QUANTUM – Quantitative and standardized imaging in daily clinical routine of MS patients

4039

Katrin Schuh[1], Roland Opfer[2], Lothar Spies[2]

[1]Novartis Pharma GmbH, Clinical Research Neuroscience, Roonstr. 25, 90429 Nuremberg, Germany

[2]jung diagnostics GmbH, Röntgenstraße 24, 22335 Hamburg, Germany

Introduction

- Magnetic resonance imaging (MRI) analyses play a key role both in the diagnosis and in treatment monitoring of patients with multiple sclerosis (MS)
- In Multiple Sclerosis (MS) clinical trials quantitative MRI analyses are carried out based on highly standardized protocols, comparable standards are yet to be implemented in clinical routine
- Tools for quantitative data analysis including brain volumetry do exist, but are not yet commonly used in daily routine practice

Objective

- The QUANTUM project aimed to evaluate if access to standardised quantification of MRI data and visualisation in reports, in addition to radiological findings provides additional benefit for neurologists working in day-to-day MS patient management
- For the first time a broad access to volumetric MRI and T2 lesion segmentation analyses in clinical routine was granted allowing amongst others a comprehensive use of NEDA-4 criteria

Methods

- MRI data were acquired in radiological competence centers, which passed a qualification process to harmonize image acquisition (elimination of inter-scanner effects)
- The standardized MRI data (3D T1 gradient-echo sequence and 2D / 3D FLAIR) were analysed by means of a centralised automatic processing pipeline (Biometrica MS®, jung diagnostics GmbH)
- The analysis comprised a volumetric quantification of brain volume, as well as T2 lesion load and number. Percentage brain volume change was computed (using an optimized SIENA pipeline) when follow-up scans were available
- The results were visualised and provided to the participating physicians as a report (**Figure 1 and 2**)
- Questionnaires were used to evaluate the value and feasibility of quantitative MRI analyses and additional characteristics of patient management
- Reasons for switching MS treatment were ranked prior to and after completion of the QUANTUM project to assess the impact of the project on therapy decision
- No patient related data was collected

Figure 1. Project overview

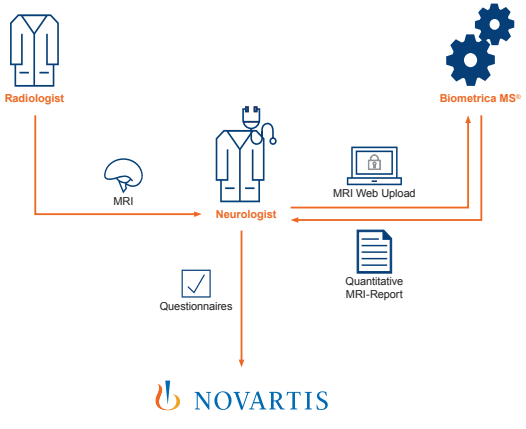
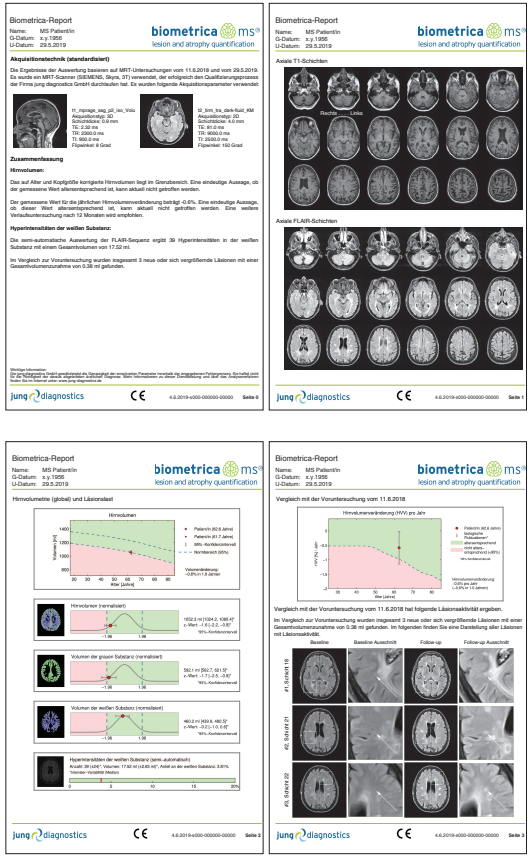


Figure 2. Example of a QUANTUM report indicating volumetric data referenced to a healthy cohort and brain volume change over time



Results

- Between July 2016 and December 2019 6.718 MS patients from 282 neurological centers received standardized MRI in 183 radiological competence centers across Germany
- In total 9.000 QUANTUM reports were provided to participating neurologists
- Relapses and new MRI activity with non-matching clinical symptoms were the main drivers for therapy switch (**Figure 4**).
- The QUANTUM project impacted decision making in approx. one third of participating neurologists: For 24,42% MRI activity became significantly more important, for 11.63% new MRI activity was ranked lower (**Figure 3**).

