AXILLARY HYPERHIDROSIS AND BOTOX®

Responding to demands: Starting a nurse-led service

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The sympathetic nervous system regulates sweating or perspiration. The process of sweating is an essential mechanism to permit the control of the body temperature during times of exercise and in warm/hot surroundings.

In approximately 1% of the UK population, over-activity of this system results in excessive and inappropriate sweating from the eccrine sweat glands of which 2-3 million are present all over the body (Hunter 2002). A greater concentration of these are present on the palms of the hands, soles of the feet and in the axillary skin (armpits). The production of an excessive amount of sweat is referred to as hyperhidrosis.

Hyperhidrosis is usually classified as follows:

- *Focal: affecting localised areas such as axillae (axillary hyperhidrosis) palms of the hands (palmar hyperhidrosis) soles of the feet (plantar hyperhidrosis) or other parts of the body*
- *Generalised: where sweating affects the entire body.*

Furthermore, hyperhidrosis may be subdivided into idiopathic (i.e. of unknown cause) and secondary (as a result of an underlying illness or medication). This condition, which can be chronic, with onset often during teenage years, has a profound impact on psychological, social and professional wellbeing and leads to deterioration of the patient's general quality of life (Naumann *et al* 2002).

Causes

Although the cause of onset of hyperhidrosis is still largely unknown, it is believed to be a result of a malfunction in the sympathetic nervous system - more specifically the thoracic sympathetic ganglion chain, which can be found running along the vertebra of the spine within the chest cavity and controlling the eccrine and apocrine sweat glands (Halford 2004). Focal or localised hyperhidrosis, manifests usually as a primary condition and is defined as excessive sweating for which no specific cause may be determined (idiopathic). It can occur rarely secondary to other conditions, can be chronic and mainly affects the axillae, palms, soles of the feet or face (Lowe *et al* 2003).

Generalised hyperhidrosis, however, is more likely to occur secondary to other medical conditions such as anxiety disorders, diabetes mellitus, hyperthyroidism, obesity, acute infections, menopause or drug withdrawal. Here the entire body is usually affected. Around 50% of hyperhidrosis sufferers have a relative with a similar problem, which could indicate a genetic predisposition. Normal sweating can be triggered by many factors, this is also the case for hyperhidrosis except the amount of sweating differs.

Triggers include:

- *exercise*
- *heat/cold*
- *alcohol, coffee or tea, smoking, hot or spicy food*
- *stress, anxiety, strong emotions.*

Symptoms

The symptoms of hyperhidrosis are extremely embarrassing and on a professional and social level often crippling for patients (Hunter *et al* 2002). Dripping hands, feet, face and armpits cause all sorts of problems and barriers in every day life, including:

- *frequent changes of clothing*
- *difficulty handling objects*
- *skin maceration*
- *skin infections*
- *social/professional interaction e.g. shaking hands.*

(Lowe *et al* 2003)
These all have an effect on patients' confidence and can be extremely disabling.

Treatments

Cliff (2003) observed that therapeutic options include antiperspirants, anticholinergics, iontophoresis, surgical intervention (sympathectomy) and more recently the injection of botulinum toxin type A (BOTOX®) into the sweat-producing areas.

Summary of treatment options:

Topical treatments:

- talcum powder
- deodorants / antiperspirants, requiring frequent and generous application
- aluminium salts (al) such as Driclor and Anhydrol, they require application to dry skin at night and should be washed off the following morning using emollient washes and moisturisers rather then a soap based cleaner. Patients are advised not to shave the skin 24 hrs before / after treatment application. Initially application is every night but this can be reduced once control has been achieved. Often treatment is discontinued due to severe skin irritation in up to 70% of users (personal observation). Life style advise should be given on avoidance of wearing tight clothing and manmade fibres such as nylon and lycra, choosing black or white colours to wear and have a change of clothing available. Identify triggers that will cause sweating and try to avoid these or modify behavior (Lowe *et al* 2003).

