NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Transcutaneous microwave ablation for severe primary axillary hyperhidrosis

Axillary hyperhidrosis is excessive underarm sweating. In this procedure, a hand-held device sends microwaves to the sweat glands in the armpit to damage them. The aim is to destroy the glands and stop the sweating.

The National Institute for Health and Care Excellence (NICE) is examining transcutaneous microwave ablation for severe primary axillary hyperhidrosis 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 draft recommendations about transcutaneous microwave ablation for severe primary axillary hyperhidrosis.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft 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 draft 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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 20 July 2017

Target date for publication of guidance: November 2017

1 Draft 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.

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 7.1).

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- 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.

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 For related NICE guidance, see the NICE website.

7.2 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.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee
June 2017