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Research Paper

The Effect of the Utilization of a Preprinted Protocol for the Use of Intravenous Pantoprazole on Its Appropriate Administration

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ABSTRACT

Background: Proton Pump Inhibitors (PPIs) are the most effective medications in acid-related disorders. Inappropriate use of Intravenous (IV) pantoprazole can cause unwanted consequences, like hypersensitivity reactions, prolonged duration of treatment, and increased treatment cost. This study aimed to evaluate the effect of the utilization of a preprinted protocol for the use of IV pantoprazole on its appropriate administration.

Methods: This prospective, cross-sectional, two-phase study was conducted in the four departments of a tertiary teaching hospital. In the first phase, from December 22, 2018, to March 19, 2019, all older than 18-year-old patients who were admitted to internal medicine, general surgery, and neurosurgery, and received IV pantoprazole were included in the study. In the second phase of the study, from April 4, 2019, to July 6, 2019, the neurology ward was added to the study according to the high consumption of IV pantoprazole. We evaluated the effect of the utilization of a preprinted protocol for the appropriate IV pantoprazole on its consumption, the frequency of appropriate administration based on the approved protocol, the need to change the patient's medication regimen, and the physician's feedback on the changes. The consumption of IV pantoprazole was compared with the same period in the last year of intervention as the pre-intervention phases.

Results: Four hundred forty-six prescriptions of IV pantoprazole were screened during the two phases of the study. The utilization of the approved protocol caused a decrease in IV pantoprazole consumption in post-intervention phases compared to pre-intervention phases in all departments. This difference was statistically significant in the general surgery (P=0.016) and neurosurgery (P=0.012) wards in phase 2. Related data to the comparison of the IV pantoprazole consumption between two phases of the

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intervention also showed a significant decrease in the neurosurgery ward (P=0.011). In the total of the two phases, the use of the protocol led to an 8.3% decrease in consumption in comparison with pre-intervention periods. During these six months, we detected that the administration of IV pantoprazole was not based on the protocol in 81.2% of patients and the use of the protocol led to correct 63.89% of physician's orders.

Conclusion: This study showed that the majority of IV pantoprazole prescriptions were inappropriate. Using the preprinted forms to administer the IV pantoprazole could improve its appropriateness in terms of indication for use, dose, and duration of treatment and decrease consumption.

Introduction

Proton Pump Inhibitors (PPIs) are the most effective medications in acid-related disorders and are widely used as the first-line treatment for Gastroesophageal Reflux Disease (GERD), Peptic Ulcer Disease (PUD), Upper Gastrointestinal Bleeding (UGIB), and prophylaxis of stress ulcer in high-risk patients [1-3].

Pantoprazole is a PPI that could be administered both orally and Intravenously (IV). Except for the faster onset of action of the IV route, the efficacy of pantoprazole is similar in both routes of the administration [1]. The use of IV pantoprazole was suggested only for patients who could not tolerate oral administration or their hemodynamic status limited the intestinal absorption because inappropriate use of IV pantoprazole can cause unwanted consequences, like hypersensitivity reactions, prolonged duration of treatment, and increased costs of health services [4].

Appropriate use is meant receiving a suitable medication based on clinical needs with an optimal dose, for an adequate duration, and with the lowest imposed cost to the patient and the health care system [3, 5-7]. Inappropriate prescribing and irrational use of medications was associated with increased adverse drug reactions and higher costs of treatment [2, 3]. Drug Utilizing Evaluation (DUE) or Drug Utilizing Research (DUR) was identified by World Health Organization (WHO) as a useful program to evaluate whether the medication was administered appropriately or not [1, 2].

This prospective, cross-sectional, two-phase study aimed to evaluate the effect of the utilization of a preprinted protocol for the use of IV pantoprazole on its appropriate administration. We evaluated this effect on the consumption, and the frequency of appropriate administration based on the approved protocol, the need to change the patient's medication regimen, and the physician's feedback on the changes.

