Subcutaneous regional targeted botulinum toxin injection technique for the treatment of chronic migraine: a randomized, sham-controlled study

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Background

Many patients with chronic migraine (CM) do not respond to PREEMPT intramuscular botulinum toxin type A (BoNTA) injection paradigm. If an individualized treatment with subcutaneous BoNTA injections decreases the headache days in these patients is unknown.

Objective

To test if subcutaneous trigeminal or occipital regional targeted (STORT) BoNTA injection technique decreases the migraine days in patients with CM.

Methods

DEMOGRAPHIC AND CHARACTERISTICS OF THE 90 PATIENTS WITH CHRONIC MIGRAINE

Patients	
Age, years, mean ± SD	41±11.2
Sex, F/M	78/12
Body mass index, kg/m2, mean ± SD	25±4
Duration, years, mean ± SD	14±9
Headache profile, n (%)	
Unilateral headache	64(71%)
Pulsating pain	64(71%)
Severity of pain Severe	 62(69%)
Cutaneous area where started pain, trigeminal occipital	 54 (60%) 36 (40%)
Frequency of headache Daily	 71 (79%)
Overuse medication	36 (40%)
ASC 12 cutaneous allodynia (allodynic score ≥6), n (%)	
Non allodynic patients	36 (40%)
Allodynic patients	54 (60%)
Patient' s disability score at baseline	
MIDAS mean ± SD	25±18
BDI-II mean ± SD	12±10
HARS mean ± SD	19±12
VAS mean ± SD	9±1

SUBCUTANEOUS TRIGEMINAL OR OCCIPITAL REGIONAL TARGETED (STORT) BONTA INJECTIONS TECHNIQUE

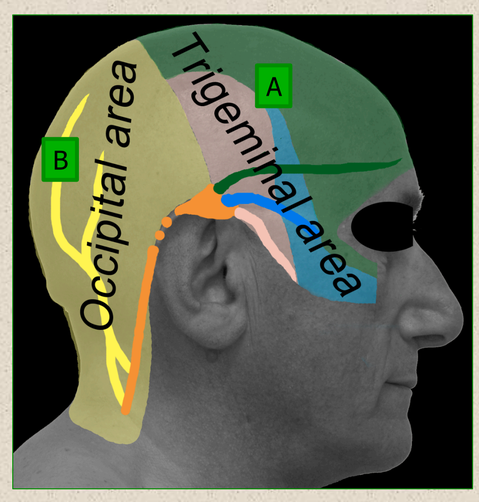

Figure 1.

A: Subcutaneous trigeminal regional targeted BoNTA injections technique and cutaneous area of maximum pain: the cutaneous area innervated by the first branch and a small part of second and third branches of trigeminal nerve.

B: Subcutaneous occipital regional targeted BoNTA injections technique and cutaneous area of maximum pain: the cutaneous area innervated by the greater, lesser and third occipital nerves.

- Subcutaneous
- Trigeminal/ Occipital
- Regional
- Targeted

40 sites

200 U BoNTA

90 consecutive patients with CM unresponsive to PREEMPT intramuscular BoNTA injections paradigm were randomized to real or sham STORT treatment. According to cutaneous area where started the pain we allocated the patients in the trigeminal or occipital regional targeted treatment. Trigeminal treatment consisted of injections in the cutaneous area innervated by the first branch of trigeminal nerve and a small part of second and third branches, while occipital treatment consisted of injections in the cutaneous area innervated by the greater, lesser and third occipital nerves. We administered BoNTA (up to 200 units) in the real treatment, and saline solution in the sham treatment. Repeated real STORT and one sham treatment were administered at the time interval of 90 days. The patients were evaluated at 30, 60 and 90 days. Primary end-point was change >50% in number of monthly headache days.

Results

According to cutaneous area where started the maximum pain patients were grouped in trigeminal/or occipital treatment. In trigeminal treatment, including 54 patients, the real STORT BoNTA injection treatment decreased significantly the number of monthly headache days in 73% of patients with CM, the majority of them were allodynic patients. While in occipital treatment, including 36 patients, the real STORT BoNTA injection treatment decreased significantly the number of monthly headache days in 80% of headache sufferers, many of them were non-allodynic patients. The efficacy lasted about 60 days. Whereas, sham STORT treatment produced a temporary response only in 28% of patients with CM.

