MAGNON – Implementation and Value of Lublin Criteria and Quantitative MRI Analysis in Clinical Routine Care of MS Patients

Olaf Hoffmann[1], Katrin Schuh[2], Veronika E. Winkelmann[2]

[1]St. Josefs-Krankenhaus Potsdam-Sanssouci, Potsdam, Germany;
[2]Novartis Pharma GmbH, Clinical Research Neuroscience, Nuremberg, Germany

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Background and objective

- The 2013 revised description of MS phenotypes (Lublin criteria)[1] provides a detailed definition of individual patient status in secondary progressive multiple sclerosis (SPMS), where patients are assessed annually based on progression and activity (MRI and/or relapse).
- Classification according to the Lublin criteria is currently not broadly used in routine care in Germany.

Objective	**MAGNON aims to evaluate whether access to standardized quantification of MRI data and assessment of MS patients based on the Lublin criteria provides additional benefit for neurologists working in day-to-day MS patient management.**

1. Lublin F et al. Neurology 2014; 83 (3):278-286

Methods

- Approximately 3600 MRI studies from 100 centers in Germany will be analyzed.
- The results are visualized and provided to the participating physicians on a standardized report.
- The value of standardized MRI analysis and the impact on patient assessment, including potential changes in Lublin classification, is evaluated by questionnaires (Figure 1).

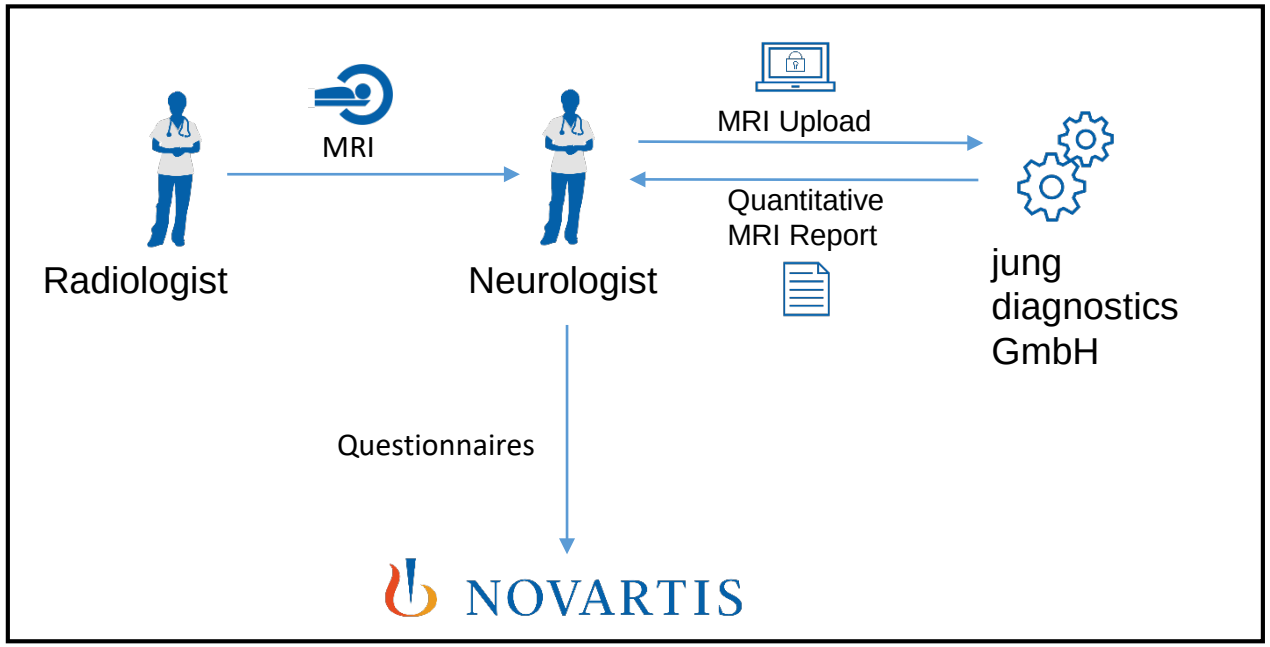


Figure 1. Project Workflow

Methods – MRI Analysis

- MRI sets are acquired by local radiologists using a standard protocol and after passing a qualification process.
- Standardized MRI analysis is performed by means of a centralized processing pipeline (Biometrica MS®, jung diagnostics GmbH, Hamburg, Germany; Figure 2, Tables 1 & 2 (next slide)).

