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Direct cost analysis for patients with severe asthma receiving omalizumab treatment

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ABSTRACT

Aim: The present study aims to reveal a direct cost analysis of patients with severe allergic asthma receiving omalizumab treatment.

Material and Method: Twenty-two adults with severe allergic asthma who were treated with omalizumab and were routinely checked on the 16th week, 1st year, and 3rd year of treatment were included in the study. Clinical and demographic features of subjects were retrospectively documented before and after omalizumab treatment as well as pharmaceutical, emergency and hospital costs.

Results: The monthly treatment cost per patient was higher during the 16th week, 1st year, and 3rd year (€411.80±190.84, €409.7±211.57, €404.2±157.30 respectively) when compared with the pre-treatment period (€107.91±48.62) ($p<0.001$). Similarly, monthly emergency visit cost per patient at 16thweek, 1st year, and 3rd year of omalizumab treatment (€0.03±0.13, €0.19±0.51, €0.56±0.41 respectively), as well as the monthly hospitalization cost per patient at 16th week, 1st year, and 3rd year of omalizumab treatment (€1.44±5.57, €1.50±5.27, €16.3±13.8 respectively) were both lower compared to pre-treatment period (€1.82±1.23 and €17.69±10.84 respectively) ($p<0.001$ for both). A statistically significant drop was observed in the frequency of asthma exacerbations as well as emergency visits, hospitalizations and number of patients receiving systemic corticosteroid with omalizumab treatment. An improvement was also detected in asthma control test scores, forced expiratory volume in 1 second, and peak expiratory flow values of patients compared to the baseline values.

Conclusion: Omalizumab treatment is clinically effective and although it adds an extra pharmaceutical cost to the patients' management it reduces the emergency and hospital costs.

Keywords: Asthma management, severe asthma, cost analysis, omalizumab

INTRODUCTION

Asthma is a serious community health problem that affects 200-300 million individuals worldwide (1,2) and causes approximately 250,000 deaths annually (3). Severe asthma accounts for 5-10% of all asthma cases (4). From the perspective of the usage of health services, it is known that severe asthma opens the gateway to higher medication costs, an increased rate of emergency visits, and a higher rate of hospitalization compared to cases involving mild or moderate asthma (5). This indicates that there is a link between the severity of asthma and serious financial problems for patients (6).

A limited number of Turkish studies have shown that as the severity of asthma increases, relevant costs increase. Çelik et al. (7) found that the direct annual cost of asthma was about $1,465 per patient, while the direct annual cost of severe asthma was about $3,491 per patient. Bavbek et al. found that the annual cost per patient with uncontrolled asthma was more than twice the annual cost per patient with controlled asthma (8). In the same study, the authors showed that the cost varied greatly depending on the attack severity (mild attack: €128.60, moderate attack: €172.60, severe attack: €308.20)(8). As discussed above, severe asthma is a clinical condition that causes a considerable increase in cost, poorer quality of life, loss of productivity at work, and a decreased number of attack-free periods. For these reasons, new agents have been introduced for the treatment of severe asthma, one of which is omalizumab.

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Omalizumab is a humanized recombinant DNA derivative as well as a human IgG1k monoclonal antibody that specifically binds free IgE in blood and interstitial fluid (9). Omalizumab treatment was licensed in Turkey in 2008 for the management of severe allergic asthmatics patients if disease control is not achieved despite high-dose inhaled corticosteroid treatment. Clinical studies and real-life data show that omalizumab leads to a significant reduction in asthma attacks, unplanned physician visits, emergency visits, and hospitalizations as well as a significant increase in quality of life for patients with severe asthma (10-15).

While there is a limited number of studies investigating the cost-effectiveness of omalizumab, they have revealed contradictory results. Omalizumab was not found to be cost-effective in one study hailing from Canada (16), whereas it was found to be cost-effective in another study hailing from Brazil (17). However, as of yet there is no Turkish-based studies regarding cost analysis of omalizumab. The present study aims to reveal treatment costs as well as clinical parameters in severe allergic asthmatics before and after omalizumab treatment.

