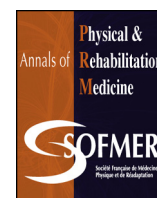




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Original article

Botulinum toxin A for treating spasticity in adults: Costly for French hospitals?



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ABSTRACT

Introduction: Intramuscular injection of botulinum toxin (BoNTA) is one of the primary treatments for focal spasticity. This treatment is considered costly and the level of reimbursement by health insurance has been decreasing in many countries for several years. The aim of this study was to determine the real cost of treating spasticity with BoNTA and to compare this with the level of reimbursement by the national health insurance in France in 2008 and with a new fee, specific to the injection of BoNTA in ambulatory services.

Method: A single-center, retrospective study using the 2008 database from a French secondary-care day-hospital unit (treating spasticity in adults with sequelae of stroke, multiple sclerosis or traumatic brain injuries). The level of reimbursement by the French ministry of health for BoNTA treatment for adults with spasticity constituted the “calculated cost” and corresponded to the hospital’s “budget”. The “real cost” (incurred by the hospital) included the sum of staffing and material costs as well as the number of toxin vials used. The calculated costs for 2009 and 2013 were based on the levels of reimbursement during those years. The difference between real and calculated cost for 2009 and 2013 was estimated considering that the real cost of 2008 was stable.

Results: In 2008, 364 patients received BoNTA, resulting in 870 day-hospital admissions. The calculated cost was 459,056 €/year and the real cost was 567,438 €/year (equivalent to 4.27 €/day/patient). The total budget deficit (hospital income minus hospital costs) was 108,383 €. The deficit was estimated at 222,892 € in 2009 and 241,188 € in 2013.

Conclusion: The daily cost of BoNTA treatment for spasticity is reasonable; however, because of the level of reimbursement by the national health insurance in France, the treatment is costly for French hospitals.

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1. Introduction

The main treatment for focal spasticity is intramuscular injection of type A botulinum toxin (BoNTA) [1]. Many studies have demonstrated patient satisfaction and functional improvement with this treatment [2–5].

Medico-economic studies of the financial impact of BoNTA treatment are generally based on the Delphi method. The results have generally shown that BoNTA treatment is cost-effective [6–12], mainly because of reduced indirect costs such as those related to fractures and hospital admissions after spasticity-related falls. However, more detailed analyses of the initial cost of the treatment are lacking. A recent prospective study in England compared the cost

of BoNTA treatment for the upper limb with that of classical rehabilitation in 150 adult patients [10] and found no difference in cost-effectiveness at 3 months. The methods used to evaluate costs were not clearly described but appeared to be global. Most studies have focused on the difference in cost and effectiveness between rehabilitation alone and rehabilitation with BoNTA injections [6–13]. One study analysed the specific costs of BoNTA treatment for spasticity, taking into account all elements related to the treatment (toxin, staffing, equipment, etc.): the cost (about 1300 €/year) was high and was greater than the cost with its use for other symptoms such as spasmodic torticollis and blepharospasm [14].

The incidence of nervous system disorders causing spasticity is relatively high. For example, in France, stroke causes 100,000 hospital admissions per year [15]. Spasticity will develop in an estimated one third of these patients [16]. Therefore, the evaluation of costs relating to the treatment of spasticity is a public health issue, and improved knowledge of the average cost of

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the treatment relative to its valuation is essential. The cost of the treatment not sufficiently covered by government health insurance could inhibit the development of its use in physical medicine and rehabilitation (PMR) departments and reduce its availability to patients.

The aim of this study was to determine the average cost of BoNTA treatment for spasticity in an adult day-hospital setting and compare the cost to the level of reimbursement by the national health insurance in France in 2008, 2009 and 2013.

2. Methods

The study was designed as a single-centre retrospective study in a secondary-care day-hospital unit specialised in treating spasticity in adults. Data for BoNTA treatment in 2008 were extracted from day-hospital reports, *le programme de médicalisation des systèmes d'information* (PMSI; a computerized classification system that classifies hospital admissions as a function of both disease and the nature and degree of the related costs) and the pharmacy register. These data were crossed and used to calculate the “calculated cost”, which was then compared with the “real cost” of treatment.

