

# BOTULINUM TOXIN TYPE A - DOSES FOR 3 DIFFERENT FORMULATIONS: A REAL-LIFE PRACTICE EXPERIENCE IN POSTSTROKE SPASTICITY TREATMENT

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## INTRODUCTION

Being a reference spasticity center since 2000, with an average number of yearly treatment sessions of 400 in the last 10 years. We considered it was relevant to analyze our practice and benchmark it against the recommended practices for post stroke spasticity treatment with BoNTA. We felt a need for some relevant reports to shed some light on the matter of a possible conversion ratio between the 3 different preparations of BoNTA available in Europe, and we believe that the non interventional practice of a reference center in a large number of cases over a long period of time would be a relevant contribution.

## OBJECTIVES

The objectives of this study were to describe:

- 1- The doses of botulinum toxin type A (BoNTA) used in a reference spasticity clinic for 3 BoNTA formulations (abo, inco and onabotulinum);
- 2- The most frequently injected muscles;
- 3 - The dose changes when treating upper limb only (UL) or upper + lower limb (UL + LL).

## MATERIAL AND METHODS

We studied all patients treated in our Botulinum Toxin Clinic in the year of 2014. Data were prospectively collected in an instrument designed specifically for the purpose. All BoNTA treatment sessions between 2001 to 2016 were retrieved from the clinical files.

We investigated the following parameters:

- 1- Limbs treated (upper limb, UL; upper + lower limb, UL + LL; lower limb, LL);
- 2- Most frequently injected muscles;
- 3- Mean total BoNTA doses for the three different formulations for the entire group;
- 4- Mean total BoNTA doses for the 3 formulations regarding whether only the UL or both UL+LL were treated;
- 5- Proportion of the mean total doses between the 3 preparations when UL only or both UL+LL were treated;
- 6- Individual muscle BoNTA dose differences whether only the UL or both UL+LL were treated;

There were 117 patients (1057 BoNTA sessions). Mean age at stroke was 54 years (standard deviation [SD], 12.37). Median time interval from stroke to first BoNTA was 0.9 years (range, 0.1 to 9.8). Among all patients, 44% had left hemiparesis and 55% had right hemiparesis. The mean number of sessions was 9 (SD, 6), and mean follow-up time was 4.2 years (SD, 3.35).

	UL-BoNTA
	N=117
Age at stroke (mean)	53,94 years (SD12,37)
Gender	
Male	56%
Female	44%
Etiology	
Ischemic	64%
Localization	
Right hemisphere	41%
left hemisphere	51%
Infratentorial	5%
Unknown	3%
Impairment	
Right hemiparesis	55%
Stroke to first BoNTA treatment time interval (mean)	0,96 years (range, 0,1 to 9,8)
Number of BoNTA sessions	9 (SD 6; range, 1-26)
Follow-up time (mean)	4,18 years (SD 3,35)

FIG 1: Patients characteristic's

**Most frequently, patients had UL + LL treated (63%), UL (27.65%), LL (9%).**

**UL muscles** most frequently injected were: flexor digitorum superficialis (FDS; 62%), biceps (60%), flexor carpi radialis (38%), flexor digitorum profundus (FDP; 36%), pronator teres (36%) and brachioradialis (36%).

**LL muscles** most frequently injected were: gastroc. medialis (59%), gastroc. lateralis (56%), soleus (48%) and tibialis posterior (21%).

## RESULTS

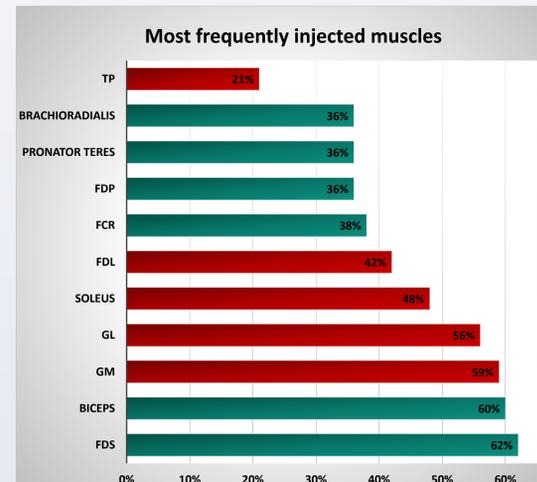


FIG 2: Most frequently injected muscles in the upper (green) and in the lower limb (red). TP: tibialis posterior; FDP: flexor digitorum profundus; FCR: flexor carpi radialis; FDL: flexor digitorum longus; GL: gastrocnemius lateralis; GM: gastrocnemius medialis; FDS: flexor digitorum superficialis

Abobotulinum toxin was used in 69% of patients; the mean total dose was 1108 U (SD, 367). Incobotulinum toxin was used in 17%, with a mean total dose of 402 U (SD, 138).

