QualiCOP: AN OPEN-LABEL, PROSPECTIVE, OBSERVATIONAL STUDY OF GLATIRAMER ACETATE IN PATIENTSWITH RELAPSING-REMITTING MULTIPLE SCLEROSIS

T. Ziemssen[1], P. Calabrese[2], I.-K. Penner[2], **A. Rainer**[3]
[1]*Neurology, University of Dresden, Germany*
[2]*Cognitive Psychology, University of Basel, Switzerland*
[3]*Medical Affairs, Teva Pharma Germany, Germany*
Rainer.Apfel@teva.de

Introduction: Multiple sclerosis (MS) has a profound impact on patients' quality of life (QoL), and improvement of cognitive function, depressive symptoms and levels of fatigue remains a goal of disease-modifying therapy. Such improvements would in turn potentially support adherence to therapy, consequently further enhancing treatment outcomes.
Methods: QualiCOP was a prospective, observational, non-interventional, open-label study similar to the Coptimize trial and conducted at 170 sites in Germany. Patients (*N*=754), primarily (95.6%) with relapsing-remitting MS, with or without previous treatment, were observed for 24 months following conversion to treatment with once-daily glatiramer acetate 20mg/1mL s.c. (GA), a first line disease modifying therapy with more than 2 Million patient/years on treatment. A series of 11examinations was conducted, including assessment of relapse rate, disease progression, overall functioning, QoL, cognition, fatigue, and depression.
Results: Treatment with GA over 24 months was associated with a reduction of annual relapse rate from 0.87 to 0.49 (*P* .0001), while the proportion of relapse-free patients rose from 11.3% to 69.5%. Total remission was achieved in 56.4% of patients. MSFC scores showed slight improvement in overall functioning (*P* .0001), while PASAT and MUSIC showed robust improvement in cognition (both *P* .0001). The CES-D also showed significant improvement of depressive symptoms (*P*=.0006). Scores on the EDSS, MUSIC-Fatigue and FAMS (all NS) showed that disease severity, fatigue, and QoL were stable over the observation period.
Conclusions: These findings suggest that patients experiencing inadequate symptom control will benefit from conversion to GA therapy, with improvements going beyond the standard measures of relapse and disease severity.