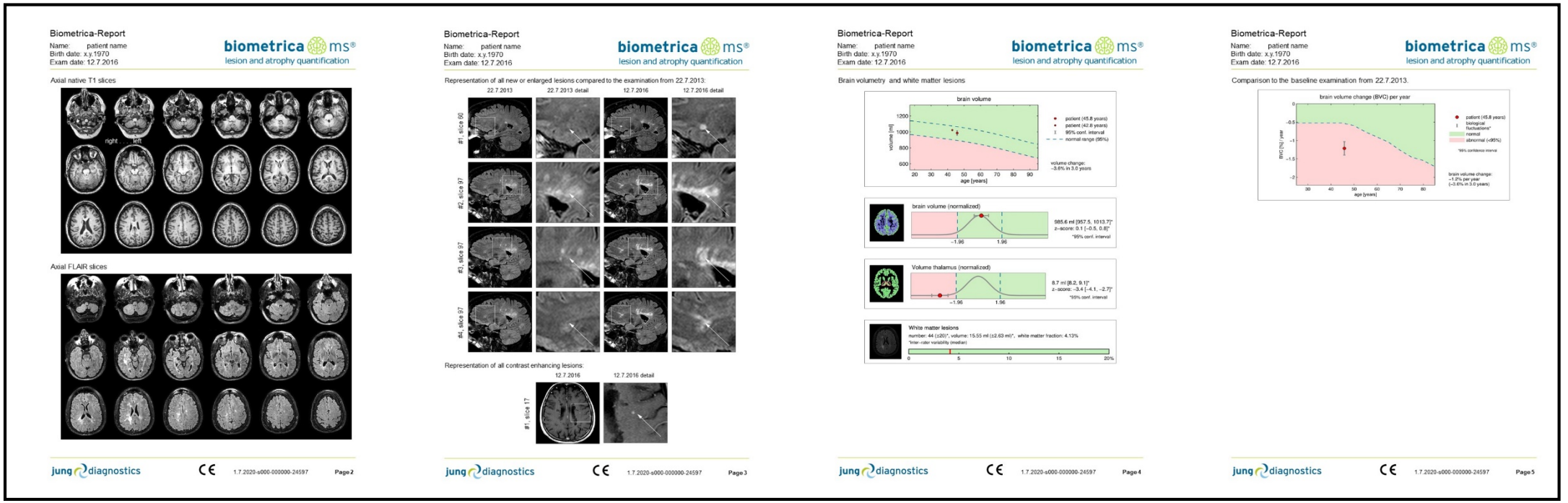


Figure 2. Example MAGNON report with analyses of the brain volume in relation to healthy subjects and volume change over time

