

PHARMACOTHERAPY

## Effect of Omalizumab as Add-On Therapy on Asthma-Related Quality of Life in Severe Allergic Asthma: A Brazilian Study (QUALITX)

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**Objective.** To assess the impact of omalizumab as an add-on therapy to standard treatment with inhaled corticosteroids (ICS) and long-acting beta-2 agonists (LABA) on asthma-related quality of life (QoL) in patients with severe allergic asthma. **Methods.** This was a 20-week, randomized, open-label, study involving Brazilian patients (>12 years) with severe persistent allergic asthma inadequately controlled despite regular treatment with, at least, ICS ( $\geq 500$   $\mu\text{g/day}$  fluticasone or equivalent) + LABA. The primary objective was to assess the mean change from baseline in overall Asthma-related Quality of Life Questionnaire (AQLQ) score in omalizumab-treated patients compared with the control group. Secondary outcome measures included rescue medication use, incidence of asthma exacerbations, perception of treatment efficacy among patients, mean change from baseline in AQLQ score, and >1.5-point increase in overall AQLQ score. **Results.** In the omalizumab group, overall AQLQ score was 3.2 (0.9) (mean [SD]) at baseline and 4.4 (1.3) at week 20 versus 3.0 (1.0) at baseline and 3.0 (1.1) at week 20 in the control group. Mean change from baseline on overall AQLQ score at week 20 in the omalizumab group was 1.2 (0.2) versus 0 (0.1) in the control group, showing a significant increase in scores from baseline in the omalizumab group ( $p < .001$ ). There was also a statistically significant difference ( $p < .001$ ) in the number of patients who showed a >1.5-point increase from baseline in overall AQLQ score after 20 weeks, thus indicating a better QoL in the omalizumab group. There was no significant difference with respect to the use of rescue medication, incidence of asthma exacerbation, and adverse events between treatment groups. The global evaluation of treatment effectiveness was significantly better for omalizumab ( $p < .001$ ). **Conclusion.** Omalizumab was well tolerated and significantly improved the overall AQLQ score. Hence, it is a potential add-on therapy for severe persistent allergic asthma not controlled by standard prescribed treatment in Brazilian patients.

**Keywords** AQLQ score, Brazilian patients, omalizumab, severe persistent allergic asthma

### INTRODUCTION

Asthma is a global health problem affecting around 300 million people across the globe and has an estimated mortality of 250,000 deaths each year (1). It is associated with high morbidity, leading to significant costs to the families and health system, resulting in hospitalizations, invaluable personal suffering, and eventually death. A survey by the International Study of Asthma and Allergies in Childhood study group, which concentrates on children and adolescents, revealed a high prevalence of asthma symptoms (20–25%) among residents of most Brazilian cities (2).

The WHO Consultation on Severe Asthma proposed a set of global definitions for asthma severity in April 2009, which should be applicable in most circumstances in all countries (1). As per that, the definition for severe refractory asthma includes poor asthma control or frequent severe exacerbations per year despite prescription of high doses and optimized treatment or asthma control only on systemic corticosteroids with risk of serious adverse effects of treatment (3–6). Despite the progress in knowledge on severe asthma in the last few decades, it still

continues to affect the quality of life (QoL) of affected patients around the world.

Omalizumab (Xolair<sup>®</sup>), a recombinant humanized monoclonal antibody, is the first of its kind therapeutic agent that targets and selectively binds to human IgE (3, 7). It is effective as an add-on therapy for patients with severe allergic asthma and approved for use in adults, adolescents, and children ( $\geq 6$  years) in the European Union (8) and in adults and adolescents ( $\geq 12$  years) with moderate-to-severe allergic asthma in the United States (9).

This study assessed the impact of omalizumab as an add-on therapy to standard treatment (long-acting beta-2 agonists [LABA] + inhaled corticosteroids [ICS]) on asthma-related QoL and in Brazilian patients with severe allergic asthma.

### METHODS

This was a 20-week, randomized, open-label, parallel group, multicenter study conducted in Brazil. It was conducted in accordance with the Declaration of Helsinki (1989), ICH Good Clinical Practice (GCP), and local applicable laws and regulations. Institutional review board or ethics committee approvals were obtained for each participating study center. All patients provided written informed consent prior to participating in the study.

