

Clinical and Healthcare Cost Characteristics of Severe Asthma Patients with Long-Term Control on Omalizumab: A Comparative Analysis with Patients Who Switched to Other Biologics

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Background and Purpose: Biologics are crucial for severe asthma treatment, but their high costs pose challenges. Omalizumab (OML) is dosed on the basis of patient-specific factors. The purpose of this study is to clarify the clinical characteristics of severe asthmatics who maintain long-term control on omalizumab including healthcare cost considerations.

Patients and Methods: A retrospective, multicenter cohort study was conducted. Patients receiving OML at three institutions were enrolled. Patients continuing OML (C-OML) were compared with those switching to other biologics (S-OML) in terms of clinical background, cost-effectiveness, and type-2 inflammation levels.

Results: Forty-seven patients were enrolled. The C-OML group achieved exacerbation control comparable to that of the S-OML group, with a median OML dose of 300 mg/month, resulting in significantly lower personal payments ($p < 0.01$). Compared with the S-OML group, the C-OML group had a greater prevalence of overweight ($p = 0.04$), a lower prevalence of eosinophilic chronic rhinosinusitis ($p < 0.01$), and a trend toward a higher prevalence of allergic rhinitis ($p = 0.06$). Effective asthma control with OML was associated with nonsevere type-2 inflammation (eosinophils $< 300/\mu\text{L}$ and FeNO < 50 ppb).

Conclusion: Patients with nonsevere type-2 inflammation and a high BMI can achieve effective asthma control with OML, reducing treatment costs. Identifying this phenotype can improve the cost-effectiveness of biologic therapies for patients with severe asthma.

Plain Language Summary: Biologic treatments are important for managing severe asthma, but they can be expensive. Patients who maintained long-term control with omalizumab had significantly lower biologic-related healthcare costs compared to those who switched therapies. They were characterized by nonsevere type 2 inflammation, elevated BMI, allergic rhinitis, and absence of ECRS. Understanding a patient's background is crucial when choosing the most appropriate treatment option.

Keywords: asthma, drug costs, omalizumab, phenotype, type-2 inflammation

Introduction

Severe asthma affects 5–10% of all individuals with asthma^{1–4} and poses a significant therapeutic challenge. A large proportion of these patients exhibit high type-2 inflammation, characterized by eosinophilic inflammation and IgE-mediated atopic responses.⁵ The introduction of biologics has enhanced the management of severe asthma by targeting these inflammatory pathways.⁶ However, the high cost of biologics raises concerns regarding healthcare resource



allocation and limits access to these treatments. This issue could be resolved by accurately identifying appropriate patients and treating them with omalizumab (OML), the oldest and one of the most widely used anti-IgE biologics for severe asthma.

OML, like other biologics, has well-established efficacy in reducing exacerbations and systemic corticosteroid use in severe asthma patients.^{7,8} However, unlike other biologics, OML dosing is dependent on body weight and serum IgE levels. This unique characteristic raises the possibility of achieving good asthma control in some patients with relatively lower doses of OML. Additionally, OML has shown efficacy in treating allergic rhinitis (AR), a common comorbidity and a known risk factor for poor asthma control.^{9,10} Considering these factors, some patients with long-term asthma control on omalizumab (OML) appear to achieve effective management of both asthma and exacerbation-related comorbidities such as allergic rhinitis with relatively low doses of OML. In such cases, the healthcare costs associated with biologic therapy may be substantially reduced. Nonetheless, despite prior studies analyzing patient characteristics associated with the clinical benefits of OML,^{11–13} few studies have specifically examined the relationships among disease control, dosage, and cost-effectiveness.

Therefore, the aim of this study was to clarify the clinical characteristics of patients with severe asthma who maintain long-term control on omalizumab (OML), focusing on both clinical profiles and healthcare cost considerations. We hypothesize the existence of a subgroup that combines clinical efficacy with a reduced economic burden. We aimed to advance personalized medicine by providing new insights into the optimal use of medical resources, complementing current strategies for biological selection.

