A comprehensive medication review of a polypharmacy patient population: A cross-sectional observational study

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A B S T R A C T

Background: It is well documented that polypharmacy status is associated with manifold drug-related problems (DRPs). In this cross-sectional observational study, a type 1 medication review of a polypharmacy patient population in Greece was carried out.
Objectives: The study aim was to quantify the prevalence of unaddressed DRPs in a representative Greek polypharmacy patient population. The secondary aim was to report on the average monthly medication cost per polypharmacy study patient.
Methods: The study population consisted of 91 older, high-risk polypharmacy patients registered at 10 community pharmacies in Athens. The cross-sectional medication review was conducted by 10 independent pharmacists during September of 2020. DRPs were assessed and classified according to 'The PCNE Classification V 5.01' by two clinical pharmacists and researchers.
Results: A median concurrent use of 8.45 medications per patient was found, with an average of 1.89 identified DRPs per study subject. A total of 172 DRPs were observed in the study population. 75.6% of all DRPs were classified as drug-drug interaction problems, with a mean of 1.42 identified drug-drug interactions per study subject. The mean monthly cost per polypharmacy patient was calculated at €38.64 ($45.20 USD).
Conclusion: There is urgent need to improve in-pharmacy medication monitoring and advising to optimize drug concordance and to reduce DRPs among polypharmacy patients in Greece. Further research is warranted to investigate larger scale polypharmacy-related iatrogenic harm potential due to overlooked and unaddressed DRPs within Europe and globally. Investigation into the predictors of and risk factors for DRP incidence in polypharmacy patient populations is also needed. Broadly, this study underscores the need for continuous and perspicacious monitoring of unaddressed DRPs in patients using multiple drugs by community pharmacists.

Background

In Europe, the percentage of people older than 65 is monotonically increasing as Europe-wide birth rates attenuate. In 2019, more than one fifth (20.3%) of the EU-27 population was aged 65 and over. Further, the share of people aged 80 years or older in the EU-27's population is projected to increase two-and-a-half fold between 2019 and 2100 (from 5.8% to 14.6% share of the total population).[21]

Polypharmacy prevalence, commonly defined as the percentage of the population that uses five or more concurrent medications daily, among older adults in EU-27 countries ranges from 26.3 to 39.9% depending on the country surveyed and is also increasing in prevalence.[1] In the cohort of Europeans older than 65, 32.1% take 5 or more medications per day.[1]

In Greece—the location of this research group—21.8% of the population is aged 65 or older, of which a reported 29.3% take 5 or more medications per day.[2] It is well documented that presence of polypharmacy is associated with drug-related problems (DRPs) ranging from persistent non-adherence and unmitigated drug interaction problems to severe adverse drug events, hospitalization, and even polypharmacy-related death.[3,4] A 2017 study estimates the outright medication cost to polypharmacy patients in Greece sums to more than €1.1 billion ($1.3 billion USD) annually, without accounting for the secondary and tertiary costs of possible adverse drug reactions and associated polypharmacy-related problems.[5]

One powerful tool in extenuating DRP risk among polypharmacy patients is the regular practice of medication review by prescribing pharmacists. Medication review is defined as a structured evaluation of an

individual patient's medicines with the aim of optimizing medication usage and dosage to improve health outcomes.[6] This typically entails detecting potential drug-related problems and recommending interventions to mitigate patient risk.[6] Consequently, medication review is an indispensable step in the pharmaceutical care process for polypharmacy patients, especially those in older age cohorts.

In Greece, the location of the present study, current regulations allow for repeated dispensation of prescribed medicines for a maximum of 6 months without prescription renewal.[7] Greek community pharmacists therefore play a pivotal role in the medicated management of chronic diseases and more broadly in the global care of patients, especially as it pertains to older patients using a concatenation of interacting molecules for extended periods of unmonitored use. As such, fastidious medication review represents one of the highest impact activities a community pharmacist performs in the service of their patients.