Methods
– MRI Analysis

Table 1

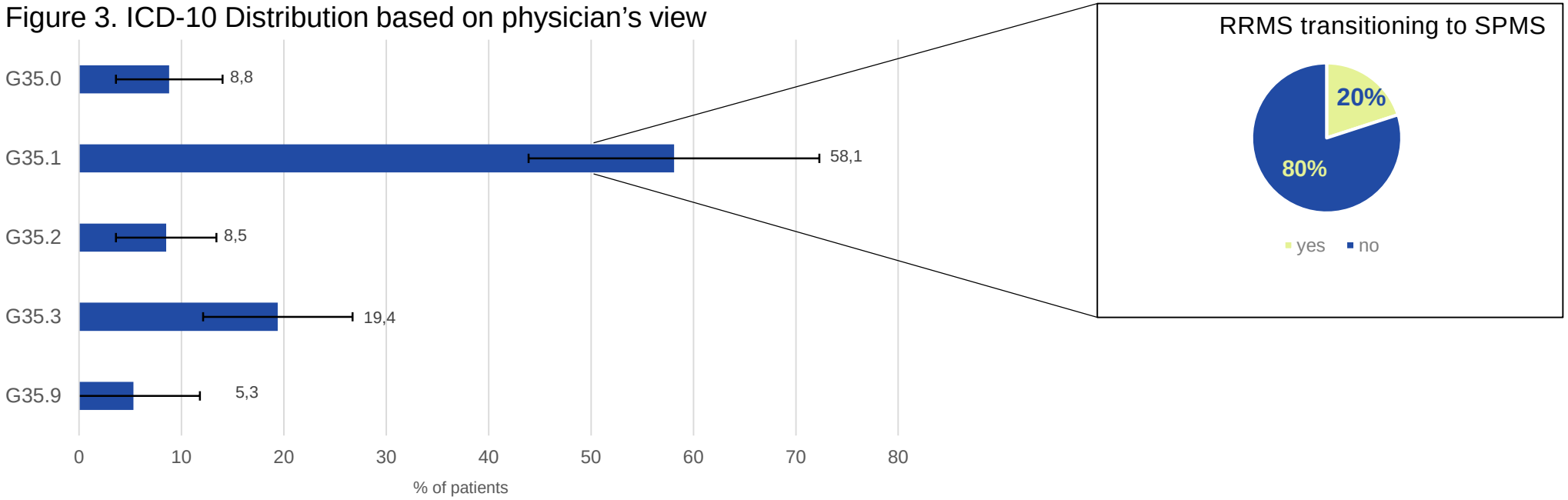
MRI Requirements
3D T1-weighted gradient echo sequence
✓Standard (vendor recommended) protocol settings (MPRAGE for Siemens, TFE for Philips, FSPGR for GE)
✓High resolution=1.0 mm
✓Slice thickness=1.2 mm
2D or 3D FLAIR
✓Standard (vendor recommended) settings
✓Axial orientation in 2D (3 mm)

Table 2

Quantitative MRI parameters of the MAGNON report
✓Quantification of total brain volume
✓Quantification of thalamic volume
✓Quantification of grey and white matter volumes
✓T2 lesion volume and lesion number
✓Percentage of brain volume change (PBVC) in case of follow-up scans

Results – Site Questionnaires 1

Figure 3. ICD-10 Distribution based on physician's view



- Between April 2020 and July 2020, the first 24 neurological sites were included for data collection.
- For preliminary analysis, baseline questionnaires were available from 13 sites, each treating 342 ± 215 patients (Mean ± SD).
- ICD coding showed a similar distribution of MS subtypes as previously published for Germany[1] (Figure 3).

Figure 3: Mean ± SD, n = 13 sites; each site treating 342 ± 215 patients (Mean ± SD)

