NICE National Institute for Health and Care Excellence

Surveillance report (exceptional review) 2018 – Fractures (non-complex): assessment and management (2016) NICE guideline NG38

Surveillance report

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Surveillance decision

We propose no update of NICE guideline NG38 on fractures (non-complex): assessment and management.

Reason for the decision

Assessing the evidence

The purpose of this exceptional review was to examine any impact on the fractures (non-complex) guideline following the publication of a National Institute for Health Research funded trial: the Fixation of Distal Tibia Fractures (FixDT) study. This study was considered to be relevant to the section on ongoing orthopaedic management. No additional evidence published since the publication of NICE's guideline on non-complex fractures in February 2016 was considered by the exceptional review.

Methods

The FixDT study is a multicentre randomised trial (28 UK trauma hospitals) that compared the effectiveness of intramedullary (IM) nail fixation to 'locking' plate fixation in 321 adults (16 years or older) with an acute displaced fracture of the distal tibia (extra-articular and closed). People were excluded if they had an open fracture, a fracture that extended to the ankle joint, contraindication for IM nail fixation or anaesthesia, or if they were unable to complete questionnaires.

Each person was randomly allocated to 1 of the 2 interventions assessed. The specific technique used in each intervention was left to the discretion of the surgeon (for example, implant system used and positions of the screws). All the participants received regular clinical follow-up as part of routine clinical practice and the same standardised physiotherapy advice. The need for any other rehabilitation was left to the discretion of the clinicians.

The main outcome assessed was Disability Rating Index (DRI) at 6 months after surgery. A DRI score of 0 indicates no disability and a score of 100 complete disability. A difference of 8 points in the DRI score was considered the minimum clinically important difference. The secondary outcomes assessed were the Olerud and Molander Score (OMAS), health-

related quality of life (EQ-5D), complications including union issues (mal-union, non-union), infection, wound complications, vascular and neurological injury, and venous thromboembolism or further surgery.

Data were collected from self-administered questionnaires, clinical assessment and hospital records. DRI, OMAS, EQ-5D were collected at baseline, 6 weeks, 3, 6 and 12 months. Complications, rehabilitation, information on resource use and other interventions were collected at 6 weeks, 3, 6, and 12 months. Radiographic evaluations were taken at baseline, 6 weeks and 12 months and were reviewed by an independent assessor. Intention to treat and per protocol analyses were performed. Results were adjusted by allocated treatment group, age, gender, baseline pre-injury score and recruiting site. Subgroup analysis by age were performed. The age was used as a surrogate indicator of the bone quality of the participants with 50 years old the cut-off at which it was considered the bone mineral density starts to decrease. A post-hoc explanatory analysis aimed at facilitating comparisons between interventions was also performed by calculating the area under the curve (AUC) using DRI scores at all time points for the 2 interventions assessed.

Results

A total of 321 people were included (161 IM nail fixation group, 160 in the 'locking' plate group, <20% of loss of follow-up). No differences were identified in the mean age and sex between the groups.

The results following an intention-to-treat analysis failed to show a difference in the disability status at 6 months between the 2 interventions assessed (mean adjusted difference [adj.MD] 4.0; 95% confidence interval [95% CI] −1.0 to 9.0). Similar results were obtained at 12 months but not at 3 months, where the IM nail fixation group obtained better DRI scores compared to the 'locking' plate group (adj.MD 8.8; 95% CI 4.3 to 13.2). OMAS at 3 and 6 months also favoured the IM nail fixation group (adj.MD −7.0; 95% CI −12.0 to −2.0 and adj.MD −6.0; 95% CI −11.2 to −0.7, respectively) but not at 12 months (adj.MD −3.6; 95% CI −9.1 to 1.9). People in the IM nail fixation group obtained better EQ-5D scores than the 'locking' plate group at 6 months (adj.MD −0.06; 95% CI −0.12 to −0.01) but not at 3 (adj.MD −0.06; 95% CI −0.12 to 0.00) or 12 months (adj.MD −0.02; 95% CI −0.07 to 0.05). A per protocol analysis showed similar results.

No differences were identified in the rate of complications between the groups. Infections and further surgery were more common in the 'locking' plate group than in the IM nail

fixation group but no statistical differences were identified. The proportion of people reporting being fully weight bearing at 6 weeks was higher in the IM nail fixation group than in the 'locking' plate group ($p<0.001$). Authors reported that the number of systemic complications were comparable between the groups but the number of unrelated serious adverse events were higher in the 'locking' plate group (80 events) compared to the IM nail fixation group (46 events).

