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 centered around relief and functional improvement, evaluated with the Expanded Disability Status Scale (EDSS) scale. The standard of care treatment is lacking for many patients for not responding, do not tolerate or become resistant to their antispasticity medications. Sativex oromucosal spray is a cannabinoid-based medicine used for adult MS patients with moderate to severe spasticity who not respond adequately to first-line antispasticity medications. The patients who responded to Sativex show an improvement from baseline in spasticity ≥ 20-30% evaluated with a numerical rating scale (NRS) scores, according to other studies(1-2).

Purpose

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

Materials and methods

A retrospective cohort study was conducted in patients who began Sativex between January 2016 and June 2018 and 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 evaluate of adverse effects 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, carried out after at least 4 weeks, and the adverse effects were evaluated during the whole period considered. The correlation between NRS score, EDSS score and age of patient was also evaluated with the statistical program SPSS.

Results

37 patients was evaluated, 70,27% of these was 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 age and NRS score ($R= 0,466$; $F= 10,628$ $\rho<0,003$) and between NRS and EDSS score ($R=0,669$; $F=29,903$; $\rho<0,0001$). The NRS score after treatment was 5,66 ±1,04 ($\Delta= -2,20 \pm 0,68$), with a statistical significance ($Z=-5,829$; $\rho<0,00001$). All patients obtained a reduction >20% of the NRS score. The adverse effect detected were fatigue (8,1%), nausea (5,4%), headache (5,4%) and vertigo (2,7%).

Conclusions

The symptomatic relief of spasticity led to quantifiable benefits in the ability to perform daily activities and it improved their quality of life. The use of Sativex was effective and well tolerated in the management of the spasticity of patients with MS with grade moderate to severe symptom, and is an effective alternative for the classical antispasticity medications.

Bibliography

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