

Unnecessary gastrointestinal medication use in patients with the common cold

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Abstract

Objectives: We evaluated the national prevalence of unnecessary GI drugs in the prescription for the common cold in ambulatory settings and the factors influencing this practice. **Method:** This cross-sectional study used the National Patients Sample data. We identified patients aged [?]20 years diagnosed with a common cold in a primary care clinic in December, 2018. We investigated whether the prescriptions for common cold of study subjects included any unnecessary GI medications. Demographic and clinical factors influencing the prescription of GI drugs were explored using multiple logistic regression analysis. **Results:** Unnecessary utilisation of GI medications in treating colds was estimated to be 43.80%. Women were more likely to be prescribed unnecessary GI medications (odds ratio [OR]=1.314). Among physician specialties, paediatricians showed the lowest odds (OR=0.479), whereas surgeons showed the highest (OR=1.655). Patients in urban and rural areas had higher odds than those in the metropolitan areas (OR=1.742). Non-steroidal anti-inflammatory drugs (NSAIDs) use was directly related to unnecessary GI medication prescription (OR=1.903) and the total number of cold drugs prescribed was inversely proportional to unnecessary GI medication use. Patients prescribed three and four or more cold medicines were less likely to receive GI drugs at odds of 0.568 and 0.471, respectively. **Conclusion:** This study demonstrates the high rate of unnecessary GI medication utilisation in common cold treatment in Korea. Factors influencing unnecessary GI drug utilisation were female sex, physician specialties (surgery), non-metropolitan areas, NSAIDs use, and prescription of fewer cold drugs.

INTRODUCTION

The common cold is an acute, self-limiting infection of the upper respiratory tract caused by viruses¹ and is one of the most frequent reasons to see a doctor.² The common cold itself is not a serious condition, but it imposes enormous costs on society in terms of visits to physicians and other health-care providers; expenditure on prescription drugs and over-the-counter medications; and absence from work, school, or daycare.^{3,4}

Drug therapies for the common cold are normally targeted at relieving symptoms⁵ such as nasal congestion, rhinorrhoea, sneezing, and cough.⁶ To temporarily relieve these symptoms, decongestants, antihistamines, expectorants, and antitussives are generally administered.^{1-3,5,7} These drugs are known to have a low incidence of gastrointestinal (GI) adverse events with temporary use, and the cold in itself does not cause any GI symptoms.⁸⁻¹⁴ Therefore, the prescription of GI drugs to patients with the common cold is not justifiable where there are no accompanying or underlying GI disorders. Prescribing unnecessary GI drugs could place further burdens on health care finances without additional therapeutic benefits.¹⁵ Concerns about prescribing habits and inappropriate use of GI medications for patients with colds have been expressed in several studies.¹⁵⁻¹⁷

Although there are many studies on inappropriate antibiotic use in patients with colds,¹⁸⁻²² few have investigated the unnecessary use of GI drugs and the influencing factors. Therefore, this study aimed to evaluate

the national prevalence of including unnecessary GI drugs in prescriptions for patients with the common cold in ambulatory settings and to investigate the influencing factors associated with this practice in Korea.

METHODS

Study data

We analysed the National Patients Sample (NPS) data from the Korean Health Insurance Review and Assessment (HIRA) Service from 2018 (HIRA-NPS-2018-0078). HIRA is a repository of claims data collected for reimbursement purposes.²³ HIRA-NPS data, a nationally representative sample of whole beneficiaries, were extracted with sex- and age-stratified random sampling methods from all patients who used medical services in 2018.²⁴ The data comprise the complete insurance claim data of 3% of the general population.²⁴

Diagnostic information for HIRA-NPS was coded according to the Korean Standard Classification of Diseases version 7 (KCD-7), which is based on the International Classification of Diseases 10th Revision (ICD-10). HIRA-NPS data contain fields representing the individual patient characteristics (age, sex, and type of insurance), medical institutions (type of institution and region), and outpatient and inpatient clinical management (medical procedures and medications).

The Institutional Review Board (IRB) of Pusan National University approved this study (PNU IRB/2021.-29.HR). This study used secondary data obtained from the HIRA and contained no personal information; therefore, written consent was waived by the IRB.

Study Subjects

We identified patients diagnosed with a common cold as the primary diagnosis in December 2018 using the KCD-7 code (J00). If there was more than one record of common cold per patient, only the first one was counted. We selected patients aged 20 years and older who visited a primary care clinic. Patients diagnosed with GI disorders (KCD-7 code: K20, K21, K22, K23, K25, K26, K27, K28, K29, and K30) within the 90 days before the diagnosis of colds and patients without any drug prescribed for a common cold were excluded (Appendix I and III).

