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

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Three-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 was safe and resulted in a positive effect in cognitive tests compared to historical controls and mathematical models. After 3 years of treatment a positive global outcome was observed in more than 40% of the patients. Dropout was less than expected.

Background

Alzheimer's disease (AD) is the major cause of dementia and one of the major predictors of death in the elderly. AD is characterized by a progressive loss of cognitive and practical abilities. Multiple double blind, placebo controlled studies have demonstrated beneficial effects of galantamine treatment on cognition and function in the short-term. Outcomes in long-term treatment in a routine clinical setting has not been investigated.

The Swedish Alzheimer Treatment Study (SATS) is an ongoing open, prospective, 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.

Objectives

To describe and evaluate the three-year outcome on cognition (MMSE, ADAS-cog) and global rating (CIBIC) of galantamine treatment in Alzheimer's disease (AD) in a routine clinical setting. To evaluate dropout.

Methods and Subjects

The first 143 patients receiving galantamine in the SATS for three years were investigated in this study. Patients were assessed with MMSE, ADAS-cog (0-70) and global rating (CIBIC). MMSE and ADAS-cog mean values over time were investigated as well as the change in the scales from baseline.

The outcome of the ADAS-cog was compared to a mathematical model of change in untreated AD-patients using the Stern equation (1). The individual rate of change in ADAS-cog was calculated for each individual and described graphically. The expected decline based on previously reported rates of change in untreated patients was estimated to 2-4 points/ year in MMSE and 4-9 points/ year in ADAS-cog (1-3). Three groups of response were defined at each interval. CIBIC 1-3 was better, 4 unchanged and 5-7 worse. The reason for dropout was monitored.

Table 1. Baseline characteristics

Patients(n)	143
Gender (male/female)	54/89
Age, mean ± SD, years	72.5±8.1
MMSE, mean ± SD	23.1±4.3
ADAS-cog (0-70), mean ± SD	17.2±9.0

Reference List

(1) Stern R.G., Mohs R.C., Davidson M. et al. A longitudinal study of Alzheimer's disease: Measurement, rate and predictors of cognitive deterioration. Am J Psychiatry 1994; 151(3):390-396.

(2) Winblad B., Wimo A., Engedal K. et al. 3-year Study of Donepezil Therapy in Alzheimer's Disease: Effects of Early and Continuous Therapy. Dement Geriatr Cogn Disord 2006; 21:353-363.

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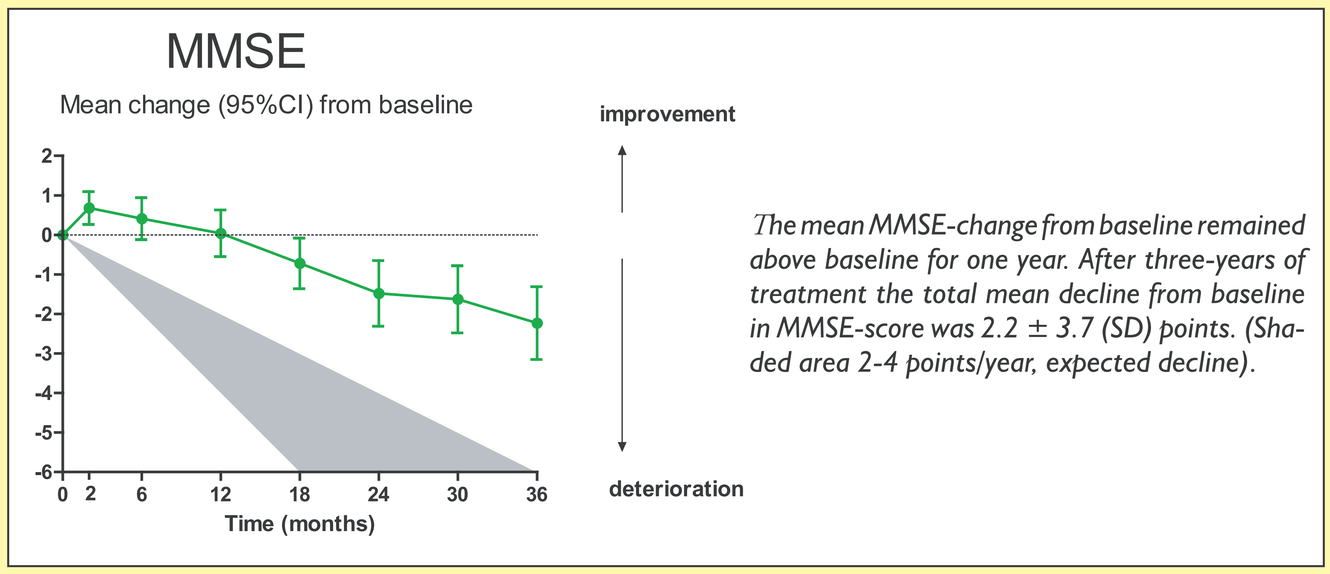
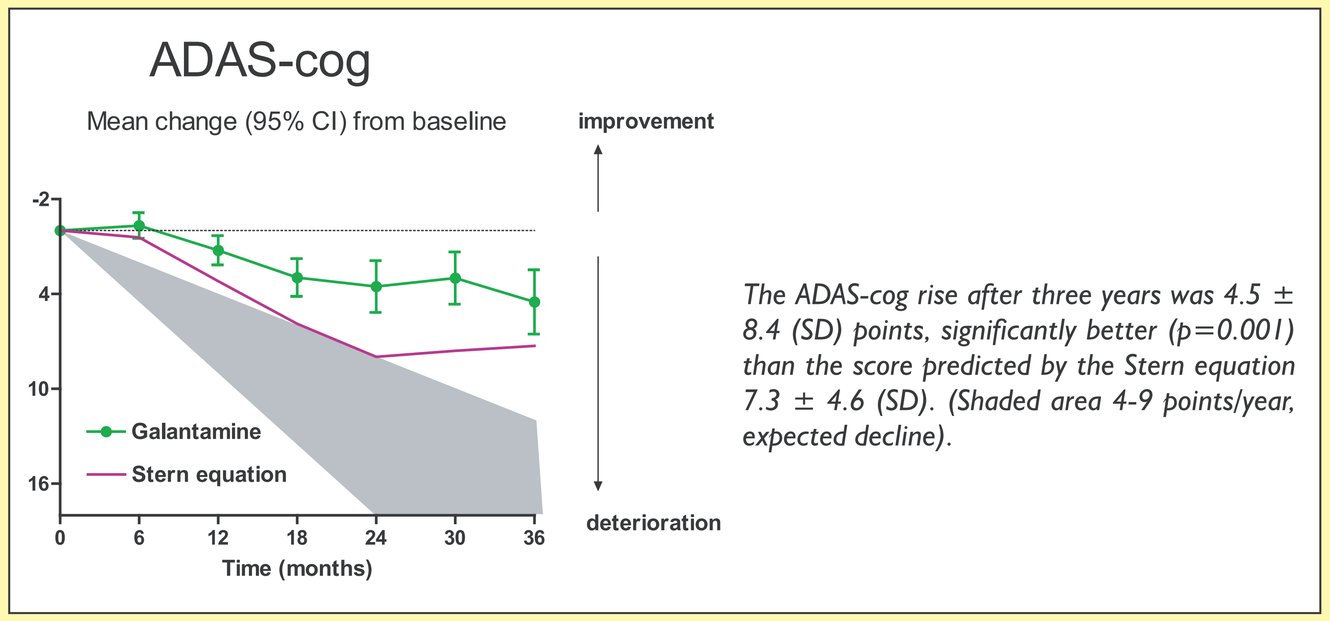
Results

