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Reclassification of NSAID hypersensitivity according to the WAO 2025 guidelines: insights from a cohort of 527 patients

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Abstract
Background: Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most common culprits of drug hypersensitivity. Previous classifications, including the European Academy of Allergy and Clinical Immunology (EAACI) and the European Network for Drug Allergy framework, left a subset of patients unclassified under the "blended" category, particularly those with anaphylaxis not fitting into standard groups. The World Allergy Organization (WAO) 2025 guidelines introduced new subcategories, such as mixed NSAID-exacerbated cutaneous disease (NECD) and mixed NSAID-exacerbated respiratory disease (NERD) to address this gap.
Objective: To evaluate how patients with reliable histories of NSAID hypersensitivity were reclassified under the WAO 2025 system, and to determine whether the new categories address the limitations of the previous framework.
Methods: We retrospectively analyzed 527 patients with cross-reactive NSAID hypersensitivity confirmed by clinical history and/or aspirin provocation testing at a tertiary allergy center. Patients were classified according to both EAACI 2019 and WAO 2025 guidelines. Demographics, comorbidities (asthma, rhinitis, urticaria, and nasal polyps), laboratory findings (immunoglobulin E, eosinophils, and tryptase), and provocation test outcomes with alternative NSAIDs were evaluated. Statistical analyses included Chi-square/Fisher's Exact tests and logistic regression.
Results: According to EAACI 2019, patients were classified as NECD (n = 228, 43.3%), NERD (n = 27, 5.1%), NSAID-induced urticaria/angioedema (NIUA) (n = 165, 31.3%), single NSAID-induced urticaria/angioedema/anaphylaxis (SNIUAA) (n = 55, 10.4%), and blended (n = 53, 10.1%). Using WAO 2025 guidelines, the blended category was eliminated and redistributed: NIUA increased to 197 (37.4%), mixed NECD (n = 7, 1.3%), and mixed NERD (n = 13, 2.5%) were newly defined. Other groups (NECD, NERD, SNIUAA) remained unchanged. Provocation testing confirmed high tolerability to paracetamol (97.8%), nimesulid (96.1%), meloxicam (94.1%), and celecoxib (92.2%), while aspirin challenge had the highest positivity (22.2%). Atopy was significantly associated with salicylate reactions (p = 0.048), and male gender with salicylate hypersensitivity (p = 0.0087).

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Conclusion: The WAO 2025 classification successfully reallocated previously blended cases, particularly into NIUA, mixed NECD, and mixed NERD, thereby improving diagnostic clarity. This updated framework reduces ambiguity and may enhance patient management by better reflecting clinical heterogeneity.

Introduction

Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most frequently reported drug classes associated with hypersensitivity reactions.[1] Although the prevalence of hypersensitivity appears to be high based on patient history, the diagnosis must be confirmed by aspirin provocation testing to ensure accuracy and to identify safe alternative medications.[2]

NSAID hypersensitivity traditionally has been categorized into immediate and delayed types. According to the previous classification of both European Academy of Allergy and Clinical Immunology (EAACI) and European Network for Drug Allergy (ENDA), immediate reactions were further divided into four subtypes: NSAID-exacerbated respiratory disease (NERD), NSAID-exacerbated cutaneous disease (NECD), NSAID-induced urticaria/angioedema (NIUA), and single NSAID-induced urticaria/angioedema/anaphylaxis (SNIUAA).

However, a subset of patients presenting with anaphylaxis could not be clearly assigned to any of these categories and were grouped under the umbrella term "blended reactions."[3] Detailed evaluation of this blended subgroup is important for understanding disease pathogenesis and guiding clinical management.

To address this gap, the World Allergy Organization (WAO) 2025 guidelines introduced new subcategories by redefining blended reactions as mixed NECD and mixed NERD, thereby offering a more precise classification. In addition, two new entities were recognized: NSAID-exacerbated food allergy (NEFA) and NSAID-induced food allergy (NIFA).[4]

In this study, we retrospectively analyzed 527 patients with reliable histories of NSAID hypersensitivity, where cross-reactivity was confirmed by aspirin provocation and/or reactions to at least two different NSAID groups. Our aim was to evaluate how patients previously categorized as blended were reclassified under the WAO 2025 framework, and to assess the extent to which the updated classification satisfies clinical needs.

