Influence of baseline score sums on treatment effect assessed by numeric rating scale in Parkinsonian patients treated with budipine

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Introduction: The efficacy of budipine in the treatment of Parkinson’s Disease (PD) was shown in different controlled studies on the Columbia University Rating Scale (CURS). However, the magnitude of effect varied between the trials. Dopamine agonist treatment was reported more effective in subjects with worse scores at baseline. In order to evaluate factors influencing the treatment benefit of patients the impact of the pre-treatment score sums of the CURS on the final results were analysed.

Aims:

- to quantify the influence of baseline on final outcome on the CURS and
- to assess the potential impact on future studies.

Methods: A meta-analysis was performed from double-blind, randomised, controlled studies with budipine in PD patients. In each study the CURS was assessed at baseline (Day 0) and on treatment Day 84. The difference in the score sums

delta_CURS=(CURS_Day84 - CURS_Day0) was calculated for each patient as efficacy parameter. A linear regression with delta_CURS vs. CURS_Day0 was calculated.

Results: The regression from N=195 patients on budipine treatment was

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delta_{CURS} = -7.44 + 0.595 \times \text{CURS}_{\text{Day0}}, \quad R=0.78 \quad (p<0.001).
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There were no relevant differences between monotherapy and adjuvant treatment with budipine to constant dopaminergic therapy: N=95, -7.65, 0.620, R=0.68 and N=100, -7.12, 0.576, R=0.67, respectively.

Conclusions: The magnitude of treatment effect on the CURS depends on the score sums at baseline. The extrapolation of delta_CURS=0, i.e. no improvement, gives a baseline CURS value of 12.5 indicating that in future studies patients with higher baseline score should be included to show efficacy on the CURS or comparable rating scales.