Iontophoresis is the passage of a low voltage, direct electrical current over the skin. It is achieved with the use of a machine running on re-chargable batteries. Affected body areas are placed in shallow baths filled with tap water, anticholinergic drugs such as Glycopyromium Bromide are sometimes added, that are connected to the machine. The patient can control the intensity of power until a tingling sensation is noted and maintained for usually 2 x 10 minutes. Iontophoresis is effective in palmar and plantar hyperhidrosis, with a usual improvement of symptoms after 4-5 sessions. Cessation of sweating can last from 2 weeks to 3 months and many patients purchase their own machine to continue maintenance treatments at home at their convenience (approx price £280). Contra-indications for iontophoresis include: pregnancy, cardiac pacemakers, and metal implants. Axillary hyperhidrosis, however, does not respond well to iontophoresis, usually due to side effects experienced by patients (Elgart 1987, Bale 2004) and also due to the complication of using the machinery under the armpits.

Anticholinergic medications are oral, prescribed drugs that block the neurotransmitter, which stimulates the production of sweat. They are associated with poorly tolerated systemic side-effects, such as dry mouth, blurred vision, restlessness and irritability, which limits their use (Naumann *et al* 2002).

Surgical Treatment. Endoscopic transthoracic sympathectomy (ETS) is the main surgical intervention. ETS involves the dividing of overactive sympathetic nerves that cause the excessive sweating and is most effective for facial and palmar hyperhidrosis. However, potential complications can occur during and after surgery, including pneumothorax, bleeding, infection and neuralgia. Clinical studies have shown that a high proportion of patients experience compensatory sweating (Furlan 2000). Surgical intervention should be used as a last resort. More recently, in 2001, the injection of botulinum toxin type A (BOTOX®) has become available and licensed in the United Kingdom (Allergan UK) as a safe and very effective treatment for axillary hyperhidrosis.

BOTOX®

BOTOX® is a purified protein type A made from tiny amounts of highly purified botulinum toxin protein, refined from the bacterium Clostridium Botulinum. BOTOX®'s efficacy in reducing sweat production is attributed to the way it successfully inhibits the release of acetylcholine, blocking as a consequence neurotransmission. Eventually neurotransmission is restored and eccrine gland activity returns.

Selection of Patients

Patients are selected for treatment by the consultant dermatologist following referrals made to the service from local general practitioners and other colleagues during clinic consultation. A full medical history is taken from patients, including a formal QOL assessment, which is the most useful indicator of the severity of disease. Criteria and questions to aid selection include the following:

- *The patient has been referred, this suggests a serious problem worthy of consideration for treatment*
- *The patient must have used topical treatments*
- *They are specifically asked if sweating affects their quality of life*
- *They are asked what difference a reduction in their sweating would make to them*
- *How often they change their clothes to accommodate their excessive sweating.*

The patient must be advised regarding the procedure and properly counselled.

Contra-indications to BOTOX® therapy include pregnancy, a known allergy to ingredients and disorders of the neuromuscular junction (myasthenia gravis, myopathies and Eaton-Lambert syndrome). Patients are advised not to shave or use deodorants 24 hours prior to treatment to avoid irritation to the axillary skin. They are also advised to wear dark, old clothing when they come for the treatment. Expectations are discussed, how soon to expect a result and the fact that there will be some residual sweating. Treatment is not permanent and re-treatments will be needed. Informed consent will be sought, verbally and in writing prior to the procedure.

Treatment procedure

The area of hyperhidrosis is carefully demarcated using the Minor's starch iodine test (if the patient has no

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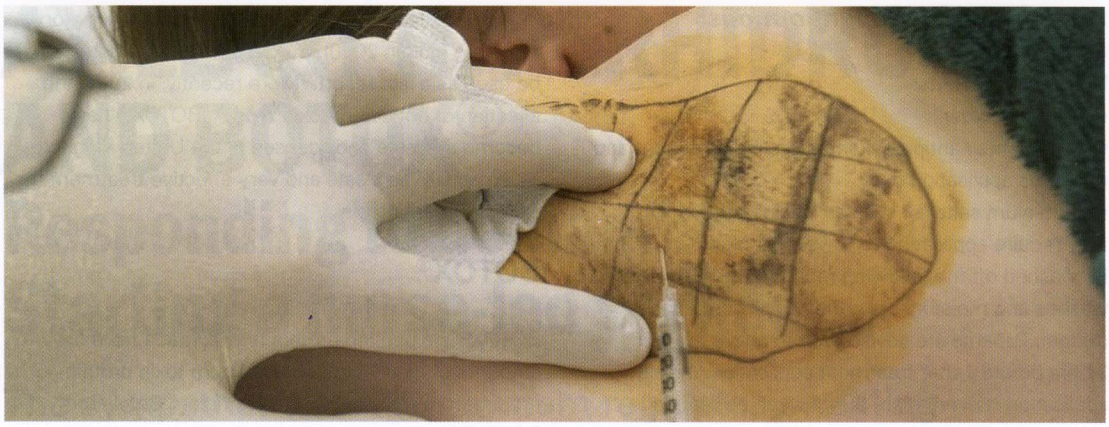
For further information see the Allergan website: www.knowsweat.info