Materials and Methods

Setting and study population

This prospective, cross-sectional, two-phase study was conducted in the four departments of Imam Hossein Medical Center, a tertiary teaching hospital, affiliated with Shahid Beheshti University of Medical Sciences (SBMU) in Tehran, Iran, between December 22, 2018, and July 6, 2019. All older than 18-year-old patients who were admitted to the internal medicine, general surgery, neurosurgery, and neurology departments, and received IV pantoprazole were included in the study.

Interventions and data collecting

In the first step, a protocol for appropriate use of IV pantoprazole was prepared based on the American Society of Health-system Pharmacists (ASHP) therapeutic guidelines on stress ulcer prophylaxis [8] and was approved by a committee consisting of gastroenterology and clinical pharmacy specialists (Table 1). All physicians and assistants were trained by the committee and were requested to administer IV pantoprazole based on the approved protocol.

The second step was the utilization of the approved protocol and evaluation of its effect on the appropriate use of IV pantoprazole. In the first phase of the second step, from December 22, 2018, to March 19, 2019, all admitted patients in the internal medicine, general surgery, and neurosurgery departments who received IV pantoprazole were identified through the Hospital Information System (HIS) and the following information was recorded for them by a pharmacist with using a predesigned data collection form: the indication of the administration of IV pantoprazole that was according to the protocol or not, the dosage regimen, and the duration of the administration. If there was a need to change the patient's medication regimen, including changing the route of administration or its dose or discontinuing it, the intervention was informed to the physician. The type of intervention and the physician's feedback were also reported.

Table 1. Intravenous (IV) pantoprazole usage protocol

Indications of IV Pantoprazole	
Upper Gastrointestinal (GI) bleeding	
NPOa patients with one of the following major risk factors	Mechanical ventilation for > 48 hours
	Coagulopathy defined as: • Platelet count <50000 per mm^3 • International Normalized Ratio (INR) >1.5 • Partial Thromboplastin Time (PTT) >2 times the control value
	History of GI ulceration or bleeding within 1 year before admission
	Head trauma with Glasgow coma score of <10
	Spinal cord injury
	Burn of >35% of body surface
	Hypoperfusion state
NPO patients with ≥2 of the following minor risk factors	Sepsis
	ICU stay for >1 week
	Occult bleeding lasting for 6 days
	High doses of corticosteroids (250 mg hydrocortisone or equal)
NPO patients who received an NSAIDb and had one of the following risk factors	Age above 65 years
	History of peptic ulcer
	History of H.pylori infection
	Co-administration with another NSAID
	Co-administration with corticosteroids
	Co-administration with antiplatelet and/or anticoagulant drugs
	Disabling comorbidities e.g. chronic heart diseases and diabetes

aNPO: Non per oral; bNSAID: Non-Steroidal Anti-inflammatory Drugs

In the second phase, from April 4, 2019, to July 6, 2019, the neurology ward was also added to the study according to the high consumption of IV pantoprazole and the committee's decision to involve this ward in the study.

The consumption of IV pantoprazole was calculated based on the number of vials and compared with the same period in the last year of intervention defined as the pre-intervention phases. Pre-intervention phase 1 was considered from December 22, 2017, to March 19, 2018, and pre-intervention phase 2 from April 4, 2017, to July 6, 2017.

Outcome

The primary outcome of the study was the effect of the utilization of a preprinted protocol for the appropriate use of IV pantoprazole on its consumption. The effect on the frequency of appropriate administration based on the approved protocol, the need to change the patient's medication regimen, and the physician's feedback on the changes were also evaluated as the second outcome.

