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Original Research

Prevalence and predictors of non-evidence based proton pump inhibitor use among elderly nursing home residents in the US



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A B S T R A C T

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Background: Proton pump inhibitors (PPIs) can lead to several adverse effects among the elderly, particularly when used inappropriately or in contrast to evidence suggested protocols.

Objective: The aim of this study was to examine the prevalence and predictors of non-evidence based PPI use in elderly nursing home residents.

Methods: A cross-sectional study was conducted using data from the 2004 National Nursing Home Survey (NNHS). The study sample included nursing home residents 65 years and older. Descriptive statistics were used to examine the prevalence of non-evidence based PPI use. Multivariable logistic regression was used to evaluate the patient and facility-level factors associated with non-evidence based PPI use among the elderly nursing home residents.

Results: A total of 355,600 elderly nursing home residents received at least one PPI for an overall prevalence of 26.99%. Among those elderly receiving PPIs, 48.59% of the use was not evidence based. Multivariable logistic regression revealed that residents with osteoporosis (Odds Ratio (OR): 0.55, 95% CI: 0.45–0.68), SSRI users (OR: 0.81, 95% CI: 0.68–0.97) and those residing in micropolitan area (OR: 0.79, 95% CI: 0.63–0.98) were negatively associated with prescription of PPIs without an indication. Patients with chronic cough (OR: 2.10, 95% CI: 1.12–3.96) and Medicare insurance (OR: 1.23, 95% CI: 1.01–1.50) were positively associated with prescription of PPIs without an indication.

Conclusions: The current study found that almost half of the elderly nursing home residents used PPIs for non-evidence based indications. Given the safety concerns and high non-evidence based use of PPIs in nursing homes, there is an urgent need to optimize PPI use in the elderly.

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Introduction

Proton pump inhibitors (PPIs) currently rank among the top three prescribed drug classes in the United States (US).¹ All PPIs irreversibly inhibit the gastric H⁺ – K⁺ ATPase by binding to active proton pumps in the gastrointestinal system and provide effective acid suppression.² PPIs are indicated for gastro-esophageal reflux disease (GERD), erosive esophagitis, duodenal ulcers, risk reduction for gastric ulcer, and other gastric disorders.^{3–11} According to the American College of Gastroenterology (ACG), an 8-week course of PPIs is the medical therapy recommended in GERD.¹² Newer PPIs

offer dosing flexibility; however, there are no major differences in efficacy between different PPIs.^{12–14}

Although PPIs are effective, recent literature suggests that PPIs are associated with severe adverse events like community-acquired pneumonia,^{15–18} *Clostridium difficile* infection (CDI)^{19–23} and fractures.²⁴ The increased risk is primarily due to decreased gastric acid secretion, facilitating bacterial growth upwards and into the lungs causing pneumonia. In addition to altering gastric pH, PPIs are implicated in disruption of the friendly gut ecology by modulating the micro flora of the gastrointestinal system (dysbiosis) and facilitating the growth of vegetative *C. difficile* organism.^{25,26} Along with other issues, PPIs have also shown to cause calcium malabsorption leading to fracture, vitamin B₁₂ and iron deficiency mainly due to its gastric acid suppressing behavior.²⁷ Thus, the US Food and Drug Administration (FDA) has recently issued warning for a

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Table 1
Proton pump inhibitors indications according to FDA and NICE guidelines

Indications	FDA	NICE
<i>Helicobacter pylori</i>	Yes	Yes
Zollinger-Ellison Syndrome (abnormality of secretion of gastrin)	Yes	Yes
Esophagitis	Yes	Yes
Gastro-esophageal reflux disease (GERD)	Yes	Yes
Barrett's esophagus	–	Yes
Gastric ulcer	Yes	Yes
Duodenal ulcer	Yes	Yes
Peptic ulcer	Yes	Yes
Gastritis and duodenitis	–	Yes
Dyspepsia	–	Yes
Concomitant use of NSAIDs	Yes	Yes
Heartburn	Yes	–

possibly increased risk of fracture.^{27,28}

PPIs are mainly approved for the treatment of gastric acid related disorders as per Table 1.^{3–11} However, they are widely used for non-evidence based indications. Studies suggest 54.1%–82% use of PPIs is for non-evidence based indications.^{3,9,10,29–33} The annual estimated cost of inappropriate PPI prescription in inpatient and outpatient setting was \$12,272 and \$59,272, respectively, as per the findings of Ladd and colleagues.³ According to Haroon et al, approximately 31% of patients were taking PPIs for ≥ 2 years and 25% were consuming the drug for about one year.⁹ About 50% of patients were inappropriately consuming PPIs 6 months after discharge. Long-term stay was the primary reason for inappropriate PPI prescription after hospital discharge as per Zink and colleagues.³² Reviewing an administrative data, Reid et al found that *C. difficile* infection was mainly found in groups of patients receiving PPIs inappropriately; 'prophylaxis' was the justification in about 56% of inappropriate users.¹⁰ In a four-year trend study by Leri et al even though a decreasing trend in inappropriate PPI use was observed, the percentage of inappropriate PPI use remains high (80%–85%) from 2005 to 2008.³¹

