IP060

Health-Related Quality of Life Outcomes in Patients With Relapsing-Remitting Multiple Sclerosis: The THEPA-MS Survey

Jennifer S Kullmann,[1] Raimar Kern,[2] Stephan Richter,[3] Tjalf Ziemssen[2]

[1]Genzyme, a Sanofi company, Neu-Isenburg, Germany; [2]Universitätsklinikum Carl Gustav Carus, Klinik und Poliklinik für Neurologie, Zentrum für klinische Neurowissenschaften, Multiple Sklerose Zentrum, Dresden, Germany; [3]NEURO MVZ, SynConcept GmbH, Stuttgart, Germany

INTRODUCTION

- In Germany, MS affects almost 200,000 patients,[1] making it the most common chronic central nervous system disease among young people[2]
- Many disease-modifying therapies (DMTs) have been shown to reduce the number of relapses and delay disability progression in patients with MS. The 2012 German guidelines recommended interferon beta or glatiramer acetate as first-line treatments for clinically isolated syndrome or relapsing-remitting MS (RRMS).[3] Azathioprine or immunoglobulin treatment were also recommended as first-line treatments for RRMS, but with restrictions[3]
- MS has a substantial impact on patients' health-related quality of life (HRQoL)[4,5]
  - Patient perceptions of HRQoL may differ from the opinions of a treating physician,[6] so it is important to evaluate HRQoL using validated patient-reported measures[7]

OBJECTIVE

- To assess the HRQoL of German patients with relapsing forms of MS, eligible for treatment with first-line DMT, in a cross-sectional survey under real-world clinical settings

METHODS

- The observational, open-label, cross-sectional, prospective survey **The**rapiezufriedenheit von **Pa**tienten mit schubförmiger **M**ultipler **S**klerose (THEPA-MS; Treatment Satisfaction in Patients With RRMS) was performed in 517 centers throughout Germany, from August 2013 to September 2014 (database lock)
- Patients eligible for inclusion were aged ≥18 years, had a diagnosis of clinically isolated syndrome or RRMS, had no prior participation in MS clinical trials or use of escalation therapy, and were either:
  - Receiving treatment with first-line DMT for MS (interferon, glatiramer acetate, azathioprine, or immunoglobulins), according to the 2012 guidelines,[3] or
  - Eligible for such therapy but not treated
- The survey used the Medical Outcomes Study Short Form-36 (SF-36) health survey questionnaire (version 2.0)[8] to assess HRQoL and health status measures
  - The SF-36 comprises 11 structured questions, giving rise to 36 items and 8 domain scores (weighted sums for items in each section)
  - Scores were directly transformed into a 0 (worst) to 100 (best) scale, assuming equal question weights
  - Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were generated from the 8 domain scores and reported using norm-based scoring (mean=50; standard deviation [SD]=10), so that a score of 50 is equivalent to the mean score of the general population
  - Results were analyzed descriptively in the total cohort
- Safety data (side effects during the past 3 months) were reported by DMT class and rated as severe, moderate, or mild

RESULTS

Patients

- Of 3766 patients screened, 3312 were included for analysis
- Patient demographics and baseline disease characteristics are shown (**Table 1**) and treatment history is shown in **Table 2**

SF-36 Survey

- SF-36 questionnaires were completed by 3290 patients (99%); results for SF-36 domains are presented in **Figure 1**
  - Scores were lowest for the Vitality and General Health domains and highest for Social Functional Capacity and Physical Functional Capacity
- Mean (SD) PCS score was 45.4 (9.7) and mean (SD) MCS score was 41.8 (12.9)
  - Mean scores are similar to those from a 2003 survey of 717 German patients with MS using an earlier version of the SF-36, which reported a mean (SD) score of 43.9 (9.9) for PCS and 46.6 (9.9) for MCS[9]

Table 1. Patient Demographics and Baseline Disease Characteristics

Gender, n (%)	
Male	878 (26.5)
Female	2428 (73.3)
Age, mean (SD), y	43.7 (11.3)
Employment status, n (%)	
Full-time employment	1507 (45.5)
Part-time employment	517 (15.6)
Unable to work (disabled)	563 (17.0)
Other	725 (21.9)
Diagnosis, n (%)	
Relapsing-remitting MS	3117 (94.1)
Clinically isolated syndrome	114 (3.4)
No information	81 (2.4)
Age at first symptoms of MS, y	
Mean (SD)	34.1 (10.4)
Median (range)	33.0 (4–68)
Age at diagnosis of MS, y	
Mean (SD)	35.6 (10.5)
Median (range)	35.0 (8–87)
Number of relapses in past 12 months, n (%)	
0	2058 (62.1)
1	916 (27.7)
2	261 (7.9)
≥3	63 (1.9)
No information	14 (0.4)
EDSS score, n (%)	
≤3.5	2600 (78.5)
>3.5	535 (16.2)

