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NHS
National Institute for Health and Clinical Excellence

Low-intensity pulsed ultrasound to promote fracture healing

1 Guidance

1.1 Current evidence on the efficacy of low-intensity pulsed ultrasound to promote fracture healing is adequate to show that this procedure can reduce fracture healing time and gives clinical benefit, particularly in circumstances of delayed healing and fracture non-union. There are no major safety concerns. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

2.1.1 Fractures are a common result of trauma, and usually heal within a few weeks after treatment by closed or open reduction and immobilisation using a cast or internal fixation. Failure of the fracture to heal resulting in non-union may require complex and prolonged management with implications for the patient's quality of life and functional capacity.

2.1.2 Fractures are described as either closed (skin over the fracture site is intact) or open (involves an open wound). The complexity of open fractures is graded from I (simple transverse or short oblique fracture, with minimal comminution or soft tissue injury) to III (involving extensive damage to the soft tissues and neurovascular structures).

2.2 Outline of the procedure

2.2.1 The aim of low-intensity pulsed ultrasound is to reduce fracture healing time and avoid non-union by delivering micro-mechanical stress to the bone to stimulate bone healing. This procedure is used to treat fractures that are slower to heal than expected (delayed healing), fractures that have failed to unite (non-union), and fresh fractures.

2.2.2 This is a non-invasive procedure. The ultrasound probe is positioned on the skin over the fracture and patients self-administer low-intensity pulsed ultrasound daily, usually for 20 minutes. If a patient's limb is immobilised in a cast, then a hole is cut into the cast for the ultrasound probe. Coupling gel is used on the skin to aid conduction of the ultrasound signal.

2.2.3 Progress towards fracture union is usually assessed radiographically. The duration of treatment ranges from a few weeks to several months.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at **www.nice.org.uk/guidance/IP/810/overview**

2.3 Efficacy

2.3.1 A meta-analysis of 13 randomised controlled trials (RCTs) including a total of 563 patients (with a mixture of fresh conservatively or operatively managed and non-united fractures) reported a 34% (95% confidence interval [CI]: 21 to 44) overall mean reduction in healing time (confirmed by imaging) in 119 patients treated by the procedure compared with 122 patients treated by a sham procedure (6 studies; follow-up not stated).

2.3.2 An RCT of 67 patients with closed or open grade I fractures of the tibial shaft (33 low-intensity pulsed ultrasound vs 34 sham) reported a mean

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This guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.
This guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by NHS QIS for implementation by NHSScotland.

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healing time (healing defined as evidence of clinical and radiographic bridging of 3 cortices) of 96 days in the ultrasound group compared with 154 days in the sham group ($p < 0.0001$).

2.3.3 A case series (register data) of 1317 patients with delayed fracture union or non-union reported healing rates of 91% (862/951) and 86% (314/366) respectively (mean fracture age 151 days vs 755 days). The method used to diagnose healing was not stated.

2.3.4 An RCT of 32 patients with fresh closed or open grade I fractures of the tibial shaft fixed with an intramedullary rod treated by the procedure ($n = 15$) or a sham procedure ($n = 17$) reported an average healing time (healing defined as radiographic bridging of 3 cortices assessed by a radiologist) of 155 days and 125 days respectively ($p = 0.76$).

2.3.5 An RCT of 21 patients with non-united fractures of the scaphoid treated by pedicle bone graft reported an average healing time (clinical healing defined as solid and not causing tenderness or pain and radiographic healing defined as complete bridging of cortices) of 56 days in patients who also received low-intensity pulsed ultrasound ($n = 10$) and 94 days in those who received sham therapy ($n = 11$) ($p < 0.001$).

2.3.6 An RCT of 30 patients with open tibial fractures or high-energy-induced complex tibial fractures treated by the procedure ($n = 16$) or a sham procedure ($n = 14$) reported an average time to full weight bearing of 9.3 weeks and 15.5 weeks respectively ($p < 0.05$).

2.3.7 The Specialist Advisers listed key efficacy outcomes as the rate of fracture healing, need for operative intervention, and time to return to function.

2.4 Safety

2.4.1 Acute compartment syndrome within the first few days of treatment was reported in 1 patient in the ultrasound group and 2 patients in the sham group in the RCT of 32 patients. All 3 patients underwent fasciotomy (secondary closure after 5 days in 2 and skin graft closure in 1).

2.4.2 Mild swelling and erythema at the application site during the first 2 weeks were reported in 4 patients treated by the procedure in the RCT of 30 patients with tibial fractures. The symptoms resolved spontaneously and treatment was not interrupted.

2.4.3 The Specialist Advisers considered theoretical adverse events to include excessive or ectopic bone formation and tumour induction.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See **www.nice.org.uk/guidance/IPG374/publicinfo**

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2392 for this guidance or N2393 for the 'Understanding NICE guidance'.

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