CLINICAL SUMMARY

Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: a randomised, parallel group, double blind, placebo-controlled trial.

Naumann M and Lowe NJ, *BMJ* 2001; **323**: 596-599.

Objective

To evaluate efficacy and tolerability of botulinum toxin type A [BOTOX®] in the treatment of bilateral primary axillary hyperhidrosis.

Method

Multicentre, randomised, parallel group, double blind, placebo-controlled trial in patients aged 18-75 with bilateral primary axillary hyperhidrosis sufficient to interfere with daily living. 465 screened, 320 randomised in a ratio of 3 active: 1 placebo; 307 completers – 234/242 active, 73/78 placebo.

Main outcome measures: percentage of responders at week 4 (defined as ≥ 50% reduction from baseline of spontaneous axillary sweat production, measured gravimetrically); patients' global assessment of treatment satisfaction.

Results

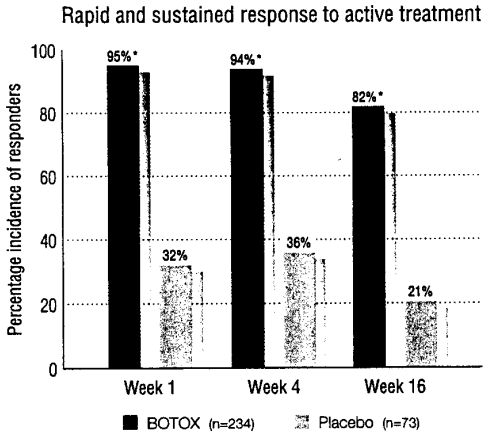
- **Highly significant reduction in sweating in the majority of patients**
- **95% of patients respond to treatment in just one week**
- **82% of patients are still responders after 16 weeks**
- **83% reduction in absolute sweat production after just one week, 84% after four weeks and 69% after 16 weeks**

Conclusion

BOTOX® is a well-tolerated and effective treatment for primary axillary hyperhidrosis with high levels of patient satisfaction. Intradermal injections of 50 U per axilla effectively reduced sweat production and provided high levels of treatment satisfaction.†

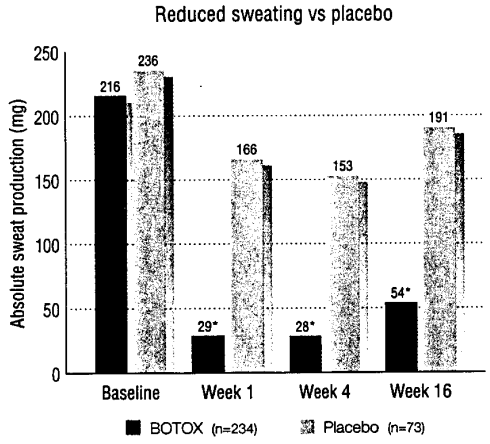
†It should be noted that the results reported in this study are based on the BOTOX® formulation of botulinum toxin type A and cannot be generalised to other formulations or other serotypes.

Throughout the trial a significantly higher proportion of patients responded to BOTOX®



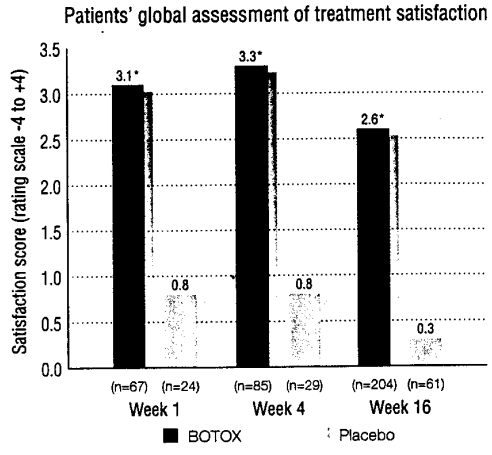
** p<0.001 vs placebo* *Response defined as ≥ 50% reduction in axillary sweating from baseline*

BOTOX® effectively reduced sweating compared with placebo



** p<0.001 vs placebo*

BOTOX® treated patients were significantly more satisfied



** p<0.001 vs placebo*

Adverse events were similar between the groups in type and incidence. The majority were mild or moderate in severity

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.

ALLERGAN