Materials and Methods

Study Design and Participants

This was a retrospective, observational, multicenter cohort study. This study included patients who were receiving ongoing biologic therapy for severe asthma at Kyoto University Hospital, Kindai University Hospital, and Kindai University Nara Hospital between 2021 and 2023, and who had a history of omalizumab treatment. Patients were excluded if they were current smokers, had significant respiratory comorbidities, or were deemed unsuitable by their physician. This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional review boards of all the participating hospitals (R4011). Informed consent was obtained in accordance with ethical guidelines for retrospective studies.

Measurements

We collected clinical data prior to the initiation of biologic therapy. These data included anthropometric measurements (height, weight, and BMI), blood test results (eosinophil count and serum IgE level), lung function test results, fractional exhaled nitric oxide (FeNO) concentrations, when available, inhaled corticosteroid (ICS) dose (fluticasone equivalent), oral corticosteroid (OCS) use, history of AR or eosinophilic chronic rhinosinusitis (ECRS), and data on exacerbations. At enrollment, we also collected data on exacerbations in the past year, history of biologics treatments, and OML dosage. Asthma exacerbations were defined as events requiring systemic corticosteroid treatment. For each type and dose of biologic used at enrollment, we also calculated monthly personal payments on the basis of the Japanese health insurance system ([Supplementary Figure 1](#)). The actual prices of biologics were derived from the syringe formulation drug prices as of December 2023. Currency conversion from yen (JPY) to US dollars (USD) was performed using the market exchange rate on December 31, 2023 (1 USD = 142 JPY).

Decisions to switch biologics are made by pulmonology and allergy specialists based on clinical judgment of poor control in exacerbations requiring systemic corticosteroid or symptoms that significantly impair daily functioning. Patients who continued OML for at least four months at enrollment were classified into the C-OML group. Patients who had previously been treated with OML but were not receiving it at enrollment due to a change to other biologics were classified into the S-OML group ([Supplementary Figure 2](#)). Type-2 inflammation severity was categorized on the basis of the blood eosinophil count and FeNO level. Patients with an elevated blood eosinophil count ($\geq 300/\mu\text{L}$) or

increased FeNO levels (≥ 50 ppb) were classified as having severe type-2 inflammation; all others were classified as having nonsevere type-2 inflammation.

Statistical Analysis

The C-OML and S-OML groups were compared using the chi-square test, *t* test, or Wilcoxon rank-sum test, as appropriate. The same statistical methods were used to compare the characteristics of patients with severe and nonsevere type-2 inflammation. A *p* value < 0.05 was considered to indicate statistical significance. All analyses were performed using JMP version 12 (SAS Institute Inc., Tokyo, Japan). The data are presented as the means \pm SDs or medians (ranges).

Results

Patients' Characteristics

A total of 47 were eligible for inclusion in this study (Supplementary Figure 2). The mean age was 64 ± 16 years, and 72% of the participants were female. The median blood eosinophil count was $243/\mu\text{L}$ (range: 148–632), the serum IgE level was 144 IU/mL (49–478), and the FeNO level (measured in 38 patients) was 37 ppb (25–75) before biologics were administered. Twenty-five patients (55%) had C-OML status, whereas 22 (45%) had S-OML status. Patients who discontinued omalizumab were subsequently treated with mepolizumab, benralizumab, or dupilumab (Table 1). Most of the reasons for the changes from OML to other medicines were exacerbations or poor disease control, including patients requiring treatment for eosinophilic pneumonia. In one patient, OML was switched to dupilumab to manage

Table 1 Patient Characteristics

Clinical Index	n = 47
Sex, female, n (%)	34 (72)
Age at enrollment, years	64 ± 16
Asthma onset, years	35 ± 16
Body mass index, m^2/kg	23.3 ± 3.5
Overweight (BMI ≥ 25), n (%)	13 (28)
Smoking history, current/ex/never, n (%)	0 (0)/9 (20)/37 (80)
Blood eosinophil counts, $\text{n}/\mu\text{L}$	243 (148 to 632)
Serum IgE, IU/mL	144 (49 to 478)
FeNO*, ppb	37 (25 to 75)
FEV ₁ as % of predicted, %	83 ± 25
FEV ₁ /FVC < 0.7 , n (%)	22 (50)
ICS dose (equivalent to fluticasone propionate), $\mu\text{g}/\text{day}$	871 ± 390
Maintenance oral corticosteroid use, n (%)	14 (30)
Allergic rhinitis, n (%)	30 (64)
Eosinophilic chronic rhinosinusitis, n	11 (23)
Patients continued OML [†] , n (%)	25 (55)
Biologics at enrollment, OML/MPO/BNR/DPL, n	25/4/7/11
Patients with exacerbations [‡] in the year prior to enrollment, n (%)	15 (32)
Patients with exacerbations [‡] in the year prior to biologics induction, n (%)	36 (77)
Number of exacerbations [‡] in the year prior to enrollment, n	0.9 ± 2.0
Number of exacerbations [‡] in the year prior to biologics induction, n	2.4 ± 2.4
Personal payment for biologics per month, yen	17488 (8744 to 34976)
Personal payment for biologics per month, US dollars [§]	123 (62 to 247)