Materials and Methods

Study design and patient selection

This is a retrospective, single-center, observational cohort study conducted at the Allergy and Immunology Clinic of SBÜ Süreyyapaşa Chest Diseases and Thoracic Surgery Training and Research Hospital (Istanbul, Türkiye). Medical records of 2547 patients who underwent diagnostic evaluation for suspected NSAID hypersensitivity between January 2015 and December 2024 were reviewed.

Patients were included in the analysis if they met at least one of the following criteria: (i) a clinical history suggestive of cross-reactivity (i.e., similar reactions to structurally unrelated NSAIDs); (ii) a positive aspirin provocation test confirming cross-reactivity. Patients without reliable clinical history or negative provocation results were excluded.

A total of 527 patients diagnosed with cross-reactive NSAID hypersensitivity based on clinical history or aspirin provocation testing between January 2015 and December 2024 were included in the study.

Data collection

The following data were systematically extracted from patient files and the electronic hospital database:

- *Demographics*: age and gender.
- Comorbidities: asthma, allergic rhinitis, chronic spontaneous urticaria (CSU), urticaria/angioedema, nasal polyps.
- Clinical features: type and severity of hypersensitivity reaction, associated comorbid conditions.
- Culprit NSAIDs: groups and subgroups identified in patient history (e.g., acetylsalicylic acid, propionic acid derivatives, heteroaryl acetic acids, oxicams, and selective COX-2 inhibitors).
- Alternative NSAIDs: agents tolerated in clinical practice or documented as safe based on negative provocation tests.
- *Classification variables*: patients were categorized according to both EAACI 2019 guidelines and WAO 2025 guidelines, and cases previously classified as "blended" were reassigned into the appropriate categories based on the updated definitions.

Classification

Using the EAACI 2019 guidelines, patients were classified under NIUA, NECD, NERD, SNIUAA, single-NSAID-induced delayed hypersensitivity reactions (SNIDHR), Multiple-NSAID–induced delayed hypersensitivity (MNNSAIDH), or blended categories.

According to the WAO 2025 guidelines, patients were reclassified into updated categories.

Particular attention was given to the redistribution of cases previously assigned to the blended category.

Statistical analysis

Continuous variables, such as age, total immunoglobulin E (IgE), absolute and percentage eosinophil counts, and serum tryptase levels were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on normality. Categorical variables, such as gender, presence of atopy, asthma, nasal polyps, and NERD, were presented as frequencies and proportions.

Comparisons between groups were performed using the Chi-square test or Fisher's Exact test for categorical variables, and independent *t*-test or Mann–Whitney U test for continuous variables. Associations between the index NSAID group (propionic acid derivatives, salicylates, acetic acid derivatives, etc.) and the presence of reliable alternative drugs were evaluated using Chi-square analysis.

Logistic regression analysis was performed to identify independent predictors of reliable alternative drug tolerance, including demographic features (age and gender), clinical comorbidities (atopy, asthma, nasal polyps, and NERD), and laboratory parameters (eosinophil count, total IgE, and serum tryptase). Odds ratios (OR) with 95% confidence intervals (CI) were reported; $P < 0.05$ was considered statistically significant. Statistical analyses were conducted using SPSS version 25.

Ethical statement

The study protocol was reviewed and approved by the SBÜ Süreyyapaşa Chest Diseases and Thoracic Surgery Training and Research Hospital Ethics Committee (approval number: 116.2017.R-299). All procedures were performed in accordance with the ethical standards of the institutional and national research committee and the 1964 Declaration of Helsinki and its later amendments.

Informed consent

As this was a retrospective chart review, the requirement for individual informed consent was waved off by the institutional ethics committee. Patient data were anonymized and handled with strict confidentiality throughout the study.

Results

The mean age of the included patients was 44.2 ± 13.0 years. The median age was 44 years (IQR: 34–53), ranging from 20 to 87 years. When stratified by age groups, 26.4% (n = 139) of patients were aged 18–35 years (group 1), 67.6% (n = 356) were aged 36–65 years (group 2), 5.5% (n = 29) were aged 66–80 years (group 3), and 0.6% (n = 3) were aged ≥81 years (group 4). The majority belonged to group 2 (age: 36–65 years). Regarding gender distribution, 65.5% (n = 345) were females and 34.5% (n = 182) were males.

Among the 527 patients included in the study, 199 (37.8%) were atopic, defined by sensitization to at least one aeroallergen. The most frequent sensitization was to house dust mite (*Dermatophagoides pteronyssinus* and/or *Dermatophagoides farinae*), which was identified in 131 patients (24.9%).

