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Proton pump inhibitors for prophylaxis of nosocomial upper gastrointestinal bleeding: the impact of standardized guidelines on prescribing practice

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Abstract

Background—Proton pump inhibitors (PPI) are frequently prescribed for prophylaxis of nosocomial upper gastrointestinal bleeding (UGIB). Some inpatients receiving PPI may be without risk factors for nosocomial UGIB, and PPI may be continued unnecessarily at hospital discharge.

Aim—To assess the impact of standardized guidelines on PPI prescribing practices. Methods: Guidelines for PPI use were implemented on the medical service at a tertiary center. We reviewed PPI use among inpatient admissions during the month prior to implementation of guidelines then prospectively evaluated PPI use among admissions during the month following implementation of guidelines.

Results—49% of patients (458/942) received PPI while inpatient, and 41% of patients (387/942) were prescribed PPI at discharge. Univariate predictors of inpatient PPI use included age, length of stay, history of GERD or UGIB, outpatient PPI use, outpatient aspirin use, and outpatient glucocorticoid use. Among patients not on outpatient PPI at admission, implementation of guidelines resulted in lower rates of inpatient PPI use (27% pre- vs 16% post-guidelines, P=0.001) and PPI prescription at discharge (16% pre- vs. 10% post-guidelines, P=0.03).

Conclusions—Introduction of standardized guidelines resulted in lower rates of PPI use among a subset of hospital inpatients and reduced the rate of PPI prescriptions at hospital discharge.

Introduction

Nosocomial upper gastrointestinal bleeding (UGIB) is associated with considerable morbidity and mortality. Gastric mucosal “stress ulcers” are frequently implicated as an underlying cause of nosocomial UGIB, and risk factors including coagulopathy and requirement for mechanical ventilation have been identified in intensive care unit (ICU)

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Contributions of the study authors are as follows: 1) Study design: all authors; 2) Data analysis: PY; 3) Initial drafting of the manuscript: PY; 4) Critical review, editing, and final approval of the manuscript: all authors.

PY had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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patients [1]. Pharmacologic gastric acid suppression can provide effective prophylaxis against UGIB in at-risk ICU patients [2].

Proton pump inhibitors (PPI) suppress gastric acid production at the level of the H+/K+-ATPase and are widely prescribed for the purpose of nosocomial UGIB prophylaxis. PPI may be overutilized among non-ICU inpatients without risk factors for UGIB [3–5]. Moreover, PPI prescribed for prophylactic purposes to hospital inpatients may be continued unnecessarily at the time of hospital discharge [3–6].

Long-term PPI use may have an effect on mineral absorption and metabolism [7] including calcium malabsorption resulting in an increased risk of hip fracture [8]. In addition, PPI use may increase the risk of both enteric infections [9] such as Clostridum difficile [10–12], as well as non-enteric [13] infections including both community-acquired and nosocomial pneumonia [14–16]. PPI may influence the action of certain other prescription medications, including the potential for PPI use to diminish the antiplatelet effects of clopidogrel in patients receiving both medications following hospitalization for acute coronary syndrome [17].

This study aimed to assess the use of PPI for UGIB prophylaxis among inpatients on a non-ICU general medicine service, and to measure the impact of standardized guidelines on PPI prescribing practices. We hypothesized that PPI are overutilized in the non-ICU medical inpatient population, and that the introduction of standardized guidelines would result in lower rates of inpatient PPI use and fewer PPI prescriptions at hospital discharge.

Study Design and Methods

The study was conducted at a single tertiary academic medical center, Massachusetts General Hospital (MGH). The study authors drafted guidelines for PPI use among hospitalized inpatients, including guidelines pertaining specifically to use of PPI for nosocomial UGIB prophylaxis.

In order to draft guidelines, a Pubmed search was performed to identify relevant English-language studies from the medical and scientific literature. Search terms included nosocomial gastrointestinal bleeding, gastrointestinal bleeding prophylaxis, stress ulcer prophylaxis, gastric acid suppression, proton pump inhibitor, proton pump inhibitor prophylaxis, and combinations thereof. Studies reporting either retrospective or controlled prospective data were eligible for review. In studies reporting an intervention consisting of pharmacologic gastric acid suppression, the outcome and magnitude of the intervention were reviewed. A formal level of evidence grade was not assigned to individual studies, however relevant findings were used to draft guidelines, which were then reviewed, edited, and endorsed by the collective faculty of the Gastrointestinal Unit. A consensus set of guidelines was subsequently approved by the hospital pharmacy administration prior to implementation. A full version of the guidelines is attached as Appendix 1.