Statistical analysis

All statistical analyses were performed using SPSS for Windows (Version 21.0; SPSS Inc., Chicago, IL, USA). Data were presented as the frequency or mean ± Standard Deviation (SD) based on the parameters. Quantitative data were tested for normality of distributions by the Kolmogorov–Smirnov test. The comparison of

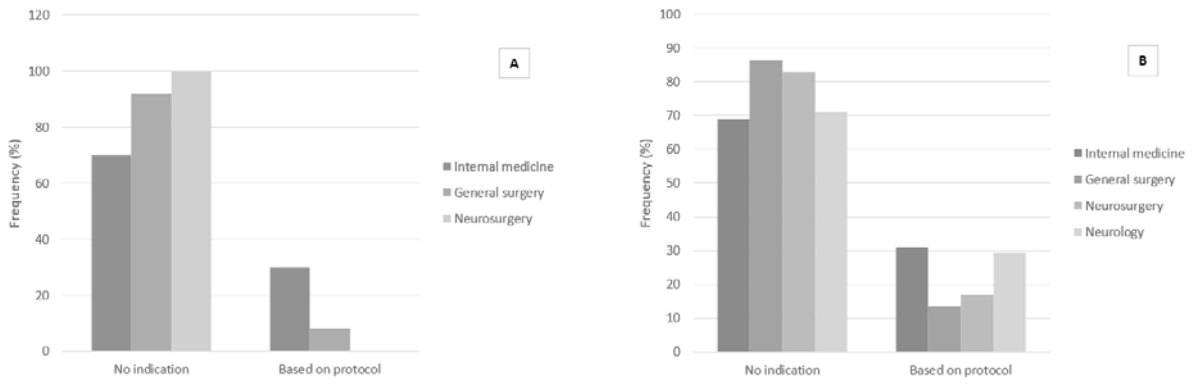

Figure 1. Frequency of the appropriate administration of the intravenous pantoprazole based on the approved protocol
(A) phase 1 of intervention from December 22, 2018, to March 19, 2019; B) phase 2 of intervention from April 4, 2019, to July 6, 2019.

the consumption of IV pantoprazole was performed by unpaired student's t-test and Mann-Whitney U test for normal and non-normal distribution data, respectively, and a P-value of < 0.05 was considered significant.

Results

Four hundred forty-six prescriptions of IV pantoprazole were screened during the six months of the study.

The primary outcome

According to Table 2, utilization of the approved protocol for the appropriate use of the IV pantoprazole caused a decrease in its consumption in post-intervention phases compared with pre-intervention phases in all departments. This difference was statistically significant in the general surgery (P=0.016) and neurosurgery (P=0.012) wards in phase 2. Related data to the comparison of the IV pantoprazole consumption between two phases of the post-intervention also showed a significant decrease in the neurosurgery ward (P=0.011) (Table 2). In two phases, the use of the protocol led to an 8.3% decrease in the consumption of IV pantoprazole in comparison with pre-intervention periods.

Table 2. The effect of the utilization of a preprinted protocol on the consumption of the IV pantoprazole[a]

	Wards	Mean±SD			
		Internal Medicine	General Surgery	Neurosurgery	Neurology
Post-intervention vs pre-intervention phase 1[b]	Pre-intervention phase	284±105.05	602±110.80	97.67±34.42	-
	Post-intervention phase	256.67±67.47	454.33±175.29	85.33±19	-
	P	0.724	0.285	0.616	-
Post-intervention vs pre-intervention phase 2[c]	Pre-intervention phase	260.5±104.35	522±63.73	87.25±28.34	95±54.59
	Post-intervention phase	232.75±77.93	339.50±88.74	24.75±20.96	60.50±18.80
	P	0.580	0.016	0.012	0.277
Post-intervention phase 1 vs Post-intervention phase 2	Post-intervention phase 1	256.67±67.47	454.33±175.29	85.33±19	103.67±48.1[d]
	Post-intervention phase 2	232.75±77.93	339.50±88.74	24.75±20.96	60.50±18.80
	P	0.689	0.301	0.011	0.155

a The consumption of IV pantoprazole was calculated based on the number of vials; bthe pre-intervention phase was defined as the same period in the last year of intervention that was considered from December 22, 2017, to March 19, 2018, for pre-intervention phase 1 and cApril 4, 2017, to July 6, 2017, for pre-intervention phase 2; dthe neurology ward was added to the study on the second phase and the consumption of IV pantoprazole during the phase 1 period was used to evaluate the effect of the intervention.

