

ONABOTULINUMTOXIN-A EFFECTIVENESS EVALUATION IN CHRONIC MIGRAINE PATIENTS WITH SHORT OR LONG DISEASE HISTORY AND PSYCHIATRIC COMORBIDITIES: AN ITALIAN MULTICENTRIC STUDY (THE BACH STUDY)

F. Vernieri[1|2], P. Pasqualetti[3], M. Marcosano[1|2], N. Brunelli[4], L. Fofi[1], D. Antonio Montisano[5], L. Grazzi[5], R. Ornello[6], C. Rosignoli[6], A. Doretti[7], E. Colombo[7], M. Albanese[8], G. Viticchi[9], S. Migliore[6], S. Sacco[6], C. Altamura[1|2]

[1]Headache and Neurosonology Unit, Fondazione Policlinico Universitario Campus Bio-Medico, Roma, Italy; [2]Department of Medicine and Surgery, Università Campus Bio-Medico di Roma, Italy; [3]Section of Health Statistics and Biometry, Department WHES (Wellbeing, Health & Environmental Sustainability), Sapienza University of Rome, Italy; [4]Department of Neurology, Vall d'Hebron Research Institute, Barcelona, Spain; [5]Headache Center, IRCCS Fondazione Istituto Neurologico "Carlo Besta", Milano, Italy; [6]Department of Biotechnological and Applied Clinical Sciences, University of L'Aquila, Italy; [7]Department of Systems Medicine, University of Rome Tor Vergata, Italy; [8]IRCCS Istituto Auxologico Italiano, Milano, Italy; [9]Neurological Clinic, Experimental and Clinical Medicine Department, Marche Polytechnic University, Ancona, Italy

Background. Onabotulinumtoxin-A (OBT-A) is a worldwide approved preventive treatment for patients suffering from Chronic Migraine (CM). The aim of the study was to o investigate whether the disease duration for over or less than 10 years can predict OBT-A effectiveness in patients with CM and to evaluate if psychopathological profile may influence their outcome.

Methods. We considered consecutive CM patients undergoing OBT-A treatment for the first time and collected Monthly Headache Days (MHDs), number of Monthly Acute Medications (MAMs), pain intensity by Numerical Rating Score (NRS), Head Impact Test (HIT-6) and Migraine Disability Assessment questionnaire (MIDAS) scores at baseline and after 3, 6, 9 and 12 months. The psychopathological profile was evaluated by Beck Depression Inventory (BDI-II), State-Trait Anxiety Inventory (STAI-Y), Toronto Alexithymia Scale (TAS-20) at baseline, 6 and 12 months. Effectiveness of OBT-A was also evaluated by the 4D Migraine composite scale, including 4 parameters: MHD, MAMs, NRS and MIDAS scores.

Results. We enrolled 183 patients (mean age 46.8 yrs, SD 15.7; 158 female); at baseline 67% had a CM history longer than 10 years, 37% were affected by depression, 36% by alexithymia and 9% by anxiety. The MHD, MAMs, MIDAS, HIT-6, NRS and 4D scores significantly decreased ($p<.001$) across the follow-up in the whole sample. In almost all cases, the trend was not influenced by disease duration, psychiatric comorbidities, or by their combination ($p>0.05$). Also TAS, STAI and BDI scores decreased during the one-year follow-up, suggesting a positive effect of OBT-A treatment also on psychiatric comorbidities. Those three scores decreased more in alexithymic, anxious and depressed patients beyond what expected for the regression-to-the-mean effect. However, those patients who presented BDI higher scores at 12 months in our sample tended to have lower benefit from the OBT-A treatment in the long term.

Conclusions. In our study OBT-A effectiveness was neither affected by disease history nor by psychiatric comorbidities. People with higher BDI scores at 12 months tended to have less benefit from the treatment.