OnabotulinumToxinA treatment in patients with chronic migraine: a retrospective observational study.

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Introduction

Chronic migraine (CM), defined as headaches ≥15 days per month for ≥3 months, affects 2% of the population; treatment is often complicated by the concomitant overuse of symptomatic medication and by the poor efficacy of standard prophylactic treatments. The aim of this study is to analyze real-life experience with OnabotulinumtoxinA in the treatment of CM in terms of clinical improvement, degree of disability and side effects.

Materials & Methods

We retrospectively included all patients referred to our Headache Centre with a diagnosis of CM with or without medication overuse, who were treated with OnabotulinumtoxinA between 2014 and 2016. We included only subjects who had received and failed other preventive therapies due to lack of efficacy or intolerable side effects. Patients were allowed to take preventive oral medication during treatment. Treatment was injected every 3 months (±1 week) following the paradigm of the PREEMPT study (155 U of OnabotulinumtoxinA administered to 31 injection sites across seven head and neck muscles up to 40 U additional administered using a "follow the pain" strategy). For each subject, a schedule of at least 2 administrations (T0-T1) was programmed, and if there was a clinical response (≥30% reduction in migraine days) at follow-up visits (T2-T3-T4), the patient was considered a responder and he continued the treatment. Data on headache frequency, headache intensity and acute medication intake days were collected by patient's diaries: data at baseline refer to one month before the first administration, while the same parameters in subsequent follow up controls refer to the mean of the previous three months. Patient degree of disability was assessed by the Migraine Disability Assessment Score (MIDAS). During the 12 months all drug adverse events were registered. The demographic and clinical characteristics at T0 were compared to those at T2 (6 months) and T4 (12 months). Wilcoxon matched-pairs signed-ranks test was performed to compare variables. P-value <0.05 was considered significant.

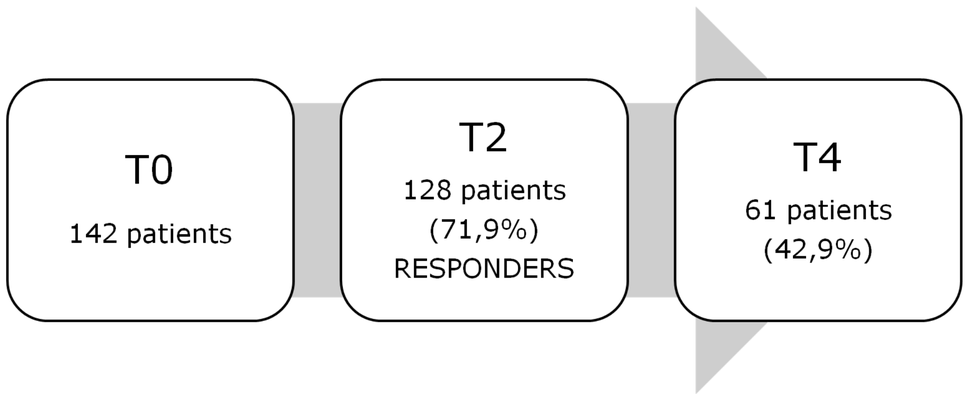
Results

On a series of 142 patients included at T0 (Tab. 1), 92 subjects (71.9%) were considered responders and underwent the third administration (T2); 61 (43.0%) underwent injection at T3 and 41 (28.9%) at T4. Comparing with baseline data, at T2 the treatment significantly reduced the headache frequency and MIDAS score. At T4 a significant reduction in headache frequency and number of acute medication intake days were reported when compared with baseline (Tab. 2). Overall, 43,9% and 41,7% of patients turned to an episodic migraine at T2 and at T4 respectively. No serious adverse events have been reported.

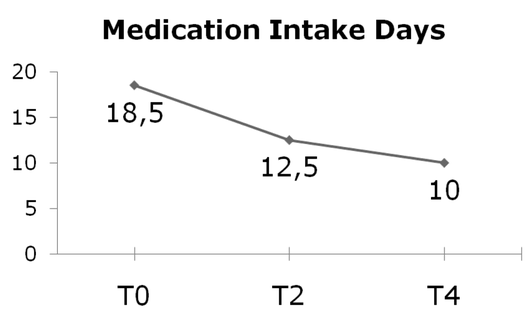
Conclusions

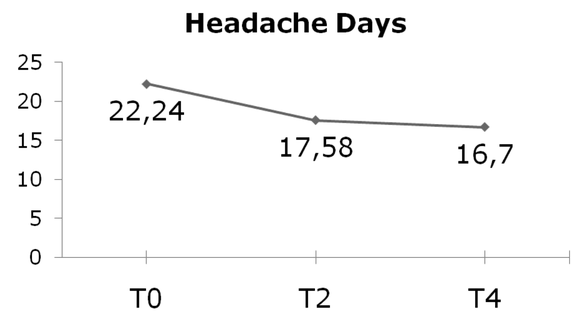
In our study the response rate of patients was similar to literature data. The reduction in headache frequency was significant both at 6 and 12 months. Positive trends on headache intensity, number of medication intake and degree of disability were reported. OnabotulinumtoxinA is an important therapeutic option in chronic migraine both for its efficacy and safety profile.

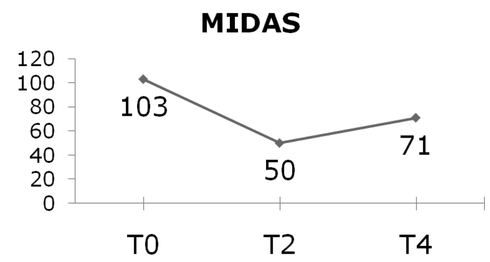
Tab. 1 - Population T0			
Total population		N	142
Age		mean ± SD	52.80 ± 10.94
Sex		N (%)	
	Men		35 (24.65)
	Women		107 (75.35)
Age at onset		med (IQR)	15 (11-21)
Age at chronicization		mean ± SD	35.8 ± 11.4
Medication Overuse		N (%)	
	Yes		112 (78.32)
	No		5 (3.50)
Headache frequency		mean ± SD	22.24 ± 5.35
Headache intensity (1-10)		mean ± SD	5.94 ± 1.81
Medication Intake Days		med (IQR)	18.5 (14-26)
MIDAS		med (IQR)	103 (45-160)



Tab. 2	T0	T2 (6 m)	p-value	T4 (12 m)	p-value
Headache Days	22.24 ± 5.35	17.58 ± 8.06	<0.001	16.70 ± 7.57	0,0046
Headache Intensity	5.94 ± 1.81	5.58 ± 1.65	0,3849	5.19 ± 1.6	0,1189
Medication Intake Days	18.5 (14-26)	12.5 (8.67-22.67)	0,0493	10 (7-19.3)	0,0057
MIDAS	103 (45-160)	50 (21-100)	<0.001	71 (25-140)	0,1243







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