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### Patients

The study population included Brazilian patients who as per the GINA guidelines (10) had severe persistent asthma uncontrolled despite treatment with, at least, ICS ( $\geq 500$   $\mu\text{g/day}$  of fluticasone equivalent) + LABA. All patients were between of 12 and 75 years of age, 20 and 150 kg body weight, and had serum total IgE levels between 30 and 700 IU/mL. Patients also had to have positive skin prick test (diameter of wheal  $\geq 3$  mm) for at least one perennial aeroallergen (11).

All included patients were capable of reading and understanding Juniper's Asthma Quality of Life Questionnaire (AQLQ) (12).

Patients with a known history of allergy or hypersensitivity to omalizumab, medical history of psychiatric disorder, outside the defined age and body-weight ranges, and history of severe anaphylactoid reactions to food or drugs were excluded from the study. Other exclusion criteria were use of systemic corticosteroids for any reason other than asthma, use of methotrexate, gold salts, cyclosporine, or any other immunosuppressant or beta-2 antagonist medications in the last 3 months prior to screening visit.

Patients were randomized to either omalizumab group (omalizumab + LABA + ICS) or the control group (LABA + ICS) in a ratio of 2:1. Omalizumab 150–375 mg was administered subcutaneously every 2 or 4 weeks. Doses (mg) and dosing frequency were determined based on total serum IgE level (IU/mL) and body weight (kg). Doses of  $>150$  mg were achieved by administering injections at multiple sites to ensure not to administer  $>150$  mg of omalizumab per site.

### Efficacy Assessments

The efficacy assessments included asthma exacerbation frequency, patient diary cards, rescue medication use, clinical symptoms scores, global evaluations, and pulmonary function (spirometry).

Baseline AQLQ scores were taken prior to conducting any clinical evaluation or administering drug. The self-administered standardized activities AQLQ was administered to all patients at screening, baseline, week 12, and week 20. The AQLQ has 32 questions (items), which are divided into four domains: activity limitations, symptoms, emotional function, and environmental stimuli (12, 13). Safety assessments included adverse events (AEs), medical history/physical examination, vital signs, electrocardiogram, and laboratory evaluations.

At the end of the treatment phase (week 20) a global evaluation of the treatment effectiveness (14) was performed by the investigator and the patient using the following scale:

- Excellent: complete control of asthma
- Good: marked improvement of asthma
- Moderate: discernible, but limited improvement in asthma
- Poor: no appreciable change in asthma
- Worsening of asthma

### Statistical Analysis

Student's *t*-test (continuous data), Mann–Whitney test (ordinal data), and  $\chi^2$ -test (categorical data) were used to assess the similarities between treatment groups at baseline. Efficacy and safety analysis was made on the intention-to-treat (ITT) population. Change in AQLQ domain and overall scores (using last-observation-carried-forward approach), spirometry parameters, vital signs, and laboratory tests were evaluated using analysis of variance. Number of rescue medications, exacerbations, treatment perception, investigator/patient global evaluation, and combined clinical symptom scores were analyzed using Mann–Whitney test. Percentage increase of  $>1.5$  and  $>0.5$  in AQLQ, use of rescue medication, asthma exacerbation, AEs, physical examination findings, parasites in stool, and use of concomitant medications were compared using  $\chi^2$ -test. AEs were described according to body system, severity, relationship to study drug, duration, and serious AEs. A *p*-value of  $<.05$  was considered significant.

## RESULTS

In total, 202 subjects were screened for the study, all of whom provided signed written informed consent. Of these, 116 subjects were randomized to the study groups: 78 in the omalizumab group and 38 in the control group. Totally, 88 subjects completed the protocol: 59 in the omalizumab group and 29 in the control group (Table 1).

The mean age of the patients was  $43.8 \pm 13.1$  years in the omalizumab group and  $45.2 \pm 12.8$  years in the control group. There was a predominance of females (omalizumab 76.9% and control 76.3%) and Caucasians/whites (omalizumab 69.2% and control 57.9%) in the study population. There was no significant difference between groups with respect to demographic data ( $p > .05$ ) (Table 2).

