Title: Optical coherence tomography in secondary progressive multiple sclerosis: a baseline data report from the MS-SMART trial

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Abstract

Background: Secondary progressive multiple sclerosis (SPMS) is characterized by accumulation of irreversible disability due to neuroaxonal loss. Optical coherence tomography (OCT) is a promising technique to predict multiple sclerosis (MS) progression by evaluating changes in the retinal nerve fibre layer (RNFL), the macular volume (MV), and the retinal ganglion cell (RGC) layer.

Aim: To report early descriptive data of the cross-sectional baseline OCT and clinical measures in a cohort of SPMS patients enrolled in the MS-SMART trial (ClinicalTrials.gov NCT01912059). The MS-SMART trial is an ongoing UK multi-centre, multi-arm, double-blind, placebo-controlled phase IIB randomised controlled trial for 440 patients with worsening SPMS randomised 1:1:1:1 between placebo, amiloride, riluzole and fluoxetine. The primary endpoint is brain atrophy (percent brain volume change) on structural magnetic resonance imaging at 96 weeks. A planned sub-group of patients are being evaluated in 2 centres (London/Edinburgh) with OCT.

Methods: In this analysis, for patients without a history of optic neuritis (ON), OCT measures were calculated as the means of the values for both eyes; for those with a history of ON, only the non-affected eye was included. We examined baseline data for the following clinical variables: age, sex, MS duration, SPMS duration, Expanded Disability Status Scale (EDSS), Multiple Sclerosis Functional Composite (MSFC), Symbol Digit Modality Test

(SDMT) and Sloan low contrast letter visual acuity (SLCVA) charts at 5%. Temporal RNFL thickness (µm), macular (full thickness) volume (mm^3) and RGC layer volume (mm^3) were evaluated using spectral-domain OCT (Spectralis, Heidelberg Engineering, Germany).

Results: A total of 104 patients (69F) were evaluated. The mean [SD] baseline features were: age 55.1yrs [6.5], disease duration 23.6yrs [10.2], disease progression 8.2yrs [6.0]. The mean [SD] clinical disability measures were: EDSS 5.8 [SD 0.82, median 6], MSFC 0.11 [0.35], SDMT 44.9 [10.6], SLCVA 5% 33.4 [11.5]. 40% of the total number of patients had contralateral ON. The mean values [SD] for OCT measures were: temporal RNFL 56.1 [15.3], MV 8.2 [0.45], and RGC volume 0.9 [0.14].

Conclusion: The study population enrolled in the MS-SMART trial represents a large cohort of subjects in which OCT and disability measures will be followed longitudinally over the next 2 years.

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