Experience with botulinum toxin therapy for axillary hyperhidrosis and comparison to modelled data for endoscopic thoracic sympathectomy — A quality of life and cost effectiveness analysis

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ABSTRACT

Aim: To estimate cost-effectiveness of botulinum toxin therapy for axillary hyperhidrosis compared to the standard surgical intervention of endoscopic thoracic sympathectomy (ETS).

Methods: The validated dermatology life quality index questionnaire was given to patients attending for treatment over a 4 month period, to assess their quality of life (QoL) over the preceding week ($n = 44$). Follow-up was performed 4—6 weeks later by telephone using the same questionnaire to validate the effectiveness of the treatment. The duration of effect of the botulinum toxin treatment was also recorded and this data was used as the basis for cost effectiveness analysis. Using HIPE data, the baseline cost for single intervention using botulinum toxin and ETS was retrieved. Using figures provided by HIPE and expert opinion of the costs of complications, a stochastic model for 10,000 patients was used to evaluate the total costs for ETS including the complications.

Results: The results from the QoL analysis show that botulinum toxin therapy is a successful therapy for improvement of symptoms. It was revealed that the mean interval before recurrence of original symptoms after botulinum toxin therapy was 5.6 months. The baseline cost for both treatments are €389 for botulinum toxin and €9389 for uncomplicated ETS. The stochastic model yields a mean cost of €11,390 for ETS including complications.

Conclusions: Treatments reached cost equivalence after 13.3 years. However, given the efficacy of the botulinum toxin therapy and the low risk we propose that botulinum toxin therapy for hyperhidrosis should be considered the gold standard.

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Introduction

Primary hyperhidrosis is an idiopathic chronic autonomic disorder with a prevalence of 0.6—2.8%.[1–3] For these patients, it is a socially debilitating condition that has a severe impact on QoL [4]. Hyperhidrosis may be generalised or localised and there are variants that may affect the axilla, palms, trunk and face, with the former 3 being the most common [1]. Established treatments available for axillary hyperhidrosis range from topical aluminium chloride preparations, through anticholinergic drugs, to surgical interventions such as endoscopic thoracic sympathectomy (ETS), which carries significant risks for a non-life-threatening disorder [1,5]. ETS has been used in the treatment of hyperhidrosis since the mid 1980's and several studies have shown it to be an effective treatment.[6,7] However, serious complications of this treatment occur infrequently and recurrence in the medium to long term is more common than previously believed.[6–11] The main complication of ETS is compensatory sweating reported as up to 70%, whereas, it is reported as only 5% for botulinum toxin therapy.[8,11–13] ETS is not routinely performed in this centre however using reviews of some of the larger retrospective studies into the long term efficacy of ETS the authors have appropriated risks for reported complications of ETS for axillary hyperhidrosis and applied a model to compare cost effectiveness of the two treatments [2, 6, 8–10]. Death is a possible complication associated with ETS. However, it is rare and there are no reliable research data to indicate how likely this is to occur. It is also difficult to assign a "cost" to this and, given these restrictions, it was not included in the model.[8]

Botulinum toxin was first reported for the treatment of hyperhidrosis in 1996 and was licenced for this use in 2001 [14]. There is a gradual waning of effect of the botulinum toxin therapy due to growth of new synapses at the end-plate and patients report variable durations of time before reversion to pre-treatment symptoms [1,14]. Many studies have looked into the duration of effects of botulinum toxin treatment and found it to have a mean duration of effect of anywhere from 4 to 12 months.[5,13,15,16].

Given the lack of available comparisons of the two main treatments for axillary hyperhidrosis, the current study was designed to compare the cost effectiveness of botulinum toxin in our clinical setting with ETS performed as a day case with a stochastic model to account for likelihood of associated complications occurring. This article will outline how the current authors derived long-term costs for botulinum toxin using patient questionnaire and ETS using literature review, HIPE figures and an expert panel to estimate costs of reported complications for ETS.

Methods

A pilot study to determine the duration of effect of botulinum toxin for the treatment of isolated axillary hyperhidrosis was conducted on a consecutive sample of 44 patients between February and May 2014, which is sampled from an overall population of 163 patients attending the clinic. These patients were recruited on the day of their appointment. All patients are return patients and there were no new patients. Patients were asked to complete the validated disease specific dermatology life quality index (DLQI) questionnaire [17]. The questionnaire consists of 10 questions based on their hyperhidrosis symptoms for the past week with a maximum score of 30 indicating poor QoL with respect to their hyperhidrosis [17]. In addition, the duration of recurrence of symptoms was recorded. A follow-up questionnaire was conducted 4—6 weeks following treatment. This allowed for validation of the treatment as being clinically effective. Comparison of the results between groups was perfomed using Student's t-test.

Patients are given tetracaine gel (Ametop, Smith & Nephew, Dublin, Ireland) prior to their botulinum toxin therapy and apply this to the axilla 45 min before treatment. Treatment with botulinum toxin (Allergan Parmaceuticals Ireland, Co. Mayo, Ireland) is as described previously [4].

Costs for the botulinum toxin therapy and ETS were taken from the Hospital Inpatient Enquiry (HIPE) data base. The HIPE system gives an estimation of the case-mix adjustment based on ICD-10 classification, for acute hospital budgets [18]. Other studies have used the HIPE system for patient care studies, epidemiological studies, monitoring practice, planning, service provision, and quality assurance studies [18]. Using this system all costs, direct and indirect, of a single outpatient treatment with botulinum toxin was €389. ETS performed as a day-case without complications incurs a cost of €9389.

These costs are baseline costs and do not account for any deviation from an uncomplicated procedure. In order to factor in the additional cost associated with serious complications, occurring infrequently, for ETS, a stochastic model drawing 10,000 patient treatments (see supplementary information) was compiled using Microsoft Excel (Microsoft Inc., USA). The model uses stochastic simulation to model the incident of "cost events" (CE) for a surgical procedure [19,20]. The underlying assumptions of the model are that the occurrence of all CE are independent of each other, and that they could occur during a given treatment with their associated probability. It also assumes that each CE can only happen once for a given operation. For a given operation, the model stochastically simulates a uniform random variable between 0 and 1 for each CE. If this random variable is less that the probability of the CE occurring, the model assumes that the CE occurs. This model simulates 10,000 surgeries to best estimate the mean cost of surgery incorporating complications and their costs. The complications, risk of complication, and associated cost are shown in Table 1. The risks are based on large case series' and reviews where percentage risks are given,[8,11,12] case reports of complications are not included.

Table 1 — Complications, risks, and estimated costs for endoscopic thoracic sympathectomy.

Complications	Risk	Cost
Pneumothorax	0.4—2.3%	€1375
Empyema	0.5%	€9000
Compensatory sweating	50—70%	€0
Severe sweating	2%	€9389
Gustatory sweating	1%	€0
Horner's syndrome	1%	€9389
Chronic pain	9.8%	€18,000