

Patient Reported Outcomes, Safety and Tolerability in the Open Label Period of GA Depot, Phase 3, Multinational, Double-Blind, Placebo-Controlled Study in Patients with Relapsing Forms of Multiple Sclerosis

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Background

Glatiramer Acetate Depot (GA Depot) is a novel long-acting GA formulation consisting of extended-release microspheres containing GA, administered IM every 28 days. GA Depot 40 mg/month significantly reduced the annualized relapse rate and the number of new enhanced lesions in the double-blind, randomized, placebo controlled (PC) phase 3 study in relapsing forms of Multiple Sclerosis (RMS).

Objective

To assess GA Depot safety, tolerability, Quality of Life and treatment satisfaction in patients with RMS in the open label (OL) period of the study.

Design/Methods

Patient Reported Outcomes (PROs) were assessed using two validated questionnaires: the EQ-5D-3L & the TSQM-9 at visit 16 (week 52, baseline for OL period) & visit 29 (week 104, end of OL period). In the OL period, 763 patients: 347 treated with GA Depot in the PC period (cGA Depot group) & 416 that received placebo during the PC period (pGA Depot group), received at least one dose of GA Depot.

PRO population included all OL completers (625 patients (81.9%)) for all descriptive analyses and patients with both visits 16 & 29 for longitudinal analysis. Safety and tolerability outcomes included adverse events (AEs) & serious adverse events (SAEs) & injection site reactions (ISRs) analyzed by yearly event rate or incidence and compared to the 1st year of treatment (PC period).

Results

Figure 1: EQ-5D-3L V16 & V29

At visit 29, majority of patients reported no problems in all dimensions of the EQ-5D-3L: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

