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Title: Unicenter double-blind, cross-over, randomised, placebo controlled clinical trial to evaluate efficacy of vardenafil in subjects with E.D. and multiple sclerosis (M.S.)

Sponsor: Unidad de Neuroinmunología Vall Hebron Hospital

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SUMMARY OF RESULTS:

Background & Aims

Multiple sclerosis (MS) is a chronic disease usually diagnosed in young adults (aged 20 to 40), characterized by alterations in the nervous connections between the brain and the bone marrow and the rest of the body due to demyelination. Up to 91% of the men with MS can present sexual dysfunction as the disease directly affects the nerves related to sexual response or because of some of the disease's symptoms, such as fatigue or spasticity.

Main objective was the evaluation of the efficacy of flexible doses of vardenafil on the erectile function (punctuation obtained on the erectile function domain of the IIEF questionnaire) in patients affected of multiple sclerosis and erectile dysfunction.

Secondary objectives were:

- Effect of the influence of vardenfil on intercourse satisfaction.
- Patient satisfaction with treatment.
- Tolerability of vardenafil on patients suffering from MS.

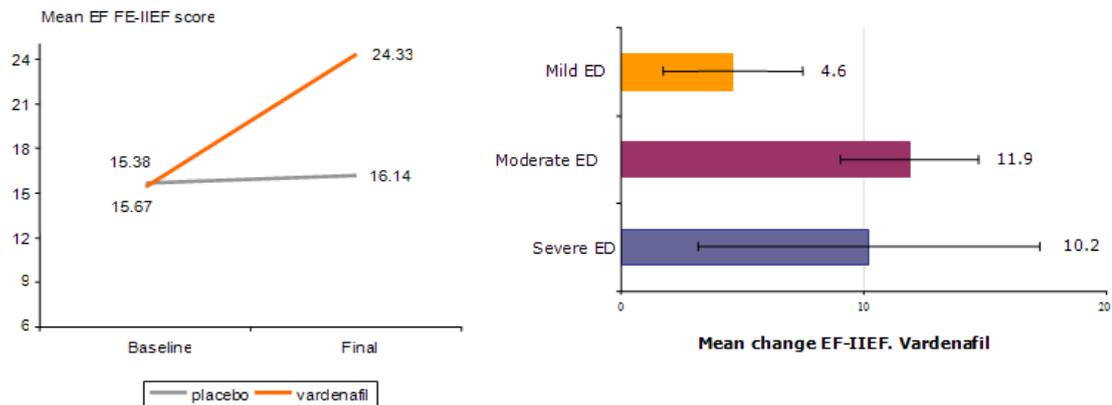
Methods

A multicentre, crossover, randomised, double-blind clinical trial was conducted in 21 men, aged from 18 to 64, mean age 43.5 years (SD 8.8), diagnosed with MS and ED to compare vardenafil and placebo. The disability of the patients with MS was assessed by the Expanded Disability Status Scale (EDSS). The severity of ED and the study's primary efficacy endpoint was determined by the score on the erectile function (EF) subscale on the IIEF survey (sum of items 1-5 and 15).

Results

A total of 57.1% of the men showed mild-moderate disability ($EDSS \geq 3$). With regards to severity of ED: in 33.3% mild, in 38.1% moderate and in 28.6% severe ED

was encountered. Treatment with placebo produced only a change of 0.48 (SD 4.43; CI -1.54;2.49) [mild ED: 0.7/moderate ED: 1.4/severe ED: -1.0]. Treatment with vardenafil resulted in a statistically significant change of 8.95 points above baseline (see figure 1) (SD 6.37- CI 6.05;11.85) [mild ED: 4.6/moderate ED: 1.9/severe ED: 10.2] (see figure 2), significantly better than placebo (p:0.0002; crossover design ANOVA). After four weeks of vardenafil treatment, the percentage of patients having no longer erectile dysfunction rose from 5.9% at baseline to 76.5%. There were no adverse effects and none of the patients dropped out of the study.



Figures 1 & 2. Evolution of the EF-IIEF score in patients treated with vardenafil.

Conclusions

While MS is primarily a neurological disorder and vardenafil primarily a vaso-active agent, vardenafil appeared to be an effective and well- tolerated drug in the treatment of erectile dysfunction in patients with multiple sclerosis.

Naturally, the approach to ED in patients suffering from MS should be comprehensive and should be part of an integral approach to their disabilities and psychological factors contributing to the problem of ED.