative to 1,000 person-years at risk, we corrected for population growth. Data on the size of the Dutch population were available from the Netherlands' Central Bureau of Statistics.
We also analyzed incidence rates per 1,000 hours of sports participation. For this, the estimated number of ankle injuries per year was divided by the estimated total number of hours of sports participation based on the measurement in IPAN.
Finally, linear regression was used to determine linear trends in ankle injuries and ankle sprains per 1,000 person-years at risk and per 1,000 hours of sports participation. A p-value <.05 was considered statistically significant.

RESULTS

IPAN

According to IPAN, 600,000 ankle injuries (sprains, fractures, contusions, bruises, etc.) occurred in the Netherlands during sports and other activities of daily living in the year 2000. In the following ten years, the total number of ankle injuries increased, to reach 910,000 in 2010. Trend analyses showed an increase from 8.2 to 17.5 ankle injuries per 1,000 person-years in 2000-2010 ($p < 0.001$) (Figure 1). The number of ankle injuries related to sports also increased in this period, namely from 29.6 to 37.5 ankle injuries per 1,000 person-years ($p = 0.001$). When the increase in sports participation was taken into account, there was no longer a statistically significant increase in ankle injuries (i.e. 0.34 ankle injuries per 1,000 person-years in both 2000 and 2010).

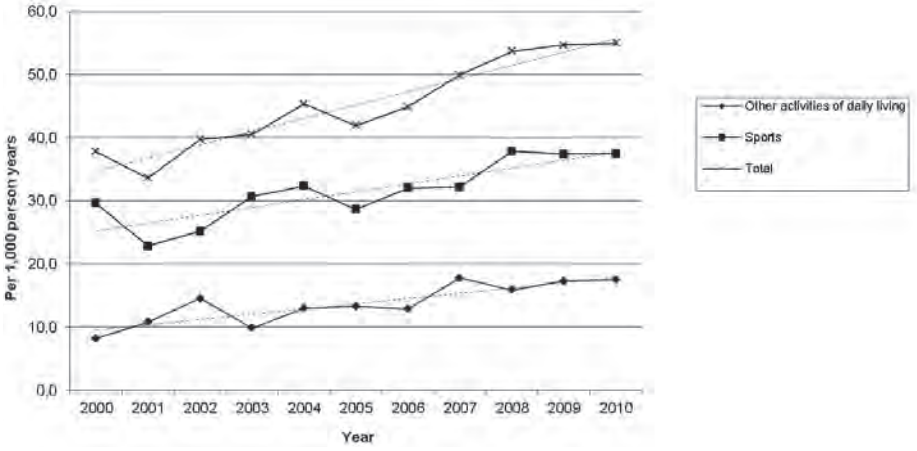

Figure 1: Ankle injuries during sport and other activities of daily living per 1,000 person-years in the Netherlands, 2000–2010

Source: IPAN 2000-2010

Medical treatment

About half of all ankle injuries in IPAN were medically treated. The total number of medically treated ankle injuries increased from 19.0 to 26.6 per 1,000 person-years between 2000 and 2010 (Figure 2; p = 0.002). Most ankle injuries were treated by GPs and physiotherapists; only a minority of all ankle injuries were presented at EDs. Treatment by GPs increased over time (p = 0.005), whereas treatment by physiotherapists decreased slightly, albeit not statistically significantly over the years (Figure 2).

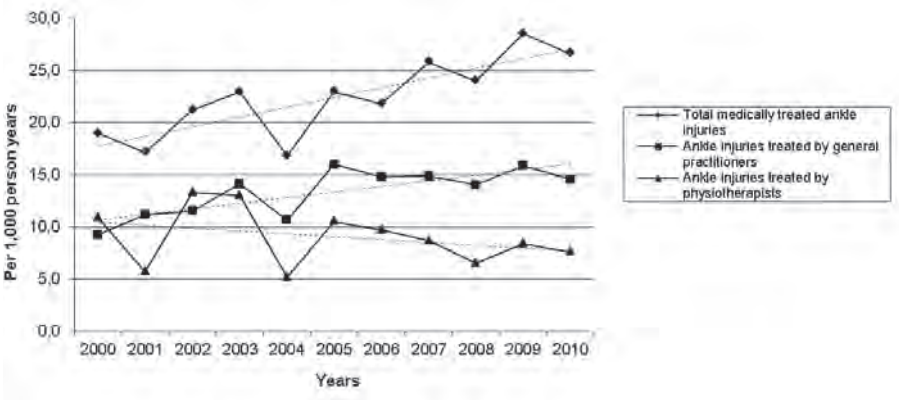

Figure 2: Medically treated ankle injuries during sport and other activities of daily living per 1,000 person-years in the Netherlands, 2000–2010

Source: IPAN 2000-2010

Gender and age

In IPAN, ankle injury trends for both men and women increased significantly between 2000 and 2010 ($p = 0.015$ and $p < 0.001$, respectively) (Figure 3). Ankle injury trends differed among the fixed age categories in IPAN. Ankle injury incidence increased only among those aged 15–24 years ($p < 0.001$) (Figure 4), while the incidence in the age groups 0–14 years, 25–54 years and 55 years or older remained stable.

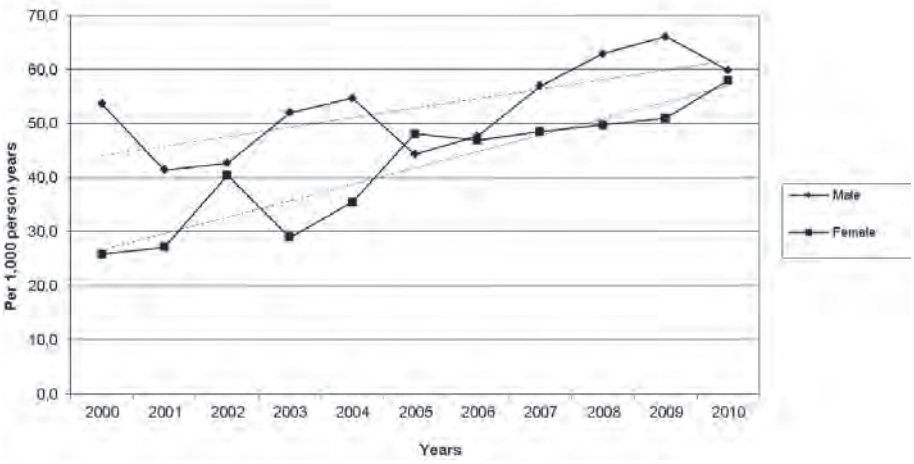

Figure 3: Ankle injuries during sport and other activities of daily living in the Netherlands according to gender, 2000–2010

Source: IPAN 2000-2010

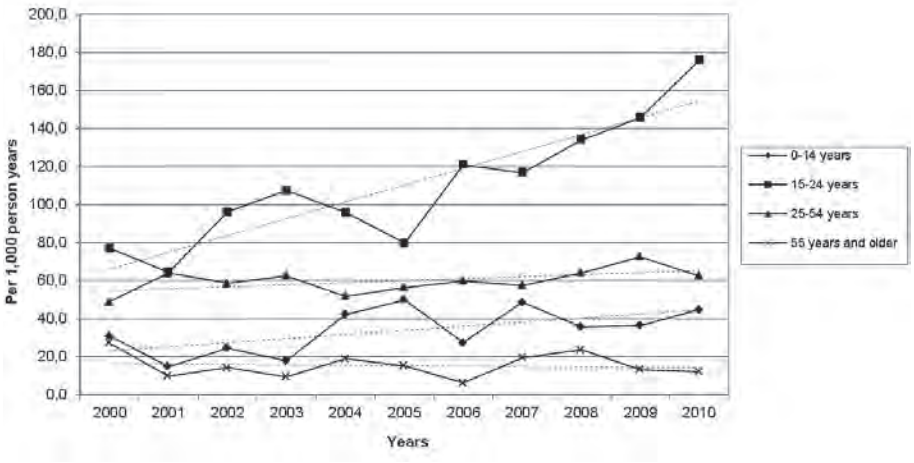

Figure 4: Ankle injuries during sport and other activities of daily living in the Netherlands according to age category, 2000–2010

Source: IPAN 2000-2010

DISS

In 1986, Dutch EDs recorded about 61,000 ankle injuries (43,800 sprains) related to sports participation, and about 46,500 ankle injuries (28,500 sprains) related to other activities of daily living. During the 25-year follow up, the total number of sports-related ankle injuries treated at EDs significantly decreased from 4.2 to 1.5 ankle injuries per 1,000 person-years ($p < 0.001$), as shown in Figure 5. Injuries related to other activities of daily lining decreased from 3.2 to 2.1 ankle injuries per 1,000 person-years ($p < 0.001$). For the most common type of ankle injury – the ankle sprain – a similar downward trend was found (Figure 5). The total number of ankle sprains related to sports participation and treated at EDs significantly decreased from 3.0 to 0.9 ankle sprains per 1,000 person-years ($p < 0.001$). The number of ankle sprains related to other activities of daily living decreased from 2.0 to 1.0 ankle injuries per 1,000 person-years ($p < 0.001$).

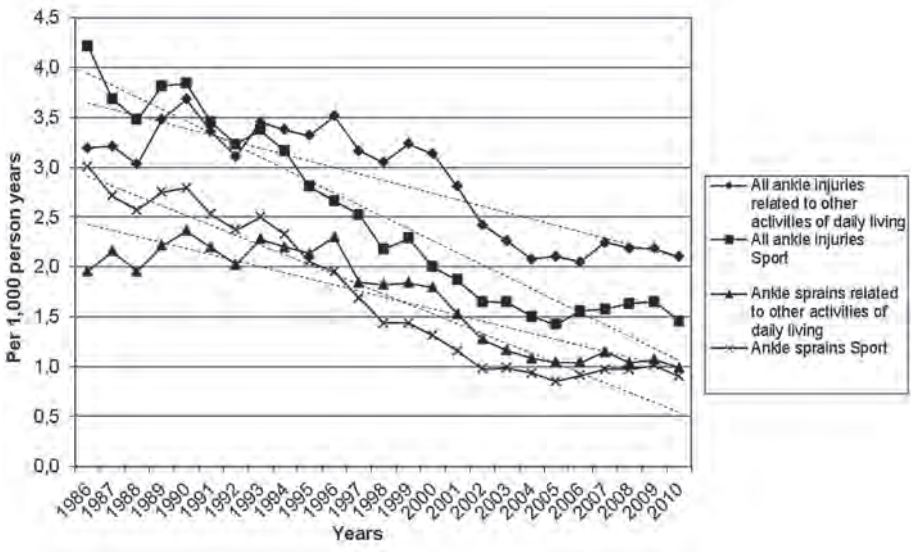

Figure 5: Trends in ankle injuries and ankle sprains sustained during sport and other activities of daily living treated at EDs, the Netherlands, and 1986–2010

Source: DISS 1986-2010

DISCUSSION

Our study investigated the nationwide, long-term incidence rates of ankle injuries related to both sports activities and other activities of daily living in the Netherlands. Trend analyses showed that in the period 2000–10, the incidence of population based

ankle injuries increased considerably from 19.0 to 26.6 per 1,000 person-years. The incidence of ankle injuries related to sports activities treated in EDs decreased from 4.2 to 1.5 ankle injuries per 1,000 person-years. The incidence of ankle injuries related to other activities of daily living treated in EDs decreased from 3.2 to 2.1 ankle injuries per 1,000 person-years.

The ED incidence rates found in our study are similar to other rates reported in the literature. The previously reported incidence rates ranged from 2.2 sprained ankles per 1,000 person-years in the USA[26] to 5.3–7.0 sprained ankles per 1,000 person-years in Europe[2,10]. Although incidence rates are similar, financial barriers to seeking care for ankle sprain are different. In the Netherlands, due the nationalized healthcare system there is no or only a small financial barrier to seeking care for ankle sprain, in contrast with Waterman Waterman et al. (2010)[26] in the US.

In the international literature, typically only data on ankle injuries presented at EDs have been published. According to our data, the incidence rates of all medically and non-medically treated ankle injuries are around 5.5 times higher than those registered at EDs. Only half of all ankle injuries in the Netherlands are treated by medical professionals, most often by GPs and physiotherapists. The worldwide problem of ankle injuries is greater than assumed on the basis of ED studies[2,10,26].
Our study showed that overall ankle injuries rates are increasing, while the number of ankle injuries treated in hospital EDs is decreasing over time. There are a number of possible reasons for this phenomenon. It might be that other healthcare professionals have become more important in the treatment of ankle injuries. The introduction of the Ottawa Ankle Rules[20] in primary care might have reduced the number of visits that patients make to EDs. The Ottawa Ankle Rules help decide whether a patient with foot or ankle pain should be X-rayed to diagnose a fracture. Most patients with ankle injuries were X-rayed in hospitals before the introduction of the rules[20].
A second explanation for the decrease in ED-treated ankle injuries might be the introduction in the early 1990s of functional treatment[14]. In accordance with Dutch guidelines for GPs[16] and the Dutch health care Policy for ankle sprain treatment, treatment of ankle injuries with ankle tape or elastic bandages became more common. Referral to the more expensive emergency and hospital care for surgery or plaster cast immobilization became unusual. Patients with acute ankle injuries may choose to visit their GPs or physiotherapists instead of EDs.

The absolute number of ankle injuries due to sport increased over time. When the concurrent increase in the amount of sports participation is adjusted for there is no increase in the incidence per hour of sports done. It is conceivable that had it been possible to take into account physical activity during other activities of daily living, the results would also have shown no significant increase in the incidence of ankle injuries related to such activities. From 2000 to 2011, the absolute length of time spent on physical activity increased from 169 to 202 minutes a day for adults in the Netherlands[8]. Physical activity included sports activities, activities at home (e.g. house cleaning, gardening), grocery shopping, walking, and bicycling. The increase was caused by an increase in light and moderate intensity activities, in particular activities at work/school and at home[8]. For youths aged between 12 and 17 years, there was an increase in physical activity from 117 to 135 minutes between 2006 and 2011. This increase was mainly caused by an increase in activities at school[8]. Being more active might have increased the injuries related to other activities of daily living. A reliable registration of ankle injuries and physical activity and sports participation is necessary to place increasing ankle injury trends in perspective. A proper registration of the level of competition and the intensity level may generate more in-depth information on low ankle injury risk and high ankle injury risk activities in sports.

A limitation of our study is that IPAN is characterized by a design involving a survey with a 3.5-month recall period. Exposure (retrospective) and outcome were assessed at the same time and might have been influenced by the recall period. The information in IPAN is self-reported. Self-reporting is one of the most commonly used methods of collecting injury data and other research data. The validity of self-reported data has been well examined. Acceptable to good levels of agreement between self-reported and more objective data have been demonstrated. In particular in relation to details such as the nature and body part injured, and the level of injury treatment sought (kappa=0.48 to 0.78)[22]. Adolescents' self-report of recent recreational injury treatment in the preceding week has also shown to be reliable[6].

Enhancement of the reliability and validity of the IPAN-data, was done by instructing the interviewers extensively. The self-reported injury data were checked by a researcher, and the identity of the selected respondent (InterviewBase member) for online questionnaires was verified. Despite the above measures there is still a risk of bias in the self-reported injury data. We therefore only used IPAN for general injury information.

In DISS injury diagnoses and mechanisms for every patient are registered by an ED nurse or physician using a modified version of the International Classification of Diseases of the World Health Organization (ICD 10th revision). The Consumer Safety Institute evaluated the quality of DISS data in 2001. They concluded that DISS gave a reliable overview of treatments at EDs (Consument en Veiligheid, 2001; no English abstract available). As healthcare professionals diagnose and register the injuries, we assume the validity and reliability are acceptable.

PERSPECTIVE

Our study shows that ED studies of ankle injury incidence[2,10,26] underestimate the actual incidence at a population level. According to our data, the incidence rates of all medically and non-medically treated ankle injuries are around 5.5 times higher than those registered at EDs. Half of all ankle injuries in the Netherlands are medically treated, most often by GPs and physiotherapists. It is important to note that trends in ankle injuries treated at EDs are thus not comparable to population-based ankle injury trends. Ankle injury trends at EDs in our study are decreasing while population-based ankle injury trends are increasing.

Trends in ankle injury rates can guide ankle injury policy and identify specific target groups for ankle injury prevention. Primary healthcare professionals are now more important in the treatment of ankle injuries. They should become more familiar with the symptoms of ankle injuries and the treatment methods that can be used to reduce the risk of re-injury and residual symptoms.

Especially men and women aged 15–24 years should be the subject of ankle injury prevention interventions and campaigns. The population at risk for ankle injuries contains both athletes and non-athletes. Ankle injury prevention programs should therefore be "population-wide". Hupperets et al. (2009) developed an eight week home based proprioceptive training program to reduce recurrences of ankle sprains[12]. This program was effective for the prevention of self-reported recurrences in athletes. We recommend making available and evaluating programs like this in the whole population at risk. A more reliable registration of physical activity and sports participation is necessary in order to place increasing ankle injury trends in perspective.

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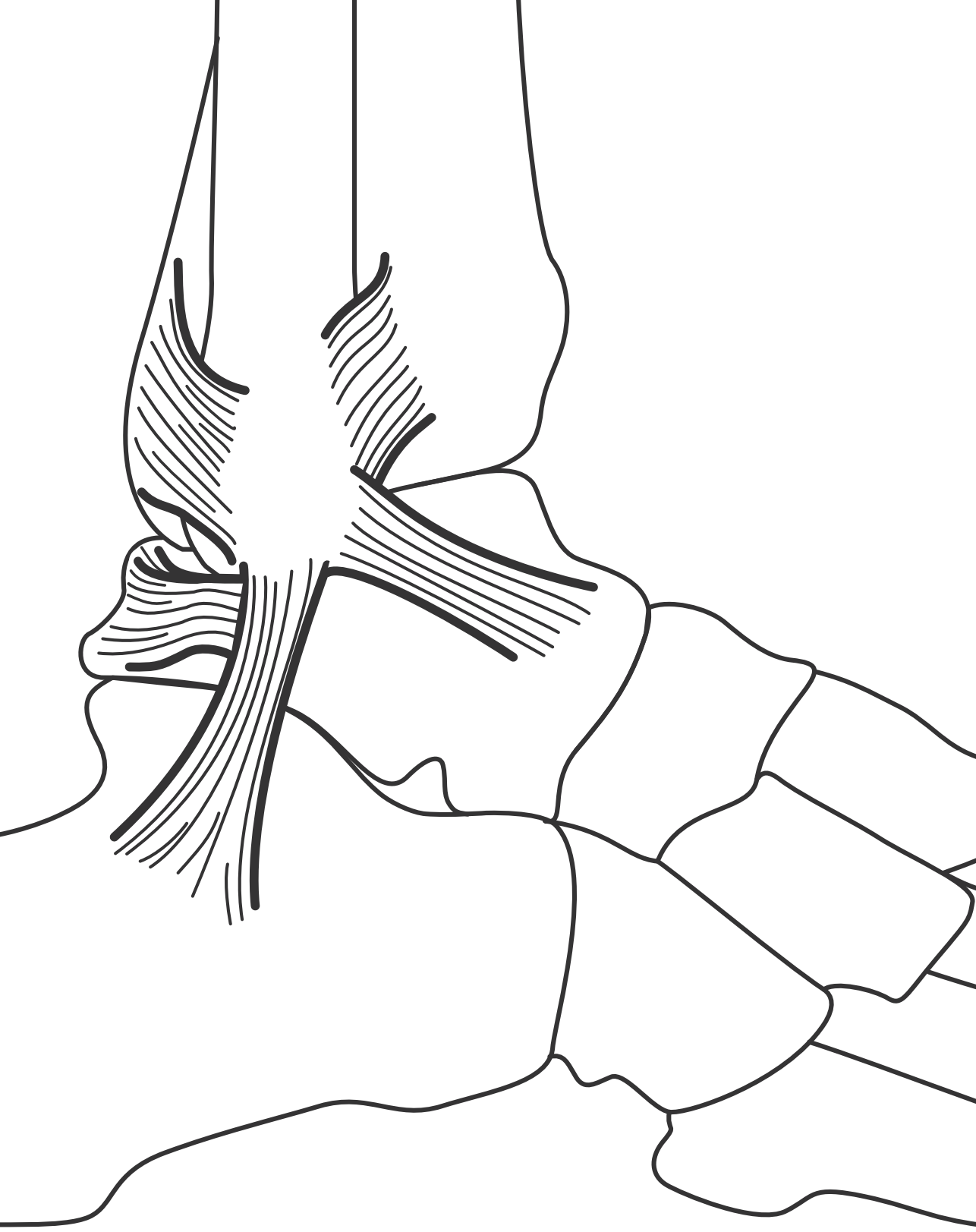

Chapter 3

A systematic review on the treatment of acute ankle sprains: Brace versus other functional treatment types

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ABSTRACT

Ankle injuries, especially ankle sprains, are a common problem in sports and medical care. Ankle sprains result in pain and absenteeism from work and/or sports participation, and can lead to physical restrictions such as ankle instability. Nowadays, treatment of ankle injury basically consists of taping the ankle. The purpose of this review is to evaluate the effectiveness of ankle braces as a treatment for acute ankle sprains compared with other types of functional treatment such as ankle tape and elastic bandages.

A computerized literature search was conducted using PubMed, EMBASE, CINAHL and the Cochrane Clinical Trial Register. This review includes randomized controlled trials in English, German and Dutch, published between 1990 and April 2009 that compared ankle braces as a treatment for lateral ankle sprains with other functional treatments. The inclusion criteria for this systematic review were (i) individuals (sports participants as well as non-sports participants) with an acute injury of the ankle (acute ankle sprains); (ii) use of an ankle brace as primary treatment for acute ankle sprains; (iii) control interventions including any other type of functional treatment (e.g. Tubigrip™, elastic wrap or ankle tape); and (iv) one of the following reported outcome measures: re-injuries, residual symptoms (pain, swelling, instability), functional outcomes and/or time to resumption of sports, daily activities and/or work. Eight studies met all inclusion criteria. Differences in outcome measures, intervention types and patient characteristics precluded pooling of the results, so best evidence syntheses were conducted. A few individual studies reported positive outcomes after treatment with an ankle brace compared with other functional methods, but our best evidence syntheses only demonstrated a better treatment result in terms of functional outcome. Other studies have suggested that ankle brace treatment is a more cost-effective method, so the use of braces after acute ankle sprains should be considered. Further research should focus on economic evaluation and on different types of ankle brace, to examine the strengths and weaknesses of ankle braces for the treatment of acute ankle sprains.

INTRODUCTION

The ankle is one of the most frequently traumatized body sites and accounts for 10–30% of all sports injuries[17]. Between 2000 and 2004, 18% of all sports injuries in the Netherlands were ankle injuries[54]. As a rough estimate, one inversion ankle injury occurs per 10,000 people each day, resulting in about 5,000 injuries a day in the UK and 23,000 in the US[8,42,52]. Most ankle injuries occurring in sports involve lateral ankle ligaments, and 77% represent ankle sprains[17].
The severity of acute ankle sprains can vary widely, and can be classified in a number of ways. Grading can be based on anatomical damage, clinical presentation, mechanism of trauma, 'severity' of the injury or a combination of these aspects[41]. The most frequently used terms to express severity are mild, moderate and severe, known as grade I, grade II and grade III, respectively[50]. Despite the difficulty of quantifying severity, the consequences of ankle sprains are often clear and can have great impact. Ankle sprains can cause pain and other impairments, resulting in utilization of healthcare resources and absenteeism from work and/or sports. In the Netherlands, Verhagen et al.[65] calculated that the mean total costs (direct and indirect) of one ankle sprain are approximately €360. All ankle sprains in the Netherlands cost about €43.2 million a year, with absence from paid or unpaid work responsible for up to 80% of these costs[65].

In addition to acute restrictions, ankle sprains can lead to chronic physical restrictions such as ankle instability. Chronic ankle instability not only limits physical activity, but can also lead to articular degeneration of the ankle joint and an increased risk of osteoarthritis[20,33]. According to Hubbard and Hicks-Little[22], up to 30% of patients show objective mechanical laxity and subjective instability up to 1 year after an initial ankle sprain. Another common long-term side effect of ankle sprain is re-injury. Ekstrand and Gilquist[16] and Tropp et al.[59] found that people who have suffered an ankle sprain are more likely to injure the same ankle again. The risk of re-sprain within a period of 3 years after the initial ankle sprain ranges from 3% to 34%[51]. Residual complaints after an ankle sprain range from 6% to 78% after 8 months to 3 years of follow-up [4,7,9,21,32,47,53,68].

In the past, a variety of treatments for ankle sprains have been used, including surgical repair, plaster cast or splint immobilization and functional treatment, consisting of an early mobilization program frequently combined with the use of an elastic bandage

or brace. Kannus and Renström[26] were among the first to conclude that functional treatment should be the preferred method in cases of complete lateral ankle ligament rupture. Their findings have been corroborated by several other researchers[24,29]. Kerkhoffs et al. assessed the effectiveness of various immobilization methods for acute ankle sprains and compared them with alternative conservative treatments[29]. They found statistically significant differences for six outcome measures (return to sports, return to work, persistent swelling, objective instability, range of motion and patient satisfaction), all in favor of functional treatment compared with cast immobilization[29]. They concluded that functional treatment seems to be a more appropriate approach and should be encouraged. In 2002, Kerkhoffs et al.[30] assessed the effectiveness of various functional treatment strategies for acute lateral ankle ligament injuries in adults. Their findings did not enable them to indicate the most effective treatment, although a lace-up brace or a semi-rigid brace gave better results in terms of reduction of swelling and speed of recovery than bandage alone.

The PRICE (Protection, Rest, Ice, Compression, Elevation) treatment protocol is commonly used for acute ankle sprain[58]. The Dutch College of General Practitioners guideline for the treatment of ankle injuries recommends treatment consisting of immobilization, compression and elevation (ICE) during the first week, followed by ankle taping for six weeks. Thereafter, sports participants are advised to use an ankle brace while engaging in sports to prevent recurrences[45].
Ankle sprains are very commonly treated with ankle tape. According to the results of previous studies, functional treatment is most effective in acute ankle sprain injuries[29]. Another type of functional therapy might be the use of an ankle brace. It is well known that an ankle brace effectively prevents recurrence of ankle sprains[18,64]. Despite convincing results on prevention, however, braces are rarely used in an earlier stage as a treatment for ankle sprains. Although some studies have investigated the use of braces in the acute stage after injury, none have systematically evaluated whether the use of an ankle brace is a more appropriate treatment for ankle sprains than other forms of protection during functional treatment. The purpose of this review is to evaluate the effectiveness of ankle braces as a treatment method for acute ankle sprains compared with other types of functional treatment (e.g. ankle tape, Tubigrip™).

METHODS

Literature Search

A computerized literature search was conducted using PubMed, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Clinical Trial Register (CCTR). Randomized controlled trials (RCTs) in English, German and Dutch, published between 1990 and April 2009 that compared ankle braces as a treatment for ankle sprains with other functional treatments were included in this review. Inclusion from 1990 onwards was chosen because functional treatment (tape, bandage or brace) of ankle sprains had been recommended since the early 1990s[26]. Keywords used in this search were 'ankle brace', 'random', 'ankle injury', 'treatment', 'ankle sprain', 'ankle trauma' and 'inversion ankle injury'. MeSH terms were 'clinical trials' and 'random allocation', and the MeSH subheading used was 'therapeutic use'. The methodological filter used in PubMed was therapy, broad sensitive search. In addition, reference lists of included articles were reviewed for potentially valid studies. The complete search strategy is available from the authors. Studies were selected by two reviewers (EK and IP) on the basis of title and abstract.

The following criteria for inclusion in this systematic review were used to select randomized or quasi-randomized clinical trials: (i) individuals (sports participants as well as non-sports participants) with an acute injury of the ankle; (ii) use of an ankle brace as a primary treatment for acute ankle sprains; (iii) control intervention including any other type of functional treatment (e.g. Tubigrip™, elastic wrap or ankle tape); and (iv) one of the following reported outcome measures: re-injuries, residual complaints (pain, swelling, instability), functional outcomes and/or time to resumption of sports, daily activities and/or work.

An acute ankle injury was considered an acute ankle sprain, which was defined as a joint injury in which some of the fibers of a supporting ligament are ruptured but the continuity of the ligament remains intact (MeSH). The cause of the injury needed to be acute, which implies a clear onset of injury as a result of trauma (e.g. from tackling, kicking or jumping). Trials aimed at the treatment of, for example, chronic ankle instability or ankle fractures were excluded. The control intervention included functional treatment, which was defined as treatment consisting of therapy (supervised or unsupervised) during which the patients conduct functional exercises with the ankle, such as flexion/extension (against resistance) and walking. While

conducting the exercises, the patients can wear Tubigrip™, elastic wrap or ankle tape, but no ankle brace. Studies comparing treatment with an ankle brace solely with cast immobilization were excluded and no restrictions were used for the follow-up period. A brace was defined as an orthopedic appliance used to support, align or hold a bodily part (i.e. the ankle) in the correct position[12].
The methodological quality of each study was assessed by two reviewers (EK and IP) using the PEDro scale[55] (Table 1). The PEDro scale is an 11-item scale designed to rate the methodological quality of RCTs, and is sufficiently reliable for use in systematic reviews[40]. The PEDro scale is used to identify the external (item 1) and internal validity (criteria 2–9), and the amount of statistical information provided to make the results interpretable (criteria 10–11). The maximum score for the PEDro scale is 10 points, since item 1 is not included in the calculation of the total PEDro score.

In case of disagreement between the two reviewers, consensus was achieved by discussion. Studies with 4 points or more on the PEDro scale are considered to be of high methodological quality, while those with 3 points or less are considered to be of low quality[47]. Kappa was used to measure the agreement between the two reviewers. When agreement is perfect, Kappa is 1.00. The interpretation of the other values is as follows: (i) <0.20 poor strength of agreement; (ii) 0.21–0.40 fair strength of agreement; (iii) 0.41–0.60 moderate strength of agreement; (iv) 0.61–0.80 good strength of agreement; and (v) 0.81–1.00 very good strength of agreement[2].

Data Extraction and Analysis

Data on all relevant outcome measures were extracted by one reviewer (EK). If possible, results of comparable studies were pooled; otherwise, a best evidence synthesis was prepared. The level of evidence was determined using the best evidence synthesis criteria proposed by Steultjens et al.,[57] based on the methodological quality score on the PEDro scale[47]. Steultjens et al.[57] modified the criteria proposed by Van Tulder et al.[61]

Table 1: The PEDro scale[55a]

Criteria	Yes	No
1. Eligibility criteria were specified	1	0
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	0
3. Allocation was concealed	1	0
4. The groups were similar at baseline regarding the most important prognostic indicators	1	0
5. There was blinding of all subjects	1	0
6. There was blinding of all therapists who administered the therapy	1	0
7. There was blinding of all assessors who measured at least one key outcome	1	0
8. Measures of at least one key outcome were obtained from >85% of the subjects initially allocated to groups	1	0
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by 'intent to treat'	1	0
10. The results of between-group statistical comparisons are reported for at least one key outcome	1	0
11. The study provides both point measures and measures of variability for at least one key outcome	1	0

a Total score is calculated using items 2–11 (range 0–10).