Figure 3. Change of impact of "new MRI activity with non-matching clinical symptoms" on treatment decisions

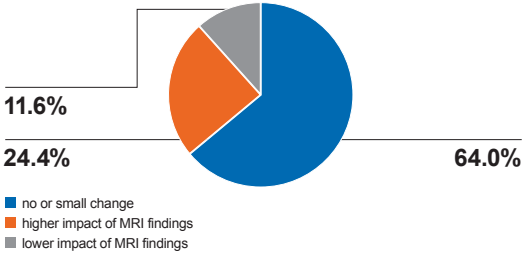
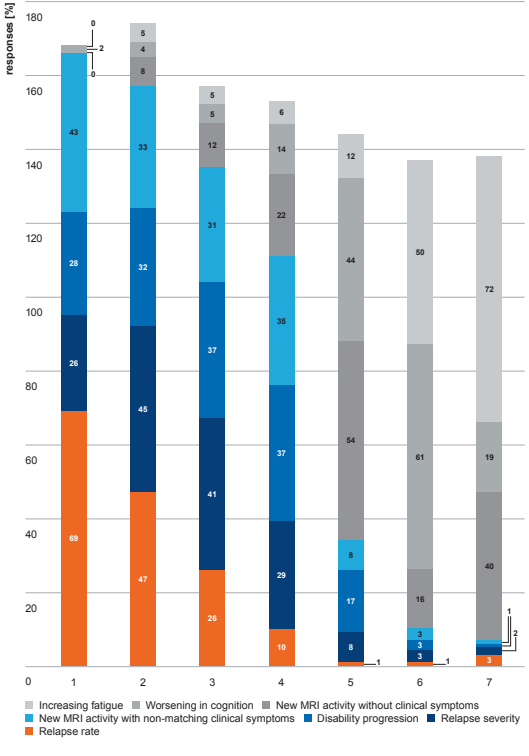
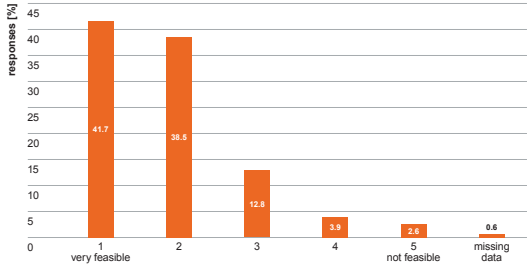


Figure 4. Reasons for treatment switch 1 – 7; 1=highest importance

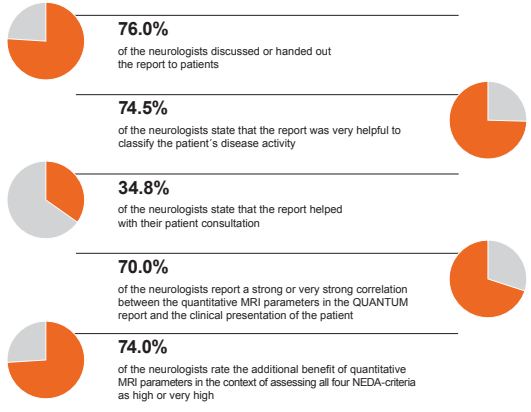


- 80.13% of neurologists report that additional volumetric MRI analyses are feasibile in daily clinical routine

Figure 5. Feasibility of quantitative MRI analyses in daily routine



- Analysis of 7775 questionnaires revealed good acceptance and usability of the QUANTUM reports among neurologists:



Conclusions

The QUANTUM project demonstrated that

- standardization of MRI protocols is feasible in clinical routine
- brain volume change and quantification of lesion load can be assessed in routine clinical practice based on standardized MRI protocols
- quantitative MRI seems to have an impact on MS therapy decision
- such initiatives could provide the basis for improved individual MS patient monitoring in daily care

Disclosures

K. Schuh is employee of Novartis Pharma GmbH. **R. Opfer** and **L. Spies** are employees of jung diagnostics GmbH.

This data collection is funded by Novartis Pharma GmbH, Germany.

presenter email address: katrin.schuh@novartis.com