Duration of allergic asthma was  $31.7 \pm 16.3$  years in the omalizumab group and  $33.1 \pm 16.9$  years in the control group. A history of seasonal allergy was reported by 25.6% and 21.1% of patients in the omalizumab and control groups, respectively. In addition, a history of food or drug allergy was reported by 30.8% and 31.6% of patients in the omalizumab and control groups, respectively. There

TABLE 1.—Total subjects number according to disposition in treatment groups and reasons for premature withdrawals.

| Number of patients             | Omalizumab + LABA + ICS, n (%) | LABA + ICS, n (%) | Total, n (%) |
|--------------------------------|--------------------------------|-------------------|--------------|
| Randomized                     | 78 (100.0)                     | 38 (100.0)        | 116 (100.0)  |
| ITT population                 | 78 (100.0)                     | 38 (100.0)        | 116 (100.0)  |
| Withdrawn                      | 8 (10.3)                       | 4 (10.5)          | 12 (10.3)    |
| Adverse events                 | 2 (2.6)                        | 0 (0.0)           | 2 (1.7)      |
| Pregnancy                      | 1 (1.3)                        | 0 (0.0)           | 1 (0.9)      |
| Significant protocol violation | 4 (5.1)                        | 1 (2.6)           | 5 (4.3)      |
| Loss of follow-up              | 0 (0.0)                        | 1 (2.6)           | 1 (0.9)      |
| Administrative issues          | 1 (1.3)                        | 0 (0.0)           | 1 (0.9)      |
| Other                          | 0 (0.0)                        | 2 (5.3)           | 2 (1.7)      |

TABLE 2.—Demographics of the randomized patients.

|                     | Omalizumab +<br>LABA + ICS<br>(n = 78) | LABA + ICS<br>(n = 38) | p-Value       |
|---------------------|----------------------------------------|------------------------|---------------|
| Age (years)         |                                        |                        |               |
| Mean (SD); median   | 43.8 (13.1); 43                        | 45.2 (12.28); 45       | $p_1 = 0.601$ |
| Range               | 13–69                                  | 20–72                  |               |
| Age category, n (%) |                                        |                        |               |
| >12 and <25 years   | 04 (5.1)                               | 04 (10.5)              |               |
| 25 and <35 years    | 15 (19.2)                              | 03 (7.9)               |               |
| 35 and <55 years    | 42 (53.8)                              | 23 (60.5)              |               |
| 55 and <65 years    | 12 (15.4)                              | 04 (10.5)              |               |
| 65 and <75 years    | 05 (6.4)                               | 04 (10.5)              |               |
| Sex, n (%)          |                                        |                        |               |
| Male                | 18 (23.1)                              | 09 (23.7)              | $p_2 = 1.000$ |
| Female              | 60 (76.9)                              | 29 (76.3)              |               |
| Race, n (%)         |                                        |                        |               |
| Caucasian/white     | 54 (69.2)                              | 22 (57.9)              | $p_2 = 0.466$ |
| Black               | 13 (16.7)                              | 08 (21.1)              |               |
| Other               | 11 (14.1)                              | 08 (21.1)              |               |

Note:  $p_1$ , Student's *t*-test;  $p_2$ ,  $\chi^2$ -test.

was no significant difference between groups with respect to history of allergy ( $p > .05$ ) (Table 3).

The two groups were comparable in all aspects including baseline IgE levels. Total serum IgE levels were  $218.8 \pm 165.0$  and  $249.2 \pm 197.0$  IU/mL in the omalizumab and control groups, respectively. The *p*-value for the difference in IgE levels between the two groups was not significant ( $p = .41$ ) (Table 3).

### Primary Objective

AQLQ scores for the omalizumab group were 3.1 (1.0) [mean (SD)] at baseline,  $4.2 \pm 1.4$  at week 12, and  $4.4 \pm 1.4$  at week 20. In the control group, the scores were  $3.1 \pm 1.1$  at baseline,  $3.2 \pm 1.2$  at week 12, and  $3.0 \pm 1.1$  at week 20 (Figure 1). In the omalizumab group, the mean change in overall AQLQ score from baseline was  $1.0 \pm 0.2$  (mean  $\pm$  SE) at week 12 and  $1.3 \pm 0.1$  at week 20, whereas in the