We introduced the guidelines to the medical housestaff via oral presentation at a scheduled didactic conference. The guidelines were described in detail, and the housestaff were notified that the guidelines would be implemented on the medical service on a one-month trial basis. We asked the housestaff to refer to the guidelines when considering use of PPI for nosocomial UGIB prophylaxis, but to realize that use of PPI on a patient-by-patient basis should ultimately be left to individual clinical judgment. We informed the housestaff that PPI use at admission, during admission, and at discharge for all admissions to the medical service over the ensuing calendar month would be measured, but that individual provider prescribing practices would not be audited. All medical housestaff subsequently received a

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copy of the guidelines (Appendix 1) by email. No further dissemination of the guidelines or reminders occurred during the one-month period.

The institutional review board approved retrospective review of the medical record for all admissions to the medical service during one calendar month prior to introduction of the guidelines, as well as all admissions during one calendar month following introduction of the guidelines. Subjects eligible for inclusion in this study included all outpatients admitted to and discharged from the inpatient ward medical service; most of these patients were admitted from the emergency room. The study excluded inpatients transferred to the ward medical service from an inpatient non-medical service within MGH, patients transferred from another inpatient medical facility, and patients transferred to the ward medical service from an intensive care unit or medical step-down unit. The study also excluded patients admitted with a primary or secondary diagnosis of gastrointestinal bleeding, patients who underwent upper gastrointestinal endoscopy during the course of their hospital stay, and patients who did not survive to hospital discharge. For patients admitted and discharged more than once during the study period, each discharge was counted as a separate study entry.

MGH uses an electronic medical record, and provider order entry (POE) is computer-based. We extracted demographic data including age and gender from the electronic medical record. Past medical history, including history of GERD or peptic ulcer disease (PUD)/ UGIB, and outpatient medication use was defined as documented in the house officer's history and physical at admission. The study defined inpatient PPI use as the presence of a physician's order for formulary PPI at any point during a patient's hospital admission, retrievable through a search of computerized POE. PPI use at discharge was defined as the inclusion of a PPI among the patient's discharge medications in the electronic discharge summary.

Statistical analysis was performed using JMP 7.0 software (SAS Institute, Cary, NC USA). Univariate analysis was performed with testing of significance using Student's *t* test for comparison of continuous variables and Chi square test for comparison of nominal or binary variables. Logistic regression analysis was performed with candidate predictors chosen on the basis of univariate analysis results and *a priori* hypotheses. A variable selection algorithm was not used for logistic regression analysis. All reported P values are two-sided with a P value <0.05 defined as the threshold for statistical significance.

Results

Main outcome measures

The final cohort consisted of 942 patients, 458 of whom were admitted and discharged during the month prior to implementation of PPI guidelines (pre-guidelines cohort) and 484 of whom were admitted and discharged during the one month following implementation of PPI guidelines (post-guidelines cohort).

In the overall cohort, outpatient PPI use was documented in 36% of patients at the time of admission, which exceeded the combined documented rates of GERD (14% of patients) and PUD/UGIB (7% of patients). 49% of all patients in the cohort were prescribed PPI while inpatient, and 41% were prescribed PPI at hospital discharge. Full demographic data are summarized in Tables 1 and 2.

In comparing the pre-guidelines and post guidelines cohorts, there was no significant difference in the proportion of patients who were prescribed PPI during admission (50% vs. 47%, P=0.36) or at hospital discharge (41% vs. 41%, P=0.97) (Table 3). However, in the

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subset of patients without documented outpatient PPI use at the time of admission, fewer patients were prescribed PPI both while inpatient (27% vs. 16%, P=0.001) and at hospital discharge (16% vs 10%, P=0.03) following implementation of PPI guidelines (Table 3).

Univariate analysis

In univariate analysis, inpatient PPI use was associated with older age, longer length of stay, and reported history of either GERD or PUD/UGIB. In addition, outpatient use of PPI, aspirin, clopidogrel, and glucocorticoids each predicted inpatient PPI use (Table 4).

Logistic regression analysis

We constructed a logistic regression model to determine predictors of inpatient PPI use while controlling for confounding and covariate factors. Model inputs included age, length of stay, history of GERD, history of peptic ulcer disease/UGIB, outpatient PPI use, outpatient aspirin use, outpatient clopidogrel use, outpatient NSAID use, and outpatient glucocorticoid use. In the overall cohort, outpatient PPI use at the time of admission was the strongest predictor of whether a patient would be prescribed PPI while inpatient (OR 69.1, P<0.0001). The only other significant predictor in multiple variable analysis was length of stay (OR 1.04 for each unit increase in length of stay, P=0.04). The model results and significance of predictors did not differ when comparing the two study time periods, before and after implementation of standardized PPI guidelines.