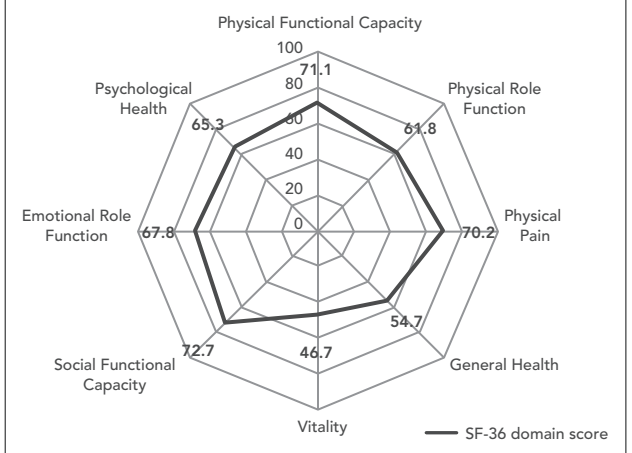
N=3312.
EDSS, Expanded Disability Status Scale; SD, standard deviation.

Table 2. Patient DMT Use and Treatment History

	Patients Receiving Treatment, n (%)	Duration of Treatment, Mean (SD) [n[a]], y
MS therapy (all patients, N=3312)		
Currently receiving DMT	2830 (85.4)	4.8 (4.2) [2677]
Received DMT in the past, not currently receiving DMT	270 (8.2)	–
Never treated with DMT	212 (6.4)	–
Current DMT (patients currently receiving DMT, N=2830)		
IFNβ-1a IM	704 (24.9)	4.5 (4.1) [670]
IFNβ-1a SC	687 (24.3)	4.9 (4.1) [658]
IFNβ-1b SC	564 (19.9)	5.5 (4.3) [547]
Glatiramer acetate	785 (27.7)	4.2 (3.4) [761]
Azathioprine oral	37 (1.3)	11.7 (9.9) [36]
Immunoglobulins IV	6 (0.2)	6.6 (2) [5]
Other	47 (1.7)	–

[a]Patients with available data.
DMT, disease-modifying therapy; IFN, interferon; IM, intramuscular; IV, intravenous; SC, subcutaneous; SD, standard deviation.

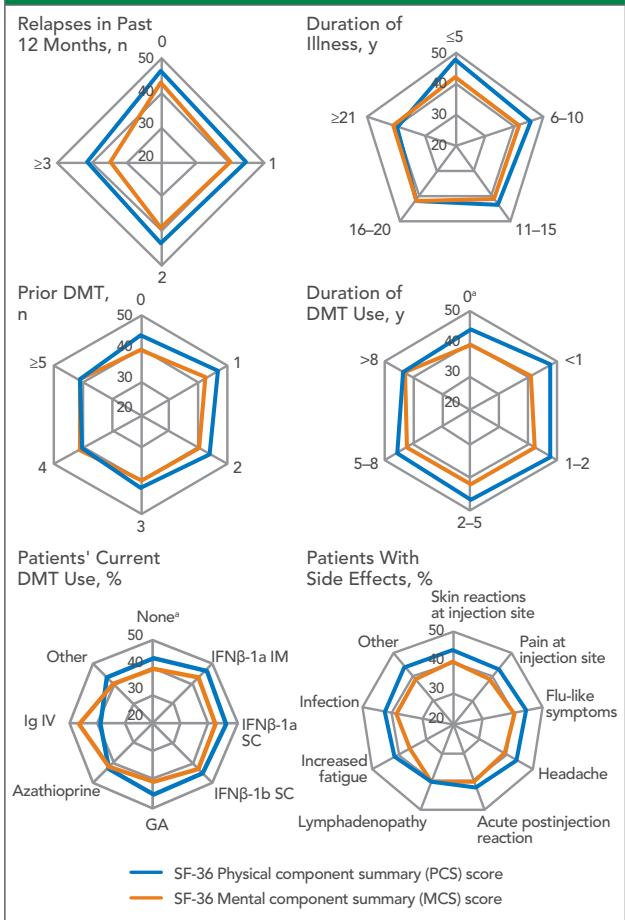
Figure 1. SF-36 Domain Scores for Patients With Relapsing-Remitting MS in THEPA-MS



SF-36, Short Form-36.