Unnecessary GI medication utilisation

We investigated whether the outpatient prescriptions of study subjects for the common cold included any GI medications and estimated the percentage of their unnecessary use. Compounds regarded as GI medications in this study were antiulcer drugs (antacids, H2-receptor blockers, proton pump inhibitors (PPIs), and mucosal protective agents) and GI tract regulators (GI tract stimulants, anticholinergics, and others; Appendix II).

Statistical analysis

Descriptive statistics of the outcome variables were calculated. Demographic and clinical characteristics of the study subjects were expressed as numbers and percentages using frequency analysis because they were categorical variables. Chi-square tests were used to determine whether there was a difference among the comparison groups related to the distribution of the dependent variable. We also performed a multiple logistic regression analysis to investigate predictors for prescribing GI medications for the common cold and reported the odds ratios (ORs) and 95% confidence intervals (CIs).

The factors considered were sex, age, physician specialty, region, non-steroidal anti-inflammatory drugs (NSAIDs) use, and the total number of cold drugs prescribed. C-statistics and the Hosmer-Lemeshow test were used to check the goodness-of-fit of the models. Data analysis was performed using R statistical software (version 4.0.3; R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was set at $P < 0.05$.

RESULTS

Subject characteristics

During the study period, 26,752 patients were identified as having had a common cold. After excluding those aged < 20 years and those who visited medical care institutions other than primary care clinics, 10,776 patients were selected. Among these patients, a total of 3,530 were included in the final analysis after excluding those without any drug prescription associated with the common cold and diagnosed with GI disorders within the 90 days before the diagnosis of colds (Fig. 1).

The demographic and clinical characteristics of the study subjects are summarised in Table 1. The proportion of female subjects was higher than that of male subjects (51.76% vs. 48.24%), and most patients were covered by the National Health Insurance (98.47%). The proportion of patients who were prescribed NSAIDs was 57.22%, and the most prevalent comorbid disorder was hypertension (16.09%), followed by diabetes mellitus (8.53%).

Unnecessary GI medication utilisation

The proportion of study subjects who were prescribed unnecessary GI medications was 43.80% (Fig. 1). Regional variations were observed, with GI drugs less likely to be prescribed in metropolitan areas (39.77%) than they were in urban (53.86%) or rural (44.55%) areas. Variations in age group and NSAIDs use were also observed. In the 50-64-year-old age group and NSAID users were prescribed unnecessary GI medications the most (48.00% and 49.26%, respectively). In terms of the physicians' specialties, the highest proportion of GI drug prescriptions was observed in surgery (54.49%). We found that the total number of drugs prescribed for cold symptoms was inversely proportional to unnecessary GI medication use (Table 1).

Analysis of unnecessary GI medicine use

Among 1,546 patients who were taking unnecessary GI drugs, three-quarters (74.15%) were prescribed antiulcer drugs, and a quarter (25.85%) were prescribed GI tract regulators. As shown in Fig. 2, the antiulcer drugs most used were mucosal protectives (i.e., rebamipide, 56.21%), followed by H2-receptor blockers (20.71%), antacids (18.18%), and PPIs (4.90%). Among GI tract regulators, GI tract stimulants such as mosapride accounted for 85.71%, followed by anticholinergics (13.38%), and others (0.91%).

Factors influencing GI medication prescription

Table 2 shows the results of the logistic regression analysis. Women were more likely than men to be prescribed unnecessary GI medications (OR=1.314, 95% CI=1.144-1.508). Physician specialties influenced unnecessary prescription of GI medication; paediatricians were the least likely to prescribe unnecessary GI medications (OR=0.479, 95% CI=0.307-0.732), whereas surgeons were most associated with unnecessary GI medication prescription (OR=1.655, 95% CI=1.171-2.345).

Geographic variations were observed across regions. People in urban areas had 1.74-fold greater odds of being prescribed unnecessary GI medications than those in metropolitan areas. A similar pattern was observed in rural areas, but with slightly lower odds (OR=1.191, 95% CI=1.016-1.396). The use of NSAIDs was directly related to the unnecessary prescription of GI medications. When study subjects were prescribed NSAIDs as cold medicine, the probability of unnecessary GI drugs being prescribed was approximately two times higher than that of those who were not prescribed NSAIDs (OR=1.903, 95% CI=1.648-2.199). Patients who were prescribed 3 and [?] 4 cold medicines were less likely to also be prescribed GI drugs, and the ORs were 0.568 (95% CI=0.440-0.731) and 0.471 (95% CI=0.360-0.616), respectively.