The results of the best evidence syntheses were categorized into five levels of evidence, depending on the quality of the study and the statistical significance of the results ($p < 0.05$) [i.e. strong evidence, moderate evidence, limited evidence, indicative findings and no or insufficient evidence (Table 2)].

Table 2: Best evidence synthesis[47,57]

Evidence level	Definition
Strong evidence	Provided by statistically significant findings in outcome measures in at least two high-quality RCTs, with PEDro scores of at least 4 points[a]
Moderate evidence	Provided by statistically significant findings in outcome measures in at least one high-quality RCT and at least one low-quality RCT (≤3 points on PEDro) or one high-quality CCT[a]
Limited evidence	Provided by statistically significant findings in outcome measures in at least one high-quality RCTa or at least two high-quality CCTs[a] (in the absence of high-quality RCTs)
Indicative findings	Provided by statistically significant findings in outcome measures in at least one high-quality CCT or low-quality RCTa (in the absence of high-quality RCTs), or two studies of a non-experimental nature with sufficient quality (in the absence of RCTs and CCTs)[a]
No or insufficient evidence	In the case where the results of eligible studies do not meet the criteria for one of the above-stated levels of evidence or in conflicting (statistically significant positive and statistically significant negative) results among RCTs and CCTs, or where there are no eligible studies

a If the number of studies showing evidence is <50% of the total number of studies found within the same category of methodological quality and study design (RCT, CCT or non-experimental studies), the classification of 'no evidence' is used. CCT(s) = controlled clinical trial(s); RCT(s) = randomized controlled trial(s).

RESULTS

Literature Search

The results of the database search and subsequent assessment of trials identified are summarized in Figure 1.

Eight articles met the inclusion criteria for this review. Differences in outcome measures, intervention types and patient characteristics precluded pooling of the results, and only best evidence analyses were conducted.

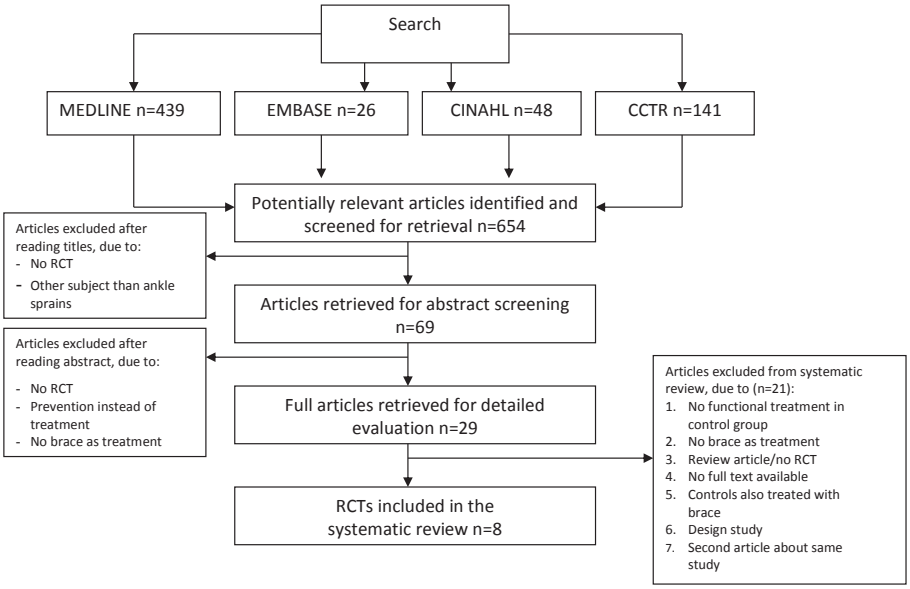

Figure 1: Total numbers of articles and randomized clinical trials (RCTs) through the different stages of the systematic review. 1 = studies[13,15,28,43,46,68]; 2 = [3,23,25,60,6]; 3 = [1,10,28,39,43]; 4= [56]; 5 = [67]; 6 = [35]; and 7 = [36]. CCTR = Cochrane Clinical Trial Register; CINAHL = Cumulative Index to Nursing and Allied Health Literature.

In total, 1,250 patients (both sports participants and non-sports participants) were involved in the included studies, 358 of whom were treated with an ankle brace. One study failed to report the number of patients in the treatment group[5]. The age of participants ranged from 9 to 61 years, and 63% were male (two studies did not classify sex[5,44]). The severity of the ankle sprains varied between grade I and grade III. Boyce et al.,[6] Karlsson et al.,[27] Leanderson and Wredmark[37] and Dettori et al.[14] focused on moderate to severe sprains (grade II and III), while Beynnon et al.[5] included only first-time grade I, II and III sprains. Twellaar et al.[62] made no distinction and included all ankle sprains, while Neumann et al.[44] and Lamb et al.[34] focused on grade III ankle sprains.

Four studies compared an ankle brace (two Aircast®, one Air-stirrup® and one semi-rigid and specially designed compression pads) with an elastic wrap or bandage[6,27,37,44]. Dettori et al.[14] compared an ankle brace with an elastic wrap and a cast, while Twellaar et al.[62] compared a confection brace (Push Med) with adhesive, non-elastic tape. Beynnon et al.[5] investigated the effect of an ankle brace compared with an Aircast® brace combined with a wrap and a cast. Lamb et al.[34] compared the Tubigrip™ with the Aircast® brace, a below-knee cast and a Bledsoe boot. Different outcome measures

were used (Table 3). The methodological quality of the eight included studies, as expressed by the PEDro scores varied between 3 and 7 with a median of 5 points. It was not possible to allocate points for items 5 and 6, because blinding of patients and therapists was impossible in the treatment strategies used. Seven trials were scored as high quality; one trial was scored as low quality (Table 4).

Table 4: Validity assessment of trials included (published between 1990 and April 2009)

Study (year)	PEDro items											
	1	2	3	4	5	6	7	8	9	10	11	Total score[a]
Twellaar et al.[62] (1993)	Y	1	0	0	0	0	0	0	1	1	1	4
Neumann et al.[44] (1994)	N	1	0	1	0	0	0	0	1	1	1	5
Dettori et al.[14] (1994)	Y	1	0	1	0	0	1	1	0	1	0	5
Leanderson and Wredmark[37] (1995)	N	0	1	0	0	0	0	0	0	1	1	3
Karlsson et al.[27] (1996)	N	0	1	0	0	0	0	1	0	1	1	4
Boyce et al.[6] (2005)	Y	1	1	1	0	0	0	0	1	1	1	6
Beynnon et al.[5] (2006)	Y	1	1	1	0	0	0	0	1	1	1	6
Lamb et al.[34] (2009)	Y	1	1	1	0	0	1	0	1	1	1	7

a Total score calculated using items 2–11 (range 0–10).
N = no; Y = yes.

The initial agreement between the two reviewers was 86% (76 of 88 items). The Kappa value for the measure of agreement between the two reviewers on the individual validity items was 0.73.

Best Evidence Syntheses

Best evidence syntheses were prepared by extracting data for the following outcomes: recurrent sprains, residual symptoms (pain, swelling and instability), functional outcome and time to resumption of sports, daily activities and work.

Recurrent Sprains

Four high-quality studies measured the number of re-injuries. Beynnon et al.[5] assessed the total number of re-injuries after 6 months in different treatment groups per injury grade. Neumann et al.[44] assessed the total number of re-injuries after 1 year, while Dettori et al.[14] measured the rate of re-injuries during a 5-week period after injury. Twellaar et al.[62] assessed how many patients had re-injured their ankle between 1.8

and 2.8 years after injury. The follow-up periods used in these studies were different, but none of the four studies found any differences in re-injuries between the groups they studied. Therefore, 'no evidence' was classified.

Table 3: Characteristics of trials included

Study (year)	Sample size (n); sex	Age (y) [range]	Participants	Follow-up	Injury severity	Sports-related injuries	Treatment (n)	Control (n)	Relevant outcomes with significant results
Twellaar et al.[62] (1993)	116; M 77, F 39	Mean 32	83% SP in the tape group and 73% SP in the brace group	Long term 1.8–2.8 y	All ankle injuries	Percentage of sports injuries not reported	Confection brace (53)	Adhesive, non-elastic tape (63)	Functional stability Swelling Blisters Pain – investigating ankle is painful in brace group: 20% vs 47% in tape group; $p < 0.05$
Neumann et al.[44] (1994)	80; not reported	SRO: mean 25.2 [16–46]; EB: mean 23.2 [11–50]	Percentage of SP not reported	Short term (3, 10 d, 3, 6 wk, 4 mo); intermediate term (12 mo)	Grade III	Percentage of sports injuries not reported	SRO (31)	EB (33)	Questionnaire with 88-point scale
Dettori et al.[14] (1994)	64; M 60, F 4	Mean 24.2–25.9	All were military personnel	Short term (5 wk)	Moderate and severe injuries	All injuries occurred during military activities	AB (24)	Elastic wrap (22); cast (18)	Number of days before return to full duty Ankle swelling Pain
Leanderson and Wredmark[37] (1995)	73; M 48, F 25	Mean 28 [15–55]	SP + NSP	Short term (24 h, 3–5 d, 2, 4, 10 wk)	Grades II and III	48% sports injuries	Air-stirrup® brace (39)	Compression bandage (34)	Karlsson's scoring scale Recording sick leave: ASB 5.3 (0–26 days) vs CB 9.1 (0–21 days); $p < 0.05$ Clinical examination with regard to localized tenderness, degree of swelling and range of plantar flexion-dorsiflexion of the ankle
Karlsson et al.[27] (1996)	86; 57 M 9 F	Mean 22 [16–38]	SP	Long term (12–24 mo, mean 18 mo)	Grades II and III	Percentage of sports injuries not reported	Functional treatment, with specially designed compression pads, weight-bearing and range-of-motion training (45)	Conservative treatment with elastic wrapping, partial weight bearing and crutches (39)	Karlsson's scoring scale Return to sports activities –functional treatment with compression pads: 9.6 ± 4.8 days vs 19.2 ± 9.5 days for conventional treatment with elastic wrapping ($p < 0.05$) Reported days of sick leave – functional treatment with compression pads: 5.6 ± 4.2 days vs 10.2 ± 6.8 days for conventional treatment with elastic wrapping ($p < 0.05$)

Table continued

Study (year)	Sample size (n); sex	Age (y) [range]	Participants	Follow-up	Injury severity	Sports-related injuries	Treatment (n)	Control (n)	Relevant outcomes with significant results
Boyce et al.[6] (2005)	50, 12 defaulted, 3 excluded (1 lateral malleolus, 1 wrong clinical appointment given and 1 foot injury); ESB M 11, AB M 10	>16 [16–58]	SP + NSP	Short term (10 d, 1 mo)	Moderate or severe	38% sports injuries	AB (18)	ESB (17)	Karlsson's scoring scale: (i) after 10 days: ESB mean = 35 vs AB mean = 50; 95% CI 1.7, 27.7; p = 0.028; (ii) after 1 mo: ESB mean = 55 vs AB mean = 68; 95% CI 1.4, 24.8; p = 0.029 Pain score Ankle girth difference
Beynnon et al.[5] (2006)	212; NR	[16–61]	SP + NSP	Short term, intermediate term (6 mo)	First-time grade I, grade II and grade III	Grade I: 34% sports injuries; grade II: 39% sports injuries; grade III: 71% sports injuries	AB (not reported)	Elastic wrap (not reported); AB with wrap (not reported); cast (not reported)	Number of days required to return to: no pain during weight bearing; full capability in normal daily activities; full capability at work or school; full capability in usual athletic or recreational physical activity Karlsson's scale Re-injuries
Lamb et al.[34] (2009)	584; M 337, F 247	Mean 30	SP not reported	Intermediate term (3 and 9 mo)	Severe ankle sprains	Percentage of sports injuries not reported	Tubigrip™ (140)	Below-knee cast (119); Bledsoe boot (148); AB (148)	FAOS including: assessments of pain, symptoms, activities of daily living, sport and quality of life

AB = Aircast® brace; EB = elastic bandage; ESB = elastic support bandage; F = female; FAOS = foot and ankle outcome score; M = male; NSP = non-sports participants; SP = sports participants; SRO = semi-rigid orthosis; ASB = Air-stirrup brace; CB = Compression bandage; CI = confidence interval.

Residual Symptoms (Pain, Swelling and Instability)

Pain

Four high-quality studies measured pain as an outcome variable. After 1.8–2.8 years of follow-up, Twellaar et al.[62] examined the ankles of patients who had sustained an ankle injury. Pain upon palpation was less frequent in the brace group than in the tape group (20% vs 47%; $p < 0.05$). Boyce et al.[6] measured the difference in pain scores on a visual analogue scale from 0 to 10, between the initial presentation and day 10. They found no significant difference ($p = 0.07$). Beynnon et al.[5] measured the period of time from the patient's onset of injury until they no longer experienced pain during weight bearing exercises. The differences between the groups were not significant. Finally, Dettori et al.[14] classified the pain that patients perceived in different phases of the study from 'pain at rest' (4+) to 'no pain with running' (0), and found no differences in effect between wraps and braces. Only one of the four studies found significant results, so 'no evidence' was classified.

Swelling

Four high-quality studies investigated swelling as an outcome variable. Boyce et al.[6] measured the difference in swelling, in millimeters, between the injured and uninjured ankles on day 10, comparing an elastic bandage group with an Aircast® brace group. Twellaar et al.[62] and Neumann et al.[44] determined the percentage of patients with swelling within the treatment groups; Twellaar et al. after an average of 2.3 years of follow-up and Neumann et al. after 1 year of follow-up. Dettori et al.[14] measured swelling by volumetry after 5 weeks. None of the studies found statistically significant differences in terms of this outcome measure. Based on these findings, 'no evidence' was classified.

Instability

Two high-quality studies measured ankle instability as an outcome variable. Twellaar et al.[62] measured mechanical instability and found no significant differences within the treatment groups. Neumann et al.[44] measured subjective instability, but reported no information about significance. We classified 'no evidence' for the effect on ankle instability.

Functional Outcome

A total of five studies measured functional outcome, four of high quality and one of low quality. Lamb et al.[34] measured the quality of ankle function using the Foot and Ankle Outcome Score (FAOS). At 3 months, there were significant clinical benefits for the Aircast® brace compared with the Tubigrip™ in terms of the quality of ankle function. No differences were found at 1 and 9 months. Four studies used Karlsson's scoring scale (or a modified version of it). Boyce et al.[6] used this scale on day 10 and at 1 month after the trauma. In both measurements, the mean score in the patient group treated with an ankle brace was higher (i.e. better) than that in the group treated with an elastic bandage ($p = 0.028$ on day 10 and $p = 0.029$ after 1 month). Beynnon et al.[5] used the same scoring scale 6 months after the onset of injury, and found no significant differences between the treatment groups. Neither did Karlsson et al.[27] who used the scale after 12–24 months of follow-up. Leanderson and Wredmark[37] applied the scale at 3–5 days, 2, 4 and 10 weeks after the initial injury and did not find any significant differences between the patient group treated with an ankle brace and the group treated with a compression bandage. Since the results of two of the four high-quality studies were significant, the evidence was classified as strong.

Time to Resumption of Sports, Daily Activities and Work

Sports

Three high-quality studies used 'return to sports' as an outcome measure[5,27,44]. Karlsson et al.[27] found that patients treated with a brace returned to sports activities significantly sooner than patients treated with elastic wrapping (9.6 ± 4.8 days vs 19.2 ± 9.5 days; $p < 0.05$). Beynnon et al.[5] and Neumann et al.[44] found no statistical differences between braces and other functional treatments. Because the number of studies showing evidence in favor of braces was <50% of the total number of studies in this category, there is no evidence to support the use of braces.

Daily Activity

One high-quality study used 'return to daily activity' as an outcome variable, expressed as the number of days it took for patients to fully resume daily activity[5]. Since the study showed no significant results, there is no evidence to show that the treatment of an ankle injury with an ankle brace reduces the number of days necessary to achieve full return to daily activities more quickly than treatment with a bandage or Tubigrip™.

Work (Sick Leave)

Six studies measured how many days the patients were unable to work. One study was rated as low quality[37], while five were of high quality[5,14,27,44,62]. The results reported by Leandersson and Wredmark[37] indicated that treatment with an ankle brace significantly reduced the duration of sick leave when compared with treatment with an elastic wrap/compression bandage. They found a mean difference of 4 days (5.3 days [range 0–26 days] vs 9.1 days [range 0–21 days]: $p < 0.05$). Of the five high-quality studies, only one reported significant results. Karlsson et al.[27] found a difference of approximately 5 days (5.6 ± 95% CI 4.2 days vs 10.2 ± 95% CI 6.8 days; $p < 0.05$) in favor of the ankle brace. Although the results of two studies (one high and one low quality) were significant, the total number of studies that found evidence in favor of braces was <50% of the total number of studies in the same category, so 'no evidence' was classified.

DISCUSSION

This systematic review examines the available evidence for the effectiveness of ankle braces as a treatment for ankle sprains compared with other functional treatment methods such as Tubigrip™, elastic bandages and ankle tape. The validity score of the eight trials that were included ranged from 3 to 7 points. Seven trials were classified as high quality (PEDro score ≥4) and one trial as low quality (PEDro score ≤3). Heterogeneity of study designs precluded pooling. Strong evidence in favor of treatment with a brace was found for functional outcome, which is a clinically relevant result, because patients who had a good functional outcome might be able to return to their normal functioning levels sooner. The favorable results for functional outcome were measured on two different scales (Karlsson's scoring scale and the FAOS), with different periods of follow-up.

Although the evidence for functional outcome in favor of the ankle brace was classified as strong, the difference between the classifications of strong evidence and no evidence is small and depends on the chosen cut-off point for methodological quality. In total, five studies measured functional outcome, four of high quality and one of low quality. It should be noted that the difference between strong evidence and no evidence was only one point on the PEDro scale. Although the cut-off points are well considered, it is always good to keep in mind the small step from no evidence to strong evidence.

Return to work was another important outcome included in this review. In contrast to what was reported by Kerkhoffs et al.[30], the best evidence synthesis did not show positive results for treatment with a brace. Based on two studies in which elastic bandages were compared with semi-rigid ankle braces[27,28], Kerkhoffs et al. concluded that the use of a semi-rigid ankle brace appeared to be associated with a quicker return to work[30]. Due to the use of broader definitions and the inclusion of recent studies, our review includes six studies in which ankle braces were compared with other functional treatment methods and sick leave/return to work was used as an outcome variable[5,14,27,37,44,62]. Two of the studies[27,37], which were also included in Kerkhoffs et al., reported a difference in the duration of sick leave of 4–5 days in favor of the ankle brace. However, because the total number of studies reporting evidence was <50%, we classified this as 'no evidence'.

Several of the studies included in this review reported results in favor of ankle braces with regard to pain[62], time to resumption of sports[27] and sick leave[27,37]. However, the findings for these outcomes were classified as 'no evidence' for brace treatment compared with other functional treatments after acute ankle sprain. This might be caused by the heterogeneity of the trials. First, studies in our review included patients with different activity levels, some of them being sports participants and some not. This might have influenced the results, as the outcome of treatment of lateral ankle ligament rupture is significantly affected by the patients' activity level. For instance, ankle instability and re-injuries are more common in the high-activity groups than in low-activity groups[19].

Second, we used a broad definition of ankle brace, resulting in the inclusion of articles in which different types of braces with different properties and qualities were used. According to Kerkhoffs et al.[30], lace-up ankle support appears to reduce swelling more effectively in the short term, compared with semi-rigid ankle support, elastic bandage and tape, and rigid braces give more mechanical support than soft braces. Our review did not consider the specific characteristics of the different ankle braces. Significant favorable results were found for the soft brace, the compression pads and for the Aircast® brace. A restriction to the Aircast® brace would not have changed the results of the review. In contrast, the exclusion of the semi-rigid Aircast® ankle brace from our review would have limited the number of studies to two and strong evidence could have been classified for three outcome variables.

Furthermore, not every brace might be appropriate for the treatment of ankle sprains[63]. Vaes et al.[63] evaluated the stabilizing effect of external support (nine different ankle braces and taping) in functionally unstable ankles. They used a standard surface electromyogram-controlled stress Roentgen test protocol to measure the talar tilt with and without external support. Two braces had a major influence on the talar tilt, and only these two (Aircast® standard brace and Step-in safety brace) were considered to be effective for immediate post-trauma treatment and the prevention of ankle sprain. Despite this conclusion, several studies included in this review[5,14,27,62] reported the opposite or were unable to uphold this conclusion.

Although our review examined several outcomes, other endpoints might also be valuable when deciding upon the preferred treatment method. Verhagen et al.[65] calculated that the mean total costs (direct and indirect) of one ankle sprain in the Netherlands to be approximately €360, and that all ankle sprains in the Netherlands together cost about €43.2 million a year. An effective treatment method could reduce the costs of ankle sprains. In a recent study, Cooke et al.[11] evaluated the cost effectiveness of several methods of ankle injury treatment, performing an economic evaluation of the below-knee cast, Aircast® brace and Bledsoe™ boot versus Tubigrip™. Cost-utility analysis, comparing incremental costs with the differential impact on health-related quality of life over 9 months, demonstrated that the Aircast® brace (£301 per quality-adjusted life-year [QALY]) and below-knee cast (£339 per QALY) were more cost effective than the Bledsoe™ boot (£2116 per QALY). Cost-effectiveness acceptability curves confirmed that the Bledsoe™ boot was the least cost effective, and that the Aircast® brace and below-knee cast had a comparably higher cost effectiveness; Cooke et al.[11] only compared an ankle brace with Tubigrip™. More research is needed to examine the cost effectiveness of ankle braces compared with other functional treatment types such as the widely used ankle tape.

Some limitations need to be considered when interpreting the results. We recognize the possibility of publication bias, as we did not systematically search unpublished studies for potentially relevant research. In addition, the literature search was restricted to articles in English, German or Dutch, although no trials were excluded because of language.

CONCLUSION

International guidelines for the treatment of ankle sprains are rare. According to the Dutch College of General Practitioners guideline for the treatment of ankle sprains, these should be treated by taping for 6 weeks. Nevertheless, our systematic review found evidence for a better functional outcome when using an ankle brace and treatment with ankle braces did not show any unfavorable effects. In addition, findings of other studies suggest that this method is more cost effective; therefore, using the brace for treatment of acute ankle sprains should be considered. Research focusing on the effectiveness and cost effectiveness of ankle braces used as a therapeutic method could produce more convincing evidence, allowing the following guidelines to be developed and adapted:

1. In terms of functional outcomes, ankle braces are more effective in the treatment of acute ankle sprains than other types of functional treatment.
2. Compared with other functional treatments, ankle braces are not less effective in the treatment of acute ankle sprains.
3. More research is needed for well-defined functional treatment methods. Research should not only focus on functional outcomes, but also on socioeconomic outcomes and on different types of ankle braces. This should provide more information on the strengths and weaknesses of ankle braces as a treatment for acute ankle sprains compared with other types of functional treatment.

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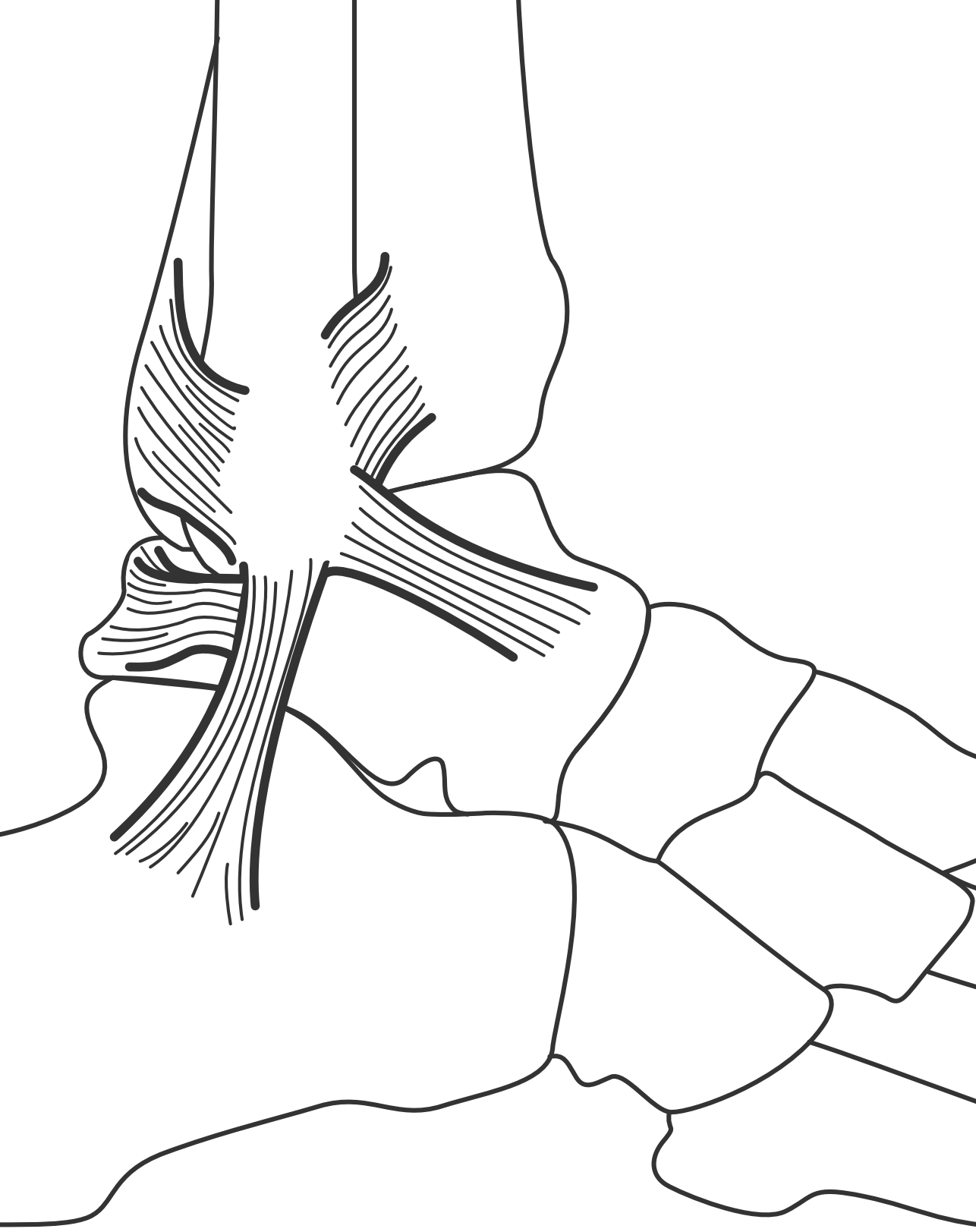

Chapter 4

Effects of soft bracing or taping on a lateral ankle sprain: a non-randomized controlled trial evaluating recurrence rates and residual symptoms at one year

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ABSTRACT

Background: After sustaining an ankle sprain, taping is often the standard treatment in primary care. Ankle braces are sometimes used as an alternative. This study aimed to compare the effects of four weeks of soft bracing or taping following acute lateral ankle ligamentous sprain (ALALS) on sprain recurrence rates and residual symptoms at one year.

Methods: In this pragmatic, non-randomized controlled trial, 157 adult participants with an ALALS caused by an inversion trauma were alternately allocated to a four week treatment with a soft brace (intervention group) or a four week treatment with ankle tape (control group) in order of presentation. The primary outcome was the 1-year incidence of the self-reported recurrence of ALALS. The secondary outcome was the occurrence of residual symptoms.

Results: Baseline characteristics did not differ appreciably between the treatment groups. Thirteen patients (17%) in the brace group reported a re-injury versus 11 patients (14%) treated with tape, corresponding to a risk difference of 3.1% (relative risk 1.2, 95% CI 0.6 to 2.6). Cox regression analysis showed a hazard ratio of self-reported ankle sprain recurrence within 52 weeks in the brace group compared to the tape group of 0.9 (95% CI 0.4 to 1.9). After one year, patients in the brace group had poorer scores on the manual anterior ankle test, corresponding to a risk difference of 15.4% (RR 2.4, 95% CI 1.1 to 5.0).

Conclusion: ALALS recurrences and residual symptoms appear to be similar at one year when an ALALS is treated with four weeks of soft bracing or taping.

Trial registration: ISRCTN92030205

Keywords: ankle sprains; braces; athletic tape; recurrence

INTRODUCTION

Ankle sprains are one of the most common musculoskeletal injuries. Reported incidence rates range from 2.2 sprained ankles per 1,000 person-years in the United States of America[41] to 5.3-7.0 sprained ankles per 1,000 person-years in Europe[6,19]. Ankle injury rates are high in sports and the general population[26,37]. Of all the ankle injuries related to sports activities, 77% are ankle sprains[12]. An ankle sprain can cause pain and other symptoms, including residual symptoms such as muscle weakness, swelling, stiffness, and ankle instability. Residual symptoms are reported by 3 to 59% of the patients 3 to 24 months after the initial injury[7,14,15,20,42,43]. Recurrences of ankle sprain are also frequently reported[36].

Functional treatment including taping, bandaging and bracing of lateral ankle ligamentous sprains has been recommended instead of surgical repair and plaster cast or splint immobilization since the early 1990s[21,22,25,30]. However, one study suggested that cast immobilization might be more effective than functional treatment[32]. Several systematic reviews were unable to determine the most effective functional treatment strategy for acute lateral ankle ligamentous sprains (ALALS)[25,31]. ALALS are commonly treated with athletic ankle tape in primary care in the Netherlands. The guidelines of the Dutch College of General Practitioners for the treatment of ALALS recommends treatment consisting of immobilization, compression, and elevation (ICE) during the first week, followed by ankle taping for six weeks[34].

Several disadvantages of treatment with ankle tape are known. Ankle tape cannot be applied when swelling and edema are still clearly present. Skin care before treatment is needed, and even then, irritation of the skin by the tape is common. Finally, tape stability decreases approximately 14% after 30 minutes of exercise[1]. Compared to ankle tape, an ankle brace is easy to apply and to adjust by patients themselves. In addition, the risk of skin irritation is much lower, and ankle braces are reusable and washable. As an ankle brace seems to be more user friendly, it might also be more appropriate to treat ALALS. A soft brace is based on the principle of the functional tape bandage and it has been developed as an alternative to ankle tape treatment.

The purpose of this study was to compare the effects of four weeks of soft bracing or taping following ALALS on sprain recurrence rates and residual symptoms at one year. The incidences of ALALS recurrences and residual symptoms were expected to be similar in both treatment groups.

