NABIXOL (SATIVEX) IN SPASTICITY RESPONDERS MULTIPLE SCLEROSIS PATIENTS IS EFFECTIVE ON SUBJECTIVE BUT ON OBJECTIVE MEASURES OF WALKING ABILITY

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INTRODUTION

Spasticity is a common symptom and a major contributor to disability in Multiple Sclerosis (MS).

Spasticity has been estimated to affect between 40% and 81 % of all MS patients and it accounts for much of the disability affecting lower limb.

Several oral antispasticity medications are currently used for treating spasticity including baclofen, diazepam, gabapentin and tizanidine.

Delta-9-tetrahydrocannabinol (THC)/cannabidiol (CBD) [Sativex(®)] is an oromucosal spray formulation, approved in a number of countries, included Italy, as add-on therapy for moderate-to-severe MS treatment-resistant spasticity due to MS who have not responded adequately to other anti-spasticity medication.

The aim of the study is evaluate the effect of Sativex(®) on walking ability evaluated with subjective and objective scales.

METHODS

This was an observational, prospective study, conducted in 2 italian MS centres.

Data was collected using a face-to-face structured questionnaire compiled by a neurologist in MS patients according to recognized Polman criteria. The questionnaire included demographic data, year of symptom onset, diagnosis and degree of spasticity.

Patients with moderate to severe spasticity were included in the study.

A battery of tests including Symbol Digit (SD), Nine Hole Peg Test (9HPT), Fatigue Severity Scale (FSS), 12-item Multiple Sclerosis Walking Scale (MSWS-12), Two Minutes Walking Test (2MWT) and Timed 25-foot Walk (T25FW) was performed at baseline (T0) and 30 days later (T1).

Responders had been defined by the literature as subjects with an improvement at the numerical rating scale score (NRS) for spasticity greater than 20%.

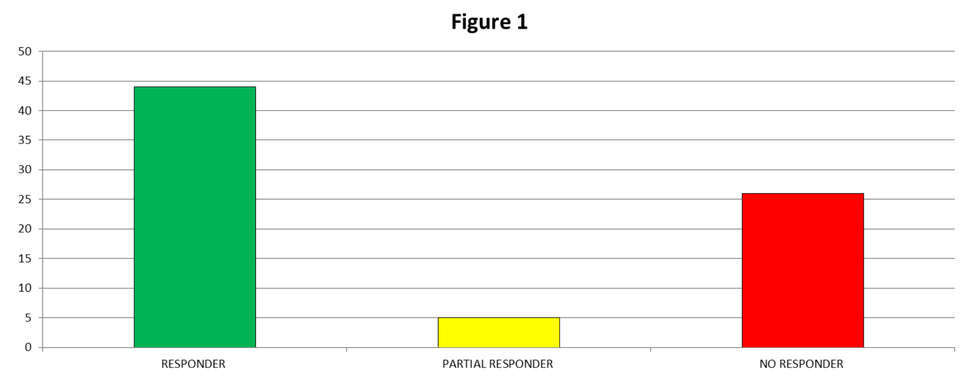
All data were registered in an ad-hoc database. The only exclusion criterion was a relapse in the last month before the beginning of the study.

RESULTS

Out of 75 subjects enrolled 33 were female and 42 male. Mean age was 53.7 years (range 28.26 – 81.43) , mean disease duration 13 years (range 0.7 – 39), 25 (29.3%) subjects had relapsing remitting, 34 (45.3%) secondary progressive and 19 (25.4%) had primary progressive disease course. Mean EDSS score was 6.2 (range 4 – 8.5). Mean NRS for spasticity at T0 was 7,8 (5-10)

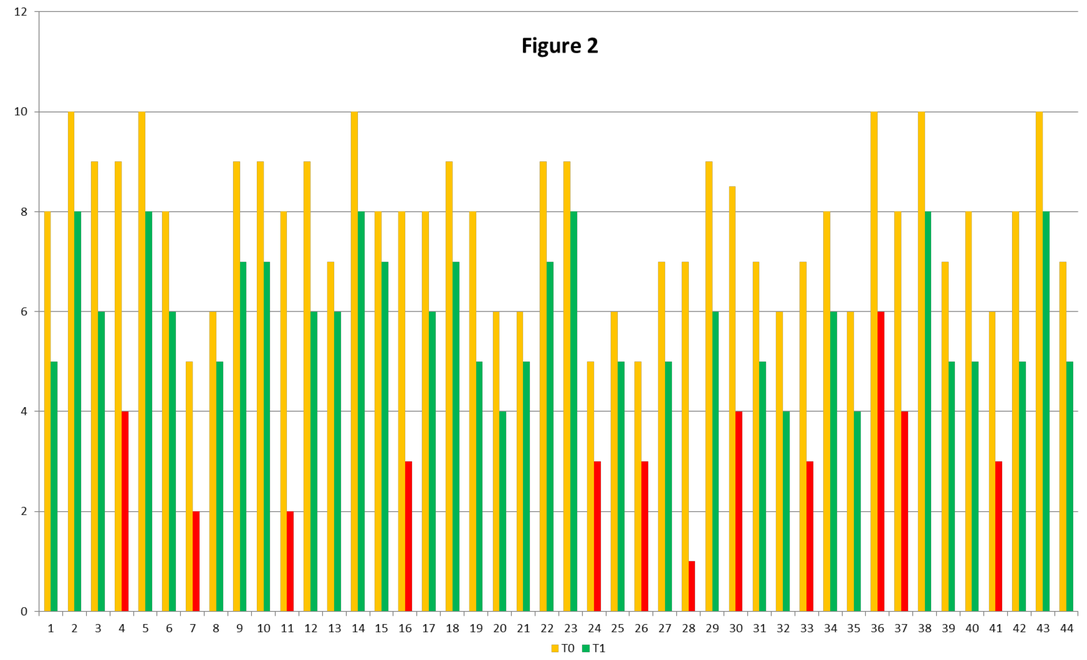
After 30 days later, a significant improvement (>20%) at NRS was observed in 44 patients (responders), 5 patients were partial responders (improvement < 20%), 26 patients were “no responders”. (figure 1)

Figure 1



Mean NRS for spasticity at T1 was 5 (range 3-8) and in 12 patients mean score decreased greater than >40%. (**Fig 2, red bars)**

Figure 2



Considering only patients able to walk (EDSS <= 6.5, n°32) mean NRS for spasticity at T0 was 7.9 (range 1-10) in 20/32 patients mean score decreased greater than >40%. MSWS-12 score decreased more than 6 points in 19/32 patients and an improvement (>20%) in FSS was reported in 5/32 subjects.

An improvement (>20%) in walking speed (T25FW) was observed in 2/32 patient and in endurance (2MWT) in only 1/32 patients. No patients improved in 9HPT, in TUG and SDT

CONCLUSIONS

Real-life data confirm Sativex(®) as an effective (58,6% responders) and well tolerated treatment option for MS patients with severe spasticity. A positive effect was highlighted on measuring patients’ perceptions scale such as fatigue, MS12 and NRS, while the effect on measuring walking performance was very low.

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