DISCUSSION

This study was performed to explore the current prevalence of unnecessary GI medication use in outpatient prescriptions for the common cold in Korea. We found that unnecessary GI medication use accounted for 43.80%. GI drugs have been routinely included in numerous prescriptions to decrease GI symptoms such as heartburn, nausea, and dyspepsia in Korea.^{16,17}(17) Byeon et al. conducted a chart review study of a large city hospital and discovered that 58.6% of patients with the common cold who did not present with symptoms or a history of GI diseases were prescribed GI drugs such as digestive enzymes, GI mobility drugs, antacids, and acid-controlling agents.¹⁵ Cho et al. conducted a study to analyse the prescription behaviours

of 148 office-based doctors using data from standardized common cold patients in Korea.¹⁶ In this study, approximately 80% of the doctors prescribed GI medicines (such as H2-blockers and motility drugs) following analgesics and NSAIDs (89.2%) to patients with the common cold. The prescription rate of unnecessary GI medications in our study was lower than that in previous studies, probably because of the differences in study designs.

The use of unnecessary GI drugs, such as when they are not indicated, could lead to various detrimental outcomes such as adverse drug reactions, drug interactions, and increased drug expenditure.¹⁷ Especially, dopamine antagonists (i.e., domperidone and metoclopramide) are known to increase the risk of extrapyramidal symptoms that generally manifest as acute dystonic reactions and hyperprolactinemia, leading to gynecomastia and impotence.²⁵ PPIs increase the risk of bone fractures,²⁶⁻²⁹ pneumonia,³⁰⁻³³ *Clostridium difficile* infection,^{34,35} and vitamin B12 deficiency.^{17,36,37}

Therefore, deprescribing GI medications for colds would be worth the outcome of reducing the risks of GI drug-related potential harm and unnecessary medical expenses. Studies evaluating the effect of deprescribing show its potential positive impact on improving health outcomes.³⁸⁻⁴¹ A review by Endsley suggests that deprescribing, which involves instituting a set of interventions to identify inappropriate or unnecessary medications and discontinue them, contributed to improvement in cognition, fewer falls, reduced risk of hospitalization, and improved survival.⁴² McGrath et al. reported that PPIs are a common target of deprescribing because of the few indications for long-term use; significant drug-drug interactions with other commonly used medications; and increased risk of bone fractures, pneumonia, *Clostridium difficile* infection, and vitamin B12 deficiency.⁴³

Variations in unnecessary GI medication prescribing related to physicians' specialties were identified in our study. The delivery system of healthcare services in Korea is different from Western countries.⁴⁴ Doctors can run a private office regardless of their specialty and patients can visit any specialists directly on their own for mild diseases such as a cold.^{44,45} Paediatricians were least likely to prescribe unnecessary GI medications. It could be considered as a cause that most GI drugs are not routinely prescribed to children. We found that NSAID use was a strong predictor of unnecessary GI medication utilisation (OR=1.903, 95% CI=1.648-2.199). NSAIDs effectively relieve pain in headaches, myalgias, and arthralgias and the fever-related discomfort experienced during a cold.^{2,7} NSAIDs inhibit cyclooxygenase-1 and -2, converting arachidonic acid to prostaglandins, and thereby exert antipyretic, analgesic, and anti-inflammatory effects.⁴⁶ However, these prostaglandins also protect the gastric mucosa, and therefore, the inhibitory actions of NSAIDs have adverse effects, mainly on the GI tract.⁴⁷ However, the majority of patients taking therapeutic doses of NSAIDs for a shorter duration and who do not have underlying GI disorder usually tolerate them well.⁴⁸ The concomitant use of GI medications such as mucosal protective agents, H2 receptor antagonists, or PPIs has no rationale in the treatment of the common cold.

Unlike a previous study¹⁵ where there was no statistically significant difference between the prescription of GI drugs and the number of cold drugs, we found that the group prescribed three and more than four cold medicines received fewer GI drugs than the group that was only prescribed one. It could be speculated that doctors find it difficult to prescribe a single drug; therefore, they try to increase the number by including unnecessary GI drugs in the prescription.

This study has certain limitations. First, because the claims data are primarily collected for the reimbursement of healthcare services and not for clinical purposes, the diagnosis information could be susceptible to up-coding by providers seeking a higher reimbursement rate.²³ A previous study that compared the designation of diagnoses in HIRA data to the actual status of health conditions based on medical record reports showed that an average of 70% of diagnoses corresponded to those in the medical charts.²³ Second, the claims data are not applicable to research on healthcare services not covered by insurance or over-the-counter drugs.⁴⁹ Third, patients diagnosed with the common cold who were included in our study could have simultaneously had other conditions. In such cases, GI medications might have been prescribed not only for the cold but also for other conditions. Therefore, the relationship between GI drug use and a specific disease should be carefully interpreted.¹⁹

Despite these limitations, the present study result has significant implications. Compared to previous studies that analysed prescription patterns in some medical institutions^{15,16}, our study targeted a much broader population group extracted from almost all Korean populations. Therefore, the results could be generalized. In addition, it is meaningful that our study also investigated the influencing factors in comparison with the existing studies that only calculated the prescription ratio^{15,16,50}.

