

Utilization of Antipsychotics in Ambulatory Elderly With Dementia in an Outpatient Setting

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This study aimed to determine the prevalence and indications of antipsychotic use in patients with dementia as well as the effects on prescription rates after the FDA regulatory warnings about antipsychotic medication use.

As the baby boomer cohort enters older adulthood, the number of people aged > 65 years will grow to 72 million (20% of the total population) by 2030.¹ The proportion of the total population with Alzheimer disease (AD) will nearly double by 2050.² Among patients with AD, neuropsychiatric symptoms (NPS), including agitation, aggression, delusions, and hallucinations, are the primary reason for nursing home placement, early institutionalization, increased cost of care, increased caregiver burden, and reduced quality of life.³⁻⁵ The prevalence of NPS is in the range of 60% to 80%, depending on the study population and assessment methods used.^{6,7}

Although practice guidelines and principles of care recommend that nonpharmacologic treatment and psychosocial interventions should

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Characteristics	Sample (N = 407)
Age (mean)	82 (SD = 6.42 years)
Gender (% male)	99.7
Race (% white)	97.3
Type of dementia (%)	
Alzheimer	64.4
Vascular	59.0
Mixed	14.4
Lewy body dementia	1.2
Dementia (not otherwise specified)	1.5

be the first-line treatment for NPS, antipsychotic medications are frequently prescribed.⁸ Currently, there are no antipsychotic medications approved by the FDA for use in patients with dementia. Studies have estimated that between 19% to 27% of community-dwelling elders with dementia were given antipsychotic medications, although there is mixed evidence regarding their efficacy and risks from use.^{9,10} The National Institute of Mental Health's Clinical Antipsychotic Trials of Intervention Effectiveness-Alzheimer Disease (CATIE-AD) reported that the sum total of the risk/benefit equation of atypical antipsychotic therapy was no greater than that achieved by placebo.¹¹ In 2005, the U.S. Food and Drug Administration (FDA) issued a

black box warning on atypical antipsychotic agents regarding their use in elderly patients with dementia due to increased risk of stroke and death, which has also been extended to conventional antipsychotics. Recent evidence suggests that although antipsychotic use may have dropped as a result, these drugs are still frequently used.^{12,13} Use of atypical antipsychotics in long-term care institutions has been the focus of research as well as emphasized and examined in routine clinical assessment of nursing home residents as part of a mandatory minimum data set. Nearly one-third of elderly nursing home residents receive antipsychotic medications.¹⁴ However, there is limited data on the prevalence and indications for clinical use of antipsychotics among an

Table 2. Characteristics of clinical profile and management

Prevalence and indications of antipsychotics			
Type of antipsychotic (N = 176)	N (%)		
Quetiapine	114 (64.8)		
Risperidone	30 (17.0)		
Olanzapine	15 (8.5)		
Haloperidol	13 (7.4)		
Aripiprazole	4 (2.3)		
Indications of antipsychotic use			
Agitation	106 (60.2)		
Delusions	50 (28.4)		
Hallucinations	38 (21.6)		
Sleep disturbance	16 (9.0)		
Irritability	5 (2.8)		
Coexisting disorders			
Psychiatric disorders	On antipsychotic (N = 176) N (%)	Not on antipsychotics (N = 231) N (%)	P value ^a
Mood	43 (24.4)	45 (19.5)	< .274
Anxiety	12 (6.8)	17 (7.4)	< 1.000
Substance use	6 (3.4)	3 (1.3)	< .183
Psychotic	1 (.56)	0 (0)	< .432
Cardiovascular risk factors			
Hypertension	110 (62.5)	154 (66.7)	< .403
Coronary artery disease	24 (13.6)	35 (15.1)	< .776
Hyperlipidemia	52 (29.5)	103 (44.6)	< .002
Diabetes mellitus	26 (14.8)	49 (21.2)	< .121
Cerebrovascular accident	16 (9.1)	22 (9.5)	< 1.000
Documentation of nonpharmacologic intervention			
Caregiver education	44 (25.0)	31 (13.4)	< .004
Attempts to cut down on antipsychotics	58 (33.0)	n/a	n/a

^a Results of a 2-sided Fisher exact test.

older ambulatory population with dementia living in the community.

