Offer of a bandage versus rigid immobilisation in 4- to 15-year-olds with distal radius torus fractures: the FORCE equivalence RCT

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Scientific summary

The FORCE equivalence RCT

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Scientific summary

Background

Torus (buckle) fractures of the radius with or without involvement of the ulna are the most common fractures in children, with around 60,000 injuries per year in the UK. Although a fracture in adults leads to a complete disruption of the cortex of the bone, children's bones can crush or 'buckle' such that there is deformation but no break in the cortex. These fractures are at a low risk of complications or deformity, and almost universally heal well.

There is considerable variation in the management of torus fractures. Some clinicians advocate rigid immobilisation (i.e. cast/splint) with outpatient follow-up. They argue that this maximises pain relief, and minimises the occurrence of complications, such as refracture. However, others argue that children with these injuries would recover equally well without any immobilisation and advocate early discharge without the need for outpatient follow-up.

The 2016 National Institute for Health and Care Excellence (NICE) guideline for non-complex fractures recommended a trial to overcome the uncertainties and to determine if no immobilisation and immediate discharge is as good as rigid splint immobilisation and outpatient follow-up [National Institute for Health and Care Excellence (NICE). *Fractures (Non-Complex): Assessment And Management*. NG38. London: NICE; 2016]. Given the high frequency of these injuries, identifying the optimal treatment strategy could have important effects on childhood pain, the number of days of school absence and the cost to the NHS.

Objectives

The aim of this pragmatic, randomised equivalence trial was to establish whether or not treating children with a torus fracture of the distal radius with the offer of a soft bandage and immediate discharge (i.e. offer of a bandage) provides the same recovery as treating them with rigid immobilisation and follow-up as per the protocol of the treating centre (i.e. rigid immobilisation).

The primary objective of the randomised controlled trial was to estimate observed differences in the Wong–Baker FACES Pain Rating Scale ('Wong–Baker Scale') scores between the offer of a bandage and rigid immobilisation at 3 days post randomisation.

The secondary objectives were to:

- assess differences in the Wong–Baker Scale scores between trial treatment groups at 1 day, 7 days, 3 weeks and 6 weeks post randomisation
- determine differences in the use of regular analgesia between trial treatment groups at 1 day, 3 days and 7 days post randomisation.
- quantify and draw inferences on functional recovery using the patient-report outcomes measurement system (PROMIS) upper extremity limb score for Children Computer Adaptive Test between the trial treatment groups at 3 days, 7 days, 3 weeks and 6 weeks post randomisation
- quantify and draw inferences on observed differences in health-related quality of life (HRQoL) using the EuroQol-5 Dimensions, youth version (EQ-5D-Y), between trial treatment groups at 3 days, 7 days, 3 weeks and 6 weeks post randomisation
- determine differences in the number of days of school absence between trial treatment groups up to 6 weeks post randomisation
- determine differences in the complication rate between trial treatment groups, including the need for further hospital attendance up to 6 weeks post randomisation

- investigate, using appropriate statistical and economic analysis methods, the resource use and comparative cost-effectiveness between trial treatment groups during the first 6 weeks post randomisation.

Methods

The study was a pragmatic, multicentre, randomised controlled equivalence trial within emergency departments treating children. All children aged 4–15 years presenting at a recruiting centre with a radiologically confirmed torus fracture of the distal radius were potentially eligible for inclusion. After agreeing to participate in the study, parents were asked to provide informed consent, and children from 8 years of age were invited to provide assent. The trial was separately powered to assess equivalence in two age groups (4–7 years and 8–15 years). A randomisation sequence, stratified by age and recruitment centre, was produced and administered through a secure web-based service. The random allocation was 1 : 1 to the rigid immobilisation group or to the offer of a bandage group. Trial participants and the treating clinician could not be blinded to the treatment allocation.

The offer of a bandage included a simple gauze bandage to use at the families' discretion, and encompassed immediate discharge from the emergency department without subsequent outpatient follow-up. Rigid immobilisation could include hard casts, soft casts, backslabs or pre-contoured removable splints, and encompassed follow-up as per the protocol of the treating centre.

