Biomedicine Hub

Methods Article

Biomed Hub 2024;9:83–88
DOI: 10.1159/000539074

Received: January 13, 2024
Accepted: April 22, 2024
Published online: May 22, 2024

Use of Potentially Inappropriate Medications among Older Adults with Dementia or Cognitive Impairment Attending Memory Clinics: A Protocol for a Systematic Review and Meta-Analysis

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Keywords
Older adults · Potentially inappropriate medication · Dementia · Cognitive impairment

Abstract

Introduction: Older adults with dementia who are on multiple medications are more vulnerable to the use of potentially inappropriate medications (PIMs), which can significantly increase the risk of adverse events and drug-related problems. PIMs use is prevalent and varies among older adults with dementia or cognitive impairment (CI) attending memory clinics. However, the prevalence of PIMs, polypharmacy, and hyper-polypharmacy among older adults with dementia or CI who are attending memory clinics is not well understood. We will conduct a systematic review and meta-analyses to examine the overall estimate of the prevalence of the PIMs, polypharmacy, and hyper-polypharmacy use among older adults attending memory clinics, with dementia or CI. The secondary objective of this study will be to compile a list of commonly implicated PIMs and to investigate factors that may be associated with using PIMs in this population. ***Methods:*** Ovid MEDLINE, Ovid Embase, Scopus, Cochrane library, EBSCOhost CINAHL, and Ovid International Pharmaceutical Abstracts (IPA) will be systematically searched by a researcher (R.S.) with the help of a librarian (C.C.). All databases will be searched from inception to May 05, 2023. Cross-sectional, cohort, randomized clinical trials, quasi-experimental, and case-control studies will be included if they assess PIM's use among older adults with dementia and/or CI. A step-by-step guide by Pai et al. [Natl Med J India. 2004;17(2):86–95] will be followed when conducting this systematic review (S.R.). The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist will be followed for reporting this SR. ***Conclusion:*** The findings from this SR/MA will identify the pooled prevalence of PIMs, providing a more precise estimate of the true prevalence of the PIMs, polypharmacy, hyper-polypharmacy in older adults with dementia or CI who are attending memory clinics at primary, secondary, or tertiary healthcare settings by considering the results of multiple studies.

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Introduction

Cognitive impairment (CI) and dementia are significant concerns in the aging population [1]. A quarter of persons 65 years and older have CI or dementia; furthermore, the prevalence increases to 40% in those aged 80 years and over [1]. The population of Canada is aging, and as it ages, the prevalence of CI and dementia will only rise. Every 5 years, the prevalence of dementia more than doubles [2]. In Canada, 402,000 older persons have dementia, including Alzheimer's dementia, and over 76,000 new cases are identified yearly [3]. In 2016, the annual cost of dementia to the healthcare system and the Canadian economy, including the out of pocket cost of caring for people with dementia) was USD 10.4 billion and this is expected to increase by 2031, per the National Population Health Study of Neurological Conditions reports [4]. Additionally, it is anticipated that by 2031, the estimated 19.2 million informal, unpaid caregiver hours from 2011 – tentatively valued at USD 1.2 billion – will double [4].

Older adults with dementia often have multiple comorbid conditions such as hypertension, diabetes mellitus, coronary artery disease, stroke, and heart failure [5]. Over half of older adults with dementia are prescribed five or more medications per day, also known as polypharmacy [6]. A cross-sectional analysis was conducted to compare the prevalence of polypharmacy and the drug classes that contribute to it among older individuals (≥65 years old) with dementia and people without dementia (PWOD) who are attending outpatient appointments in the USA. A comparison of the number of medications being prescribed to persons with dementia (PWD) and PWOD revealed that five or more medications were prescribed more often in PWD than PWOD (72% vs. 44%) as were ten or more medications (43% vs. 20%) [7]. Comparing PWD and PWOD, PWD had a 3-fold greater likelihood of receiving a prescription for five and 2.8 folds of receiving ten drugs [7]. Polypharmacy or hyperpolypharmacy (≥10 medications per day) use and age-related physiological changes in older adults can pose a significant increase in the risk of PIMs use in this population [6, 8, 9]. Polypharmacy use in older adults with CI or dementia can increase the risk of adverse drug reaction, falls resulting in head injury, drug-related hospital admission, mortality, and worsening of dementia [9]. Furthermore, polypharmacy use in this population, especially PIMs such as anticholinergic and sedative agents, may exacerbate memory loss, and increase functional impairment [10]. Furthermore, increase in PIMs use with polypharmacy leads to poor medication compliance, poor quality of life, drug-related hospital admission, and increased healthcare cost for the patient [10–13]. Addressing this issue in this population is imperative to prevent various drug-related problems, improve medication adherence, and get optimal patient outcomes.