1. Heibel M et al. Presented at *AAN.* 2020; Abstract ID:4169

Results – SPMS Patient Distribution

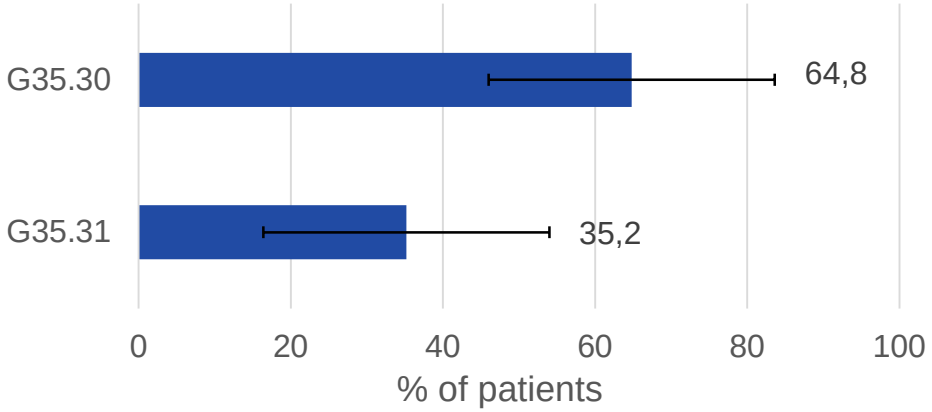


Figure 4. ICD-10 Classification G35.3

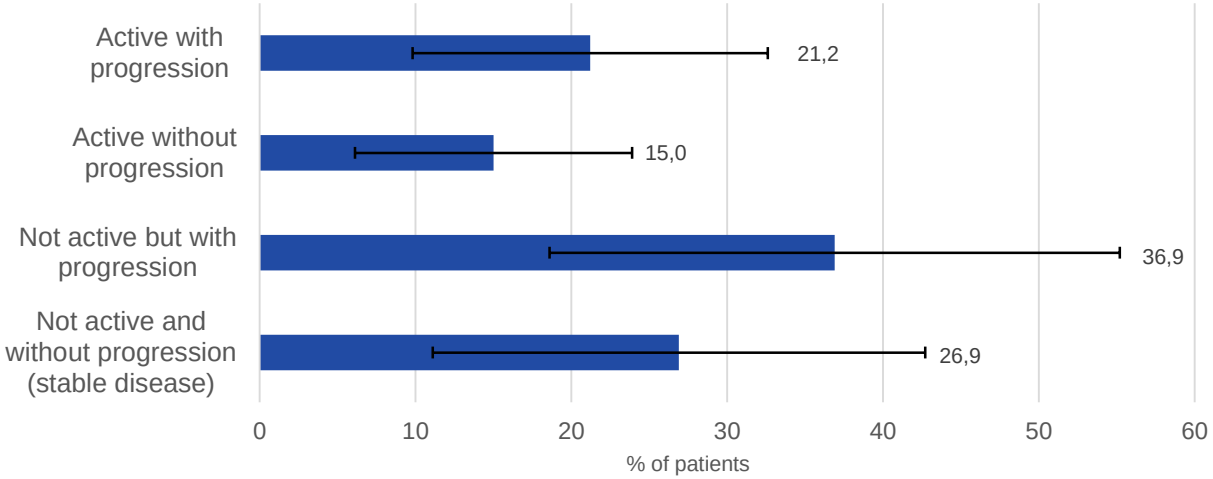


Figure 5. SPMS Patient distribution according to the Lublin criteria

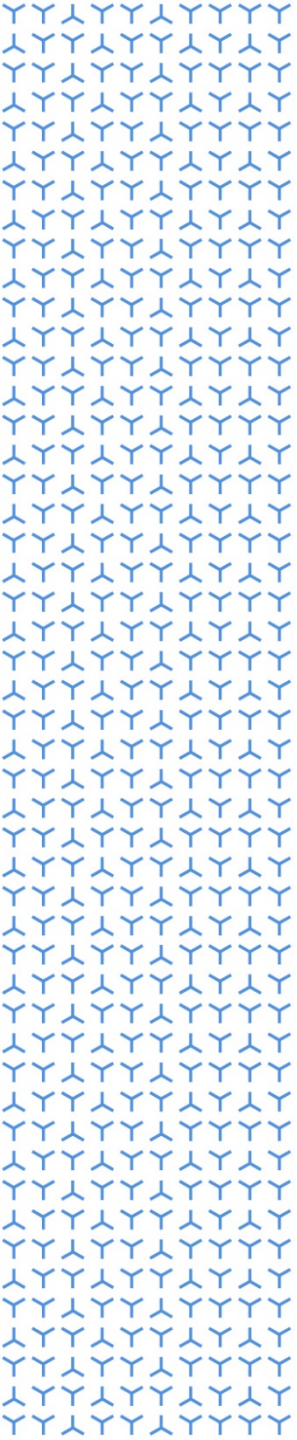
- 64.8% of SPMS patients were classified as G35.30 (no imposed relapses or progression[1]), while 35.2% of SPMS patients were considered to have relapses or progression (G35.31; Figure 4).
- Applying the Lublin criteria, physicians considered 36.2% of their SPMS patients to be active, either with progression (21.2%) or without progression (15.0%; Figure 5).

Figure 4 & 5: Mean ± SD, n= 13; each site treating 342 ± 215 patients (Mean ± SD)

1. https://www.icd-code.de/icd/code/G35.-.html (accessed 04.August 2020)

Conclusions

- Based on the first available baseline data, participating centers show a similar distribution of MS subtypes (ICD-10 35.x) as previously reported, indicating a representative sample of MS patients in Germany.
- More than one third of SPMS patients were classified as having relapses or progression (ICD-10 35.31).
- More than one third of SPMS patients (36.2%) have active SPMS according to the Lublin criteria.
- Quantification of lesions as well as brain and thalamic atrophy during follow-up in MAGNON are expected to inform the individual assessment of disease activity and progression according to the Lublin criteria, leading to a more accurate classification of MS phenotypes.
- MAGNON will help to gauge the potential of quantitative MRI analysis in routine clinical practice.



Thank you