SEVERE DISABILITY AND UNEMPLOYMENT ARE ASSOCIATED WITH NABIXIMOLS THERAPY DISCONTINUATION IN MS PATIENTS

L. MANCINELLI[1], F. POLIDORO[1], V. DI TOMMASO[1], M. DI IOIA[1], E. PIETROLONGO[1], D. TRAVAGLINI[1], G. DE LUCA[1], D. FARINA[1], A. LUGARESI[2,3]

1 Department of Neuroscience Imaging and Clinical Science - University "G. d'Annunzio" Chieti

2 Department of Biomedical and NeuroMotor Sciences (DIBINEM) - Alma Mater Studiorum University of Bologna

3 IRCCS Istituto delle Scienze Neurologiche – UOSI Riabilitazione Sclerosi Multipla – Ospedale Bellaria Bologna

Introduction

Sativex® (nabiximols) is the first endocannabinoid system modulator that has been approved as add-on therapy for Multiple Sclerosis (MS) patients (pts) with moderate to severe spasticity. Its efficacy is evaluated demonstrating a ≥20% improvement, 4 weeks after treatment start, in the patient's self-assessed Numerical Rating Scale (NRS) for spasticity.

Objective

To search for predictors of nabiximols therapy response, through a cohort analysis.

Materials and methods:

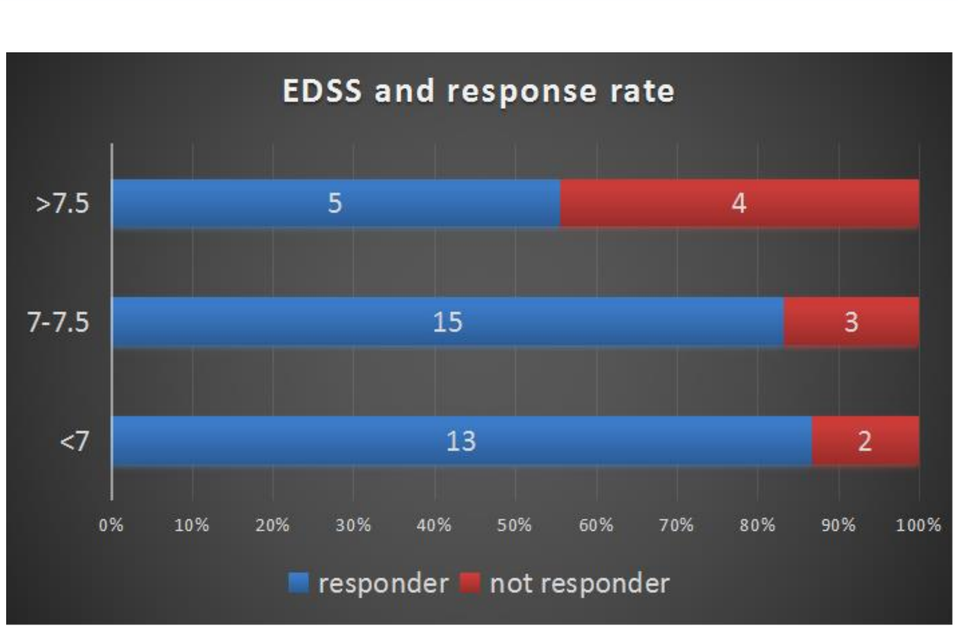
All patients treated with Sativex® for at least 6 months at the MS Centre of Chieti between April 2013 and October 2015 were included in the study. We analyzed data concerning demography (education and employment status included), disease (duration, course, disability, concomitant anti-spasticity drugs) and clinical status, with a particular focus on spasticity. Time points of evaluation corresponded to treatment start (T0), three and six months later (T1 and T2 respectively, only for pts continuing therapy after the initial 4-weeks trial period).

