PANGAEA 2.0 EVOLUTION: Clinical and non-clinical parameters in the early assessment of SPMS patients in clinical routine

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Disclosures

- Christoph Lassek received speaking honoraria and financial support for research activities from Biogen, Bristol Myers Squibb, Celgene, Janssen-Cilag, Merck, Novartis, Roche, Sanofi and Teva.
- Cordula Weiss is an employee of Novartis Pharma GmbH, Germany.
- Tjalf Ziemssen received speaking honoraria and financial support for research activities from Almirall, Biogen, Celgene, Novartis, Roche, Teva, and Sanofi.

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Introduction

- 85% of MS patients are diagnosed with relapsing remitting multiple sclerosis (RRMS)[1] and 60% will convert to secondary progressive multiple sclerosis (SPMS) within 20 years due to evolvement of the disease over time[2,3].
- Inconsistent criteria to define the transition from RRMS to SPMS and previous lack of treatment options for SPMS led to late and mostly retrospective diagnosis of SPMS[4,5].
- PANGAEA 2.0 is a post-authorization, non-interventional study in MS patients. The study aims to better understand the disease progression of MS and especially the conversion from RRMS to SPMS with the goal to develop new diagnostic tools. A new study arm was added to PANGAEA 2.0, termed PANGAEA 2.0 EVOLUTION and focusing on RRMS-patients with high risk for SPMS and SPMS patients.
- Objective: The aim of PANGAEA 2.0 EVOLUTION is to evaluate and compare clinical parameters and patient reported outcomes of patients with RRMS at high risk to develop SPMS with SPMS patients in order to characterize the transition between these two stages of MS.

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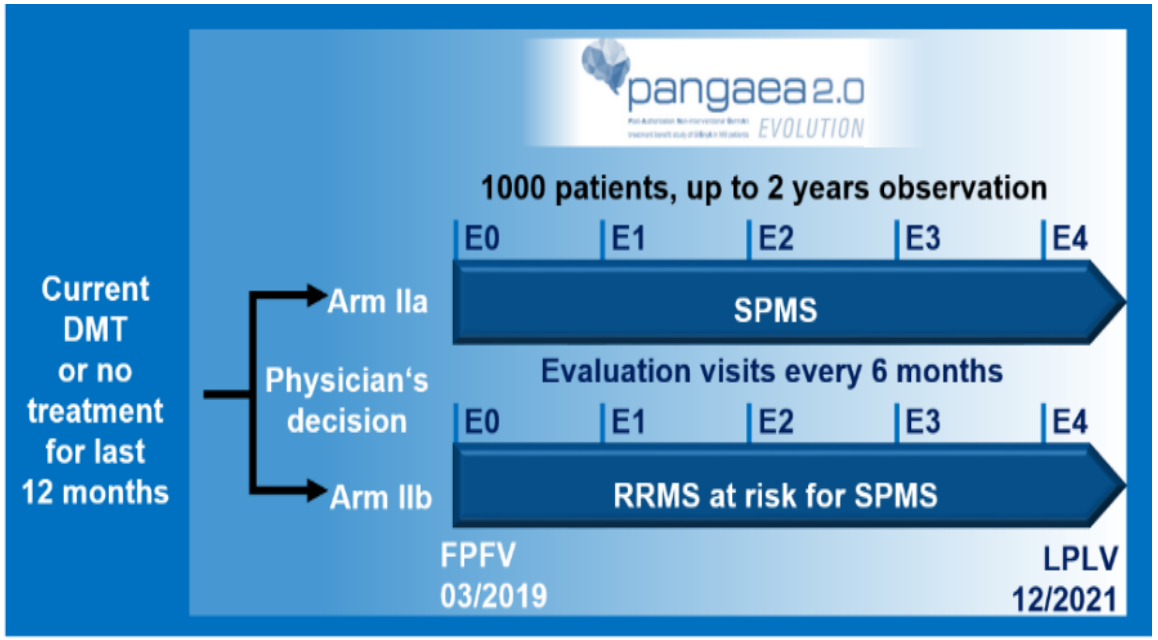
Methods

- In the prospective non-interventional study PANGAEA 2.0 EVOLUTION 609 patients with either SPMS or RRMS at high risk for SPMS were followed independently of treatment for up to 2 years (**Fig. 1)**.
- Physicians independently assigned patients to either the ‘SPMS’ (SPMS cohort, Arm IIa) or the ‘high risk for SPMS’ (High Risk cohort, Arm IIb) cohort after a comprehensive evaluation of symptoms according to daily practice.
- Routine clinical measurements were documented at 6-month intervals.

Figure 1. Study Design.