The model was re-run including only the cohort of patients not on outpatient PPI at the time of admission. Among this cohort, inpatient PPI use was independently predicted by length of stay and by outpatient glucocorticoid use.

Discussion

Prior studies have demonstrated overutilization of PPI in the non-ICU inpatient setting [3–5], as well as on medical subspecialty services [18,19] and in long-term nursing facilities [20]. This study demonstrates that PPI use is prevalent among non-ICU medical inpatients at a tertiary teaching hospital, nearly half of all medical inpatients over the course of the two-month study period received PPI during their inpatient stay, and that implementation of standardized guidelines may have a measurable impact on PPI utilization rates.

In the overall cohort, rates of inpatient PPI use and PPI prescriptions at discharge did not diminish following implementation of guidelines – suggesting, at face value, a negligible impact of the intervention. However, the impact of the intervention may be masked by the high rate of outpatient PPI use, and the fact that a higher percentage of patients reported outpatient PPI use at admission in post-guidelines compared with pre-guidelines study period (39% vs 34%). Among the cohort of patients not taking PPI at the time of admission, the rate of inpatient PPI use declined from 27% to 16% following implementation of guidelines (P=0.001), and the percentage of these patients receiving PPI prescriptions at discharge declined from 16% at baseline to 10% following implementation of guidelines (P=0.03). While this resulted in only 38 fewer inpatient PPI prescriptions and 21 fewer outpatient prescriptions over the course of a one month trial period on a selected inpatient population, the volume and impact of such a decline would be substantial when considered for hospital-wide implementation.

The strongest predictor of inpatient PPI use in our cohort was whether an individual patient reported PPI use at the time of admission. More than one third of patients (36%) reported PPI use at the time of admission. This is consistent with a prior study from an academic teaching hospital medical service, in which 29% of patients reported taking acid suppression medication prior to admission [5]. It is uncertain whether the strong impact of outpatient PPI

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use on inpatient PPI use represents continuation of appropriate outpatient PPI therapy for an accepted indication, continuation of outpatient PPI therapy (irrespective of indication) for inpatient prophylactic purposes, or rote continuation of an outpatient regimen without re-evaluation at the time of admission. Our study was not specifically designed to assess whether PPI therapy was appropriate on a patient-by-patient basis, and in our protocol providers were not asked to specify indications for PPI therapy. However, the study intervention (implementation of PPI guidelines) was designed to discourage use of PPI for prophylaxis of nosocomial UGIB in patients without clear risk factors for nosocomial UGIB.

Length of stay also predicted inpatient PPI therapy in our cohort, a finding consistent with prior published data [6]. It is uncertain whether this is a function of increased inpatient exposure providing increased opportunity for initiation of inpatient PPI therapy, development of an appropriate indication for PPI therapy, or a nonspecific marker of severity of illness.

The goal of the study was to assess PPI use for prophylactic purposes in a non-ICU setting. By design, therefore, the study cohort excluded patients with an alternative indication for PPI therapy, specifically patients with an admitting diagnosis of gastrointestinal bleeding. In addition, the cohort excluded patients admitted to the general medical ward from the ICU or medical step-down unit, as PPI therapy in these patients might reflect inadvertent continuation of stress ulcer prophylaxis initiated in the ICU in at-risk patients, rather than *de novo* PPI prophylaxis in average risk inpatients. While these exclusion criteria eliminate some potential confounders from our cohort, they may also limit the external validity of the study.

The study design posed several additional limitations. Much of the data were retrieved from chart review. Patient recall bias may have resulted in under- or over-reporting of outpatient medication use, including use of prescription or non-prescription PPI, and prescription or non-prescription aspirin or NSAIDs. Additional factors not included in the univariate or logistic regression analyses may have influenced inpatient PPI use. For instance, our analysis does not include measures of severity of illness or specific admitting diagnoses, which may be predictive of inpatient PPI therapy. In addition, we did not measure initiation of new inpatient antiplatelet or anticoagulant therapy, and are therefore unable to assess the influence of these medications on inpatient PPI use. We also did not measure rates of inpatient or outpatient use of histamine (H2)-receptor antagonists, and therefore cannot assess whether prescribers simply substituted these medications for PPIs following implementation of guidelines. Finally, this study was not designed to assess whether PPI utilization rates translate into any, either beneficial or adverse, meaningful clinical outcomes.