2.1. Calculation of the “calculated cost” of treatment with BoNTA

In France, BoNTA can only be administered to patients who are admitted to a hospital, health-care centre or day-hospital (hospital use only; Article R. 5121-83 of the French Public Health Code). It can be administered within a secondary- or tertiary-care setting (in France, secondary-care includes medicine, surgery and obstetrics, and tertiary-care includes long-term care and rehabilitation).

In tertiary-care, the toxin is funded from the hospital's annual budget or by the daily rate in private centres, which is submitted to the Quantified National Target on expenditures. This type of funding takes no account of the number of treatments and doses administered.

In secondary-care, the treatment is funded only by the case-mix-based hospital prospective payment system (T2A). In this system, resources are allocated after assessment of the level of activity produced. The value of each activity is fixed annually by the health minister via the homogeneous hospital-stay group/homogeneous patient group (GHS/GHM) mechanism (adapted from the US “diagnostic related groups”). The patient classification system (PMSI) is used to assign each patient's stay in a GHM to which one (or sometimes several) GHSs are associated. The group determines the level of reimbursement by the national health insurance. In acute secondary-care departments (such as that in which the present study was carried out), the patient must be admitted in order to receive BoNTA. Thus, the level of reimbursement is determined by the GHM assigned to the patient. In 2008, GHMs differed depending on the pathology (stroke, cerebral palsy, traumatic brain injury, etc.) and type of symptoms (claw hand, equinus, varus foot, etc.). We used the PMSI code for BoNTA injection (acte CCAM PCLB003) to search the database for all BoNTA injections that had been performed in specialised day-hospitals in 2008. The values for each patient's GHM were then summed. This sum constituted the “calculated cost” and corresponded to the hospital's “income” for 2008.

In 2009, a specific GHM (GHM 01K04J) was created to ensure funding for botulinum toxin in ambulatory care. This GHM was homogenous for all patients treated with botulinum toxin and was attributed a fee of 396.03 € in 2009 (version 10 of the GHM). The fee has been lowered each year since then, decreasing to 375 € in 2013 (version 11 of the GHM). The calculated cost was estimated for 2009 and 2013 by using the GHM fees for those years, based on the number of patients treated in 2008.

2.2. Calculation of the “real costs” of treatment with BoNTA

Patients were recalled every 3 months for repeat injections. The PMR physicians (all part-time) performed the evaluations and follow-up as well as the injections. They were assisted by one nurse (full-time) and one nursing assistant. The nurse and assistant managed the appointments and all the administration.

All patients had central nervous system lesions with spasticity. The injections were often multi-site, with 3 to 10 muscle groups injected. Muscles were located by using electromyographic stimulation and patients were given inhaled nitrous oxide to aid relaxation. Each session lasted from 30 to 45 min depending on the number of muscles treated and any technical difficulties.

In 2008, 2 drugs were available: Botox[®] (100 UI/vial) and Dysport[®] (500 UI/vial).

The real cost of the BoNTA injections in the day-hospital was determined by summing the cost of staff, treatment, small equipment used, and consumables for 2008. This information was obtained from the finance department and the manager in charge of the unit. The cost was considered stable for 2009 and 2013 because of only minor changes in the costs incurred by our hospital between 2008 and 2013 (vials, medical material and salaries, etc.).

3. Results

In 2008, there were 870 day-hospital admissions involving 364 patients. The mean number of treatment sessions per patient was 2.39 (range 1–4). Botox[®] was used in 809 treatment sessions (2474 vials, mean dose 291 ± 140 units/session) and Dysport[®] in 61 sessions (97 vials, mean dose 757 ± 325 units/session).

3.1. Real cost

To calculate the real cost of treatment, the costs incurred in 2008 were summed from the following: one part-time PMR doctor = 57,046 €/year; one full-time nurse + 1 part-time assistant = 81,524 €/year; medical material (needles, sterile gloves, swabs, nitrous oxide, etc.) and administrative material (consumables, computers, printers, etc.) = 44,455 €/year; type A botulinum toxin (Botox[®] and Dysport[®]) = 384,413 €. The total real cost in 2008 was 567,438 €. The mean real cost per patient treated was 1559 €/year (4.27 €/day) and the mean cost per treatment session was 652.23 €.

