

Transcutaneous microwave ablation for severe primary axillary hyperhidrosis

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg601

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.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of transcutaneous microwave ablation for severe primary axillary hyperhidrosis is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do transcutaneous microwave ablation for severe primary axillary hyperhidrosis should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In particular, during the consent process patients should be informed about the possibility of nerve damage. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having transcutaneous microwave ablation for severe primary axillary hyperhidrosis (see section 7.3).
- 1.3 NICE encourages further research into transcutaneous microwave ablation for severe primary axillary hyperhidrosis and may update the guidance on publication of further evidence. Further research should include information on patient selection, objective measures of physiological effect, patient-reported outcome measures and long-term outcomes.

2 Indications and current treatments

- 2.1 Primary axillary hyperhidrosis typically begins during childhood or adolescence, but can happen at any age. It is usually life-long, although in a few people symptoms can spontaneously improve over time. Severe primary axillary hyperhidrosis can be defined as a score of 3 or 4 on the Hyperhidrosis Disease Severity Scale. Excessive sweating can have a profound effect on quality of life, interfering with daily activities and causing anxiety and embarrassment.
- 2.2 First-line management of primary axillary hyperhidrosis includes lifestyle measures such as avoiding known triggers and tight clothing, and using antiperspirants (including aluminium chloride hexahydrate). Other treatments include iontophoresis, botulinum-toxin A injection, and oral medications such as anticholinergics, antimuscarinics, beta-blockers, antihypertensives and anxiolytics. If these do not work, surgical options include local sweat-gland excision by subcutaneous curettage, tumescent liposuction, or thoracic sympathectomy.

3 The procedure

- 3.1 Transcutaneous microwave ablation for primary severe axillary hyperhidrosis is done under local anaesthesia using a machine with a hand-piece that emits microwaves. After numbing the underarm with several injections of local anaesthesia, the hand-piece is placed on the area where the sweat glands are and microwaves are applied, with the intention of ablating the sweat glands. The machine has a cooling system that prevents damage to the superficial skin layers and a vacuum system that lifts the underlying skin to help isolate the target tissue from underlying structures. The procedure takes about 1 hour; patients typically have a second treatment session about 3 months later to get the greatest benefit. Patients may need to take oral analgesics and apply ice packs to reduce swelling of the treated area for a few days after the procedure.

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](#).

- 4.1 In a randomised controlled trial (RCT) of 120 patients who had active or sham microwave ablation for severe primary axillary hyperhidrosis, the proportion of patients with an Hyperhidrosis Disease Severity Scale (HDSS) score of 1 or 2 (unnoticeable or tolerable sweating) was 89% (72/81) and 54% (21/39) respectively at 30-day follow-up ($p<0.001$). At 6-month follow-up, 67% and 44% had an HDSS score of 1 or 2 ($p=0.02$) respectively. In the active treatment group, 69% of patients had an HDSS score of 1 or 2 at the 9-month and 12-month follow-up. The proportion of patients with an HDSS score reduced by 2 or more at 6-month follow-up was 47% in the active treatment group and 13% in the sham group ($p<0.001$). The proportion of patients, who had active treatment, with an HDSS score reduced by 2 or more at the 9- and 12-month follow-up was 42% and 38% respectively. In a case series of 20 patients, the mean reduction in HDSS score at a mean follow-up of 5 months was 2 (95% [confidence interval] CI 1.85 to 2.15, $p<0.0001$), and 95% (19/20) had an HDSS score of 2 or lower. In a case series of 31 patients, 90% (28/31) of patients had HDSS scores of 1 or 2 at 12-month follow-up; 94% (29/31) of patients had at least a 1-point drop and 55% (17/31) had a drop of 2 or more points in HDSS.
- 4.2 In the RCT of 120 patients who had active or sham microwave ablation, the proportion of patients with a 50% or more reduction in weighed sweat compared with baseline was 80% and 67% respectively at 30-day follow-up ($p=0.07$), and 63% and 59% ($p=0.69$) respectively at 6-month follow-up. The proportion of patients with a 75% or more reduction was 62% in the active group and 39% in the sham group ($p=0.01$) at 30-day follow-up, and 41% and 36% ($p=0.60$) respectively at 6-month follow-up. In the case series of 31 patients, 90% (28/31) of patients had at least a 50% reduction in axillary sweat from baseline at 30-day follow-up.
- 4.3 In the case series of 31 patients, 85% (23/31) had an improvement of at least 5 points on the Dermatologic Life Quality Index (score ranges from

0 to 30 with higher scores indicating poorer quality of life) at 12-month follow-up.

