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ORIGINAL ARTICLE

Medicine Science International Medical Journal

Medicine Science 2026;15(1):426-9

Clinical characteristics of biologic-treated patients with nonsteroidal anti-inflammatory drug–exacerbated respiratory disease: A comparative analysis of hypertensive and non-hypertensive groups

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Received 19 November 2025; Accepted 24 December 2025
Available online 26 February 2026 with doi: 10.5455/medscience.2025.11.322

Abstract

Hypertension (HT) is one of the most frequent comorbidities in asthma and may negatively affect disease control. This study aimed to compare the clinical characteristics of nonsteroidal anti-inflammatory drug–exacerbated respiratory disease (NERD) patients receiving biologics, with and without HT. This observational real-life study included 23 NERD patients treated with omalizumab or mepolizumab. Four (17%) were receiving omalizumab, and 19 (83%) were receiving mepolizumab. HT was present in five patients (22%). The median age was 43 years, and was higher in patients with HT. A family history of asthma was more frequent in hypertensive patients compared to those without HT. There was no significant difference between patients with and without HT in terms of asthma duration, duration of biological therapy, or asthma control. HT was present in approximately one-fifth of severe asthmatics with NERD receiving biological therapy. The coexistence of HT did not appear to adversely affect asthma control or treatment outcomes.

Keywords: Asthma, hypertension, NERD, asthma control, omalizumab, mepolizumab

Introduction

Hypertension (HT) is among the systemic diseases accompanying asthma, and in a multicenter study conducted in Turkey, the prevalence of HT in patients with asthma was found to be 16.3% [1]. In addition to being a potential risk factor for asthma, evidence in the literature suggests that antihypertensive medications used in the management of HT may also negatively affect asthma control [2-4]. In a study conducted among Korean patients with asthma, HT was found to increase the risk of asthma by 1.43-fold [5]. Genetic studies investigating the coexistence of HT and asthma have also been conducted; however, a direct association between asthma and HT has not yet been demonstrated [6,7].

A distinct subgroup of patients with severe asthma consists of those with non-steroidal anti-inflammatory drug–induced respiratory disease (NERD). Samter syndrome, first described in 1967 by the immunologist Max Samter, was originally defined as a triad of aspirin sensitivity, nasal polyps, and asthma [8]. This condition is currently referred to as aspirin-exacerbated respiratory disease (AERD) in the United States, whereas the term NERD is more commonly used in European and Middle Eastern countries [8]. According to current asthma diagnosis and treatment guidelines, NERD is characterized by the exacerbation of respiratory symptoms following the intake of non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin (acetylsalicylic acid, ASA) in patients with chronic rhinosinusitis accompanied by asthma and/or nasal polyposis [9]. The oral aspirin provocation test remains the gold standard for confirming NSAID hypersensitivity [9]. In our country, the reported prevalence of NERD ranges widely from 1.8% to 44%, depending on the diagnostic methods used and the patient populations studied [9]. In a study conducted by Bavbek et al. involving 1,344 asthmatic patients, the prevalence of NERD was reported as 13.6% [10]. In patients with aspirin sensitivity, aspirin desensitization—particularly following endoscopic sinus surgery—has been shown to improve asthma and rhinitis symptoms and to prevent

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Tuncay G. Clinical characteristics of biologic-treated patients with nonsteroidal anti-inflammatory drug–exacerbated respiratory disease: A comparative analysis of hypertensive and non-hypertensive groups. Med Science. 2026;15(1):426-9.

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DOI: 10.5455/medscience.2025.11.322

the formation of new nasal polyps [8,11]. However, due to the potential side effects and contraindications associated with aspirin therapy, conventional treatments such as inhaled and intranasal corticosteroids and leukotriene receptor antagonists are often insufficient to adequately control asthma and rhinitis symptoms or to reduce nasal polyps and prevent their recurrence in patients who are unable to undergo aspirin desensitization. As alternative treatment strategies continue to be explored for patients who cannot tolerate aspirin, the advent of biological therapies has introduced new therapeutic options for individuals with NERD [8]. Nevertheless, in our country, biological agents are approved exclusively for patients with severe asthma. Omalizumab and mepolizumab are among the biological therapies approved for the treatment of severe asthma in many European countries, including ours. To date in Turkey, there is no study evaluating asthma control in patients with severe asthma accompanied by HT. The aim of this study was to compare the clinical characteristics of patients with severe asthma, with and without HT, whose disease is exacerbated by NERD and who are receiving biological therapy, and to contribute to the existing literature.