The present study is a cross-sectional medication review of a polypharmacy patient population. It was conducted in Greece as it is the EU-27 country with highest density of pharmacies per capita. Greece has 88 pharmacies per 100,000 residents[26]. For reference, the Organization for Economic Co-operation and Development (OECD) member country average is 29 pharmacies per 100,000 residents[26]. Pharmacies in Greece are therefore comparatively ubiquitous, from small villages and island regions to focal *agoras* of Greece's largest cities. Increasingly, Greek pharmacists are bridging the clinical care gap and functioning as point-of-care providers by furnishing services like nutritional and weight loss counseling, as demonstrated by work recently reported.[8] Further, Greek pharmacists are highly educated and trained professionals and are thusly ideal research confederates. This *sui generis* status, in conjunction with Greece's instituting of complete electronic medical and prescribing records for all citizens from 2011 onward,[9] makes the Greek community pharmacy setting an ideal testbed for implementing pharmaceutical care interventions and for promoting clinical pharmacy services like polypharmacy patient advising.

Aim of the study

The primary study aim was to quantify and categorize the overall prevalence of drug related problems (DRPs) among polypharmacy patients in 10 representative community pharmacies in Athens, Greece. The secondary aim of the present study is to report on the average medications cost per polypharmacy patient in this Greek polypharmacy patient population.

Methods

Study design

We carried out a cross-sectional observational study in the form of a Type 1 Medication Review, as defined by the PCNE.[1] A Type 1 Medication review solely utilizes patient medication history information to assess drug-related problems and drug-related interactions and is defined as a "Simple MR" by the PCNE[6]:

PCNE Type 1: **Simple MR**: A simple medication review is based on the available medication history in the pharmacy.

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[1] The Pharmaceutical Care Network Europe (PCNE) was established in 1994 by several European pharmaceutical care researchers. It became an official association (under Dutch law) in 2004. According to the bylaws, the aim of PCNE is to help to develop pharmacy along the lines of pharmaceutical care in the involved European countries through:

- stimulating pharmaceutical care and pharmacy related outcome research in Europe;
- stimulating research and implementation projects carried out in more countries simultaneously;
- organising a bi-annual working conference around pharmaceutical care and pharmacy practice research;
- all other possible activities that serve the aim of the association.

Parameters included: drug names and interactions, side-effect profile of listed drugs, unusual dosage identification, and patient adherence issues if reported.

Eligibility for study pharmacists

All 10 participating pharmacists attended a short training prior to commencement of the study. The training session included an overview of best practice pharmaceutical care and medication review, instruction on each study component and inclusion criteria outlined below, a reinforcement on the need for protocol compliance, and a declaration of rights and responsibilities of the study pharmacists. Pharmacists were required to give written consent pursuant to the study protocol. Further, solely "responsible pharmacists" of each participating pharmacy were eligible for the study; according to Greek law, a "responsible pharmacist" is defined as the primary principal responsible for the safe and effective running of the pharmacy.[10] No further training on the execution of the medication review was offered.

Study population

The study population consisted of older, high-risk polypharmacy patients registered at 10 community pharmacies in the South suburbs of Athens in the September of 2020. The inclusion criteria remained syntonic with criteria used in analogous European studies[11–13]:

Patients aged 65 years and older, presently and concurrently using five or more types of prescribed medicines over a greater than 3-month period, and having one or more of the following risk factors:

- Three or more diagnosed diseases.
- Impaired cognition (according to the Short Test of Mental Status (STMS)).
- Increased risk of falling.
- Signs of poor compliance to medication instruction (operationalized as patients who reported to pharmacists that they had missed two or more doses over the preceding 3-month period and/or were truant in refilling two or more prescriptions during that same period).

Drug-related problem (DRP) classification scheme

DRPs were assessed and classified according to 'The PCNE Classification V 5.01' by two clinical pharmacists and researchers. These group classifications were assigned using a proprietary Clinical Decision Support System (CDSS) which utilizes the European Medicines Agency's (EMA) Summary of Product Characterizations (SPCs) to subdivide DRPs into 1.) drug interactions, 2.) drug choice problems, 3.) dosing problems, and 4.) drug use problems. This proprietary CDSS is updated every three months according to the Greek Medicines Agency's (GMC) quarterly publication on the circulation of novel drug compounds.

