Estudio de la Utilidad de la electromiografía de superficie en la detección de diferencias objetivas en pacientes con espasticidad debida a Esclerosis Múltiple identificados como "respondedores" y "no respondedores"en tratamiento con Sativex. ELDESSA Study

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Report of results

Spasticity is one of the most challenging problems to treat in patients with Multiple Sclerosis (MS), leading to important impairment of quality of life.

A new drug, Sativex®, a product derived from cannabinoids, has recently been approved for the treatment of spasticity. Around 35-50% patients report an improvement on their spasticity and quality of life while on this drug.

Although efforts have been made to objectively measure spasticity, currently available scales are rather subjective and have a low inter-rater consistency.

The aim of this study was to test the sensibility of electromyography (EMG) in detecting and measuring spasticity; and secondly to assess whether Sativex is able to improve objective neurophysiological parameters. A secondary objective was to evaluate whether improvement reported by patients was related to psychological effects of the drug rather than physical.

Material and Methods

The study was carried out in fourcentres in Madrid, Spain: three of the centres recruited MS patients and the fourth centre made centralized EMG assessment.

It was designed as a pilot prospective observational study. Inclusion criteria where patients with MS diagnosis going to start Sativex according to label conditions. According to manufacturer, Sativex prescription should be re-assessed four weeks after initiation to detect patients who do not respond to the drug. Evaluation of response status is made by Ashworth scale and Numeric Rating Score (NRS). When a patient is not considered responder, drug termination is recommended.A responder patient was defined as a patient with an improvement of at least 20% measured by NRS and/or Ashworth Scale.

We then defined two groups: clinically responders and not-responders. Only responders continued with Sativex. Both groups were followed-up for four additional weeks.

EMG was done three times: study start, four weeks and at eight weeks. EMG was done by two explorers (A.T. and I.S.) in a blind-manner.

Results

Despite efforts to include eleven Centres from Madrid in this study, ethics committees allowed only four centres to be involved in the study, making recruiting hard.

From an initial objective of 30 patients, only eight patients were recruited: 7 at Gregorio Marañon Hospital, 1 at Severo Ochoa hospital and 1 at Infanta Leonor Hospital. 9 patients completed study as per protocol.Data were lost for one patient (Infanta Leonor Hospital), so final analysis was made on 8 patients.

3 patients had a Relapsing-Remitting MS in the responders group (group A), 4 remaining patients had a secondary Progressive MS. In the not-responder group (group B), the patient had a secondary progressive MS. 3 patients in group A were female. The remaining patients (5) were male. Mean basal EDSS was 6,29 for responders and 6,5 for the not responder. Mean Ashworth Scale at baseline was 37,14 in group A and 54 in group B; basal NRS was 8,71 in group A and 9 in group B. 2 patients in group A did not use other antispastic treatments. 1 patient was on tizanidine 6mg QOD, 3 on baclofen 10mg TID and 1 on baclofen 50mg QOD. Not responder was on baclofen 62,5mg QOD.

At week 4, only 1 patient was classified as 'not responder', the remaining 6 were responders to Sativex. With this little population, no stratification on responder/not-responder status could be made.

Neurophysiological data were incomplete due to data lost on EMG computer breakdown. On recovery, only partial data were obtained after the study. Thus, the primary objective of the study could not be carried out due to the paucity of available data.

There were statistically significant differences between NRS basal and Visit 1 in responders (med 8 vs 5 respectively, z-score -2,71, $p<0,00001$), but not in Ashworth scale. These differences continued in visit 2 but did not differ between V1 and V2.

We analyzed MsQoL-54 throughout groups and found no statistically relevant differences on Sativex responders between basal visit, visit 1 or visit 2 in either emotional or physical parameters. Our study is probably not powerful enough to detect differences due to the lack of recruitment.

Mean Sativex dose was 9,2 pulverizations/day

Conclusions

Due to lack of recruitment, and technical issues, primary objective of this study was not reached. Data were insufficient for further analysis.

On these grounds, no publication is expected.