



Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 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 is recommended.
 - <u>Audit</u> and review clinical outcomes of all patients having radiofrequency ablation for symptomatic Morton's neuroma (see section 6.1).
- 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

- 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.
- 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

Radiofrequency ablation (RFA) for symptomatic interdigital (Morton's) neuroma is a percutaneous treatment, which is usually done as an outpatient procedure under local anaesthesia. Using imaging guidance, an RFA probe attached to a generator is inserted into the web space between the toes and into the area of the neuroma. 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.

- 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 (p value not reported).
- 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 for 74% of neuromas there was complete or partial resolution of symptoms and for 26% there was 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).
- 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 symptom relief had repeat RFA treatment but were not satisfied with the outcome at an average follow-up of 10.6 months.
- A case series of 29 patients (with 32 neuromas treated) reported symptom recurrence in 1 patient at 9-month 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 for 29% (11/38) of neuromas (3 neuromas in patients with partial symptom relief and 8 neuromas in patients with no symptom 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 (p value not reported).

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 <u>interventional procedure overview</u>.

- 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.
- 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.
- Moderate haematoma was reported in 1 patient in a case series of 20 patients. This was treated with antibiotics, non-steroidal anti-inflammatory drugs and elevation of the foot.
- 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 an early case series of 71 patients published in 1989. These patients were each off work for a week.
- 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, 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

This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an <u>audit tool</u> (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers (<u>information for the public</u>). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.