

ONABOTULINUMTOXIN A IN CHRONIC MIGRAINE: IS SAFE AND EFFECTIVE EVEN AFTER TWO YEARS OF TREATMENT?

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INTRODUCTION

Chronic migraine (CM) is a disabling neurologic disorder that affects 1.4-2.2% of the general population. Most CM patients overuse symptomatic headache medications. An effective, safe, and well-tolerated prophylactic headache medication will improve the patient's clinical condition and should reduce acute headache medication consumption. Onabotulinumtoxin-A (BT-A) is one of the authorized prophylactic therapy in chronic migraine (CM). Its efficacy has been proved by both clinical trial and observational open label study.

A few data are still available on the effectiveness of BT-A injection and on the most adequate treatment interval after the first year of follow-up

OBJECTIVES: 1) to verify the effectiveness and safety of BT-A injections in CM patients during the second year of treatment; 2) to establish the most adequate timing for retreatment.

Patients	110 (73% F)
Age	49 (19-76)
Disease duration	11 (1-40)
Abuser	72 %

PATIENTS AND METHODS

We prospectively collected data of 110 CM patients treated with BT-A in our center. After the fourth BT-A treatment we decided to retreat patients on the basis of the clinical response. The patients recorded in a diary some parameters: headache days, migraine days, hours of headache, number of acute headache medication intake. Moreover during the visit, they completed the MIDAS and HIT-6 questionnaires. In the second year we planned the control visit after 4 months, giving the possibility to the patient to anticipate the visit because of a new increase of headache frequency.

RESULTS

We registered a statistically significant improvement of all considered clinical variables throughout the entire follow up period. Adverse events were rare and did not require treatment discontinuation. 31 patients dropped out; 19 were stopped by the physician for inefficacy, 12 dropped early in the follow up due to unknown causes.

20 patients have actually completed 2 years of follow up (17 females and 3 males). Most of them continued to perform trimestral treatment (13). 5 were treated every four months and 2 with a longer interval. 7 out of 20 patients were taking prophylaxis drugs at T0 (4 Topiramate, 3 Gabapentin). During the second year 1 patient stopped prophylaxis medication and 2 patients reduced the dosage.