TABLE 3.—Patient distribution in treatment groups by asthma and allergic history.

|                                | Omalizumab +<br>LABA + ICS<br>(n = 78) | LABA + ICS<br>(n = 38) | p-Value       |
|--------------------------------|----------------------------------------|------------------------|---------------|
| Duration of asthma (years)     |                                        |                        |               |
| Mean (SD)                      | 31.7 (16.3)                            | 33.1 (16.9)            | $p_1 = 0.665$ |
| Median                         | 33                                     | 34                     |               |
| Range                          | 1–66                                   | 2–72                   |               |
| Total IgE (IU/mL) at screening |                                        |                        |               |
| Mean (SD)                      | 218.8 (165)                            | 249.2 (197)            | $p_1 = 0.415$ |
| Median                         | 164                                    | 235                    |               |
| Range                          | 34–680                                 | 33–639                 |               |
| Seasonal allergy, n (%)        |                                        |                        |               |
| No                             | 58 (74.4)                              | 30 (78.9)              | $p_2 = 0.756$ |
| Yes                            | 20 (25.6)                              | 08 (21.1)              |               |
| Food or drugs allergy, n (%)   |                                        |                        |               |
| No                             | 54 (69.2)                              | 26 (68.4)              | $p_2 = 1.000$ |
| Yes                            | 24 (30.8)                              | 12 (31.6)              |               |

Note:  $p_1$ , Student's *t*-test;  $p_2$ ,  $\chi^2$ -test.

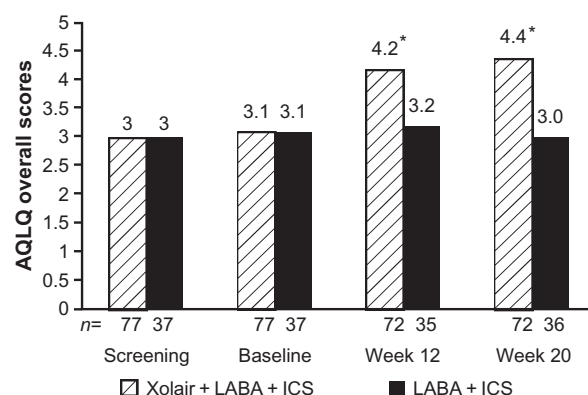


FIGURE 1.—AQLQ overall scores distribution in both treatment groups. Note: \* $p < .001$  (weeks 12 and 20) change from baseline.

control group this change was  $0.2 \pm 0.1$  at week 12 and  $-0.1 \pm 0.1$  at week 20. The improvement of AQLQ score from baseline to weeks 12 and 20 was significant only in the omalizumab group ( $p < .001$ ). Difference between the groups was detected at weeks 12 and 20 ( $p < .001$ ), indicating a better QoL in omalizumab group (Figure 1).

The mean changes from baseline on AQLQ symptoms scores were  $1.0 \pm 0.2$  (mean  $\pm$  SE) and  $0.1 \pm 0.2$  at week 12 and  $1.3 \pm 0.2$  and  $-0.2 \pm 0.2$  at week 20 in the omalizumab and control groups, respectively. The increase in score from baseline to weeks 12 and 20 was significant only in the omalizumab group ( $p < .001$ ). Difference between groups was observed at week 12 ( $p = .002$ ) and week 20 ( $p < .001$ ), evidencing a better QoL related to symptoms in the omalizumab group (Figure 2). The changes from baseline in specific AQLQ domains for the omalizumab and control groups are summarized in Table 4.

### Secondary Objectives

**Increase >1.5 on AQLQ.** The percentage of patients with a >1.5-point increase from baseline in the overall AQLQ score was 29.6% and 11.4% at week 12 and 41.9% and 2.8% at week 20 in the omalizumab and control groups, respectively. There was a significant difference between

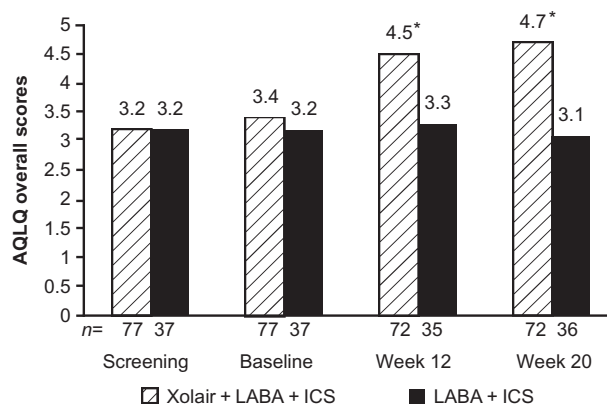


FIGURE 2.—AQLQ symptoms score distribution in both treatment groups. Note: \* $p = .002$  (week 12);  $p < .001$  (week 20) change from baseline.

