10-day below-knee cast for management of severe ankle sprains

S E Lamb and colleagues (Feb 14, p 575)1 investigated the effectiveness of three types of mechanical support for acute ankle sprains and found that a short period of immobilisation with a below-knee cast resulted in better ankle function than a tubular compression bandage.

Clinically important benefits (foot and ankle score) were found at 3 months’ follow-up with the below-knee cast; however, no self-perceived benefits were found at this time. To what extent, then, did the knee cast result in a faster recovery? A systematic review2 reported a resprain occurrence of 3–34% within 1 year of the initial injury. It is regrettable that Lamb and colleagues did not present the number of resprains that occurred during the follow-up period. It is plausible that the number of resprains is strongly correlated with self-perceived recovery.

Another point of discussion is the patients’ correct use of the mechanical supports. Lamb and colleagues report that they were unable to attain accurate reports on compliance with the bracings protocol, but they expected similar compliance across all groups. It is however probable that patients with a removable support such as the tubular compression bandage, the Bledsoe boot, and the Aircast are more likely to violate the protocol than patients with a below-knee cast that could not be removed. Incidentally, Lamb and colleagues report that 19 patients were wearing the below-knee cast at 1-month follow-up “now and then”. How is this possible for a non-removable support?

Finally, Lamb and colleagues emphasise the importance of limiting movement of the ankle joint, but one might also argue the importance of the non-weight-bearing period. The weight-bearing period might be more guaranteed by the below-knee cast support and therefore account for the treatment effect.

The number of resprains and the possible lack of compliance with the protocols could have overestimated the study effects; therefore, Lamb and colleagues’ recommendation should be interpreted with some caution.

We declare that we have no conflicts of interest.

Rogier M van Rijn, *Marienke van Middelkoop
m.vanmiddelkoop@erasmusmc.nl
Department of General Practice, Erasmus MC, PO Box 2040, 3000 CA Rotterdam, Netherlands


The title and conclusion of S E Lamb and colleagues’ paper suggest that this trial fills at least part of the gap in evidence-based treatment recommendations for lateral ankle ligament injuries.2,3 However, the remainder of the trial is disappointing.

All patients with ankle pain that caused the patient not to be able to bear weight for at least 3 days after the trauma were included. Lamb and colleagues claim to use practical, routinely used diagnostic criteria to establish injury severity; however, they do not use the current gold standard4—delayed physical examination 5–7 days after trauma—to exclude simple distortions. Such injuries might well cause a patient pain and disable weight-bearing 3 days after trauma, but it needs no further treatment. This group of patients should therefore not have been included in this trial.

The intervention of interest was applied for 10 days and there was no protocol for treatment after that period. Patients could basically do whatever they preferred to do and take whatever medication they wanted: they were only asked to report additional treatments at follow-up. Further treatment besides the interventions of interest was unclear and could grossly affect the results.

The primary outcome measure was ankle function, and Lamb and colleagues state in the Summary that outcome assessment was blinded. However, only data entry was blinded since all outcome measures were derived from postal questionnaires. Besides the weakness of basing results purely on a questionnaire, a 17% dropout rate at 1 month when treatment of severe ankle sprains is not yet finished does not seem ideal.

To give further direction to the discussion on optimum treatment of severe ankle sprains, a non-pragmatic trial with clear inclusion criteria, well described treatment strategies, and objective outcome measures not derived from questionnaires is needed.

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*G M Kerkhoffs, M P van den Bekerom, P A Struijs, C N van Dijk
g.m.kerkhoffs@amc.uva.nl

Department of Orthopedic Surgery, Orthopedic Research Center Amsterdam, Academic Medical Center, 1100 DD Amsterdam, Netherlands


S E Lamb and colleagues conclude that a period of immobilisation with a below-knee cast is the most effective treatment for fast recovery from severe ankle sprains. Two major comments on methods ought to be considered.

First, the severity of the ankle sprain has a striking effect on recovery, and should be classified according to standard measures. Delayed physical examination after 3–5 days allows diagnosis of ligament ruptures with a sensitivity of 96%. Lamb and colleagues’ classification of severe ankle sprains according to the inability to bear weight fully is a new concept which is not supported by the literature.

Second, treatment with immobilisation was not compared with functional treatment, although it is the treatment of choice at present. In a meta-analysis of 20 randomised trials of acceptable quality comparing immobilisation with functional treatment, functional treatment was favourable across seven outcome measures; none favoured immobilisation. This finding aligns with those of several other meta-analyses and reviews. They all agree that functional treatment—ie, a combination of early mobilisation plus external support—is the treatment of choice.

Although the study by Lamb and colleagues is remarkable for the large number of patients enrolled and the adherence of its design to the CONSORT statement, care should be taken in declaring immobilisation with cast as the most favourable treatment for severe ankle sprains.

I declare that I have no conflicts of interest.

Hans Polzer
Hans.Polzer@med.uni-muenchen.de

Department of Trauma, Surgery Campus Innenstadt, Ludwig-Maximilian’s University, Munich 80336, Germany


Authors’ reply
We thank colleagues for their comments on our paper. Many of the judgments rest on an understanding of pragmatic trials.

Pragmatic trials are designed to test the effectiveness of interventions provided in everyday settings. They are not intended to test theories about mechanisms of effect, or determine a clinical effect in artificially controlled situations. In everyday life, patients self-medicate, seek alternatives, and comply or not with the treatments provided. These possibilities are included implicitly within a pragmatic trial.

Careful preparatory work showed that UK emergency departments do not wait 5–7 days to diagnose and treat severe ankle sprains. Weight-bearing status is the most common indicator, and was checked twice, including just before randomisation. Criteria to determine weight-bearing status were exacting and are described in detail elsewhere. Inclusion of non-limiting injuries is unlikely. Although we set limits for time to treatment, the aim was to examine treatments in the context of acute management in emergency departments. Most patients were well below the time window for valid use of various ligament stress and tilt tests. We are happy to accept that our method might not map precisely to other definitions. However, we contend that we provide relevant evidence about acute treatments to emergency care clinicians.

The outcome measures were investigator-blinded. Understandably, it was impossible to blind patients. However, all outcome data were ascertained, collated, processed, and analysed by investigators entirely independently of the clinicians and researchers who recruited individuals into the trial or provided treatment. We rebut strongly any suggestion that the trial method was not as we describe or suboptimal.

The foot and ankle score scale includes items relating to recurrent sprain. In the pilot study, additional questions about resprain were not well completed and hence excluded from the main trial. All treatments were associated with self-perceived benefits. Many things, including comfort and aesthetics, can influence perception of benefit. Participants who did not accept a below-knee cast (or while they were waiting for application) were provided with a tubi-grip. This is entirely removable.

We did a large, well designed study, which has produced an unexpected finding. We acknowledge that further trials are needed to substantiate the findings and should examine various treatment strategies, including delayed physical examination. Whether future trials should be pragmatic or non-pragmatic is likely to be a subject for continued debate, but the benefit of taking a different approach to investigate an old question should not be dismissed.

We declare that we have no conflicts of interest.

Sarah E Lamb, Matthew W Cooke, Jane L Hutton, Jennifer L Marsh, on behalf of the CAST Team
S.Lamb@warwick.ac.uk

Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry CV4 7AL, UK
