The German MS Register: update on immunotherapy

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Background:

Disease-modifying drugs (DMD) serve to alter the long-term course of MS by reducing the inflammatory aspects of the disease. Currently, immunotherapy is available for relapsing-remitting (RRMS) and secondary progressive (SPMS) forms of MS, none of the licensed drugs has proven efficacy in primary progressive MS (PPMS) and thus current S2e-guidelines in Germany do not foresee DMD treatment. Conversely, a recent German study by Petersen et al. (2014) based on claims data by health insurance funds showed high numbers (32%) of PPMS-patients receiving DMD-treatment (1). Data from the German MS-Register were analysed in an attempt to verify these findings based on clinical data.

Methods:

In 2014 the German MS-Register established a new data set and register infrastructure. Currently 88 out of 169 participating centres in the register already use the new dataset and infrastructure, and further are currently migrating. The presented analysis is based on data sets collected from 2014 until 22/08/2016. A total of 5934 patients are enrolled in the new database. Data related to DMD-treatment and course of disease is available for 4871 registered patients. Proportion of patients receiving treatment are given for each disease course along with 95%-Clopper-Pearson confidence intervals. Global tests for differences between courses are done with Chi²-test.

For a subset of 877 patients additional data on the drugs prescribed over the course of their MS is available.

n = 4871	age (years)	MS-duration (years)	EDSS	female (%)
CIS (128)	42.58 ± 11,87	3.84 ± 8.03	1.78 ± 1.5	73.8%
RRMS (3539)	43.69 ± 10.8	11.17 ± 8.04	2.45 ± 1.7	73.7%
SPMS (908)	55.38 ± 10.15	22.14 ± 9.80	5.62 ± 1.77	69.1%
PPMS (296)	57.00 ± 9.75	14.7 ± 9.53	5.1 ± 1.91	60.1%

Table 1: Demographics and disease-specific information on the population

Results:

The number of patients receiving DMD-treatment differed substantially between CIS, RRMS, SPMS and PPMS (p<0.001): 69.5% of patients with CIS (95%-CI: [60.78-77.35%]; n=128) received DMD-treatment, as well as 85.3% of patients with RRMS (95%-CI: [84.1-86.46%]; n=3539), while 56.6% of SPMS patients (95%-CI: [53.31-59.86%]; n=908) were treated with DMDs. 38,6% of the PPMS patients (95%-CI: [33.27-44.66%]; n=296) received DMD treatment.

The drug-prescription data indicates a shift in the drugs prescribed (see Figure 2).



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amount of patients on therapy

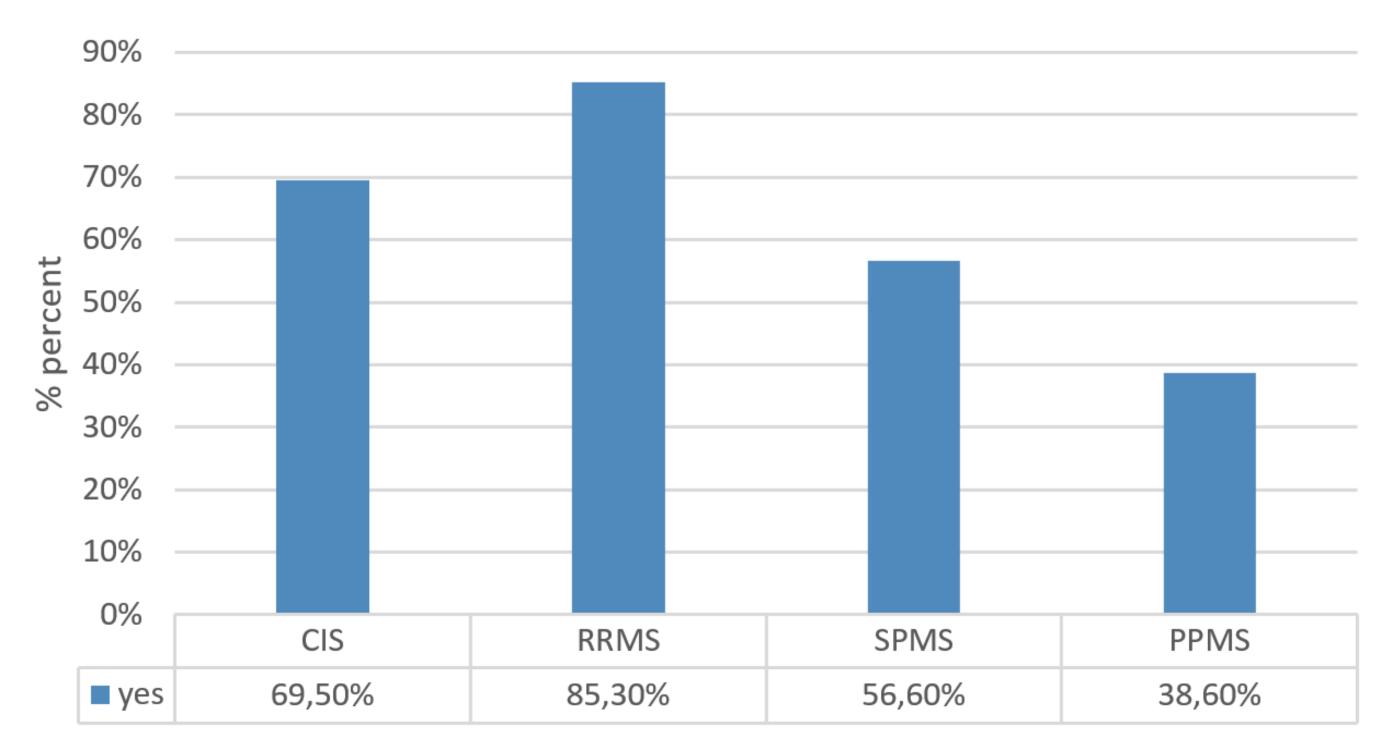


Figure 1: percentage of patients per disease course receiving disease modifying treatments