METHODS

This study was a pragmatic, non-randomized controlled trial.

Participants and procedure

Patients aged 18 years and older and diagnosed with an ALALS caused by an inversion trauma were recruited from 20 family practices, nine physical therapy practices, the emergency department of a regional hospital and an university hospital located in the central part of the Netherlands. Patients were recruited between May 2006 and October 2008. Those aged younger than 18 years old were excluded from this study.

Patients with a possible ALALS were referred to the Department of Sports Medicine as soon as possible. The research assistant contacted the patients by phone and conducted the first screening for inclusion and exclusion criteria (age, multiple trauma, complicated trauma, history of surgery) by means of a short standard questionnaire. If the patient was eligible for inclusion in this study, the research assistant allocated them to the brace or tape group based on the order of presentation. The research assistant was blinded for the severity of the inclusion injury, was not a medical expert, and was not responsible for determining the final eligibility of the patients. To check if the patients were indeed eligible for inclusion, a sports physician conducted a baseline assessment. The sports physician diagnosed an ALALS based on the following items: swelling of the injured ankle; any discoloration by hematoma; limited dorsiflexion in the injured ankle; clear tenderness at one or more anatomical locations related to the injured ankle; difference in the anterior drawer sign between the injured and contralateral ankle; and difference in the talar tilt test between the injured and contralateral ankle. Patients who had an ALALS caused by an eversion trauma, multiple trauma, or complicated trauma (including cartilage injuries, fractures and dislocation) or who had a history of ankle surgery were excluded. Patients diagnosed as having a mental illness or cognitive impairment were also excluded from this study. The medical ethics committee of the University Medical Center Utrecht (UMC Utrecht) approved the protocol (protocol number 05/153). All participants gave written informed consent.

Interventions

During the first five days after the ALALS, patients were treated with immobilization, compression and elevation (ICE). As the diagnosis of an ALALS and inclusion were

based on history and delayed physical examination[3,10], the allocated intervention started as soon as possible but at least within 14 days after the initial trauma. Only in case of very severe ankle swelling the ICE treatment was continued and the allocated intervention was postponed for a few additional days (average 3-4, with a maximum of 6 days). At initial treatment, no specific pain medication protocol was prescribed.

Intervention group

The intervention group received instructions from the sports physician about using and applying the soft brace. The soft brace (Push® med Ankle Brace (Nea International bv))[9] is based on the principles of the functional tape bandage (Figure 1). Participants were instructed to wear the soft brace for four weeks, except for at night and when taking a shower.

Figure 1: Push Med Ankle brace

Control group

The control group received usual care for ALALS for four weeks, which starts with ankle taping after ICE[34]. The general practitioner, primary care assistant, physical therapist, or plaster technician applied the athletic tape bandage. The healthcare professional decided on the most appropriate application technique for the specific patient. Patients were instructed to wear the ankle tape for four weeks. In the Netherlands, it is common to wear a tape bandage for two weeks before refreshing[34]. Two weeks after the first application the tape was refreshed by their healthcare professional. When necessary, due to the loss of stability or hygiene, the tape bandage in the control group was replaced earlier, by the same healthcare professional. After four weeks the ankle tape was removed and discontinued.

Data collection and outcomes

Baseline data were obtained by the sports physicians and consisted of a clinical history and a physical examination of the ankle. All the sports physicians received standardized training for measuring outcomes. All participants were invited for a

reassessment by one of the sports physicians one year after treatment allocation. This assessment included the same physical examination as at the baseline. In addition, participants were asked about re-injuries, current residual symptoms and pain, and the use of additional therapy or aids. The sports physicians could not be blinded to treatment allocation.

The primary outcome was the proportion of participants with a recurrence of ALALS within one year. A recurrence of ALALS was defined as a new inversion trauma of the same ankle, reported by the patient during a year following treatment allocation. To register the recurrences of ALALS participants filled in online questionnaires 5, 9, 13, 26, and 39 weeks after the initial injury. Participants had to answer the following questions: "Did you re-injure your ankle after the start of this study?" (answer: yes or no) and "What was the nature of the injury?" (response options: sprain, broken ankle, overuse injury, I don't know, other). Ankle fractures or overload of the affected ankle were not regarded as recurrences of ALALS.

The secondary outcome was the occurrence of residual symptoms. This included: (i) residual swelling (substantial / moderate / minimal / no), (ii) functional outcome (no limited dorsiflexion / injured ankle better than non-injured ankle / limited dorsiflexion), and (iii) passive and active stability assessed by the sports physician based on clinical interpretation. Passive stability was defined as ligament stability. The manual anterior ankle test as described by Van Dijk et al. (1996) and the talar tilt test were used to measure ligament stability. Active stability was defined as muscular stability while performing a one-leg stance test – four variations of the one-leg stance test with an increasing difficulty were used to measure this type of stability[11]. The four variations were: (i) eyes open, (ii) eyes closed, (iii) eyes closed and knee in 45 degrees flexion, (iv) eyes closed, knee in 45 degrees flexion and standing on forefoot[38]. Both legs were tested barefoot. The time in seconds a participant could stand on one leg was measured. The score was then dichotomized with a 'successful' test recorded if the participant could perform the one-leg stance test for 15 seconds or more. Standing on one leg for less than 15 seconds meant that a patient had failed the one-leg stance test.

Pain in the ankle joint during walking, running, pivoting and jumping was reported by the patient. Participants were classified as having pain (yes / no) when they reported pain in the ankle joint during at least one of these activities. Although no specific

pain medication protocol was prescribed in this study, participants were asked whether they did use pain medication or not. This was similar for manual therapy and physiotherapy.

Self-reported data on the compliance of wearing the soft brace or tape were collected once in the five-week online questionnaire.

Sample size

The incidences of ALALS recurrences were expected to be similar in both treatment groups. However, a clinically worthwhile difference for interventions, (i.e. the difference or the ratio of the cumulative incidence of re-injury between the two treatments) was not available to use for an *a priori* sample size calculation. Thus, we aimed to include as many participants as possible in this study within a period of 30 months.

Statistical analyses

Baseline characteristics were described and compared using chi-square tests and independent sample *t*-test. The one year cumulative incidence of self-reported recurrence of ALALS and the prevalence of residual symptoms at one year for both treatment groups, and risk differences and relative risks (RR) with 95% confidence intervals were calculated using crosstabs with risk estimation. In addition, when comparing the risk for re-injury, Cox regression analysis (hazard ratio: HR) was also used, taking into account the time between initial injury and re-injury. In the analyses of self-reported recurrence of ALALS, all participants were included as specified by the allocation to the treatment groups (i.e. for this analysis, we used the intention to treat principle). In the analyses of residual symptoms, all participants who were reassessed by a sports physician one year after the treatment allocation were included as specified by the allocation to the treatment groups. Participants who underwent no physical examination after one year of follow-up were excluded from the analyses of residual symptoms. For compliance, the RR was calculated using crosstabs with risk estimates. In case of baseline differences between the two groups, we planned multivariable regression analyses (logistic regression for the one year incidence and Cox regression) to adjust for potential confounders.
Data for all the respondents were analyzed using the IBM SPSS statistical software package, version 18.0. A p-value <.05 was considered statistically significant.

RESULTS

A total of 164 patients were assessed for eligibility in this study (Figure 2). Seven patients were excluded due to the following reasons: age under 18 years (n = 3), ankle fracture (n = 2), treatment already started before treatment allocation (n = 1) and an eversion ankle sprain (n = 1). The age of the 157 included participants ranged from 18 to 64 years (mean 31.1 years); 88 participants (56%) were male. One hundred (64%) of the reported ALALS occurred during sports participation. On average, the allocated treatment started 6.1 days (SD 2.3) and 5.8 days (SD 2.0) after the initial injury in the brace and tape group, respectively. Baseline characteristics did not differ appreciably between the treatment groups (Table 1).

Table 1: Comparison of demographic and baseline characteristics between groups

	Soft Bracing N=77	Taping N=80	P-value
Mean age in years (SD)	30.7 (11.3)	31.4 (12.0)	0.708
Time from injury to start of treatment, mean in days (SD)	6.1 (2.3)	5.8 (2.0)	0.467
Gender, male, n (%)	41 (53.2)	47 (58.8)	0.487
Sports participants[1], n (%)	66 (85.7)	66 (83.3)	0.582
Injury severity[2]			0.110
- Mild, n (%)	28 (36.4)	17 (21.3)	
- Moderate, n (%)	38 (49.4)	48 (60.0)	
- Severe, n (%)	11 (14.3)	15 (18.8)	
Previous sprains of the injured ankle			0.178
- Yes, n (%)	34 (44.2)	24 (30.0)	
- No, n (%)	32 (41.6)	43 (53.8)	
- Unknown, n (%)	11 (14.3)	13 (16.3)	

SD, Standard Deviation

[1] *Participating in sports in the week prior to the occurrence of the initial injury*

[2] *For a detailed explanation of Injury severity, see Appendix A*

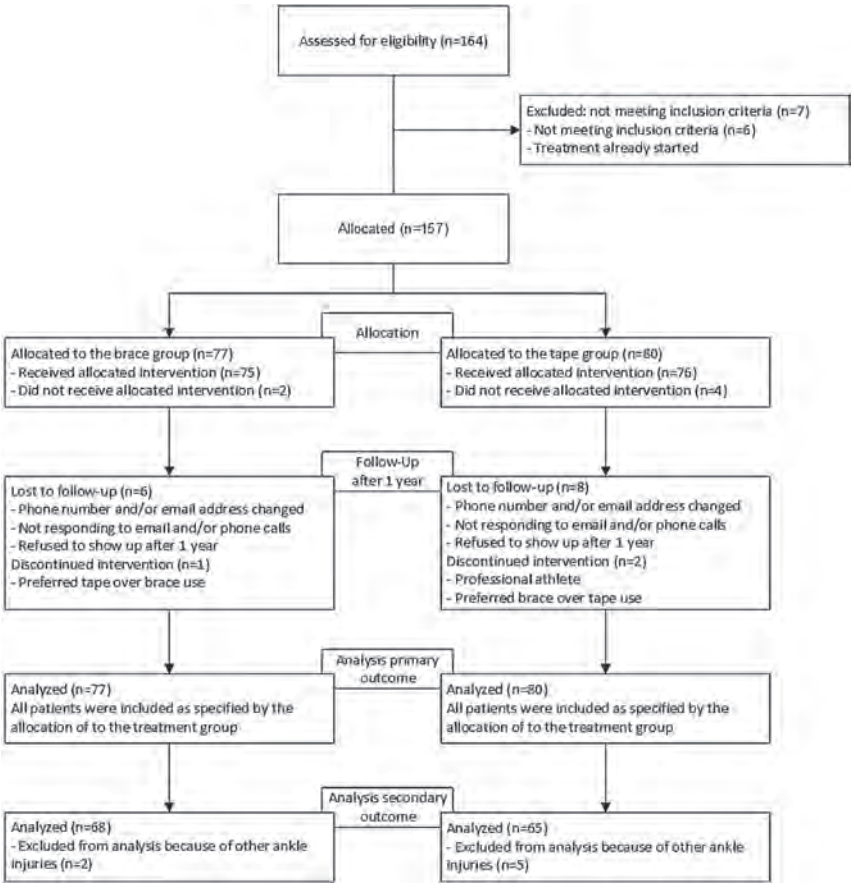

Figure 2: Trial profile

Additional therapy and the use of medication

A total of 57 participants (36%) visited a physical or manual therapist during the treatment period and one year follow-up after the initial trauma; of these, 30 were in the brace group (mean of 8 visits per participant) and 27 in the tape group (mean of 11 visits per participant). Thirty seven participants (24%) used some kind of medication; of these, 23 were in the brace group and 14 were in the tape group. No significant differences were found for the use of medication and additional therapy.

Re-injuries

Within 52 weeks after the initial trauma, 13 of the 77 participants (17%) in the brace group compared to 11 of the 80 participants (14%) in the tape group reported a re-injury, corresponding to a risk difference of 3.1% (RR 1.2, 95% CI 0.6 to 2.6). Two participants (3%) in the brace group and no participants in the tape group reported a re-injury of the affected ankle within the treatment period of four weeks. Cox regression analysis showed a HR for self-reported ankle sprain recurrence within 52 weeks in the brace group compared to the tape group of 0.9 (95% CI 0.4 to 1.9).

Residual symptoms

Seventeen participants (11% of the total sample) were lost to follow-up and therefore did not have a physical examination after one year. Another 7 participants (4% of the total sample) were excluded from the analyses because of other ankle injuries (in total 9 and 15 respondents in the brace and tape group, respectively). The 24 participants (15% of the total sample) who were excluded from the residual symptoms analyses did not have different baseline characteristics to those included in the analyses.

One year after the initial ankle trauma, no differences between the groups were reported on swelling, functional outcome, active stability and pain (Table 2). However, participants in the brace group showed poorer scores on the manual anterior ankle test, corresponding to a risk difference of 15.4% (RR 2.4, 95% CI 1.1 to 5.0).

Compliance

A total of 81 participants (54%) completed their prescribed four weeks treatment as instructed; of those, 38 were in the brace group and 43 in the tape group. No difference in compliance between the treatment groups was found (RR 1.1, 95% CI 0.8 to 1.6). The main reason for not completing the four week treatment as instructed was skin irritation (39% in total; 27% in the brace group and 52% in the tape group).

Table 2: Residual symptoms in ALALS participants after one year of follow-up

	Soft bracing		Taping N=65[1]		RR (95% CI)	*P-value*
Swelling, n (%)	11	(16.2)	12	(18.5)	0.9 (0.42 to 1.84)	*0.820*
Functional outcome (limited flexion), n (%)	20	(29.4)	18	(27.7)	1.1 (0.62 to 1.82)	*0.850*
Passive instability (anterior ankle test), n (%)	20	(29.4)	8	(12.3)	2.4 (1.13 to 5.04)	*0.019*
Passive instability (talar tilt test), n (%)	16	(23.9)	17	(26.2)	0.9 (0.51 to 1.65)	*0.842*
Active instability of injured ankle, n (%)						
Active instability with, n (%):						
- one leg stance, eyes open	5	(7.4)	4	(6.2)	1.2 (0.35 to 4.26)	*1.000*
- one leg stance, eyes closed	48	(70.6)	39	(60.0)	1.2 (0.92 to 1.51)	*0.208*
- one leg stance, eyes closed, with knee in 45° flexion	50	(73.5)	44	(67.7)	1.1 (0.87 to 1.35)	*0.568*
- one leg stance, eyes closed, with knee in 45° flexion, standing on the forefoot	68	(100.0)	65	(100.0)	1.0 (1.00 to 1.00)	*1.000*
Pain in the ankle joint during walking, running, pivoting and jumping, n (%)	21	(27.7)	18	(30.9)	1.1 (0.66 to 1.89)	*0.707*

[1] *17 participants underwent no physical examination after one year of follow-up and 7 participants were excluded from the analyses because of other ankle injuries (tape n=15; brace n=9)*

DISCUSSION

In our study comparing four-week treatment with a soft brace and ankle tape in participants with ALALS, the one-year incidence of re-injury was comparable in both groups with a risk difference of 3.1% (RR 1.2, 95% CI 0.6 to 2.8). The proportion of participants with re-injuries found in this study (15%) is similar to other studies[36].

For passive stability (ligament stability), using the manual anterior ankle test, a difference between the two treatment groups was found at 52 weeks in favor of the tape group. Passive stability did not differ at baseline, but the test was often performed a couple of days after the initial ankle injury. Thus, it is unknown whether the difference in passive stability already existed before the start of this trial (and the initial ankle injury) or was related to the allocated treatment. In this study, the manual anterior ankle test and talar tilt test were used. The use of these manual tests is difficult to discuss because of their subjective nature, and the inability to produce reproducible and quantitative results[13]. Both manual tests are, however, still frequently used to estimate ankle joint laxity. Several devices have been developed

to objectively measure ankle joint laxity; for example, the dynamic anterior ankle tester (DAAT)[28]. At the start of our study, the reliability of this device had been found to be high, but its validity needed further investigation[29]. Furthermore, at the time of the study, the apparatus itself was not suitable for clinical practice[28]. As the manual anterior ankle test and talar tilt test were frequently used in clinical practice, we chose to use these manual tests in this pragmatic trial.

Active stability, or muscular stability, did not differ after one year. Several earlier studies have demonstrated that passive or mechanical stability is related to active stability or functional stability[23,39]. However, a recent study demonstrated the opposite[18]. In 2002, Hertel developed a model of functional and mechanical insufficiency, which can be helpful in explaining the causative spectrum related to Chronic Ankle Instability (CAI)[16]. In this model two subgroups are included, classified according to the presence of either mechanical instability or functional instability. When both mechanical and functional instability are present in a patient, a third subgroup of recurrent ankle sprains arises. In a recent study, Hiller et al. (2011) proposed a modification of the Hertel model for CAI. In the new model mechanical instability, perceived or functional instability, and recurrent ankle sprain can exist independently or in combination, with seven subgroups of patients now differentiated[17]. The results of our trial seem to fit this latest model proposed by Hiller et al. However, it was not our purpose to evaluate the relationship between functional and mechanical ankle instability.

In the early 1990s, Twellaar et al. compared one of the first prototypes of the soft brace with ankle tape[40]. After an average follow-up period of 2.3 years, tenderness at the lateral ligaments occurred more often after applying tape. They concluded that soft bracing might be preferred over ankle taping for practical reasons, with a lower risk for skin irritation being one of these. The results of our study showed that skin irritation was the main reason for not completing the prescribed treatment, especially in the tape group. The percentage of participants who were not compliant to the treatment was almost twice as high in the tape group compared to the brace group (52% to 27%).

Several studies have compared ankle braces with elastic wrapping or Tubigrip™[4,5,32]. In a recent review, Kemler et al. compared the effectiveness of ankle brace treatment with other functional treatment and classified the evidence for the effectiveness of ankle bracing on functional outcomes as strong[25]. This result was based on studies from Boyce et al.[5] Beynnon et al.[4], Lamb et al.[32], Karlsson et al.[24] and Leanderson and

Wredmark[33]. The results of this review seem to contrast with our findings. However, the heterogeneity of these studies should be taken into account. For example, the studies had different follow-up periods, used other types of ankle braces, the ankle brace was compared with treatment methods other than tape, and different outcome measurements were used.

Several limitations of our pragmatic trial should be discussed. Firstly, different application techniques for ankle taping were used by the clinicians involved. The use of different application methods was, however, in line with usual care as described in the guideline of the Dutch College of General Practitioners. In all cases, the tape was applied by a healthcare professional using the most appropriate method for that patient. Secondly, for logistical reasons, the allocation of participants to the treatment groups was based on the order of presentation, and thus not on a formal randomization scheme. The comparability of the two groups (Table 1) clearly indicates that our allocation scheme resulted in groups with similar participant characteristics and therefore, similar prognosis. Thirdly, in this study an 'all complaints' definition of recurrent ankle sprains was used instead of a 'medical attention' or 'time-loss definition'[8]. The data may be a good representation of the total burden of ALALS, but their validity may be suspect. Participants were required to judge and decide for themselves whether their new sprain was a re-injury according to the following definition: 'a re-injury is an ankle sprain (injury) to the same ankle'. As a re-injury was not assessed by a medical professional, no detailed information about the severity of these new injuries was available. Fourthly, an *a priori* sample size calculation was not performed. A post-hoc power analysis was not performed because it is controversial regarding its risk of a "power approach paradox", whereby if a significant difference is not found and a post hoc power analysis is performed after the study, the study will automatically be found to be underpowered. However, it is possible that there is truly no significant difference between the two treatments (i.e. that both treatments are in fact equal to each other). Indeed, our findings indicate that the effects of both treatments are comparable. Although, the 95% confidence intervals are rather wide, so we cannot rule out that our study may have been underpowered and not able to identify smaller differences in treatment effects. Finally, the assessors in our study, the sports physicians, were not blinded to group assignment. The sports physicians had to instruct all participants about the allocated treatment method and had to apply the ankle brace if a participant was assigned to the brace group. We do not expect that this has influenced our results, but we cannot discount the possibility of

ascertainment bias. The seven sports physicians who participated in this study were all independent and had no conflicts of interest. Furthermore, the primary outcome was self-reported by the participants.

Our results underline the considerations that both an ankle brace and ankle tape can be used in the treatment of ALALS. According to Kerkhoffs et al. (2012), a lace-up brace or a semi-rigid brace is preferable and recommended in the treatment of ALALS[27]. However, in (professional) sports, the use of tape can also be considered[27]. Van den Bekerom et al. (2013) also concluded that tape, a semi-rigid ankle brace, or a lace-up brace can be used in functional treatment of ALALS[2].

Functional treatment (including tape, bandage or brace) of ALALS has been recommended instead of surgical repair and plaster cast or splint immobilization since the early 1990s[21,22,25,30]. However, the discussion regarding the use of a short period of immobilization, followed by functional treatment, exists again[2,27,32,35]. Additional research focusing on effectiveness of the treatment of ALALS needs to be conducted. In addition, while both the ankle brace and ankle tape can be used for ALALS treatment, an economic evaluation including treatment costs, medical costs and costs due to absence from paid work, unpaid work and school would provide more insight into the cost-related aspects of both treatments.

CONCLUSIONS

The results after one-year follow-up indicate that in participants with ALALS, treatment with a soft brace or ankle tape shows similar effects on the incidence of ALALS recurrence and on residual symptoms.

Competing interests
Nea International bv, manufacturer of the Push Med ankle brace, gave financial support to initiate and perform this study. Furthermore, they provided the soft braces that the intervention group used. We fulfilled this study without any influence or interference of the sponsor. The content of this report is solely the responsibility of the authors and does not necessarily represent the official view of Nea International. The authors have no conflicts of interest to report that are directly relevant to the content of this paper.

Authors' contributions

EK: Collected or assembled data; performed analyses; interpreted the results; wrote the initial draft of this article. IP: interpreted the results; reviewed drafts of manuscript and provided feedback. SS: provided statistical expertise; reviewed drafts of manuscript and provided feedback. BH: reviewed drafts of manuscript and provided feedback. AH: provided statistical expertise; reviewed drafts of manuscript and provided feedback. FB: designed the study; interpreted the results; reviewed drafts of manuscript and provided feedback. All authors reviewed and approved the final version of the paper.

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APPENDIX A

The injury severity score (range 0-6) was determined by the sports physician at baseline based on six items, scored as 1 when present and 0 when absent:
(1) swelling of the injured ankle;
(2) any discoloration by hematoma;
(3) limited dorsiflexion in the injured ankle;
(4) clear tenderness at one or more anatomical locations related to the injured ankle;
(5) difference in the anterior drawer sign between the injured and contralateral ankle, and;
(6) difference in the talar tilt test between the injured and contralateral ankle.

Injury severity was based on the total score (0-6) in relation to the number of days between the onset of the initial trauma and assessment of the injury severity score, and was categorized as follows:

- Severe lateral ankle ligamentous sprain (score of 6 and physical exam at least four days after the injury).
- Moderate lateral ankle ligamentous sprain (score of 6 and physical exam on days one-three after the injury *OR* score of 5 or 4 and physical exam at least four days after the injury).
- Mild lateral ankle ligamentous sprain (all other combinations).

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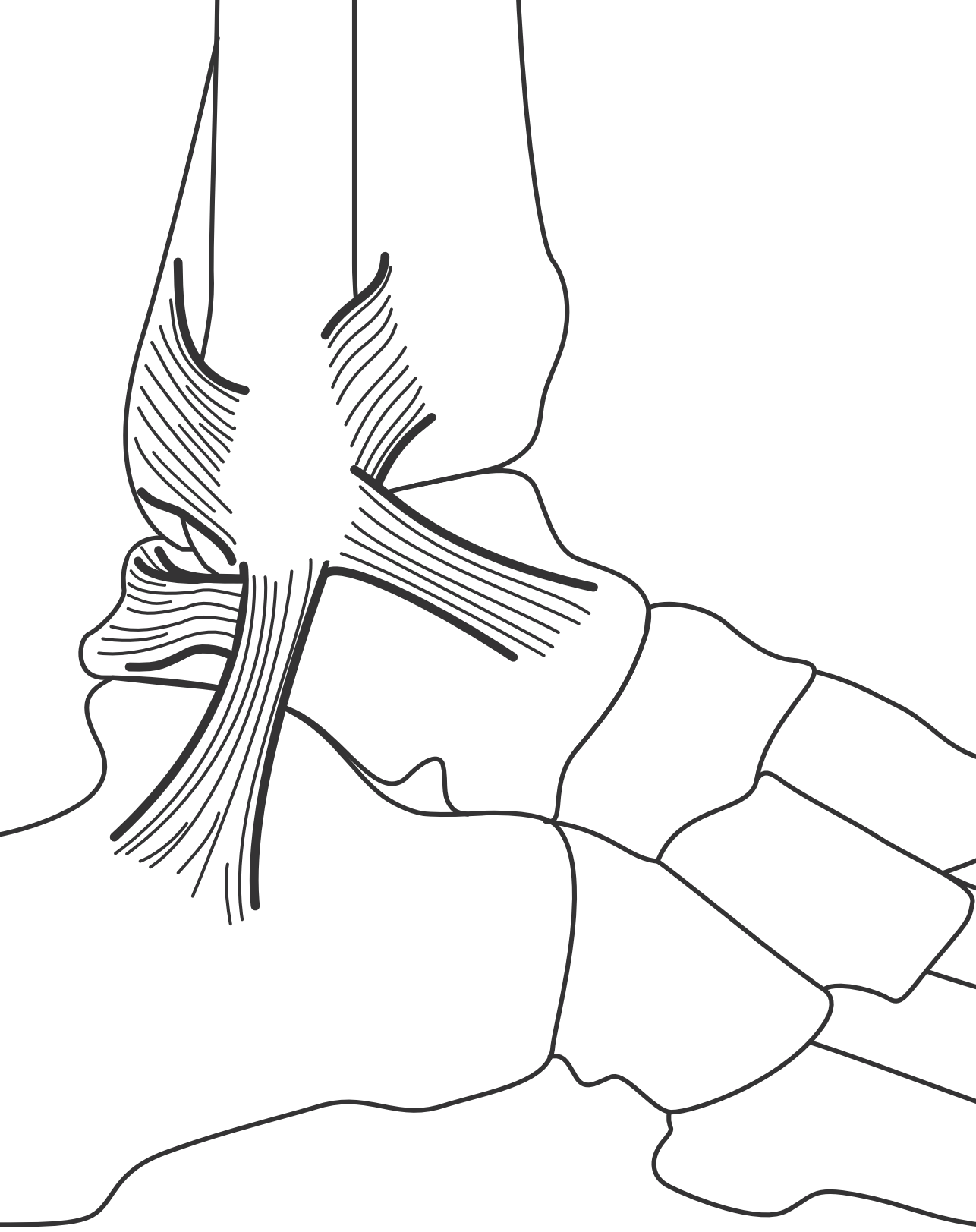

Chapter 5

Economic evaluation of a soft ankle brace compared to tape in acute lateral ankle ligamentous sprains

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ABSTRACT

Background: Ankle sprains are common injuries and they are associated with high healthcare and societal costs. Ankle taping is the standard treatment after sustaining an acute ankle sprain in the Netherlands, while braces are sometimes used as an alternative. The aim of the present study was to assess the cost-effectiveness of soft ankle bracing compared with that of ankle tape treatment in patients with an acute lateral ankle ligamentous sprain (ALALS).

Methods: We conducted an economic evaluation from a societal perspective alongside a controlled trial. In order of presentation, patients with an ALALS were alternately allocated to a four week treatment with either a soft ankle brace (intervention group) or a four week treatment with ankle tape (control group). Costs and clinical outcomes with respect to re-injuries were derived from online patient questionnaires at 5, 9, 13, 26, 39, and 52 weeks after inclusion. Univariate and probabilistic sensitivity analyses were performed. Cost-effectiveness was assessed using bootstrapping with 5,000 replications.

Results: In total 157 patients with an ALALS were included, of which 151 (tape n=76, brace n=75) were analyzed. At the one-year follow-up, no significant clinical differences were found between the two treatment groups. The mean total costs were €1,634 (standard deviation (SD) 261) per patient in the brace group and €1,846 (SD 296) per patient in the tape group; the mean difference was -€212 (95% CI -854 to 436). The use of an ankle brace was less expensive in 71% of the bootstrap replications.

Conclusions: In patients with ALALS, soft ankle bracing compared to ankle taping had similar clinical effect, but the costs of soft bracing were lower, although this difference was not statistically significant.

Key Terms: ankle sprain, soft brace, ankle tape, cost-effectiveness, re-injuries.

INTRODUCTION

Lateral ankle sprains are one of the most common musculoskeletal injuries. Incidence rates of 1.5-7 per 1,000 person-years have been reported in emergency departments in the general European population[3,11,17]. The total number of medically and non-medically treated ankle injuries related to sports activities and other activities of daily living increased from 19.0 to 26.6 per 1,000 person-years over the period 2000-2010[17]. In the Netherlands, the number of sports-related ankle injuries is estimated to be 650,000 each year[7]. The mean total costs (direct health care costs and indirect non-health care costs/productivity losses) of one ankle sprain were estimated at €360.60[37] (€42.50 direct health care costs and €318.10 indirect non-health care costs), corresponding to a total cost of €234 million a year. These high direct healthcare costs are the result of medical consumption, (sometimes lengthy) rehabilitation[31,36], persistent residual symptoms[1,31,36] and high recurrence rates[10,33,36]. Furthermore, ankle sprains may cause sick leave, especially in the first period after the trauma[13]. The mean duration of sick leave of medically treated ankle sprains is 2.5 weeks in the Netherlands, with 90% having resumed work after 6 weeks[8].

Several methods of acute lateral ankle ligamentous sprain (ALALS) treatment have been used in the past, but the three main modalities are the following: immobilization, functional treatment and surgical treatment[5,19]. After the acute phase, the current trend in treatment of ALALS is functional treatment[13,14,22,23], as it has been shown to be more effective compared to treatment using immobilization[13,20,21]. Reviews and guidelines therefore recommend functional treatment of ALALS[20,21], although a short period of immobilization might be desirable in the acute phase of severe ankle sprains to reduce pain and swollenness[23,28].

Functional treatment consists of early-mobilization and weight-bearing with semi-rigid external support, combined with neuromuscular training[19,31]. For external support an ankle brace or tape can be used. A recent review of Lin et al. (2012) concluded that the current evidence regarding the cost-effectiveness of ankle sprain treatment is limited[26]. Studies comparing the costs of ankle brace treatment to the costs of other treatment options, such as compression bandage and a plaster cast were included in the review, but the results were ambiguous. In an economic evaluation, the below-knee plaster cast was the most cost-effective option compared to the air cast brace or Bledsoe boot[5], whereas in two cost analyses the use of a semi

rigid protective device was associated with lower costs compared to a compression bandage[25] or immobilization with a plaster cast[34]. There is still a lack of evidence on the cost-effectiveness of the treatment modalities[26]. The aim of the present study was to compare the cost-effectiveness of soft ankle bracing and ankle tape treatment in patients with an ALALS.

