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Title: Long-term follow up of an Italian cohort of pediatric Multiple Sclerosis patients

Shirt Title: Real world data from San Raffaele Hospital

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Background: Multiple Sclerosis (MS) onset during childhood occurs in 3%-10% of cases. Pediatric MS (ped-MS) is characterized by relapsing-remitting course and high relapse rate. Data on disease modifying treatments (DMTs) in ped-MS are scarce and derive from observational studies. Our aim is to present baseline characteristics and long-term follow up (FU) of an Italian cohort of ped-MS subjects.

Methods: Data regarding MS onset, annualized relapse rate (ARR), Expanded Disability Status Scale (EDSS) score and treatments were retrospectively collected from clinical records at San Raffaele Hospital MS Center.

Results: 144 patients (101 females) were included, mean age at onset and at last FU 14.4±2.6 and 24.7±6.1 years. 109 subjects had a monofocal onset. Mean ARR and median EDSS at onset were 4.5±4.9 and 1.5 (0-6). Mean FU was 9.8±6.6 years. Mean age at therapy initiation was 15.1±2.1 years and 59.7% of subjects were initially treated with interferon-beta (IFN). Induction at onset was performed in 4.9%, while second-line treatments as first therapy were chosen in 17.4%. 50.5% of subjects were treated with Natalizumab, 13.2% as first therapy. 82.6% underwent at least one switch, the first after a mean of 2.3±3.3 years, predominantly to high-frequency IFN; subsequent switches were mainly to second-line therapy. ARR was reduced during first treatment (from 4.4±4.7 to 0.8±1.8) and last FU (0.02± 0.1), p>0.001 in both instances. 15.3% of subjects had an EDSS worsening, while 76% had no evidence of clinical disease activity at last FU. A polyfocal disease onset seemed to be associated with a higher risk of disability progression (OR 0.3, p=0.08).

Conclusions: Ped-MS patients benefited from first-line agents, but the majority had to switch to more powerful DMTs. A polyfocal onset seemed to be associated with an increased risk of disability progression. Our findings highlight the importance of treatment selection and accurate clinical FU in ped-MS population.