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Australian population trends and disparities in cholinesterase inhibitor use, 2003 to 2010

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Abstract

Background: The Australian Pharmaceutical Benefits Scheme (PBS) first subsidized cholinesterase inhibitors (CEIs) for Alzheimer's disease in 2001, introducing a novel therapy for a previously untreatable common condition. This study aims to determine Australian rates of CEI use and to assess equality of access to treatment based on socioeconomic status and geographic remoteness.

Methods: Pharmaceutical claims records were used to identify all Australians prescribed CEIs between January 2003 and December 2010. Age-standardized and sex-adjusted index prescription rates were derived using the total Australian population as the denominator to examine temporal trends and the impacts of socioeconomic and geographic disadvantage on CEI index prescription rates.

Results: Index prescription rates peaked in 2004 at 92.5 per 100,000 person-years, declining to between 70.2 and 73.5 for years 2006 to 2010. Rates were highest in the 85- to 89-year age group and 2.6-fold higher in the least socioeconomic disadvantaged population when compared with the most disadvantaged population. In major cities in Australia, index prescription rates were 1.4 to 1.7 times greater compared with remote areas.

Conclusions: Increasing geographic remoteness and socioeconomic disadvantage are associated with lower CEI index prescription rates, indicating inequities in the management of Alzheimer's disease in Australia.

Keywords: Epidemiology; Alzheimer's disease; Retrospective studies; Drug prescriptions; Cholinesterase inhibitors; Age-specific rates; Remoteness; Socioeconomic disadvantage

1. Introduction

Projections for growth in the number of people with dementia suggest that, during the next 20 years, there will be a 71% increase in numbers in Australia, 63% in North America, and 40% in Europe [1]. Greater increases are expected in developing regions such as India, China, and Latin America as a result of more rapid population aging. In 2010, more than 1.1% of the Australian population—approximately 242,500 people—had dementia [2], of whom 50% to 75% of cases were considered to be the result of Alzheimer's disease (AD) [1]. Two classes of drugs have been approved in Australia for use in AD: cholinesterase inhibitors (CEIs) for use in mild to moderate stages of AD, and memantine for more severe stages of the disease. Treatment with CEIs leads to modest improvements in cognition and reduced rates of functional decline [3–6] and may delay the need for residential care [7] and improve the quality of life for patients and caregivers [8]. However, the effectiveness of these drugs has been called into question [9,10] and they appear to have no impact on longevity or mortality rates [9,11,12].

The Pharmaceutical Benefits Scheme (PBS) is part of a universal health insurance system that provides access to listed pharmaceutical drugs at subsidized prices to all

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Australian residents. With this universal health insurance system, all Australians are eligible for subsidized access to medical care. At the doctor's discretion, the patient may be bulk billed (i.e., no fee is charged to the patient). Patients with concessional entitlements, such as social security recipients, elderly pensioners, and other low-income earners, pay a substantially lower copayment than the rest of the community [13]. In Australia, the CEI donepezil was first licensed for use in 1998, but access was limited because of lack of government subsidy, and treatment was limited to a few centers. The Australian government, under the national PBS, subsidized donepezil and rivastigmine in February 2001, then galantamine in November 2001, making all three CEIs affordable for Australian residents with mild to moderately severe AD [14]. In 2002, the dispensing price for each CEI was AUD$158.66; however, concession beneficiaries were required to pay only AUD$3.60, and other Australian residents paid no more than AUD$22.40 per prescription item (usual supply for 1 month). Because 80% of PBS beneficiaries are concessional patients [13], one might expect that cost would not be a barrier for Australians accessing CEIs.

The PBS mandated tightly controlled prescribing and eligibility rules to access the three CEIs. The diagnosis of mild to moderate AD had to be made by an internal medicine specialist physician or a psychiatrist. The patients were required to have a Mini-Mental State Examination (MMSE) score between 10 points and 24 points. If the MMSE score was more than 24 points, the patient was required to undergo additional evaluation using the cognitive subsection of the Alzheimer's Disease Assessment Scale (ADAS-Cog). Prolonged subsidy, beyond a trial period of 6 months, required objective improvement in MMSE score or ADAS-Cog score. The specialist physician had to provide confirmation to the PBS that the MMSE score had improved by 2 points or more, or that there was a 4-point improvement in the ADAS-Cog score. PBS listing of CEIs led to a greater need for specialist assessment at a time when there were few specialist or memory clinics devoted to determining patient eligibility. Potential barriers to the use of CEIs included the lack of an established pathway or process in Australia for assessing and diagnosing dementia [15], the paucity of dementia specialists [16], and reported delays in the diagnosis of early dementia [17] likely to be exacerbated in rural and remote areas [18]. Potential counteracting influences included disease awareness campaigns conducted by relevant lay organizations [19] and the pharmaceutical industry [20].

The introduction of a novel therapy for a previously untreatable common condition provides a unique opportunity to study how the Australian health service responded. In the case of CEIs, there was initial enthusiasm [21,22] that was tempered around 2004/2005 by some controversy concerning CEI effectiveness that is likely to have altered referral patterns or prescribing habits. To assist in managing patients with AD, we need to understand prescription rates and have information on the demographic profile of the people using CEIs. There has only been one published study of national CEI prescribing trends in Australia [23]. This previous study was limited in that it relied on aggregated prescription data and was therefore restricted to examining total number of CEI prescriptions per calendar period. Lacking access to person identifiers meant that this previous study could neither quantify the number of people prescribed with a CEI nor describe their demographic characteristics. The aim of the current study was to meet this gap in the literature by calculating yearly, Australian adult age-specific and age- and sex-standardized index CEI prescriptions rates from 2003 to 2010. In addition to examining temporal trends in CEI prescribing patterns, this study was designed to assess whether socioeconomic status and/or geographic remoteness were associated with access to these medications.

2. Method

2.1. Study cohort

Study data were obtained in December 2011 following approval from the Curtin University Human Research Ethics Committee and the Western Australian Department of Health, Human Research Ethics Committee. The PBS claims data (which included Repatriation PBS data) were examined to identify all Australians older than 20 years who received their first subsidized prescription for a CEI between January 1, 2003, and December 31, 2010. Claims data before May 2002 were not used because it was not until the introduction of the Improved Monitoring of Entitlements program in May 2002 that (*i*) general beneficiaries were included in the PBS data collection and (*ii*) drugs dispensed to Safety Net entitlement card holders were registered to the person using the drug rather than the family member holding the card. PBS claims data from May to December 2002 were used to exclude persons who received a CEI before 2003. The additional benefit of using data from 2003 in the estimation of the index prescription rates is that we have excluded long-term prevalent cases likely to have caused an upsurge in the prescription rate resulting from the initial release in 2001. In this study, index prescription refers to initiation of CEI treatment as identified by a first record of a subsidized prescription in the PBS data. Sex, age, and details on the dose and type of CEI supplied, geographic remoteness location, and socioeconomic disadvantage status were available for analysis. The rules relating to the validity of a prescription are checked by Medicare Australia as part of the online claim lodgment process as well as during the validation of paper scripts, which occurs monthly [24].

The accessibility and remoteness index of Australia was used to describe geographic disadvantage at the time of index prescription of CEI [25]. This index measures access in terms of physical distance from services and is divided into five broad levels of remoteness area: major cities of Australia and inner regional, outer regional, remote, and very remote Australia.

The index of relative socioeconomic disadvantage is a validated product of Australia's national statistical agency,