



# Allergologia et immunopathologia

Sociedad Española de Inmunología Clínica,  
Alergología y Asma Pediátrica

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ORIGINAL ARTICLE

OPEN ACCESS

## Hypersensitivity reactions with proton pump inhibitors: five years of clinical experience

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Received 9 May 2025; Accepted 11 November 2025;  
Available online 1 March 2026

### KEYWORDS

drug hypersensitivity reaction;  
drug provocation test;  
esomeprazole;  
lansoprazole;  
omeprazole;  
pantoprazole;  
proton pump inhibitor;  
rabeprazole

### Abstract

**Introduction:** Proton pump inhibitors (PPIs) are generally well tolerated and are frequently prescribed drugs because their risk of adverse effects is 1-3%. Although PPIs have a good safety profile, allergic reactions to these molecules can occur. We aimed to investigate hypersensitivity reactions in patients who underwent oral provocation tests with PPIs in our clinic. **Methods:** In all, 58 subjects who applied to allergy clinic between January 2018 and December 2023 with a history of early allergic reactions with PPIs and subsequently underwent oral provocation testing to find a diagnostic or safe alternative PPI were included in our study. Information on the subjects' demographic and clinical data and the results of provocation tests was recorded by reviewing patient records.

**Results:** Of the 58 subjects included in the study, 44 (75.9%) were females. The mean age of the patients was  $54.4 \pm 13.8$  years. Fifty-three (91.4%) subjects had a history of allergic reactions to a single PPI and 5 (8.6%) subjects had a history of allergic reactions to two different PPIs, such as lansoprazole, pantoprazole, rabeprazole, esomeprazole, and omeprazole. Intradermal skin testing was performed in 51 (87.9%) of the subjects and all were found to be negative. After the provocation test, only two patients (3.4%) developed early-onset hypersensitivity reactions, one with lansoprazole and the other with esomeprazole.

**Conclusion:** Skin testing is a valuable tool in predicting hypersensitivity reactions associated with PPIs. Although rare, hypersensitivity reactions may occur in patients with negative skin tests.

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<https://doi.org/10.15586/aei.v54i2.1537>

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## Introduction

Proton pump inhibitors (PPIs) are used to prevent damage by suppressing gastric acid secretion in the treatment of gastroesophageal reflux, peptic ulcers, helicobacter pylori diseases, and in long-term use of corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>1,2</sup> Although PPIs have a good safety profile, hypersensitivity reactions can occur with these agents, although very rarely.<sup>3</sup> Various immediate and delayed hypersensitivity reactions, angioedema, generalized erythema, rhinorrhea, and immunoglobulin E (IgE)-mediated reactions, such as anaphylaxis, have been reported due to PPIs.<sup>4,5</sup> In addition, cases of allergic contact dermatitis, fixed drug eruptions, and Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) related to PPIs have also been reported.<sup>6,7</sup>

The aim of our study was to investigate the characteristics and frequency of allergic reactions that developed in patients who underwent provocation testing with PPIs.

## Material and Methods

### *Research method and ethics committee approval*

This retrospective clinical observational study used real-world data and was carried out at the immunology and allergy clinic of a tertiary chest diseases hospital. All procedures adhered to good clinical practices and the principles outlined in the Declaration of Helsinki. Ethics approval for the study was obtained from the local ethics committee (2024-BÇEK/32, February 28, 2024).

### *Study population*

Subjects aged  $\geq 18$  years who presented to the allergy clinic of our hospital between January 2018 and December 2023 with a history of type 1 early allergic reaction (urticaria, anaphylaxis, angioedema, shortness of breath, etc.) with PPIs and who underwent provocation test with PPI and whose records were accessed were included in our study. Patients were identified by searching electronic medical records for those carrying a documented history of immediate-type (type I) hypersensitivity to PPIs and who had undergone drug provocation test during the study period. Only patients with accessible and complete provocation test results were included. Patients with non-IgE-mediated late-type reactions (e.g., maculopapular rashes, contact dermatitis, Stevens-Johnson syndrome/toxic epidermal necrolysis) and those with missing key data (demographics, reaction description, or provocation outcome) were excluded from the study.

### *Data acquisition*

Demographic and clinical data of the patients and information on provocation test results were recorded by reviewing patient records. Information on patients' history about asthma, atopy, drug allergy, food allergy, and

bee allergy were recorded. The hypersensitivity reactions experienced by patients during PPI use were categorized as early-onset or late-onset types. Results of oral PPI provocation test performed for diagnostic purposes or to find a safe alternative to PPI was noted in the patients included in the study.

