Update on the German MS Register - Immunotherapy and drug discontinuation

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Introduction and Purpose

Disease-modifying drugs (DMDs) may alter the long-term course of MS by reducing the inflammatory aspects of the disease. Immunotherapy is licensed available for the relapsing-remitting (RRMS) and secondary progressive (SPMS) forms of MS, whereas none of these drugs has proven efficacy in primary progressive MS (PPMS). Based on the results from clinical trials, recommendations for MS treatment in Germany have been developed by the Multiple Sclerosis Therapy Consensus Group (MSTCG). Whether and to what extent these recommendations are implemented in routine clinical practice is not known. Therefore, data from the German MS Registry were analysed in an attempt to monitor the current health care situation in Germany.

Methods

The MS Registry was initiated in 2001 by the German MS Society (DMSG Bundesverband, e.V.). The minimal data set was agreed upon consensus with leading MS experts all over Germany and modified after a 2-year pilot phase. In the extension phase starting in 2005, new centres were continuously recruited. Up to March/31/2009, datasets from 8,695 patients could be analysed with regard to the different immunomodulatory/suppressive treatment strategies. Patients were divided into 5 groups according to the disease course and relapse activity. Significance of differences between groups were tested with the chi-square test and ANOVA, respectively using the statistical Software SPSS@.

Demographic Data

		age (years)	MS-duration (years)	EDSS	Female (%)
total (8695)		44.5 ± 11.5	13.0 ± 9.5	4.0	70.7 %
RRMS (4980)	complete and incomplete remission	39.9 ± 10.0	9.5 ± 7.5	2.5	75.0 %
SPMS (2954)	relapses (1550)	48.3 ± 9.5	16.94 ± 9.19	6.0	67.9 %
	no relapses (1389)	52.0 ± 10.5	20.3 ± 9.8	6.5	66.2 %
PPMS (761)	relapses (212)	49.3 ± 12.4	12.85 ± 9.44	5.0	57.0 %
	no relapses (543)	54.5 ± 10.6	15.2 ± 10.4	6.0	55.0 %

The study population had a mean age (SD) of 44.5 (11.5) years, and a mean (SD) MS-duration of 13.0 (9.5) years. Median EDSS was 4.0. Almost 71% of all patients were female. Most of the patients had RRMS (57%). Compared to SPMS and PPMS patients, this group was younger, had the shortest MS-duration and the lowest disability. These differences were statistically significant (p<0.01).



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The number of patients treated with immunotherapy was significantly related to the course of disease (p< 0.001): more than 85% of patients with RRMS were on immunotherapy, while 82% of SPMS patients with relapses and 64% of those without relapses were treated with any DMD. Seventy-two percentage of PPMS patients with relapse activity, and even 54% of those without relapses were on immunotherapy.



The kind of treatment was significantly related to the type of MS (p<0.001). The most frequently administered drugs were beta-interferons (56% of all DMDs). This was true for all types of MS except for PPMS without relapses; this form was mostly (31% of patients) treated with steroid pulses.





Immunotherapy according to EDSS and MS-duration



The higher the EDSS of the patients the less likely it was that they were on immunotherapy. This difference was statistically significant (p<0.001). An increased EDSS was significantly related to a higher number of patients who ever discontinued therapy (p<0.001). Over 60% of patients with EDSS > 6.5 were still on DMDs.

The longer the MS-duration the 2173 80 % smaller the number of patients 1176 70 on immunotherapy and the 60 higher the number of patients who ever discontinued therapy. 50 ç This difference was statistically 40 significant (p<0.001). 30 20 597 10 0 to 10 vears 11 to 20vears >20 vears Conclusions

In agreement with other studies the results show that a high proportion of MS patients is treated with immunotherapy. However, a lot of patients with MS ever changed or even stopped therapy. Further analysis in regard to reasons for and timeframe of therapy discontinuation will be done in the future.