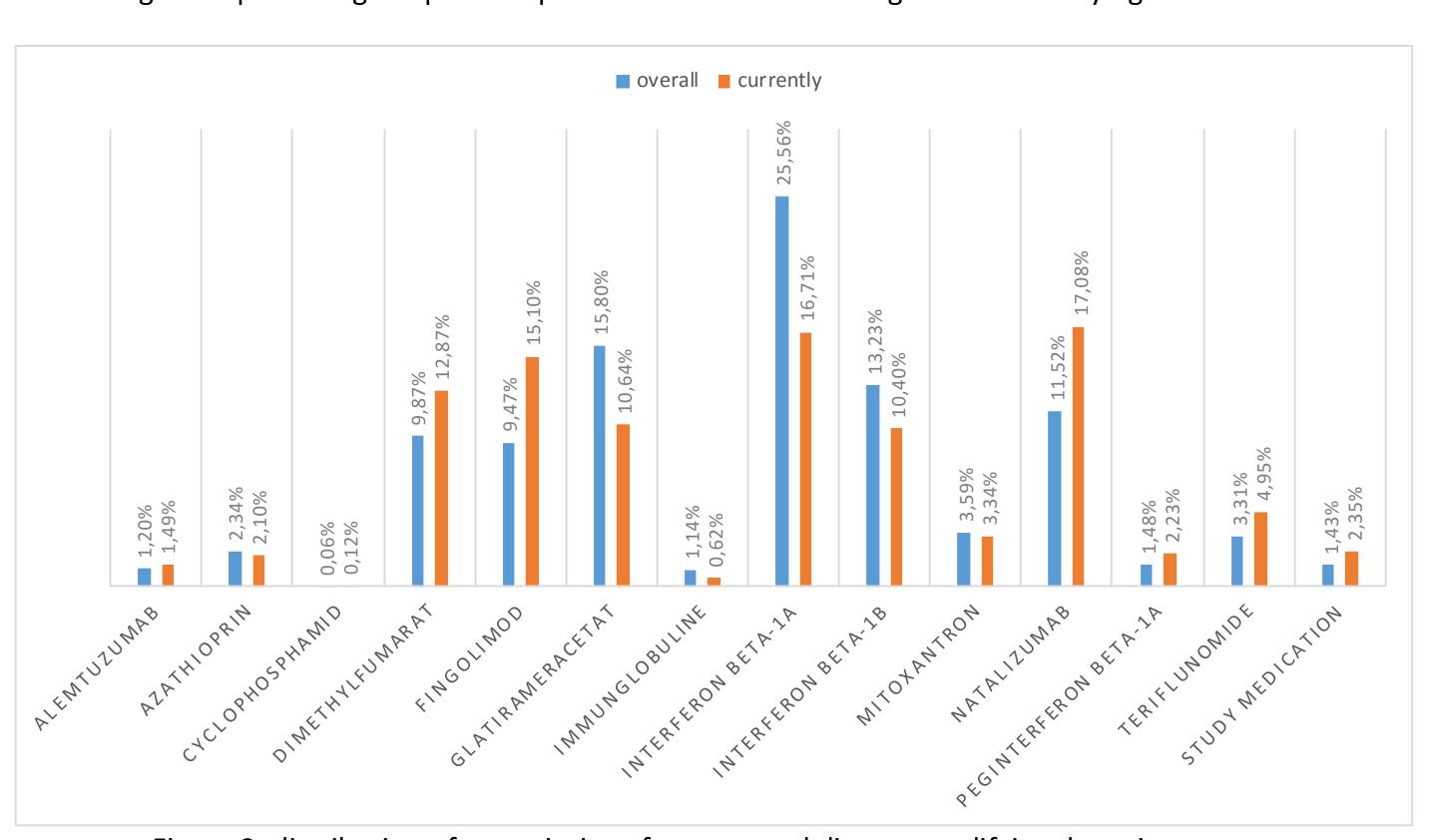


Figure 2: distribution of prescriptions for approved disease modifying drugs in percent comparing all prescriptions over time (blue) with the ongoing prescriptions (orange)

Conclusions:

The updated results (see Figure 2) show that a high proportion of MS patients receive DMD treatment, which is in line with previous analyses and other investigations. The amount of PPMS patients receiving DMD treatment in conflict with the guidelines is lower than in our previous analysis from 2009. The numbers though are still high and confirm the findings of the population based analysis (1). The noticeable reduction [in 2009 59% of PPMS patients received DMD treatment] in DMD treatments of PPMS patients could indicate a stronger adherence to the guidelines. This might be influenced by health insurance funds claiming damages if treatment is not in line with the guidelines.

The shift (see Figure 2) in the drugs prescribed correlates with the availability of additional treatment options in the last couple of years.

1) Petersen G, Wittmann R, Arndt V, Göpffarth D. Epidemiologie der Multiplen Sklerose in Deutschland. Der Nervenarzt. 2014;85(8):990–998.

Disclosure – Declaration of Interest

Karoline Buckow, David Ellenberger, Michaela Mai, Tina Meißner and Alexander Stahmann have nothing to disclose.

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The German MS Society, National Association yearly publishes the received grants and sources of funding: www.dmsg.de - The consented guidelines by the association of self-help
organizations and the DMSG-guidelines for co-operation with (pharmaceutical) companies apply.







