Registry on assessing the quality of life improvement with triamcinolone in the treatment of moderate-to-severe persistent allergic rhinitis in egyptian patients

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Background
Allergic rhinitis is a common disorder that can significantly impact the quality of life of patient. It is strongly linked to asthma and conjunctivitis. The classic symptoms of the disorder are nasal congestion and itching, rhinorrhea, and sneezing. Currently, steroids have played a role in the management of allergic rhinitis. The aim of the study was to assess the efficacy and safety of triamcinolone in the treatment of allergic rhinitis in Egypt.

Patients and methods
A total of 308 Egyptian patients who were suffering from moderate-to-severe allergic rhinitis and were prescribed triamcinolone were enrolled. The improvement in the quality of life of patients receiving triamcinolone after 4 weeks of treatment was assessed using the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). All adverse events were recorded during the study duration.

Results
The RQLQ showed a significant improvement in the quality of life of patients after using triamcinolone. The mean RQLQ score before triamcinolone administration was 2.99±1.015 versus 0.68±0.706 after 4 weeks of treatment ($P<0.001$), with a mean percent reduction of −76.78±23.62%. The individual domain scores of the RQLQ after 4 weeks of treatment showed a significant improvement in the level of all domains. No adverse events were reported and the drug showed a high tolerability profile.

Conclusion
Triamcinolone is considered an efficient and safe drug in the management of allergic rhinitis. It has a positive impact on the quality of life of patients with moderate-to-severe persistent allergic rhinitis under conditions of daily practice in patients receiving triamcinolone after 4 weeks of treatment.

Keywords:
allergic rhinitis, quality-of-life improvement with triamcinolone, registry on assessing the quality

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Introduction

Allergic rhinitis is a global health problem that causes major illness and disability worldwide. Allergic rhinitis is an inflammation of the nasal membranes that is characterized by rhinorrhea, nasal obstruction, nasal itching, and sneezing [1]. It is a common disorder that affects up to 40% of the population [2]. It affects social life, sleep, school, and work. The goal of allergic rhinitis treatment is to prevent or reduce the symptoms caused by the inflammation of affected tissues. Nasal steroids delivered through a nasal spray are the first-line treatment for the symptoms of allergic rhinitis [3]. They are particularly useful as they decrease membrane permeability and inhibit both early and late phase reactions to allergens. They minimize nasal secretory response and reduce the sensitivity of local nasal irritant receptors. A potential benefit of topical application is the flushing action of the nasal mucosa, which may reduce allergens and secretions [4]. Intranasal corticosteroids are the most effective medication class for controlling symptoms of allergic rhinitis, because the high drug concentrations can be achieved at receptor sites in the nasal mucosa with a minimal risk for systemic adverse effects [5,6]. They are effective in improving all symptoms of allergic rhinitis as well as ocular symptoms [7–9]. The efficacy of intranasal triamcinolone in seasonal and allergic rhinitis has been evaluated in clinical trials [4]. The aim of the study was to assess the improvement in the quality of life in patients receiving triamcinolone in Egypt for 4 weeks, and to evaluate under conditions of daily practice the safety of triamcinolone in patients with moderate-to-severe allergic rhinitis.

Patients and methods

Study population

The current prospective observational study included patients who were 21 years or older suffering from moderate-to-severe allergic rhinitis and were prescribed triamcinolone for 4 weeks between November 2012 and April 2013. A total of 308 patients were enrolled at 23 centers, distributed all over Egypt. Patients suffering from mild allergic rhinitis, and pregnant and breastfeeding women were excluded. Patient management remained at the discretion of local practitioners. The study protocol was approved by the institutional committee on human research at each site, and patients provided informed consent before study entry. Of the initial registry participants (N=308), 299 (97.09%) completed the study and were eligible for the efficacy analysis.

Data collection and follow-up

At each enrolling center, patients were assessed clinically at treatment initiation (visit 1) and after 4 weeks of treatment, at follow-up (visit 2). All symptoms were evaluated. Evaluation of triamcinolone efficacy in the management of allergic rhinitis was carried out during both visits: first, by assessing the quality of life in these patients using the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and, second, by determining the status of related signs and symptoms of allergic rhinitis after 4 weeks of treatment with triamcinolone and the physician's assessment for the clinical outcome. The RQLQ consists of 28 questions on a seven-point scale in seven domains (activity limitation, sleep problems, nose symptoms, eye symptoms, non-nose/eye symptoms, practical problems, and emotional function) [10]. Overall tolerability was assessed depending on both physician's and patient's assessment at the end of the study.

Baseline data collection forms captured standard demographic variables, previous medical history questions, concomitant disease or medications, and allergic rhinitis-related signs and symptoms. The follow-up data were gathered as regards all aspects of current status of treatment with triamcinolone and clinical response according to the physician's assessment. All adverse events during the treatment period were also documented, both those observed by the investigator or reported by the patient. Data were record by the investigator or the authorized designee into a case report forms.