- 4.4 In the case series of 31 patients, 90% (27/30), 96% (27/28), 93% (25/27) and 89% (23/26) of patients were very or somewhat satisfied after 30 days, 3 months, 6 months and 12 months respectively. In the case series of 20 patients, all patients stated that they would have the treatment again.
- 4.5 The specialist adviser listed the key efficacy outcomes as dryness (measured by the HDSS), and improved quality of life (number of episodes of bothersome sweating per week).

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](#).

- 5.1 Transient neuropathy of the left arm with associated muscle weakness after the procedure was reported in 1 patient in a case series of 31 patients. The neuropathy had improved by 6 months, after which the patient was lost to follow-up. Transient median and ulnar neuropathy was described in 1 patient in a case report. After 6 months of rehabilitation, the patient's motor power and sensory deficit had improved but the thenar muscles remained atrophic. Brachial plexus injury was described in 1 patient in a case report. The patient had sensory and motor dysfunction in her fingers, which had not fully recovered after 6 months of rehabilitation.
- 5.2 Altered sensation in the skin of the upper arm (change in sensitivity, tingling or numbness) was reported in 10% (8/81) of patients who had active microwave ablation (mean duration 67 days) and 3% (1/39) of patients who had a sham treatment (duration 79 days) in a RCT of 120 patients. Temporary numbness was reported in 20% of patients in a case series of 20 patients. Altered sensation in the skin of the axillae was reported in 65% of patients in the case series of 31 patients (median duration 37 days, range 4 days to 4 months). Altered sensation in the

skin of the treated limb was reported in 39% (12/31) of patients in the same study (median duration 50 days, range 6 days to 12 months). Loss of sensation in the lateral area of both forearms was reported in 1 patient in a case series of 11 patients. This gradually improved, and the patient recovered fully within 3 months.

- 5.3 Blisters, burns or ulcerations were reported in 5% (4/81) of patients in the active treatment group (mean duration 28 days, range 12 to 40) and no patients in the sham treatment group in the RCT of 120 patients.
- 5.4 Axillary bumps or nodules were reported in 3% (2/81) of patients in the active treatment group (mean duration 30 days, range 8 to 52) and 3% (1/39) of patients in the sham treatment group (2 episodes; duration 10 to 12 days). Nodule formation, lasting up to 4 weeks, was reported in 25% of patients in the case series of 20 patients. Palpable bumps under the skin of the axillae was reported in 71% of patients in the case series of 31 patients (median duration 41 days; still present in 2 patients at study exit).
- 5.5 Compensatory sweating was reported in 3% (2/81) of patients in the active treatment group and no patients in the sham treatment group in the RCT of 120 patients.
- 5.6 There are several reports on the US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) website, describing events after microwave ablation for axillary hyperhidrosis. These include nerve damage, infections, abscesses, ulcers, burns, cellulitis, blisters and skin or tissue necrosis. It is not possible to calculate the incidence of these events because the total number of procedures is unknown.
- 5.7 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 happen, even if they have never done so). For this procedure, a specialist adviser described the following anecdotal adverse event: infection. They considered that scarring was a theoretical adverse event.

6 Committee comments

- 6.1 The committee was informed that the technique has changed to using a larger volume of dilute local anaesthesia, with the aim of reducing the likelihood of local nerve damage.

7 Further information

- 7.1 Patient commentary was sought but none was received.
- 7.2 For related NICE guidance, see the [NICE website](#).
- 7.3 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed [NICE's interventional procedure outcomes audit tool](#) (which is for use at local discretion).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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 [Healthcare Improvement Scotland](#).