Clinical Course and Therapeutic Management of Secondary Progressive Multiple Sclerosis in France: a retrospective real-world multicentric observational study (ODYSSEP Study)

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Introduction

Background

- The French Multiple Sclerosis Registry (OFSEP) is a French national cohort of people with multiple sclerosis (MS)[1]. The OFSEP project aims at collecting data in a routine clinical setting, to foster clinical, basic and translational research in MS and involves 41 hospitals. The database included 62,062 patients at June 15, 2019.
- There is little descriptive data about Secondary Progressive Multiple Sclerosis (SPMS) in France, notably because of the lack of therapeutic options to slow down the disease progression during that phase

Objective

- To describe patients characteristics, clinical course and therapeutic management in an observational multicentric cohort of French SPMS patients in order to get an up-to-date picture of the SPMS patients and disease-modifying therapies (DMT) used in France

[1] *Confavreux C, Compston DAS, Hommes OR, McDonald WI, Thompson AJ. EDMUS, a European database for multiple sclerosis. J Neurol Neurosurg Psychiatry 1992; 55: 671-676*

Methods

General design

- Retrospective observational study using the OFSEP database (see *www.ofsep.org* for details)
- Inclusion criteria
  - Patient with neurologist-based diagnosis of SPMS fulfilled in the OFSEP database
  - With at least one clinical examination within the inclusion period (2013, January 1st to 2019, June15th), at distance of +/- 6 months from neurologist-based SPMS diagnosis
- Sensitivity analysis based on an automatized SPMS algorithm[1]
  - Patients with an increase in EDSS score between two clinical assessments separated of at least 12 months
  - Without any activity (relapses and/or evidence of new MRI activity) between these two assessments

Statistical analyses

- Description of
  - Patients characteristics (age, sex, date of onset, etc.)
  - Disability (EDSS score)
  - Activity (relapses, MRI)
  - Treatments (1st line / 2nd line / off-label / temporary authorization / clinical trial / none)

At three moments:

- ✓ **At conversion into SPMS**
- ✓ **During the whole SP phase**
- ✓ **At the last clinical evaluation**

[1] *Lorscheider, J. et al. Defining secondary progressive multiple sclerosis. Brain J. Neurol. 139, 2395–2405* (2016)

Results - Patients' characteristics

- 3140 patients with SPMS included in the main analysis
- 454 additional patients detected through the automatized algorithm