TABLE 4.—Change from baseline in AQLQ-specific domain scores.

| AQLQ-specific domains       | Change from baseline on AQLQ             |                               |
|-----------------------------|------------------------------------------|-------------------------------|
|                             | Omalizumab + LABA + ICS ( <i>n</i> = 77) | LABA + ICS ( <i>n</i> = 36)   |
| Activity limitation score   | 1.3 ± 0.1 ( <i>p</i> < .001)             | −0.2 ± 0.1 ( <i>p</i> = .490) |
| Symptoms score              | 1.2 ± 0.2 ( <i>p</i> < .001)             | −0.2 ± 0.2 ( <i>p</i> = .469) |
| Emotional function score    | 1.3 ± 0.2 ( <i>p</i> < .001)             | 0 ± 0.1 ( <i>p</i> = .877)    |
| Environmental stimuli score | 1.2 ± 0.2 ( <i>p</i> < .001)             | 0 ± 0.2 ( <i>p</i> = .844)    |

Note: Values are in mean ± SE (*p*-value).

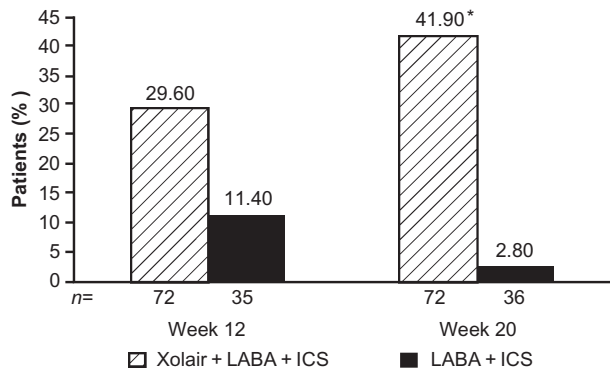


FIGURE 3.—Increase of >1.5 point from baseline on AQLQ overall score, difference among treatment groups.

Note: \**p* < .001,  $\chi^2$ -test.

groups in favor of omalizumab at week 20 (*p* < .001) (Figure 3).

The percentage of patients with a >0.5-point increase from baseline on AQLQ activity limitations score was 56.3% and 25.7% at week 12 and 70.3% and 22.2% at week 20 in the omalizumab and control groups, respectively. There were significant differences between groups at weeks 12 (*p* = .006) and 20 (*p* < .001) in favor of omalizumab (Figure 4).

**Pulmonary Function.** In the omalizumab group, the mean change from baseline on forced expiratory volume in 1

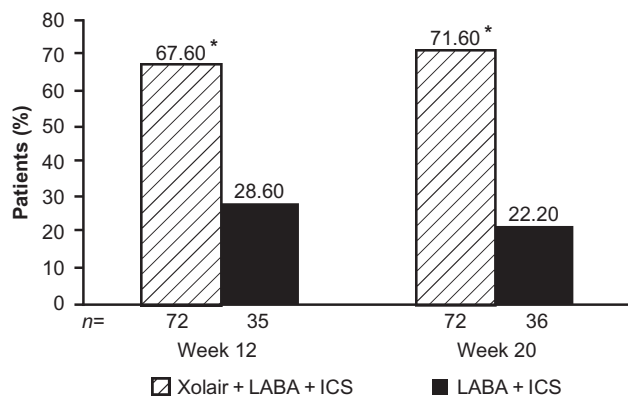


FIGURE 4.—Increase of >0.5 point from baseline on AQLQ overall score, difference in treatment groups.

Note: \**p* < .001 (week 12); *p* < .001 (week 20);  $\chi^2$ -test.

