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Two-year outcome of Galantamine treatment in Alzheimer's disease in a routine clinical setting

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Conclusion

Long-term galantamine treatment in a routine clinical setting resulted in a positive effect in cognitive tests compared to historical controls and mathematical models. After 2 years of treatment a positive global outcome was observed in half of the patients. Dropout was less than expected.

Introduction

Alzheimer's disease (AD) is the major cause of dementia in the elderly and is a devastating disease for patients and their families experiencing a gradual loss of functions and independence. Multiple double blind, placebo controlled studies have shown beneficial effects of galantamine treatment on cognition and function. What to expect in long-term treatment in a routine clinical setting has not been investigated. The Swedish Alzheimer Treatment Study (SATS) is a prospective, open, longitudinal, multicenter study evaluating cholinesterase inhibitor (ChEI) treatment in AD. Patients are investigated at baseline, at 2 months and every 6 months for a total period of three years. Here we present the two-year outcome for the first 122 patients receiving the ChEI galantamine in SATS.

Objective

To evaluate the two-year outcome on cognition (MMSE, ADAS-cog) and global rating (CIBIC) in a routine clinical setting. To evaluate dropout.

Methods and Subjects

The first 122 patients receiving galantamine in the SATS for two years were investigated in this study.

Patients were assessed with MMSE, ADAS-cog (0-70) and global rating (CIBIC).

The outcome of the ADAS-cog was compared to a mathematical model of change in untreated AD-patients, the Stern equation(1). The individual rate of change in ADAS-cog was calculated for each individual and described graphically. The expected decline in MMSE score was estimated to 2-4 points a year and the ADAS-cog score to 4-9 points a year, based on previously reported rates of change in untreated patients.

Three groups of response were defined at each interval. CIBIC 1-3 was better, 4 unchanged and 5-7 worse.

Baseline characteristics

Patients(n)	**122**
Gender (male/female)	**48 / 74**
Age, mean ± SD, years	**72.3±7.7**
Duration, mean ± SD,	**3.0±2.0**
MMSE, mean ± SD mean, (n)	**23.2 ± 4.2**
ADAS-cog (0-70), mean ± SD, (n)	**17.2 ± 8.4**

Reference List

(1) Stern R.G., Mohs R.C., Davidson M., Schmeidler J., Silverman J., Kramer-Ginsberg E. et al. A longitudinal study of Alzheimer's disease: Measurement, rate and predictors of cognitive deterioration. Am J Psychiatry 1994 March;151(3):390-6.

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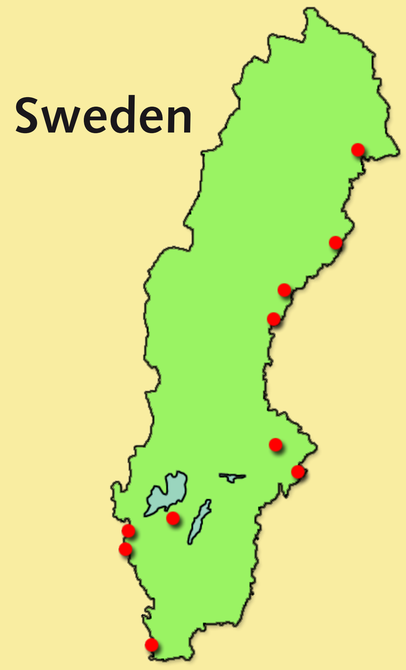
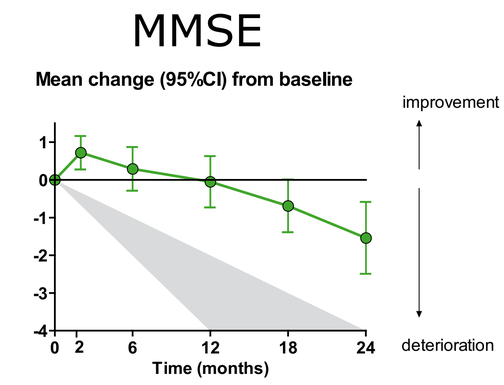
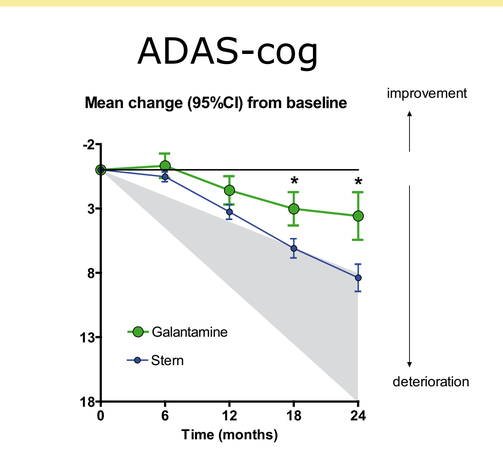


Results

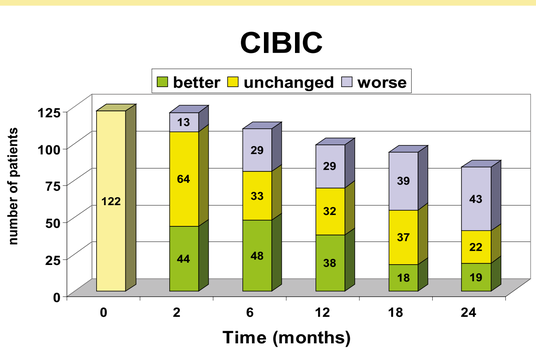
The mean galantamine dose was 15.5 - 19.8 mg/day.



The mean MMSE score remained above baseline for one year. After two years of treatment the total mean decline from baseline in MMSE-score was 1.6 points (95% CI, 0.6 - 2.6). (Shaded area 2-4 points/year, expected decline).



The ADAS-cog rise after 18 months (3.0 points) and two years (3.8 points) was significantly better than the score predicted by the Stern equation (6.1 points and 8.3 points). (Shaded area 4-9 points/year, expected decline).



Half of the patients were considered unchanged or better in the CIBIC-rating after two years of treatment. After two years 94 patients (78%) remained in the study.

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