3.2. Calculated cost

In 2008, the hospital received 459,056 € for the treatment of spasticity by BoNTA, based on the cost calculated by multiplying

Mean “real cost” per treatment session in 2008

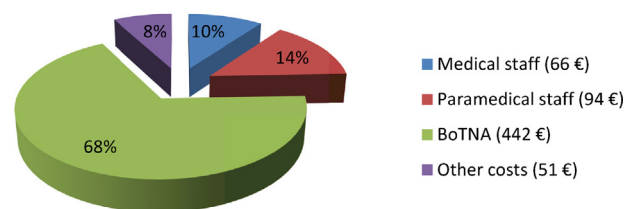


Fig. 1. Distribution of spending for treating spasticity per treatment session in the day-hospital in 2008. BoNTA: botulinum toxin type A; other costs: costs relating to functioning not including housing costs.

Table 1

Studies of mean cost of intramuscular injection of botulinum toxin A for treating spasticity in adults.

Authors	Number of patients included	Symptoms	Mean cost (€)	Variables studied
Burbaud et al. [14]	122	UL spasticity	1233/year	Cost of the toxin, equipment and staff
Burbaud et al. [14]	143	LL spasticity	1321/year	Cost of the toxin, equipment and staff
de Andrés-Nogales et al. [11]	NA, evaluation	Adults with spasticity	794/year	Cost of the toxin
Svensson et al. [12]	16	MS-related spasticity	223/year	Cost of the toxin
Ward et al. [9]	NA evaluation	Stroke-related wrist spasticity	943/year	Cost of the toxin
Shaw et al. [10]	333	Stroke-related UL spasticity	222/session	Cost of the toxin and consultation

NA: non-attributed; UL: upper limb; LL: lower limb; MS: multiple sclerosis.

the number of day-hospital admissions ($n = 870$) by the attributed fee for the specific GHM for spasticity in the day-hospital (527.65 €) (Fig. 1). The mean calculated cost per patient treated was 1261 €/year (3.45 €/day) and the mean cost per treatment session was 527.65 €.

In 2008, the total funding deficit (hospital revenue minus hospital costs) was 108,382 €, equivalent to 125 € per treatment session. Considering the real cost to be stable, the deficit was estimated at 222,892 € in 2009 ($567,438 - 870 \times 396.03$ €) and 241,188 € in 2013 ($567,438 - 870 \times 375$ €) because of the new fees in those years (396.03 € in 2009 and 375 € in 2013).

4. Discussion

This retrospective study including a large sample of patients who had received BoNTA for focal spasticity in France showed a financial deficit related to spending/valuation. However, the real cost of treatment per day (4.27 €) appeared to be reasonable, especially as compared with that for oral baclofen (up to 1.80 €/day) or intermittent self-catheterisation (20 €/day).

The cost of BoNTA treatment has been evaluated in previous studies, but most considered only the cost of the toxin itself (Table 1). Burbaud et al. performed a large study of the real cost of treatment for different conditions in a French health centre [13] and found that the cost of multi-site treatment for spasticity was 6.58 ± 1.38 €/day, which is similar to the present findings. Moreover, the authors showed that spasticity was 9 times more expensive to treat than hemifacial spasm and twice as expensive to treat as spasmodic torticollis. The authors suggested that this cost was mostly due to the large doses of botulinum toxin required for treating spasticity. Comparing the results of the present study with those of other studies is difficult because the aims slightly differed; other studies mostly focused on the cost-effectiveness ratio and not the real cost of BoNTA injections.

With regard to problems relating to the funding of BoNTA treatment, the real cost relative to the valuation of BoNTA treatment for patients with spasticity needed to be clearly defined, particularly because a large number of patients receive this treatment in our hospital. The “real cost” per treatment session per year was 652.23 € and the reimbursement per treatment session was 527.65 €, for a deficit of 108,383 €/year for the hospital. This is a large deficit, but considering the potential costs of complications avoided (fractures, bedsores, etc.), it seems acceptable. This observation is similar to that made by Zoons et al. in a recent medico-economical study of the impact of botulinum toxin treatment for focal dystonia [17].