METHODS

Participants and setting

This economic evaluation was carried out alongside a pragmatic controlled trial. Details of the study design have been published elsewhere[16]. In summary, patients with an ALALS were eligible for the study. They were recruited from 20 general practitioner practices, 9 physiotherapist practices and 2 emergency departments (ED). Patients (both athletes and non-athletes) had to be 18 years or older and diagnosed with an ALALS caused by an inversion trauma. They were recruited between May 2006 and October 2008. Patients were excluded if they sustained an eversion ankle sprain, multilevel or complicated trauma, or previously had surgery on the same ankle. Patients diagnosed as having a mental illness or cognitive impairment were also excluded from this study.

Study design and procedure

All eligible patients were referred to the UMC Utrecht Department of Sports Medicine. The research assistant contacted the patients by phone and conducted the first screening for inclusion and exclusion criteria (age, multiple trauma, complicated trauma, history of surgery) by means of a short standard questionnaire. If the patient was eligible for inclusion, the research assistant allocated him/her to the brace or tape group based on the order of presentation. The research assistant was blinded for the severity of the inclusion injury, was not a medical expert, and was not responsible for determining the final eligibility of the patients. To check if the patients were indeed eligible for inclusion, a sports physician conducted a baseline assessment.

The protocol was approved by the medical ethics committee (Institutional Review Board) of the University Medical Center Utrecht (UMC Utrecht) and was registered in the Dutch trial register (ISRCTN92030205). All participants provided written informed consent.

Treatment

During the first 2-12 days after the onset of the ALALS, all patients were treated with immobilization, compression, and elevation (ICE), depending of the swollenness of the injured ankle. The allocated intervention (soft brace or tape) started as soon as possible, but within 14 days of the initial trauma[16].

Patients in the intervention group were instructed to wear a soft ankle brace for four weeks, except at night and when taking a shower. They received instructions from the sports physician about using and applying the soft brace. The soft ankle brace (type Push Med; manufacturer Nea Int) is based on the principle of functional ankle tape bandage.

The control group received four weeks of ankle taping, which is the usual care in the Netherlands[29]. The general practitioner, primary care assistant, physical therapist, or plaster technician applied the athletic tape bandage. After two weeks the tape was replaced.

Data collection and outcomes

After informed consent was obtained, baseline data were obtained by the sports physicians. Data collection consisted of a standardized history taking and a physical examination of the patient's ankle. At 5, 9, 13, 26, and 39 weeks after inclusion, patients received a (digital) questionnaire. Information was registered regarding ankle re-sprains, residual symptoms, compliance with the allocated treatment, absenteeism from paid- and unpaid work (hours) and from school, sport resumption, medical consumption (volumes of medical resources used) and costs of treatments (out-of-pocket costs). All participants were invited for a reassessment by one of the sports physicians 52 weeks after treatment allocation. All the sports physicians received a standardized training on assessing the outcomes. This assessment included the same physical examination as at baseline and completion of a final questionnaire as indicated above.

In this economic evaluation, the primary clinical outcome was the proportion of patients reporting re-sprains at the one-year follow-up after the initial ALALS. A re-injury was defined as a new inversion trauma involving the same ankle, as reported by the patient.

Economic framework

Economic analysis was performed from a societal perspective, which means that all significant costs associated with the injury were considered, regardless of who pays them[6,9]. The economic evaluation was designed as a cost-effectiveness analysis (CEA)[6], with costs per prevented recurrent ankle sprain as the outcome parameter. The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in mean total costs per patient between both treatment groups by the mean difference in number of recurrent ankle sprains between the groups. The ICER represents the incremental costs of preventing one recurrent ankle sprain when ankle brace treatment is applied, compared to usual care with ankle tape treatment. Discounting was not applied as the time horizon of this study did not exceed 1 year.

Costs

All costs related to the initial ALALS or a recurrent ankle sprain that were incurred within one-year were registered. Costs were divided into intervention costs, direct healthcare costs (medical costs), direct non-healthcare costs (patient costs, i.e. related to the use of complementary medicine and medical devices) and indirect non-healthcare costs (costs due to absence from paid work, unpaid work and school).

The first contact moment (after onset of injury) with a general practitioner (GP), physiotherapist or visit to an emergency department (ED) was not reported by all patients. Intervention costs for patients in the brace group were therefore standardized to one ED visit and the costs of the soft ankle brace. The intervention costs for patients in the tape group were standardized to one ED visit, one GP visit (guideline-directed refreshment of tape after two weeks) and ankle tape. The total costs were the sum of intervention costs, direct healthcare costs, direct non-healthcare costs and indirect non-healthcare costs. The mean costs per patient in both treatment groups were calculated. Cost calculations were performed according to the Dutch guidelines for cost calculations in health care[9]. All costs were calculated for the year 2009, the last year of data collection for the clinical study.

Direct healthcare costs

The direct healthcare costs consisted of costs for visiting the GP, medical specialist, physical therapist, and costs related to diagnostic testing (i.e. imaging, including ultrasound), and medication. Medication use was reported by the patient. Medication costs were estimated on the basis of prices communicated by the

Pharmacotherapeutical Compass (2009) as provided by the Dutch Healthcare Insurance Board[27]. Costs were calculated by multiplying the volumes of use by standardized costs prices.

Direct non-healthcare costs

The direct non-healthcare costs consisted of costs for complementary medicine consultation and medical devices. These costs, which were reported by the patient, were also analyzed.

Indirect non-healthcare costs

Costs related to absenteeism from (un)paid work and school were incorporated as indirect non-healthcare costs. In this study the maximum reported period of productivity-loss was 13 weeks. The costs per hour for productivity losses related to paid work were based on age- and sex- dependent income of the Dutch population (see Appendix B). A shadow price of €12.50 per hour was applied to productivity loss for household and volunteer work[9]. To calculate the costs for absenteeism from school the cost of employing someone at the age of 23 (net minimal youth wages) was used (set at €8.07 per hour)[9].

Statistical analyses

Differences in costs and effects were analyzed according to the intention-to-treat principle. Baseline characteristics between both groups were analyzed with Chi-square test or Fisher-exact test for dichotomous outcome and the independent student t-test or Mann-Whitney for continuous variables. The difference in the proportion of ankle sprain recurrences between the two groups was analyzed using Chi-square analyses, controlling for baseline differences between the groups.

Cost-effectiveness pairs were obtained by bootstrapping with 5,000 replications. Cost-effectiveness planes were obtained by plotting the incremental costs (vertical axis) against the incremental effects (horizontal axis) of each single bootstrap[2]. Four sensitivity analyses were performed: 1) from a healthcare perspective, i.e. only including healthcare costs and excluding all costs outside health care; 2) with complete cases only (66 in the brace group and 68 in the tape group), excluding cases with missing data; 3) excluding costs for absenteeism from unpaid work and school (i.e., only including productivity losses associated with paid work); and 4) excluding seven participants who sustained ankle injuries other than an ankle sprain (e.g., ankle fracture or overload injury).

Participants in this study had to fill out six questionnaires during one year follow-up. Eleven percent of the cases (n = 17) in the study were not complete at the end of the clinical trial. Missing cost data regarding healthcare resource use, out-of-pocket costs, and productivity losses (3.9% of all the data points) were imputed using the last observation carried forward. Multiple imputation was used to assess missing data (n=12) for ankle sprain recurrences.
The analyses were performed using IBM SPSS 23.0 for Windows and Microsoft Excel. All tests were two-tailed and a p value <.05 was considered statistically significant.

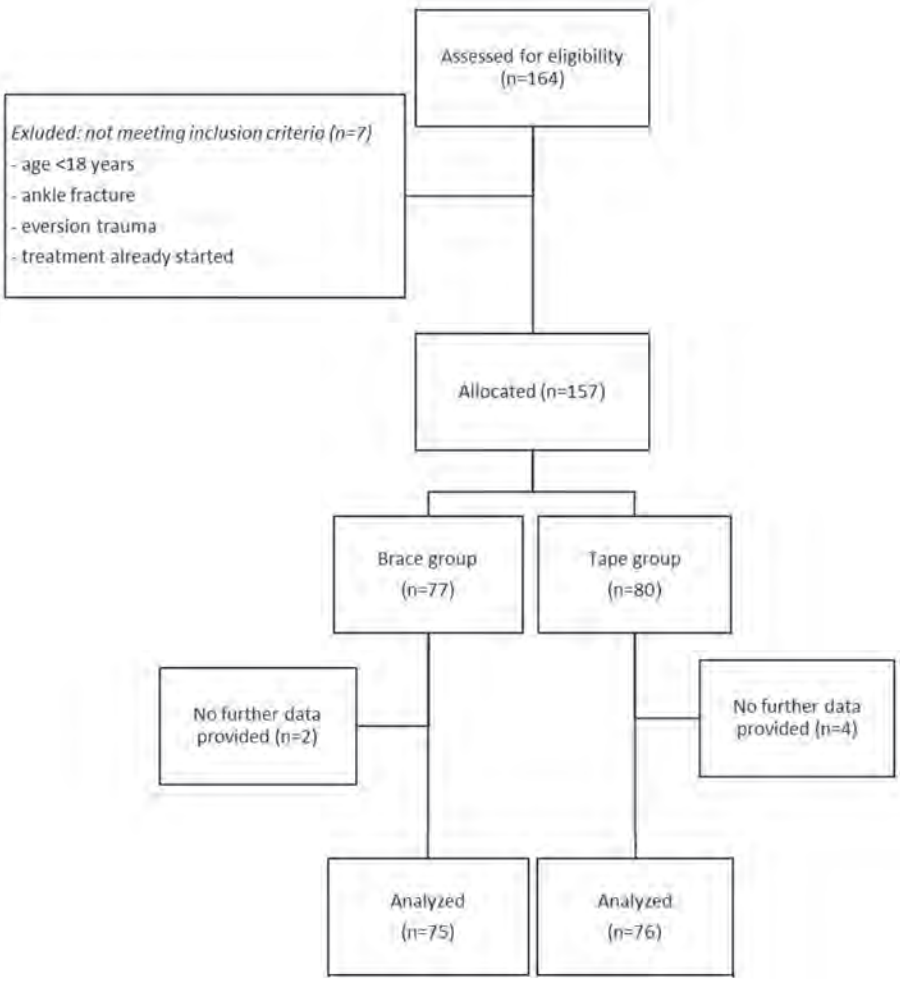

Figure 1: Flowchart of research groups

RESULTS

In total 164 patients were assessed for eligibility in this study (Figure 1). Seven patients were excluded for the following reasons: age under 18 years (n=3), ankle fracture (n=2), eversion ankle sprain (n=1), and treatment already started before randomization (n=1). After allocation, another 6 patients were excluded from the analyses because they were unwilling to complete any study questionnaire (brace=2, tape=4).
The 151 included participants ranged in age from 18 to 64 years (mean 31.1 years); 85 participants (56%) were male. On average, the allocated treatment started 6.0 days (SD 2.3) and 5.9 days (SD 2.0) after the initial injury in the brace and tape group, respectively. Baseline characteristics did not differ between the treatment groups (Table 1).

Table 1: Baseline characteristics treatment groups

	Brace (n=75)	Tape (n=76)
Gender, male, n (%)	41 (55%)	44 (58%)
Mean age in years (SD)	30.4 (11.1)	31.7 (12.2)
Severity of ankle sprain[a]		
Mild, n (%)	26 (35%)	17 (22%)
Moderate, n (%)	38 (51%)	45 (59%)
Severe, n (%)	11 (15%)	14 (18%)
History of ankle sprain		
Yes, n (%)	32 (43%)	24 (29%)
No, n (%)	32 (43%)	42 (55%)
Unknown, n (%)	11 (15%)	12 (16%)
Sports participants, n (%)	65 (87%)	63 (83%)
Time from injury to start of treatment (days) (±SD)	6.0 (2.3)	5.9 (2.0)
Patients with paid job[b]	66 (88%)	64 (84%)
Type of work (sitting, n (%))	35 (53%)	36 (56%)
Mean hours of paid work (SD)	28.4 (15.3)	25.9 (16.7)
Students[b], n (%)	17 (22%)	23 (30%)
Mean hours of study (SD)	23.9 (12.4)	26.4 (16.7)

[a] *See appendix A*
[a] *25 students had a paid job (brace=11, tape=14).*

Effects of intervention

Within 52 weeks after the initial trauma, 16 of the 75 participants (21%) in the brace group compared to 17 of the 76 participants (22%) in the tape group reported a re-injury, corresponding to a risk difference of 1.0% (95% CI -12% to 14%) and a relative risk of 1.0 (95% CI 0.5 to 1.8).

Cost effectiveness

Table 2 shows the unit costs, volumes of healthcare resource use and mean costs per patient for both treatment groups. The mean total costs in the brace group were €1,639 (SD 2,271) and €1,846 (SD 2,624) in the tape group. After bootstrapping, the mean total costs were €1,634 (SD 261) per patient in the brace group and €1,846 (SD 296) per patient in the tape group (Table 3). The mean difference was not statistically significant (-€212 (95% CI -854 to 436). Direct healthcare costs with a mean difference of €94 (95% CI -116 to 341) and indirect non-healthcare costs with a mean difference of -€315 (95% CI -846 to 198) were not significantly different between the groups. The direct non-healthcare costs per patient were lower in the intervention group with a mean difference of -€31 (95% CI -49 to -15). The mean difference in total costs was mainly caused by a difference in indirect non-healthcare costs (€973 in the brace group compared to €1,289 in the tape group).

Table 2: Mean (Standard deviation) intervention costs, direct healthcare costs, direct non-healthcare costs, indirect non-healthcare costs and total costs (€) for both treatment groups.

		Brace (n=75)		Tape (n=76)	
	Cost per Unit (€)	*Volumes*	*Mean costs (€;SD)*	*Volumes*	*Mean costs (€; SD)*
Intervention costs					
Accidents and Emergency department (one visit) [a]	151.00	-	151.00	-	151.00
General practitioner (one visit) [a]	28.00	-	-	-	28.00
Brace[b] / Tape[a]	80.00/12.90	-	80.00	-	12.90
Intervention costs per patient		-	*231.00*	-	*191.90*
Direct healthcare costs					
General practitioner (*per visit*) [a]	28.00	62	23.15 (55.50)	98	36.11 (61.14)
General practitioner (*phone consultation*) [a]	14.00	10	1.87 (7.39)	22	4.05 (15.00)
General practitioner (*home consultation*) [a]	43.00	3	1.72 (14.90)	5	2.83 (17.67)
Medical specialist [a]	129.00	61	104.92 (244.29)	65	110.33 (285.52)
Therapist [a,c]	36.00	531	254.88 (1,028.34)	313	148.26 (289.85)
Hospital stay; day care (days) [a]	251.00	0	0(0.0)	1	3.30 (28.79)
Supplementary diagnostics [a]					
- Ultrasound	48.30	3	1.93 (12.40)	2	1.27 (11.08)
- Radiograph	42.70	17	9.68 (29.43)	17	9.55 (24.75)
- MRI-scan	184.50	6	14.76 (78.86)	4	9.71 (41.47)
- CT-scan	180.77	1	2.41 (20.87)	1	2.38 (20.74)
- Bone scan	150.50	0	0 (0.0)	0	0 (0.0)
Medication[d]	Variable[d]	7	4.85 (10.95)	4	3.16 (13.32)
Total direct healthcare costs			*420.80 (1,094.01)*		*326.57 (580.78)*
Direct non-healthcare costs					
Complementary medicine (*per visit*)[e]	According to Patient specification	4	3.33 (21.31)	17	7.50 (65.38)
Medical devices (i.e. insoles, cold packs, wheelchair) [c]	According to Patient specification	0.2	6.39 (23.23)	0.9	32.66 (57.31)
Total direct non-healthcare costs			*9.72 (30.83)*		*40.16 (84.04)*
Indirect non-healthcare costs					
Absenteeism - paid work[f]	See Appendix B	2,547	844.50 (1,514.89)	3,090	1,005.45 (2,008.63)
Absenteeism - unpaid work	12.50	672	112.00 (205.43)	1,564	257.24 (427.37)
Absenteeism – school	8.07	198	21.30 (117.33)	237	25.17 (69.51)
Total indirect non-healthcare costs			*977.81 (1,600.44)*		*1,287.86 (2,284.50)*
Total costs					
Total costs per patient			*1,639.32 (2,270.51)*		*1,846.49 (2,623.70)*

[a] *Prices according to Dutch guidelines for health care costs*[9]
[b] *Price for the soft brace obtained from the manufacturer.*
[c] *Including cost for consultations with the physiotherapist, manual therapist, occupational therapist and Caesar therapist.*
[d] *Drug prices according to the Pharmacotherapeutical Compass as provided by the Dutch Healthcare Insurance Board*[27]
[e] *Out-of-pocket costs for use of complementary medicine and medical devices were registered by the patient.*
[f] *Indirect costs for paid work was calculated by age and sex specific income of the Dutch population*[9].

Table 3: Mean (SD) of costs per patient in Euro and mean differences (95% confidence intervals)[a] between treatment groups in one year

	Brace (n=75)	Tape (n=76)	Bootstrap Mean difference	Bootstrap 95% CI of Difference Lower	Bootstrap 95% CI of Difference Upper
Intervention costs	231.00	191.90	39.10		
Direct healthcare costs	419.86 (123.74)	325.64 (65.76)	94.22	-116.37	340.54
Direct non-healthcare costs	9.75 (3.52)	40.36 (9.70)	-30.61	-48.94	-14.81
Indirect non-healthcare costs	973.42 (184.92)	1,288.53 (256.79)	-315.12	-845.87	197.65
Total costs	1,634.03 (261.13)	1,846.43 (295.54)	-212.41	-854.20	436.45

a Obtained by calculating bootstrap confidence intervals

From a cost perspective, the ankle brace was associated with fewer costs in 71% of bootstrap replicates. The cost-effectiveness plane with all incremental cost effectiveness ratios (5,000 bootstrap samples) is presented in Figure 2. The bootstrap analyses (Table 4) showed that treatment with a soft ankle brace was cost-saving and more effective in 38% of the bootstrap replicates and cost-saving but less effective in 33%.

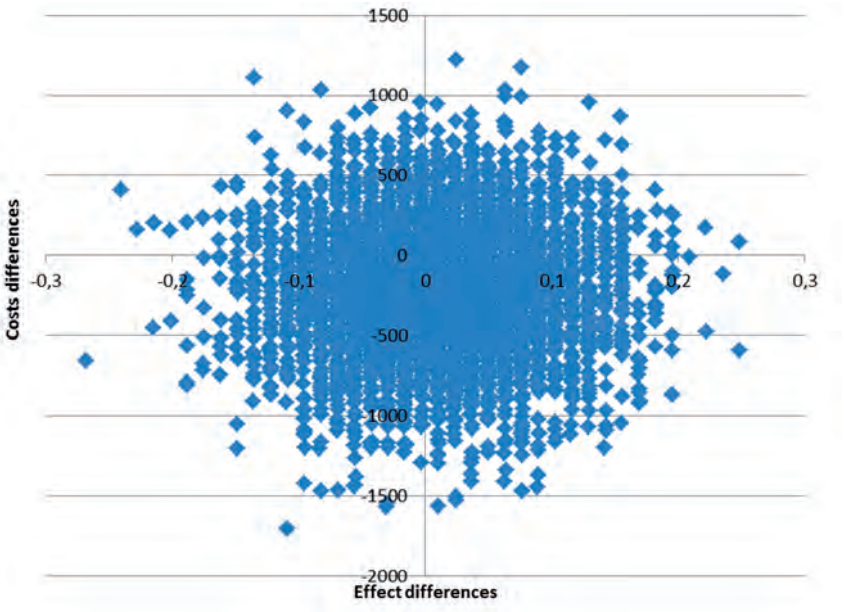

Figure 2: Cost-effectiveness plane presenting costs and effect pairs after bootstrapping (5,000 samples).

Sensitivity analyses

Four sensitivity analyses were performed (see Table 4). In the first sensitivity analysis, only intervention costs and direct healthcare costs were included. This first analysis suggests that the ankle brace was cost-saving in only 18% of the bootstrap replicates (cost-saving and more effective 12%; cost-saving and less effective 6%) and the ankle brace was more expensive and effective in 47% of the bootstrapping analyses. In the second sensitivity analysis only complete cases were included. In this analysis the ankle brace was cost-saving and more effective in 64% of the bootstrap replicates and cost-saving and less effective in 24%. In the third sensitivity analysis costs for absenteeism from unpaid work and school were not included. The ankle brace was cost-saving and more effective in 31%, and cost-saving and less effective in 25%. In the fourth sensitivity analysis, seven participants who sustained ankle injuries other than an ankle sprain (e.g., ankle fracture or overload injury) were excluded. In this analysis, the ankle brace was cost-saving and more effective in 23% of the bootstrap replicates and cost-saving and less effective in 43%.

Table 4: Results of sensitivity analyses

Analyses	Δ Cost (€) (95% CI)	Δ Effect (€) (95% CI)	North East#	South East†	South West¥	North West‡
Base case analysis: Societal perspective	-212 (-854 to 436)	0.0099 (-0.0960 to 0.1167)	0.16	0.38	0.33	0.13
Sensitivity analyses:						
Healthcare perspective	132 (-81 to 380)	0.0105 (-0.0960 to 0.1168)	0.47	0.12	0.06	0.36
Complete cases	-486 (-1,157 to 208)	0.0384 (-0.0775 to 0.1448)	0.09	0.64	0.24	0.03
Only including productivity losses associated with paid work	-55 (-660 to 552)	0.0089 (-0.0963 to 0.1167)	0.26	0.31	0.25	0.18
Excluding patients with other ankle injuries than acute lateral ankle sprain	-175 (-858 to 488)	-0.0227 (-0.1327 to 0.0770)	0.12	0.23	0.43	0.22

Δ Cost is the mean difference in the costs of 5,000 bootstrapped samples.

Δ Effect is the mean difference in the effect of 5,000 bootstrapped samples.

 # Soft brace is more effective and more costly than tape

† Soft brace is more effective and less costly than tape

¥ Soft brace is less effective and less costly than tape

‡ Soft brace is less effective and more costly than ankle tape

DISCUSSION

In this study comparing the effect and costs of soft brace treatment and ankle tape treatment in ALALS, a non-significant injury reduction was accompanied by a non-significant cost saving. However, according to the cost-effectiveness analysis, treatment with a soft ankle brace was less expensive in 71% of the 5,000 samples. In 29% of the samples ankle brace treatment was cost-saving and more effective. Three of the four sensitivity analyses underline the results of the primary analysis showing that the soft ankle brace is less expensive (in 56% to 87% of the bootstrap replicates). Importantly, this difference is mainly attributable to productivity losses which occur at the patients' own expense.

Previous studies on the cost-effectiveness[24] and cost-savings[25] of external supports in the treatment of ALALS showed significant reduction of direct and/or indirect costs in favor of the ankle brace. Leanderson and Wredmark (1995)[25] found a significant reduction in sick leave, resulting in lower indirect costs, with an Air-Stirrup ankle brace treatment compared to a compression bandage. In a study of Lamb et al. (2009)[23,24] regarding severe ankle sprains, the Aircast® brace and 10-day below-knee cast™ were more cost-effective, in terms of costs per quality adjusted life years (QALYs), compared to Tubigrip®. In the current study, the soft brace was not more cost-effective than an ankle tape after one year of follow-up. However, our study differs from the aforementioned studies with respect to the kind of ankle brace used, the reference treatment (tape versus compression bandage in other studies) and the severity of ankle sprains. From a clinical perspective we did not expect a significant difference in effect as the soft brace used in this study was based on the principles of ankle taping.

Verhagen et al. estimated the mean total costs (direct healthcare costs and indirect non-healthcare costs) of one ankle sprain at €360.60[37]. The mean costs per patient in our study were much higher. In our study costs are reported per participant and not per ankle sprain. All 151 participants in our study had an ankle sprain (the initial ankle sprain), 33 participants (20%) had at least one ankle sprain recurrence. Furthermore, all our participants sought medical treatment for their initial ankle sprain (inherent to the inclusion criteria), compared to 79% only in the study by Verhagen et al[37]. In 2013 mean direct medical costs and indirect non-healthcare costs related to ankle injuries treated at EDs in the Netherlands were €1,710 for patients aged 15-34 and €3,070 for patients aged 35 and older[35]. As the mean age of our study population is 31, these costs are more in line with our results.

From a societal perspective, the use of a soft brace in the treatment of ALALS did not lead to additional costs, despite the higher purchasing cost of the ankle brace. The higher price of the brace treatment seems to be negated by lower mean non-healthcare costs per patient treated with a soft brace compared to patients with ankle tape treatment. In this study, the costs of the soft ankle brace were regarded as intervention costs. The costs of ankle braces are rarely reimbursed by healthcare insurance companies in the Netherlands. Thus, treatment with a soft ankle brace will increase the direct non-healthcare costs (out-of-pocket costs for patients). Despite our finding that using the soft brace is associated with lower societal costs, these higher out-of-pocket costs might be a barrier for the use of ankle braces in treating ankle sprains. Other arguments, such as patient comfort and lifestyle activities may also be important in the choice between brace and tape.

As in the other studies[5,6,37], the majority of the costs were attributable to productivity loss. From an employer's perspective, the soft ankle brace might be preferred over ankle tape treatment, for the soft brace tends to result in a quicker return to work or school. Patients might have benefited from the comfort and adjustability of the brace and this may have led to the prevention of absenteeism. However, in a systematic review of Kemler et al. (2011) no evidence that the ankle brace was associated with a quicker return to work was found[15]. Further research should focus more specifically on the severity of the ankle sprain and type of work (predominantly sedentary or active) in relation to work absenteeism in the first period of an ankle sprain injury.

In this study, the information about recurrent ALALS and costs was collected by using structured online cost questionnaires. In the first three months a fixed time interval of four weeks was used. This short time-interval and the use of structured questionnaires reduced the likelihood of bias. Nevertheless, missing or double reporting of the cost data and misdiagnosis of ankle re-sprains during the follow-up period could have occurred in both groups. After three months a time interval of 13 weeks was used, increasing the risk for recall bias and missing data. Self-reporting methods for recurrent ALALS have been used in previous trials on treatment and prevention of ankle re-sprains[12,32] and is common in economic evaluations alongside clinical trials. With respect to recall of volumes of resources used and out-of-pocket costs, it has been shown that the use of cost-questionnaires can replace cost dairies with a recall period up to 6 months[4]. We therefore feel confident that our economic evaluation is reliable.

Missing costs data were imputed according to the 'last observation carried forward' principle. Although multiple imputation is often the favored technique, we assume that our method did not significantly influence the final results as only 3.9% of our data points were missing.

In this economic evaluation, the ankle brace was less expensive in 71% of the bootstrap replicates. This might indicate that, from a societal perspective, the use of a soft ankle brace reduces the total costs related to ALALS, but more research is needed to confirm these findings.
At the time of our study, ankle taping was the usual care in the Netherlands in accordance with the existing clinical guideline[29]. According to recent considerations, a lace-up brace or a semi-rigid brace is preferable and recommended in the treatment of ALALS[18]. In (professional) sports, the use of tape can also be considered for ankle sprain treatment[18]. Patients will probably have to bear the additional costs of the purchase of a soft ankle brace in daily life. Without compensation for the purchasing costs, considerations other than cost-effectiveness may influence the decision to treat ALALS with a brace or with tape.

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Statement of financial disclosure and conflict of interest
The content of this report is solely the responsibility of the authors and does not necessarily represent the official view of Nea International. We declare that we have no conflict of interest. Prof. FJG Backx declares that Nea International has given unrestricted financial support to initiate and perform this study. Furthermore, Nea International offered the ankle braces (type Push Med) used in the intervention. We fulfilled this study without any influence or interference of the sponsor.

APPENDIX A

The injury severity score (range 0-6) was determined by the sports physician at baseline based on six items, scored as 1 when present and 0 when absent:

(1) swelling of the injured ankle;
(2) any discoloration by hematoma;
(3) limited dorsiflexion in the injured ankle;
(4) clear tenderness at one or more anatomical locations related to the injured ankle;
(5) difference in the anterior drawer sign between the injured and contralateral ankle, and;
(6) difference in the talar tilt test between the injured and contralateral ankle.

Injury severity was based on the total score (0-6) in relation to the number of days between the onset of the initial trauma and assessment of the injury severity score, and was categorized as follows:

- Severe lateral ankle ligamentous sprain (score of 6 and physical exam at least four days after the injury).
- Moderate lateral ankle ligamentous sprain (score of 6 and physical exam on days one-three after the injury *OR* score of 5 or 4 and physical exam at least four days after the injury).
- Mild lateral ankle ligamentous sprain (all other combinations).