Follow-up was through a web link sent to families by text message and/or e-mail at the prespecified follow-up time points. Participants were followed up to 6 weeks, with questionnaires at 1, 3 and 7 days and then 3 and 6 weeks post randomisation. The questionnaires were administered centrally using a bespoke software application. If the participant indicated a return to hospital or potential complication, then the hospital was prompted to complete a complication form. The Wong–Baker Scale was self-reported in all participants. In participants aged < 8 years, other outcomes were proxy reported. The PROMIS and EQ-5D-Y was self-reported by participants aged ≥ 8 years. In addition, at the prespecified time points, information was requested with regard to resource use, complications and school absence.

Outcome

The main analysis investigated the difference in the primary outcome measure, the Wong–Baker Scale, at 3 days post randomisation. The stratified randomisation procedure ensured balance in the recruitment centres and age groups between study interventions. The within-trial economic evaluation was conducted in line with the reference case required by NICE, such that costs were estimated from an NHS and Personal Social Services perspective, and health utilities were derived from the EQ-5D-Y instrument, using UK tariffs for adults in the absence of child-specific tariffs.

Results

A total of 965 children were randomised from January 2019 to July 2020 from 23 UK emergency departments treating children. In total, 300 children were in the 4–7 years age group and 665 children were in the 8–15 years age group. The primary outcome was completed for 908 (94.1%) participants.

The Wong–Baker Scale score at 3 days post randomisation was equivalent for both treatment groups. With reference to the prespecified equivalence margin of 1.0, the adjusted difference in the intention-to-treat population was −0.10 [95% confidence interval (CI) −0.37 to 0.17] and that for the per-protocol population (analysis by treatment received) was −0.06 (95% CI −0.34 to 0.21). The trial was separately powered to assess equivalence in two age groups (i.e. 4–7 years and 8–15 years) and there was

equivalence in both of these subgroups. Similarly, there was evidence of equivalence in the Wong–Baker Scale score at all secondary follow-up time points throughout the trial.

There was no difference in the rate of complications, with five complications (1.0%) in the offer of a bandage group and three complications (0.6%) in the rigid immobilisation group. Seven of these complications were treatment changes owing to a change in the fracture diagnosis after randomisation and one was a refracture. No complications required intervention beyond the application of a plaster cast without the need for manipulation.

There were no differences between the two groups in functional recovery or HRQoL at any point during follow-up. The median school absence was 1.5 days (interquartile range 1–2 days), which was the same in both intervention groups. There was a small but statistically significant difference in the use of analgesia at day 1, which was slightly higher in the offer of a bandage group than in the rigid immobilisation group (83% vs. 78% use), but there was no difference at other time points. Parental satisfaction at day 1 was slightly better (extremely satisfied vs. very satisfied) in the rigid immobilisation group than in the offer of a bandage group, but there was no difference by 6 weeks post randomisation.

Using a bandage instead of rigid immobilisation resulted in a small but statistically significant saving of £12.55 (95% CI £5.30 to £19.51). The incremental cost-effectiveness ratio in the base-case analysis was −£10,680 per quality-adjusted life-year gained, which indicated that the offer of a bandage had lower costs and marginally better outcomes than provision of rigid mobilisation. The offer of a bandage significantly reduced the cost of treatment and had a high probability of cost-effectiveness at a willingness-to-pay threshold of £30,000 per quality-adjusted life-year.

Conclusions

There was clear evidence of equivalence in reported pain between those children treated with the offer of a bandage and those treated with rigid immobilisation. There was no difference in the rate of complications, functional recovery, HRQoL or school absence. The offer of a bandage is very likely to be cost-effective.

In conclusion, the offer of a bandage and immediate discharge from hospital was equivalent to rigid immobilisation, with a clear economic benefit.

Trial registration

This trial is registered as ISRCTN13955395 and UKCRN Portfolio 39678.

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This report

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