Observational approach

The individual patient medication reviews were carried out by each of the 10 "responsible pharmacists", a term for owner-operating pharmacists in Greece,[10] in the 10 participating community pharmacies. Initially, the researchers enlisted the participation of 25 community pharmacies in the Kallithea suburb. Kallithea is the region where Harokopio University, the academic affiliation of the study authors, is located. Of the 25 contacted pharmacies, 10 agreed to study participation. The study power analysis was calculated according to a standardized $\alpha = 0.05$, $\beta = 0.20$, and an expected effect size of $r = 0.25$, yielding a sample size of 123 patients. Due to fininacial limitations, the study population was limited to 100 polypharmacy patients.

Each pharmacist self-selected 10 representative patients, who according to his/her professional judgment met the study inclusion criteria as delineated by the pre-study training protocol and as is detailed in the "Study

Population" subsection. As such, patient population randomization was not possible. Each "responsible pharmacist" subsequently self-performed a Type 1 Medication Review for each of his/her 10 respective polypharmacy patients, specifically with the intent of identifying heretofore latent DRPs as indicated by the pharmacies' databases.

Final data analysis and clinical review was conducted by two researchers, a clinical pharmacist and an academic pharmacist, after the initial data collection. Medication costs were calculated for the study population according to the standardized 2020 GMC pricing schedule for pharmaceuticals in Greece. The preventability of DRPs in this polypharmacy patient population was not assessed and is beyond the scope of this observational approach.

Data collection

The medication profiles of each patient were used to derive information on demographic characteristics and medication status. Specifically, the present study documentation the following patient-specific information:

· prescription medication taken for >3 months.
· drug name, active ingredient, strength, & dosage.
· branded or generic drug.
· patient diagnoses & concomitant drug indication.
· monthly cost for patients.
· age.
· sex.

Data analysis

All analyses were conducted by applying the Statistical Package for the Social Sciences (SPSS 21.0 for Windows, Chicago, IL, USA) and Microsoft Excel. Descriptive statistics were performed, and values are presented as mean and percentile ranks of the study population. Inferential statistics were not performed in this analysis.

Patient personal data privacy statement

Patient data from pharmacies' databases were used in this study; accordingly, full electronic patient records were not accessed nor provided. The data used in this study was processed anonymously; no nexus between patient data and identity was formed. Further, in each of the ten pharmacies a confidentiality agreement interdicting the sharing of any of the confidential patient information and metadata was signed by all participating pharmacists and the study authors.

Ethics approval statement

The current study did not require patient consent nor approval by an ethics committee, as no intervention was involved, data were anonymized, and no patient identifying information was provided. All information regarding participants' clinical condition, medication, and medical history were provided anonymously by the ten prescribing clinicians; as such, no nexus between patient identity and treatment protocol nor indication was formed. However, the study protocol was approved by the Department of Pharmacies of the Southern District of Athens. Written proof of study approbation can be obtained from the study authors on reasonable request.

Results

Patient characteristics

One hundred patients were initially included in the study. After conclusion of the medication reviews and completion of the monitoring phase by the clinical and academic pharmacists, 9 patients were excluded from the cross-sectional report as they did not match the inclusion criteria. Namely, these patients did not meet the age-related requirements as defined by the

Table 1
DRP classifications among polypharmacy patient study population.

DRP Classification	Number (%)
Drug-Drug Interaction	130 (75.6)
Drug Choice Problem	36 (20.9)
Dosing Problem	2 (1.2)
Drug Use Problem	4 (2.3)
	172

study protocol and were thus erroneously included by a responsible pharmacist. Other subjects were further precluded as they were found to be taking less than 5 concurrent medications; though these subjects qualify as polypharmacy patients under some categorization criteria, under the operational definition of this review these subjects were excluded. Concurrent use was operationalized in the study as a patient having at minimum a three-month refill on medication. Patients who had changes in medication within one month of the study were also excluded. 91 patients remained, representing a 9% rate of false study inclusion. The population consisted of 52 women and 39 men. The mean age of the patient population was 78.64 years old.

Drug Related Problems (DRPs)

The total number of Drug Related Problems (DRPs) identified was 172. The mean number of observed DRPs per patient was 1.89. DRPs were further subdivided into 4 subcategories: drug interactions ($n = 130$), drug choice problems ($n = 36$), dosing problems ($n = 2$), and drug use problems ($n = 4$) (Table 1).

