REPEATED SUBCUTANEOUS INJECTIONS OF BOTULINUM TOXIN TYPE A FOR PROPHYLAXIS OF HEADACHES IN REFRACTORY CHRONIC MIGRAINE: A RANDOMIZED PLACEBO-CONTROLLED STUDY

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Background

There is the evidence that repeated subcutaneous injections of botulinum toxin type A (BoNTA) provide analgesic relief to patients with neuropathic pain. Moreover, it is now recognized that there is an anatomical substrate of extracranial/intracranial interactions. This latter evidence suggests that the activation of peripheral nociceptors may contribute to the pathophysiology of migraine (CM).

Aim

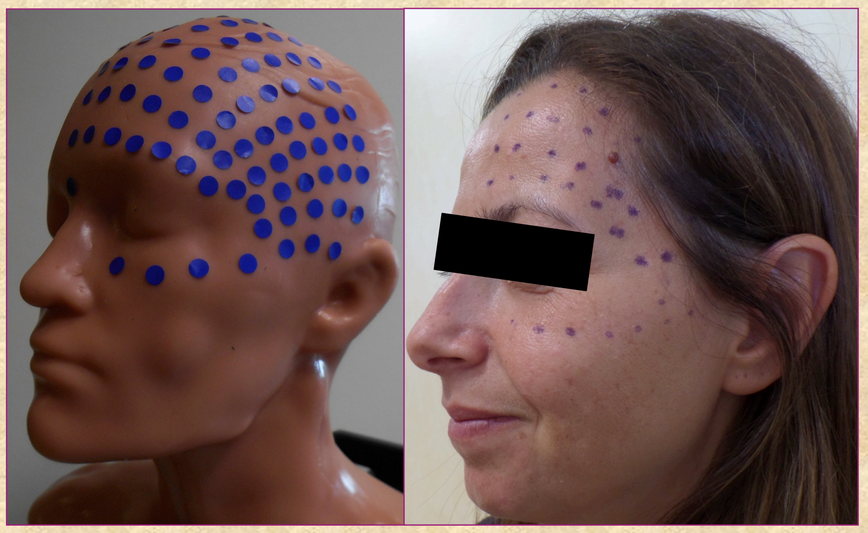
To test if repeated subcutaneous BoNTA injections in trigeminal or occipital area of the scalp are effective for prophylaxis of headache in patients with refractory CM.

Method

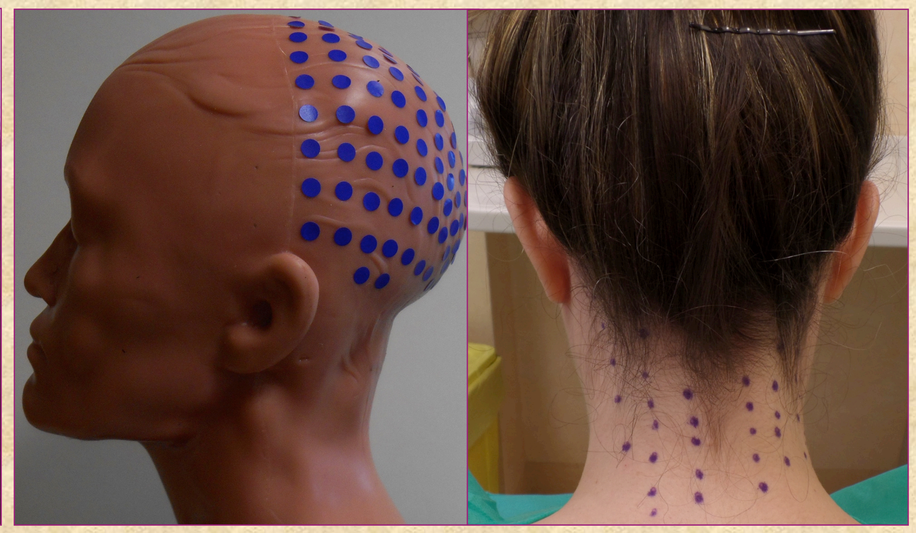
In this prospective study we recruited 69 consecutive patients with CM unresponsive to intramuscular injections of BoNTA (PREEMPT paradigm) .

	All subjects (n =69)
Age, years, mean ± SD	41±11
Sex, F/M	61/8
Body mass index, kg/m2, mean ± SD	25±3
Overuse medication, n (%)	24 (35)
Cutaneous Allodynia (Allodynia Symptoms Checklist-12 scale) , n	
None (score 0-2)	10
Mild (score 3-5)	11
Moderate (score 6-8)	15
Severe (score >9)	33
Patient' s disability score at baseline	
Total headache days	22±8
MIDAS	25±21
Beck	18±8