APPENDIX B

Mean indirect costs for work loss per hour by age and sex

Age	Males Euro/hour	Females Euro/hour	Total Euro/hour
15-19 years	9.65	8.76	9.27
20-24 years	17,75	17.18	17.51
25-29 years	24.19	23.62	23.93
30-34 years	29.65	27.54	28.80
35-39 years	34.03	29.25	32.25
40-44 years	36.67	29.06	33.92
45-49 years	38.32	28.91	34.87
50-54 years	39.06	29.25	35.61
55-59 years	39.38	29.50	36.37
60-65 years	39.13	28.67	36.41
Total	32.49	25.94	30.02

Source: Dutch guidelines for healthcare costs[9]

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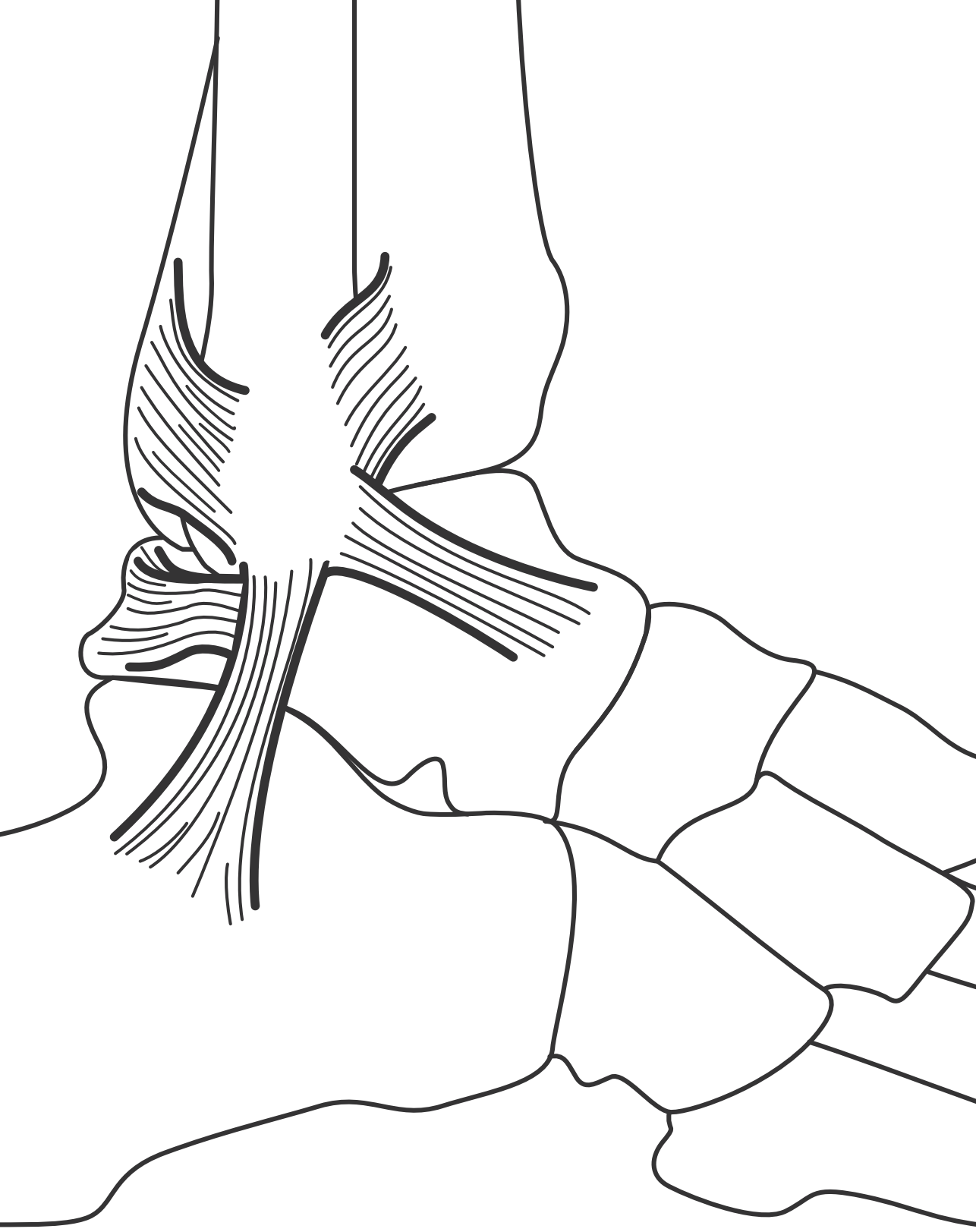

Chapter 6

Long-term prognosis of acute lateral ankle ligamentous sprains: high incidence of recurrences and residual symptoms

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ABSTRACT

Background: Acute lateral ankle ligamentous sprains (ALALS) are common injuries. This injury does not always have a favorable long-term outcome and recurrences and residual symptoms may impact a patient's life, even years after the event. However, studies reporting the prognosis of ALALS after functional treatment are scarce.
Objective: To determine the prognosis of functionally treated ALALS in the population at large, in terms of recurrent ankle ligament sprains and residual symptoms.
Methods: Patients with ALALS who were treated with an ankle brace or ankle tape were invited to participate in this study 2.5 to 5 years after their initial injury. They were invited for an assessment by a sports medicine physician. It consisted of history taking and physical examination to determine swelling, ankle function limitations, (active and passive) ankle stability and pain.
Results: A total of 44 patients were included, with an average follow-up period after the initial ankle sprain of 204 weeks (range 150-274 weeks). Eight patients (18.1%) had reinjured their ankle within this follow-up period. Ankle pain during everyday activities was reported in 29.5% of the patients and 45.5% experienced explicit pain around the ankle joint at physical examination. Clinical symptoms of anterior ankle impingement were present in 25% of the patients (all were athletes), with radiologically confirmed tibiotalar osteophyte bone formation in 82% of them.
Conclusions: A large proportion of patients with ALALS experience recurrences and persistent symptoms after their initial ankle injury. Anterior ankle impingement syndromes were diagnosed in 25% of the patients. This illustrates the need for early assessment of this impairment in patients with persistent complaints.
Keywords: long-term consequences, ankle sprains, recurrences, residual symptoms, impingement.

BACKGROUND

Acute lateral ankle ligamentous sprains (ALALS) frequently occur in everyday life and during sports participation. Incidence rates range from 2.2 to 7.0 per 1,000 person-years[2,9,27]. Acute ankle sprains are usually caused by an excessive inversion movement of the ankle, in which the lateral ligaments are stretched out[5]. Depending on the severity of the sprain, the fibers of the ligaments are either intact or (partially) disrupted[11]. The long-term outcome after an ankle sprain is often unfavorable, which is alarming considering the high frequency of this injury. Evidently, recurrent sprains and residual symptoms (e.g. pain, swelling, ankle instability, and impingement syndromes) after ALALS can impact a patient's everyday life. Even after years, the discomfort and lack of trust in the injured ankle can cause patients to make sacrifices, particularly in their sports performance level[16].

Despite the abovementioned indications of a poor prognosis of ALALS, studies focusing on the patients receiving only functional treatment are limited. Most studies reporting about the long-term consequences of ALALS include patients who received surgical treatment (as well)[17,20-22] or focus on immobilizing treatment[6,19,24,26]. However, functional treatment after ALALS is currently recommended as the treatment of choice[10,11,14]. Furthermore, the reported studies are frequently performed using athletic populations[1,18,20,29]. It is likely that the incidence of recurrent sprains and residual symptoms is different for the general population, compared to the athletic population[13]. The objective of the current study is to determine the long-term prognosis of functionally treated ALALS in terms of recurrent ankle ligamentous sprains and residual symptoms.

METHODS

Participants

Patients included in a clinical trial on the treatment of ALALS[12] were invited to participate in this cohort study. Between May 2006 and October 2008, patients were recruited from 20 general practitioner practices and 9 physical therapy practices in the Netherlands (region Utrecht), and from the emergency departments of a regional hospital (Zuwe Hofpoort Hospital, Woerden, the Netherlands) and a university hospital (University Medical Center Utrecht (UMC Utrecht), Utrecht, the

Netherlands). Patients 18 years or older who were clinically diagnosed with ALALS caused by an inversion trauma were eligible for the trial. Patients were excluded if they sustained an eversion trauma, multiple traumas, complicated trauma (including cartilage injuries, fractures and dislocation), or had a history of ankle surgery. Patients diagnosed as mentally ill or with dementia were also excluded. Patients were eligible for the present cohort study if they had completed at least one-year follow-up after the initial injury (because we were interested in the long-term prognosis). Patients from the clinical trial study who sustained ankle injuries other than ALALS (e.g. fractures, overuse injuries) during the one-year follow-up period were excluded from analyses. These patients (n=7) were also excluded from the current cohort study to prevent bias. A total of 136 patients (of the 157 in the clinical trial) were eligible for participation in the cohort study. The medical ethics committee of the UMC Utrecht approved the study protocol. All patients gave their written informed consent.

Procedures

This study was executed 2.5 to 5 years after inclusion of patients in the clinical trial. Patients were invited by email to fill out a short online questionnaire about their willingness and availability to participate in the current cohort study. When necessary, a reminder was sent after two weeks. In case of an incorrect email address, patients were contacted by telephone (when available) or by a letter sent to their home address.

A sports medicine physician at the UMC Utrecht invited the patients who were willing to participate for a clinical assessment. This assessment consisted of standardized history taking and physical examination to determine pain in everyday life, local tenderness around the ankle, swelling, ankle function and mechanical and functional stability. A limited ankle dorsiflexion, pain at the anterior and anteromedial ankle, pain at the talar head and diffuse swelling were defined as symptoms of anterior ankle impingement. In the presence of at least one of the clinical symptoms of anterior impingement, standard anteroposterior radiographs, lateral radiographs and an oblique radiograph were performed to detect the presence of osteophytes at the talus and/or anterior rim of the tibia. In the oblique anteromedial impingement (AMI) view, the beam was tilted into a 45° craniocaudal direction with the leg in 30° of external rotation and the foot plantar flexed in relation to the standard lateral radiograph position[12].

Outcome measures

The primary outcome was the proportion of patients with a recurrence of ALALS. A recurrence was defined as a new inversion trauma of the same ankle, after the initial injury in the clinical trial.

The secondary outcome was the occurrence of residual symptoms at the follow-up assessment by the sports medicine physician. These symptoms included: pain during walking, running, pivoting and/or jumping (Yes/No); local tenderness at physical examination of the ankle; swelling (Substantial/Moderate/Minimal/No); functional outcome (No limited dorsiflexion/ Limited dorsiflexion); mechanical and functional instability; and the clinical presence of ankle impingement syndromes. Mechanical stability was defined as ligamentous stability. The manual tests used to measure ligamentous stability were the manual anterior ankle test and the talar tilt test. Functional stability was defined as proprioceptive and neuromuscular stability. A clinical balance test, consisting of four one-leg stance tests, was used to identify functional stability impairments. Individuals were instructed to balance on a bare foot with their non-weight-bearing leg flexed 90° at the hip and their hands crossed over their chest, and remain as motionless as possible for 15 seconds without moving their arms or non-weight-bearing leg. The first one-leg stance test was conducted with the eyes open, the second with the eyes open and the knee in 45° flexion, the third with eyes closed and the knee in 45° flexion and last, and most difficult, with eyes closed and the knee in 45° flexion while raising the heel from the ground (standing on the forefoot). Both legs were tested identically. Successful accomplishment of the one-leg stance test was defined as being able to stand on one leg for 15 seconds.

Statistical analysis

The baseline characteristics of the patients and the outcome measures were presented using descriptive statistics. Non-parametric Chi-square tests or t-tests were applied to compare baseline characteristics of responders and non-responders. Two-sided p values of less than 0.05 were considered to indicate statistical significance. All data were analyzed using IBM SPSS Statistical software package (version 19).

RESULTS

Study population

Of the 136 eligible subjects, 47 (34.6%) were willing to participate in the cohort study, including the assessment by the sports medicine physician (Figure 1). Three responders with ankle/foot injuries other than recurrent sprain (inflammation of upper tarsal joint, two unknown injuries) during the follow-up period were excluded (see Figure 1). As a result, 44 responders were included in the current analysis after a mean follow-up period of 204 weeks (range 150-274, SD±35 weeks).

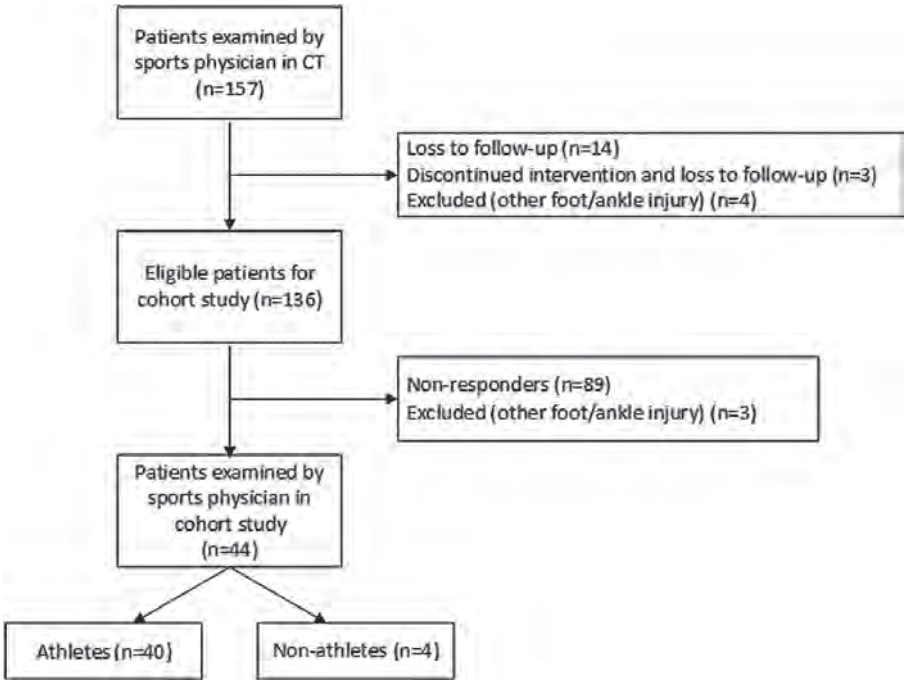

Figure 1: Flow-chart of the study population

Demographic and baseline characteristics

There were only a few demographic differences between the eligible participants who responded and the non-responders; the responders were somewhat older and the reported recurrence rate in the responders was higher than in the non-responders (23 versus 13%, p=0.15) (see Table 1).

Table 1: Comparison of baseline characteristics between eligible participants with ALALS from the clinical trial responders versus non-responders

	Non-responders n=89 (%)		Responders long-term study n=44 (%)		p-value
Gender					
Male, n (%)	51	(57.3)	26	(59.1)	0.844
Mean age, y (SD)	31.1	(10.6)	33.1	(14.0)	0.095
Sports participants, n (%)	76	(85.4)	39	(88.6)	0.607
Intervention during the trial					
Brace, n (%)	44	(49.4)	24	(54.5)	0.579
Tape, n (%)	45	(50.6)	20	(45.5)	
Injury severity#					
Mild, n (%)	24	(27.0)	11	(27.7)	0.950
Moderate, n (%)	50	(56.2)	26	(57.4)	
Severe, n (%)	15	(16.9)	7	(14.9)	
History of ankle sprain injured ankle prior to index injury trial					
Yes, n (%)	36	(40.4)	12	(27.2)	0.294
No, n (%)	39	(43.8)	25	(56.8)	
Unknown, n (%)	14	(15.7)	7	(15.9)	
Recurrent ALALS after one year, n (%)	14	(13.2)	10	(22.7)	0.148

SD, Standard Deviation, y= years, ALALS= Acute lateral ankle ligamentous sprain

 # See Appendix A

Re-injuries

Of the 44 responders, eight (18.1%) reinjured their ankle after the initial ALALS from the trial, of which seven participated in sports and one did not. Of these eight responders, five reported a recurrence within one year after the initial ALALS. Five additional responders had complaints of recurrent "giving way" without swelling and discoloration of the ankle (11.4%).

Residual symptoms

Of the responders, 29.5% still reported pain of the injured ankle during daily life activities at long-term follow-up (Table 2). At physical examination, 45.5% had explicit tenderness around the ankle joint, of which 85% at the region of the sinus tarsi. Clinical symptoms of anterior ankle impingement, e.g. focal anteromedial pain, exacerbated on dorsiflexion and limited dorsiflexion, were present in 11 responders (25.0%; all of whom were athletes).

Table 2: Residual symptoms after long-term follow-up (mean 204 weeks) in participants with ALALS (n=44)

Residual symptom	N	%
*Pain**	13	29.5
Tenderness at physical examination	20	45.5
Sinus tarsi	17	38.6
Lateral malleolus	4	9.1
Anteromedial gutter	4	9.1
Swelling	4	9.1
Functional outcome		
No limited dorsiflexion	33	75.0
Limited dorsiflexion	11	25.0
Mechanical stability		
Ankles equal	32	72.7
Injured ankle worse	7	15.9
Injured ankle better	5	11.4
Good functional stability of injured ankle		
One-leg stance, eyes open	42	95.5
One-leg squat (knee 45° flexion), eyes open	38	86.4
One-leg squat (knee 45° flexion), eyes closed	7	15.9
One-leg squat (knee 45° flexion), eyes closed, standing on forefoot	0	-
Anterior impingement	11	25.0
Posterior impingement	3	6.8

** Pain was defined as pain during walking, or running or turning or jumping*
ALALS= Acute Lateral ankle ligamentous sprain

Radiological evaluation

Of the 11 responders with a symptomatic anterior impingement, nine (82%) showed clear anterior tibiotalar osteophyte bone formation at radiographic evaluation. One responder had already been operatively treated for persistent ankle complaints after the initial ALALS. Pre- versus postoperative radiological evaluation showed clear anterior talar bone formation in this person.

DISCUSSION

In our cohort among 44 responders with ALALS receiving functional treatment, 18.1% reported re-injuries and almost one third of the responders reported pain, while 45.5% had explicit tenderness around the ankle joint after the mean follow-up period of nearly four years. Symptoms of anterior tibiotalar osteophyte bone formation were present in 25% of the responders.

The results of our study are in line with earlier studies, in which both athletes and non-athletes were included[16,23,26]. In a systematic review, Van Rijn et al. (2008) reported that 3 to 34% of the patients with an acute lateral ankle sprain have suffered at least one recurrent ankle sprain during the follow-up period ranging from two weeks to three years[23]. Many patients (15 to 64%) still experienced residual symptoms such as pain and subjective instability three years after their initial ankle sprain. Konradsen et al. (2002) reported chronic complaints, swelling or recurrent sprains in 32% of the subjects after seven years of follow-up[16]. All patients in these studies were recruited from a hospital, which is different from our study. Our study population is probably more diverse. In a study among the general population in the Netherlands, Verhagen et al. (1995) found a high incidence of ankle sprain recurrences (46%) and residual complaints (30%) after 6.5 years follow-up[26]. The higher incidence of recurrences in their study might be explained by the inclusion in the study population of more severe forms of ALALS requiring further second-line hospital evaluation or by the longer follow-up period in their study[26].

Anandacoomarasamy and Barnsley (2005) studied patients presenting themselves at a sport medicine clinic in Australia. In this study, 74% of the patients had at least one residual symptom when assessed 1.5–4 years after their initial injury[1].

In the current study, ankle pain was mostly localized laterally, with the maximal pain at the sinus tarsi. This is an indicator of sinus tarsi syndrome. It is a common clinical entity characterized by persistent anterolateral ankle pain. In 70% of the cases the anterolateral ankle pain occurs secondary to traumatic injuries to the ankle[7]. In our study sinus tarsi syndrome was clinically detected in 38.6% of the responders with pain. To our knowledge, there are no other clinical studies comparable to ours regarding information about this syndrome after ALALS. Klein and Spreitzer (1993), for example, used an MRI to observe abnormal signals within the region of the sinus

tarsi. They found abnormal signals on the MRI (1-48 months after trauma) in 39% of their patients with disruption of the lateral ankle ligaments[15]. As we did not use an MRI in our study, it is not possible to conclude that the results of our study and those of Klein and Spreitzer (1993) are comparable.

In total, 25% of the responders (n=11) were diagnosed with symptomatic anterior impingement syndrome. All were athletes. Nine subjects (82% the participants with anterior ankle impingement) had radiologically confirmed anterior tibiotalar osteophyte bone formation ('spurs'). It is thought that hyper dorsiflexion, repetitive (micro) traumata and ankle instability are possible causes for the development of these bone spurs in general[4]. However, more than 50% of active athletes have ankle osteophytes without complaints. This indicates that radiologic changes are not necessarily symptomatic. Cheng and Ferkel (1998) found asymptomatic spurs in the ankles of 45% of football players and in 59% of dancers[3]. Subsequently, these spurs can become symptomatic when hypertrophic synovia, scar tissue or the anterior capsule is squeezed between the tibiotalar osteophytes[4,25]. It is believed that recurrent trauma and decreased functional and mechanical ankle stability have a negative contribution to this phenomenon. Only 2 of our 11 responders with clinical signs of anterior impingement showed no radiologic tibiotalar spurs. Soft-tissue compression of the joint capsule is most probably the cause of their anterior impingement syndrome.

Signs of posterior ankle impingement were found in three responders (6.8%). These subjects also had symptomatic anterior ankle impingement. The etiology of symptoms in those responders is probably the same, causing impingement of hypertrophic synovia both anteriorly and posteriorly. Much like anterior impingement, posterior impingement syndromes can manifest sub acutely after other ankle injuries or repetitive trauma with compression of soft-tissue components.

Another frequently seen residual symptom is ankle instability. This instability can be mechanical when laxity of the capsular ligamentous complex has been identified through physical examination, or functional, when patients complain about an instable feeling ('giving way'). Functional ankle instability is caused by deficits in proprioception, neuromuscular control, postural control and/or muscular strength[8,28]. In this study 95.9% of the patients had good functional (active) stability in the one-leg stance test with the knee in 45° flexion and open eyes. This is in accordance with the

results after one-year follow-up[12]. Performing the one-leg stance test with the knee in 45° and eyes closed, the results after one year of follow-up were however better than after a mean follow-up period of 204 weeks post initial ankle injury (29.3% had good functional stability after one year versus 15.9% after a mean follow-up of 204 weeks). This might indicate that the active stabilizers of the ankle diminish in their function with time, which highlights the need for a repeated execution of active ankle stability exercises. More research is needed to clarify the function of the active ankle stabilizers over time.

This study has some limitations. Our primary outcome was ankle sprain recurrences, which are self-reported by the patients and collected retrospectively. Prospective registration of ankle sprain recurrences would be more accurate, especially when recurrences are not only reported by patients but also verified by skilled physicians. To our knowledge, no study has ever taken such a rigorous approach. The number of responders included in our cohort study is relatively small (n=44). There are no indications however that the responders included in this long-term study differ from the non-responders. We do not know if they already showed signs of anterior impingement and/or tibiotalar spurs before the initial ALALS. Furthermore, only those responders with clinical symptoms of anterior ankle impingement were examined with radiographs. Therefore, whether there is a causal relation between the initial ALALS and the presence of impingement signs at follow-up cannot be determined.
A major strength of our study is the measurement of the secondary outcome variables by a sports medicine physician.

Our study underlines the high percentage of patients dealing with recurrences and/or persistent symptoms after a frequently occurring ALALS. An impingement syndrome seems to be a less well-known residual symptom. As 25% of our responders were diagnosed with this syndrome, it deserves more attention in education aimed at physicians and physical therapists. Both patients as well as physicians should be aware of the fact that there is no such thing as an ordinary ALALS. Primary care providers, such as general practitioners and physiotherapists, should be aware of the clinical presence of ankle impingement syndromes in order to prevent long-term residual complaints.

In future research it is relevant to evaluate the prognostic factors that contribute to residual symptoms in order to identify the population at risk for long-term complaints in an early stage. Subsequently, treatment adjustment and/or prevention strategies can possibly improve long-term outcomes.

APPENDIX A

The injury severity score (range 0-6) was determined by the sports medicine physician at baseline based on six items, scored as 1 when present and 0 when absent: (1) swelling of the injured ankle; (2) any discoloration by hematoma; (3) limited dorsiflexion in the injured ankle; (4) clear tenderness at at least one of the anatomical locations of the injured ankle, (5) difference in the anterior drawer sign between the injured and heterolateral ankle and 6) difference in the talar tilt test between the injured and heterolateral ankle.

Injury severity was based on the total score (0-6) in relation to the number of days between the onset of the initial trauma and assessment of the injury severity score, and was categorized as follows:

- Severe lateral ankle ligamentous sprain: score of 6 and physical exam at least 4 days after the initial injury.
- Moderate lateral ankle ligamentous sprain: score of 6 and physical exam on days 1-3 after the initial injury *OR* score of 5 or 4 and physical exam at least 4 days after the injury.
- Mild lateral ankle ligamentous sprain: all other combinations.

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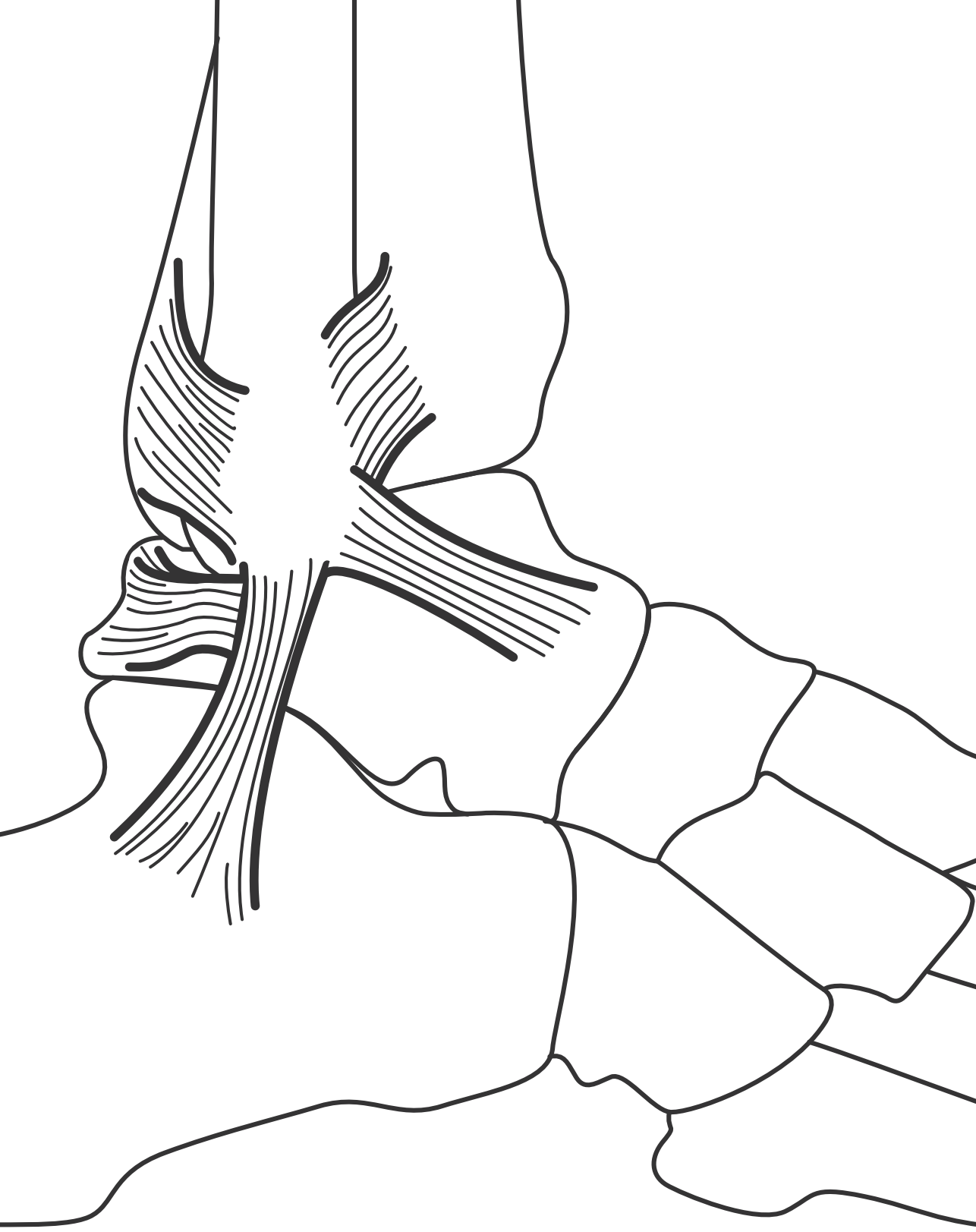

Chapter 7

Incidence and determinants of recurrent lateral ankle ligamentous sprains

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ABSTRACT

Objective: Little is known about the incidence and determinants of recurrent acute lateral ankle ligamentous sprain (ALALS) in the general population. The purposes of this study were to determine the proportion of patients suffering from one or more recurrent ALALS during one year follow-up after the initial injury and to identify risk factors for sustaining a recurrent ALALS.

Design: Prospective cohort study.

Setting: Patients were recruited from 20 family practices, nine physical therapy practices and the emergency departments of a regional and a university hospital.

Subjects: Adult patients with an ALALS caused by an inversion trauma.

Methods: Univariable and multivariable Cox regression analysis.

Results: After 52 weeks follow-up, 29 of the 157 patients (18%; 95% CI 12.4-24.5) had experienced a recurrent lateral ankle sprain. Univariable Cox regression analysis showed that younger age, a lower body mass index (BMI), having had more than one ankle injury, sports participation and the number of hours of sports per week were associated with the risk of recurrent ALALS. Multivariable Cox regression analysis showed that with increasing age the risk to suffer a recurrent lateral ankle sprain decreases (hazard ratio per year 0.92 (95% CI 0.87-0.98).

Conclusions: Nearly one fifth of the patients with ALALS suffer from a re-injury within 12 months and the injury risk decreases with increasing age. This highlights the importance of optimal treatment and preventive programs in younger adults, to reduce the burden from recurrent lateral ankle ligamentous sprains.

Key words: ankle sprain, re-injuries, risk factors, prognosis, prevention.

INTRODUCTION

After the knee, the ankle is the most injured body site in athletes (11% to 21%)[12]. Depending on the population studied, ankle sprains account for 33-73% of all ankle injuries in athletes[12]. Reported incidence rates for ankle sprains in the general population vary from 1.5 up to almost 7 per 1,000 person-years[7,16,19,29]. Most ankle sprains (85%) are located on the lateral side[10].

The consequences of acute lateral ankle ligamentous sprains (ALALS) can sustain over a long period of time. One of the most important long-term consequences is recurrent ALALS, although studies reporting on the incidence of recurrent sprains tend to report large differences. A systematic review by van Rijn et al. (2008) showed that 3-34% of the patients suffer a recurrent ALALS of the injured ankle within 3 years[22]. The highest rates of recurrent lateral ankle sprains are reported among athletes, mainly active in team sports[6,27]. The mean time to return to sports after a recurrent sprain seems to be higher than after a first-time ankle sprain[10]. A recurrent ALALS causes longer absence of players in team sports[21] and causes additional work absenteeism in the general population[28].

From earlier research it is known that a previous lateral ankle sprain in an athlete's history is one of the most important risk factors for sustaining an ankle sprain[5,9]. It is useful to identify people who are more at risk for sustaining a recurrent sprain, because the occurrence of a recurrent sprain has a large impact on a patient's daily functioning and sports participation. In addition, information about risk factors for recurrences yields important input for targeted preventive strategies.

Two earlier studies identified risk factors for a recurrent ALALS. Pre-injury activity level[14] and grade of initial injury[21] were significant predictors of recurrent ALALS. However, one study[14] included only athletes and neither of these studies performed multivariable analysis and thus did not identify independent predictors.

The purposes of this study were to determine the proportion of patients (athletes and non-athletes) that suffer one or more recurrent ALALS during the first year after the initial injury and to identify determinants of sustaining a recurrent ALALS.

METHODS

Study design

This prospective cohort study was part of a controlled trial on treatment of acute lateral ankle ligamentous sprains[18]. Between May 2006 and October 2008, 164 patients were recruited for this pragmatic trial of which 157 were eligible for inclusion. Patients were randomly allocated to 4-week functional treatment with either a soft ankle brace or ankle tape. The protocol for this study was approved by the medical ethics committee of the University Medical Center (UMC) Utrecht. All patients included gave their written informed consent. The results of the trial showed no significant differences between the two treatment groups[18]. Based on this conclusion, both study groups were combined to one cohort of patients for the present study.

Participants

Patients were recruited from 20 general practitioner practices, nine physical therapy practices (region of Utrecht, the Netherlands) and the emergency departments of two hospitals, namely Zuwe Hofpoort hospital in Woerden and the UMC Utrecht, both in the Netherlands. All included patients suffered an ALALS due to an inversion trauma within 14 days previous to inclusion. Patients were excluded if they were younger than 18 years, if they suffered an eversion trauma, multiple trauma or complicated trauma (including cartilage injuries and dislocation), or had a history of ankle surgery. Patients with documented mental illness or cognitive impairment were also excluded from this study.