Medication cost characteristics

Overall, 769 drugs were examined, of which 68% ($n = 524$) were branded and 32% ($n = 245$) were generics. The mean number of prescribed drugs per patient in this study population was 8.45. The mean monthly cost per patient was calculated at €38.64 ($45.20 USD) and ranged from €0 to €127.51 per month ($0 to $149.16 USD) (Fig. 1).

Discussion

Few Greek studies have been conducted concerning polypharmacy, its multifarious medication characteristics, and its broader population-level impact; the present study adds to the sparse literature in the space. The EU-funded Stimulate Innovation in the Management of Polypharmacy and Adherence in the Elderly (SIMPATHY) project provides an extensive overview of polypharmacy management initiatives in EU-27 countries, however.

As presented by McIntosh et al. in 2018,[14] Greece has no formal nation-wide polypharmacy safety initiative as a country-specific analog to the SIMPATHY project, mostly owing to collaborative deficits and poor top-down medical coordination efforts. The existing literature on the status of polypharmacy in Greek concluded that its population prevalence was 29.3%[2] and 22.5%,[15] respectively. Older work found that polypharmacy status in Greece is positively and strongly correlated with age, especially in cohorts over 65 years.[7] An unfortunate limitation of this incipient literature in Greece is that all previous studies have been reliant on self-reported patient data.

Research on polypharmacy in Greece is sparse. Presently, only two substantive additions to the literature have been published: Papaioannidou & Michailidou[5] estimates that 28% of community pharmacy patients in Greece aged 65 years or older take 5 or more drugs concurrently, though this estimate is hindered by non-representative study design limitations as it was conducted in a limited geographic region; Charalampopoulou et al.[16] found that polypharmacy prevalence in older Greek adults (>65 years of age) may extend as high as 56.5%, when accounting for expanded
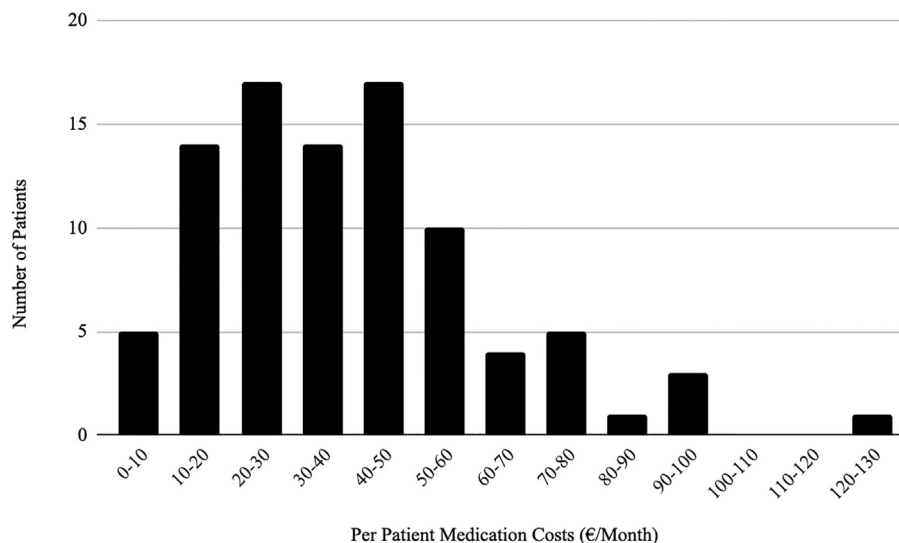
Fig. 1. Monthly medication costs per polypharmacy patient.

drug categories like over-the-counter (OTC) medication for the maintenance of chronic diseases.

Heterogeneity in the samples of the extant Greek polypharmacy literature is an additional problem. As the rather nebulous terms "elderly" and "polypharmacy" are capacious, there exists some discrepancy around the age at which a person is medically deemed "elderly" and historically some oscillating debate over the "polypharmacy" medication minimum threshold, with definitions ranging from concurrent use of 2 to 11 medications or greater. A general and consistent upshot of the existing literature and this present study is, however, that as polypharmacy status increases so does the concomitant risk of drug related problems, specifically drug-drug interactions.[11,17,18] Though this conclusion is intuitive, it represents an important step in the development of comprehensive medication review and treatment protocols for this growing subset of pharmacy patients.