TABLE 5.—Changes in FEV<sub>1</sub> from baseline in both treatment groups.

| FEV <sub>1</sub> (L) omalizumab + LABA + ICS group | Week 12         | Week 20                      |
|----------------------------------------------------|-----------------|------------------------------|
|                                                    | <i>n</i> = 71   | <i>n</i> = 76                |
| Mean ± SE                                          | 0.06 ± 0.04     | 0.13 ± 0.04                  |
| CI (95%) – mean change                             | [−0.02; 0.14]   | [0.06; 0.21]                 |
| Median                                             | 0.1             | 0.1                          |
| Range                                              | −0.87 to 1.2    | −1.04 to 1.13                |
| <i>p</i> -Value (time)                             | –               | <i>p</i> <sub>2</sub> = .001 |
| FEV <sub>1</sub> (L) LABA + ICS group              | <i>n</i> = 36   | <i>n</i> = 37                |
| Mean ± SE                                          | 0.01 ± 0.04     | −0.003 ± 0.06                |
| CI (95%) – mean change                             | [−0.09; 0.07]   | [−0.12; 0.12]                |
| Median                                             | 0.0             | 0.0                          |
| Range                                              | −0.72 to 0.44   | −1.25 to 0.98                |
| <i>p</i> -Value (time)                             | <i>p</i> = .123 | <i>p</i> <sub>2</sub> = .957 |
| <i>p</i> -Value (treatment)                        | <i>p</i> = .456 | <i>p</i> <sub>1</sub> = .049 |
| <i>p</i> -Value (treatment × time)                 | <i>p</i> = .267 | <i>p</i> = .049              |

Note: *p*, repeated measures analysis of variance; *p*<sub>1</sub>, two-sample Student's *t*-test for change from baseline; *p*<sub>2</sub>, one-sample Student's *t*-test (change from baseline = 0).

second (FEV<sub>1</sub>) was 0.06 ± 0.04 (mean ± SE) at week 12 and 0.13 ± 0.04 at week 20 and that in the control group was −0.01 ± 0.04 at week 12 and −0.003 ± 0.06 at week 20. The increase on FEV<sub>1</sub> from baseline to week 20 was significant only in the omalizumab group (*p* = .001). Difference in FEV<sub>1</sub> between groups was detected at week 20 (*p* = .049) (Table 5). No difference was observed regarding forced vital capacity (FVC) and forced expiratory flow at 25–75% of FVC.

**Global Evaluation of Treatment Effectiveness.** The investigator judged the treatment as excellent or good for 74.6% patients in the omalizumab group and 13.8% patients in the control group; 81.4% patients in the omalizumab group and 48.2% patients in the control group rated the treatment as excellent or good. The global evaluation of treatment effectiveness was significantly better for omalizumab (*p* < .001) (Table 6).

**Adverse Events.** Headache (18.8% of the AEs in the omalizumab group and 14.3% in the control group), rhinitis

TABLE 6.—Global evaluation of treatment effectiveness as rated by the investigator and patients.

|                                              | Omalizumab + LABA + ICS | LABA + ICS | <i>p</i> -Value |
|----------------------------------------------|-------------------------|------------|-----------------|
| Investigator global evaluation, <i>n</i> (%) |                         |            |                 |
| Excellent                                    | 19 (32.2)               | 2 (6.9)    | <i>p</i> < .001 |
| Good                                         | 25 (42.4)               | 2 (6.9)    |                 |
| Moderate                                     | 10 (16.9)               | 11 (37.9)  |                 |
| Poor                                         | 5 (8.5)                 | 13 (44.8)  |                 |
| Worsening of asthma                          | 0 (0.0)                 | 1 (3.4)    |                 |
| Total no. of patients                        | 59                      | 29         |                 |
| Patient global evaluation, <i>n</i> (%)      |                         |            |                 |
| Excellent                                    | 28 (47.5)               | 3 (10.3)   | <i>p</i> < .001 |
| Good                                         | 20 (33.9)               | 11 (37.9)  |                 |
| Moderate                                     | 10 (16.9)               | 7 (24.1)   |                 |
| Poor                                         | 1 (1.7)                 | 7 (24.1)   |                 |
| Worsening of asthma                          | 0 (0.0)                 | 1 (3.4)    |                 |
| Total no. of patients                        | 59                      | 29         |                 |

Note: *p*, Mann-Whitney test.