### *Drug provocation test*

PPI provocation tests were performed in patients with no contraindication for testing. Precautionary measures regarding medical equipment and trained staff were present in case of any emergency. The tests were performed at least 6 weeks after patient's history of hypersensitivity reaction. Skin prick tests were performed on the volar forearm. Histamine 0.01% was used as a positive control and 0.9% physiological serum was used as a negative control. Test solution (0.03 mL) was injected into the skin to create a blister. Tests were considered positive if the initial wheal's size increased by at least 3 mm in diameter and was surrounded by erythema 15-20 min after application of test solution. To ensure test validity and reproducibility, reagent stability was maintained according to manufacturers' recommendations and all tests were performed by trained personnel; if the positive control (histamine) did not produce the expected wheal, the test was repeated. The intradermal test concentrations used in this study (omeprazole, esomeprazole, and pantoprazole 4 mg/mL in 1/1000, 1/100, and 1/10 dilutions) are based on the recommendations reported in the European Academy of Allergy and Clinical Immunology (EAACI)/European Network on Drug Allergy (ENDA) guidelines and previously published in national and international studies.<sup>8-10</sup> Patients with negative skin tests underwent single-blind, placebo-controlled oral provocation tests with alternative PPIs and/or diagnostic tests with culprit PPIs. During these tests, omeprazole (5-, 10-, and 20-mg capsules), lansoprazole (7.5-, 15-, and 30-mg capsules), pantoprazole (5-, 10-, and 20-mg tablets), rabeprazole (5-, 10-, and 20-mg tablets), and esomeprazole (5-, 10-, and 20-mg tablets) were administered in increasing doses at 30-min intervals until the full dose was reached or any allergic reaction occurred. Test results were considered positive if urticaria, angioedema, bronchospasm, or a 20% decrease in Forced Expiratory Volume in 1 sec (FEV1) were observed. Patients were monitored for possible hypersensitivity reactions, and signed informed consent was obtained from all patients prior to the tests. All patients were observed for 8 h on the test day. After 24 h, they were re-examined and evaluated for any manifestation of allergic reaction. PPI provocation, evaluation of post-test hypersensitivity reactions, and management of reactions were performed in accordance with the ENDA guidelines.<sup>8</sup> Hypersensitivity reactions during PPI provocation were classified as early-onset or late-onset reactions. Early-onset reactions were defined as symptoms such as urticaria, angioedema, dyspnea, or anaphylaxis occurring within the first hour of drug administration, whereas late-onset reactions were defined as symptoms such as erythema, maculopapular rash, or pruritus occurring between 1 and 24 h of drug administration. These definitions were added in accordance with the ENDA guidelines.<sup>8</sup>

## Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, NY, USA). Continuous variables are shown as mean  $\pm$  standard deviation (SD) and categorical variables are shown as numbers and percentages. Comparative analyses were conducted to explore possible associations between demographic and clinical variables (gender, age, asthma, atopy, and allergy history) and provocation test outcomes. Categorical variables were compared using the Chi-squared test or Fisher's exact test, as appropriate. Continuous variables were compared using the Mann-Whitney U test;  $P < 0.05$  was considered statistically significant.

## Results

In all, 58 subjects were included in the study. The mean age of the subjects was  $54.4 \pm 13.8$  years. Of these, 44 (75.9%) subjects were females; 5 (8.6%) subjects had concomitant asthma and 9 (15.5) subjects were atopic (Table 1). PPI use was indicated for gastroprotective prophylaxis in 28 (48.3%) subjects, for treatment of *Helicobacter pylori* in 8 (13.8%) subjects, and for treatment of gastroesophageal reflux in 2 (3.4%) subjects. Fifty-three (91.4%) subjects had a history of allergic reactions with a single PPI and 5 (8.6%) subjects had a history of allergic reactions with two different PPIs. The PPIs with which the subjects experienced allergic reactions are shown in Table 1.

Intradermal skin testing was performed in 51 (87.9%) subjects, all of which were negative. Intradermal skin testing could not be performed in 7 (12.1%) patients because the relevant drug was not available in injectable form. Histamine, used as a positive control, elicited an adequate wheal-and-flare response in all patients, confirming the validity of negative results. Only history of two (3.4%) patients showed their having diagnostic oral provocation testing with the drug. Oral provocation test was performed with an alternative PPI in 56 (96.6%) patients. Early-onset hypersensitivity reactions were observed in two patients (3.4%). The first patient, a 64-year-old male with a history

of hypersensitivity to esomeprazole, developed generalized urticaria approximately 1 h after receiving omeprazole, and symptoms resolved within 4 h after administering oral antihistamines without complications. The second patient, a 31-year-old female with a history of hypersensitivity to lansoprazole, developed urticaria 15 min after receiving omeprazole, and oral antihistamines led to complete resolution within 3 h without further treatment. No late-onset hypersensitivity reactions were observed during the 24-h follow-up. Information about these patients and the reactions that developed are shown in Table 2. To summarize the provocation outcomes for each PPI, Table 3 presents the number of patients tested with each drug and the results of oral provocation tests.