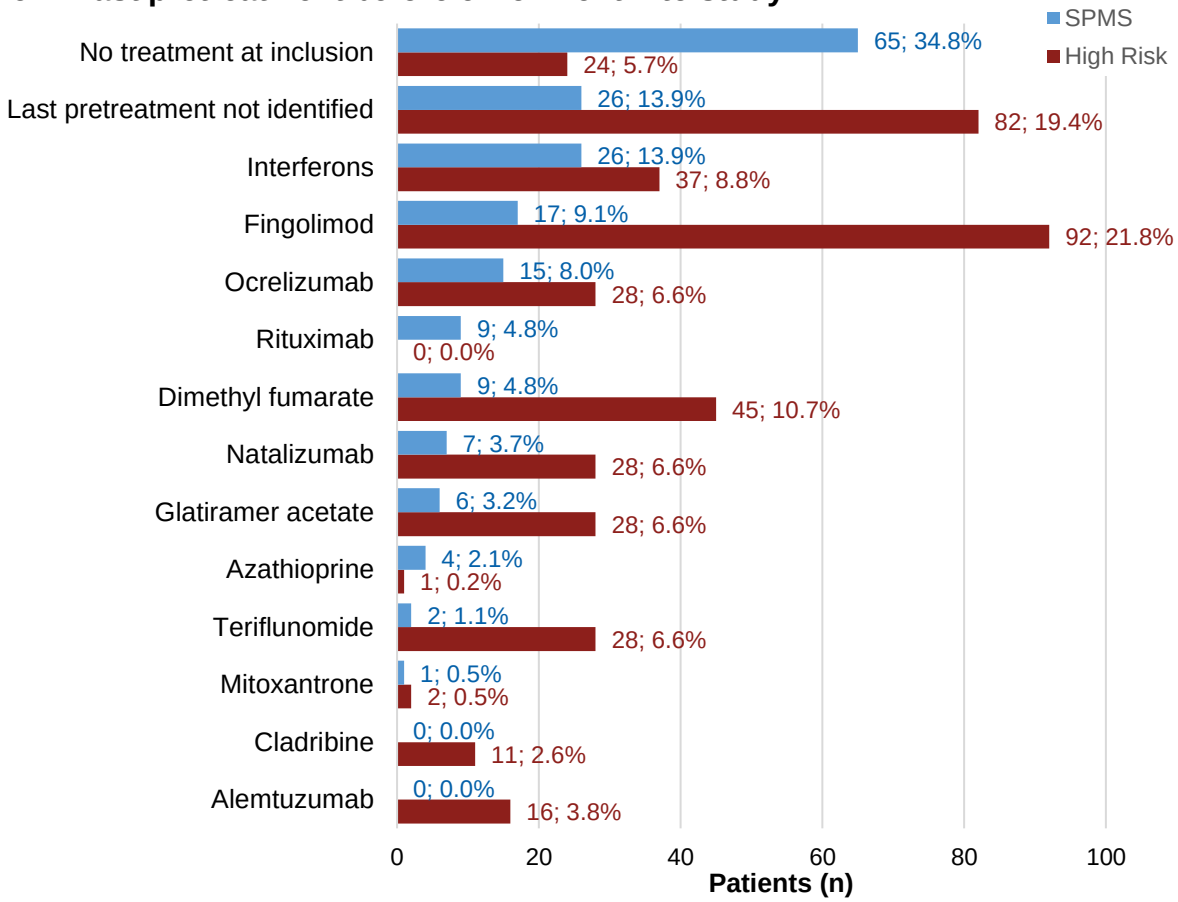
Results

- The baseline characteristics of the study population are shown in **Table 1**. The diagnosis of the SPMS cohort was longer ago and SPMS patients had a higher EDSS than the High Risk cohort at baseline.
- Despite having a similar average number of pretreatments (**Tab. 1**), most SPMS patients did not receive any treatment at enrollment into the study, more than 20% High Risk patients were on fingolimod (**Fig. 2**).

Table 1. Baseline characteristics of RRMS patients at high risk for SPMS (High Risk) and SPMS patients.

Variable	High Risk	SPMS
Number of patients, n	422	187
Mean age, years±SD	49.5±9.0	53.7±7.1
Female, n (%)	301 (71.3)	141 (75.4)
Mean time since diagnoses, years±SD	14.0±8.0	17.2±9.5
Mean number of relapses in 24 months before inclusion, n±SD	0.46±0.89	0.28±0.66
Mean number of pretreatments, n±SD	2.4±1.4	2.1±1.5
EDSS. score±SD	4.2±1.1	5.1±1.1

Figure 2. Last pretreatment before enrollment into study.



Results

- FSMC score of the SPMS cohort remained stable over 24 months while a worsening was observed for RRMS patients at high risk for SPMS (High Risk cohort) (**Fig. 3)**.
- After 24 months, the motor fatigue score of the SPMS cohort had improved slightly while the initially lower score of the High Risk cohort had worsened (increased) to match the average score of the SPMS cohort (**Fig. 4**).
- The cognitive fatigue scores of both cohorts increased with a slightly higher worsening seen in the High Risk cohort (**Fig. 5**).