In the post-hoc analysis, the calculated AUC was lower for the IM nail fixation group than the 'locking' plate group. A higher level of AUC means greater disability, so the IM nail fixation group experienced less disability than the 'locking' plate group at 12 months of follow up.

Authors concluded IM nail fixation and 'locking' plate fixation are both effective interventions to treat distal tibia fractures but IM nail fixation provides a faster recovery.

Guideline development

The current guideline does not include recommendations about specific techniques of surgical fixation for fractures of the distal tibia. The topics included in the guideline were chosen based on their prevalence, their importance in the patient pathway of care or if it was considered there was variation in the clinical practice, including if the assessment, management or follow-up was considered unclear.

Views of topic experts

We engaged with topic experts who were also members of the guideline committee involved in the development of NICE guideline NG38. We received mixed views. Two topic experts considered that the evidence identified does not have an impact on NICE guideline NG38. This area is not currently included in the guideline and the topic experts did not feel it should be added. One topic expert noted that the results of the FixDT study bring some clarity to the area but not enough to have an impact on NICE guideline NG38 given the findings in the different outcomes assessed. It was also highlighted that there are other techniques used in the treatment of these type of fractures, for example external fixation or plaster cast which are not assessed in the FixDT study. Conversely, the other topic expert noted that the findings of the study have an impact on this common injury, potentially reducing the current variability in surgical practice in this area. It was also highlighted that including this new area could be used as an index condition that may help surgeons in the management of other similar injuries.

Impact

Surgical management of fractures in the distal tibia is not currently included in NICE guideline NG38 although there are recommendations on ongoing orthopaedic management.

The results of FixDT study did not show any differences in the effectiveness between the IM nail fixation and the 'locking' plate fixation as orthopaedic management of distal fractures of the tibia (extra-articular and closed) in adults. However, some benefits in terms of faster recovery following IM nail fixation were identified.

This study has some limitations mainly related to potential selection and performance bias. During the randomisation process, one of the main reasons for non-randomisation of eligible participants was a surgeon or patient preference for a specific technique. In most of the cases there was a preference for IM nail fixation over 'locking' plate fixation. Also, people were only recruited during week days given an absence of research staff available over the weekends. Additionally, given the characteristics of the study, only the assessors were blinded to the interventions. The study also has several strengths: the loss of follow-up was less than 20% but the sample size was calculated taking into account this percentage of loss of follow-up. They reported low level of missing data and imputation analyses were presented showing similar results. The cross-over between the interventions was lower than expected, with more than 90% of the participants receiving the intervention initially allocated. However, there were more patients crossed-over in the 'locking' plate fixation group than in the IM nail fixation group (23 and 5 respectively) which could indicate a surgeon's preference for the IM nail fixation technique. The study included relevant patient-reported outcomes, all of them relevant for the guideline and considered in the development of other questions included.

It is important to highlight that even if no differences were identified in terms of effectiveness between the groups at the end of the follow-up period, the data presented showed that the people did not return to their pre-injury state with either intervention assessed. This indicates that a distal tibia fracture produces a persistent disability that could lead to long-term complications.

Topic expert feedback was mixed but more views considered that FixDT studies does not have an impact on NICE guideline NG38. There was a suggestion that there may be an opportunity to reduce variability in surgical practice in this area. However, it is not currently known how widespread an issue this is, how important it is to address and if the evidence

identified could be enough help to resolve it.

NICE guideline NG38 was not intended to include every fracture type, only those in which it was considered there was variation in clinical practice or in which the assessment, management or follow-up were considered unclear. Following the consideration of the results published in the FixDT trial (including the strengths and limitations of this trial), as well as topic expert feedback, the new evidence identified is considered not to impact on NICE guideline NG38.

Other clinical areas

This exceptional surveillance review did not search for new evidence relating to other clinical areas in the guideline.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

See how we made the decision for further information.

How we made the decision

Exceptionally, significant new evidence may mean an update of a guideline is agreed before the next scheduled check of the need for an update. The evidence might be a single piece of evidence, an accumulation of evidence or other published NICE guidance.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence

This exceptional review provides an overview of 1 study published since the end of the search period for the guideline (April 2015). The results of this study were considered in detail to determine if there is an impact on guideline recommendations.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Because this was an exceptional surveillance review we did not consult on the decision.

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