Comparative analyses were conducted to explore possible associations between demographic or clinical variables and the outcomes of provocation tests. No statistically significant associations were recorded between demographic or clinical factors (gender, asthma, or atopy) and the provocation outcomes ( $P > 0.05$ ). Similarly, no significant

**Table 1** Demographic and clinical characteristics of subjects (n = 58).

Age (years; mean $\pm$ SD)	54.4 $\pm$ 13.8
Gender (females)	44 (75.9)
Concomitant asthma	5 (8.6)
<b>PPIs that caused allergic reactions</b>	
Lansoprazole	18 (31.0)
Pantoprazole	15 (25.9)
Esomeprazole	8 (13.8)
Rabeprazole	9 (15.5)
Omeprazole	3 (5.2)
Pantoprazole and lansoprazole	2 (3.4)
Esomeprazole and omeprazole	1 (1.7)
Rabeprazole and lansoprazole	1 (1.7)
Esomeprazole and lansoprazole	1 (1.7)

Note: Data are given as n (%) if not indicated otherwise. SD: standard deviation, PPI: proton pump inhibitor.

**Table 2** Characteristics of subjects who developed reactions in the oral PPI provocation test and the reactions that developed (n = 2).

	Subject 1	Subject 2
Age (years)	64	31
Gender	Male	Female
Asthma	No	No
PPI to which the subject had an allergic reaction in his/her history	Esomeprazole	Lansoprazole
Intradermal skin test	Negative	Negative
<b>Oral PPI provocation</b>		
PPI to which the subject had an allergic reaction in the provocation test	Omeprazole	Omeprazole
Reaction type	Early onset	Early onset
Manifestations	Urticaria	Urticaria
Time to reaction after last dose	1 h	15 min

Note: PPI: proton pump inhibitor.

**Table 3** Oral provocation test results for each PPI (n = 58).

PPI tested	Number of patients	Positive test	Negative test
Omeprazole	36	2	34
Lansoprazole	15	0	15
Pantoprazole	12	0	12
Rabeprazole	8	0	8
Esomeprazole	7	0	7

Notes: PPI: proton pump inhibitor. Some patients were tested with more than one PPI depending on their reaction history and the availability of alternative PPIs.

differences were observed between patients with and without a prior history of PPI hypersensitivity. These findings probably reflected the limited sample size and low number of reaction cases, which reduced statistical power of the analysis.

## Discussion

Proton pump inhibitors are the most potent inhibitors of gastric acid secretion. They are the drugs that have a low incidence of adverse effects and are generally well tolerated.<sup>1</sup> The increasing frequency of life-threatening reactions because of immediate hypersensitivity to PPIs in recent years, together with the widespread use of these drugs, has made PPI hypersensitivity a clinically significant problem. In this study, we reported the clinical features and allergic work-up results of 58 subjects with PPI hypersensitivity. The drug that most frequently caused an allergic reaction in the patients' history was lansoprazole. Similarly, in two different past studies reported from Türkiye, lansoprazole was found to be the drug most frequently responsible for hypersensitivity reactions.<sup>11,12</sup> This may be due to lansoprazole being the most frequently prescribed PPI in Türkiye. The PPIs that were most frequently involved in hypersensitivity reactions were esomeprazole and lansoprazole in Italian studies, omeprazole in Spanish studies, and lansoprazole in the US studies.<sup>9,13,14</sup> The proportions determined in the studies probably reflect the consumption-prescription ratio.