Material and Methods

This real-world, prospective observational study included 23 patients with NERD who were treated with biologic agents between June 1, 2022, and June 1, 2023, in a tertiary allergy center. Eligible participants were adults (≥18 years) who provided written informed consent and had been receiving a biologic therapy for at least six months. Individuals diagnosed with eosinophilic granulomatosis with polyangiitis were excluded. Because only omalizumab and mepolizumab are approved for severe asthma in Turkey, all patients were using one of these treatments. NERD was diagnosed in individuals with asthma and nasal polyps who reported at least two reproducible respiratory reactions to aspirin or other nonsteroidal anti-inflammatory drugs within the preceding five years, and the diagnosis was confirmed through an oral aspirin challenge in every case [8,12,13].

According to GINA recommendations, add-on biologics targeting type 2 inflammation are considered for patients with persistent symptoms or frequent exacerbations despite high-dose inhaled corticosteroids (ICS)-long acting beta agonists therapy and the presence of allergic or eosinophilic biomarkers [13]. In this study, indications for omalizumab or mepolizumab included uncontrolled asthma despite high-dose ICS combined with one or two additional controller medications within the last three months [1-4]. Baseline assessments included blood eosinophils, total serum immunoglobulin E (IgE), and sensitization to inhalant allergens. Mepolizumab was prescribed for patients with blood eosinophils ≥150 cells/mm³ while on continuous high-dose ICS or daily OCS, and for all others with eosinophils ≥300 cells/mm³ [13]. Omalizumab dosing was determined by total IgE levels and body weight in patients sensitized to perennial aeroallergens [8,12-14]. Patients who met criteria for mepolizumab and remained uncontrolled after at least 16 weeks of omalizumab were switched accordingly. Follow-up visits occurred every three months.

The study complied with the ethical principles of the 2013 revision of the Declaration of Helsinki and received approval from the Hacettepe University Ethics Committee on May 10, 2022 (Project No: GO 22/443, protocol number: 2022/09-28). Written informed consent was obtained from all participants. Data collected included asthma treatment steps, presence of atopy, disease duration, asthma control test scores, number of exacerbations requiring OCS, blood eosinophil levels, total serum IgE, and history of nasal polypectomy. Demographic information and laboratory findings were retrieved from hospital records and patient files.

Statistical Analyses

Statistical analyses were performed using SPSS version 25.0. Categorical variables were summarized as counts and percentages. For numerical data, normally distributed values were reported as mean ± standard deviation, whereas non-normally distributed data were expressed as median with interquartile ranges. Comparisons between categorical variables were conducted with the Chi-square test or Fisher's exact test when appropriate. The Mann–Whitney U test was used for non-parametric continuous variables, while parametric comparisons between two groups were assessed using the Independent Samples t-test. Correlations for non-normally distributed variables were examined using Spearman's rank correlation. A p-value below 0.05 was regarded as statistically significant.

Result

A total of 23 patients with NERD who were receiving omalizumab or mepolizumab therapy were included in the study. Of these, four patients (17%) were treated with omalizumab and 19 patients (83%) with mepolizumab. There was no significant difference in the frequency of HT between patients receiving omalizumab and those receiving mepolizumab ($p = 0.25$). HT was present in five patients (22%), whereas 18 (78%) patients did not have HT. The median age of the study population was 43 years (IQR: 37–53), and there was no significant age difference between patients with and without HT. Twelve patients were female, and the female-to-male ratio was similar between the two groups. Clinical characteristics are summarized in Table 1.

All patients with HT were university graduates, whereas 44% of patients without HT had a university degree. There was no significant difference in body mass index (BMI) between patients with and without HT. A family history of asthma was more common among patients with HT compared with those without (80% vs. 35%). There was no significant difference between patients with and without HT in terms of asthma duration, duration of biological therapy, or asthma control. None of the patients, either with or without HT, had been admitted to the intensive care unit during the previous year. However, one patient (5%) without HT presented to the emergency department due to an asthma exacerbation.

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Table 1. Clinical characteristics of NERD patients with and without HT

