NICE National Institute for Health and Care Excellence

NICE

2018 exceptional surveillance of fractures (complex): assessment and management (NICE guideline NG37)

Surveillance report

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Contents

Surveillance decision

We will plan a partial update of fractures (complex): assessment and management. This update will focus on the role of negative pressure wound therapy in open fractures after wound excision or surgical debridement.

Reason for the decision

Assessing the evidence

The purpose of this exceptional review was to examine any impact on NICE's guideline on complex fractures following the publication of a National Institute for Health Research funded trial: The Wound management of Open Lower Limb Fractures (WOLLF). No additional evidence published since NICE's guideline in February 2016 was considered by the exceptional review.

Methods

The WOLLF study is a multicentre randomised controlled trial (24 UK specialist trauma hospitals involved) that compared the effectiveness of negative pressure wound therapy (NPWT) with standard wound management in adults (≥16 years) with an open fracture of the lower limb. Only people admitted to the trial centres within 72 hours after the injury and with an open fracture (Gustilo and Anderson Grade 2 or 3) were included in the study. Exclusion criteria included contraindication to anaesthesia or people unable to adhere to the trial procedures or complete questionnaires. Once the fracture was debrided and fixed (using internal or external fixation), the participants in which the wound could not be closed primarily were randomised to receive NPWT or standard care (standard dressing with non-adhesive layers covered by a sealed dressing or bandage). The NPWT consisted of the application of an 'open-cell' solid foam covered with an adherent sealed dressing. The specific dressing materials or pressure (mmHg in the NPWT group) were left to the discretion of the clinicians. After the intervention, both groups received normal post-operative management as per routine care.

The main outcome assessed was the Disability Rating Index (DRI) at 12 months after the open fracture. A DRI score of zero 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. Secondary outcomes included deep surgical site infection, health-related quality of life (EQ-5D, SF-12) and other complications. The data for DRI, EQ-5D and SF-12 were collected using self-administered questionnaires at baseline, 6 weeks, 3 months, 9 month and 12 months. Routine radiographs of leg wounds were taken at baseline, 6 weeks and 12 months and used to assess signs of infection. Photographs of the wound were also taken at 6 weeks and used to assess the wound

healing and signs of infection. Data on complications were recorded at similar time points as the questionnaires.

Results

A total of 460 patients were included in the study (226 in the NPWT group; 234 in the standard dressing group). In the intention to treat analysis, no differences in the disability status at 12 months between the NPWT group and the standard dressing group were identified (mean adjusted difference [adj. MD] −3.9; 95% confidence interval [CI] −8.9 to 1.2). No differences were identified in DRI score at 3 (adj. MD 0.7; 95% CI −3.7 to 5.0), 6 (adj. MD −3.5; 95% CI −8.4 to 1.5) and 9 months (adj. MD −4.4; 95% CI −10.0 to 1.3) between the groups. Per protocol analysis showed similar results.

No differences were identified in the EQ-5D or SF-12 at any time point between the groups. Similarly, no differences were identified in any of the local complications assessed. In terms of systemic complications potentially related to the interventions, 10 deaths occurred during the study.

The authors concluded that there is no difference in terms of effectiveness between the 2 interventions compared in adults with an open fracture of the lower limb.

Guideline development

Two randomised controlled trials were evaluated relevant to this intervention during guideline development. One compared NPWT with saline-soaked dressing (conducted in Pakistan) and the other one NPWT with saline wet to moist dressing (conducted in UK). Three main outcomes were reported in the guideline: deep infection at 11 weeks, wound healed within 30 days, and quality of life at 3 months (measured with SF-36 physical component). Outcomes reported narratively were time to wound healing and length of stay in hospital. The evidence showed that NPWT was clinically beneficial compared to standard treatment in terms of risk of deep infection at 11 weeks (1 study; n=58; relative risk [RR] 0.04; 95% CI 0.04 to 0.83), wound healed within 30 days (1 study; n=50; RR 1.89; 95% CI 1.3 to 2.74) and quality of life at 3 months (1 study, n=58; MD 11.4; 95% CI 2.67 to 20.13). The quality of evidence was considered low to very low due to the high risk of bias of the studies included and the imprecision of the results found. No differences were identified in the other outcomes assessed. A cost-effectiveness analysis was not conducted but the costs and the consequences of the interventions were considered, leading to the decision that the additional costs incurred by the use of the NPWT were lower than the cost associated with a deep infection (requiring further interventions and length of stay).

Views of topic experts

In this exceptional review we engaged with topic experts who were also members of the guideline committee involved in the development of NICE guideline NG37. Two topic experts highlighted that NPWT is broadly used in clinical practice as a dressing for open fractures. One of them stated that, currently, there are few situations when NPWT is not used: 1) risk of very heavy bleeding and 2) compression of vital structures. It was suggested that the results of the new study could have an impact on the guideline and it needs to be reviewed. However, there were some concerns regarding to the need of strong and explicit evidence to change the recommendation and current clinical practice.

Impact

Recommendation 1.2.31 currently states that NPWT could be considered after debridement if immediate definitive soft tissue cover has not been performed.

The new evidence identified showed that the NPWT does not provide any benefits in terms of clinical effectiveness compared to standard dressing therapy, in people with an open fracture of the lower limb.

Regarding the strengths and limitations of the WOLLF study, most of the eligible persons that were randomised accepted to be part of the study lowering the risk of selection bias. The loss of follow-up were slightly higher than expected (loss of follow-up expected 10%; loss of follow-up during the study 12%) but it does not seem to have an important impact on the results of the study. Missing data were imputed using appropriate methods, and the findings showed similar results. The cross-over between the interventions was very low, so most of the participants received the treatment to which they were allocated. Topic experts noted that the use of NPWT is widely used for the treatment of open fractures and noted that the results of the WOLLF study are directly applicable to the UK context and may provide a stronger evidence in this area than the evidence previously available.

The recommendation included in the guideline was based on 2 small studies considered to be a high risk of bias and the quality of the body of the evidence identified was considered low to very low.

Following consideration of the results published in the WOLLF trial, as well as topic expert feedback, the new evidence may have an impact on the current recommendation to consider NPWT after debridement if immediate definitive soft tissue cover has not been performed.

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 surveillance report 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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