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Clinically Defined Conversion to SPMS Approaching Objectively Data-driven Incidence in RWE in the Czech Republic in years 2016-2021

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CONCLUSIONS

- The ReMuS registry data reveals an increase in the annual incidence of newly clinically diagnosed Secondary Progressive Multiple Sclerosis (SPMS) patients in the Czech Republic from 2016 to 2021, which is approaching data-driven incidence rate.
- The SPMS prevalence according to ReMuS for 2021 was 11.05 cases per 100,000 inhabitants, based on clinically assigned diagnoses – consistent with the EU, which ranges between 3-50 per 100,000 in EU (Ziemssen et al., 2023).

INTRODUCTION

- Secondary progressive multiple sclerosis (SPMS) leads to progressive neurological disability.
- With the new therapeutic options for SPMS, Siponimod has received reimbursement in the Czech Republic as of 2021. This makes early and correct diagnosis even more important, but clinical diagnosis is often made retrospectively and with a delay.
- (Lorscheider et al., 2016) provides a standardized, more objective, data-driven definition of SPMS with the possibility for earlier diagnosis.

OBJECTIVE

- To determine the number of newly diagnosed SPMS patients in the Czech Republic and describe their characteristics at SPMS diagnosis before Siponimod reimbursement (years 2016-20) and in 2021.
- To describe similarities between Clinical (C) and objective Data-driven (D) diagnosis of SPMS patients' cohorts.

METHODS

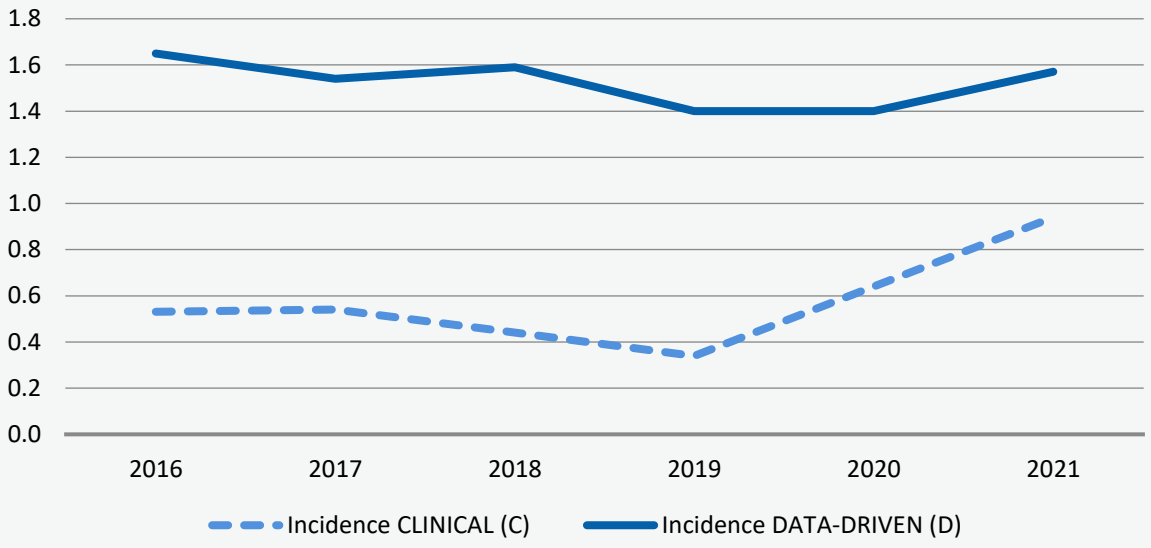
We used secondary data from 17,864 patients with MS who have been followed in the Czech national MS registry (ReMuS) during the period 2016-2021. We analysed:

- changes in the number of SPMS patients and their characteristics at SPMS onset (demographic, working status, EDSS, prior ARR, and active disease modifying treatment (DMT) class: platform (P-DMT) and high-efficacy DMT (HE-DMT)) in years 2016-20, 2021, and
- convergence of Cohort C to D. The reported incidence and prevalence rate is per 100,000 population.