According to the American Geriatric Society (AGS), PIMs are medications that impose a risk of adverse effects outweighing their benefits, especially when equally effective and safer treatment alternatives are available [14]. Various implicit and explicit criteria have been proposed by researchers to identify PIMs in older adults [15, 16]. Explicit criteria (e.g., Beers criteria 2023, Screening Tool of Older Person's Prescriptions [STOPP]/Screening Tool to Alert Doctors to Right Treatment [START] criteria version 3) involve predefined lists or guidelines that outline medications that are considered potentially inappropriate for certain patient populations [15, 17]. On the other hand, implicit criteria (e.g., Medication Appropriateness criteria) are based on clinical judgment and expert opinions, rather than predefined lists [18]. Healthcare professionals use their clinical experience and knowledge to assess whether a medication is appropriate for a particular patient [18]. Several epidemiological studies have explored the extent of PIMs usage in older adults. Literature reports a higher prevalence of PIMss use among older adults with CI or dementia from different settings and countries, ranging from 10% to 64% [8, 19–21]. To determine the prevalence of PIMs in older persons with CI or dementia residing in the community, Patel et al. [9] reported prevalence between 15% and 46.8%, with anticholinergics and benzodiazepines as the most frequently listed PIMs, in their literature review. Roux et al. [22] conducted population-based research using the Quebec (QC) Integrated Chronic Disease Surveillance System to assess the 1-year persistence of PIMs usage and identify related characteristics in community-dwelling older individuals in QC, Canada. "One year of PIM's use" refers to the period of uninterrupted, continuous PIMs therapy lasting more than 60 days between prescription renewals. A quarter of individuals (19,051/75,844) had used at least one PIM for 1 year. Persistence was substantially connected with increasing age, male gender, taking many medications, and having chronic illnesses [22].

Memory clinics, often called memory assessment clinics or clinics for memory disorders, are specialized healthcare facilities or departments that offer thorough examination, diagnosis, and treatment of memory and CI [23, 24]. Memory clinics are typically run by an interdisciplinary team of healthcare professionals who

specialize in assessing, treating, and caring for patients suffering from memory-related conditions, such as Alzheimer's disease and other forms of dementia [24, 25]. Several observational studies have been conducted worldwide to assess the prevalence of PIMs in the older population with dementia or CI who attend memory clinics in different healthcare settings and the studies have reported varied prevalence of PIMs in older adults with dementia or CI. A cross-sectional and longitudinal analysis reported a prevalence of PIMs of 37.3% (360/964). The study was conducted on older adults living in the community with dementia or moderate CI who attended nine memory clinics [26]. The prevalence of patients with PIMs varies significantly depending on the criteria used, population, healthcare setting, and country of study. Moreover, the population presenting in memory clinics differs significantly from other healthcare settings due to the specialized focus on cognitive health, memory disorders, and the unique needs of individuals with CI and their caregivers. The multidisciplinary approach, comprehensive assessments, and tailored interventions in memory clinics make them uniquely suited to address the complexities of memory-related conditions. Therefore, it is pertinent to explore the prevalence of PIMs, polypharmacy, and hyper-polypharmacy among older adults with dementia or CI attending memory clinics in different healthcare settings to ensure patient safety, optimization of medication management, and the enhancement of the quality of care for individuals with CIs. Thus, this SR aimed to examine the overall estimate of the prevalence of the PIMs, polypharmacy, and hyper-polypharmacy use among older adults with dementia or CI attending memory clinics at either primary, secondary, or tertiary healthcare settings. Our secondary objectives will determine the frequently implicated medications and factors associated with using PIMs in this population.

Methods

A step-by-step guide by Pai et al. [27] will be followed when conducting this SR and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines will be followed for reporting this SR [27, 28]. Data will be extracted and reported according to the PRISMA checklist. The research protocol is registered (CRD42023423001) on the International prospective register of systematic reviews (PROSPERO). In this SR, we utilized the adapted checklist for protocol submissions to Systematic Reviews, derived from Table 3 in Moher et al.'s [29] "Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation," to ensure compliance with established guidelines (see online suppl. Table 1; for all online suppl. material, see https://doi.org/10.1159/000539074).