Comorbidities included asthma in 15.8% (n = 83), rhinitis in 67.6% (n = 356), urticaria or angioedema in 49.8% (n = 262), chronic sinusitis in 7.2% (n = 38), nasal polyps in 5.7% (n = 30), and mastocytosis in 0.4% (n = 2) patients. Among 83 patients with asthma, phenotypic distribution was as follows: 34.2% atopic eosinophilic (n = 28), 14.6% non-atopic eosinophilic (n = 12), 25.6% atopic non-eosinophilic (n = 21), and 25.6% non-atopic non-eosinophilic (n = 21). Additionally, asthma–nasal polyp co-occurrence was observed in 23 patients (4.4%), of whom 19 (82.6%) had recurrent polyps.

The mean age at the onset of NSAID hypersensitivity (available for 524 patients) was 35.9 ± 13.0 years, with a median of 35 years (IQR: 26–44). The earliest onset was at 5 years, while the latest occurred at 81 years.

The mean number of NSAID groups implicated per index reaction was 2.01, with a median of 2. Patients had a minimum of one and a maximum of four different NSAID groups implicated. Overall, 19.8% (n = 104) had reactions to one group, 62.9% (n = 330) to two groups, 14.3% (n = 75) to three groups, and 3.0% (n = 16) to four groups.

Regarding offender NSAID groups, the most frequent were propionic acid derivatives (n = 382, 72.6%), followed by paracetamol (n = 228, 43.5%), acetic acid derivatives (n = 206, 39.5%), salicylic acid (n = 136, 26.0%), pyrazolones (n = 93, 17.8%), oxicams (n = 10, 1.9%), selective COX-2 inhibitors (n = 3, 0.6%), and fenamates (n = 1, 0.2%).

When the relationship between atopy and NSAID reactions was analyzed, reactions to propionic acid derivatives appeared to be more frequent in atopic patients; however, this difference was not statistically significant ($P = 0.222$). Salicylic acid reactions were significantly more common in patients with atopy ($P = 0.048$). In the acetic acid group, no significant association was discovered between atopy and the presence of reactions ($P = 0.107$).

According to the EAACI 2019/WAO 2025 classification, patients were distributed as follows: NECD in 228 cases (43.3%), NERD in 27 cases (5.1%), NIUA in 165 cases (31.3%), SNIUAA in 55 cases (10.4%), and blended reactions in 53 cases (10.1%).

When reclassified according to the updated WAO 2025 system, the distribution changed as follows: NECD in 228 cases (43.3%), NERD in 27 cases (5.1%), NIUA in 197 cases (37.4%), and SNIUAA remained at 55 cases (10.4%). Importantly, patients previously categorized under the "blended" group were redistributed into more specific categories: mixed NECD (7 cases, 1.3%) and mixed NERD (13 cases, 2.5%).

Patient Distribution According to EAACI 2019 Classification

For 527 patients, the distribution was as follows:

NECD: 228 patients (43.3%)
NERD: 27 patients (5.1%)
NIUA: 165 patients (31.3%)
SNIUAA: 55 patients (10.4%)
Blended: 53 patients (10.1%)

Patient Distribution According to WAO 2025 Classification

Using the updated classification, the distribution was as follows:

NECD: 228 patients (43.3%)
NERD: 27 patients (5.1%)
NIUA: 197 patients (37.4%)
SNIUAA: 55 patients (10.4%)
Mixed NECD: 7 patients (1.3%)
Mixed NERD: 13 patients (2.5%)

Transition between classifications

Patients classified as NECD, NERD, and SNIUAA remained unchanged. NIUA increased from 165 to 197 patients, partly because of reclassification of 33 patients from the blended group.

The blended group (n = 53) was redistributed into:

NIUA (n = 33)
Mixed NECD (n = 7)
Mixed NERD (n = 13)

This redistribution highlights that the WAO 2025 classification provided new categories (mixed NECD and mixed NERD), which more precisely reflected patients with overlapping reaction patterns, while the majority of blended patients were reassigned to NIUA group.

Overall, the most prominent change was the increase in NIUA cases under the new system, while the blended category was eliminated and replaced by more clearly defined mixed groups.

When the relationship between gender and NSAID reactions was evaluated, no significant differences were discovered for propionic acid (P = 0.619) or acetic acid (P = 0.947) groups. However, salicylic acid reactions were significantly more frequent in males (P = 0.0087).