Notes: Data before biologic administration are presented, except for age at enrollment and monthly payments for biologics (data at enrollment). Data are expressed as the means \pm SDs, except for blood eosinophil counts, serum IgE levels, FeNO and personal payment for biologics, which are presented as medians (ranges). *Data were collected from 38 patients. [†]Patients treated with OML for at least four months at the time of enrollment. [‡]Asthma exacerbation requiring systemic corticosteroid administration. [§]Converted at the yen-to-dollar exchange rate as of December 2023.

Abbreviations: BMI, body mass index; FeNO, fractional exhaled nitric oxide; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; ICS, inhaled corticosteroid; OML, omalizumab; MPO, mepolizumab; BNR, benralizumab; DPL, dupilumab; US, United States.

ECRS. Both groups were stably continuing their respective biologics for more than four months at the time of enrollment. The median personal payment of biologic therapy was 123 USD (62–247) per month across all subjects.

Comparison of the C-OML and S-OML Groups

The median duration of omalizumab use in the C-OML group was 40 months. There were no significant differences between the two groups in baseline ICS dose, pulmonary function, or exacerbation history prior to biologic initiation (Table 2). On the other hand, compared with the S-OML group, the C-OML group presented a significantly greater prevalence of overweight (BMI \geq 25) (40% vs 14%, $p = 0.04$), a lower frequency of comorbid ECRS (8% vs 41%, $p < 0.01$), lower FeNO levels (median 25 ppb vs 57 ppb, $p < 0.01$), and trends toward a higher frequency of comorbid AR (76% vs 50%, $p = 0.06$) and lower blood eosinophil counts (median 220/ μ L vs 452/ μ L, $p = 0.08$) (Table 2). In the multivariate analysis including these factors, only ECRS remained significantly different between the groups. In a subgroup analysis excluding patients with ECRS, elevated FeNO ($p = 0.03$) and comorbid AR ($p = 0.01$) were significantly more frequent in the C-OML group. At the time of enrollment, ie, while on biologics, the C-OML group achieved exacerbation control comparable to that of the S-OML group, with a median OML dose of 300 mg/month, and had significantly lower monthly personal payments for biologics than did the S-OML group (median: \$62 [57 to 154] vs \$225 [123 to 249], $p < 0.01$; Table 2 and Figure 1).