Searches

The databases, Ovid MEDLINE, Ovid Embase, Scopus, Cochrane Library, EBSCOhost CINAHL, and Ovid International Pharmaceutical Abstracts (IPA) will be systematically searched by a researcher (R.S.) with the help of a librarian (C.C.). All databases will be searched from inception to May 05, 2023. A search strategy will be created using the population, intervention, control, and outcomes (PICO) framework. The search terms used in each database will include a combination of medical subject headings and keywords related to polypharmacy, PIM, older adults, and dementia linked by Boolean operators (AND, OR). Truncation will be used on keywords where appropriate. To supplement the electronic database search, reference lists of important articles will be reviewed to identify any additional articles of relevance. A detailed description of the electronic database search strategies can be found in online supplementary material Table 2.

Searching Bibliography and Grey Literature

To extend the scope of the review, a bibliographic search of eligible identified articles was conducted to identify any articles that were not identified in the electronic database search.

Identification of Studies

The inclusion-exclusion criteria (as shown in Table 1) were developed using the PICO framework.

Selection of Studies

All the search results from the different databases will be exported into the systematic review software, Covidence (Veritas Health Innovation, Melbourne, Australia), where duplicates will be removed. Two stages of study selection will be performed: title and abstract screening and full-text screening. Two researchers (R.S. and J.K.G.) will independently screen the titles and abstracts of the included articles according to the inclusion criteria outlined in Table 1. Subsequently, in the second stage, included full-text articles will be reviewed by the same researchers using the same inclusion/exclusion criteria. The inter-rater reliability between the two researchers will be determined using the Kappa coefficient. Conflict will be resolved by a third researcher (T.P.). The number of studies initially screened, evaluated, and excluded following a full-text review will be detailed in the PRISMA flow diagram, along with the reason(s) for exclusion.

Data Extraction

Once the eligible studies have been identified, data from the included studies will be extracted and pooled to obtain an overall estimate of the prevalence of PIMs, polypharmacy, and hyper-polypharmacy among older adults with dementia attending memory clinics. Data extraction from eligible studies will be completed using a Microsoft® Excel® (Office 365 ProPlus Version 1906) spreadsheet. Two researchers (R.S. and J.K.G.) will independently extract data from all included papers; data will only be included if both researchers come to the same results after comparing them to ensure accuracy. A third researcher will help with the decision-making process, when there are differences in

Table 1. Inclusion-exclusion criteria for SR

Item	Inclusion	Exclusion
Population	1. Older adults (age ≥60 years) 2. Diagnosed with dementia and/or CI	1) Studies population age <60 years 2) Studies on animals
Intervention/ exposure	Patients exposed to PIMs, polypharmacy, hyper-polypharmacy	
Comparator/ control	NA	
Outcomes	1. Prevalence of PIM in older adults with dementia based on criteria utilized with further analysis based on whether the PIM criteria were implicit or explicit 2. Polypharmacy, hyper-polypharmacy prevalence in older adults with dementia 3. Most frequently prescribed PIM in older adults with dementia or CI attending memory clinics Additional outcomes Quality of life, incidence of mortality, cost of PIM, falls, hospital admission, adverse events	
Study design	Cross-sectional studies, cohort studies, observational studies, randomized controlled trials (RCT), quasi experimental studies, case-control studies	Editorials, commentaries, opinions, letters to the editor, case reports
Study setting	Memory clinics located in primary, secondary, or tertiary healthcare settings	Other than memory clinics
Language	English	Not published in English

opinion. A pre-designed data extraction sheet will be used to extract the information from the included studies. The following data will be extracted:

1. Study characteristics: author names, study setting, country, year of publication, type of care setting for memory clinics (primary, secondary, or tertiary healthcare settings), study design (cross-sectional studies, cohort studies, randomized controlled trials, quasi experimental studies, case-control studies)
2. Population characteristics: sample size, age, sex, gender or both (if reported), number and type of comorbidities, race, ethnicity, education, and employment (if stated)
3. Intervention/exposure: criteria used to identify PIMs (implicit or explicit criteria)
4. Outcomes: type of clinical outcomes (proportion of patients prescribed at least one PIM, total number of PIMs prescribed, proportion of patients in polypharmacy or hyper-polypharmacy, number of changes in a prescribed medication, reduced PIMs prescribing in a patient, changes in drug-related problems, mortality, falls, hospital admission, changes in quality-of-life measures)
5. Study setting: type of healthcare setting for the memory clinic (primary, secondary, or tertiary)

Risk of Bias (Quality) Assessment

Two researchers (R.S. and J.K.G.) will independently perform the quality assessment for the included studies and cross-check between the researchers to ensure accuracy. Any researcher disputes will be settled through conversation or consulting a third researcher. The researchers will use the Newcastle Ottawa Scale (NOS) for cross-sectional and cohort studies to evaluate the methodological quality of the included studies [30]. The Cochrane Collaboration tool for evaluating the risk of bias for randomized trials tool 2 (ROB2) will be utilized [31]. Downs and Black checklist will be used for non-randomized controlled trials [32]. The National Institutes of Health (NIH) quality assessment tool will be used to assess before-after (pre-post) studies without a control group [33].

