

ROLE OF EARLY BOTULINUM TOXIN-A INJECTION IN THE TREATMENT OF PATIENTS WITH POST-STROKE SPASTICITY: PRELIMINARY RESULTS OF AN OBSERVATIONAL STUDY

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INTRODUCTION

Stroke is a leading cause of acquired adult disability in developed countries [1]. Lesions in the pyramidal and parapyramidal tracts may raise positive and negative symptoms.

Spasticity is a well-recognized disabling consequence of stroke that mainly occurs within the first few months after the onset [2]. The risk of developing spasticity after stroke has been showed to mainly relate with the degree of initial paresis [2].

Botulinum toxin type A (BoNT-A) has proven to be effective and safe in the treatment of post-stroke spasticity (PSS) [3].

To date there is encouraging evidence regarding BoNT-A as an early intervention for PSS. However, its early use is not common in daily clinical practice [4].

AIMS OF THE STUDY

On these bases, and considering that BoNT-A is usually administered in sub-chronic stroke patients, we decided to conduct an observational study designed to assess the role of time elapsed between the onset and BoNT-A injection for reducing PSS, in accordance with clinical routine practice

METHODS

INCLUSION CRITERIA

- Age > 18 years
- Spasticity as a consequence of ischemic or hemorrhagic stroke
- Muscle tone $\geq 1+$ on the modified Ashworth scale (MAS) [5] at the main districts of the affected limbs
- Muscle weakness ≤ 2 on the Medical Research Council (MRC) [6] at the main districts of the affected limbs
- Time from stroke onset < 12 months
- No previous BoNT-A treatment of PSS

EXCLUSION CRITERIA

- Inclusion in other trials
- Fixed contractures (tone graded at 4 on the MAS) or bony deformities at the affected limbs
- Additional antispastic medications
- Other neurological or orthopedic conditions involving the affected limbs

OUTCOMES

MAS (*primary outcome*) [5]

Motricity Index (MI) [7]

Fugl-Meyer Assessment (FMA) [8]

Modified Rankin' Scale (MRS) [9]



RESULTS

A total of 84 stroke patients with PSS were enrolled from June 2015 to August 2018. Here we report as to the preliminary analysis of data about 59 patients (37 men, 22 women; mean age 64.9 years) who concluded the study during this period. Forty-eight patients had ischemic stroke and 11 had hemorrhagic stroke. Thirty-four patients presented with right hemiparesis and 25 with left hemiparesis.

The mean time between stroke onset and BoNT-A injection was 127.8 days. Twenty-one subjects were inpatients; 32 were outpatients; 11 patients were treated in Day Hospital regimen. Sixteen patients underwent injections with manual needle placement; seven patients received injections with electrical stimulation/EMG guidance; 36 patients were injected under ultrasonographic guidance. Thirty-three patients were injected with AbobotulinumtoxinA (mean total dose 796 units); 11 patients were injected with IncobotulinumtoxinA (mean total dose 250 units); 15 patients were injected with OnabotulinumtoxinA (mean total dose 256 units).

As to the primary outcome, we found that time between stroke onset and BoNT-A injection was directly associated (Spearman correlation) with the MAS score of the following muscle: elbow flexors at T1 ($P=0,046$) and T2 ($P=0,020$); forearm pronators at T2 ($P=0,021$) and T3 ($P=0,031$); wrist flexors at T1 ($P=0,019$) and T2 ($P=0,043$); finger flexors at T1 ($P=0,001$) and T2 ($P=0,003$); thumb flexor at T1 ($P=0,017$); ankle plantar flexors at T1 ($P=0,020$) and T2 ($P=0,020$).

We failed to observe a significant correlation (Spearman correlation) between the other outcomes (MI, FMA and MRS) and the time between stroke onset and BoNT-A injection.

CONCLUSIONS

Our preliminary results support the hypothesis that early treatment of PSS with BoNT-A may lead to lower levels of muscle hypertonia up to 1, 3 and 6 months after injection

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