Procedure

All patients were treated according to the ICE-protocol (immobilization, compression and elevation) during the acute period. Functional treatment (tape or brace) started as soon as possible but at least within 14 days after the initial trauma. Baseline measurements of all patients were obtained in a standardized manner by a sports physician. Participants were asked to fill out online questionnaires at 5, 9, 13, 26 and 39 weeks after the initial ankle sprain. In week 52, a final questionnaire was combined with a physical re-examination by a sports physician.

Outcome variable

The outcome variable, recurrent ALALS, was defined as an inversion trauma of the same ankle affected at baseline[18]. Other injury types (e.g. strain, fracture, and

overload) were not classified as ALALS. Information on the outcome variable was obtained from the self-reported online questionnaires during the follow-up period and the final questionnaire administered at 52 weeks.

Determinants of recurrence

The following potential determinants were measured: gender, age, body mass index (BMI), the number of ankle injuries in the patient's history, having had an ankle injury within one year prior to the start of the study, sports participation, the severity of the initial ankle sprain and the allocated treatment.

To gain more insight into the age distribution, age was divided into quartiles. BMI was calculated as weight/length^2 (kg/m2) and divided into normal weight (≤ 25) and overweight (> 25). The number of ankle injuries in a patient's history included the initial injury from this study and was dichotomized in one and more than one. Sports participation at baseline was reported as yes or no and in mean number of hours of sports participation per week. The hours of sports participation were also divided into quartiles. No definition of sports was given in advance. The severity of the ankle sprain at baseline was classified into three categories: mild, moderate or severe. The severity score was based on data from the physical examination at baseline, corrected for the number of days between the physical examination and the initial inversion trauma (see Appendix A).

Statistical analysis

Baseline characteristics were described using mean with standard deviation (SD), range or frequencies, where appropriate. The Incidences of a recurrent acute lateral ankle ligamentous sprains during 1 year follow-up were analyzed with Chi-square test or Fisher-exact test for dichotomous variables. For this analysis, age and hours of sports participation were divided into quartiles and dichotomized BMI were used. Multiple imputation was used to assess missing data (n=18) for ankle sprain recurrences. Sensitivity analyses were performed with complete cases only (n=139).

The association between each determinant and the occurrence of a recurrent sprain was examined using univariable Cox regression analysis. All variables were tested for the proportional hazards assumption. If the interaction term between the variable and the natural logarithm of time was not significant ($p>0.05$), the proportional hazards assumption was considered being met[24]. Variables with a p-level of <0.1 in

the univariable analysis, showing no multicollinearity, were included in a multivariate Cox regression analysis. The p-level of 0.1 was chosen liberally to avoid that possible predictors were missed in the multivariable analysis. Multicollinearity was tested by obtaining variance inflation factors (VIF) and tolerance values, a VIF value <10 and a tolerance value >0.1 was interpreted as no indication for multicollinearity[11]. All data were analyzed using IBM SPSS Statistical software package (version 23.0).

RESULTS

In total, 157 patients were included in the trial. The baseline characteristics of the study population are presented in Table 1. Patients had a mean age of 31 years (SD 11.6), a mean BMI of 24.5 kg/m^2 (SD 4.27) and 88 participants (56%) were male. Participants in this study had to fill out six questionnaires during the 1-year follow-up period. For 11% of the participants (n = 18) data were not complete at the end of the clinical trial. Nine participants did not fill out the last questionnaire, one participant missed three measurements, another one missed four measurements and one participant did not fill out five questionnaires. Six participants did not fill out any questionnaire.
For 63% of the included patients, the initial ankle sprain was their first time ankle injury, 37% had two or more ankle injuries. Ten patients (6.4%) had an ankle injury within one year prior to the start of this study. Most ALALS at baseline (55%) were of moderate severity. The majority of the patients (84%) were sports participants, reporting a mean duration of sports participation of 4.4 (SD 3.7) hours per week.

After 52 weeks follow-up, 29 patients (18%: 95% CI 12.4-24.5) experienced at least one recurrent ALALS. Two patients suffered two recurrent ALALS and two more patients suffered three recurrences, thus in total 35 recurrent ALALS were reported.

Table 1: Baseline characteristics of all patients with an acute lateral ankle ligamentous sprain (n=157)

Baseline characteristics	
Male gender, n (%)	88 (56.1 %)
Mean age (SD) in years	31.1 (11.6)
Mean BMI (SD) * in years	24.5 (4.3)
History of ankle injury, n (%)	
- One ankle injury (initial injury of the study)	99 (63.1%)
- More than one ankle injury	58 (36.9%)
Respondents who had an ankle injury within one year prior to the start of the study, n (%)	10 (6.4%)
Sports participation#, n (%)	132 (84.1%)
Mean hours of sports participation (SD)	4.4 (3.7)
Severity of initial injury, n (%)	
- Mild	45 (28.7%)
- Moderate	86 (54.8%)
- Severe	26 (16.6%)
Treatment, n (%)	
- Brace	77 (49.0%)
- Tape	80 (51.0%)

*n = number, * n= 156, #Number of ankle injuries includes initial injury of the study, SD = Standard deviation # Participating in sports in the week prior to the occurrence of the initial injury*

The proportion of patients with a recurrent ALALS was higher among athletes compared to non-athletes (21.2% vs. 4.0%; p = 0.048), and this proportion increased with an increasing hours of sports participation per week. Furthermore, the proportion of patients with a recurrent ALALS was higher amongst those aged 18 < 27 (p<0.001; Table 2).

For all variables, the proportional hazards assumption was met. Univariable analysis showed associations (p<0.10) between a recurrent ALALS and a younger age, a lower BMI, a history of more than one ankle injury (including the initial injury of this study), sports participation and a higher number of hours of sports per week (Table 3).

In the multivariable Cox regression analysis only a younger age (HR 0.92 per year, 95% CI 0.87-0.98) was an independent predictor of recurrent ALALS within 52 weeks (Table 3).

In a sensitivity analyses with only 139 complete cases included, univariable analysis showed associations ($p<0.10$) between a recurrent ALALS and a younger age, and a history of more than one ankle injury (including the initial injury of this study). In the multivariable Cox regression analysis only a younger age was an independent predictor of a recurrent ALALS (HR 0.91 per year (95% CI 0.86-0.97).

Table 2: Incidences of a recurrent acute lateral ankle ligamentous sprains during 1 year follow-up

	Proportion of patients with ALALS	p-value
Sex		
- Males	21.6	0.303
- Females	14.5	
Age (quartiles)		
- 18 < 21.5 years	30.8	<0.001
- 21.5 to 27 years	33.3	
- 27 to 38 years	9.5	
- > 38 years	2.5	
BMI		
- Normal weight	19.4	0.460
- Overweight	12.2	
History of ankle injury		
- One ankle injury (initial injury)	14.1	0.088
- More than one ankle injury	25.9	
Having had an ankle injury one year prior to study		
- Yes	20.1	1.000
- No	18.4	
Sports participation		
- Yes	21.2	0.048#
- No	4.0	
Hours of sports participation per week (quartiles)		
- 0 < 2.25	5.1	0.007
- 2.25 to 4.00	15.4	
- 4.00 to 5.50	17.1	
- > 5.5	34.1	
Severity initial injury		
- Mild	24.4	0.471
- Moderate	16.3	
- Severe	15.4	
Treatment		
- Brace	18.2	1.000
- Tape	18.8	

#1 cells (25,0%) have expected count less than 5. The minimum expected count is 4,62

ALALS = acute lateral ankle ligamentous sprain

Table 3. Univariable and multivariable Cox regression analyses of potential predictors for a recurrent lateral ankle ligamentous sprain

	Univariable analysis			Multivariable analysis		
Independent Variables	**β**	**SE**	**HR (95% CI)**	**β**	**SE**	**HR (95% CI)**
Gender (male)	0.37	0.39	1.45 (0.68-3.12)			
Age *	-0.11	0.03	0.90 (0.85-0.95)	-0.08	0.03	0.92 (0.87-0.98)
BMI *	-0.14	0.06	0.87 (0.77-0.99)	-0.06	0.07	0.94 (0.83-1.07)
More than one ankle injury in history *	0.69	0.37	1.98 (0.96-4.11)	0.43	0.38	1.54 (0.74-3.21)
Ankle injury one year prior to study	-0.02	0.73	0.98 (0.23-4.11)			
Sports participation (yes) *	1.65	1.02	5.20 (0.71-38.22)	-0.45	1.09	0.64 (0.08-5.36)
Sports participation (hours/week) *	0.09	0.04	1.08 (1.00-1.17)	0.07	0.06	1.07 (0.96-1.19)
Severity initial injury						
- Mild			Reference category			
- Moderate	-0.52	0.40	0.59 (0.27-1.31)			
- Severe	-0.59	0.58	0.55 (0.18-1.74)			
Treatment (brace)	-0.08	0.37	0.92 (0.44-1.91)			

BMI = body mass index, HR = Hazard Ratio, β = β-coefficient, SE = standard error of the estimate
** Predictors (p<0.1) for a recurrent sprain in univariate analysis*

DISCUSSION

Of all participants, 18% experienced a recurrent ALALS within one year after the initial ankle sprain. The frequency of recurrent sprains in this study is in line with the findings from earlier studies, where 1-year incidences ranging from 8-30% were reported[1,8,9,14,15,20,23]. Van Rijn et al. (2008) found in their systematic review that 3-34% of the patients with an ALALS suffered a recurrent sprain within 3 years and that 15-64% did not fully recover from their ankle sprain within this period[22]. This confirms the current idea that a seemingly innocent injury, such as a lateral ankle ligamentous sprain, can have long-term consequences such as pain and subjective instability for a patient[10].

Age was the only independent predictor of ALALS recurrence in our study. The risk to suffer a recurrent ALALS is highest in young adults. A sensitivity analysis restricted to complete cases showed similar results. Braun (1999) also found recurrent sprains

mainly to be reported by younger patients[6]. Perhaps the reason for this result is a certain rashness of young people when participating in sports and other physical activities. Another explanation might be that a greater portion of young people participate in competitive sports, involving pivoting and jumping. In team sports and court games, ankle sprains are most common[12]. In our study, 132 patients were active in sports in the week prior to the occurrence of the initial injury and 78 of the sports participants were active in competitive sports like soccer, basketball, volleyball, tennis and korfball. The association, between being engaged in sports and ankle sprains recurrences, we observed in the univariable analysis was statistically significant, but not very strong. Earlier research by Haraguchi et al. (2009) and Linde et al. (1986) also showed that patients with a higher level of physical activity are more prone to suffer a recurrent ALALS. Interestingly, the association with sports participation disappeared in our multivariable analysis, including other determinants and in particular age. It is important to keep in mind, however, that the information about sports participation might not be detailed enough to fully elucidate the role of sporting activities on the incidence of recurrent ALALS.

Having a history of ankle injury is a well-known risk factor for sustaining a new lateral ankle sprain in general[2,4,8,26]. Earlier research of Engebretsen et al. (2010) showed that the number of acute ankle injuries in the past is positively correlated with the risk for a new acute ankle injury[9]. This seems to be in line with our univariable results, where we dichotomized the number of ankle injuries in one and more than one. The number of patients with three of four ankle injuries in the past was too small to estimate the recurrence risk in these patients.

In our univariable analysis, the present study showed a significant association between a lower BMI and a recurrent sprain. Our finding is in contrast to an earlier study of Timm et al. (2005) who found a positive, but non-statistically significant, association between a higher BMI and a recurrent ankle sprain in obese children[25]. The role of BMI as a risk factor for ankle sprains in general, both first and recurrent sprain, remains unclear[2,3,9].

In contrast to Malliaropoulos et al. (2009), who found a mild/moderate lateral ankle sprain (grade I and II) to be a prognostic factor for a recurrent sprain, we found no relationship between severity and recurrences[21].

Although the proportion of recurrent ALALS in this study is in line with earlier reported studies[1,8,9,14,15,20,23], a limitation of our study is the lack of power to assess the role of multiple determinants. Risk factors with a small to moderate association might not be identified through this study due to the small number of recurrent ALALS cases[3]. Moreover, considering the 1:10 'rule', i.e. per variable considered as predictors of recurrent ALALS one should have 10 patients with the outcome (recurrent ALALS), we had to be very restrictive in the number of variables we included in the analyses.

Hyperflexibility (and prior subluxation of other joints), might be a determinant of recurrence of ankle sprains. However, as this study was part of a controlled trial on the treatment of acute lateral ligamentous ankle sprains, information about hyperflexibility was not our primary goal and therefore not systematically assessed. A post-hoc analysis showed that the Talar tilt and drawer sign of the heterolateral ankle (possible signs of hyperflexibility) were not univariably associated with recurrence.

Identification of risk factors for recurrent ALALS is important, because more insight in these risk factors can underline the importance of preventing recurrent ankle sprains. When patients with a higher risk for a recurrent sprain could be identified adequately, tailored advice about the best prevention programs could be given. Our study highlights the importance of optimal treatment and preventive programs in young adults, to reduce the burden from recurrent lateral ankle ligamentous sprains.

In this study, nearly one fifth of the patients with ALALS suffered from a re-injury within 12 months and the injury risk decreases with increasing age. This highlights the importance of optimal treatment and preventive programs in younger adults.

APPENDIX A

The injury severity score (range 0-6) was determined by the sports physician at baseline based on six items, scored as 1 when present and 0 when absent: (1) swelling of the injured ankle; (2) any discoloration by hematoma; (3) limited dorsiflexion in the injured ankle; (4) clear tenderness at at least one of the anatomical locations of the injured ankle, (5) difference in the anterior drawer sign between the injured and heterolateral ankle and 6) difference in the talar tilt test between the injured and heterolateral ankle.

Injury severity was based on the total score (0-6) in relation to the number of days between the onset of the initial trauma and assessment of the injury severity score, and was categorized as follows:

- Severe lateral ankle sprain: score of 6 and physical exam at least four days after the injury.
- Moderate lateral ankle sprain: score of 6 and physical exam on days one-three after the injury *OR* score of 5 or 4 and physical exam at least four days after the injury.
- Mild lateral ankle sprain: all other combinations.

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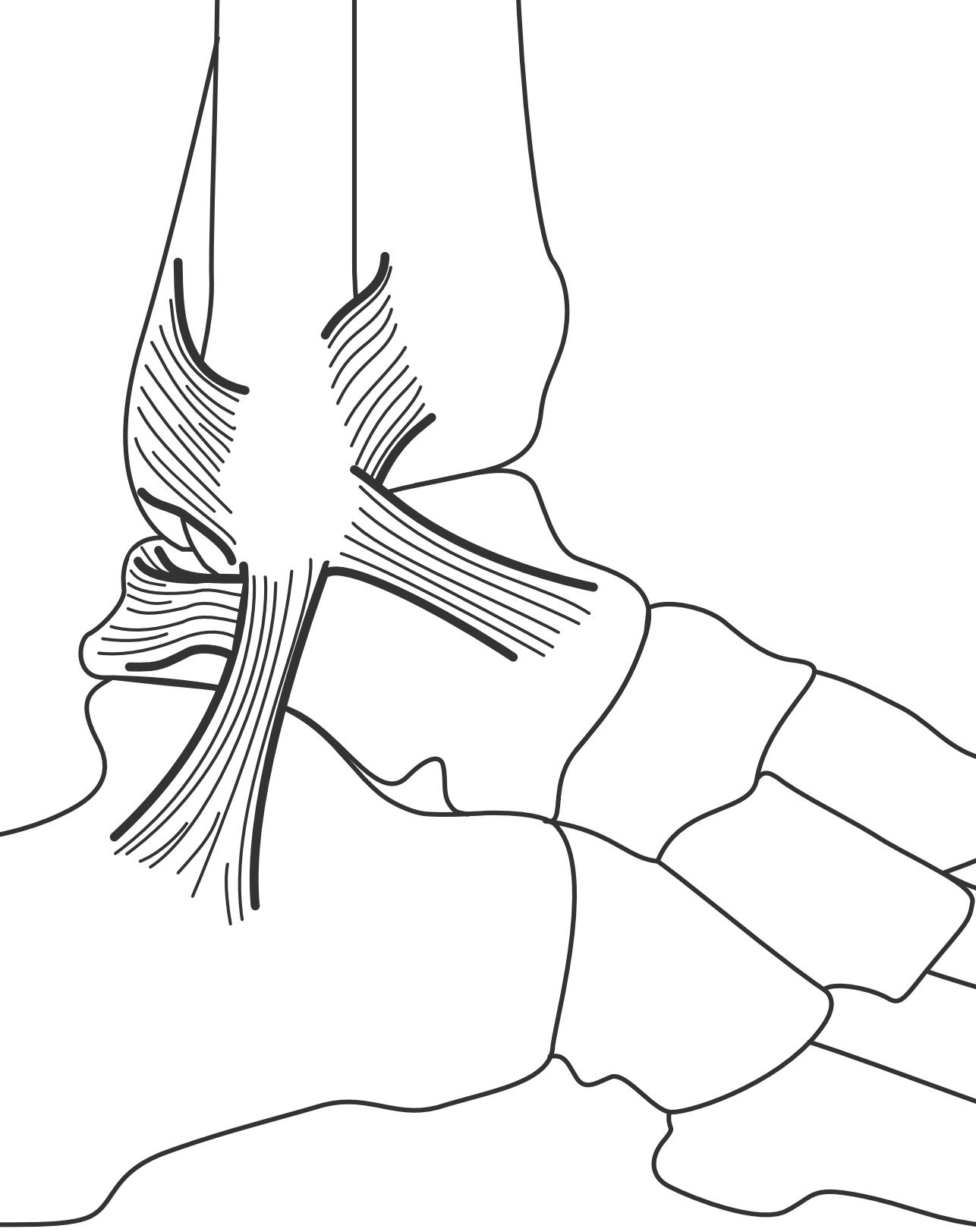

Chapter 8

Strengthen your Ankle, prevent injuries: the development of an implementation strategy for a behavioral intervention with effective elements using Intervention Mapping

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SUMMARY

This article presents an overview of the implementation of a behavioral intervention aimed at preventing ankle injuries. The implementation made use of Intervention Mapping. Based on the six steps of Intervention Mapping, this article described how the implementation of the behavioral intervention 'Strengthen your Ankle, prevent injuries' was realized, and what choices were made during this process.

INTRODUCTION

For years now, ankle injuries are among the most common sports injuries in the Netherlands[11,13]. Aside from a proper treatment to facilitate swift recovery and prevent residual symptoms, it is also vital to focus on ankle injury prevention to limit injury recurrence. A considerable amount of research has already gone into the causes, risk factors and effective preventive measures as regards ankle injuries. One finding demonstrated that the use of an ankle brace or ankle tape and/or performing balance- and stabilizing exercises reduced the risks of ankle injuries[8,14,15].

However, athletes do not automatically apply effective measures for injury prevention. This calls for a specific behavioral change. There are different ways to accomplish the aforementioned. One way is to make the use of effective measures mandatory. A fine example to illustrate this is the mandatory use of shin guards during football matches, after which the number of lower leg injuries dropped drastically[17].

Strictly imposing preventive measures to prevent ankle injuries hardly seems a fitting strategy. Measures to prevent ankle injuries are mostly relevant to athletes with a medical history of ankle sprains and/or a decreased stability (secondary prevention). It is therefore less obvious to make these measures mandatory for all athletes. The use of preventive measures must then be stimulated for the relevant target group, by persuading it of the use behind the measures and by removing any existing presuppositions about any negative side-effects. In any case, it is the athlete who decides whether he/she incorporates measures that might include the use of an ankle brace and/or performs balance and stabilizing exercises.

VeiligheidNL has developed a diverse range of successful behavioral interventions that implement effective measures for the prevention of accidents, damages and injuries[5]. This article describes the process of implementing the behavioral intervention 'Strengthen your Ankle, prevent injuries' for the purpose of limiting the risk of ankle injuries. This process made use of intervention Mapping (IM).

Intervention Mapping

Intervention Mapping (IM) is a protocol for the use of empirical data and theoretical insights to develop programs and interventions to stimulate healthy behavior[2]. While less common, IM can also be used to successfully implement (behavioral) interventions.

The IM procedure consists of six steps (Figure 1). The first step, 'Needs assessment', determines the exact health issue. It tracks the corresponding behavior to that health issue and the factors that underpin the issue.

The second step of IM is choosing the change goals. This involves a selection of specific goals for important changeable factors and (sub) target groups. The third step determines the methodology and techniques that are used to accomplish the change goals. A method is a change process derived from theory, whilst a technique is the practical form that is imbued with the method[3]. Step 4 combines the different techniques into a single intervention and it designs the actual intervention materials. The materials undergo testing at the target group, to then be produced *en masse*. Step 5 performs the intervention and registers all actions and results. The sixth and final step evaluates the effect of the intervention, analyses the health changes, the quality of living and the behavioral changes, and it checks if the goals have been met.

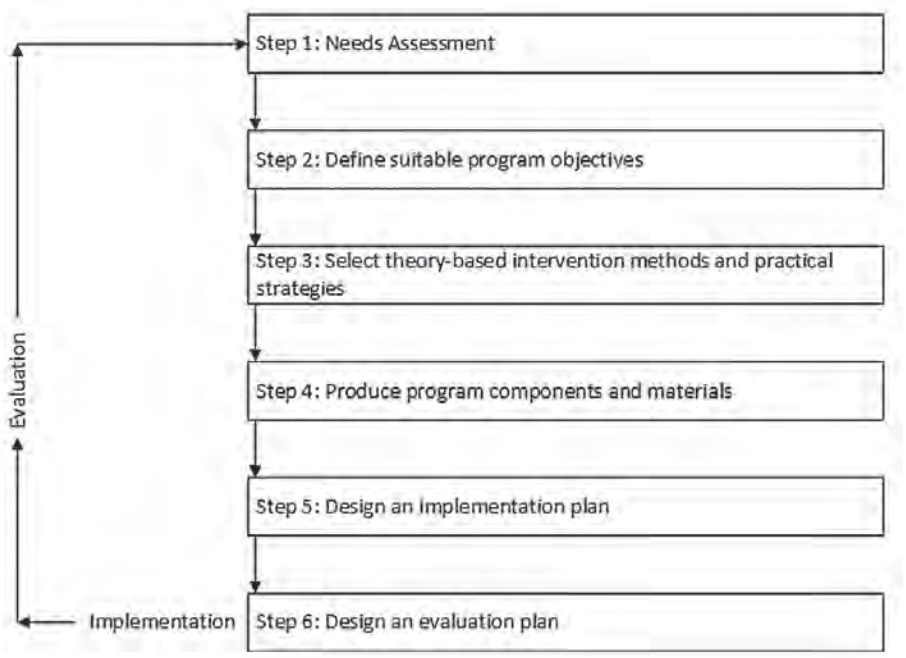

Figure 1: Intervention Mapping in six steps
Original figure from Viester et al. BMC Public Health 2012; 12:89 doi:10.1186/1471-2458-12-89

Step 1: Needs assessment

The health issue involved with the 'Strengthen your Ankle, prevent injuries' intervention is about ankle injuries. The needs assessment looked into which sports most commonly suffer from ankle injuries. In addition, it looked at the determinants at play in deciding (not) to use effective measures, namely the use of a brace and performing balance and stabilizing exercises.

Ankle injuries are prevalent in many dynamic sporting disciplines. When examining the total amount of ankle injuries in the Netherlands, the 2006-2008 period listed football (31%), running (11%) and volleyball (6%) as the most significant sporting disciplines. When it comes to more severe ankle injuries, two out of five (39%, 10,000) ankle injuries that brought athletes to the emergency department (ED) were inflicted during field football. Volleyball players (6%, 1,700) also reported in for treatment at an ED relatively often[4]. VeiligheidNL decided to centralize these two sporting disciplines (field football and volleyball). Ankle injuries were prevalent in these team sports and injury prevention was already subject to study in the past[12,15].

Behavioral determinants

In order to implement an effective behavioral intervention, it is required to gain insight into the -changeable- determinants that come with accepting the intervention. Examples of behavioral determinants are Knowledge, Awareness, Attitude and Social influence.

Both the use of an ankle brace and performing balance and stabilizing exercises are proven measures when it comes to ankle injury prevention[14]. Still, many athletes remain either unaware of these measures or simply refrain from using them because they feel negatively about their use *(For more information about athlete determinants, see framed text box 1)*.

Framed text box 1: ASE-model

The ASE model lends itself as a valid tool to see how behavioral change can be achieved. ASE represents the three determinants: Attitude, Social influence and self-Efficacy (de Vries, 1998)[9].

* *Attitude* is the attitude of a person towards certain behavior. Attitudes can be changed by providing the involved parties with additional knowledge.

* The *Social influence* is determined by social norms, the perceived behavior of others and the experienced social pressure or support for the behavior of relevant thirds.

* *Self Efficacy* deals with the judgement of a person about his own options and the confidence in his own ability as regards performing the behavior in spite of barriers.

These three determinants collectively determine the intention, or in other words, the motivation of a person to perform a certain behavior. Whether this behavior is actually displayed depends entirely on the skills and experienced barriers (Jongert, 2007)[18].

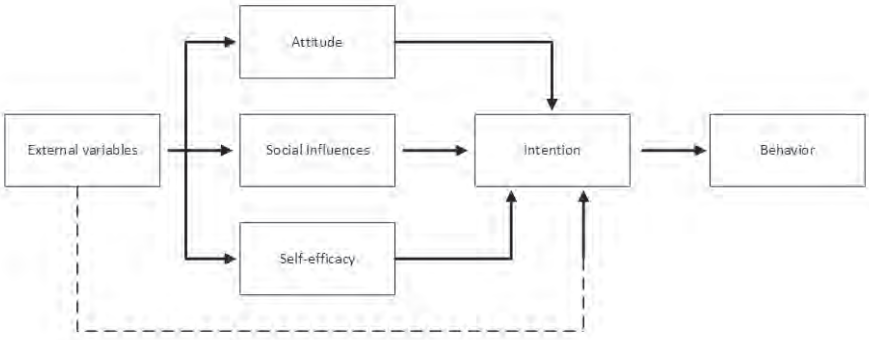

Figure 2: ASE-model[18]

Effective measures as regards ankle injury prevention do not seem sufficiently integrated with athletes. Prior to implementing the 'Strengthen your Ankle, prevent injuries' behavioral intervention, the target group was asked how they can and want to be reached about injury prevention.

A large-scale study of safety perception (injury prevention) among athletes[1] revealed that both football and volleyball players strongly prefer information transfer (transfer

of knowledge) through the internet (46% of field football players and 44% of volleyball players). In addition, athletes also preferred information transfer through the sports club/coach (39% of field football players and 28% of volleyball players[1]).

Target group

Both the football players and volleyball players were open to a transfer of knowledge through their sports club[1]. Various intermediaries, including coaches, support staff (football and volleyball) and physiotherapists are involved with the target group within a sports club. Qualitative and quantitative studies among these intermediaries[7] showed that trainers/coaches were the best intermediaries to reach the target group, namely football players and volleyball players. Trainers/coaches were open to injury prevention if:

- the behavioral intervention was aimed at preventing recurrences of ankle injuries and not at preventing ankle injuries in general;
- the information they received would be easy to apply;
- balance and stabilizing exercises were relevant and easy to apply; preferably within game situations so that they could easily be integrated in existing training schemes;
- the provider of the behavioral intervention was a renowned and relevant expert (sporting confederation, umbrella organization or famous player/club);
- the materials of the behavioral intervention were preferably offered by solely the club or confederation.

Following this study, and given the fact that both sports disciplines are team sports, VeiligheidNL selected to use coaches as an intermediary target group. Seeing how both disciplines approach and tutor their coaches in different ways, the choice was made to design the behavioral intervention specifically to the discipline. Next to the behavioral intervention specific to the discipline, a general informational website was developed. Given that the volleyball program was the first to finish, this article will only further describe this sporting discipline.

Step 2: Change goals

The main goal of the intervention was aimed at volleyball players to stimulate the use of an ankle brace and to perform ankle balance and stabilization exercises. Focus group talks with volleyball players revealed that knowledge and attitude were decisive determinants to them. As such, we selected knowledge and attitude as the

foremost changeable determinants and we wanted to reach the target group through an intermediary target group consisting of trainers/coaches.
Examples of formulated (sub)goals include:

- After the behavioral intervention, the trainer/coach knows that it is wise to permanently wear a brace during matches and training sessions after an ankle injury.
- After the behavioral intervention, the trainer/coach knows that the use of an ankle brace does not hinder a full recovery of the ankle ligaments.
- After the behavioral intervention, the trainer/coach knows that the use of an ankle brace does not decrease the stability of ankle ligaments.
- After the behavioral intervention, the trainer/coach knows which balance and stabilization exercises athletes must complete for a certain period after an ankle injury.
- The trainer/coach knows how to incorporate ankle balance and stabilization exercises in his training sessions.

Step 3: Theoretical methods and practical techniques

In the target group study among intermediaries, the coaches commented that the exercises they would implement or recommend had to be easily applicable and relevant[7]. During the 2001-2002 season, Verhagen et al. (2004) studied the effects of a training program with a balance board[15]. This program proved effective in preventing ankle injury recurrences. In 2009 another effective home exercise program for the prevention of ankle injury recurrences was published[8]. The choice was made to include exercises from both programs in the intervention.

The techniques used by VeiligheidNL for this behavioral intervention included a slogan, fold-out card, coaching set, practice wobble board, advice booklet and a PowerPoint presentation (PPP) aptly named 'Train the Trainer'.

1) The intervention concisely summarized the message in a slogan ('Strengthen your Ankle, prevent injuries'), where VeiligheidNL showed the athletes that an ankle does not just automatically recover after injury, but that it needs to be strengthened (by means of a brace and/or exercise) to prevent any recurrence (Table 1). The use of a slogan fits within the *chunking* method. This method utilizes a label or acronym to make information easy to remember (see also Table 1).
2) VeiligheidNL developed a special, practical fold-out card for the athletes (information transfer *method*). The fold-out card centralized the complete practice

regimen of Hupperets et al. (2009), to allow athletes to continue exercising at home. It also listed the advantages and disadvantages of the ankle brace, whilst trying to remove common misconceptions tied to it (method *new arguments*).