RESULTS

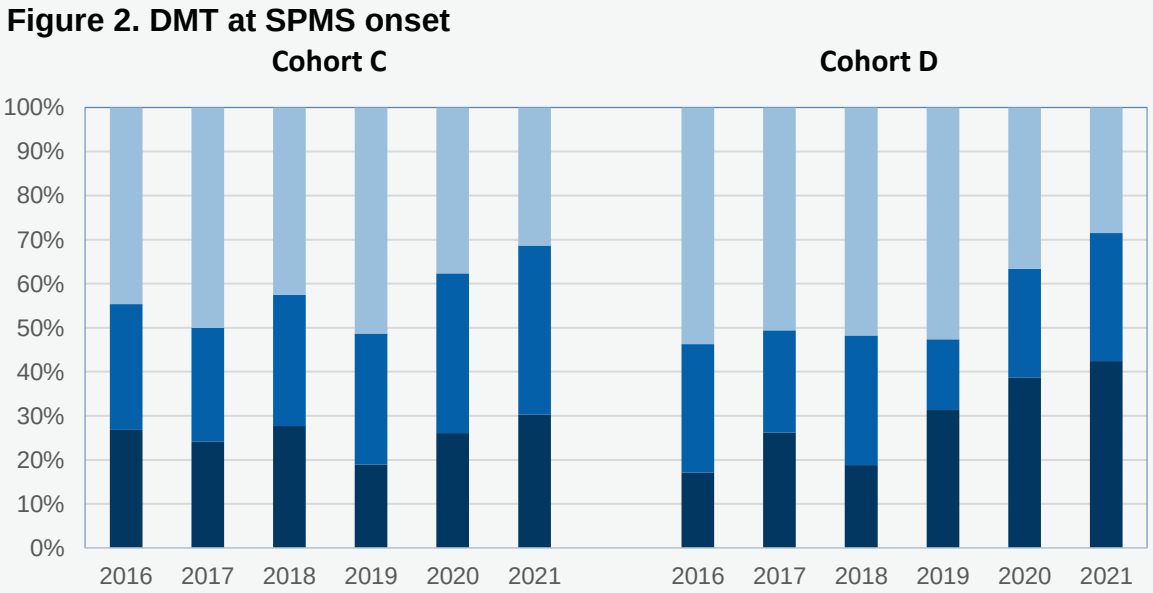
- The annual incidence of **clinically diagnosed SPMS** patients in the ReMuS registry increased from an average of 53 (incidence rate 0.34-0.64) in 2016-2020 to 99 (0.94) in 2021 for Cohort C. This is approaching the rates for Cohort D, which relies on objective, **data-driven diagnoses**, with an incidence rate of 162 (rate 1.4-1.65) and 165 (1.57) for the same periods (**Figure 1**).
- Due to the requirement of historical data at the time of SPMS conversion for data-driven methods, the prevalence of SPMS in the Czech Republic can only be calculated for clinically assigned and followed patients in the ReMuS Registry. In 2021, the prevalence rate was stood at 11.05 SPMS patients per 100,000 population.
- No significant demographic differences exist between Cohorts C and D. Both had approximately 65-69% females. The mean age for Cohort C was 49.8±9.4 years during 2016-20 and 49.3±8.6 in 2021. For Cohort D, it was 50.2±10.7 (2016-20) and 51.0±11.56 (2021).
- The proportion of DMT at SPMS onset has changed for cohort C as follows: HE-DMT 25.1 % (average in 2016-20) to 30.3 % (2021), PDM-T 30.3 to 38.4, for D: HE-DMT 26.0 % to 42.4 %, PDM-T 24.7 to 29.1 (**Figure 2**).
- Median EDSS for Cohort C increased slightly from 5.0 to 5.5, while Cohort D remained stable at 6.0. Median ARR before SPMS diagnosis decreased in Cohort C to align closer with Cohort D (**Figure 3**).
- Duration to SPMS diagnosis prolonged for Cohort D from 15.2 to 17.2 years, but remained stable for Cohort C at around 16 years.
- A notable increase in working patients at SPMS onset was observed in Cohort D (from 34% to 50.7%), while Cohort C remained stable (44.3% to 45.7%) (**Figure 4**).

Figure 1. Incidence Rate of SP patients (yearly)



Footnotes: SPMS patients' cohorts: C–Clinically diagnosed; D–Objectively Data-driven dg.
INC C/D-Incidence Rate of SP patients per 100,000 population in the Czech Republic.

Figure 2. DMT at SPMS onset

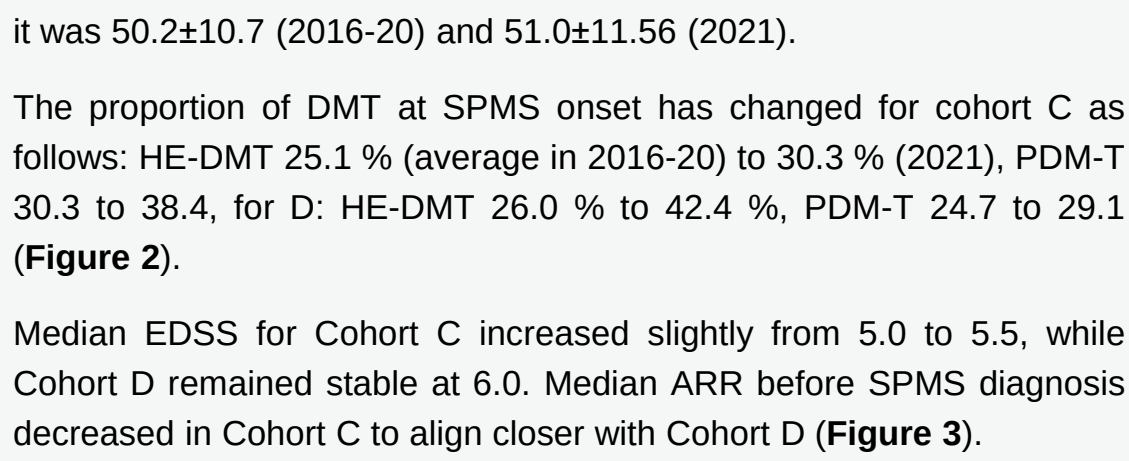


Footnotes: Stacked columns on the left-side of column chart illustrate the proportions of DMT classes (P-DMT, HE-DMT, no active DMT) administered in cohort C from 2016-2021 and the proportion of DMT for cohort D can be found on the right side of Figure 2.

Figure 3. ARR

Footnotes: Figure 3 shows time trend in annualized relapse rate (ARR) since both MS onset to SP dg., and since 1st visit at MS centre to SP dg. Trend is represented by mean values±standard deviation (error bars).

Figure 4. Working status at SPMS onset



Footnotes: Stacked column chart shows the proportions of SP patients: (i) working (fully and partially), (ii) unemployed, (and iii) studying or at maternity leave in cohorts C and D.

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