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Original Study

Use of Antipsychotic Drugs Among Residents With Dementia in European Long-Term Care Facilities: Results From the SHELTER Study

Andrea D. Foebel PhD [a,b,*], Rosa Liperoti MD, MPH [b], Graziano Onder MD, PhD [b], Harriet Finne-Soveri MD, PhD [c], Jean Claude Henrard PhD [d,e], Albert Lukas MD [f], Michael D. Denkinger MD [f], Giovanni Gambassi MD [b], Roberto Bernabei MD [b] on behalf of the SHELTER Study Investigators

[a] School of Public Health and Health Systems, University of Waterloo, Waterloo, Canada
[b] Centro Medicina dell'Invecchiamento, Università Cattolica del Sacro Cuore, Rome, Italy
[c] Ageing and Services Unit, National Institute for Health and Welfare, Helsinki, Finland
[d] Laboratoire Santé Environnement Vieillissement, Université de Versailles-Saint-Quentin en Yvelines, Paris, France
[e] Centre de Gérontologie, Hôpital Sainte Périne APHP, Paris, France
[f] AGAPLESION Bethesda Clinic, Geriatric Center, Ulm University, Ulm, Germany

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A B S T R A C T

Background: Behavioral and psychological symptoms of dementia (BPSD) are common reasons for use of antipsychotic drugs among older individuals with dementia. These drugs are not approved for such use and both the Food and Drug Administration and European Medicines Agency have issued warnings to limit such use.
Objectives: This study aimed to describe patterns of antipsychotic drug use in a sample of nursing home residents with dementia in 7 European countries and Israel.
Design: This cross-sectional, retrospective cohort study used data from the SHELTER study that collected comprehensive resident data using the interRAI Long-Term Care Facility instrument.
Methods: Fifty-seven long-term care facilities participated from 8 countries, and the sample included 4156 long-term care residents from these settings. Individuals with dementia, both Alzheimer and non-Alzheimer types, were identified. Potential correlates of any antipsychotic and atypical versus conventional antipsychotic drug use among residents with dementia were identified using generalized estimation equation modeling.
Results: A total of 2091 individuals with dementia were identified. Antipsychotic drug use among these individuals varied by country, with overall prevalence of use being 32.8% (n = 662). Among antipsychotic users, 7 in 10 were receiving atypical agents. Generalized estimation equation analysis revealed that the strongest correlate of any antipsychotic drug use was severe behavioral symptoms, which increased the likelihood by 2.84. Correlates of atypical versus conventional antipsychotic drug use included psychiatric services, more than 10 medications, moderate behavioral symptoms, and female gender.
Conclusion: Despite recommendations to avoid the use of antipsychotic drugs in patients with dementia, a large proportion of residents in European long-term care facilities continue to receive such agents. Future work should not only establish the appropriateness of such use through outcomes studies, but explore withdrawal strategies as well as alternative treatment modalities.

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* Address correspondence to Andrea D. Foebel, PhD, School of Public Health and Health Systems, University of Waterloo, 200 University Avenue West, Waterloo, ON N2L 3G1 Canada.
E-mail address: adfoebel@uwaterloo.ca (A.D. Foebel).

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Behavioral and psychological symptoms of dementia (BPSDs) include a wide spectrum of noncognitive symptoms (including agitation, oppositional behavior, aggression, delusions, hallucinations, apathy, anxiety, sleep disturbances, and wandering), and appear in up to 90% of patients, regardless of disease stage.[1] BPSDs represent the most disruptive symptoms of this disease and are known predictors of institutionalization,[2–4] lower quality of life,[5] and caregiver distress.[6,7] Guidelines recommend initial management with nonpharmacological means,[8] but antipsychotic drugs are the most common pharmacological treatment of BPSDs. Although generally not approved for this use, these drugs are prescribed to patients with dementia and evidence of their efficacy is modest. In the past decade, safety data from randomized clinical trials and observational studies have led regulatory agencies worldwide, such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA), to issue official warnings on a possible increased risk of ischemic cerebrovascular events and all-cause death associated with the use of both atypical and conventional antipsychotics in patients with dementia.[9–11]