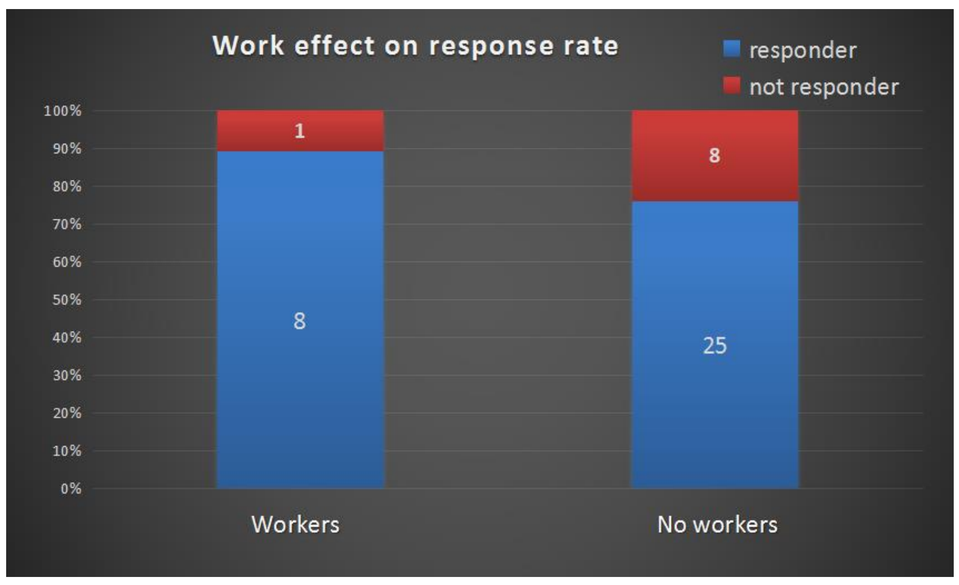
Results

A total of 42 pts met eligible criteria. They had a quite high Expanded Disability Status Scale (EDSS) score: 7.0±0.7, with a 60% ratio showing a progressive course of disease. Oral baclofen (48% of pts) followed by benzodiazepines (31%) and tizanidine (21%) resulted the most frequent concomitant anti-spasticity drugs. 33 pts (79%), defined as treatment responders, remained on therapy after the trial period, presenting a drop in the NRS score for spasticity from 8.8±1.5 at T0 to 6.2±1.5 at T1 (p=0.0061). Mean sprays/day number was 7.3±2.1. Dividing subjects in classes of disability (EDSS score <7.0, 7.0-7.5, >7.5) Sativex® response rate showed a decrease from 87% to 83% to 55%, respectively. Eight out of the nine worker pts (89%) were drug responder, versus twentyfive out of thirtythree (76%) between retired and unemployed ones (Fischer exact test: p=0.28); mean EDSS score was equal to 6.6 and 7.2, respectively.

Demographic and clinical data

Sex	25 women		17 men	
Age	54 ± 8	35-49: 36%	50-59: 40%	60-70: 24%
EDSS	7 ± 0.7	<7: 36%	7.0-7.5: 43%	>7.5: 21%
Course	RR: 40%	SP: 31%	PP: 19%	PR: 10%
N. puff daily	7 ± 2	<8: 43%	8-9: 40%	10-12: 17%
Education	pr./sec. school: 40%	high school: 45%	university: 14%	
Occupational status	workers: 9 pts (21%)		unemployed/retired: 33 pts (79%)	
NRS	T0: 8.8 ± 1.5		T1: 6.2 ± 1.5	





Discussion and conclusions

We found no correlations between therapy response and demographic and clinical data such as age, education level, course and duration of the disease. On the other hand, it emerged that both a higher disability and unemployment could predict a lower treatment response rate. This possible correlation needs to be confirmed in a larger sample of pts. Possible confounding factors such as depression, which is likely to be more prevalent among disabled and unemployed subjects, should be investigated.

Sin

XLVII CONGRESSO NAZIONALE
22-25 OTTOBRE 2016 – VENEZIA

WebPoster