(4.8% of the AEs in the omalizumab group and 8.6% in the control group), and sinusitis (5.3% of the AEs in the omalizumab group and 2.9% in the control group) were the most frequently observed AEs. There were three serious AEs in the omalizumab group. AEs associated with omalizumab that led to the permanent discontinuation of the drug were headache, insomnia, pneumothorax, and pregnancy. There was no significant difference between the two groups with respect to AEs ( $p = .134$ ). Asthma exacerbation episodes ( $p > .05$ ) showed no significant difference between groups; 43.6% patients in the omalizumab group had some exacerbation episodes versus 52.6% in control group. It has to be noted that the present study was not powered enough to detect difference between groups regarding the number of exacerbation episodes. Also there was no significant difference between groups regarding the use of rescue medication ( $p > .05$ ).

## DISCUSSION

Severe asthma remains a poorly understood and difficult to manage allergic respiratory condition. The QoL in patients with chronic diseases like asthma is a subject that is increasingly being researched.

Previous studies (15–17) and reviews (18, 19) have shown that omalizumab leads to a clinically meaningful improvement in all aspects of asthma-related QoL for patients requiring moderate-to-high doses of ICS for severe allergic asthma. The current Brazilian patient study demonstrated that omalizumab significantly improved the overall AQLQ score and was well tolerated.

This was an open-label study with a higher frequency of injection-only visits for patients randomized to omalizumab therapy (to allow injections to take place every 2 or 4 weeks). This approach was adopted so as to perform the study as close to the real-life situation as possible.

In the INNOVATE trial, now commonly used as an omalizumab efficacy benchmark study, treatment efficacy and improvement in asthma-related QoL was clinically meaningful after 28 weeks of treatment. As in the INNOVATE study, significant improvement in the overall AQLQ score was demonstrated in the present study (20). This Brazilian study, conducted in patients with severe persistent allergic asthma not controlled with high-dose ICS and LABA, also demonstrated that treatment with omalizumab leads to significant improvements in AQLQ scores.

With the development of rigorous, disease-specific questionnaires, such as the AQLQ, changes in subjective functional status can now be reliably and accurately determined, thereby providing a more complete assessment of overall health status during asthma therapy (18). Both adolescent ( $\geq 12$  years) and adult patients with severe allergic asthma were enrolled and the adult version of the AQLQ was used exclusively in this study. Although both adult and pediatric versions of the AQLQ (12, 13) are validated locally, only the adult AQLQ was used for standardization purposes.

Previous analyses of the AQLQ have determined that a  $\geq 0.5$ -point improvement in domain-overall score is clinically meaningful from the patient's perspective (21). Statistically significant difference was observed in all four domains evaluated (activity limitations, symptoms, emotional function, environmental stimuli) from baseline to weeks 12 and 20 in the omalizumab group ( $p < .001$ ). In the AQLQ symptoms score, significant difference between groups was detected at weeks 12 ( $p = .001$ ) and 20 ( $p < .001$ ), evidencing a better QoL in the omalizumab group.

The physician-rated effectiveness was good or excellent in majority of patients in the omalizumab group. The investigator judged the treatment as excellent or good for 75% of the patients in the omalizumab group and 16.2% in the control group confirming the clinically relevant effect of omalizumab. Changes in FEV<sub>1</sub> from baseline to week 12 and week 20 were statistically significant in the study in favor of omalizumab, even though this was not clinically significant. The patients in the control group presented with a higher number of exacerbation episodes compared with the omalizumab group (53% in the control group vs. 43% of patients in the omalizumab group). There was no significant difference between the groups with respect to the use of rescue medication and AEs.

## CONCLUSION

In conclusion, the results of the present Brazilian study justify the use of omalizumab as an add-on therapy and demonstrate that omalizumab leads to a clinically meaningful improvement of asthma-related QoL in patients with severe persistent allergic asthma (uncontrolled despite high-dose ICS and LABA treatment). This re-emphasizes the role of omalizumab as a novel add-on therapy to treat uncontrolled persistent allergic asthma.

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## DECLARATION OF INTEREST

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