Response to real and sham STORT BoNTA treatment

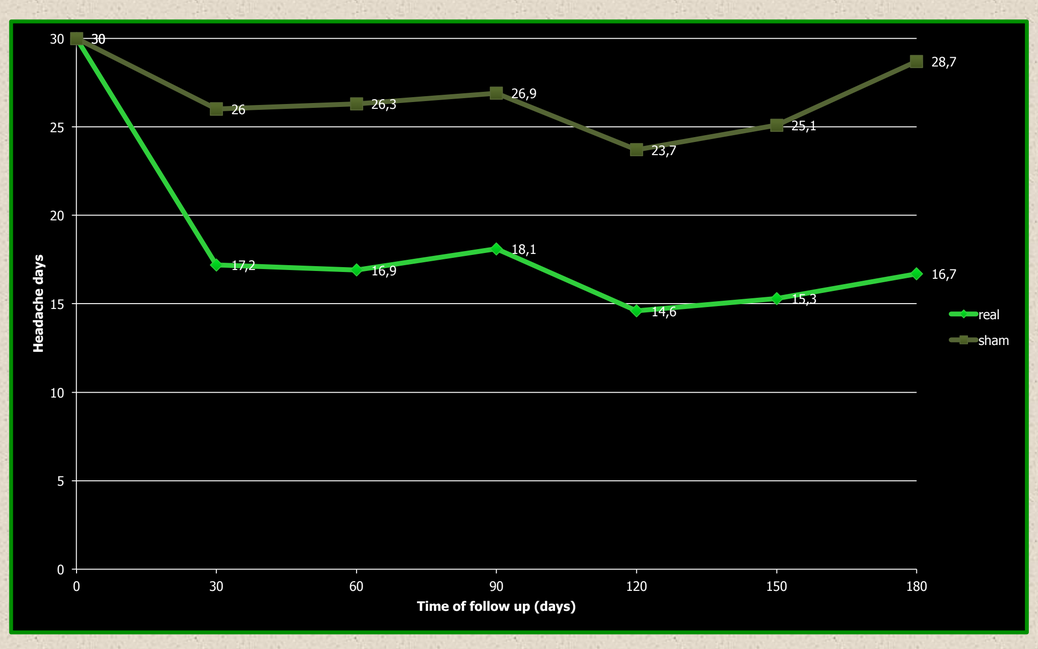

Figure 2. Headache days frequency at baseline and after BoNTA treatment compared to STORT sham. Mean change from baseline in headache days frequency: -13.2 for real treatment vs -1.2 giorni for sham treatment, p < .0001. (primary endpoint).

Response to real STORT BoNTA treatment in 90 patients grouped in trigeminal (n=54) or occipital (n=36) according to area of maximum pain

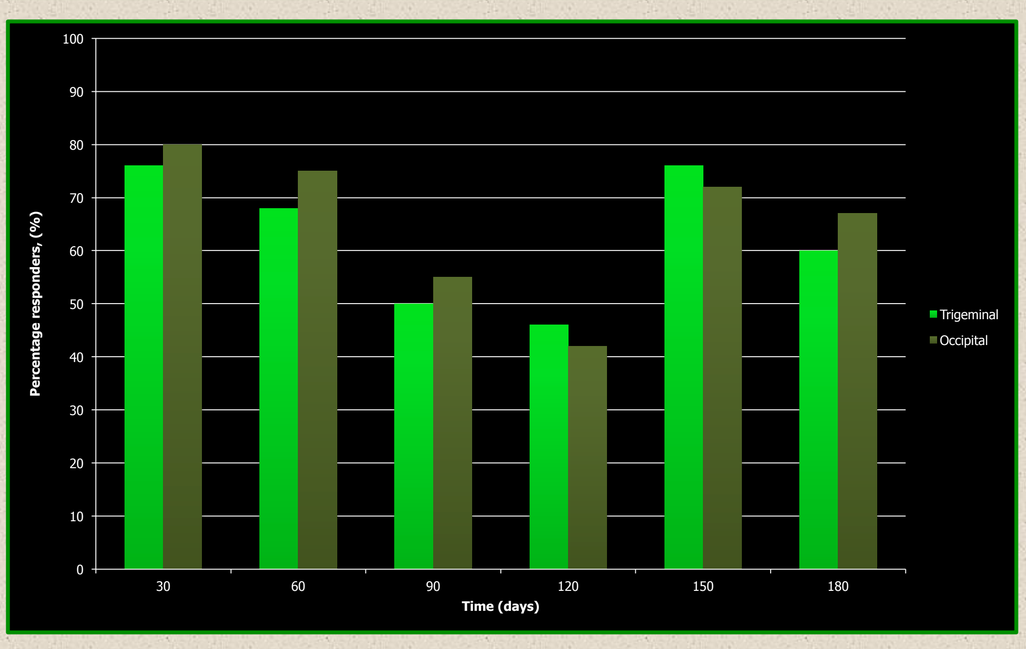

Figure 3. Percentage of responders after BoNTA treatment during follow-up in patients with trigeminal or occipital headache.

Conclusions

Repeated subcutaneous trigeminal or occipital regional targeted BoNTA injections decrease headaches days in patients with CM unresponsive to PREEMPT intramuscular injection paradigm.

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