MATERIAL AND METHOD

This study was approved by Ankara Keçiören Training and Research Hospital Clinical Researchs Ethics Committee (Date: 12.27. 2017, Decision:1553). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Study Population and Design

This retrospective study was planned in the allergy and immunology clinic at Atatürk Chest Disease and Chest Surgery Training and Research Hospital between January 1st–and April 1st, 2018. Adults with severe allergic asthma who have treated with omalizumab after a follow-up for at least one year in our clinic between 2008 and 2015 were included in the study. Patients with missing data regarding spirometric values, asthma control test (ACT) scores, record of asthma exacerbations, emergency visits and hospitalizations in hospital files were excluded from the study.

Patients' demographic characteristics, comorbid conditions, atopy status, omalizumab dose, administration interval, pre- and post-treatment (16th week, 1st year, and 3rd year) forced expiratory volume in 1 second (FEV_1), peak expiratory flow (PEF) and FEV_1/FVC (forced vital capacity) values, ACT scores, number of asthma attacks, number of emergency visits, number of hospitalizations, medications and drug doses were recorded from their patients' files.

Omalizumab Administration Protocol

Omalizumab is administered in subjects with asthma if disease control was not achieved with high-dose inhaled corticosteroid plus long-acting beta2 agonist and/or leukotriene receptor antagonists, with a skin test or specific IgE positivity to at least one perennial allergen (house dust mite, cat-dog hair, cockroaches or mold spores) and with a total serum IgE level between 30–1500 IU/mL. Omalizumab treatment was administered subcutaneously every two or four weeks with doses and dosing frequencies determined according to baseline serum total IgE level and body weight (18). At 16th week after commencing treatment clinical response was evaluated according to symptoms, reliever drug use, frequency of exacerbations and asthma control (10). The treatment is maintained with the same dose in patients who benefit from the treatment, and is terminated in patients who do not.

Evaluation of the Cost

The cost of all medications used by the patients before and after treatment (including omalizumab) was specified as the 'direct medical cost'. The average amount invoiced in cases where the patient had visited the emergency room and was hospitalized due to asthma was calculated based on the current cost information received from the accounting department within our hospital. The 'hospitalization cost' was calculated as the hospital cost+the pharmacy cost. The 'total cost' was calculated as being the direct medical cost+the total emergency room cost+the total hospitalization cost. All costs were calculated as being the total monthly cost and monthly cost per patient. The medical costs (medications regularly used by the patient and omalizumab) and hospital costs were calculated based on the pricing stipulated in the Turkish Social Security Institution's Communique on Medical Practices. The costs as calculated in Turkish Liras (TRY) were converted to Euros using the mid-term exchange rate in 2018, which was TRY 5.66.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) for Windows 20 (IBM SPSS Inc., Chicago, USA) was used for statistical assessments. The normal distribution of the data was evaluated using the Kolmogorov-Smirnov test. Values with a normal distribution were presented as being the mean±standard deviation and values without normal distribution were presented as being the median (min-max). Categorical variables were presented as numbers and percentages. The differences between pre- and post-treatment follow-ups were evaluated using the mixed model analysis in repeating samples. $P<0.05$ was considered to be statistically significant in the statistical analysis.

RESULTS

Table 1 shows the demographic characteristics of the patients. The study population consisted of 22 patients, including 12 (54.5%) males and 10 (45.5%) females.

72.7% of the patients had rhinitis-nasal polyposis, 13.6% had drug allergies, 77.3% were sensitive to house dust mites, 22.7% were sensitive to cat-dog hair, 45.5% were sensitive to mold, 22.7% were sensitive to cockroaches, and %22.7 were sensitive to pollen.

The average pre-treatment body weight among the patients was 81.6±16.2 kg (min-max: 49-110), and the median total IgE was 218 IU/ml (min-max: 31-990). The median omalizumab dose was 300 mg (min-max: 150-600) and the median monthly total omalizumab dose was 375 mg (min-max: 150-1200).

