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

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2006

*Document Version:*

Publisher's PDF, also known as Version of record

[Link to publication](#)

*Citation for published version (APA):*

Wallin, Å., Wattmo, C., Björkman, A., Eriksson, S., Andreasen, N., & Minthon, L. (2006). *Two-year outcome of Galantamine treatment in Alzheimer's disease in a routine clinical setting..* Poster session presented at 9th International Geneva/Springfield Symposium on Advances in Alzheimer Therapy, Geneva, Switzerland.

*Total number of authors:*

6

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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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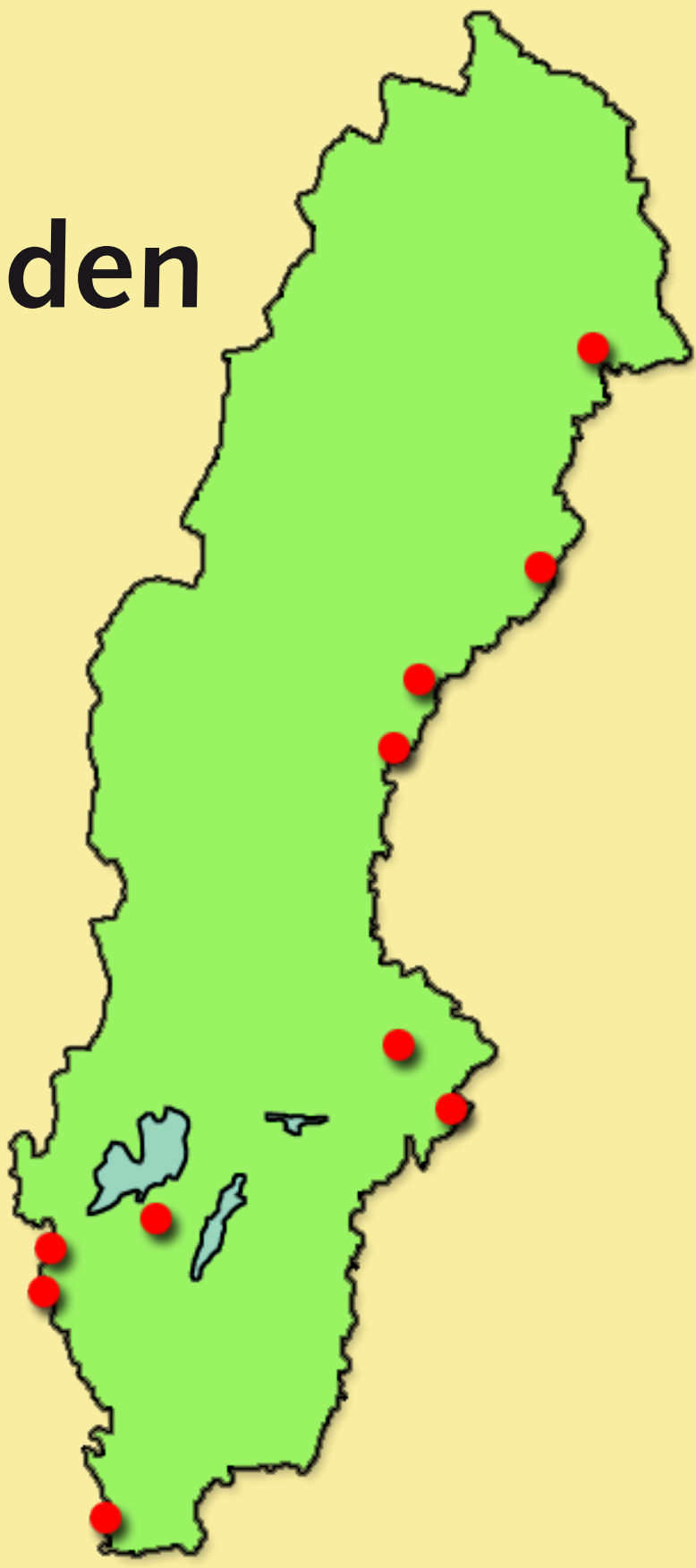
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### Results

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.