In our study, early-onset hypersensitivity reactions during PPI provocation developed in only two subjects of the 58 participants. Both subjects developed urticaria, the first one 1 h after taking the drug and the other 15 min later. All hypersensitivity reactions were mild. There are numerous case reports and studies of hypersensitivity reactions to PPIs, ranging from mild to severe reactions, usually occurring within a few hours after intake of drug.<sup>15-18</sup> The most frequently reported symptoms are urticaria (65%), angioedema (42%), dyspnea (22%), and pruritus (33%).<sup>9,19</sup> Other studies reported that approximately half of early hypersensitivity reactions to PPIs were anaphylaxis, with prevalence ranging from 9.1% to 69.0%, while urticaria

and/or angioedema were reported in 26.2-90.9% of cases.<sup>6,15,20</sup> Dyspnea, pruritus, nausea, vomiting, diarrhea, and rhinitis were also described.<sup>12,19</sup>

Immediate hypersensitivity reactions to PPIs are reported to occur in a wide range of age (14-78 years) and predominantly in females (72%).<sup>12,14,19</sup> Consistent with these results, the mean age of our subjects was 54.4 ± 13.8 years, and 44 (75.9%) were females. In our study, one of the patients who developed hypersensitivity during the PPI provocation test was female and the other was male.

All intradermal skin tests performed in our study were negative. This finding raises two possible interpretations that: (1) current intradermal testing protocols have limited sensitivity for detecting true hypersensitivity to PPIs, or (2) some reactions may be mediated by non-IgE mechanisms, such as T-cell-mediated or pseudoallergic pathways. These hypotheses are consistent with previous studies suggesting that negative skin test results do not reliably exclude clinical reactivity to PPIs.<sup>9,10</sup>

Our findings are also consistent with the recent EAACI Position Paper, which states that negative skin tests cannot exclude hypersensitivity and that oral provocation testing remains the diagnostic gold standard.<sup>3</sup> In our cohort, two patients developed urticaria during provocation despite negative skin tests, supporting this recommendation and emphasizing that clinical observation during oral challenge is indispensable.

People allergic to lansoprazole often tolerate omeprazole. Porcel et al. noted that patients allergic to lansoprazole are cross-reactive to rabeprazole but tolerant to omeprazole, pantoprazole, and esomeprazole.<sup>21</sup> In the present study, 17 patients who were allergic to lansoprazole tolerated omeprazole well. Our results were consistent with those of Lobera et al.<sup>13</sup> and Porcel et al.<sup>21</sup> Bonadonna et al. reported that patients with positive skin tests to pantoprazole also had positive skin tests to omeprazole and, less frequently, to esomeprazole.<sup>9</sup> In contrast, patients monosensitized to lansoprazole and rabeprazole showed negative test results to omeprazole, pantoprazole, and esomeprazole.<sup>11</sup>

This study has several limitations. First, it was retrospective in design, and the sample size was relatively small. Second, confirmatory *in vitro* tests, such as basophil activation testing, were not available, which limits mechanistic interpretation. Finally, the study was conducted at a single center, which may affect generalizability. The future research should focus on the standardization of PPI testing reagents, including optimized concentrations and validated protocols for skin and *in vitro* assays. Multicenter, prospective studies are needed to better define diagnostic algorithms, clarify underlying mechanisms, and improve patient safety through reliable identification of cross-reactivity patterns.

## Conclusion

Our results indicate that skin testing alone has limited sensitivity in predicting PPI hypersensitivity reactions. Oral provocation testing remains essential for confirming hypersensitivity and identifying safe alternatives in accordance with the EAACI recommendations.

## Mandatory Disclosure on Use of Artificial Intelligence

The authors declare that no AI-assisted tools were used in the preparation of this manuscript. All references have been manually verified for accuracy and relevance.

## Impact Statement

In managing the patients with PPI hypersensitivity, skin testing and oral challenge tests may play a critical role in determining patient tolerance and determining treatment options.

## Data Availability

The data set used and/or analyzed in the present study is available upon reasonable request.

## Author Contributions

Kurtuluş Aksu constructed the research hypothesis; Kurtuluş Aksu, Melis Yağdıran, Özgür Akkale, Hatice Çelik Tuğlu, Onur Telli, Fatma Dindar Çelik, and Gürgün Tuğçe Vural Solak contributed substantially to the study design; Melis Yağdıran, Kurtuluş Aksu, Özgür Akkale, Hatice Çelik Tuğlu, Onur Telli, Fatma Dindar Çelik, and Gürgün Tuğçe Vural Solak contributed substantially to data collection; Melis Yağdıran performed data analysis and interpretation; Kurtuluş Aksu and Melis Yağdıran substantially contributed to the writing of the manuscript; and Kurtuluş Aksu, Melis Yağdıran, Özgür Akkale, Hatice Çelik Tuğlu, Onur Telli, Fatma Dindar Çelik, and Gürgün Tuğçe Vural Solak approved the final manuscript.

## Conflict of Interest

The authors declared not to have any conflict of interest that may be considered to influence directly or indirectly the content of the manuscript.

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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