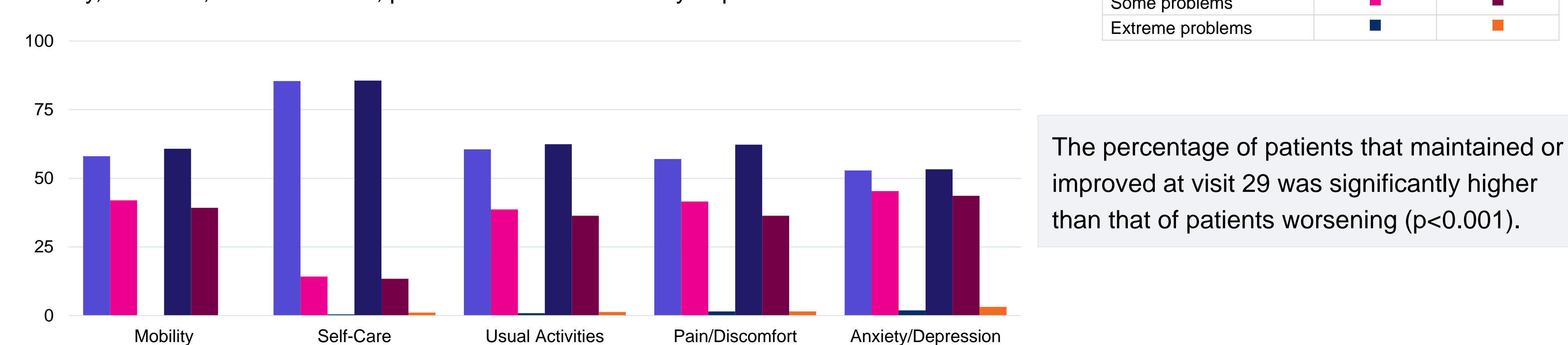
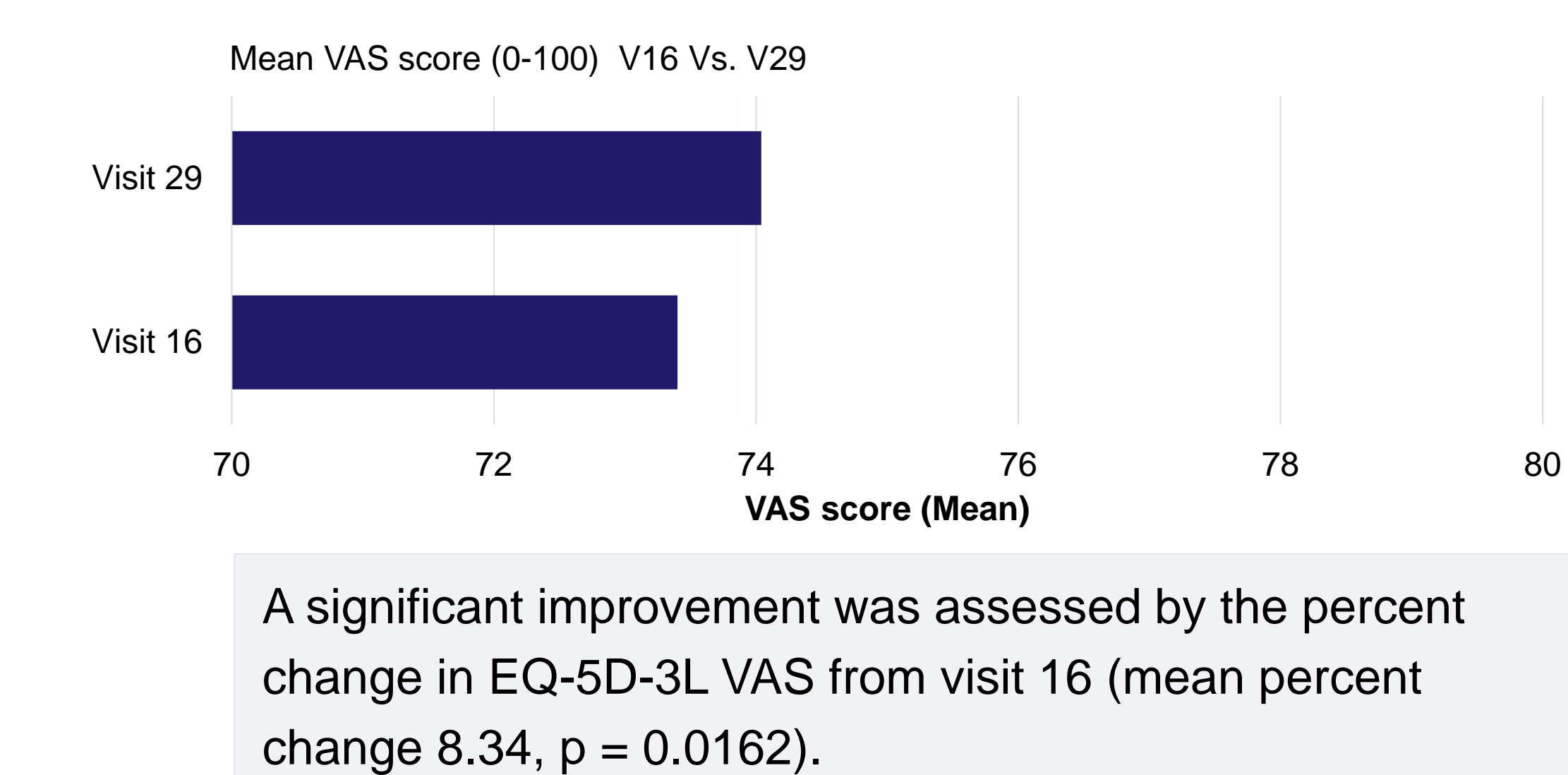


Figure 3: TSQM-9 Questionnaire Descriptive statistics by Question (grouped answer) V29



Figure 2: EQ5D Mean VAS score



Conclusions

Patient reported outcomes remained stable or improved during the OL period for all patients treated with GA Depot. The high treatment satisfaction (>90% of subjects satisfied with treatment) and the safety observed in the OL period confirm GA Depot's favorable safety and tolerability profile established in the PC period, positioning GA Depot as a safe and convenient treatment option that may increase treatment adherence in RMS patients.