Table 2 Clinical Characteristics of the C-OML and S-OML Groups

	C-OML* (n = 25)	S-OML [†] (n = 22)	P Value
Sex, female, n (%)	17 (77)	17 (68)	0.48
Age at enrollment, years	60 \pm 19	69 \pm 11	0.07
Asthma onset, years	33 \pm 18	38 \pm 13	0.25
Body mass index, m ² /kg	24.1 \pm 4.1	22.5 \pm 2.6	0.11
Overweight (BMI \geq 25), n (%)	10 (40)	3 (14)	0.04
Smoking history, current/ex/never, n (%)	0 (0)/5 (21)/19 (79)	0 (0)/4 (18)/18 (82)	0.82
Blood eosinophil counts, n/ μ L	220 (120 to 391)	452 (149 to 1004)	0.08
Serum IgE, IU/mL	138 (53 to 394)	190 (42 to 511)	0.78
FeNO [‡] , ppb	25 (13 to 34)	57 (37 to 100)	< 0.01
FEV ₁ as % of predicted, %	86 \pm 22	80 \pm 28	0.38
FEV ₁ /FVC < 0.7, n (%)	11 (48)	11 (52)	0.76
ICS dose (equivalent to fluticasone propionate), μ g/day	822 \pm 352	929 \pm 430	0.35
Maintenance oral corticosteroid use, n (%)	7 (28)	7 (32)	0.78
Allergic Rhinitis, n (%)	19 (76)	11 (50)	0.06
Eosinophilic chronic rhinosinusitis, n	2 (8)	9 (41)	< 0.01
OML dose, mg/month	300 (150 to 450)	–	–
Duration of OML treatment, months	40 (34 to 127)	29 (7 to 38)	< 0.01
Patients with exacerbations [§] in the year prior to enrollment, n (%)	10 (40)	5 (23)	0.21
Patients with exacerbations [§] in the year prior to biologics induction, n (%)	20 (80)	16 (73)	0.56
Number of exacerbations [§] in the year prior to enrollment, n	1.1 \pm 2.5	0.5 \pm 1.3	0.34
Number of exacerbations [§] in the year prior to biologics induction, n (%)	2.0 \pm 1.8	2.8 \pm 2.9	0.30
Personal payment for biologics per month, yen	8744 (7287 to 21860)	31,956 (15984 to 35265)	< 0.01
Personal payment for biologics per month, US dollars [¶]	62 (52 to 154)	225 (123 to 249)	< 0.01

Notes: Data before biologic administration are presented, except for age at enrollment, OML dose, exacerbation history, and monthly payments for biologics (data at enrollment). Data are expressed as the means \pm SDs, except for blood eosinophil counts, serum IgE levels, FeNO, OML dose, and personal payment for biologics, which are presented as medians (ranges). *Patients treated with OML for at least four months at the time of enrollment. [†]Patients previously treated with OML but not receiving it at enrollment owing to a change in regimen. [‡]Data were collected from 38 subjects. [§]Asthma exacerbation requiring systemic corticosteroid administration. [¶]Converted at the yen-to-dollar exchange rate as of December 2023.

Abbreviations: C-OML, continued omalizumab; S-OML, switched from omalizumab; BMI, body mass index; FeNO, fractional exhaled nitric oxide; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; ICS, inhaled corticosteroid; US, United States.

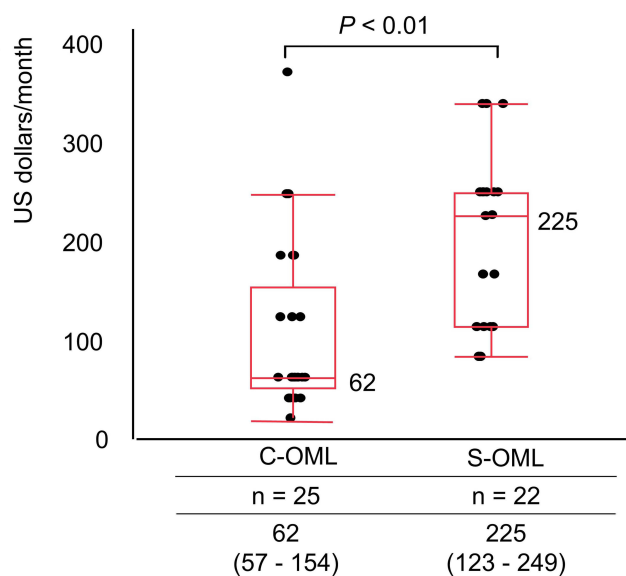


Figure 1 Comparison of monthly personal payments for biologics between the C-OML and S-OML groups.

Notes: The boxes represent the interquartile range, encompassing the middle 50% of the data. The lines within the box indicate the median value. The whiskers depict the range of the data, extending from the lower to the upper quartiles.

Abbreviations: US, United States; C-OML, continued omalizumab; S-OML, switched from omalizumab.

Type-2 Inflammation and OML Response

The status of type 2 inflammation prior to biologic initiation, assessed by eosinophil count or FeNO, was available for 40 patients. Among these, 26 patients (65%) were classified into the severe type-2 inflammation group (eosinophils $\geq 300/\mu\text{L}$ or FeNO ≥ 50 ppb), whereas 14 patients (35%) were classified into the nonsevere type-2 inflammation group (Table 3). In the nonsevere type-2 inflammation group, a significantly greater proportion of C-OML cases was observed (Figure 2 and Table 3, 79% vs 31%, $p < 0.01$). Additionally, monthly biologic costs were significantly lower in this group (median: \$62 [41–195] vs \$166 [106–249], $p = 0.02$). The proportion of patients who experienced exacerbations in the year prior to enrollment was similar between the two groups.