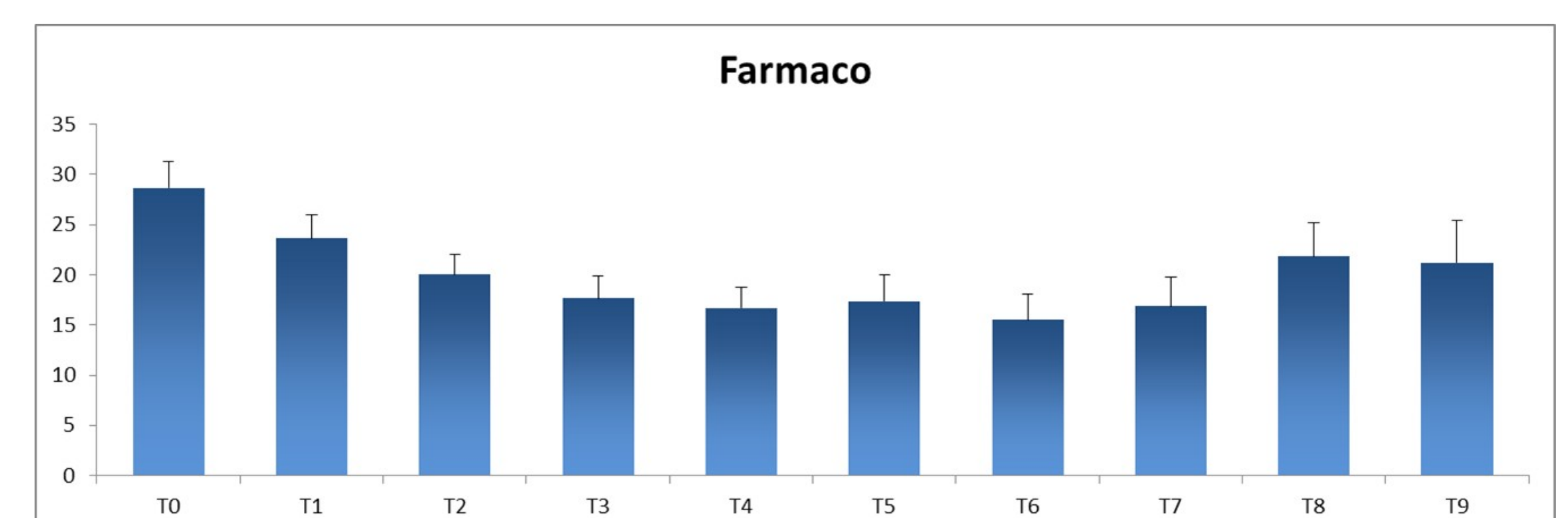
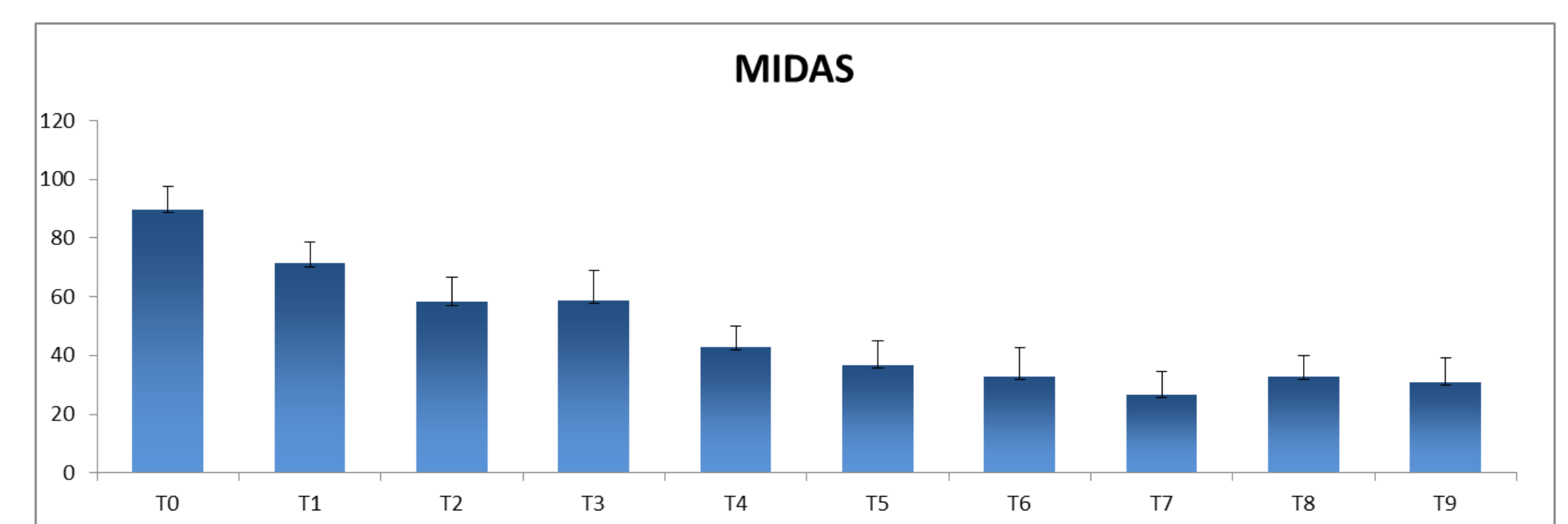
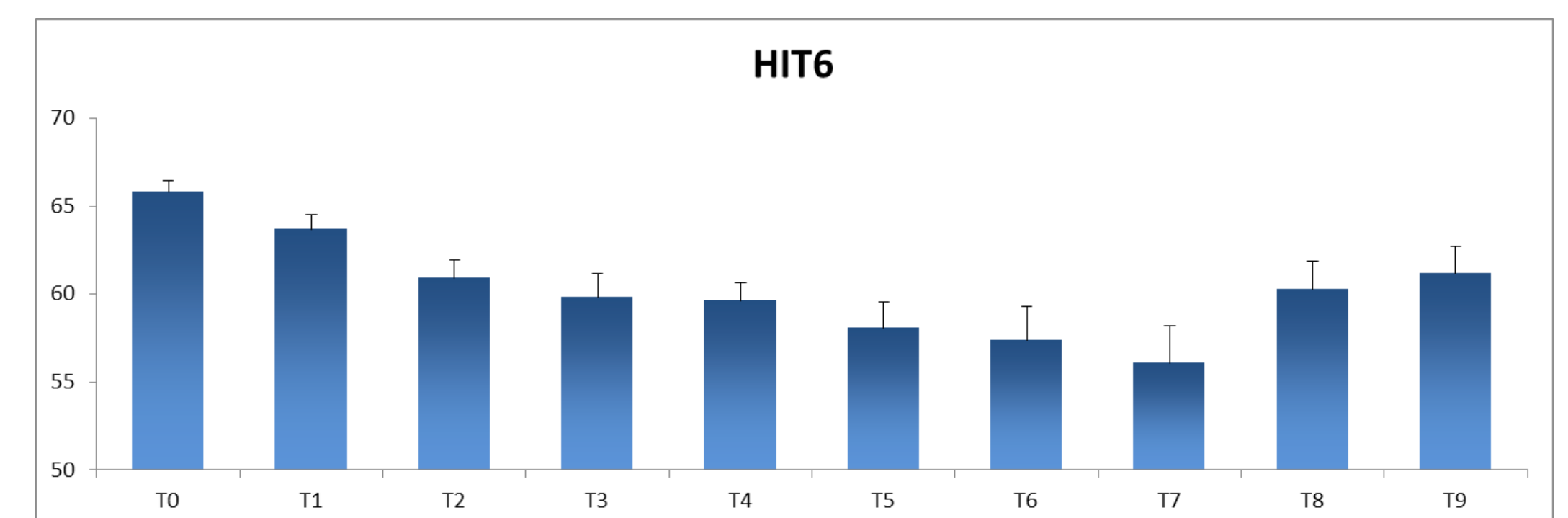
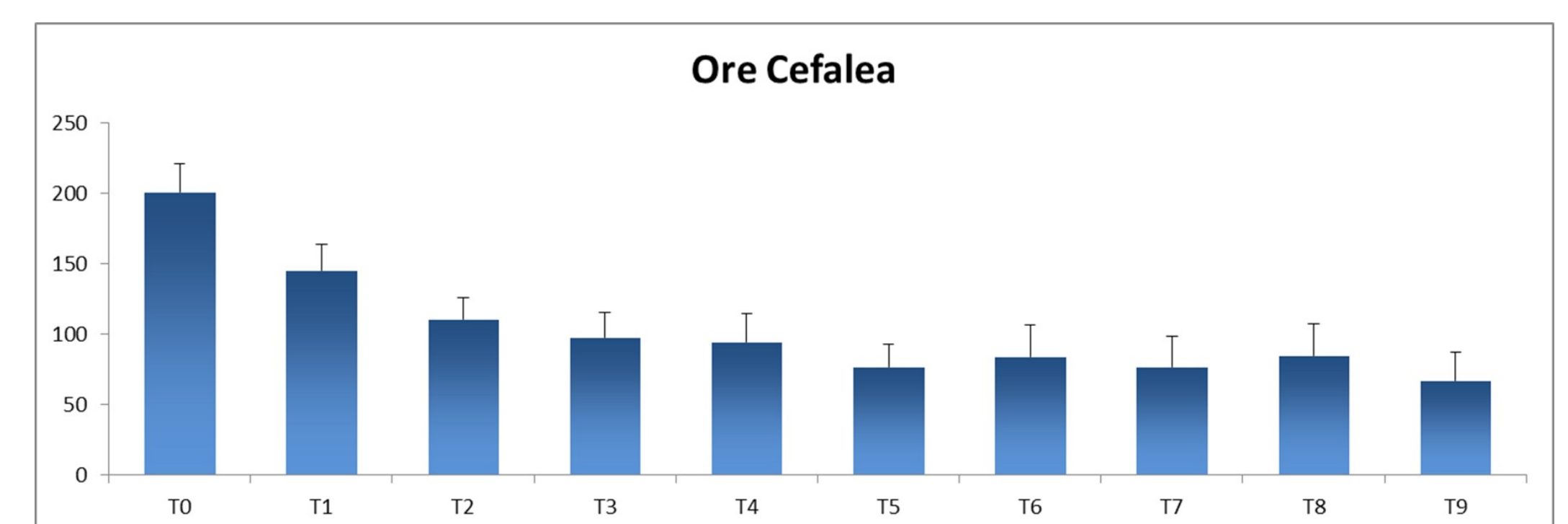
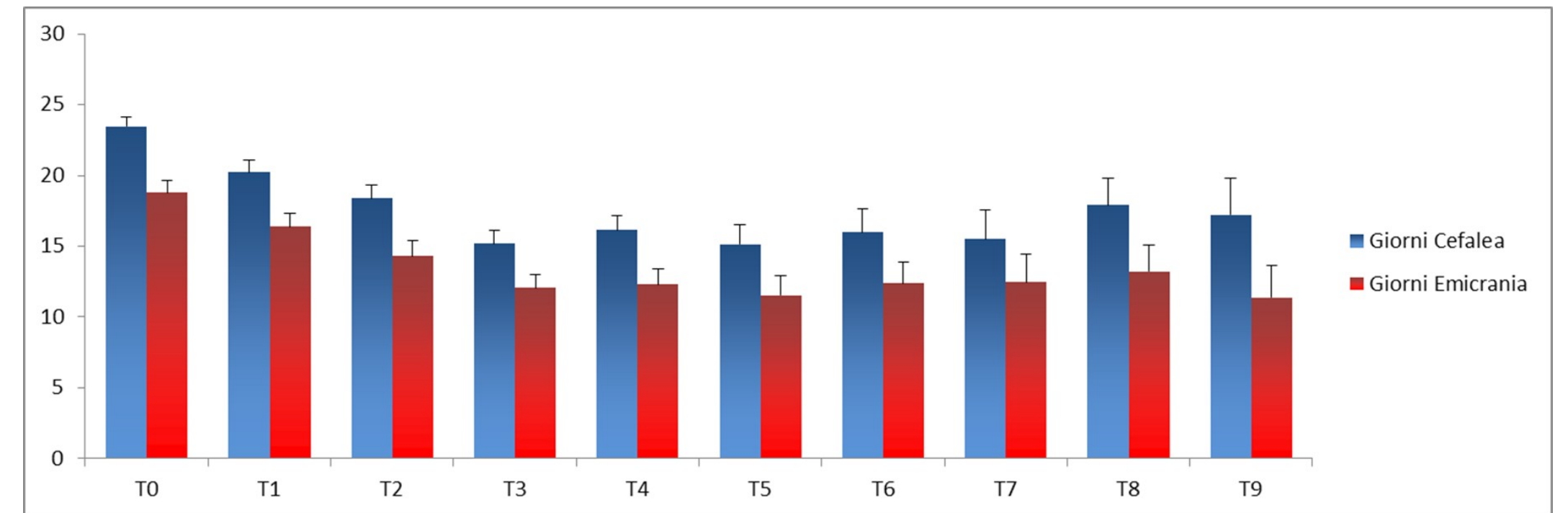
DISCUSSION

The clinical improvement, in term of reduction of headache days, hours and less symptomatic drugs consumption, evidenced during the first year persisted throughout the second year of BT-A treatment.

The decision to continue BT-A administration regularly in responder patients, allowed to maintain a good control of migraine and a lower impact of the disease in patients' life. According to the clinical outcome, extrapolated by the monthly diary completed by the patients, it has been possible to increase the interval treatment in 35% of patient. Moreover, in a few cases, it has been possible to reduce and/or to stop the oral prophylaxis therapy.

CONCLUSIONS

BT-A in CM patients is effective and safe even after two years of treatment, using individualized treatment interval according to the clinical outcome.



STATISTICAL ANALYSIS - in order to check the normality of data distribution we performed the Kolmogorov-Smirnov test. Since data were not normally distributed, non parametric tests have been used (Friedman Test, Wilcoxon Test)

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