Patients who did not complete the study and for whom no endpoint data were available were considered as lost to follow-up and were excluded from all efficacy analysis after testing the statistically significant difference with those completed the study with regard to baseline characteristics.

Statistical methods

Data were summarized using mean, SD, and 95% confidence interval for continuous parameters and using counts and percentages for categorical parameters. All statistical tests were performed using two-tailed tests at a 5% level of significance. The one-sample χ^2-test and its subsidiaries were used to compare the significant change in incidence of allergic rhinitis symptoms before and after triamcinolone treatment. Wilcoxon's signed-rank test and the Mc Nemar test were used to compare the RQLQ score and the status of allergic rhinitis-related signs and symptoms between baseline and after 4 weeks of treatment.

Results

A total of 308 Egyptian patients who were suffering from moderate-to-severe allergic rhinitis and were prescribed intranasal spray of triamcinolone participated in the study. The mean daily dose was 4.05±1.68 puffs/day for 30.28±3.82 days. The mean age of the participants was 34.15 (±9.56) years; 152 (49.4%) patients were female and 156 (50.6%) were male. The allergic rhinitis signs and symptoms are differentiated into early and late phases at baseline and follow-up visits (Table 1). At baseline visit, 168 (54.5%) patients were prescribed one or more additional medications along with triamcinolone. The most frequently prescribed medication was fexofenadine, desloratadine, paracetamol, saline nasal wash, cetirizine, ambroxol, loratadine, ebastine, and sterile sea water.

The quality of life using the RQLQ at baseline (visit 1) and after 4 weeks (visit 2) showed a significant improvement in the quality of life of patients after using triamcinolone. The mean RQLQ score at baseline was 2.99±1.015 versus 0.68±0.706 at visit 2 (P<0.001), with a mean reduction of −2.30±1.04 and a mean percent reduction of −76.78±23.62%. Moreover, the individual domain scores of the RQLQ at visits 1 and 2 showed a significant improvement in the level of all domains at P value less than 0.001 (Fig. 1).

Patient compliance to triamcinolone treatment was good; only one patient (0.3%) did not comply due to increased dosage to increase its efficacy and speed-up the treatment. Adverse events were not reported by

any patient of the study population. The assessments of the overall tolerability of the 305 valid patients who were prescribed triamcinolone showed tolerability profile.

According to the physicians, assessment was excellent for 273 (89.5%) and fair for 32 (10.5%) patients, and according to patient's assessment, it was excellent for 262 patients (85.9%), fair for 42 (13.8%), and poor in only one (0.3%) patient.

The clinical outcome after the prescription of triamcinolone according to the physicians' assessment showed significant improvement (Fig. 2).

Table 1 Allergic rhinitis signs and symptoms at visit 1 and 2

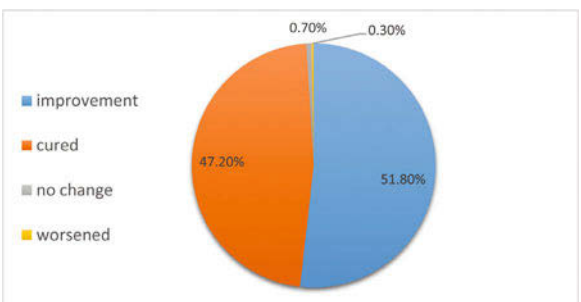
Allergic rhinitis signs and symptoms	Baseline (visit 1) [*n* (%)]	Follow-up (visit 2) [*n* (%)]	*P*
Early phase	299 (97.1)	<0.001	
Runny nose	281 (94)	5 (1.7)	
Sneezing	276 (92.3)	7 (2.3)	
Itchy nose and throat	220 (73.6)	8 (2.7)	
Watery or itchy eyes	206 (68.9)	12 (4)	
Late phase	304 (98.7)		
Nasal congestion	283 (94.6)	5 (1.7)	
Plugged ears	110 (36.8)	7 (2.3)	<0.001
Sinus headache	256 (85.6)	7 (2.3)	
Postnasal drip	252 (84.3)	22 (7.4)	
Fatigue	193 (64.5)	11 (3.7)	
Dark circles under eye	69 (23.1)	12 (4)	
Puffy eye lid	70 (23.4)	12 (4)	
Decreased attention span	57 (19.1)	12 (4)	
Irritability	105 (35.1)	8 (2.7)	

Discussion

Allergic rhinitis is a common disorder that can significantly influence patient's quality of life. The diagnosis is made through a comprehensive history taking and physical examination. It is often accompanied by allergic conjunctivitis (a disease complex sometimes referred to as allergic rhinoconjunctivitis) that produces symptoms of itchy eyes and tearing [11]. The therapeutic options available for the treatment of allergic rhinitis are effective in managing symptoms and are generally safe and well tolerated. Second-generation oral antihistamines and intranasal corticosteroids are the mainstay of treatment for the disorder [12].

