NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma

Interdigital (Morton's) neuroma affects one of the nerves leading to the toes. It can cause a burning pain in the ball of the foot and pain, tingling and numbness in the toes.

In this procedure, a thin probe is inserted at the base of one of the toes into the affected nerve. An electric current passed through the probe destroys the nerve with radiofrequency heat energy.

The National Institute for Health and Care Excellence (NICE) is examining radiofrequency ablation for symptomatic interdigital (Morton's) neuroma and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about radiofrequency ablation for symptomatic interdigital (Morton's) neuroma.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 25 September 2015

Target date for publication of guidance: December 2015

1 Provisional recommendations

1.1 Current evidence on radiofrequency ablation for symptomatic interdigital (Morton's) neuroma raises no major safety concerns. The evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do radiofrequency ablation for symptomatic Morton's neuroma should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public *[[URL to be added at publication]]* is recommended.
- Audit *[URL to audit tool to be added at publication]* and review clinical outcomes of all patients having radiofrequency ablation for symptomatic Morton's neuroma (see section 7.2).

1.3 NICE encourages further research into radiofrequency ablation for symptomatic Morton's neuroma. Further research should include details of patient selection and previous treatments. Studies should compare the procedure against other non-surgical treatments, such as steroid injections. Outcome measures should include pain relief, the duration of treatment effect, and the need for subsequent treatments.

2 Indications and current treatments

2.1 Symptomatic interdigital (Morton's) neuroma is caused by perineural fibrosis which creates scar tissue, resulting in compression of an interdigital nerve. It usually occurs between the metatarsal heads of the third and fourth toes but can sometimes occur between the second and third toes. Symptoms include severe intermittent pain, a burning sensation, and paraesthesia in the front part of the sole of the foot, extending into the toes.

2.2 Initial management of symptomatic Morton's neuroma includes rest, anti-inflammatory medications, using an orthosis in the shoe

and wearing a different type of shoe. Injection of steroids and local anaesthetic may be used. Persistent symptoms may be treated by cryoablation or surgical removal of the nerve (neurectomy).

3 The procedure

3.1 Radiofrequency ablation (RFA) for symptomatic interdigital (Morton's) neuroma is a percutaneous treatment, which is usually done as an outpatient procedure. A local anaesthetic block of the posterior tibial nerve is done by injecting it posterior to the medial malleolus under ultrasound guidance. Further local anaesthetic is injected around the neuroma. Using imaging guidance (X-ray fluoroscopy, ultrasound or MRI), an RFA probe attached to a generator is inserted into the web space between the toes and into the centre of the nerve. Controlled pulses of radiofrequency energy are delivered, which cause thermal ablation of the nerve. After the procedure, a steroid injection is usually given to reduce pain and inflammation. Patients are discharged as soon as comfortable and advised to limit their walking for 1 or 2 days. Any pain is managed with analgesics. The procedure can be repeated if necessary after a few weeks.

4 Efficacy

This section describes efficacy 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 interventional procedure overview ***[add URL]***.

4.1 A case series of 25 patients (30 feet) with symptomatic interdigital (Morton's) neuroma reported a statistically significant reduction in pain scores on activity after ultrasound guided radiofrequency

ablation (RFA) treatment. Pain scores were measured on a visual analogue scale (assessed on a scale of 0–10, with lower scores indicating less pain) and were an average of 6.0 at baseline compared with 1.7 at 6-month follow-up ($p<0.001$). A case series of 37 patients (38 neuromas) for whom conservative management failed and who had RFA, reported median numerical pain scores (assessed on a scale of 0–10, with lower scores indicating less pain). Pain scores decreased significantly from 9.0 at baseline to 5.0 at an average follow-up of 10.6 months.

4.2 The case series of 25 patients reported that the average overall symptom improvement (as described by patients, not otherwise defined) was 76%. The case series of 37 patients (38 neuromas) reported that 74% of neuromas had complete or partial resolution of symptoms and 26% had no benefit at an average follow-up of 10.6 months. All patients with neuromas in the third web space (n=18) reported complete or partial relief of symptoms compared with only 50% of those with second web space neuromas (n=20).

4.3 The case series of 37 patients reported that 87% (32/37) of patients were satisfied with RFA treatment at an average follow-up of 10.6 months. Most patients (84%) said that they would have the procedure again.

4.4 The case series of 37 patients reported that 2 patients with no relief had repeat RFA treatment but were not satisfied with the outcome at an average follow-up of 10.6 months.

4.5 A case series of 29 patients (32 feet) reported symptom recurrence in 1 patient at 9 months follow-up. This was successfully treated with an injection of steroid and local anaesthetic.

4.6 Progression to surgical removal of the neuromas was reported in 29% (11/38) of neuromas (3 with partial relief and 8 with no relief) in the case series of 37 patients (38 neuromas) at an average follow-up of 10.6 months. Of the patients who had surgical removal, 6 patients had complete relief of symptoms, 3 had partial relief, 1 had no change in symptoms and 1 got worse. The average numerical pain score decreased from 6.9 to 2.7.

4.7 The specialist advisers listed key efficacy outcomes as relief or reduction of pain and avoiding the need for surgery.

5 Safety

This section describes 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 interventional procedure overview ***[add URL]***.

5.1 Superficial cellulitis 5 days after radiofrequency ablation treatment was reported in 1 patient in a case series of 29 patients. This was treated with a course of antibiotics.

5.2 Burns at the site of the inactive (grounding) electrode (explained by the authors as a result of the electrode being placed too superficially) were reported in 2 patients in a case series of 71 patients. These patients were each off work for a week.

5.3 Irritation of the posterior tibial nerve for 3 weeks after the procedure was reported in 1 patient in a case series of 25 patients. This resolved completely.

5.4 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which

they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: bruising, bone infarction, infection and hypertrophic scarring around the nerve. They considered that the following were theoretical adverse events: thermal necrosis of the skin, fat necrosis, injury to ligaments or adjacent structures, haematoma or abscess formation, numbness, recurrence of pain after initial improvement, inadvertent nerve damage with pain and disability, deep vein thrombosis, pulmonary embolism, stump neuroma formation and osteonecrosis of metatarsal head.

6 Further information

6.1 For related NICE guidance, see the NICE website.

6.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

Bruce Campbell
Chairman, Interventional Procedures Advisory Committee
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