Mechanical ankle support versus tubular bandage for severe ankle sprain – the CAST trial

Treatment of severe ankle sprain: a pragmatic randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of three types of mechanical ankle support with tubular bandage. The CAST trial

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Executive summary

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Executive summary

Background

The optimal treatment for severe ankle sprains is unclear. Potential treatments include no intervention, physiotherapy, different types of supports, immobilisation and surgical repair of the ligaments. Recent systematic reviews highlight a lack of good-quality evidence to aid clinical decision-making. There is a need for well-conducted and adequately powered randomised controlled trials of the effectiveness of different clinical approaches.

Objectives

Objectives were, first, to estimate the clinical effectiveness of three different methods of ankle support [below knee cast, Aircast® ankle brace (DJO Incorporated, Vista, CA) and Bledsoe® boot (Bledsoe Boot Systems, Grand Prairie, TX)] in comparison with double layer tubular compression bandage in terms of recovery of function (primary outcome), recovery of normal occupation (secondary outcome) and avoidance of residual symptoms including recurrent instability, lasting limitation of physical activity and need for further medical, rehabilitation or surgical treatment (secondary outcomes); and, second, to measure the cost-effectiveness of each strategy, including treatment and subsequent health-care costs.

Design

A pragmatic randomised controlled trial was designed to reflect a model of practice used in the majority of UK hospital emergency departments. It included an integral evaluation of the cost-effectiveness of the different therapies. A total of 584 participants were recruited and randomised to one of four treatment arms: tubular bandage, below knee cast (10 days), Aircast brace or Bledsoe boot. Follow-up was by postal questionnaire at 4 weeks, 12 weeks and 9 months, with response rates of 83%, 82% and 76% respectively.

Participants

Participants aged 16 or over with acute severe ankle sprain, unable to weight bear, with no fracture, were recruited from eight emergency departments across the UK.

Intervention

Treatments were applied 2–3 days after presentation to allow time for swelling to resolve. Participants were given written and verbal instructions regarding the use of supports. Instructions were standardised across all centres and derived from a combination of the manufacturer's recommendations, results of a national survey carried out to inform the design of the trial, and current clinical guidelines.

Main outcome measures

A disease-specific measure [Foot and Ankle Outcome Score (FAOS)] and generic measures [Functional Limitations Profile (FLP), short form questionnaire with 12 items (SF-12) and EuroQol 5 dimensions (EQ-5D)] were used to assess the response to treatment, and information was gathered to assess resource use.

Results

After adjustment for age, sex and baseline score, the below knee cast offered a small but statistically significant benefit at 4 weeks in terms of pain, foot- and ankle-related quality of life (QoL), and the physical component score of the SF-12. Neither the Aircast brace nor the Bledsoe boot was statistically significantly or clinically different from tubular bandage.

At 12 weeks, and in comparison with tubular bandage, the below knee cast was statistically

significantly better in terms of pain, activities of daily living, return to sports and QoL. Calculation of effect sizes suggests that these benefits were small to moderate, depending on the domain of outcome. The Aircast brace was associated with clinically and statistically significant changes in ankle-related QoL and mental health but not in other domains. The Bledsoe boot conferred no significant advantage over tubular bandage.

By 9 months there were no significant differences between the three comparator supports and tubular bandage for any outcome measure.

Economic evaluation results

Mean direct health-care costs per participant indicated that the Bledsoe boot was the most expensive support (£215 including fitting), with tubular bandage the least expensive (£1.44); Aircast (£39.23) was more expensive than the below knee cast (£16.46). Inclusion of indirect costs (sick leave) raised overall costs substantially, resulting in no significant difference between the groups.

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 least cost-effective and that the Aircast brace and below knee cast differences were broadly similar.

Inclusion of indirect costs produced different rank orders depending on the assumptions made; results should be treated with some caution.

Conclusions

Ankle sprains with an inability to weight bear have a prolonged recovery. The prognosis should be cautious, explaining that the injury, independent of treatment, has a significant risk of some disability in the form of symptoms, limitations of mobility or activities at 9 months.

Such patients, initially treated with 2–3 days of elevation, ice and non-weight-bearing exercise, had a more rapid resolution of symptoms and return to normal activities in the first 3 months when treated with a below knee cast for 10 days than when treated with tubular bandage.

By 9 months all treatments were equally effective. Mental health deteriorated in the early stages of recovery but returned to normal by 12 weeks. The study suggests that choice of treatment may affect speed of recovery but not long-term outcome.

Implications for health care

Two devices appeared to offer cost-effective alternatives to tubular bandage: the below knee cast and the Aircast brace. The below knee cast resulted in the fastest recovery and higher levels of sporting function and overall quality of recovery by 3 months. There were no differences in long-term outcome and the decision about which brace to apply should incorporate an assessment of likely compliance and acceptability to patients.

Recommendations for research

1. The role of physiotherapy is not known in these injuries. In view of the poor prognosis in relatively active people, the effects of a regime of physiotherapy during and after the period of functional support or as an alternative to immobilisation should be investigated.
2. There are still no adequately powered studies of less severe ankle sprains.
3. In the UK, anticoagulants are not routinely used in lower limb injury, whereas this is standard practice in most of mainland Europe. More research is needed to determine the risk–benefit of such strategies.

Trial registration

This trial is registered as ISRCTN37807450.

Publication

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NIHR Health Technology Assessment Programme

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