known allergy to iodine). This will help to highlight and identify the injection sites. The treatment area is then marked with indelible ink into squares of approximately 1 – 1.5 cm.

The BOTOX® is at this point reconstituted, using 4 ml of non-preserved saline (100U per vial). Caution should be taken when reconstituting as the protein is fragile and aggressive reconstitution may denature the product and render it ineffective.

The alcohol applied to the cap for cleansing should be allowed to evaporate thoroughly, because it may potentially inactivate the product if accidentally introduced into the vial. The reconstituted BOTOX® is drawn up in 0.5 ml aliquots in insulin syringes (30G needle).

When injecting, the skin is gently stretched and each square starting in the center of the grid, is injected with 0.1 ml (2.5 U) at a 20 degrees angle to the skin, intradermally raising a "bleb". Care should be taken when withdrawing to avoid accidental spillage of the toxin. Both axillae are treated in one sitting. The patient can resume normal activity immediately post treatment. A response is usually noted within 72 hours reaching its peak within 2 weeks. The response is sustained for 4 – 18 months. Treatment is well tolerated in the axilla, with a virtual 100% response rate. Pain is not a major problem for patients; however, for some patients pre-treatment with ice packs to numb the area has been effective. Quality of life improvements after BOTOX® treatment have been considerable for patients.

Innovative roles

Treatment of patients will be quicker once proficiency has been achieved but will take usually 15-30 minutes. The effect of treatment wears off after 4-7 months. Further treatment may then be requested by patients. Depending on the number of patients referred for BOTOX® treatment, this can cause a significant amount of pressure on the already oversubscribed and overstretched Dermatology Outpatients service, increasing the waiting times for routine appointments. The NHS Plan (2000) and "Making a Difference" (DOH 1999) document, advocate the need to introduce new increasing roles for Specialist Nurses both in primary and secondary care to help improve services and delivery of high quality patient treatment and care. In 2002 the Nursing and Midwifery Council (NMC 2002) published new regulations supporting extended practice. In view of this and the current pressures experienced with waiting times for first appointments in the Dermatology Consultants' clinics, it was proposed that patients requiring BOTOX® treatment would, in the first instance, been seen by the Consultant Dermatologist. If selected for treatment, the patient would be referred to the Clinical Nurse Specialist (CNS) Dermatology for treatment, counselling, re-assessment and follow up care. The CNS attended a BOTOX® training course and underwent a period of supervised practice with the consultant dermatologist, who is very supportive of the development of the nurses role, until competency was gained. Protocol and Patient Group Direction for the service have recently been completed. The consultant dermatologist will remain available for advice during clinic sessions and patients will retain the right to request treatment by a doctor. It is hoped that the nurse-led service will contribute positively to waiting times for patients.

Conclusion

Hyperhidrosis – the excessive sweating producing a negative impact on an individual's quality of life – causes a lot of patients significant amounts of suffering. This article has attempted to summarise the available treatment options and to highlight the pros and cons of each treatment. The relatively recent licensing of BOTOX® for the treatment of axillary hyperhidrosis has produced a relatively simple yet effective treatment for this disabling condition. With the continued demands being placed upon NHS resources we have described our practice locally of training a CNS to deliver this treatment for patients with the full support and training provided by the consultant dermatologist. This novel service has proved popular with patients ensuring continuity of care and a point of contact for patients requiring further therapy.