3) The coaching set was developed for the intermediary target group of trainers/ coaches, consisting of easy-to-apply and relevant balance & stabilization exercises[8,15]. Every exercise was printed onto a separate card, easily accessible during training sessions. It also contained a diagram that listed how the exercises should be performed as well as information about the ankle brace's advantages and disadvantages. The technique fits with the methods *information transfer* and *advance organizers*.
4) A wobble board was used when performing the listed exercises in the coaching set. By providing the target group with a wobble board, one obstacle for performing the exercises was removed. By introducing players and coaches with the wobble board (method *direct experience*), the attempt was made to also influence the self-efficacy / skills of the athletes and coaches.
5) The advice booklet of the NeVoBo is an existing booklet that contains information about measures for injury prevention. Information about the ankle brace and the balance and stabilization exercises were added to it. Coaches already used this booklet, allowing for more *information transfer* to take place.
6) In order to promote information transfer, VeiligheidNL launched a special website (www.voorkomblessures.nl/enkel). This website was host to extensive general information about ankle injuries, ankle braces & tapes and exercises. The website matches the methods of *information transfer* and *(new) arguments*.

Step 4: Program design and production

The materials for the volleyball pilot intervention consisted of the slogan, fold-out card, coaching set, wobble board, advice booklet and the website. The materials were presented to the target group for evaluation. Following this pre-test, small adjustments were carried through (mostly design of the card and coaching set and the presenting of information) before moving on to the production phase.

Table 1: Techniques and methods for behavioral change as regards 'Strengthen your Ankle, prevent injuries' for volleyball players

Techniques	Methods	Target group	Goal	Program execution
1. Slogan	Chunking	Athlete	Easily remember key message	The slogan was listed on all campaign manifestations
2. Fold-out card	Information transfer Advance organizers New arguments	Athlete	Education, behavioral change, exercise performance Purchase advice brace and tape and comparisons	Distributed through coaches and physiotherapists to athletes with an ankle injury. Contained exercises from the home exercise program (Hupperets, 2009)
3. Coaching set	Information transfer Facilitating	Coaches and Athletes	Removing the obstacles of not knowing what exercises to perform, education	At a theme meeting, volleyball coaches received a coaching set that allowed them to focus on ankle injury prevention during the warm-up of their training session.
4. Practice wobble board	Direct experience	Coach and Athlete	Influencing self-efficacy / skills of athletes	A practice wobble board was used when performing various exercises in the coaching set.
5. Advice booklet	Information transfer, new arguments	Coaches	Education	The advice booklet provided coaches with information about ankle braces and balance & stabilization exercises.
6. Website	New arguments	Athlete, intermediary and physiotherapist	Behavioral change and education about the campaign, ankle injury and ankle injury prevention, all materials are also available for view/ download here	All campaign manifestations referred to the website. The website was also host to extensive information about ankle injuries and ankle injury prevention

Step 5: Plan program implementation and use

In order to deploy the intervention, VeiligheidNL and NeVoBo wanted to use existing NeVoBo meetings that volleyball coaches regularly attend. A meeting for ankle injury prevention was developed, supervised by a physiotherapist. NeVoBo and VeiligheidNL instructed the physiotherapist about the subject, the content and the performance of the intervention. A PowerPoint presentation was drafted to be used as a guideline during the theme meetings. Amongst other things, it listed the exercises and information about ankle injuries (numbers, causes, impact and anatomy). The theme meeting consisted of a theory part, followed by practice. The coaches were given the coaching set, the wobble board and a set of fold-out cards for them to take with them to the sports club.

Step 6: Plan program evaluation pilot volleyball

Given how the new intervention used two effective practice programs, one in a volleyball environment and one in a home environment (Verhagen et al., 2004; Hupperets et al., 2009), no effect measurement was done. A process evaluation was performed to check if the selected implementation method sufficed in reaching the coaches and urged them to use the exercises in their training sessions and if injured athletes were stimulated to follow the home exercise program[10].

At the start of the 2010-2011 season, four of these meetings were held in the volleyball region Noord. The meetings were attended by 78 coaches. Prior to and directly after the theme meetings, and following the volleyball season, the coaches were requested to fill out a questionnaire. It contained questions about the rating of the meeting, the knowledge of coaches and the rating & use of the materials.

The post-measurement was filled out by three out of ten trainers (n=22). Results:

- The coaches rated the meetings positively. They experienced the meeting to be professional (86%), informative (86%), useful (91%) and entertaining (86%).
- Three quarters of all coaches would not change any aspect of the theme meeting and all coaches (n=22) would recommend the meeting to others.
- Nearly 70% of them indicated they used the coaching set when holding (preparations for) their training sessions.
- The advice booklet was used by 77% and the practice wobble board was used by 50% of all coaches.
- Nearly 73% of all coaches distributed the fold-out card with the home exercise program to their athletes. Fifty percent of them only distributed the

card to injured athletes. The remaining coaches distributed it to both of the aforementioned groups.
- The coaching set and the fold-out card were highly rated.
- Nearly three quarters of all coaches (68%) indicated during the post-measurement that the theme meeting led them to be more knowledgeable about ankle injury prevention.
- The percentage of coaches that valued injury prevention following the theme meeting rose from 62% to 90%.
- Following the meeting, more coaches paid attention to injury prevention (85% versus 35%).
- Twenty-two percent of all coaches indicated that they began thinking differently about ankle injury prevention.
- Prior to the theme meeting, a portion of the coaches (55%) already incorporated injury preventive exercises in their training sessions. After the meeting, 36% indicated they changed their training regimen. In particular, they began to use more exercises.

National deployment campaign 'Strengthen your Ankle, prevent injuries'

While the number of respondents in the post-measurement of the process evaluation was limited, the positive results from this evaluation and the positive feedback following the theme meeting provided ample reason to further implement the intervention, starting from the 2011-2012 season. In total, this first season contained 16 theme meetings that were attended by 314 volleyball coaches of 120 volleyball clubs. To support the intervention, VeiligheidNL also developed a smartphone app, followed by an app for tablets. The practice program of Hupperets et al. (2009) and information about ankle braces and tapes were starting points for this application. In addition, collaboration with the VSG (Sports Medicine Association) resulted in the development of instructional videos for ankle exercises. These videos are up for view in the app and on the website www.voorkomblessures.nl/enkel , which also describes the home exercise program.

Acknowledgement intervention by Acknowledgement Commission Interventions

In order to optimize the quality of health interventions, intervention owners can have their intervention evaluated since 2008 by the Acknowledgement committee Interventions belonging to the Center for Healthy Living (CGL) of the Dutch National Institute for Public Health and the Environment (RIVM). The 'Strengthen your Ankle,

prevent injuries' intervention is based on scientifically proven effective exercise programs and fits the demands of the sports union and the intermediary target group of coaches. As such, 'Strengthen your Ankle, prevent injuries' was awarded the verdict "Good indication for efficacy" in June of 2012. The utilized exercise programs were proven to be effective in earlier studies, enabling the assumption that they can also be used in this intervention to prevent ankle injuries. However, the effect of implementing the intervention and using theme meetings was only researched in a pilot and not in a large-scale project. Because this final large-scale study was missing, the verdict of "Good indication for efficacy" was the maximum achievable level for this intervention.

And finally

While it appears sensible to follow up on a developed intervention by implementing it, this is often trickier than expected[6,16]. For example, the study population of an efficacy study is a select subgroup of the total population. More often than not, it only includes highly motivated participants. What's more, there are various moments of contact in a study, which keeps engagement levels of participants high. The setting of a study thus differs considerably from daily practice. This means that findings of an effective study cannot simply be copied in practice.

IM is a useful method for the systematic implementation of an effective intervention in practice. IM enables:

- becoming aware of the whole implementation process. IM forces that all things be considered. It uses systematic planning.
- a careful substantiation of all choices.
- the use of existing methods and techniques.
- checking with the (intermediary) target group which changeable behavioral determinants must be subject to the implementation of the intervention (step 1 and 2).
- synergy of the used methods and techniques with the wishes/demands and practice/habits of the (intermediary) target group (step 3).
- involvement of the (intermediary) target group with the implementation process (step 4, 5 and 6).

After the implementation of the 'Strengthen your Ankle, prevent injuries' intervention within volleyball, a sports-specific intervention has been developed for football, korfball and basketball. The implementation of these interventions once again used IM.

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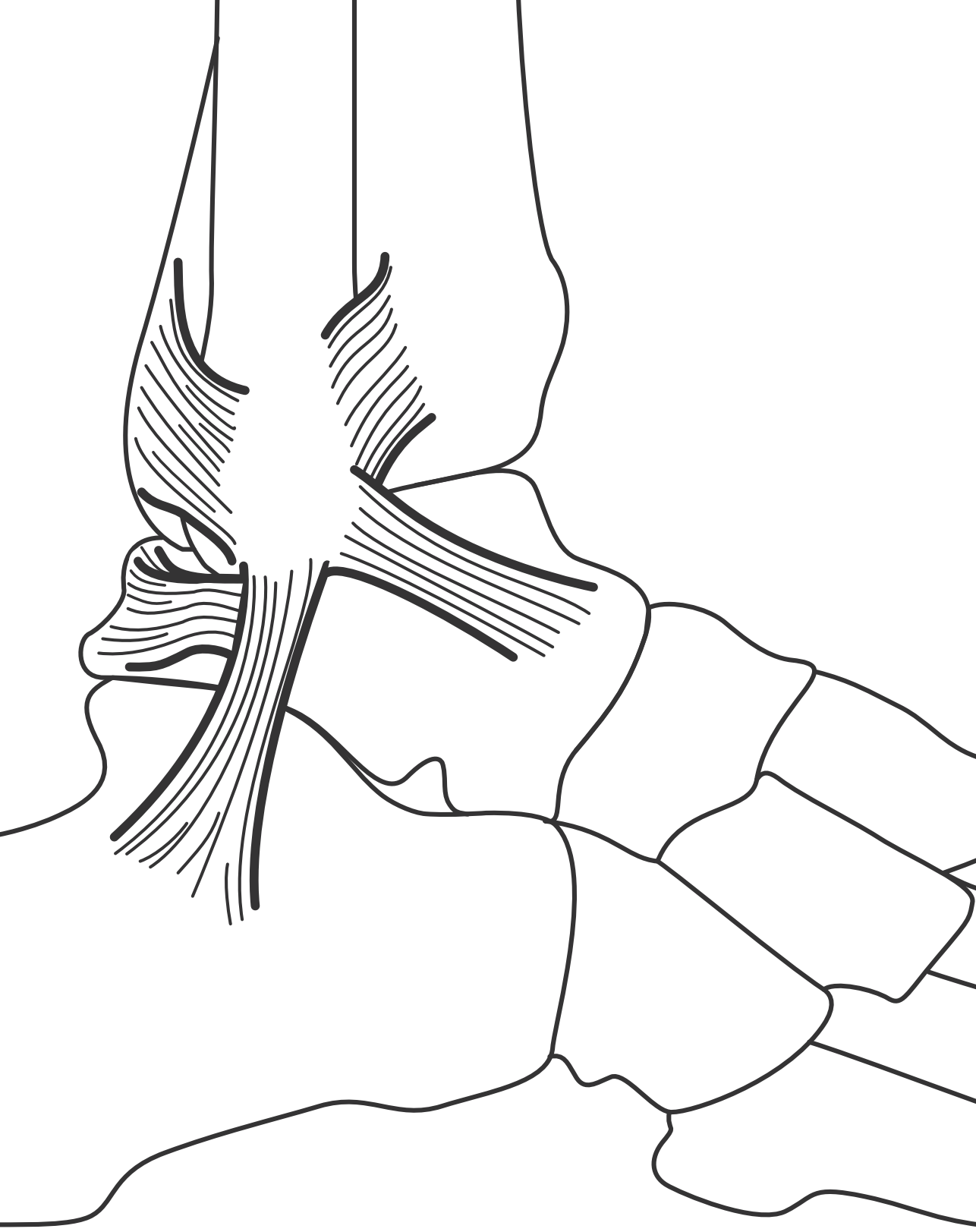

Chapter 9

General discussion

Ankle sprains are common in daily life and often considered to be minor injuries. The objective in this thesis was to provide more evidence on the burden and optimal management of ankle sprains in terms of the magnitude of the problem, the prognostic consequences and ways to improve treatment and prevention.

Guidelines for healthcare professionals

Ankle sprains are a commonly reported injury in daily life and especially in sports. Healthcare professionals have developed guidelines to ensure proper management of these injuries. In the year 2000 the Dutch College of General Practitioners (NHG) created a guideline for the treatment of ankle distortions and sprains[16]. This guideline recommended treatment consisting of immobilization, compression and elevation (ICE) during the first week, followed by ankle taping for six weeks, with a refreshment of the ankle tape every two weeks, or sooner if necessary.

In the years following the publication of this guideline, new prototypes of ankle braces, based on the principles of a functional tape bandage, became available. This brace seemed a valuable addition to the available treatment interventions, as this soft ankle brace was more user friendly because it is easier for the patients to apply and adjust themselves. Therefore we decided to compare this new brace with the conventional method of taping to treat acute lateral ankle ligamentous sprains (ALALS). In a clinical trial we evaluated the effects of four weeks of soft bracing versus taping following ALALS on sprain recurrence rates and residual symptoms at one year. Prior to this clinical trial we performed a systematic review in which we specifically compared ankle bracing with other types of functional treatment of ankle sprains.

Partly based on the results of our systematic review, in which it was shown that treatment with the brace resulted in better functional outcome[10], the Dutch guideline for ankle sprain treatment was revised in 2012. According to the revised guideline, both ankle tape and ankle brace can be used as the primary treatment of acute lateral ankle sprain[16]. Similar recommendations are given in other guidelines, e.g. in the Royal Dutch Society for Physical Therapy guideline for acute lateral ankle sprains and a multidisciplinary clinical practice guideline from Kerkhoffs et al. (2012). According to this latter guideline, a lace-up brace or a semi-rigid brace is preferable and recommended in the treatment of ALALS. However, in (professional) sports, the use of tape can also be considered as an effective treatment option[12]. The results of our clinical trial underline that both an ankle brace and ankle tape can be used in the

treatment of ALALS. Furthermore, not only a lace-up brace or a semi-rigid brace, but also a soft ankle brace can be used. The choice for one of these treatment methods should be based on the preference of the patient and the circumstances in daily practice, including the availability of ankle braces and ankle tape skills.

Treatment period and compliance

Besides choosing the most effective therapy method, the treatment period is an issue which needs consideration. In the current Dutch College of General Practitioners guideline treatment is still advised for six weeks after ICE treatment. This principle is based on the assumption that it takes at least six weeks to three months before ligament healing occurs. At six weeks to one year after their sprain, approximately 30% of participants still have objective mechanical laxity and subjective ankle instability[6]. However, most patients who were active in sports are able to resume their sports activities step-by-step six weeks after the initial injury[16].

In contrast to the Dutch College of General Practitioners guideline, where the treatment period is six weeks, in our CT all ankle sprains were treated (by either ankle tape treatment or soft bracing) for four weeks. We decided to include a period of four weeks because there is no solid evidence for a six week period and keeping in mind the fact that most ankle sprains are mild to moderate[11](chapter 4). Moreover, a four week period is more convenient for both patients and treating healthcare professionals, especially when applying ankle tape treatment.

In our trial the patients were instructed to wear the ankle tape or soft brace for four weeks. Patients in the brace group were allowed to take off the soft brace at night and when taking a shower. The patients showed a compliance rate of 54% (51% in the brace group and 57% in the tape group). Of the patients with a mild ankle sprain 44% were compliant with the treatment period of four weeks, compared to 56% to 58% of the patients with severe or moderate ankle sprains. This suggests that severity of the injury is related to the compliance. Since in our trial the treatment period was equal for both interventions, we are unable to conclude if a longer treatment period of for example six weeks would decrease the risk for ankle sprain recurrences and residual symptoms. However, as the compliance in the trial was moderate, one might conclude that prolonging the treatment method will further decrease the compliance. In addition, longer treatment might not be necessary since most ankle injuries are mild to moderate (84%). The Dutch clinical guideline for ALALS states that functional treatment for a period of four to six weeks is preferable[12]. In our opinion, the severity

of ankle sprains should be leading factor in the determination of the functional treatment period. So only in severe ankle sprains six weeks is necessary.

Treatment preference

As both an ankle brace and ankle tape can be used in the treatment of ALALS, the healthcare professional and the patient should jointly decide on the definite treatment method. Treatment costs can be a crucial factor in this decision. In our economic evaluation over one year, the ankle brace was less expensive in 71% of the bootstrap replicates. This indicates that from a societal perspective, the use of a soft ankle brace reduces the total costs related to ALALS. Furthermore, the non-healthcare costs per patient treated with a soft brace were lower compared to patients treated with ankle tape. According to this result, and to the Dutch clinical guideline for ankle sprain treatment[12], employees with ALALS should preferably be treated with a brace to speed up work resumption and reduce indirect non-healthcare costs. However, an ankle brace is more expensive for the patient, because the costs of ankle braces are usually not or rarely reimbursed by healthcare insurance companies in the Netherlands. If patients are not compensated, the purchasing costs might strongly influence the shared decision process.

Based on the existing clinical guidelines and the findings from the studies in this thesis we propose the adjustments in the treatment recommendations in the current Dutch guidelines for ankle sprain treatment:

- In addition to the current ankle brace treatment advice, being the use of a lace-up brace or a semi-rigid brace or ankle tape[12, 16], a soft ankle brace can be used in the treatment of ALALS as well.
- The severity of the ankle sprain should be leading factor in the determination of the duration of the functional treatment period: a treatment period of two weeks for mild ankle sprains, four weeks for moderate ankle sprains and six weeks for severe ankle sprains is recommended. In addition, we think ankle brace treatment should be reimbursed by healthcare insurance companies.

Focus on self-management

The available guidelines for the treatment of ankle sprains typically focus on situations where the injured person visits a healthcare professional to seek treatment for a sprained ankle. It is well known, however, that persons with an ankle injury often underestimate their injury and do not seek medical attention. According to the

Injuries and Physical Activity in the Netherlands (IPAN) survey, an estimated 680,000 sports-related ankle injuries occurred in the Netherlands in 2013. Of these ankle injuries, only 43% was medically treated[23]. This is in line with our previous observation that most ankle injuries are mild to moderate and therefore could be adequately managed by the patients themselves. Since we want the best treatment for the injured persons, without unnecessarily using medical care, and knowing that after an ankle sprain negative effects can last for a long time, we need to ensure the injured person has the information and skills to play a central role in the diagnostic decision making as well as in the treatment, rehabilitation and prevention of the injury.
Providing injured persons with adequate information and tools pertaining to the diagnosis, treatment, rehabilitation and prevention might reduce the negative consequences and costs related to ankle sprains. Facilitating self-management of patients and optimizing shared-decision making is in line with the current trends in Dutch health care[15]. When self-management and shared decision-making are implemented, the injured persons take the decisions, while the healthcare professionals only offer their expertise. As mentioned before, the choices of the injured persons may influence the process of recovery strongly: did they apply ICE-treatment in the first few days? Were ankle fractures ruled out? Was ankle tape or ankle brace treatment applied? Did they return to sports or daily activities too early or after full recovery?

The first decision an injured person has to make is whether or not to seek medical attention as described in the model of Bol et al. (Figure 1, chapter 1[1)]. They can judge their injury to be minor, and continue their activities immediately; subjectively the injury is then considered not severe enough to quit the activities and to seek medical attention. If injured persons judge their injury as severe; they will often decide to seek the expert opinion of e.g. a healthcare professional or a non-professional healthcare provider, such as their trainer or teammates.
To guide this decision and the determination of the severity of the injury, several instructions can be provided to the injured person. First, the persons need to be made aware of the immobilization, compression and elevation (ICE) treatment. This treatment minimizes the implications of inflammation. Normally the result of acute soft tissue injuries around the ankle is a physiological inflammation caused by a (micro)hematoma. This inflammation causes pain, edema, and limitation in the range of motion. Accumulation of fluid and edema around an injury site also increases tissue damage, delays healing, and can result in some degree of chronic disability[13,17].

Injured persons who do not apply ICE treatment during the first few days after the injury, do not benefit from its anti-inflammatory effects and may even increase their injury severity and consequently the duration of complaints. Since ICE treatment can easily be applied by the individuals themselves, it is very important for the information about using ICE treatment to be readily available to the injured person.
Next, the exclusion of an ankle fracture is important. After a short period of ICE treatment, an adequate physical examination, applying the Ottawa ankle rules[20] (Figure 1) can provide a high-quality assessment of the presence of an ankle fracture[4]. Injured persons who choose not to visit a healthcare professional should consequently have knowledge of the Ottawa Ankle rules (Figure 1) to exclude ankle fractures which need total immobilization. The Ottawa Ankle rules can be explained in a clear image with a comprehensible explanation of the rules and the medical terminology used.

If injured persons are not able to walk four steps without assistance shortly after the onset of the injury or do have pain in one of the four indicated areas, visiting a healthcare professional is advised. In the likely case that injured persons or non-professional healthcare providers are not able to apply the Ottawa Ankle Rules themselves, it is advisable the injured persons visit a healthcare professional if they cannot walk four steps without assistance.

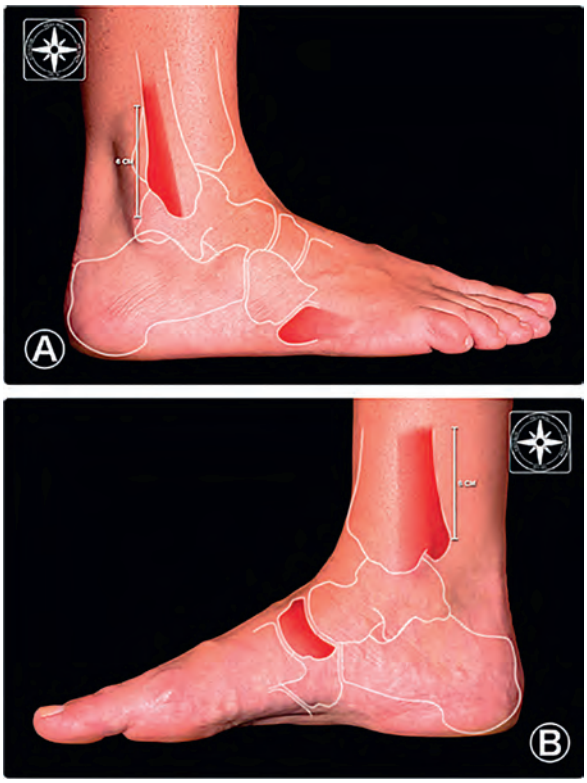

Figure 1: Ottawa foot and ankle rules. X-ray is required only if there is any pain in the areas identified in red color. A) Lateral view. B) Medial view (Image processed by Dr. Pau Golano[5])

After the correct diagnosis, the injured person should start the self-treatment if medical attention is not needed. The persons have to decide which treatment suits them best. In the current ankle sprain guidelines, both ankle tape and ankle brace treatment is advised. As an ankle brace can easily be applied by injured persons, they can start the treatment by themselves. To treat their sprained ankle after ICE treatment, injured persons are advised to use a semi-rigid ankle brace, lace up ankle brace, or – according to this study – a soft brace.

We mentioned earlier in this chapter that assessment of the severity of the ankle sprain should play an important role in determining the duration of the functional treatment period. After 4 to 5 days, patients can evaluate the severity of their ankle sprain using four criteria. These criteria are:

- the extent of swelling of the injured ankle
- any discoloration because of hematoma (medial and/or lateral)
- limited dorsiflexion in the injured ankle compared to the contralateral ankle
- clear tenderness at one or more anatomical locations related to the injured ankle (see Figure 1)

A positive score on all four criteria indicates a more severe ankle sprain and a functional treatment period of at least 4 to 6 weeks is advised. A positive score on three of the four criteria indicates a moderate ankle sprain and a shorter treatment period of four weeks is indicated. A positive score on one or two of the four criteria indicates a mild ankle sprain, which corresponds with a treatment period of two or three weeks.
Although the criteria give some insight into the severity of the damage, injured persons who are in doubt should always visit a healthcare professional.

After the treatment period the injured persons have to determine whether they are able to return to their activities of daily living or sports. It is important not to fully return to sports or activities of daily living too early in order not to disturb the healing process. Although to our knowledge there is no solid evidence of a direct causal relationship between an early return to sports and ankle sprain recurrences and residual symptoms, it is likely that an incomplete healing process can increase the risk of experiencing a new ankle sprain.

It is often difficult to determine what the right time is to return to the full usual daily activities or sports, especially when employment or team interests are at stake. Typically, tissue healing timeframes for ligaments range from 6 to 12 weeks, which is the time it takes for scar tissue to mature to full tensile strength[6]. However, sports participants often return to sports much earlier[14]. The current body of literature lacks evidence to provide guidelines to assess whether the injury is fully recovered or to assist in the decision when to resume daily activities or to return to sports[3,14].
According to Kaminski et al. (2013) the patient's perception of function and functional performance testing should be included in any decision making regarding a return to sports[9]. Patient self-reports can provide valuable information about an athlete's

readiness to resume sport activities. Several instruments are available to help identify the injured person's perception of function and aid in the return to sports decision process. Examples of these instruments are the Foot and Ankle Disability Index (FADI)[2], Foot and Ankle Ability Measure (FAAM)[2] and the Sports Ankle Rating System[25]. Rating the outcomes of the instruments and functional performance tests should give sports participants information about full recovery and a safe or safer return to sports. Evidence that such instruments actually improve the patient's prognosis is, however, lacking.

Meanwhile, it is known that ALALS can result in long-lasting residual symptoms and may result in a predisposition to re-injury for up to three years[18]. As residual symptoms and ankle sprain recurrence rates seem consistent over time, one-third of the ankle injuries in the Netherlands are recurrent injuries[23]. Consequently, secondary injury prevention is very important. Also here, the injured persons themselves can play an important role.

Prevention

Fortunately, several effective ankle injury preventive measures are known and most of them are very easy to apply. First of all, as for the treatment of the initial injury, both ankle tape and ankle braces can be used in the prevention of ankle sprain recurrences[12]. According to the current literature, it is unclear which of these measures is most effective. Thus the choice of injury preventive measure should depend on the preferences of the injured person. Further, proprioceptive training programs and coordination and balance training can prevent ankle sprain recurrences[12,19]. Verhagen & Bay (2010) concluded that (in theory) a combination of an external prophylactic measure (i.e. tape or brace) and neuromuscular training will achieve the best preventive outcomes with minimal burden for the athlete[21]. In a recent study, Janssen et al. (2014) evaluated the effectiveness of combined bracing and neuromuscular training compared to bracing alone, and the use of neuromuscular training on recurrences of ankle sprain[8]. The risk of self-reported recurrences of index ankle sprain was significantly lower for the brace group versus the training group (relative risk 0.53; 95% CI 0.29 to 0.97) and also lower, but not significantly different for the combi group versus the training group (relative risk 0.71; 95% CI 0.41 to 1.23).The findings support the prescription of bracing as a stand-alone secondary preventive measure for the prevention of ankle sprain recurrences. Therefore, after it is used in the treatment phase of ALALS, an ankle brace should continue to be used for secondary injury prevention, instead of being phased out[8].

In our opinion, there are many tools and a great deal of information available to support the injured person in the decision making process, as a part of self-management of an ankle sprain. However, the information is somehow fragmented. We recommend supplementing the current available information with our findings and integrating it all in one place. This 'place' could be for example a website, a smartphone/tablet application, a factsheet for distribution by healthcare professionals or sport clubs, a poster to show in sports canteens, or a flyer to distribute to sport clubs and trainers.
The website www.thuisarts.nl is an example of one of these 'places'. This website provides reliable and independent information composed by general practitioners about health and diseases. The information on sprained ankles is well written and understandable, but the information regarding ankle sprain treatment should be improved by adding information on:

- the Ottawa Ankle rules.
- criteria for ankle sprain severity and related treatment periods.
- the types of ankle brace that can be used in ankle sprain treatment besides ankle tape treatment (i.e. semi-rigid ankle brace, lace up ankle brace, or a soft ankle brace).
- the possible consequences of an ankle sprain to prevent underestimation of the injury.

How can we reach those who are injured

An important challenge we face is how to implement treatment interventions and scientifically effective preventive measures in daily practice. We can determine which information regarding ankle sprain treatment and prevention is absolutely necessary, but we need to distribute this information in a way that fits the injured persons' needs, otherwise we will not reach them and most of our efforts will be in vain. This is illustrated by the implementation of the 'Strengthen your Ankle, prevent injuries' intervention (Figure 2). This intervention was developed by VeiligheidNL to prevent ankle sprain recurrences. The evidence from studies by Verhagen et al. (2004) and Hupperets et al. (2009) was translated into several materials, including a coaching-set, fold-out card and an application for smartphones and tablets. All materials contain an evidenced-based and home-based proprioceptive training program and information about ankle braces and ankle tape.

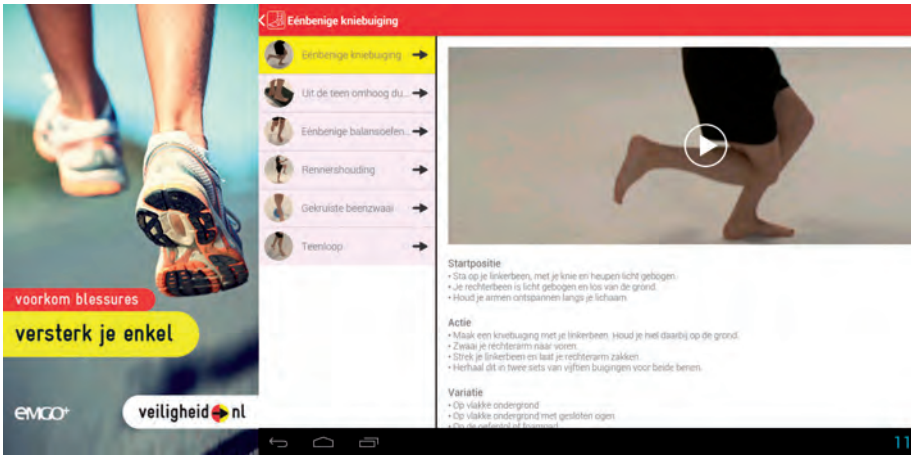

Figure 2: Images from the 'Strengthen your Ankle, prevent injuries' intervention for smartphones and iPads, used with the permission of VeiligheidNL.

The free availability of these materials does not imply that injured persons will adopt the injury prevention measures. An appropriate implementation strategy is necessary to cause structural behavioral changes. The injured persons (and/or their environment) need to adjust their behavior, but behavioral changes are often difficult to accomplish.