In France, health-care related expenses for chronic diseases such as stroke, paraplegia, and multiple sclerosis, including all patients with spasticity, are fully reimbursed by the national health insurance. In addition, BoNTA is reserved for hospital use. In France, patients who are hospitalized cannot be charged for this category of drug. The cost is funded by hospitals and included in the GHS for secondary-care and in the hospital's annual budget for tertiary-care. There are no extra charges for patients according to

Mean cost per treatment session National Scale of costs 2011

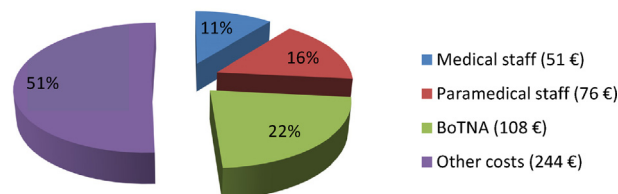


Fig. 2. Distribution of spending for treating spasticity per treatment session according to the national scale of costs. BoNTA: botulinum toxin type A; other costs: costs relating to functioning including housing costs.

the French Public Health Code. Therefore, patients incur no charges for this spasticity treatment. However, the method of funding in tertiary-care departments (with no funding other than the annual budget) greatly limits its use for spasticity in these centres. As well, in secondary-care, the low GHM valuation demonstrated in this study limits its use.

Such financial constraints have affected treatment. For example, there are regional inequalities, patients may have to attend centres far from their homes, and clinicians cannot always follow the recommendations regarding doses or timing of repeat injections, for example. Therefore, the valuation of this treatment must be improved.

The GHM rate covers costs as long as the treatment is limited to weak doses of BoNTA per patient. According to data from ENC 2011 (ATIH – 2011 DGF Référentiel v11e), the decomposition of GHM 01K04J (for all conditions) (Figs. 1 and 2) indicates that the drug itself (mean cost = 105 €) represents 22% of the mean cost to the GHM (estimated at 481 €). However, from our study, with BoNTA used specifically for treating spasticity, the drug itself constitutes almost 68% of the calculated cost of a day-hospital treatment session (652.23 €) (Fig. 1) (equal to 441.90 €), mainly because the doses of BoNTA necessary for treating spasticity are much greater than previously estimated.

In Spain and Italy, funding botulinum toxin for spasticity is not an issue because botulinum toxin is a hospital drug that is separately reimbursed by the national health insurance in those countries, with no charge to the patient. The situation is similar in the United Kingdom, where botulinum toxin is mainly used in the hospital setting (secondary-care) and is reimbursed separately as a high-cost drug with no patient charges.

The determination of a new GHS fee for secondary-care specific for treating spasticity and taking into account the real doses of BoNTA dispensed is essential to ensure complete funding for this treatment, including all resources involved. Another option would be to consider separate funding by the national health insurance for BoNTA as a high-cost drug, as in other European countries.

The study has some limitations. It was a retrospective study, which may not have been exhaustive. However, all attempts were made to be as exhaustive as possible by comparing 3 formal

registers (medical, medical-administrative and pharmacy) that are managed by the hospital's department of medical information. The study was facilitated by the specificity of the unit in which it was carried out because the sole activity of this unit is treating spasticity with BoNTA. Housing costs were not taken into consideration (use of facilities, water and electricity, etc.) or patient transport; however, these costs are difficult to calculate and because they vary among centres, difficult to interpret. The recent commercialisation of Botox[®] 50 and 200 U and Dysport[®] 300 U has facilitated the adjustment of doses, and costs are decreasing, probably in part because of the estimations carried out in 2009 and 2013. Finally, we could not clearly identify the different aetiologies of spasticity. The patients receiving care in this unit were often severely disabled and required large doses of BoNTA.

5. Conclusion

BoNTA injections are currently the primary treatment for focal spasticity. Because of the high incidence of central nervous system disorders (such as stroke), precisely establishing the costs and spending related to this treatment as well as its valuation is essential. The results of this retrospective study of a large sample of patients receiving treatment for focal spasticity showed a deficit related to spending/valuation, but the mean daily cost (4.27 €) was reasonable. Because of the annual reduction in reimbursement for the treatment, the total hospital budget deficit was 222,892 € in 2009 and 241,188 € in 2013. This treatment should be revaluated to avoid suboptimal clinical practices.

Disclosure of interest

A. Schnitzler and F. Genêt are trainers and consultants for Allergan (12, place de la Défense, 74370 Courbevoie), Merz (101, avenue François-Arago, 92000 Nanterre) and Ipsen (65, quai Georges-Gorse, 92100 Boulogne-Billancourt) laboratories.

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