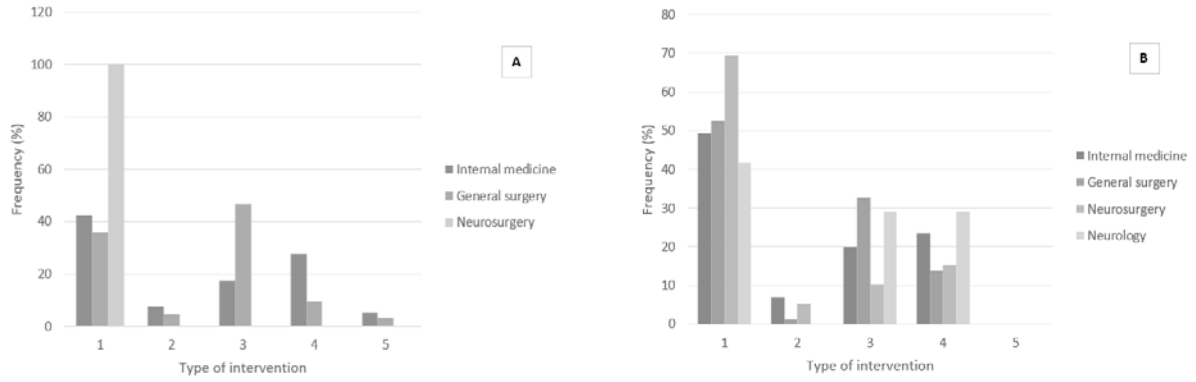

Figure 2. The frequency of the need to change the patient's medication regimen

A) phase 1 of intervention from December 22, 2018, to March 19, 2019; B) phase 2 of intervention from April 4, 2019, to July 6, 2019.

Type of the changes: 1, change the route of administration; 2, change the dose; 3, discontinue; 4, no need to change; and 5, not possible to contact the physician.

The secondary outcome

The comparison of the two phases of the intervention showed a significant increase in the frequency of appropriate IV pantoprazole administration based on the protocol in the neurosurgery, internal medicine, and general surgery departments in phase 2 compared to phase 1 (Figure 1). The frequency of the need to change the patient's medication regimen and the physician's feedback on the changes also were reported in Figures 2 and 3, respectively.

In three wards evaluated in phase 1, IV pantoprazole was not administered based on the protocol in 83.7% of patients, and changing the route of the administration (49.7%) and discontinuation of the IV pantoprazole (34.6%) were the most important interventions that were needed in this phase. In phase 2, total IV pantoprazole administrations that were not based on the protocol decreased to 80.4%. Change in the route of the administration (53%) and discontinuation of the IV pantoprazole (26.5%) were still the most important interventions that were needed in phase 2 (Figures 1 and 2). The highest acceptance rate belonged to the neurosurgery and internal medicine wards with the frequency of 80% and 57%, respectively (Figure 3).

Discussion

The present study was designed to determine the effect of the utilization of a preprinted protocol for the use of IV pantoprazole on its appropriate administration.

According to the studies, the administration of IV pantoprazole was inappropriate in 25-75 % of patients who received it in terms of either indication of use, dose, or duration of treatment [1, 2, 9, 10]. Asl et al. reported 22.67% irrational prescription of pantoprazole among 150 patients who were evaluated respectively. Irrational prescriptions were mostly due to a lack of any indication for using it [1]. The appropriate use of IV pantoprazole was also evaluated by George et al. on 141 administered