- Mean scores are lower than the general population mean scores of 50, indicating reduced HRQoL in the THEPA-MS study population
- Lower values for PCS and MCS scores were noted in patients with Expanded Disability Status Scale (EDSS) scores >3.5 (35.6 and 39.4, respectively), compared with patients with EDSS scores ≤3.5 (47.3 and 42.2)
- Overall, lower summary scores were observed in patients with a greater number of relapses in the last 12 months, longer duration of disease, and increasing number of prior therapies (**Figure 2**)
- PCS scores were lower with increasing duration of DMT use. Azathioprine use was associated with a higher MCS score and lower PCS score compared with other DMTs (**Figure 2**)

Figure 2. SF-36 PCS and MCS Scores by Disease Characteristics and Treatment



Scores shown for patients with data, N=3176.
[a]Category includes patients with and without a history of prior DMT use, with no current DMT use.
DMT, disease-modifying therapy; GA, glatiramer acetate; IFN, interferon; Ig, immunoglobulin; IM, intramuscular; IV, intravenous; SC, subcutaneous; SF-36, Short Form-36.

Safety

- In the 3 months prior to assessment, 1210 patients (42.8%) reported DMT-related side effects
- The most frequent side effects of current MS therapy were injection-site skin reactions (24.9%) and flu-like symptoms (23.6%) followed by pain at injection site (13.9%)
- The majority of side effects were assessed as mild

CONCLUSIONS

- The real-world THEPA-MS survey makes a valuable contribution to our understanding of the experience of a large sample of German patients with relapsing forms of MS
- Overall, HRQoL in patients with MS treated with first-line DMT was compromised
  - PCS and MCS scores derived from the SF-36 were lower than mean scores for the general population
  - Disease characteristics correlating with poorer patient-report HRQoL included increasing disease duration, disability, relapses, and increasing number of prior DMTs

REFERENCES

1. Petersen et al. *Nervenarzt*. 2014;85:990. 2. DGN Diagnose und Therapie der Multiplen Sklerose, updated 2014. http://www.awmf.org/leitlinien/detail/ll/030-050.html. Accessed Jun 2015. 3. DGN/KKNMS Leitlinie zur Diagnose und Therapie der Multiplen Sklerose, 2012. http://www.kompetenznetz-multiplesklerose.de/images/stories/PDF_Dateien/Leitlinie/dgn-kknms_ms-ll_20120809_frei.pdf. Accessed Jun 2015. 4. Aronson. *Neurology*. 1997;48:74. 5. Ford et al. *Disabil Rehabil*. 2001;23:516. 6. Kremenchutzky, Walt. *Can J Neurol Sci*. 2013;40:210. 7. Gavelova et al. *Disabil Health J*. 2015;8:372. 8. Ware. http://www.sf-36.org/tools/SF36.shtml. Accessed Jun 2015. 9. Haupts et al. *Nervenarzt*. 2003;74:144.

Acknowledgments

This poster was reviewed by Larisa Miller, PharmD, and Alex Lublin, PhD, of Genzyme, a Sanofi company. Editorial support for this poster was provided by Victoria Lawson, of Fishawack Communications, and was funded by Genzyme.

Disclosures

JSK: Employee of Genzyme. **RK:** Compensation for activities (Bayer, Biogen Idec, Genzyme, Novartis, Sanofi, Teva Neuroscience). **SR:** Compensation for activities (Bayer, Biogen Idec, Genzyme, Novartis, Teva). **TZ:** Compensation for participation on advisory boards, trial steering committees, data and safety monitoring committees, scientific talks, project support (Bayer HealthCare, Biogen Idec, Elan, Genzyme, Merck Serono, Novartis, Roche, Sanofi, Synthon, Teva).

Presented at the 88th Congress of the Deutschen Gesellschaft für Neurologie (DGN), September 23–26, 2015, Düsseldorf, Germany
Funding provided by Genzyme, a Sanofi company