The developed set of guidelines are designed as a general framework for prescribing practices, do not address every clinical circumstance in which prophylactic PPI therapy might be considered, and are therefore subject to individual interpretation which may vary by provider. This reflects in part the relative lack of controlled, published data demonstrating specific risk factors for nosocomial UGIB in a non-ICU population, and also our desire to implement practical, easy-to-use guidelines which posed neither excessive restrictions nor a cumbersome algorithm. One can therefore argue that the introduction of guidelines and the subsequent measured decline in PPI utilization do not represent a true cause-and-effect relationship. There may be some natural variability in PPI utilization rates on a month-by-month basis, depending on the prescribing practices of individual providers rotating through the inpatient medical service. It is also conceivable that mere awareness that PPI utilization rates were being measured as part of this study, rather than an understanding of the guidelines, may have influenced provider prescribing practices.

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Therefore, while the results of this study should be considered hypothesis-generating, the potential financial and health-related impact of such an intervention may be significant, and our results should provide impetus for a more comprehensive, longer study to determine the impact of PPI guidelines on inpatient and outpatient PPI prescribing practices, rate of inpatient UGIB, and cost.

An important question is whether the observed decline in PPI utilization rates among a subset of inpatients will be durable and sustained following completion of this study. Our study was not designed to answer this question. Prior data have questioned both the sustained effectiveness and cost-effectiveness of interventions aimed at reducing prescriptions of acid suppressive drugs in the outpatient/general practitioner setting [21]. One option available in the inpatient setting, and which we are considering, is embedding a clinical decision support module in provider order entry (POE): when a health care provider attempts to order an inpatient PPI, the provider is prompted with a review of guidelines for appropriate PPI use, and is then offered the option to either continue with or abandon the PPI prescription. Data suggest that such prescribing computerized decision support systems do have the potential to alter provider behavior [22], and might significantly enhance the impact of PPI prescribing guidelines among housestaff.

In summary, inpatient PPI therapy was prevalent in our cohort, with nearly half of all medical inpatients receiving an inpatient PPI, and more than 40% of patients prescribed PPI at hospital discharge. These figures appear to be driven by high outpatient rates of PPI use. Factors associated with inpatient PPI therapy include outpatient PPI use and length of stay. Implementation of standardized guidelines regarding appropriateness of inpatient PPI use results in a decrease in both inpatient and discharge PPI therapy among patients not receiving outpatient PPI therapy at the time of admission.

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Table 1

Cohort demographics

N	942
Age	63.3 ± 18.4 yrs
Male gender	547 (58%)
History of GERD	136 (14%)
History of peptic ulcer/upper GI bleed	66 (7%)
Outpatient medication use at admission	
PPI	341 (36%)
Aspirin	334 (35%)
Clopidogrel	58 (6%)
Cyclooxygenase-2 inhibitor	1 (0.1%)
Non-selective NSAID	47 (5%)
Glucocorticoid	59 (6%)
Prescribed PPI as inpatient	458 (49%)
Prescribed PPI at discharge	387 (41%)

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Table 2

Demographics/baseline characteristics by study time period

	Pre-guidelines	Post-guidelines
N	458	484
Age	63.2 ± 18.8 yrs	63.4 ± 18.0 yrs
Male gender	272 (58%)	275 (59%)
History of GERD	58 (12%)	78 (17%)
History of PUD/UGIB	34 (7%)	32 (7%)
Outpatient medications		
PPI	160 (34%)	181 (39%)
Aspirin	171 (36%)	163 (35%)
Clopidogrel	38 (8%)	20 (4%)
NSAID	26 (5%)	21 (4%)
Glucocorticoid	35 (7%)	24 (5%)

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Table 3

PPI usage while inpatient and at hospital discharge

	Pre-guidelines	Post-guidelines	P value
All patients			
N	458	484	
Inpatient PPI	237 (50%)	221 (47%)	0.36
Discharge PPI	194 (41%)	193 (41%)	0.97
Patients not on outpatient PPI			
N	313	288	
Inpatient PPI	85 (27%)	47 (16%)	0.001
Discharge PPI	50 (16%)	29 (10%)	0.03

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Table 4

Univariate predictors of inpatient PPI use

	PPI prescribed	PPI not prescribed	P value
N	458	484	
Age	66.0 yrs	60.8 yrs	<0.0001
Length of stay	6.8 days	5.8 days	0.006
Gender			
Male	253 (46%)	294 (54%)	0.09
Female	205 (52%)	190 (48%)	
History of GERD	109/458 (24%)	27/484 (6%)	<0.0001
History of PUD/UGIB	51/458 (11%)	15/484 (3%)	0.0003
Outpatient meds			
PPI	326/458 (71%)	15/484 (3%)	<0.0001
Aspirin	183/458 (40%)	151/484 (31%)	0.005
Clopidogrel	37/458 (8%)	21/484 (4%)	0.02
NSAID	24/458 (5%)	23/484 (5%)	0.73
Glucocorticoid	45/458 (10%)	14/484 (3%)	<0.0001