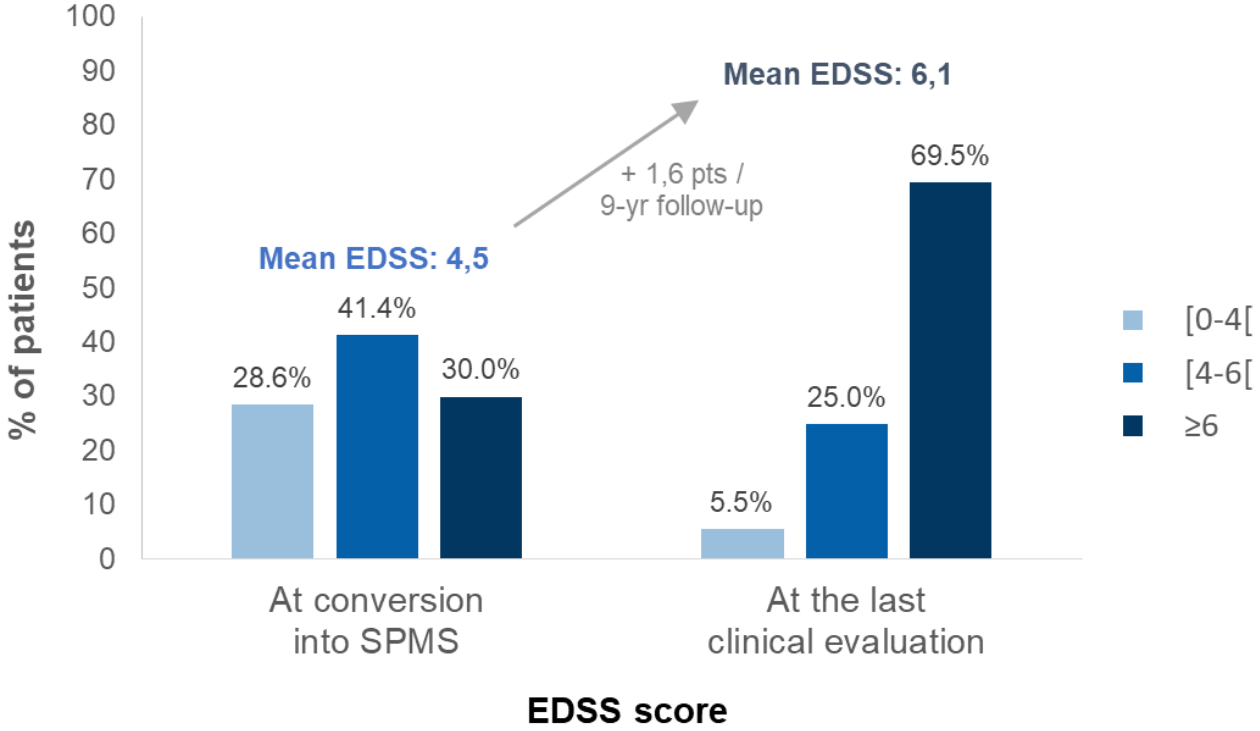
Characteristics of the 3140 patients with SPMS included in the main analysis

	At SP diagnosis	At the last evaluation
Mean age, years	45.7	54.5
Women, %	67.8	
Mean duration of MS since diagnosis, years	13.7	22.5
Mean duration of SP phase, years		8.8
Activity* in the previous year, %	50.2	14.1
Relapse in the previous year, %	45.6	10.3
Relapse during SP, %	26.6	
EDSS score, mean	4.5	6.1
EDSS score, median [min-max]	4.5 [0-8.5]	6.0 [0-9.5]

** Defined as any relapse and/or evidence of new MRI activity*

Results - Disability after ≈ 9 years of follow-up

All patients (n=3140)



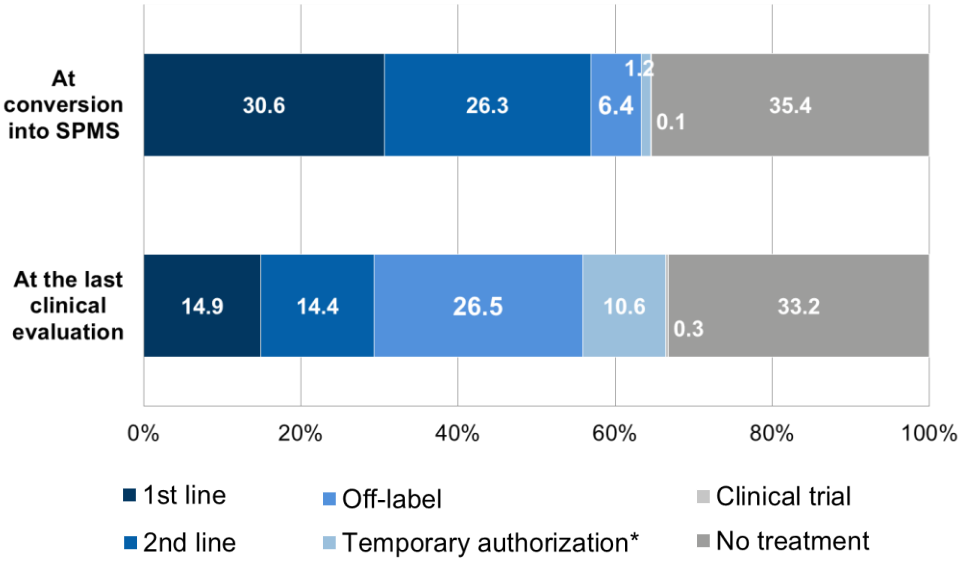
Results - Disability evolution after ≈ 2.5 years of follow-up