Table 3 Clinical Background of the Nonsevere Vs Severe Type-2 Inflammatory Groups

	Non Severe* (n = 14)	Severe* (n = 26)	P Value
Sex, female, n (%)	10 (71)	21 (81)	0.50
Age at enrollment, years	65 \pm 18	67 \pm 11	0.73
Asthma onset, years	34 \pm 19	39 \pm 14	0.38
Body mass index, m ² /kg	24.7 \pm 4.5	22.4 \pm 2.9	0.05
Overweight (BMI ≥ 25), n (%)	6 (43)	4 (15)	0.06
Smoking history, current/ex/never, n (%)	0 (0)/3 (23)/10 (77)	0 (0)/5 (19)/21 (81)	0.78
Blood eosinophil counts, n/ μL	153 (89 to 226)	600 (330 to 958)	< 0.01 [†]
Serum IgE, IU/mL	91 (33 to 205)	194 (113 to 511)	0.02 [†]
FeNO [†] , ppb	17 (10 to 28)	66 (38 to 110)	< 0.01 [†]
FEV ₁ as % of predicted, %	88 \pm 30	81 \pm 24	0.43
FEV ₁ /FVC < 0.7, n (%)	6 (43)	14 (56)	0.43
ICS dose (equivalent to fluticasone propionate), $\mu\text{g}/\text{day}$	974 \pm 413	833 \pm 79	0.29
Maintenance oral corticosteroid use, n (%)	5 (36)	8 (31)	0.75
Allergic Rhinitis, n (%)	10 (71)	16 (62)	0.53
Eosinophilic chronic rhinosinusitis, n	0 (0)	11 (42)	< 0.01
OML dose, mg/month	150 (150 to 300)	300 (150 to 600)	0.13

(Continued)

Table 3 (Continued).

	Non Severe* (n = 14)	Severe* (n = 26)	P Value
C-OML [‡] , n (%)	11 (79)	8 (31)	< 0.01
Patients with exacerbations [§] in the year prior to enrollment, n (%)	5 (36)	7 (27)	0.56
Personal payment for biologics per month, yen	8744 (5829 to 27658)	23,510 (14914 to 35265)	0.02
Personal payment for biologics per month, US dollars [¶]	62 (41 to 195)	166 (106 to 249)	0.02

Notes: Data before biologic administration are presented, except for age at enrollment, OML dose, number of C-OML subjects, exacerbation history, and monthly payments for biologics (data at enrollment). Data are expressed as the means \pm SDs, except for blood eosinophil counts, serum IgE levels, FeNO, and OML doses, and personal payments for biologics, which are presented as medians (ranges). *Patients with increased blood eosinophils ($\geq 300/\mu\text{L}$) or elevated FeNO (≥ 50 ppb) were classified as having severe type-2 inflammation; all others were classified as having nonsevere type-2 inflammation. †Data were collected from 38 subjects. ‡Patients treated with OML for at least four months at the time of enrollment. §Asthma exacerbation requiring systemic corticosteroid administration. Converted at the yen-to-dollar exchange rate as of December 2023.

Abbreviations: BMI, body mass index; FeNO, fractional exhaled nitric oxide; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; ICS, inhaled corticosteroid; C-OML, continued omalizumab.

Discussion

In this study, we compared patients who responded well to omalizumab with those who required switching to other biologics and identified characteristics of the former group. These patients were more likely to have allergic rhinitis and relatively higher BMI, and they incurred significantly lower out-of-pocket costs for biologic therapy. Our findings suggest that considering these clinical characteristics could help optimize biologic selection and enhance cost-effectiveness in severe asthma management.

