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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

### Results

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 longterm 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 I-3 was better, 4 unchanged and 5-7 worse. The reason for dropout was monitored.

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

# MMSE



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  $2.2 \pm 3.7$  (SD) points. (Shaded area 2-4 points/year, expected decline).

ADAS-cog

Mean change (95% CI) from baseline

improvement

-2-

 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



The ADAS-cog rise after three years was  $4.5 \pm$ 8.4 (SD) points, significantly better (p=0.001) than the score predicted by the Stern equation  $7.3 \pm 4.6$  (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%)

fter three years 50% of the paents remained in the study. The ost frequent cause of withdrawal om the study was initiating concoitant memantine therapy (31%) continuing galantamine treatent outside the protocol.

CIBIC

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ADAS-cog (0-70), mean ± SD	17.2±9.0

### **Reference** List

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- better □ unchanged worse After three years of treatment 42% of the 32 atie 100 patients were considered unchanged or Q of 80 better in the global rating (CIBIC) nber 42 23 20 12 18 24 30 Ω 36 Time (months)

Contact address: Åsa K. Wallin, MD, Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, SE 205 02 Malmö, Sweden. Tel +46 40 33 55 19, Fax + 46 40 33 56 54 , E mail: asa.k.wallin@skane.se Poster presented at the IPA 2007 Osaka Silver Congress.