Strategy for Data-Synthesis

Based on the studies identified from the SR, a qualitative synthesis of evidence will be carried out for using polypharmacy, hyper-polypharmacy, and PIMs among older adults with dementia. The findings from the various studies will be tabulated and summarized, including an overview of the study design, patient population, types of care setting for memory clinics (primary, secondary, or tertiary healthcare settings), sample size, follow-up duration, and primary and secondary outcomes.

The data will be presented in proportions (%) with corresponding 95% confidence intervals (CI) for PIM's use (number of patients exposed to inappropriate prescribing/total number of study participants). Similarly, the extent of polypharmacy (considered 5–9 medications per day) or hyperpolypharmacy (≥10 medications per day)/(total number of patients studied). The criteria for the data synthesis will be considered based on the number of studies that report on PIMs and polypharmacy among the older population being studied. The I^2 statistic (%

residual variation due to heterogeneity) will be used to assess the magnitude of heterogeneity between the studies. I^2 levels vary from 0 to 100%; I^2 values under 25% are regarded as low, between 25 and 50% as modest, and those over 50% as high [34]. We will perform a meta-analysis using a random effect if the I^2 heterogeneity is >50% and consider the fixed model if the heterogeneity is <50%. Tau2 (method of moment estimate of between-study variance) will be used for each pooled estimate [34]. The risk of publication bias will be assessed using the symmetry of the funnel plot [35].

Analysis of Subgroups or Subsets

If the necessary data are available, subgroup analyses will be conducted for sex differences, study design, country, and type of care setting for memory clinics (primary, secondary, or tertiary healthcare settings).

Discussion

PIM's use in older adults with dementia or CI is among the major concerns. Polypharmacy is a common issue among older adults with multiple comorbidities, and suboptimal prescribing practices can significantly increase their likelihood of being exposed to PIMs which can pose a risk to their health. A previous SR conducted by Hukins et al. [36] reported a prevalence of PIMs ranging from 14 to 74% in older people with dementia in any healthcare setting (community, primary care, secondary care, tertiary care, social care, and palliative care). Benzodiazepines hypnotics and anticholinergic medications were the most commonly prescribed PIMs. The review highlights the differences in tools applied which contributes to variations in the PIMs usage reported in the SR. The authors also highlight even though when same tools were applied in the study, but how the tools were applied varied across the studies. A total of twenty-six studies were included in the review. Of 26 studies, 11 studies have reported the prevalence of polypharmacy among older adults with dementia, and the prevalence ranged from 25% to 98%. However, the study did not report much data on how the studies conducted in different healthcare setting will affect PIMs prevalence among older adults with dementia or CI. Patients attending memory clinics often have more pronounced CIs and are thus more vulnerable to the adverse effects of PIMs, polypharmacy, and hyper-polypharmacy. Understanding the prevalence and patterns of PIMs, polypharmacy, and hyper-polypharmacy in memory clinic settings allows for the development of targeted screening strategies. These strategies can facilitate early interventions, reducing the risk of adverse outcomes and potentially improving the quality of care for individuals with CIs. Data on the prevalence and impacts of PIMs, polypharmacy, and hyper-polypharmacy in memory clinic attendees can guide policy decisions and practice guidelines. This can lead to more informed healthcare delivery and the adoption of safer prescribing practices tailored to the unique needs of older adults with dementia or CI. Moreover, there has been no SR conducted which has reported the prevalence of PIMs in memory clinics. This review will provide synthesized evidence of the pooled prevalence of polypharmacy, hyper polypharmacy, and PIM's use among older adults with dementia or CI attending memory clinics. Moreover, this study will provide a comprehensive list of frequently occurring PIMs among this population.

Statement of Ethics

Statement of Ethics is not applicable because this study is based exclusively on published literature.

Conflict of Interest Statement

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding Sources

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Author Contributions

- Study concept and design: Tejal Patel, Rishabh Sharma, Manik Chhabra, and Kota Vidyasagar.
- Drafting of the manuscript: Tejal Patel, Rishabh Sharma, Caitlin Carter, Jasdeep Kaur Gill, Wajd Alkabbani, Kota Vidyasagar, Linda Lee, and Feng Chang.
- Critical revision of the manuscript: Tejal Patel, Caitlin Carter, Wajd Alkabbani, Kota Vidyasagar, Linda Lee, and Feng Chang.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author (Dr. Tejal Patel; email: tejal.patel@uwaterloo.ca).

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