Referring to the ASE model (Attitude, Social Influences, Efficacy[24]; see chapter 8), the injured persons need to have the right attitude to change. This can be attained by providing them with adequate knowledge. This includes knowledge about the possible (long term) consequences of an "ordinary" ankle sprain. From research it is known that a previous injury and active involvement in high-risk sports with lots of jumping and pivoting are important risk factors for prolonged complaints or recurrences. Our own study showed that younger people are at a higher risk of suffering a recurrent sprain. Young people especially should be made aware of the risk, and must be informed about the available preventive measures. Additionally, the patient's social environment is important to achieve behavioral change. When persons are advised to use tape or a brace or to do neuromuscular exercises, this needs to be accepted and encouraged by for example their parents, schoolteachers, sports instructors, trainers and team members. The other component in the ASE model is (self-)efficacy. When injured patients have low self-efficacy, they doubt their judgment and abilities to properly handle their anke sprains. Their self-efficacy will

improve by providing them with, for example, information about treatment methods and injury preventive measures that are easy to apply and correspond to their competencies. Keeping in mind that modification of behavior is complicated, self-management and injury prevention require a lot of effort from different directions to facilitate and persuade an injured person to take appropriate measures.
For the implementation of the intervention 'Strengthen your Ankle, prevent injuries', VeiligheidNL therefore used Intervention Mapping (IM) taking into account the wishes and demands of the target group, i.e. the persons with or at high risk of sprained ankles. Intervention Mapping is a tool used in the planning and development of health promotion interventions to change health-related behavior. Due to the focus on the modification of health related behavior and on the involvement of the appropriate target group, IM is thus also useful for the systematic implementation of an effective injury preventive intervention in practice and for a treatment intervention to facilitate self-management of ankle sprains.

Injury Sequence model in retrospection and suggestions for improvement of the model
In the first chapter of this thesis the Injury Sequence model by Bol et al. was introduced[1]. Although the model integrated the stages of injury occurrence, diagnosis, treatment, and rehabilitation of an injury in relation to full recovery or return to sport, several adjustments based on new insights obtained from the studies in this thesis can be proposed (Figure 3). The injured person should be the new center of the model (stage 1) in which self-management is emphasized (stage 3), as injured persons should be more and more responsible for the course of their own recovery in the current healthcare system. They need to adopt a decisive role in the diagnostic decision making, treatment, rehabilitation and prevention of the ankle sprain. In addition, prevention was missing in the model of Bol et al.[1]. Prevention is an essential phase after the rehabilitation knowing that the risk to experience a recurrent injury is high. We added (secondary) prevention as stage 5 in the model.

By focusing on the injured person and injury prevention, a strategy is created to tackle the underestimation of the acute lateral ankle sprain. Once an ankle sprain, not always an ankle sprain.

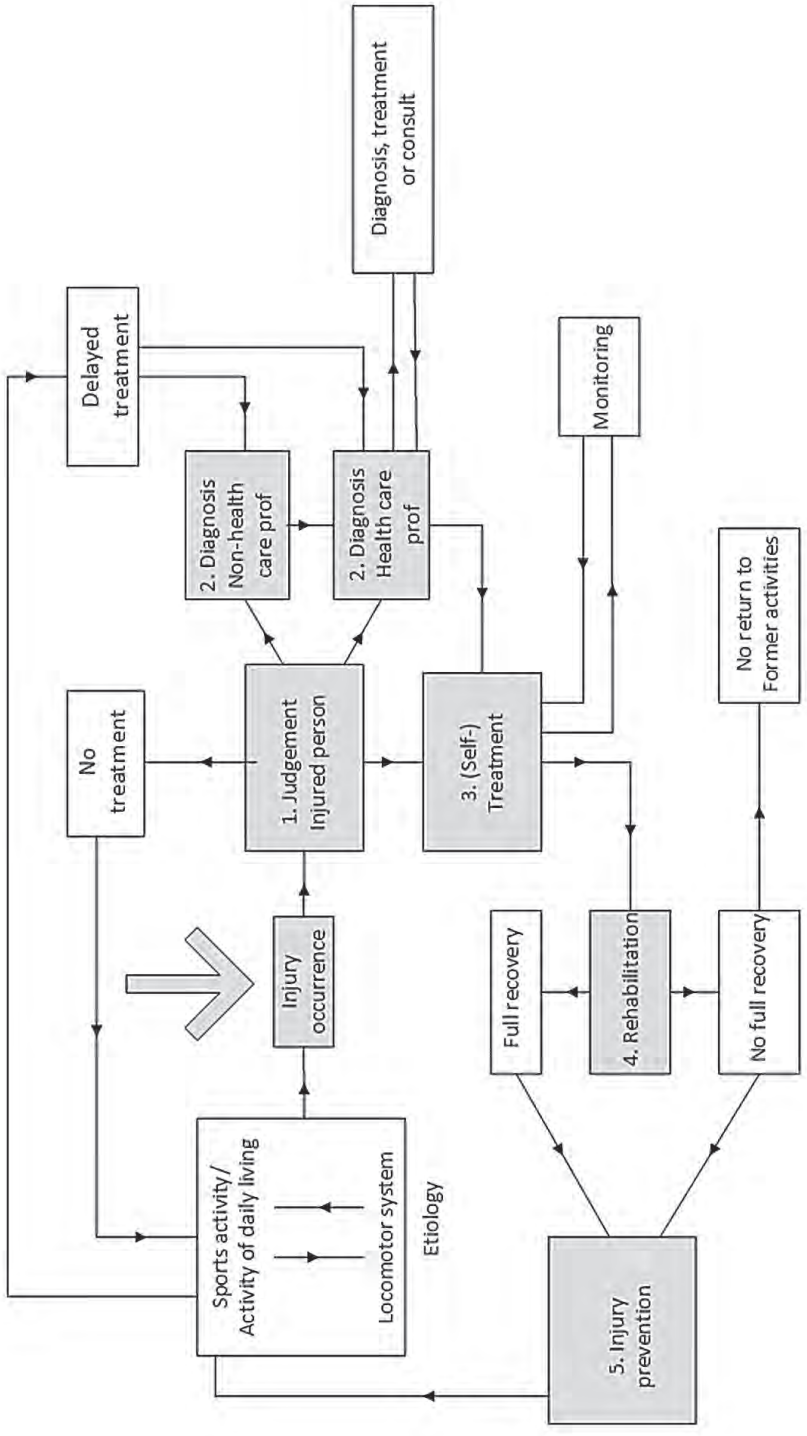

Figure 3: Injury sequence model (Bol et al., 1991; adjusted by Kemler, 2015)

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SUMMARY

Ankle sprains are common in daily life and often considered to be minor injuries. The objective in this thesis was to provide more evidence on the burden and optimal management of ankle sprains in terms of the magnitude of the problem, the prognostic consequences and ways to improve treatment and prevention.

Chapter 1 introduces the main stages in the recovery process after an injury in general. These main stages are summarized in the Injury Sequence model by Bol et al. (1991). This model integrates the stages of injury occurrence, diagnosis, treatment, and rehabilitation of an injury in relation to returning to daily activities, including sports. The model is applicable for both injuries in the general population and sports injuries and is used in this thesis to demonstrate the stages of recovery and their implications after an ankle sprain.

In **Chapter 2** time trends (10-25 years) of ankle injuries and sprains in the population at large and treated at emergency departments (ED) are presented. In the past, the incidence of acute ankle sprains has often been studied in athletic cohorts solely. This may have led to an underestimation of the extent of the ankle injury problem. In this chapter all ankle sprains were incorporated to demonstrate that ankle sprains are not only a sports related problem. Our trend analyses showed an increase of ankle injuries related to both sports and to other activities of daily living. Although the number of ankle injuries related to sports is high (37.5 ankle injuries per 1,000 person years in 2010), the number of ankle injuries related to activities of daily living is also substantial (17.5 ankle injuries per 1,000 person years). In addition, most injury data originates from ED studies. According to the data in our trend analysis, the incidence rates of all medically and non-medically treated ankle injuries are around 5.5 times higher than those registered at EDs, indicating that ankle sprains in ED studies only represent the tip of the iceberg.

Approximately 40% of the ankle injuries are (para)medically treated. And although functional treatment is the recommended treatment for acute lateral ankle sprains for almost 25 years now, there are still controversies over the best functional treatment type. In a review in **Chapter 3** we evaluated the effectiveness of ankle braces as a treatment method for acute ankle sprains compared to other types of functional treatment. The included studies reported about at least one of the

following outcome measures: re-injuries, symptoms (pain, swelling, and instability), functional outcomes and/or time to resumption of sports, daily activities and/or work. Although a few individual studies reported positive outcomes after treatment with an ankle brace compared with other functional methods, our best evidence syntheses only demonstrated a better treatment result in terms of functional outcome, but not on recurrent sprains, residual complaints, and time to resumption of sports, daily activities or work.

In **Chapter 4** our clinical trial (CT) is described. In this trial the effects of four weeks of soft bracing or taping following acute lateral ankle ligamentous sprain (ALALS) on sprain recurrence rates and residual symptoms at one year were evaluated. The CT could not bring the controversy about the best functional treatment type to a decisive close. The results after one-year follow-up indicated that in participants with ALALS, treatment with a soft brace or ankle tape showed similar effects on the incidence of ALALS recurrence and on residual symptoms. Our results underline the considerations that both an ankle brace and ankle tape can be used in the treatment of ALALS.

Alongside our CT, we assessed the costs of soft ankle bracing compared to ankle tape treatment in patients with an ALALS. **Chapter 5** represents the results of our economic evaluation. All costs within one year related to the initial ALALS or a recurrent ankle sprain were registered. Costs were divided into intervention costs, direct healthcare costs (medical costs), direct non-healthcare costs (patient costs, i.e. related to the use of complementary medicine and medical devices) and indirect non-healthcare costs (costs due to absence from paid work, unpaid work and study). The costs of soft ankle bracing were lower than for ankle taping, although this difference was not statistically significant.

Our study regarding long term outcomes of acute lateral ankle sprains (**Chapter 6**) subscribes the high percentage of patients dealing with recurrences and persistent symptoms after an ankle sprain. An impingement syndrome seems to be a less well-known residual symptom, but is rather common. More than two years after the initial ankle sprain in total 25% of our ALALS-patients was diagnosed with symptomatic anterior impingement syndrome. 82% of anterior impingement patients had radiological confirmed anterior tibiotalar osteophyte bone formation ('spurs'). This indicates that a symptomatic anterior impingement syndrome is a reliable predictor of anterior tibiotalar osteophyte bone formation. Impingement syndromes as a long-term result of acute lateral ankle sprains deserve more attention.

In **Chapter 7** the proportion of patients suffering from one or more recurrent ALALS during one year follow-up after the initial injury was determined and risk factors for sustaining a recurrent ALALS were identified. The results of this study show that the risk of ankle sprain recurrences decreases with increasing age. This highlights the importance of optimal treatment and preventive programs in younger adults, to reduce the burden from recurrent lateral ankle ligamentous sprains.

The subject of **Chapter 8** concerns the prevention of ankle sprains. Fortunately, several effective ankle injury preventive measures are known and most of them are very easy to apply. However, athletes do not automatically apply effective measures for secondary injury prevention. This asks for a specific behavioral change. Therefore, the use of preventive measures must be stimulated for relevant target groups, by persuading them of the benefits of applying the measures and by removing assumptions concerning negative side-effects. Chapter 8 describes the process of implementing the behavioral intervention 'Strengthen your Ankle, prevent injuries' for the purpose of limiting the risk of ankle injuries. In this implementation process Intervention Mapping was used. Intervention Mapping is not only a useful method for the systematic development of an effective intervention, but also for the structural implementation of an effective intervention in relevant practices.

In the final chapter, **Chapter 9**, the implications of the results presented in **Chapters 2 to 8** are discussed. Recommendation to adjust current guidelines for ankle sprain treatment are made. In addition to the current ankle brace treatment advice, being the use of a lace-up brace or a semi-rigid brace or ankle tape, a soft ankle brace can be used in the treatment of ALALS as well. Furthermore, the severity of the ankle sprain should be leading factor in the determination of the duration of the functional treatment period: a treatment period of two weeks for mild ankle sprains, four weeks for moderate ankle sprains and six weeks for severe ankle sprains is recommended. In addition, we think ankle brace treatment should be reimbursed by healthcare insurance companies.

As the choices of the injured persons may influence the process of recovery strongly, injured persons should be more and more responsible for the course of their own recovery. Injured persons need to adopt a decisive role in the diagnostic decision making, treatment, rehabilitation and prevention of the ankle sprain. This so-called self-management can be facilitated with adequate information and tools pertaining to the diagnosis, treatment, rehabilitation and prevention.
Finally, several adjustments based on new insights obtained from the studies in this thesis are proposed to further adjust the Injury Sequence model.

SAMENVATTING

Enkelbandletsels komen veel voor in het dagelijkse leven en worden vaak betiteld als minder ernstige letsels. Het doel van dit proefschrift was het verwerven van nieuwe inzichten in de hinder die enkelbandletsels met zich meebrengen en het optimaliseren van de aanpak van enkelbandletsel als het gaat om de omvang van het probleem, de gevolgen en prognose evenals de manieren om de behandeling en preventie te verbeteren.

Hoofdstuk 1 introduceert de belangrijkste fasen in het herstelproces na een blessure of letsel. Deze fasen worden weergegeven in het Blessure Sequentie Model van Bol et al. (1991). Dit model integreert de fasen van het ontstaan van de blessure, de diagnose, de behandeling en revalidatie van een blessure in relatie tot de terugkeer naar de dagelijkse activiteiten, inclusief sport. Het model is toepasbaar voor zowel letsels in de algemene populatie als bij sportblessures en is in dit proefschrift gebruikt om de fasen van herstel en hun implicaties na een enkelbandletsel te illustreren.

In **Hoofdstuk 2** worden de lange termijn trends (10-25 jaar) gepresenteerd van enkelletsels, inclusief enkelbandletsels, in de algemene populatie en welke behandeld zijn op een SpoedEisendeHulp (SEH) afdeling van een ziekenhuis. In het verleden is de incidentie van enkelbandletsels vaak alleen bestudeerd in sportpopulaties. Dit heeft geleid tot een onderschatting van de omvang van het probleem betreffende enkelbandletsels. In dit hoofdstuk zijn alle enkel(band)letsels meegenomen om aan te tonen dat deze letsels niet alleen een sportgerelateerd probleem zijn. De trendanalyses toonden een toename van sportgerelateerde enkelletsels en enkelletsels die zijn ontstaan tijdens activiteiten in het dagelijkse leven. Hoewel het aantal sportgerelateerde enkelletsels hoog is (37,5 enkelletsels per 1000 persoonsjaren in 2010), is het aantal enkelletsels gerelateerd aan activiteiten in het dagelijks leven ook substantieel (17,5 enkelletsels per 1000 persoonsjaren).
Veel informatie over enkelletsels is afkomstig van SEH afdelingen. Op basis van de data in deze studie blijkt de incidentie van medisch en niet-medisch behandelde enkelletsels ongeveer 5,5 keer zo hoog te zijn dan de incidentie van SEH-behandelde enkelletsels. Dit is een indicatie dat letselinformatie van SEH afdelingen alleen het topje van de ijsberg laat zien.

Ongeveer 40% van de enkelletsels wordt (para)medisch behandeld. Hoewel functionele behandeling al ongeveer 25 jaar de aanbevolen behandeling voor acute laterale enkelbandletsels is, bestaan er nog steeds controverses over de meest geschikte functionele behandelingsmethode. In een review (in **Hoofdstuk 3**) is de effectiviteit van enkelbraces als een behandelingsmethode voor enkelbandletsels geëvalueerd en vergeleken met andere functionele behandelingsmethoden. De geïncludeerde studies rapporteerden over minimaal één van de volgende uitkomstmaten: recidiefletsel, restklachten (pijn, zwelling en instabiliteit), functionaliteit en/of de tijd tot hervatting van sport, werk en activiteiten in het dagelijkse leven. Hoewel enkele individuele studies een positieve uitkomst rapporteerden na een behandeling met een enkelbrace ten opzichte van andere functionele behandelingsmethoden, werd er in de best evidence synthese alleen een positief resultaat gevonden voor functionaliteit, maar niet voor recidiefletsel, restklachten en de tijd tot hervatting van sport, werk en activiteiten in het dagelijks leven.

In **Hoofdstuk 4** is onze klinische trial beschreven. In deze trial zijn de effecten na een jaar vergeleken van een behandeling van vier weken met een soft brace of enkeltape na een acuut lateraal enkelbandletsel op recidiefletsel en restklachten. De klinische trial kon geen beslissing brengen in de controverse over de beste functionele behandelingsmethode. De resultaten na een jaar follow-up wezen uit dat bij patiënten met een acuut lateraal enkelbandletsel, de behandeling met een soft brace of enkeltape gelijke effecten gaven voor recidiefletsel en restklachten. De resultaten onderstrepen de wetenschappelijke opinie dat zowel een enkelbrace als enkeltape gebruikt kunnen worden in de behandeling van acuut lateraal enkelbandletsel.

Tijdens onze klinische trial zijn tevens de kosten van soft enkelbrace behandeling vergeleken met enkeltape behandeling in patiënten met een acuut lateraal enkelbandletsel. In **Hoofdstuk 5** staan de resultaten van deze economische vergelijking weergegeven. Alle kosten binnen een jaar, gerelateerd aan het initiële enkelbandletsel of een recidiefletsel, zijn geregistreerd. Kosten werden verdeeld in interventiekosten, directe gezondheidszorg gebonden kosten (medische kosten), directe niet-gezondheidszorg gebonden kosten (kosten van patiënten, gerelateerd aan het gebruik van alternatieve geneeskunde en medische hulpmiddelen) en indirecte niet gezondheidszorg gebonden kosten (kosten door verzuim van werk, onbetaald werk en studie). De kosten voor de behandeling met een soft enkelbrace waren lager dan voor de behandeling met enkeltape, maar dit verschil was statistisch niet significant.

De studie met betrekking tot de lange termijn gevolgen van acute laterale enkelbandletsels (**Hoofdstuk 6**) onderschrijft het hoge percentage van patiënten dat nog hinder ondervindt van recidiefletsel en restklachten na een enkelbandletsel. Een impingement syndroom lijkt een minder bekende restklacht te zijn, maar komt toch vaak voor. Meer dan twee jaar na het initiële enkelbandletsel, werd 25% van de onderzoeksgroep gediagnosticeerd met een symptomatisch anterieur impingement syndroom. Meer dan 80% van de patiënten met een anterieur impingement syndroom had radiologisch bevestigde botvorming aan de voorzijde van het bovenste spronggewricht ('spurs'). Dit is een indicatie dat een symptomatisch anterieur impingement syndroom een betrouwbare voorspeller is van 'spurs'. Impingementklachten als een lange termijn gevolg van acuut lateraal enkelbandletsel verdienen meer aandacht.

In **Hoofdstuk 7** is de subgroep patiënten met één of meerdere recidiefletsels binnen één jaar bepaald en zijn risicofactoren voor het oplopen van een recidief acuut lateraal enkelbandletsel uitgezocht. De resultaten van deze studie toonden ondermeer dat het risico op recidief enkelbandletsel afnam bij een stijgende leeftijd. Dit benadrukt de noodzaak van optimale behandeling en preventieve programma's voor jongvolwassenen, om zo de kans op recidief acuut lateraal enkelbandletsel te verminderen.

Het onderwerp van **Hoofdstuk 8** betreft de preventie van enkelbandletsels. Gelukkig zijn er diverse enkelblessure preventieve maatregelen bekend, en de meeste zijn erg makkelijk toepasbaar. Indien een maatregel effectief blijkt bij de preventie van blessures, impliceert dat niet dat sporters deze maatregel automatisch gaan toepassen. Hiervoor is vaak een gedragsverandering noodzakelijk. Het gebruik van preventieve maatregelen dient meer gestimuleerd te worden in relevante doelgroepen. De doelgroep moet overtuigd worden van de voordelen van het gebruik van de effectieve maatregelen en bezwaren tegen het gebruik moeten worden weggenomen. Hoofdstuk 8 beschrijft het implementatieproces van de gedragsinterventie 'Versterk je Enkel, voorkom blessures' welke als doel had het risico op enkel(band)letsels te verminderen. In dit implementatieproces is gebruik gemaakt van Intervention Mapping. Intervention Mapping is niet alleen een nuttige methode voor de systematische ontwikkeling van een effectieve interventie, maar ook voor de gestructureerde implementatie van een effectieve interventie.

In het laatste hoofdstuk (**Hoofdstuk 9**) zijn de implicaties van de resultaten uit **Hoofdstuk 2 t/m 8** bediscussieerd. Hierbij zijn aanbevelingen gedaan voor het aanpassen van de huidige richtlijnen voor de behandeling van enkelbandletsel. Zo kan bij de behandeling van acuut lateraal enkelbandletsel niet alleen gebruik gemaakt worden van een veterbrace, semi rigide brace of enkeltape, maar ook van een soft brace. Tevens moet de ernst van het enkelbandletsel leidend zijn in de duur van de functionele behandeling: een periode van twee weken voor milde enkelbandletsels, vier weken voor matige enkelbandletsels en zes weken voor ernstige enkelbandletsels. Tevens zou een behandeling met een enkelbrace vergoed moeten worden door zorgverzekeraars, die daar zelf ook financieel voordeel van kunnen ondervinden.
De keuzes die geblesseerde personen maken, kunnen het herstelproces na een enkelbandletsel sterk beïnvloeden. Geblesseerde personen zelf zouden daarom meer en meer een verantwoordelijke rol op zich moeten nemen bij het stellen van de diagnose, de behandeling, revalidatie en preventie van het enkelbandletsel. Dit zelfmanagement kan gefaciliteerd worden met adequate informatie en tools ten behoeve van de diagnose, behandeling, revalidatie en preventie. Dit zal moeten leiden tot minder onderschatting van het enkelbandletsel. Tot slot zijn er op basis van nieuwe inzichten uit de studies in dit proefschrift diverse aanpassingen voorgesteld voor het Blessure Sequentie Model.

DANKWOORD

Dit proefschrift had uiteraard niet tot stand kunnen komen zonder de hulp van vele mensen. Een woord van dank is daarom op zijn plaats voor iedereen die heeft bijgedragen en voor een aantal personen in het bijzonder.

In de eerste plaats wil ik mijn promotoren en copromotor bedanken. Frank, vijftien jaar geleden leerde ik je kennen toen ik nog een stage onderzoek deed bij het KNKV. Ik wilde graag wat meer ervaring met onderzoek opdoen en werd zodoende door Jan Sjouke van den Bos aan jou voorgesteld. Het onderzoek naar talentontwikkeling bij korfbal pupillen was het eerste onderzoek dat we samen deden. Ik had toen niet kunnen bedenken wat deze kennismaking me allemaal zou brengen. Nu zijn we vele onderzoeken en publicaties verder, maar het onderzoek naar talentontwikkeling en het enkelonderzoek staan toch wel centraal. Voor we aan dit promotietraject begonnen had je me wel eens gevraagd of ik interesse had om te promoveren. Dat had ik wel, al was het dan wel op talentontwikkeling. Uiteindelijk is het toch het enkelonderzoek geworden, en nee, ik heb er geen spijt van. Ik wil je bedanken voor de kans die je me geboden hebt, je vertrouwen en je onverwoestbare enthousiasme. Op momenten dat ik vast liep, bleef jij er in geloven. Dank je.

Ingrid dank voor je begeleiding in de afgelopen jaren als copromotor. Ik moest wel even slikken toen je vertelde dat je bij Revant ging werken, maar je bleef naast je nieuwe baan gelukkig wel betrokken bij dit project. Met regelmaat speelde je advocaat van de duivel om de discussie aan te zwengelen, of om het enthousiasme binnen de perken en de doelen realistisch te houden. Je helicopterview was erg verhelderend en in de eindsprint die we samen hebben gemaakt bij het schrijven van de discussie ook onmisbaar!

Beste Arno, pas later heb jij je aangesloten bij ons team als promotor, maar je bijdrage aan mijn promotie was er niet minder om. Als ik terugdenk aan onze samenwerking, dan denk ik vooral aan je heldere commentaren en duidelijke uitleg. Ik heb er veel aan gehad en veel van opgestoken. Dank daarvoor.

Naast mijn promotiecommissie ben ik nog diverse (ex-)collega's een dankwoord verschuldigd.

Mark, tijdens mijn tweede verlof in 2012 heb jij de eerste kostenanalyses op je genomen en een belangrijke bijdrage geleverd aan dit hoofdstuk. Begin juni 2015 kregen we te horen dat de standaarden voor kostenonderzoek sterk gestegen waren en ons artikel niet meer voldeed. Samen hebben we toen de spreekwoordelijke schouders er onder gezet. Door jouw voorbereidende werk en heldere uitleg is het mij uiteindelijk gelukt om binnen anderhalve maand alle analyses over te doen en het artikel te herschrijven. Ardine mag in dit verhaal natuurlijk niet ontbreken, maar jouw bijdrage was onmisbaar! Fijn dat je vandaag als paranimf aan mijn zijde wilt staan. En Ardine, dank voor de spoedcursus in de wereld van het kostenonderzoek!

Karin, je hebt een belangrijke rol gespeeld bij het in kaart brengen van de lange termijn gevolgen van enkelbandletsels. Ik vond het prettig om met je samen te werken. Naast al je drukke werkzaamheden als sportarts en bondsarts van de Nederlandse voetbalvrouwen, streef jij nu ook naar een promotie. Ik hoop dat mijn bijdrage aan jouw boekje net zo waardevol zal zijn. Ook jou heb ik gevraagd om vandaag als paranimf aan mijn zijde te staan, wetende dat je, als alles goed gaat, hoogzwanger zult zijn. Ik hoop dat je er vandaag daadwerkelijk bij bent.

Sandor, samen met jou heb ik de eerste echte stappen in de wetenschappelijke onderzoekswereld gemaakt. Dank voor je wijze lessen, ik maak er nog steeds gebruik van.

Bionka, ik heb je leren kennen op het spreekwoordelijke dieptepunt van mijn promotietraject. Het wilde maar niet lukken om één van de artikelen geaccepteerd te krijgen. Zonder voorkennis heb je dit artikel en de bijbehorende commentaren doorgenomen en samen hebben we er een versie 2.0 van gemaakt, en met succes! In maart 2015 werd het artikel geaccepteerd. Na dit keerpunt is alles in een stroomversnelling geraakt, negen maanden later staan we nu hier. Ik hoop dat we nog vele mooie artikelen samen mogen schrijven!

Ilse, ik leerde je kennen toen je stage kwam lopen op de afdeling. Je was zoals dat heet absoluut een ideale stagiaire. Je werktempo was niet bij te houden, en je bijdragen van hoge kwaliteit. Dank je voor de bijdragen aan mijn proefschrift. Een aantal jaar na je stage ben je zelf begonnen aan een promotietraject. Veel succes!

Uiteraard mag VeiligheidNL en mogen mijn collega's bij VeiligheidNL niet in dit rijtje ontbreken. Gedurende dit promotietraject ben ik werkzaam geweest bij VeiligheidNL. Het combineren van twee functies zorgde niet alleen voor voldoende afwisseling in mijn werkend bestaan, maar heeft voor deze promotie ook tot een mooie samenwerking geleid. Saskia en Marco, bedankt voor het mogelijk maken van deze samenwerking. Huib, Lize, Victor en Casper bedankt voor jullie bijdrage als mede auteur. En tot slot de 'andere' collega's, mijn kamergenoten, ganggenoten, teamgenoten en anderen, bedankt voor jullie adviezen, luisterend oor en het meeleven.

Zonder patiënten geen onderzoek. Mijn dank gaat uit naar hen die ondanks het feit dat ze geblesseerd waren en pijn hadden, mee wilden doen aan het onderzoek. Jullie waren bereid om vijf keer in een jaar een vragenlijst in te vullen en om terug te komen voor een nameting een jaar na het oplopen van jullie enkelbandletsel. Een deel van de onderzoeksgroep was zelfs bereid om na 2,5 tot 5 jaar nog eens bij de sportarts langs te gaan. Zonder jullie deelname en bereidwilligheid had dit onderzoek niet uitgevoerd kunnen worden!

Niet alleen patiënten zijn onmisbaar, in dit onderzoek speelden ook de sportartsen een grote rol. Om mij als pedagoog in een medisch onderzoek te kunnen handhaven, was jullie hulp van groot belang. Ria, Wout, Frank, David, Bernard, Anne en Carola dank dat jullie het medische deel in dit onderzoek op jullie hebben genomen.

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In 2006 ben ik betrokken geraakt bij dit onderzoek. De voorbereiding was echter al gestart in 2005. Janet, jij hebt de basis voor dit onderzoek gelegd met het schrijven van het protocol, dank daarvoor.

Lieke, ook jij mag hier niet ontbreken. Jij hebt de taak op je genomen om van de losse hoofdstukken in dit boekje een geheel te maken ten behoeve van het manuscript voor de beoordelingscommissie. Doordat jij de opmaak van mijn manuscript verzorgde, heb je me veel werk uit handen genomen.

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Tot slot, een laatste woord van dank voor jou Bart, voor je steun in de afgelopen jaren. Je hebt de frustratie en irritatie gezien als het weer eens niet ging zoals ik wilde, maar ook de vreugde na bijvoorbeeld de acceptatie van een artikel. Sinds maart 2015 is het hele promotietraject in een stroomversnelling geraakt. We belandden samen door werk en promotie in een heel turbulente periode. We hebben toen tegen elkaar gezegd 'blijven volhouden, de eindstreep is in zicht'. Vandaag hebben we de finish gehaald en wil ik graag samen met jou en de kinderen proosten op de afsluiting van deze periode en op onze mooie toekomst samen.

CURRICULUM VITAE

Helena Jacoba (Ellen) Kemler was born in Utrecht in 1980 on June 12th. She was raised in Vianen and Culemborg were she finished secondary school at the Koningin Wilhelmina College (VWO) in 1998. Thereafter she started her academic education at the University of Utrecht with pedagogy. In 2002 she received her doctorandus degree after conducting a research project in her favorite sport Korfball. Together with a fellow student, she questioned youth korfball players about the fulfillment of recreational korfball: *"Jongeren over Korfbal: een kwantitatief onderzoek naar de mening van jongeren over de invulling van het breedtekorfbal"*, for the Royal Dutch Korfball Association (KNKV). In 2001 she met prof. dr. Frank Backx, who asked her to participate on a research project regarding talent development in Korfball which he started in 1998. After 15 years of research, they finished this longitudinal project.

At the end of 2002 she started to work at the department of Sports Medicine at the University Medical Center Utrecht as a secretary. In the course of 2003 she continued to work for this department as a part-time researcher with a focus on the epidemiology of sports injuries. In 2006 she was asked to perform the research project which was eventually the base of this thesis. As a coincidence a short time later she sprained her ankle badly playing korfball. In the same year she started with a master education Epidemiology at the VU Medical Center/EMGO Institute (finished in 2008) and she became a part-time researcher at the Consumer Safety Institute, which is now VeiligheidNL. Important topics in her work at VeiligheidNL were, and still are, 'epidemiology of sports injuries' and 'injury prevention'. In the following years she combined both jobs and since 2011 she officially became a PhD candidate, with dr. Ingrid van de Port as her co-promotor, and prof. dr. Frank Backx together with prof. dr. as Arno Hoes as her promotors. In the meanwhile she brought two children into the world (Coen and Benthe). Since 2013 she completed this thesis in her free time.

She currently lives in Ede with her husband Bart and their two children.

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