To the best knowledge of this research group, the present study is the first conducted with a Greek pharmacy patient population to assess DRPs through a thorough Type 1 Medication Review. As delineated in the Results section, the main finding is that the mean number of DRPs per patient in this study population was 1.89, with the associated mean number of drug-drug interactions at 1.42. On average, this patient group evinced nearly 2 DRPs per individual, with a majority of those DRPs being categorized as drug-drug interactions. Investigating these interactions, it was discovered that the drugs most likely to give rise to a DRP are primarily for the treatment of cardiovascular problems. As cardiovascular diseases are the leading cause of death globally[20] and contribute to one death every 36 s in the United States[22] , it is unsurprising that a higher proportion of pharmacy patients is undergoing medicated treatment for cardiovascular disease and is thusly at higher risk of DRPs and iatrogenic effects due to the multimodal treatment of primary cardiovascular disease and its associated sequelae. Relatedly and in Greece, ischemic heart disease and stroke are reported as the leading causes of death[23] .

These findings underscore the significance of providing thorough and circumspect pharmaceutical care to elderly polypharmacy patients, especially those receiving multi-medication treatment for cardiovascular diseases and related chronic illnesses. These findings further highlight the need for prescribers and dispensing pharmacists to perspicaciously evaluate the risk of DRPs when prescribing multiple pharmaceuticals for concurrent treatment, especially in aging populations.

With respect to the financial burden of polypharmacy on Greek patients and as asseverated by Michas, Karvelas, & Trikas (2019)[24], there is evidence supporting the claim that Greek government-debt crisis (beginning in the early 2009 fiscal year until present) will significantly increase cardiovascular disease prevalence in Greece in the long-term. In a country with a

GDP per capita of $17,671 (€15,106.07) and an unemployment rate of 15.47% in 2020[21], minor perturbations in the prevalence of diseases like cardiovascular disease can foment significant, negative, and large-scale socio-economic ramifications that perseverate far into the future. On an individual patient basis, the mean monthly cost of medication per patient of €38.64 ($45.20 USD) in this study can represent a significant expense. A reported 82.3% of Greek citizens over 65 years of age are pensioners, receiving a monthly payment of €345.50 ($404.16 USD)[25]. This amount represents the entire monthly income for many elderly Greek citizens, who become eligible for pensioner status at 67 years of age. At the high end of monthly polypharmacy-related costs as assessed by this report, a full 36.9% of monthly income could be spent solely on essential medication outlays. Further research and reporting are needed to elucidate the extent of the financial burden placed on Greek polypharmacy patients writ large.

Limitations

This study has limitations. A comparatively small sample size of 91 polypharmacy patients in a southern suburb of Athens, though representative in many respects, does not allow for extrapolation to infer population-level statistics in Greece. Furthermore, a notable selection bias is at play given the 10 participating "responsible pharmacists" had discretionary control over patient inclusion. Individual pharmacists' inclusion criteria, though constrained by the study inclusion criteria, were nevertheless invariably non-standardized, as each pharmacist possessed different tacit assumptions about study patient qualification. Moreover, this study featured no intervention, but rather solely aimed to identify DRPs among polypharmacy patients in a community pharmacy setting via an observational and descriptive medication review.

Further research is warranted to investigate larger scale polypharmacy-related iatrogenic harm potential due to overlooked and unaddressed DRPs within Europe and globally. Investigation into the predictors and risk factors for DRP presence in polypharmacy patient populations is also needed.

Conclusion

This study provides a pioneering look into the degree and prevalence of polypharmacy in Greece and adds to the limited Greek literature on polypharmacy from the vantage point of community pharmacies. This study represents the first Type 1 Medication Review on a population of elderly polypharmacy patients in Greece and demonstrates the urgent need to optimize multiple drug use and drug concordance to decrease DRPs among an at-risk polypharmacy patient population. There is a pressing need to

broaden the purview of pharmacy services offered, such as the offering of medication reviews for patient consultation in Greece; however, this necessary expansion of community pharmacy services unfortunately remains in an inchoate stage.

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Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

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