Table 1. Demographic and clinical findings of patients

Variables	n (%)
Gender	
Male	12 (54.5)
Female	10 (45.5)
Rhinitis-nasal polyp	16 (72.7)
Drug allergy	3 (13.6)
Urticaria angioedema	1 (4.5)
Other	
Anemia+OSAS	1 (4.5)
Hypertension	1 (4.5)
Hypertension+OSAS	1 (4.5)
Chronic sinusitis	2 (9.1)
Latex allergy	1 (4.5)
Obesity	1 (4.5)
OSAS	2 (9.1)
Osteoporosis+Thrombocytopenia	1 (4.5)
Reflux	1 (4.5)
Reflux+Hypertension	1 (4.5)
Reflux+Hypertension+ OSAS	1 (4.5)
Reflux+Venous insufficiency	1 (4.5)
Ulcer	1 (4.5)
House dust mite sensitization	17 (77.3)
Cat-dog sensitization	5 (22.7)
Mold sensitization	10 (45.5)
Cockroach sensitization	5 (22.7)
Pollen sensitization	5 (22.7)

Categorical variables were shown as number (%).
Abbreviations: OSAS: Obstructive sleep apnea syndrome

While the average post-treatment FEV_1(%) level, PEF(%) level, and ACT scores of the patients were significantly higher compared to the pre-treatment period (p=0.005, p=0.003, and p<0.001 respectively), they did not show a significant difference between follow-ups (16th week, 1st year, and 3rd year). There was no significant difference between any of the follow-ups before or after the treatment in terms of the average FEV_1 (ml), average PEF (ml), and average FEV_1/FVC ratio (**Table 2**).

Table 3 shows the change in the number of attacks, emergency visits, hospitalizations, and cost distribution between the pre- and post-treatment period in detail.

The average cost of emergency visits per patient was lower in all of post-treatment follow-ups compared to the pre-treatment period, while it was higher in the 3rd year compared to the 16th week and the 1st year (p<0.001). The average total hospitalization cost per patient among those who were hospitalized was lower in the 16th week and 1st year compared to the pre-treatment period (p<0.001), while no significant difference was found between the 3rd year and the pre-treatment period. The average total pre-treatment cost of the patients was found to be significantly lower compared to the average total post-treatment cost (p<0.001). Despite this, no significant difference between the post-treatment follow-up periods (16th week, 1st year, and 3rd year) in terms of the average total cost was found (**Figure**).

Figure. Cost diagram before and after treatment

Table 2. Changes in pulmonary function tests and asthma control before and after Omalizumab treatment

Variables	Pre-treatment n=22	16th week n=22	First year n=22	Third year n=17	p
FEV_1 (%)	69.5±18.8	82.5±18.3	83±19.6	78.6±22.4	0.005*
FEV_1 (ml)	2286.4±743.5	2535.9±865.9	2525.5±824.9	2245.9±891.1	0.306
PEF (%)	71.2±23.3	81.4±23.5	83.1±24.7	80.2±25.9	0.003*
PEF (ml)	5745±1994.6	6256.4±2238.2	6192.3±2016.7	5652.9±2345.7	0.209
FEV_1/FVC ratio	76.5±7.8	80.3±6.7	80±11.3	75.6±10.2	0.327
ACT (score)	11.4±2.9	22±2.2	22.2±3.2	22.3±4.6	<0.001*

Normally distributed numerical variables were shown as mean±standard deviation. * p<0.05 shows statistical significance.
Abbreviations: FEV_1: Forced expiratory volume in 1 second, PEF: Peak expiratory flow, FVC: Forced vital capacity, ACT: Asthma control test

Table 3. The number of attacks, emergency room admissions, hospitalization and cost distribution of the patients compared to the pre and post treatment period.