Inappropriate medication use is a major concern in the elderly due to age-related factors, polypharmacy, and comorbidities.^{32,33} Nursing home residents are at an increased risk for medication related morbidity as they use more medications than patients in any other setting, mainly due to the increased number and severity of chronic diseases.³⁴ Very few studies have examined the use of PPIs in US nursing home settings.^{29,35} In a 2011 nursing home study, Burdsall et al found no appropriate diagnosis for PPI use in 65.3% of patients, with GERD used as a diagnosis for majority of PPI users without a follow-up or symptomatic evidence documented for active GERD.²⁹ A study by Chia et al observed a prevalence of 54.1% of off-label PPI use in an inpatient setting; the indication-based PPI use was defined as per the US FDA guidelines.³⁴

The objective of this study was to examine the prevalence of non-evidence based use of PPIs in elderly nursing home residents and to evaluate the factors associated with non-evidence based PPI use. Identification of patient and facility factors associated with inappropriate prescribing of PPIs among the elderly can help to better target interventions aimed at optimizing PPI use in this vulnerable population.

Methods

Data source

The current study used cross-sectional data from the 2004 National Nursing Home Survey (NNHS) to examine the prevalence of non-evidence based use of PPIs in elderly nursing home residents.³⁶ The 2004 NNHS is the most recent national survey

available. This nationally representative survey provides information on two facets of nursing homes: service providers and care recipients. The survey was conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention to provide nationally representative data. Public-use data files from the 2004 NNHS were used to conduct secondary data analyses. This study was approved by the institutional review board (IRB) of the University of Houston under the exempt category.

The sampling of NNHS involved a stratified two-stage probability design. The first stage involved selection of facilities, and the second stage comprised selection of residents from the sampled facilities. Overall, 78% of response rate was observed from 13,507 residents residing in 1174 facilities from the 2004 NNHS. Computer-assisted personal interviewing (CAPI) system was administered in sampled nursing home facilities. The survey contained facility-level and resident-level modules. The facility-level module was completed by the interviewer before completing the resident-level module to confirm the eligibility of the facility for the survey. Provider characteristics contained in the facility data were facility size, facility ownership, Medicare and Medicaid certification, services provided, specialty programs offered, and charges for services.

Resident data was not obtained through direct interaction but by consulting with the designated staff member familiar with the residents and his or her overall care. Recipient data contained demographic characteristics, health status, diagnoses, medications taken by the recipient, and sources of payment. Prescription medication data contained up to 25 medications administered in the 24 hrs before the interview and up to 15 medications taken by the resident on a regular basis in the month before the interview but not taken in the prior 24 hrs. Prescribed medications were coded for products and generic ingredients as per a unique classification scheme developed by NCHS, and National Drug Code (NDC) numbers were used for categorizing drug classes.³⁷

At the time of interview, the resident file captured most comprehensive diagnostic data including up to 34 diagnostic conditions from the medical chart. These included two primary diagnostic conditions at the time of admission to the nursing home, two current primary diagnostic conditions, and up to 30 current secondary diagnostic conditions. All the diagnostic conditions were coded as per the ICD-9-CM coding system. Further information regarding the data collection systems, sampling scheme, and definitions used in the NNHS can be found elsewhere.^{36,38}

Study sample and definitions

The study sample consisted of elderly (aged 65 years and older) nursing home residents who were prescribed at least one PPI. PPIs were operationally defined using American Hospital Formulary Service (AHFS) classification and included use of: omeprazole, pantoprazole, lansoprazole, rabeprazole and esomeprazole. Because of unavailability of drug regimen and duration, this study used an indication-based definition of non-evidence based PPI user. All PPI use indications approved by the FDA and those included in the National Institute for Health and Care Excellence (NICE) guidelines issued by the National Health Service (NHS) of UK, on or before 2004, were used to define evidence base in the current study.^{3,9,39–44} Table 1 provides the list of evidence-based indications for PPIs. PPI use was considered non-evidence-based if none of the patient diagnoses (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] codes) could be matched with those from the evidence-based list, or those without a co-prescription for non-steroidal anti-inflammatory drugs (NSAIDs).

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