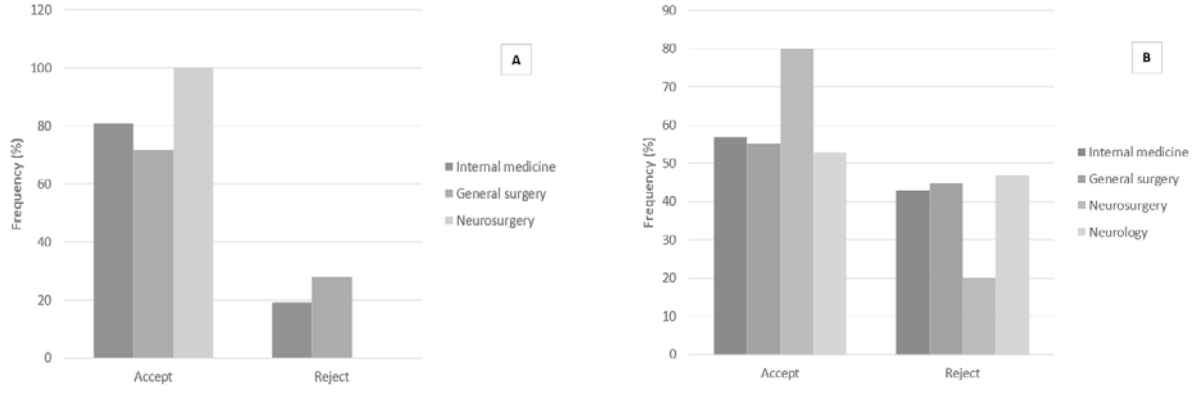

Figure 3. The frequency of physician's feedback on the changes in terms of the accept it or reject

A) phase 1 of intervention from December 22, 2018, to March 19, 2019ک B) phase 2 of intervention from April 4, 2019, to July 6, 2019.

patients. They found that 36.87% of IV pantoprazole prescriptions were inappropriate either in terms of dose, duration, and indication for use [4]. We also observed that in the total of the two phases, the administration of IV pantoprazole was not based on the protocol in 81.2% of patients. The change in the route of the administration and discontinuation of the IV pantoprazole were the most important interventions in our study.

Bollavaram et al. evaluated the effect of implementing the intervention for the appropriate use of pantoprazole on its use. They reported a decrease in the use of pantoprazole as prophylactic therapy in 227 out of 506 patients (44.9%) in phase 1 of the study (pre-intervention) to 126 out of 506 patients (24.9%) in phase 2 (post-intervention). However, its use as an actual treatment was increased from 133 patients (6.26.3%) in phase 1 to 246 ones (48.6%) in phase 2 [3].

In the two phases of our study, the use of the protocol led to an 8.3% decrease in consumption of IV pantoprazole in comparison with pre-intervention periods, and overall, the trend was fallen in all wards, but there was no statistically significant decline except for one department. This result further supports the idea of implementation of the DUE program, such as using the preprinted forms to administer the IV pantoprazole could improve its appropriateness in terms of indication for use, dose, and duration of treatment and could decrease consumption as in our study, the use of the protocol led to correct 63.89% of physician's orders and confirm the effectiveness of the DUE program.

Conclusion

This study showed that the majority of IV pantoprazole prescriptions were inappropriate. The DUE program, such as using the preprinted forms to administer the IV pantoprazole could improve its appropriateness in terms of indication for use, dose, and duration of treatment and decrease consumption.

Ethical Considerations

Compliance with ethical guidelines

There were no ethical considerations to be considered in this research.

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Authors' contributions

Conceptualization and Supervision: Majid Iranshahi, Mohammad Sistanizad, and Habib Malekpour; Data collection and Data analysis: Arezoo Ashnagar, Elham Pourheidar, and Mohammad Sistanizad; Writing-original draft: Arezoo Ashnagar and Rezvan Hassanpour; Writing-review & editing: Investigation: Elham Pourheidar; All authors helped to final approval of the version to be submitted.

Conflict of interest

All authors declare no potential conflicts of interest for the research, authorship, and/or publication of this article.

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