This study aimed to find the prevalence and indications of antipsychotic use in patients with dementia. Retrospective data on elderly patients with dementia, who were ambulatory and living in the community, were collected. Using the electronic medi-

cal records (EMR), the focus of the study was to determine the following:

1. Prevalence and indications of antipsychotic use in elderly outpatients with dementia.
2. Effects on prescription rates after the FDA regulatory warnings about antipsychotic medication use.

METHODS

Study design and subjects

This was a retrospective study, and the data were obtained from the EMR. All outpatients who received a new diagnosis of dementia between 2001 and 2009 and who were enrolled in the Memory Disorders Clinic (MDC) were included in the

study. The population included patients living in the community and who had not been institutionalized during the study period. The MDC is a specialty clinic, and patients are evaluated and treated by a multidisciplinary team, including a geriatric psychiatrist, nurse, social worker, and occupational therapist. A dementia diagnosis was determined based on ICD-9-CM codes as well as notes by the mental health provider. This research study was approved by the medical center's Research and Development Committee and Institutional Review Board.

Medical records review and variables

To ensure that all charts were reviewed in a standardized manner, a protocol and checklist were created for the chart review, which also examined the prevalence and indications of antipsychotic use. To ensure uniformity and interrater reliability, the study team was trained and supervised by a board-certified geriatric psychiatrist. Based on chart reviews, changes in trends after the issue of regulatory warnings by the FDA were assessed. The team also reviewed notes written by the MDC team and the staff geriatric psychiatrist. The following data were extracted:

1. Demographic variables: age, gender, race.
2. Diagnostic information: type of dementia, coexisting psychiatric diagnoses, and cardiovascular risk factors.
3. Antipsychotic use: This use was based on records of outpatient prescriptions following the diagnosis of dementia. Medications prescribed during the inpatient stay or medications used on an as-needed basis were not included. The antipsychotic agents

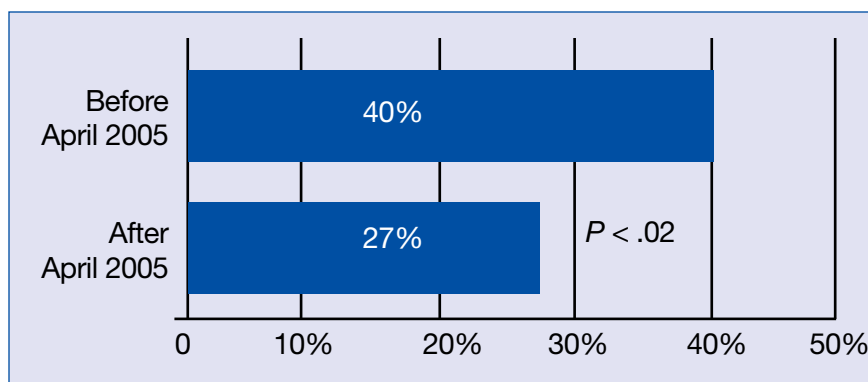


Figure 1. Change of antipsychotic prescription use before and after FDA black box warning.

were initiated or approved by a geriatric psychiatrist in the MDC.

4. Other medication-related information: This information included the documented indication for antipsychotic use, any changes or attempts to taper or discontinue the antipsychotic, and documented reassessment of use. Types of antipsychotics used were also documented as well as the date the medication was first prescribed.
5. Documentation of nonpharmacologic interventions in medical records.

STATISTICAL ANALYSIS

The proportion of patients with dementia who were prescribed antipsychotics was calculated, and neuropsychiatric symptoms, coexisting disorders, and nonpharmacologic interventions were summarized. A 2-sided Fisher exact test was used to compare 2 groups of dementia patients diagnosed before and after regulatory warning as well as to compare patients with and without antipsychotic prescriptions.

RESULTS

A total of 407 medical records were reviewed in the MDC. The charac-

teristics of the sample are described in Table 1.

Presence of antipsychotic

Of 407 patients with dementia, 176 (43.2%) were prescribed antipsychotics during the course of their illness and 231 (56.7%) were not prescribed any antipsychotic medication. These 2 groups did not differ statistically in age, sex, race, and type of dementia.

Type of antipsychotic and indications of use

Table 2 summarizes the antipsychotics used as well as common documented indications for their use. The most commonly prescribed antipsychotics were quetiapine (N = 114, 64.8%), followed by risperidone (N = 30, 17%). None of the patients were given a combination of antipsychotics at any time during the course of their illness.