In conclusion, considering both atopy and gender, a statistically significant association was identified only for salicylic acid reactions, whereas no significant differences were discovered for other NSAID groups (Table 1).

Provocation tests

The NSAID oral provocation tests (OPT) were performed for several agents:

Paracetamol: 92 patients tested, 2 positive (2.2%)
Nimesulid: 76 patients tested, 3 positive (3.9%)
Meloxicam: 68 patients tested, 4 positive (5.9%)
Celecoxib: 64 patients tested, 5 positive (7.8%)
Aspirin: 54 patients tested, 12 positive (22.2%)

Paracetamol, nimesulid, meloxicam, and celecoxib were well tolerated in the majority of patients, supporting their role as safe alternatives. In contrast, aspirin provocation showed the highest rate of positive reactions.

Regarding laboratory parameters, total IgE was available for 404 patients, with a mean of 226.4 ± 345.6 IU/mL and a median of 120.5 IU/mL (IQR: 45.0–257.3). For patients with available data, the eosinophil count averaged 230 ± 210 cells/μL, with a median of 200 cells/μL (IQR: 100–300). The eosinophil percentage had a mean value of 2.7 ± 2.0% and a median of 2.0% (IQR: 1.3–3.5). Tryptase levels were available in few patients only, preventing reliable statistical analysis; however, most values were within normal reference range. Among autoimmune markers, antinuclear antibody (ANA; n = 262), antineutrophil cytoplasmic antibody (ANCA; n = 217), and extractable nuclear antigen (ENA; n = 183) were predominantly negative, with only a few patients showing positivity.

Discussion

In this large single-center cohort of 527 patients with cross-reactive NSAID hypersensitivity, we showed that the newly introduced WAO 2025 classification provided a clearer framework for categorizing patients, particularly those previously assigned to the ambiguous “blended” group. By redistributing these cases into NIUA, mixed NECD, and mixed NERD, the updated system eliminated diagnostic uncertainty and offered more precise phenotypic definitions, which may facilitate both clinical management and the future research.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the leading causes of drug hypersensitivity reactions.[5,6] NSAIDs are chemically classified into several subgroups, such as salicylic acid derivatives, para-aminophenol derivatives, propionic acid derivatives, acetic acid derivatives, enolic acid derivatives, fenamic acid derivatives, and selective cyclooxygenase (COX) inhibitors.[7] Hypersensitivity to these agents is primarily mediated through COX inhibition, resulting in an imbalance of arachidonic acid metabolites, leading to clinical manifestations.[8]

Two main clinical approaches are proposed to confirm NSAID hypersensitivity and evaluate cross-reactivity: (i) aspirin provocation testing, which remains the gold standard for diagnosis,[9,10] and (ii) the assessment of tolerance or reactions to NSAIDs from different chemical classes, which may help to identify safe alternatives.[9] Until recently,

Table 1 Association of atopy and gender with NSAID reactions.

NSAID group	Atopy (P value)	Atopy interpretation	Gender (P value)	Gender interpretation
Propionic acid	0.222	Not significant	0.619	Not significant
Salicylic acid	0.048	Significant (more frequent in atopic patients)	0.0087	Significant (more frequent in males)
Acetic acid	0.107	Not significant	0.947	Not significant

patients with confirmed cross-reactivity were classified according to the EAACI/ENDA guidelines.[3,11,12] However, during clinical practice and research, a subset of patients could not be clearly assigned to a single category and were thus defined as having blended reactions. The recognition of these blended cases highlighted the need for a more refined classification system. In our current cohort of 527 patients, we observed that a considerable proportion of those previously labeled as blended could now be reassigned into newly defined categories introduced by the WAO 2025 guidelines. This reclassification provides a better understanding of disease heterogeneity and significantly reduces the number of patients remaining in ambiguous categories. Specifically, blended cases were redistributed into mixed NERD and mixed NECD, while the majority of other patients retained their classification as NERD, NECD, NIUA, or SNIUAA. These findings suggest that the updated WAO 2025 classification successfully addresses one of the major limitations of previous guidelines by clarifying the position of blended cases. Nevertheless, rare or atypical presentations still highlight the ongoing need for further refinement in future updates.