	Total (n=23)	HT[a] (+) (n=5)	HT (-) (n=18)	P value
Age, median years, IQR*	43 (53-37)	65 (67-48)	39 (51-35)	0.01
Female, n (%)	12 (52)	2 (40)	10 (56)	0.54
Education, n (%)	13 (57)	5 (100)	8 (44)	0.03
Working Status, n (%)	17 (74)	4 (80)	13 (72)	0.73
BMI, median (IQR)	24.9 (29.7-23.8)	24.5 (30.3-24.1)	25.9 (30-23.6)	0.54
Ex-smoker, n (%)	9 (39)	2 (40)	7 (39)	0.96
Comordities, n (%)	13 (57)	5 (100)	8 (44)	0.03
Diabetes mellitus	4 (17)	2 (40)	2 (11)	0.13
GERD[b]	3 (13)	1 (20)	2 (11)	0.60
Thyroid diseases	3 (13)	2 (40)	1 (5)	0.11
Urticaria	2 (9)	0 (0)	2 (11)	1.00
Coronary Artery Disease	2 (9)	2 (40)	0 (0)	0.04
Hyperlipidemie	2 (9)	2 (40)	0 (0)	0.04
Other**	4 (17)	1 (20)	3 (16)	NA
Family history of asthma, n (%)	8 (35)	4 (80)	4 (22)	0.02
Family history of rhinitis, n (%)	6 (26)	3 (60)	3 (17)	0.05
Duration of asthma, median months (IQR)	183 (243-111)	243 (381-147)	171 (225-93)	0.10
Duration of biologicals, median months (IQR)	16 (28-5)	13 (31-5)	20 (28-5)	0.85
Duration of nasal polyp, median months (IQR)	146 (216-75)	150 (222-74)	146 (229-193)	0.71
Number of nasal polypectomy, median (IQR)	3 (3-1)	3 (4-2)	3 (3-1)	0.82
Admission to intensive care unit, n (%)	0 (0)	0 (0)	0 (0)	NA
Admission to emergency room due to asthma attack in the last year, n (%)	1(4)	0 (0)	1 (5)	NA
OCS[1] use due to astma attack, n (%)	4 (17)	0 (0)	4 (22)	NA
Baseline blood eosinophil count, median / mm³	700 (1000-600)	700 (925-450)	715 (1170-600)	0.37
Baseline total IgE, median UI/mL	88 (210-33)	178 (379-87)	68 (186-20)	0.12
ACT [c], median (IQR)	25 (25-22)	25 (25-25)	25 (25-21)	0.15

HT: Hypertension, [b]GERD: Gastroesophageal reflux disease, [c]ACT:Asthma control test. *IQR: Interquartile range, **Breast Cancer (n=1); chronic kidney disease (n=1); panic disorder (n=1), rheumatoid arthritis (n=1). [1]OCS: oral corticosteroid

Discussion

This study evaluated the clinical characteristics of patients with NERD receiving biological therapy, with a specific focus on the presence of HT. In our cohort, the prevalence of HT was 22%, which appears slightly higher than the 16.3% reported in a multicenter study of asthmatic patients in Turkey [1]. Although the sample size was limited, this finding may indicate that comorbid HT is relatively common among patients with NERD, consistent with previous studies suggesting that metabolic and cardiovascular comorbidities are more frequent in this population [2-4].

The coexistence of HT and asthma has been reported in several studies, and the mechanisms underlying this association remain unclear. Potential explanations include shared inflammatory pathways, systemic corticosteroid exposure, endothelial dysfunction, and lifestyle factors such as obesity and reduced physical activity [5-7]. In our study, there was no significant difference in BMI between patients with and without HT, suggesting that obesity alone may not fully explain the observed comorbidity.

All patients with HT in our study were university graduates, which may reflect a higher awareness and diagnosis rate among

DOI: 10.5455/medscience.2025.11.322

individuals with greater health literacy, rather than a true socioeconomic correlation. Interestingly, a family history of asthma was more common in patients with HT compared to those without, suggesting that genetic or familial predisposition might play a role in the overlap between the two conditions. Although several genetic studies have investigated shared loci between asthma and HT, a direct link has yet to be demonstrated [6,7].

No differences were observed in terms of the duration of biological therapy or asthma control outcomes between patients with and without HT. None of the patients required intensive care admission within the past year, and only one patient—without HT—had an emergency department visit due to an asthma exacerbation. These findings suggest that the presence of HT does not appear to adversely affect short-term asthma control in patients receiving biological therapy. However, given the small sample size, subtle effects on disease activity or treatment response cannot be ruled out.

Previous reports have indicated that certain antihypertensive agents, such as β-blockers, may worsen asthma control, whereas others, including calcium channel blockers or angiotensin receptor blockers, may have neutral or even beneficial effects on airway inflammation [3,4]. Unfortunately, our dataset did not include information on the specific antihypertensive medications used, which limits interpretation in this regard. Future studies should examine the impact of different antihypertensive drug classes on asthma outcomes in patients with NERD.

The main limitations of this study are its retrospective design, small sample size, and single-center nature, which may limit generalizability. Nevertheless, the study provides valuable real-life data from a well-characterized cohort of severe asthmatics with NERD, a subgroup that remains underrepresented in the literature.

Conclusion

HT was present in approximately one-fifth of severe asthmatics with NERD receiving biological therapy. The coexistence of HT did not significantly affect asthma control parameters or treatment outcomes in this cohort. Larger prospective studies are warranted to further explore the clinical and mechanistic links between asthma and HT, particularly in patients with type 2–high asthma phenotypes receiving biological treatments.

Conflict of Interests

The authors declare that there is no conflict of interest in the study.

Financial Disclosure

The authors declare that they have received no financial support for the study.

Ethical Approval

The study received ethical approval from the Hacettepe University Ethics Committeeon May 10, 2022 (Project No: GO 22/443, protocol number: 2022/09-28)

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