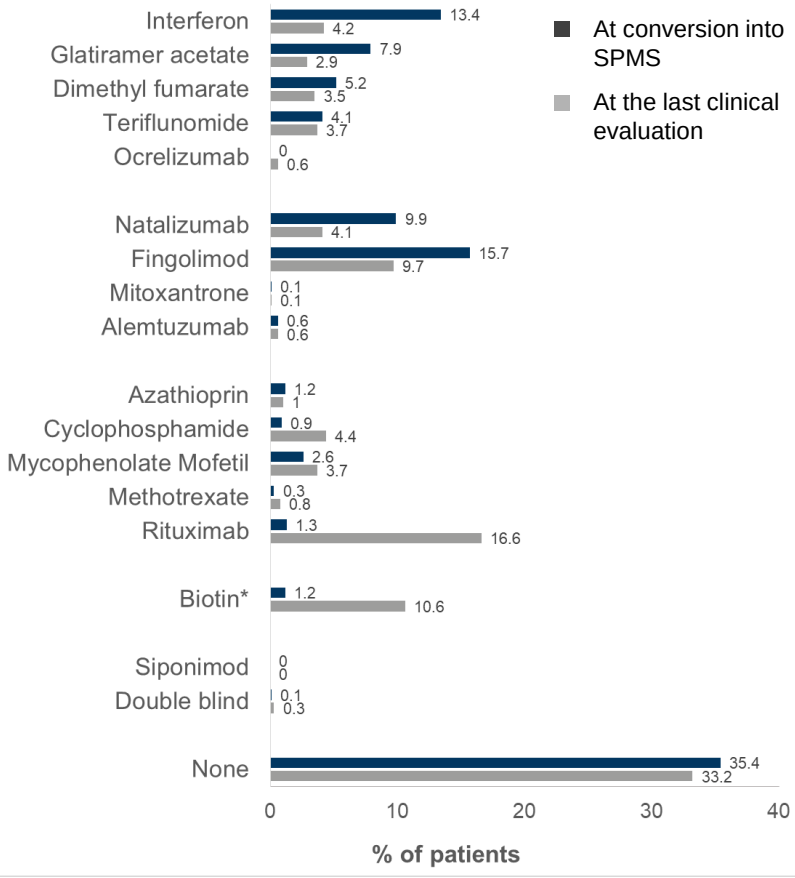
SPMS diagnosed over 2013 (n=908)

EDSS score at SP phase transition	EDSS score at the last clinical evaluation: [0-4[	[4-6[	[≥6[
[0-4[	91 (40.4%)	88 (39.1%)	46 (20.4%)
[4-6[	3 (0.8%)	221 (61.4%)	136 (37.8%)
[≥6[	0 (0.0%)	22 (6.8%)	301 (93.2%)

Results : treatments

SPMS diagnosed after 2013 (n=908)





19.8% of patients received no treatment during the whole duration of the SPMS phase

** Patients treated with biotin only*

Discussion / conclusion

- Most of SMPS patients were diagnosed based on neurologists expertise (only 454 supplementary patients were detected through the automatized algorithm
- This large and multicentric real-world cohort allowed a reliable up-to-date description of treatments used for SPMS
- Most of patients are either untreated or take off-label drugs:
  - Highlights the lack of satisfactory therapeutic options
  - Reflects the need for new therapeutic alternative approved for SPMS

References

- *Confavreux C, Compston DAS, Hommes OR, McDonald WI, Thompson AJ. EDMUS, a European database for multiple sclerosis. J Neurol Neurosurg Psychiatry 1992; 55: 671-676*
- *Lorscheider, J. et al. Defining secondary progressive multiple sclerosis. Brain J. Neurol. 139, 2395–2405 (2016)*