CLINICAL SUMMARY

Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomised controlled trial.

Naumann MK, Hamm H and Lowe NJ, Br J Dermatol, 2002, **147:** 1-9.

Objective

To assess the impact on quality of life (QOL) of botulinum toxin type A [BOTOX®] treatment in patients with bilateral primary axillary hyperhidrosis.

Method

Multicentre, randomised, double-blind, placebo-controlled trial involving 320 patients with persistent, bilateral, primary axillary hyperhidrosis sufficient to interfere with daily activities. QOL was assessed using the Hyperhidrosis Impact Questionnaire© (HHIQ) at baseline and 1, 4, 8, 12 and 16 weeks post-treatment. Patients also completed the Medical Outcomes Trust Short Form – 12 Health Survey© (SF-12) at baseline and 16 weeks post-treatment.

Outcome Measures

The HHIQ is a valid and reliable hyperhidrosis-specific questionnaire comprising one 41-item module for baseline disease impact assessment and one 10-item module for follow-up longitudinal assessment/comparison. The SF-12 is a validated, general health-related QOL questionnaire comprising 12 items designed to assess patients' views about their general health. There were 307 evaluable patients: 234 Botox® and 73 placebo.

Results

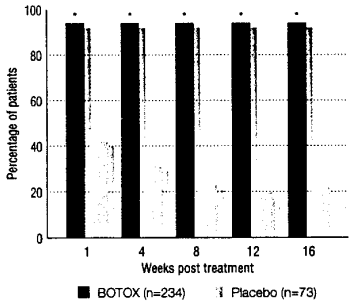
- **Satisfaction levels with BOTOX® treatment were 89% after 1 week and remained above 93% throughout the study**
- **Productivity and performance at work significantly improved**
- **Four weeks after treatment, less than 10% of patients had to change clothing more than once per day**
- **Emotional status improved, inhibition in public places and when meeting people was significantly reduced**

Conclusion

"In particular, treatment of axillary hyperhidrosis with BTX-A [BOTOX®] led to a marked improvement in emotional status, ability to participate in many aspects of daily life and social activities, and in satisfaction with productivity at work."†

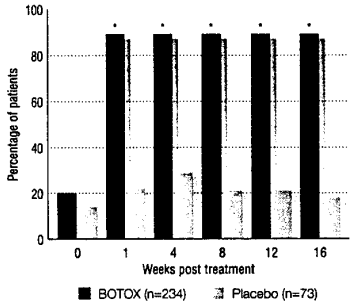
†It should be noted that the results reported in this study are based on the BOTOX® formulation of botulinum toxin type A and cannot be generalised to other formulations or serotypes.

Satisfaction compared with previous treatment



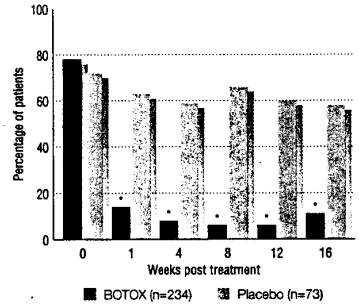
Percentage of patients much more, or somewhat more satisfied with BOTOX® than their previous treatment **p<0.001 vs placebo*

Satisfaction with ability to perform activites



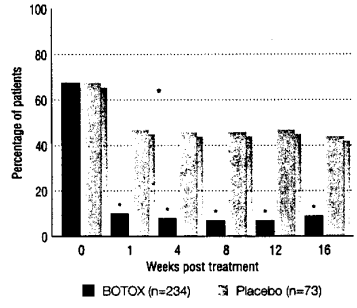
Percentage of patients very satisfied or somewhat satisfied in their ability to perform current work activites **p<0.001 vs placebo*

Reduced need to change clothing



Percentage of patients with a need to change clothing more than once daily **p<0.001 vs placebo*

Reduced feelings of personal limitation in public



Percentage of patients feeling at least moderately limited in public places **p<0.001 vs placebo*

Abbreviated Prescribing Information BOTOX® ▼

Please refer to the Summary of Product Characteristics before prescribing. **Presentation:** Contains 100 units (U) of Clostridium botulinum type A neurotoxin complex (900kD). **Uses:** BOTOX® is indicated for the symptomatic relief of blepharospasm, hemifacial spasm, idiopathic cervical dystonia (spasmodic torticollis) and severe axillary hyperhidrosis. The safety and efficacy of BOTOX® in children with these conditions has not been demonstrated. BOTOX® is also indicated for the treatment, in hospital specialist centres with appropriately trained personnel, of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older. **Dosage and administration:** BOTOX® is reconstituted prior to use with sterile unpreserved normal saline (0.9% sodium chloride for injection). **Doses recommended for BOTOX® are not interchangeable with other preparations of botulinum toxin.** ***Hyperhidrosis of the axillae:*** The recommended injection volume for intradermal injection in axillary hyperhidrosis is 0.1 - 0.2 mL. Reconstituted BOTOX® (100 U/4.0 mL) is injected using a 30 gauge needle. 50 U of BOTOX® is injected intradermally to each axilla, evenly distributed in multiple sites approximately 1-2 cm apart. The hyperhidrotic area to be injected may be defined by using standard staining techniques, e.g. Minor's iodine-starch test. **Contra-indications:** BOTOX® is contra-indicated, a) in individuals with a known hypersensitivity to any constituent of the formulation; b) when there are generalised disorders of muscle activity (e.g. myasthenia gravis); c) when aminoglycoside antibiotics or spectinomycin are already being used or are likely to be used; d) when there are bleeding disorders of any type, in case of anticoagulant therapy and whenever there is any reason to avoid intramuscular injections and e) during pregnancy or lactation. **Warnings and special precautions:** The relevant anatomy, and any alterations to the anatomy due to prior surgical procedures, must be understood prior to administering BOTOX®. Extra caution should be paid in the case of injection sites close to structures such as the carotid artery and pleural apices. The recommended dosages and frequencies of administration of BOTOX® should not be exceeded. **Reconstituted BOTOX® is for intramuscular injection and in the treatment of hyperhidrosis for intradermal injections ONLY.** Adrenaline and other anaphylactic measures should be available. ***Hyperhidrosis of the axillae:*** Causes of secondary hyperhidrosis (e.g. hyperthyroidism, pheochromacytoma) should be considered to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of underlying disease. **Side effects:** Side effects may occur from misplaced injections of BOTOX® temporarily paralysing nearby muscle groups. Excessive doses may cause paralysis in muscles distant to the injection site. In axillary hyperhidrosis perceived increase in non axillary sweating was reported in 4.5% of patients. Weakness of arm has been reported uncommonly (0.7%) **Interactions:** The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or any other drugs that interfere with neuromuscular transmission e.g. tubocurarine-type muscle relaxants. Polymyxins, tetracyclines, lincomycin and muscle relaxants should be used with caution. Concomitant use of BOTOX® with aminoglycosides or spectinomycin is contra-indicated. **Pharmaceutical precautions:** Unopened vials should be stored in a freezer at or below -5°C. After reconstitution BOTOX® may be stored in a refrigerator (2-8°C) for up to 4 hours prior to use. **Cost:** £128.93 per vial (excl VAT) **POM** PL0426/0074. **Date of preparation:** November 2002. Allergan, Coronation Road, High Wycombe, Bucks HP12 3SH UK. Further information available on request.

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