The mean galantamine dose was 15.6-19.6 mg/day.



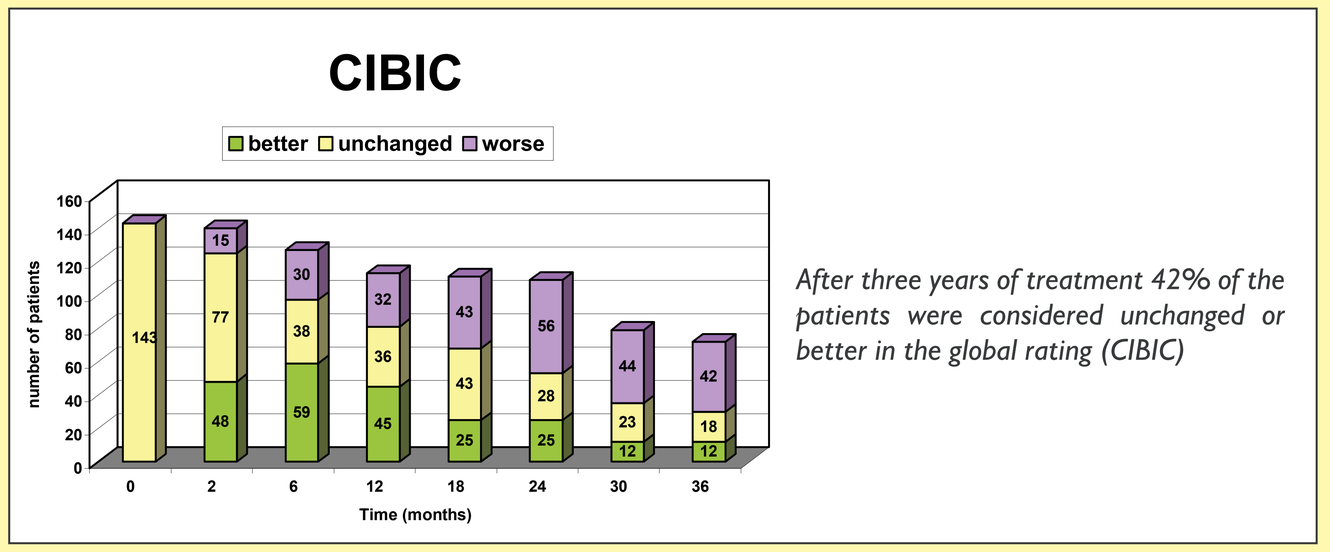
The mean MMSE-change from baseline remained above baseline for one year. After three-years of treatment the total mean decline from baseline in MMSE-score was 2.2 ± 3.7 (SD) points. (Shaded area 2-4 points/year, expected decline).



The ADAS-cog rise after three years was 4.5 ± 8.4 (SD) points, significantly better (p=0.001) than the score predicted by the Stern equation 7.3 ± 4.6 (SD). (Shaded area 4-9 points/year, expected decline).

Table 2. Reason for dropout	Patients withdrawing from study (n=71)
memantine added	22 (31%)
nursing home admission	9 (13%)
included in other study	6 (8%)
compliance problems	5 (7%)
withdrawal of consent	5 (7%)
side effect	5 (7%)
death	5 (7%)
change to other ChEI	4(6%)
insufficient response	4(6%)
other reasons	6 (8%)

After three years 50% of the patients remained in the study. The most frequent cause of withdrawal from the study was initiating concomitant memantine therapy (31%) i.e continuing galantamine treatment outside the protocol.



After three years of treatment 42% of the patients were considered unchanged or better in the global rating (CIBIC)

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