It is important to change the perception that adding GI medication to symptom-relieving drugs for the common cold is beneficial or at least not harmful in patients with the common cold. Shin et al. reported that promoting public health campaigns and developing practical guidelines, educational resources, and restrictive drug policy resulted in reducing inappropriate prescriptions.¹⁹

Patel et al. conducted an observational, cross-sectional, questionnaire-based study to assess the prescribing pattern of doctors to patients presenting with the common cold.⁵¹ In that study, the authors reported that inappropriate prescriptions by doctors is due to a lack of adequate training, lack of self-confidence, or both.⁵¹ Hence, it would be expedient to address this issue by emphasizing the need for proper training of prescribers during their formative years and additional re-enforcement through continuing medical education programs.

More efforts are needed to increase awareness of the need to institute deprescribing GI medications for the common cold in the primary care setting and improve the quality of prescription by determining whether a prescription is necessary. In addition, continued research on unnecessary GI medication utilisation, public health campaigns, and regulatory policies from various healthcare stakeholders are needed.

CONCLUSION

This study demonstrates a high rate of unnecessary GI medication utilisation for the treatment of the common cold in Korea. The factors that influence the prescription of GI drugs were sex, physician specialties, region, NSAID use, and the number of drugs prescribed.

ACKNOWLEDGEMENTS

We used the National Patient Sample data collected by the Korean Health Insurance Review and Assessment Service (HIRA-NPS-2018-0078); however, the results do not concern the Ministry of Health and Welfare or HIRA.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request

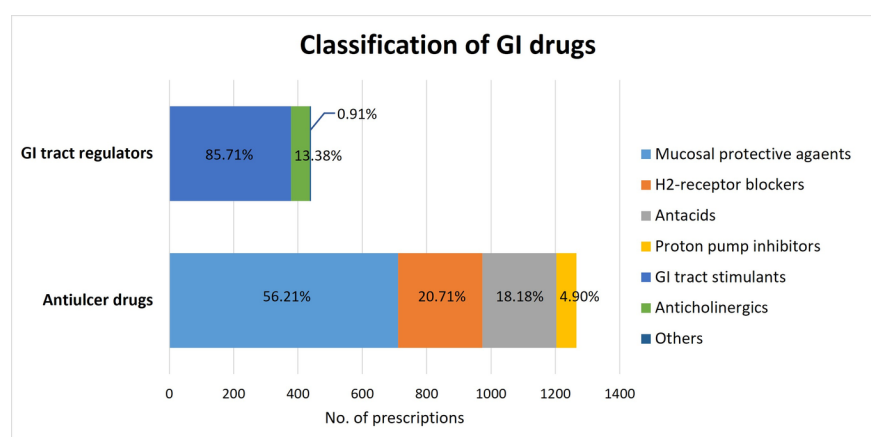
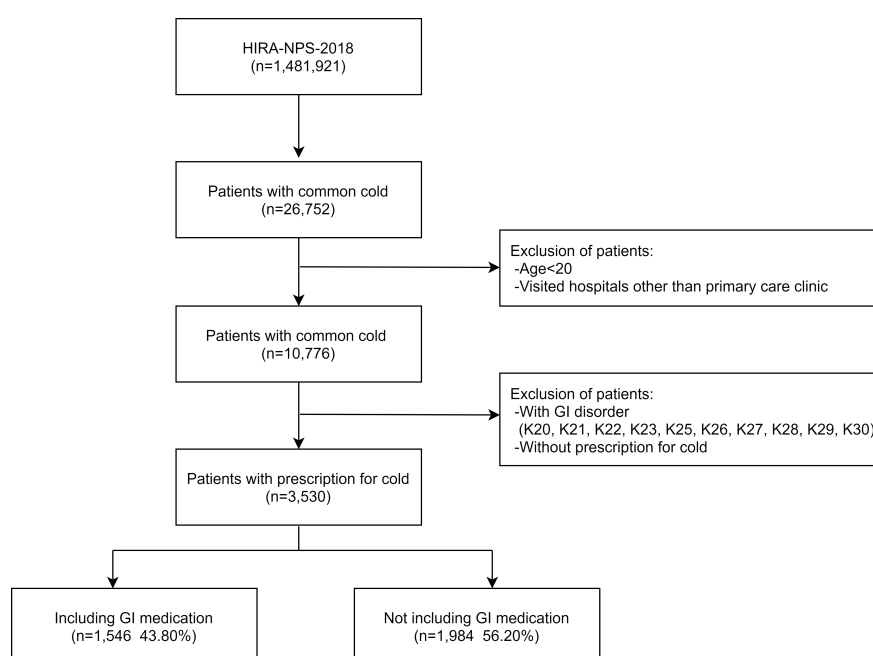
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