Variables	Pre-treatment n=22	16th week n=22	First year n=22	Third year n=17	p
Direct medical cost (€)	1900.13	9026.99	8999.13	6591.24	
Average cost per person (€)	86.37±30.44	410.31±268.30	409.05±267.40	387.7±194.53	<0.001*
Number of patients suffering from attack, n(%)	13 (59.1)	3 (13.6)	6 (27.3)	10 (58.8)	0.007*
Total number of attacks (n)	37	3	8	24	-
Average number of attacks per person (n)	2.0±1.7	0.1±0.4	0.4±0.7	1.5±1.4	0.001*
Number of patients admitted to emergency, n (%)	8 (36.4)	1 (4.5)	4 (18.1)	7 (41.2)	0.020*
Total number of emergency applications (n)	20	1	4	15	-
Average number of emergency applications per person (n)	2.5±1.9	0.1±0.2	0.2±0.5	1.1±1.0	0.003*
Total Emergency cost (€)	40.09	0.61	3.89	10.95	-
Average Emergency cost per person (€)	1.82±1.23	0.03±0.13	0.19±0.51	0.56±0.41	<0.001*
Number of hospitalized patients, n(%)	11 (50.0)	2 (9.1)	3 (13.6)	5 (29.4)	<0.001*
Total number of hospitalizations (n)	17	2	3	11	-
Average number of hospitalizations per person (n)	1.6±0.8	0.1±0.3	0.1±0.4	0.8±1.0	<0.001*
Total hospital cost (€)	307.85	27.04	24.10	215.60	-
Average cost of hospital per person (€)	14.0±8.75	1.23±4.62	1.09±3.72	10.4±9.1	<0.001*
Total Pharmacy costs (€)	81.39	4.57	8.92	118.14	-
Average pharmacy cost per person (€)	3.70±2.59	0.21±0.98	0.41±1.60	5.8±4.9	<0.001*
Total hospitalization cost (€)	389.30	31.61	33.02	333.74	-
Average total hospitalization cost per person (€)	17.69±10.84	1.44±5.57	1.50±5.27	16.3±13.8	<0.001*
Total cost per person (€)	107.91±48.62	411.80±190.84	409.7±211.57	404.2±157.30	<0.001*

Normally distributed numerical variables were shown as mean±standard deviation. Numerical variables that do not show normal distribution were shown with median (min-max). Categorical variables were shown as number (%). * p <0.05 shows statistical significance.

There was a significant decrease in the rate of patients experiencing attacks in the 16th (13.6%) and the 1st year (27.3%) compared to the pre-treatment period (59.1%). Moreover, there was a significant increase in the rate of patients experiencing attacks in the 3rd year (58.8%) compared to the 16th week and the 1st year and it was similar to the rate of patients experiencing attacks in the pre-treatment period (p=0.007). While the average number of attacks among these patients showed a significant difference in the 16th week and the 1st year post-treatment (p=0.001), it was similar in the 3rd year post-treatment and the pre-treatment period.

There was a significant decrease in the rate of patients visiting emergency room in the 16th week (4.5%) and the 1st year (18.1%) post-treatment compared to the pre-treatment period (36.4%). The average number of emergency room visits among these patients was lower in all post-treatment follow-ups compared to the pre-treatment period (p=0.003).

There was a significant decrease in the rate of hospitalization in all post-treatment follow-ups compared to the pre-treatment period. While there was a significant increase in the rate of hospitalization in the 3rd year compared to the 16th week and the 1st year post-treatment, it was lower compared to the pre-treatment period (p<0.001). The average number of hospitalizations among these patients was lower in all of the post-treatment follow-up periods compared to the pre-treatment period. Even though omalizumab use led to a significant increase in medical cost, the number of attacks did decrease by 91.9% in the 16th week, 78.4% in the 1st year, and 35.1% in the 3rd year post-treatment compared to the pre-treatment period. The number of emergency room visits decreased by 95% in the 16th week, 80% in the 1st year and 25% in the 3rd year post-treatment compared to the pre-treatment period. The number of hospitalizations decreased by 88.2% in the 16th week post-treatment, 82.3% in the 1st year post-treatment, and 35.3% in the 3rd year post-treatment compared to the pre-treatment period.

The ratio of the patients receiving systemic steroid therapy was at its highest before treatment, it was found to significantly decrease in the 16th week and the 1st year, and to increase in the 3rd year compared to the 16th week and the 1st year; however, it still was significantly lower compared to the pre-treatment period (p<0.001). Median systemic steroid dose was not significantly different in 16th week, 1st year, and 3rd year after treatment and before treatment [690 mg (160-5171) versus 120 mg (16-678) versus 400 mg (80-3200) versus 506 mg (40-2656), respectively; p=0.187].