While biologics are highly effective in controlling severe asthma and reducing exacerbations,^{6,14} their high cost remains a significant concern.¹⁵ In countries such as Japan, where insurance systems result in personal payments that vary depending on treatment regimens, the financial burden of biologics remains a significant barrier.¹⁶ The monthly cost of 300 mg of OML for users in the 30%-payer group of the Japanese insurance system, the largest group in this study, was 17,488 yen (123.2 USD). In comparison, the costs of other drugs were at least double the cost: mepolizumab at 47,967 yen (337.8 USD), benralizumab at 47,901 yen (337.3 USD), and dupilumab at 35,265 yen (248.3 USD). Conversely, the costs of other agents are comparable to those of 600 mg of OML. Among biologics, OML has demonstrated good cost-effectiveness in several studies, as evaluated using quality-adjusted life years (QALYs)¹⁷ and the incremental cost-effectiveness ratio (ICER).¹⁸ This study extends previous research by identifying a population that can be effectively controlled with relatively low-dose OML (median 300 mg/month), offering a potential solution to this economic issue. Biologics have become indispensable in the management of severe asthma. To ensure access for all eligible patients, it is essential to develop strategies that address not only disease pathophysiology and therapeutic efficacy but also economic considerations.

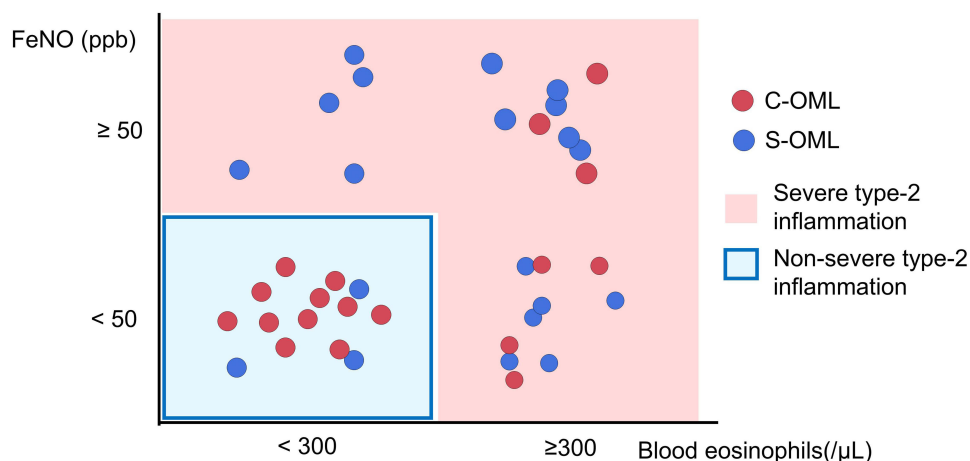


Figure 2 Distribution of C-OML and S-OML subjects according to type-2 inflammation status.

Notes: The distributions of C-OML and S-OML subjects according to type-2 inflammation are shown. Subjects with blood eosinophils $\geq 300/\mu\text{L}$ or FeNO ≥ 50 ppb at enrollment were classified into the severe type-2 inflammation group, whereas those meeting neither criterion were classified into the nonsevere type-2 inflammation group. Dots represent individual patient data, illustrating the distribution. The red panel indicates severe type-2 inflammatory status, whereas the blue panel indicates nonsevere type-2 inflammatory status.

Abbreviations: FeNO, fractional exhaled nitric oxide; C-OML, continued omalizumab; S-OML, switched from omalizumab.

Our study identified patients with nonsevere type-2 inflammation as a population sensitive to OML. Numerous studies have described the characteristics of responders and nonresponders to biologics in severe asthma,^{19,20} generally reporting that biologics, including OML, are more effective in patients with high type-2 inflammation.¹⁹ However, one study reported that the efficacy of OML is not influenced by blood eosinophil counts.²¹ Furthermore, a network meta-analysis indicated that OML demonstrated relatively mild effects compared with other biologics in terms of exacerbation suppression, symptom improvement, and lung function improvement in patients with eosinophilic ($\geq 300/\mu\text{L}$) asthma.²² Our findings align with these reports, suggesting that the efficacy of OML appears to be limited in patients with excessively elevated type-2 inflammation but is effective in patients with nonsevere type-2 inflammation.

