NICE guidance

Low-intensity pulsed ultrasound to promote healing of fresh fractures at high risk of non-healing

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg622

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG374.

1 Recommendations

1.1 The evidence for low-intensity pulsed ultrasound to promote healing of fresh fractures at high risk of non-healing raises no major safety concerns. The current evidence on efficacy is very limited in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should include details of patient selection, fracture site, and risk factors and comorbidities that delay fracture healing.

2 The condition, current treatments and procedure

The condition

2.1 Fractures are a common result of trauma, and are usually described as either closed (skin over the fracture site is intact) or open (involves an open wound). They may vary in complexity from a single break (transverse or oblique) to comminuted, in which the bone has broken into

several pieces.

Current treatments

2.2 Fractures usually heal within a few weeks after treatment by closed or open reduction, and immobilisation using a cast or internal fixation. Sometimes, healing may be delayed or not happen at all (non-union). There is no agreed precise definition of a fracture non-union but, typically, it is considered to be when there is failure of bony union 6 to 9 months after the fracture. Risk factors for non-union of fractures include: systemic medical conditions (for example, diabetes, malnutrition, osteoporosis); smoking; use of non-steroidal anti-inflammatory drugs; local factors such as infection; vascular problems; magnitude of injury (for example, fracture location and gap, traumatic fractures); advanced age; and other iatrogenic factors. Treatment of non-union may need complex and prolonged management with implications for the patient's quality of life and functional capacity.

The procedure

2.3 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.

2.4 An 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, a hole is cut into the cast for the ultrasound probe. The probe delivers acoustic radiation and coupling gel is used on the skin to aid conduction of the ultrasound signal. An operating frequency of 1.5 MHz, pulse width of 200 microseconds, repetition rate of 1 kHz, and a temporal average power of 30 milliwatts/cm^2 is typically used. The exact treatment protocol and duration of treatment may vary.

2.5 Progress towards fracture healing is usually assessed radiographically. Treatment duration ranges from a few weeks to several months.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 randomised controlled trial and 1 cohort study and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: fracture healing or union, functional outcomes and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcome to be: need for subsequent reoperation.

3.4 Three commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

3.5 The evidence came from a variety of fracture types and different sites.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.