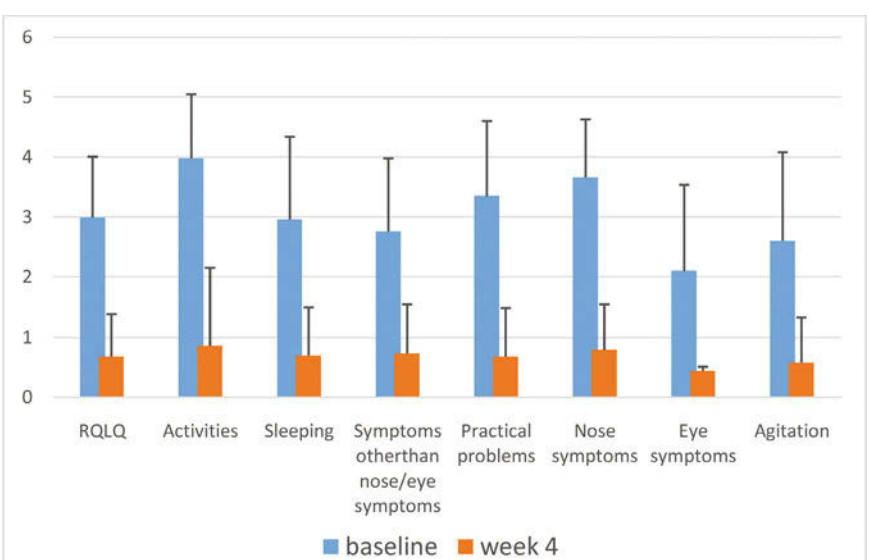
According to the parameters developed by the Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma, and Immunology; the American College of Allergy, Asthma, and Immunology; and the Joint Council of Allergy, Asthma, and Immunology, intranasal corticosteroids are

Figure 2



Clinical outcome.

Figure 1



The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) domains at baseline and at visit 2.

the most effective medication class for controlling symptoms of allergic rhinitis [4]. The main mechanism through which corticosteroids relieve the symptoms of allergic rhinitis is through their anti-inflammatory activity [13]. The concept of delivering corticosteroids locally to the nasal airways was developed to minimize potential side effects of using systemic corticosteroids [4].

The objective of this registry was to assess the quality of life improvement with triamcinolone in the treatment of moderate-to-severe persistent allergic rhinitis in Egyptian patients. Intranasal corticosteroids are also first-line therapeutic options for patients with mild persistent or moderate/severe symptoms. When used regularly and correctly, intranasal corticosteroids effectively reduce inflammation of the nasal mucosa and improve mucosal pathology. Studies and meta-analyses have shown that intranasal corticosteroids are superior to antihistamines and leukotriene receptor antagonists in controlling the symptoms of allergic rhinitis, including nasal congestion and rhinorrhea [14–19]. They have also been shown to improve ocular symptoms and reduce lower airway symptoms in patients with concurrent asthma and allergic rhinitis [20].

In the current study, efficacy of triamcinolone was assessed by comparing the quality of life using the RQLQ at baseline and after 4 weeks, and the results showed a significant mean reduction [−2.30 (±1.04] with a percent mean reduction of −76.78±23.62%) ($P<0.001$). The comparison between the individual domain scores of the RQLQ at baseline and after 4 weeks showed a significant improvement in the level of all domains ($P<0.001$).

Similar results were reported in other studies evaluating triamcinolone efficacy in rhinitis-related quality of life [21,22]. In these studies, triamcinolone was significantly ($P<0.05$) effective in controlling nasal symptoms of seasonal allergic rhinitis and maintaining a better quality of life for the patients [21]. It also proved to improve nocturnal rhinitis-related quality of life in patients treated in primary care setting [22].

Our study showed a significant improvement in all allergic rhinitis-related signs and symptoms after 4 weeks of treatment with triamcinolone ($P<0.001$). It showed effectiveness in reducing both early and late phases of allergic rhinitis: sneezing, itching in nose, throat, and eyes, nasal congestion, sinus headache, and fatigue. Studies have proved that intranasal corticosteroids are typically the most effective medication class for controlling sneezing, itching, rhinorrhea, and nasal congestion, the four major symptoms of allergic rhinitis [4,23]. Intranasal corticosteroids when given in recommended doses are not generally associated with clinically significant systemic side effects. Studies have failed to demonstrate any consistent, clinically relevant side effect from intranasal corticosteroids [24–31]. Although local side effects are minimal, if the patient is carefully instructed in the use of this class of drugs, nasal irritation and bleeding may occur. In the current study, no adverse events were recorded and triamcinolone was well tolerated. Studies confirmed that local side effects of intranasal corticosteroids such as nasal irritation, bleeding, and nasal septal perforation are rare and can be avoided with proper administration technique [32,33].

Conclusion

Triamcinolone showed significant efficacy and safety in the treatment of moderate-to-severe persistent allergic rhinitis in Egyptian patients. It is recommended that triamcinolone be used as the first line of treatment for allergic rhinitis in Egypt. Triamcinolone has a positive impact on the quality of life of patients suffering from allergic rhinitis in Egypt.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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