TRIGEMINAL SUBCUTANEOUS INJECTIONS



OCCIPITAL/CERVICAL SUBBCUTANEOUS/INTRAMUSCULAR INJECTIONS

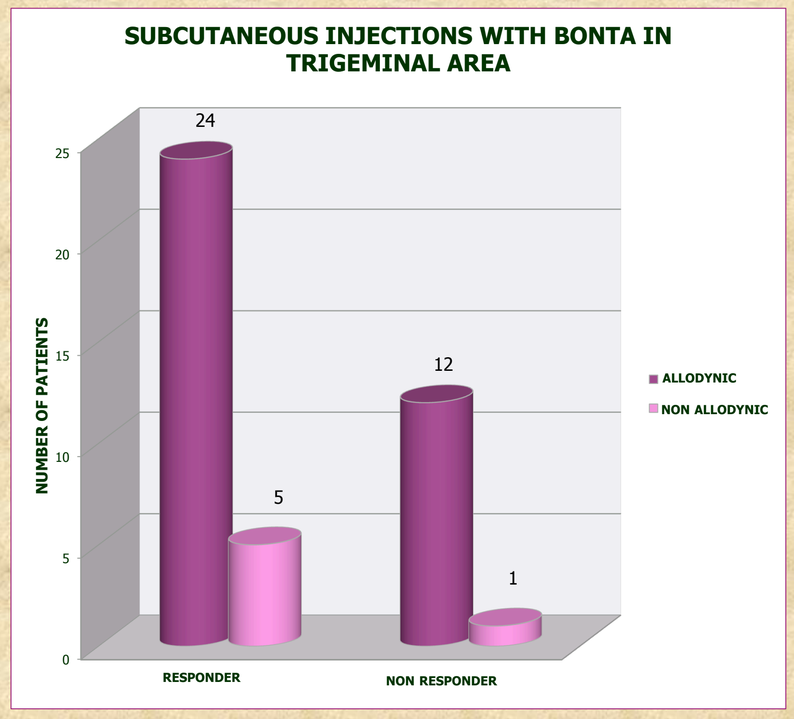


All patients underwent a careful clinical evaluation to detect the main location of pain (trigeminal or occipital areas) and severity of cutaneous allodynia (according to Allodynia Symptoms Checklist-12). These patients were assigned, according to area of maximum pain (trigeminal or occipital) and severity of cutaneous allodynia, to receive two subcutaneous administrations of BoNTA (which comprised several injections up to 200 units) or placebo. Patients with trigeminal location of the pain performed subcutaneous BoNTA injections in the cutaneous area innervated by first branch of trigeminal nerve; instead patients with occipital location of pain performed subcutaneous injections in the cutaneous area innervated by greater and lesser occipital nerves. During the follow up patients were evaluated at 30, 60 and 90 days. Primary end-point was change >50% in number of monthly headache days.

Results

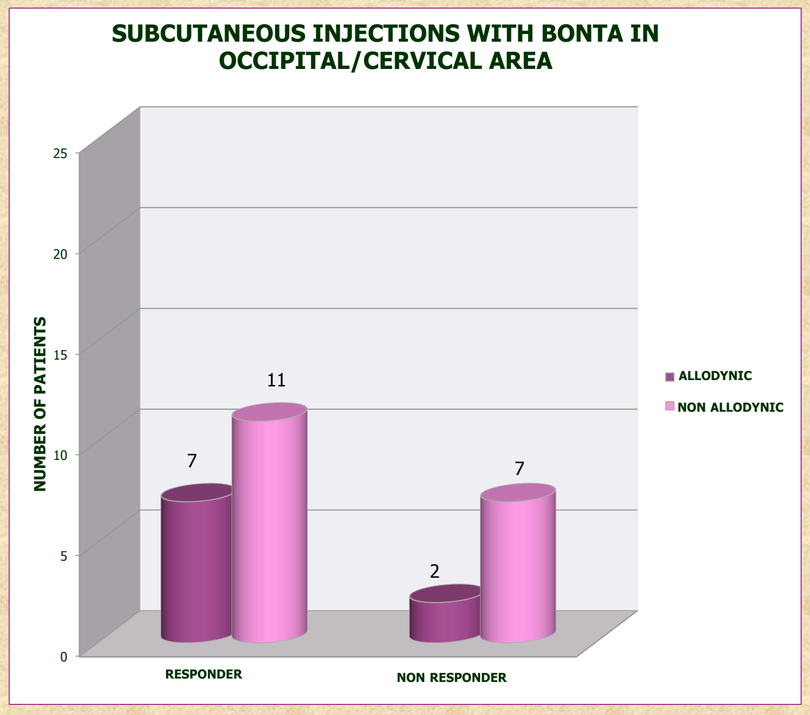
According to area of maximum pain and severity of cutaneous allodyniac, patients were divided in 2 groups: Group 1, included 36 allodynic patients with trigeminal area of maximum pain, who performed subcutaneous BoNTA injections in the cutaneous area innervated by first branch of trigeminal nerve; Group 2, consisted of 18 non allodynic patients with occipital area of maximum pain, who performed subcutaneous injections in the cutaneous area innervated by greater and lesser occipital nerves. The efficacy lasted about 60 days. While, 30% of patients had a temporary response to false treatment.

GROUP 1



The treatment decreased significantly the number of monthly headache days in 66% of patients

GROUP 2



The treatment decreased significantly the number of monthly headache-free days in 61 % of patients.

Conclusions

Repeated subcutaneous injections of BoNTA have a sustained efficacy for prophylaxis of headache in patients with refractory CM who do not respond to PREEMPT paradigm.

Our findings highlight the efficacy of subcutaneous BoNTA administration for treatment of patients with refractory chronic migraine.

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