Onabotulinum toxin was used in 13%, with a mean total dose of 368 U (SD, 113).

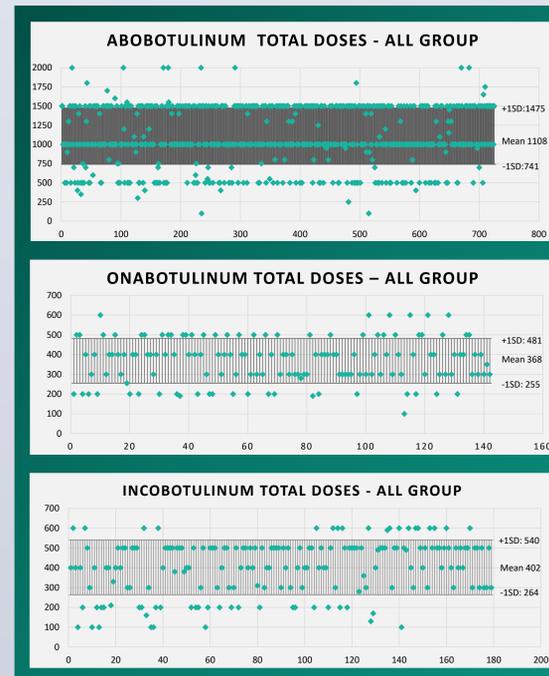


FIG 3: Total BoNTA doses distribution in the entire group for the different formulations

Globally, mean dose proportion between BoNTA preparations both for UL + LL and for UL only were 2.4:1 for InT/AbT and 2.6:1 for OnT/AbT, and this difference was statistically significant ( $P=0.048$  for UL + LL;  $P=0.02$  for UL only).

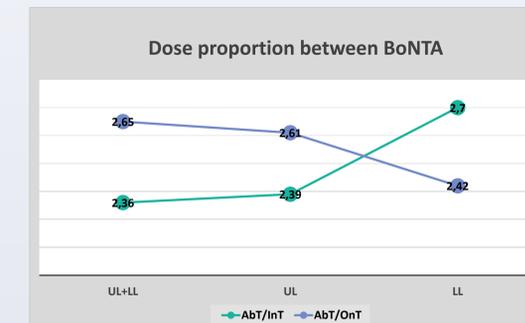


FIG 4: Doses proportion between the BoNTA formulations for UL+LL, UL and LL treatments. AbT/InT: abobotulinum toxin/incobotulinum toxin; AbT/OnT: abobotulinum toxin/Onabotulinum toxin.

When we looked at each particular muscle, the Incobotulinum/Abobotulinum as well as the Onabotulinum/Abobotulinum ratios were similar, but these values were different from one muscle to another.

When UL + LL were treated, the mean doses for some UL muscles seemed to decrease, namely: subscapularis ( $P<0.001$ ), biceps ( $P=0.02$ ), flexor digitorum superficialis ( $P=0.01$ ), and flexor digitorum profundus ( $P=0.01$ ).

	AbT dose UL (mean)	AbT dose UL+LL (mean)	P value
Subscapularis	142.13	116.17	<0.001
Biceps	181.17	167.78	0.018
FDS	158.02	147.43	0.001
FPD	139.51	124.33	0.009

FIG 5: Differences in muscle doses when injected only upper or both limbs. AbT: Abobotulinum toxin.

## CONCLUSIONS

This is a long-term, real-practice experience of BoNTA treatment in patients with post stroke spasticity in a reference center.

We found that there is no fixed conversion ratio between the 3 preparations of BoNTA available in our setting, as they varied from one muscle to another.

We realized that we had a tendency to decrease the doses per muscle slightly in some UL muscles when injecting UL + LL in the same treatment session.



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## ACKNOWLEDGEMENTS AND CONTACT

The authors thanks all the multidisciplinary team that treated these patients.

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