Figure 3. Mean FSMC total score at baseline (BL) and after 24 months (24M).

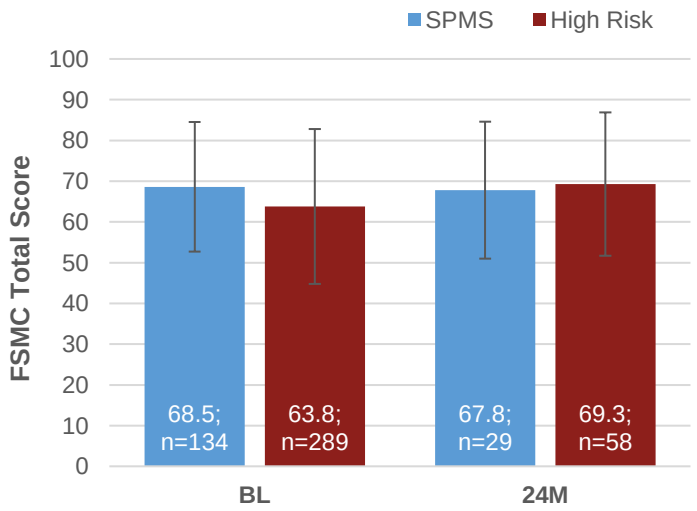


Figure 4. Mean FSMC motor score at baseline (BL) and after 24 months (24M).

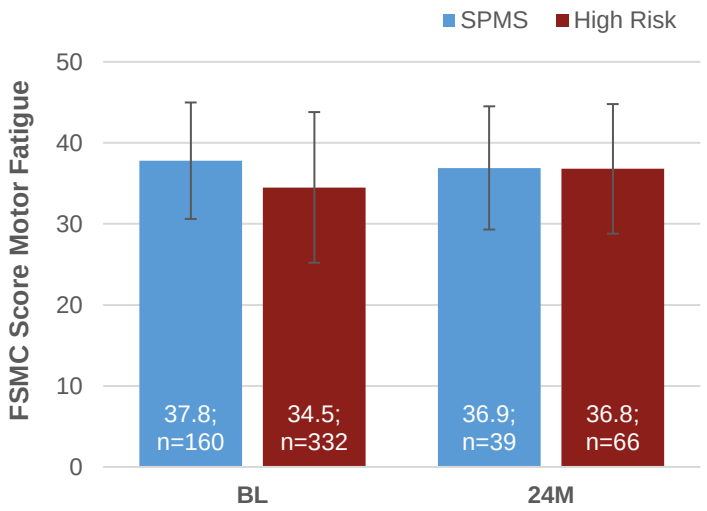
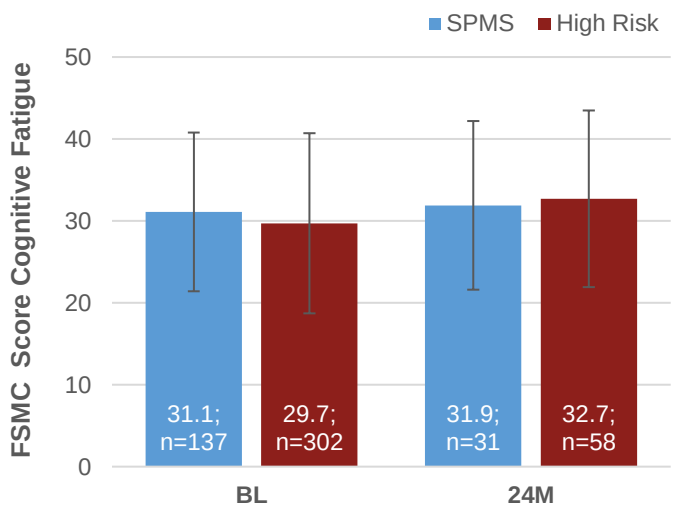


Figure 5. Mean FSMC cognitive score at baseline (BL) and after 24 months (24M).



Conclusion

- SPMS patients presented with a higher EDSS score at baseline compared to RRMS patients at high risk for SPMS.
- SPMS patients and RRMS patients at high risk for SPMS have been prescriber a similar number of pretreatments.
- The total FSMC score of SPMS patients remained stable over 24 months. In contrast, the total FSMC score of RRMS patients with risk for SPMS worsened.
- The average motor fatigue score of RRMS patients with high risk for SPMS worsened over 24 months and reached the same average score documented for SPMS patients.
- The cognitive fatigue of all patients worsened slightly over 24 months.

→ The combination of clinical and non-clinical parameters in individual patient profiles can support the early diagnosis of SPMS.