Another characteristic of patients in whom OML was effective was increased BMI. Overweight and obesity have been linked to poorer responses to biologics,¹⁹ possibly because severe type-2 inflammation is more commonly observed in leaner patients,^{23,24} and neutrophilic systemic inflammation in obesity may hinder the response to biologics.^{25,26} Indeed, patients who were overweight tended to be more likely to be in the nonsevere type 2 inflammation group in this study. However, most of the patients with a BMI ≥ 25 were classified as having “relatively increased body weight” rather than being severely obese, suggesting that systemic nontype-2 inflammation was likely mild in this study of Japanese participants. One might assume that the cost of OML in obese patients increases since the dose of OML increases with weight gain. However, 300 mg/month OML can still be administered to patients weighing up to 90 kg if their IgE levels are less than 200 IU/mL. Taken together, this population may be treated with OML in a cost-effective manner.

The high prevalence of comorbid AR in this cohort is also important to consider. A previous study revealed that the coexistence of AR and overweight (BMI ≥ 25) worsens lung function and airway inflammation.²⁷ Continued OML treatment in overweight or obese patients may have contributed to better AR management,²⁶ which in turn likely improved asthma control. AR is associated with exacerbated mood disorders, reduced activity levels,²⁸ and increased sleep disturbances,²⁹ all of which are risk factors for asthma exacerbations. This study suggests that even when factors such as nonsevere type-2 inflammation or overweight seemingly indicate poor responsiveness to biologics, addressing coexisting treatable traits can help maximize the therapeutic potential of biologic treatments.

The ultimate goal in severe asthma management is off-treatment remission.³⁰ However, ongoing biologic therapy is crucial, as discontinuation increases the risk of exacerbations and symptom worsening.^{31–34} Sustained use of biologics minimizes these risks, enhances remission rates, and stabilizes asthma control.³⁵ While the high cost of biologics often hinders their use, OML’s affordability and strong safety profile^{36–39} make it a practical option for continued treatment of severe asthma.

This study has several limitations. First, since this was a retrospective analysis, a prospective study is needed to confirm whether the identified phenotype truly benefits from OML treatment. Second, medical cost evaluations may lack accuracy. In Japan, a high-cost medical expense system covers costs exceeding a threshold on the basis of income, but this was not accounted for in the present study. We also focused solely on costs related to the use of biologics, and we excluded expenses related to severe asthma exacerbations. However, even in hypothetical evaluations where the S-OML group used the high-cost medical system, the C-OML group incurred less expenses (data not shown). Moreover, as exacerbation frequencies were similar between the groups, the results are unlikely to be significantly affected. Third, in the present study, we defined effectiveness as the stable continuation of OML, whereas clinical remission has become the treatment goal.³⁰ These may be insufficient as clinical indicators. However, this study emphasizes economic aspects, and we confirmed that there was no significant difference in exacerbation history between the two groups. Fourth, the small sample size may limit the reliability of the results. To address this limitation, we performed an analysis using data from multiple institutions; however, further studies with larger cohorts and external validation are needed to strengthen the generalizability of the findings.

Conclusion

In conclusion, this study clarified the characteristics of patients with severe asthma who achieved long-term stability with omalizumab (OML). These patients exhibited relatively high BMI and mild type 2 inflammation, and were associated with a lower treatment burden related to biologic therapy. Further investigation with a larger sample size and validation are necessary, but these findings suggest the importance of considering both clinical and economic factors when personalizing biologic therapy for severe asthma.

Abbreviations

OML, omalizumab; FeNO, fractional exhaled nitric oxide; ICS, inhaled corticosteroid; OCS, oral corticosteroid; AR, allergic rhinitis; ECRS, eosinophilic chronic rhinosinusitis; C-OML, patients who continued omalizumab; S-OML, patients who switched from omalizumab; USD, United States dollars; JPY, Japanese yen.

Data Sharing Statement

The datasets used in this study can be obtained from the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

The study protocol was approved by the institutional review boards of all the participating hospitals (R4011). Informed consent was obtained in accordance with ethical guidelines for retrospective studies.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; have drafted or written, or substantially revised or critically reviewed the article; have agreed on the journal to which the article will be submitted; reviewed and agreed on all versions of the article before submission, during revision, the final version accepted for publication, and any significant changes introduced at the proofing stage; Agree to take responsibility and be accountable for the contents of the article.

Disclosure

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