The widespread use of antipsychotic drugs in nursing homes (NHs) has been a concern for many years. US data indicate that as many as 40% of residents with dementia receive antipsychotics, many at doses above the recommended level.[12] Also, despite FDA safety warnings, there has been little change in the rate of antipsychotic prescription in US NHs over the past decade.[13–17] Evidence regarding the use of antipsychotics in European long-term care facilities is modest, but studies from the Netherlands, Austria, and Germany describe rates of antipsychotic prescription as high as 50% to 70% in NH residents, whereas Belgian and earlier Finnish studies report rates between 30% and 40%.[18–21] Data from European NHs suggest that once initiated, prescription of these drugs continues.[18] Initiatives aimed at reducing the use of antipsychotics in NHs through facility staff training, high-quality care promotion, and abuse prevention have been promoted and there is evidence to suggest that withdrawal of antipsychotic drugs may reduce mortality.[12,22]

The aim of this study was to describe the pattern of use of antipsychotic drugs in a sample of nursing home residents with dementia in 7 European countries and Israel and to identify individual sociodemographic and clinical characteristics as well as facility-related factors that correlate with their use.

Methods

Sample

The sample for this retrospective, cross-sectional study was derived from the larger Services and Health for Elderly in Long TERm care (SHELTER) project, an international collaborative effort funded by the Seventh Framework Programme of the European Union.[23] A total of 4156 residents were included from the 57 NHs participating in this study (10 in the Czech Republic, 9 in England, 4 in Finland, 4 in France, 9 in Germany, 7 in Israel, 10 in Italy, and 4 in the Netherlands) and this study has been fully described elsewhere.[23] The SHELTER study used the new interRAI long-term care facilities (interRAI-LTCF) assessment instrument, which is a component of the interRAI suite built around a common set of items.[24,25] The aims of the SHELTER study were to assess the validity and reliability of this standardized instrument when translated in the languages of the participating countries and to assess care needs and provisions of care of NH residents, among a European sample.

Setting

Between 2009 and 2011, study partners in each country identified NHs willing to participate. Therefore, this convenience sample was not randomly selected and does not necessarily reflect all practices in NHs in participating countries. In participating facilities, all long-stay residents and those newly admitted within 3 months of the study start date were assessed using the interRAI LTCF and were included in the study if they wished to participate. The breakdown of number of residents by country was as follows: Czech Republic = 500; Germany = 496; England = 507; Finland = 484; France = 493; Israel = 580; Italy = 548; Netherlands = 488. Of these residents, individuals without drug information were excluded (from Italy [n = 73] and Finland [n = 60], 3.2%). Of the remaining 4023 individuals, residents with dementia were identified to make up the final sample and were included in all subsequent analyses. Individuals with schizophrenia (n = 48) were excluded from the final sample. Ethics approval was obtained following local regulations for all facilities in all participating countries and from the Comitato Etico of Universita Cattolica del Sacro Cuore – Policlinico A. Gemelli, Rome, Italy.

Data Source

The interRAI LTCF instrument is composed of more than 250 items to describe comprehensively client characteristics and includes items about sociodemographic variables, clinical characteristics, including both physical and cognitive status, medical diagnoses, current services, and drug use.[24,25] The interRAI LTCF has been shown to reliably capture resident information, facilitating the creation of databases to allow comparisons of resident characteristics across countries, languages, and cultures.[24] Study researchers collecting data in each country received training in performing interRAI LTCF assessments using a previously validated procedure.[26] Researchers accrued information using various sources, including direct observation; interviews with residents, family members, and formal service providers; and review of clinical records where available.

Dementia Diagnosis

From the interRAI LTCF assessment, a number of disease diagnoses are listed as check-box items; assessors are trained to gather and verify information from as many sources as possible, including the patient, the general practitioner, medical charts and other clinical documentation, and previous medical history. For identification of residents with dementia, all records with Alzheimer disease or dementia other than Alzheimer disease were used. The validity of such diagnostic information has been verified using comparisons to administrative records, with recent work demonstrating high specificity and sensitivity (0.80 and 0.83, respectively) for the combined dementia measure.[27]

Measuring Antipsychotic Use

As part of the interRAI LTCF assessment, researchers collected information about all drugs that residents were using in the 3-day period before assessment. This information was collected and verified using multiple sources, including physician order sheets and drug administration records. This drug information includes proprietary names, Anatomical Therapeutic and Chemical (ATC) codes of the World Health Organization Collaborating Centre for Drug Statistics Methodology (www.whocc.no), formulation, dosage, frequency, and route of administration. For the purposes of this study, both conventional and atypical antipsychotic drugs were identified. The classes of drugs, including ATC codes, can be found in supplementary Table S1. Residents were classified as taking either no antipsychotic drugs, 1 antipsychotic drug (either a conventional or atypical agent), or more than 1 antipsychotic drug; whether these drugs were taken on an as-needed basis was determined.