Although pyrazolones or propionic acid derivatives are reported as the most frequent offender drug group in NSAID hypersensitivity, in our study, propionic acid derivatives were the most common group.[13,14] This discrepancy may be related to differences in prescribing practices between countries, or the fact that these drugs are more easily accessible as over-the-counter (OTC) medications. The mean age of our patients was 44.2 ± 13.0 years (the middle-age group), which was consistent with previous reports.[13]

Atopy has been reported in 40–50% of NIUA patients, 20–30% of NERD patients, 30–40% of NECD patients, and 30–40% of SNIUAA patients. Overall, atopy is mentioned in 30–50% of NSAID hypersensitivity cases.[15] In our cohort, the prevalence of atopy was 40%, most frequently because of sensitization to house dust mites. A novel observation in our study was the significant association of salicylate reactions with both atopy and male gender, which differs from most previously published reports.

According to the ENDA classification, NSAID hypersensitivity is grouped as cross-reactive and selective. However, patients presenting with a combination of cutaneous, respiratory, and gastrointestinal symptoms could not be clearly assigned, leading to the introduction of the so-called "blended" category.[16] For a long time, the need for a new classification has been emphasized due to the challenges posed by the blended group.[17] One study reported the prevalence of blended reactions to be around 30%.[16] Correct allocation of these blended patients is clinically important for both diagnostic clarity and management strategies. In our study, approximately 10% of patients who were previously classified as blended could be reassigned into the newly defined groups of the WAO 2025 guidelines. This reclassification eliminated previous uncertainty and fulfilled an important unmet clinical requirement.

For patients who are correctly classified into cross-reactive or selective groups, the identification of safe alternative NSAIDs becomes more straightforward. In selective reactors, tolerance to other NSAIDs is expected, while in cross-reactive patients, safe alternatives must be identified through drug provocation testing.[14] Selective COX-2 inhibitors are generally considered safe in this group, although tolerance should always be confirmed by testing.[18] Even in cases where reactions occurred to COX-2 inhibitors, alternative tolerated drugs were eventually identified.[19] In our cohort, OPT successfully identified safe alternatives, with hypersensitivity reactions occurring in only 2–8% of tests, highlighting the clinical value of systematic testing.

Recently, the WAO 2025 position paper introduced new categories such as NEFA and NIFA, highlighting the role of NSAIDs as cofactors in food allergy reactions.[4] However, in our cohort, no such cases were identified, and these phenotypes did not emerge. This difference could be explained by population characteristics, dietary habits, or referral patterns.

Laboratory parameters, such as total IgE, eosinophil count, and serum tryptase, were also evaluated. Although the mean IgE levels in our cohort were within a broad range, the prevalence of atopy was 40%, most commonly because of house dust mite sensitization, and salicylate reactions were significantly associated with atopy. This suggests that IgE may reflect an underlying atopic background, rather than serving as a direct diagnostic biomarker for NSAID hypersensitivity. Peripheral eosinophil counts were mostly within the normal range, but higher levels might be expected in subgroups such as NERD, where eosinophilic inflammation plays a central role.[11] Finally, autoimmune markers (ANA, ANCA, and ENA) were largely negative, supporting the concept that NSAID hypersensitivity is not linked to systemic autoimmune mechanisms.

Our study has several limitations. First, it was a retrospective, single-center analysis, which may limit the generalizability of the findings to other populations or clinical settings. Second, although aspirin provocation testing was performed in a large subset of patients, not all patients underwent standardized provocation with multiple NSAID groups; therefore, some classifications relied on detailed clinical history, which carries the risk of recall bias. Third, laboratory markers, such as total IgE, eosinophil counts, and serum tryptase, were not available for all patients, and their utility as biomarkers of NSAID hypersensitivity remains uncertain. Fourth, our cohort did not include cases of NEFA or NIFA, newly described in the WAO 2025 guidelines, which lessened our ability to evaluate these phenotypes in the context of the updated classification. Finally, since this was a single-country cohort, prescribing patterns and drug availability may have influenced the distribution of culprit NSAID groups, and international multicenter studies are needed to validate these findings.

Data Availability

The datasets generated and analyzed in the current study are available from the corresponding author on reasonable request. Owing to patient privacy regulations, individual-level data cannot be shared publicly.

Author's Contribution

Ismet Bulut: Conceptualization, data collection, data analysis, data interpretation, manuscript drafting,

critical revision, and final approval. Zeynep Yegin Katran: Conceptualization, data collection, data analysis, data interpretation, manuscript drafting, critical revision, and final approval.

Conflict of Interest

The authors declared no conflict of interest related to this work.

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