The most common neuropsychiatric symptom documented for using an antipsychotic was agitation (n = 106, 60.2%), followed by delusions (n = 50, 28.4%). Thirty eight patients (21.6%) were prescribed antipsychotics for hallucinations related to their dementia. In comparison with those prescribed and not pre-

scribed antipsychotics, it was noted that the group on antipsychotics had a significantly lower rate of hyperlipidemia and were more likely to have been provided with caregiver education as a nonpharmacologic intervention.

Effects of the regulatory warning on antipsychotic use

Figure 1 shows a comparison of prescription rates before and after the FDA regulatory warning on antipsychotic medications. In the MDC, a total of 249 patients were newly diagnosed with dementia from 2001 to April 2005. Of these patients, 100 (40%) were prescribed antipsychotics. The number of newly diagnosed dementia patients after April 2005 until 2009 was 107, of whom 28 (27%) were prescribed antipsychotic medications. This decrease in prescription rate from 40% to 27% was statistically significant ($P < .02$).

DISCUSSION

This study contributes to the growing literature on patterns of antipsychotic use in ambulatory older adults with dementia. The overall rate of prescription in this sample, 43.2%, was higher than that reported in previous studies of community-dwelling elderly with dementia (27%-32%).^{9,15} The rate of antipsychotic use in a sample of newly diagnosed aggressive dementia patients is reported to be 46%.¹⁶ Therefore, these findings fall within the previously reported range. The high prescription rate can be attributed to the fact that the study population was from a specialty clinic. As reported in other studies, the most common reason for prescribing antipsychotics was agitation. Among the atypical antipsychotics, quetiapine was the most frequently prescribed. Although quetiapine now has an additional black box warning

for torsades de pointes, these data were collected before 2011; therefore, this was not considered in the study. It was also found that once prescribed, there were very few documented reassessments and attempts to taper or decrease the dose of antipsychotics and that a coexisting psychiatric diagnosis did not seem to dictate the use of antipsychotic medications.

Although practice guidelines emphasize the use of nonpharmacologic interventions for neuropsychiatric symptoms, these results mirror previous studies suggesting that these are not used extensively. Only 25% of patients on antipsychotics had documented caregiver education regarding nonpharmacologic intervention for behavioral symptoms of dementia. This number was even smaller (13.4%) in the group that was not treated with antipsychotics. There has been an increasing emphasis on use and effectiveness of psychosocial interventions in the treatment of elderly patients with dementia. Various interventions have been incorporated in the dementia guidelines, such as physical activities, behavioral management, recreation activities use, cognitive stimulation, music and aroma therapy, animal-assisted therapy, and emotion-oriented care.¹⁷ However, barriers to the practical implementation of these psychosocial interventions still exist, including training the clinicians and caregivers, limited access to interventions, and costs.

A significant decline in antipsychotic prescription rates after the FDA regulatory warning about antipsychotic use in elderly patients with dementia was found, echoing one recent study.¹³ This decline indicates that to some extent the FDA's regulatory warning did have an impact in protecting vulnerable patients from

adverse effects of medications.

These findings must be interpreted in light of the study limitations. The results are drawn from a single specialty clinic and may not be generalized easily. The sample was limited to male veterans only and was based on a retrospective chart review and is subject to biases arising from documentation. Also, there were no data on atypical antipsychotic dosage, and concomitant use of other psychotropics was not evaluated. However, there are strengths to this approach, which offset some of these limitations. The sample is from a well-defined ambulatory, community-dwelling elderly population with the diagnosis of dementia established in a specialty MDC. Also, the sample size was relatively large, thus granting the study sufficient power.

CONCLUSION

There is a significant number of elderly patients with dementia who receive antipsychotic medications despite their being used off-label and in the presence of the FDA's boxed warning. The study also suggests that there are no adequate alternatives to antipsychotics for patients with dementia, and the findings point to a greater need for implementing psychosocial interventions for ambulatory patients with dementia and agitation. It is also important for providers to educate their patients and their caregivers about the risks associated with the use of antipsychotic agents in patients with dementia. This idea would help patients and caregivers make an informed decision regarding the use of antipsychotics. Although these findings are preliminary, they may guide future longitudinal studies in this area. ●

Author disclosures

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tial conflicts of interest with regard to this article.

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