DISCUSSION

In our study, the monthly total cost per patient was higher in the 16th week, 1st year, and 3rd year post-treatment compared to the pre-treatment period. The increase in the total post-treatment cost was largely caused by the increase in the direct medical cost. The

direct medical cost, in turn, increased largely due to the cost of omalizumab itself. The monthly emergency visit cost per patient as well as the monthly hospitalization cost per patient in the 16th week, 1st year, and 3rd year post-treatment was lower compared to the pre-treatment period. This study is the first to investigate this subject in Turkey. A serious drop was observed in the monthly number of attacks, emergency visits, hospitalizations, and patients using systemic steroids following treatment with Omalizumab. An increase was observed in ACT, FEV_1, and PEF values.

If we review other studies available in the literature, in a Polish study, Jahnz-Różyk et al. (19) found that the hospitalization cost per patient, the cost of emergency room visit, the number of office visits, and the dose of oral corticosteroids had decreased, while the total treatment cost increased. The researchers highlighted that this increase was largely due to the cost of omalizumab. In a Japanese study, omalizumab was not found to be cost-effective for patients with severe asthma and the authors suggested that cost-effectiveness could be achieved by lowering the price of omalizumab(20). Similarly, in an American study, omalizumab was not found to be cost-effective in patients with allergic asthma patients, whereby this was attributed to the high price of omalizumab (21). In a Canadian study, similarly to the above studies, Tadrous et al. (16) had found that omalizumab was not cost-effective in patients suffering from either moderate or severe asthma. Likewise, similar to the above-mentioned studies, the total cost after omalizumab treatment was found to be higher than the total cost before the treatment in our study. Conversely, we observed a dramatic decrease in the number of attacks, the number of emergency room visits, and the hospitalization costs during the post-treatment period. We believe that this may be associated with the high price of omalizumab, similar to what was observed in Japan and Poland, as well as associated with the low average emergency room visit fees and hospitalization costs in Turkey — the latter give that Turkey has lower average emergency and hospitalization costs compared to both the United States and much of Europe. Unlike our and the other aforementioned studies, it was shown in other studies from Ireland, Spain, Italy, Brazil, the Netherlands, and the United States that the omalizumab was both cost-effective and that led to a considerably lower number of hospitalizations, the number of emergency room visits, loss of productivity at work, oral corticosteroid use, and the number of outpatient clinic visits. Also, a marked increase was observed in FEV_1 and PEF values and quality of life (17,22-27).

When the data of the patients in our study, whose asthma control was unexpectedly deteriorated in the 3rd year and who had an increase in the number of attacks, emergency admissions, and therefore the hospitalization cost, were re-examined, it was observed that systemic steroid use was discontinued at the end of the 1st year in most of these asthmatic patients who were well controlled with omalizumab treatment. As a result, worsening of asthma may have been observed in the later periods of the patients. Our study consists of the analysis of real-life data, and the outcome of the patients was like this.

In a handful of other studies, it was emphasized that the omalizumab treatment had to be administered to select groups of patients suffering from severe asthma for it to be cost-effective as well as effective for clinical recovery (28,29).

The most significant limitation of our study is its retrospective design. The study was performed using the information available in patients' files. For this reason, this descriptive study provides an estimation of costs and outcomes for a defined patient group. Provided that our data did not allow for the calculating of the quality-adjusted life-year (QALY) and the incremental cost-effectiveness ratio (ICER), this study is related to the direct cost of omalizumab rather than the analysis of its cost-effectiveness. Nevertheless, we can say that it is clinically effective given that leads to a lower number of attacks, emergency room visits, and hospitalization rates. The lack of 3rd year follow-up data for some patients is also another limitation of our study. One of the important limitations of our study is that indirect cost (payments for missed workdays covered by the employee's disability and sick-leave program), could not be calculated.

CONCLUSION

We found that the addition of omalizumab to the treatment regime of patients diagnosed with severe allergic asthma led to a serious increase in the total post-treatment cost. Yet, we also observed a decrease in the average emergency room visit and hospitalization costs after the omalizumab treatment. We believe that reducing omalizumab prices in our country would provide a direct cost reduction in severe allergic asthma patients. Furthermore, prospective studies involving a greater number of patients are needed to better examine the direct cost analysis of omalizumab in the Turkish context.

ETHICAL DECLARATIONS

Ethics Committee Approval: This study was approved by Ankara Keçiören Training and Researchs Hospital Clinical Research Ethics Committee (Date: 12.27. 2017, Decision:1553).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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