

5PSQ-081 **Δ-9-TETRAHYDROCANNABINOL (SATIVEX) FOR THE TREATMENT OF MULTIPLE SCLEROSIS SPASTICITY: EVALUATION OF EFFECTIVENESS AND SAFETY**

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Background Spasticity is a common and disabling symptom of multiple sclerosis (MS). The management of MS spasticity is centred around relief and functional improvement, evaluated with the Expanded Disability Status Scale (EDSS). Sativex oromucosal spray is a cannabinoid-based medicine used for adult MS patients with moderate to severe spasticity who do not respond adequately to first-line antispasticity medications. The patients who responded to Sativex showed an improvement from baseline in spasticity $\geq 20\%$ – 30% evaluated with a numerical rating scale (NRS) scores.¹

Purpose The aim of the study was to review the use of oromucosal spray Sativex in patients with moderate to severe MS.

Material and methods A retrospective cohort study was conducted in patients who began using Sativex between January 2016 and June 2018. The data was retrieved from the web-based register of the Italian Medicines Agency. The primary endpoint was the change in the degree of severity of spasticity assessed by the NRS scale and the evaluation of adverse effects in order to assess safety. The efficacy of Sativex was established by a medium reduction of 20%, according to the NRS scale, from the value at the baseline to the value of the last re-evaluation of the disease. The adverse effects were evaluated during the whole period considered.

Results Thirty-seven patients were evaluated, 70.27% of these were female. The medium age was 56 ± 9 years, the mean NRS and the mean EDSS score before treatment was 7.86 ± 1.00 and 5.95 ± 1.47 , respectively. A medium correlation was found between NRS and EDSS score ($R=0.669$; $F=29.903$; $p<0.0001$). The NRS score after treatment was 5.66 ± 1.04 ($\Delta = -2.20 \pm 0.68$), with a statistical significance ($Z=-5.829$; $p<0.00001$). All patients obtained a reduction $>20\%$ of the NRS score. The adverse effects detected were fatigue (8.1%), nausea (5.4%), headache (5.4%) and vertigo (2.7%).

Conclusion The symptomatic relief of spasticity led to quantifiable benefits in the ability to perform daily activities and it improved the patients' quality of life. These findings are in line with other studies, which show the use of Sativex as effective and well tolerated for the management of the spasticity of patients with MS with moderate to severe grade symptoms.

REFERENCES AND/OR ACKNOWLEDGEMENTS

- Giacoppo S, et al. *Multi SclerRel Disords* 2017;17
No conflict of interest.

5PSQ-082 **ABSTRACT WITHDRAWN**

5PSQ-083 **DEVELOPMENT AND VALIDATION OF QUALITY INDICATORS FOR BENZODIAZEPINE USE IN GENERAL AND MENTAL HEALTH HOSPITALS: SHORTCOMINGS OF AVAILABLE REIMBURSEMENT DATA**

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Background Quality of care monitoring is an important aspect in healthcare and depends on the availability of valid quality indicators (QI), easily obtainable from available data sources. This is important particularly for benzodiazepines and Z-drugs (BZD) given their important side effects, so good QIs are needed.

Purpose To develop QIs for BZD use in general and mental health hospitals, based on available reimbursement data (RD).