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

Mahmoud Elsammaa

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 $-76.78\pm23.62\%$. 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

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.

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work noncommercially, as long as the author is credited and the new creations are licensed under the identical terms.
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 $\chi^2$-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 $4.05\pm1.68$ puffs/day for $30.28\pm3.82$ days. The mean age of the participants was $34.15 (\pm9.56)$ 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 $2.99\pm1.015$ versus $0.68\pm0.706$ at visit 2 ($P<0.001$), with a mean reduction of $-2.30\pm1.04$ and a mean percent reduction of $-76.78\pm23.62\%$. 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)                  | <0.001 |
| Nasal congestion                    | 283 (94.6)                | 5 (1.7)                     |   |
| Plugged ears                        | 110 (36.8)                | 7 (2.3)                     |   |
| 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
showed a significant mean reduction \( RQLQ \) at baseline and after 4 weeks, and the results assessed by comparing the quality of life using the In the current study, efficacy of triamcinolone was [20].

In patients with concurrent asthma and allergic rhinitis ocular symptoms and reduce lower airway symptoms rhinitis, including nasal congestion and rhinorrhea 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. Triamcinolone has a positive impact on the quality of life of patients suffering from allergic rhinitis in Egypt.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Bousquet J, Van Cauwenberge P, Khaltaev N. Allergic rhinitis and its impact on asthma. J Allergy Clin Immunol 2001; 108 (Suppl 5): S147–S334. Allergy 2008: 63 (Suppl 86): S–160 Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 Update (in collaboration with the World Health Organization, GA2LEN* and AllerGen**) 2. Small P, Frenkel S, Becker A, Boisvert P, Bouchard JMD, Carr S, et al. The Canadian Rhinitis Working Group. Rhinitis: a practical and comprehensive approach to assessment and therapy. J Otolaryngol 2007; 36 (Suppl 1): S5–S27.

3. Gawchik SM, Saccar CL. A risk-benefit assessment of intranasal triamcinolone acetonide in allergic rhinitis. Drug Saf 2000; 23: 309–322.

4. Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, et al. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol 2008; 122(Suppl):S1–S84.

5. Weiner JM, Abramson MJ, Puy RM. Intranasal corticosteroids versus oral H1 receptor antagonists for the treatment of allergic rhinitis: a systematic review with meta-analysis. Ann Allergy Asthma Immunol 2002; 89:479–484.

6. Yanez A, Rodrigo GJ. Intranasal corticosteroids versus topical H1 receptor antagonists for the treatment of allergic rhinitis: a systematic review with meta-analysis. Ann Allergy Asthma Immunol 1998; 31:1624–1629.

7. Bernstein DI, Levy AL, Hambel FC, Baidoo CA, Cook CK, Philpot EE, Rickard KA Treatment with intranasal fluticasone propionate significantly improves ocular symptoms in patients with seasonal allergic rhinitis. Clin Exp Allergy 2004; 34:952–957.
8 DeWester J, Philpot EE, Westlund RE, Cook CK, Rickard KA. The efficacy of intranasal fluticasone propionate in the relief of ocular symptoms associated with seasonal allergic rhinitis. Allergy Asthma Proc 2003; 24:331–337.
9 Schenkel E. Features of mometasone furoate nasal spray and its utility in the management of allergic rhinitis. Expert Opin Pharmacother 2003; 4:1579–1591.
10 Juniper EF, Guyatt GH, Griffith LE, Ferrie PJ. Interpretation of rhinoconjunctivitis quality of life questionnaire data. J Allergy Clin Immunol 1996; 98:843–845.
11 Bielory L. Differential diagnoses of conjunctivitis for clinical allergist-immunologists. Ann Allergy Asthma Immunol 2007; 98:105–114. quiz 14–7, 52
12 Small P, Kim H. Allergic rhinitis. Allergy Asthma Clin Immunol 2011; 7: (Suppl 1):S3.
13 Pauwels R. Mode of action of corticosteroids in asthma and rhinitis. Clin Allergy 1986; 16:281–288.
14 Pullerits T, Praks L, Ristioja V, Lõtvall J. Comparison of a nasal glucocorticoid, antileukotriene, and a combination of antileukotriene and antihistamine in the treatment of seasonal allergic rhinitis. J Allergy Clin Immunol 2002; 109:949–955.
15 Di Lorenzo G, Pacor ML, Pellitteri ME, Morici G, Di Gregoli A, Lo Bianco C, et al. Randomized placebo-controlled trial comparing fluticasone aqueous nasal spray in mono-therapy, fluticasone plus cetirizine, fluticasone plus montelukast and cetirizine plus montelukast for seasonal allergic rhinitis. Clin Exp Allergy 2004; 34:259–267.
16 Wilson AM, O’Byrne PM, Parameswaran K. Leukotriene receptor antagonists for allergic rhinitis: a systematic review and meta-analysis. 4:1579–1591 2004; 116:338–344.
17 Wilson AM, Orr LC, Sims EJ, Dempsey OJ, Lipworth BJ. Antileukotriene effects of mediator blockade versus topical corticosteroids in allergic rhinitis and asthma. Am J Respir Crit Care Med 2000; 162(Pt 1):1297–1301.
18 Wilson AM, Orr LC, Sims EJ, Lipworth BJ. Effects of monotherapy with intranasal corticosteroid or combined oral histamine and leukotriene receptor antagonists in seasonal allergic rhinitis. Clin Exp Allergy 2001; 31:61–68.
19 Yañez A, Rodrigo GJ. Intranasal corticosteroids versus topical H1 receptor antagonists for the treatment of allergic rhinitis: a systematic review with meta-analysis. Ann Allergy Asthma Immunol 2002; 89:479–484.
20 Watson WT, Becker AB, Simons FE. Treatment of allergic rhinitis with intranasal corticosteroids in patients with mild asthma: effect on lower airway responsiveness. J Allergy Clin Immunol 1993; 91(Pt 1):97–101.
21 Condejim J, Schulz R, Lim J. Triamcinolone acetonide aqueous nasal spray versus loratadine in seasonal allergic rhinitis: efficacy and quality of life. Ann Allergy Asthma Immunol 2000; 84:533–538.
22 Mintz M, Garcia J, Diener P, Liao Y, Duplay L, Georges G. Triamcinolone acetonide aqueous nasal spray improves nocturnal rhinitis-related quality of life in patients treated in a primary care setting: the Quality of Sleep in Allergic Rhinitis study. Ann Allergy Asthma Immunol 2004; 92:255–261.
23 Juniper EF, Ståhl E, Doty RL, Simons FE, Allen DB, Howarth PH. Clinical outcomes and adverse effect monitoring in allergic rhinitis. J Allergy Clin Immunol 2005; 115(Suppl 1):S390–S390 S413.
24 Wihl JA, Andersson KE, Johansson SA. Systemic effects of two nasally administered glucocorticosteroids. Allergy 1997; 52:620–626.
25 Howland WC III, Dockhorn R, Gillman S, Gross GN, Hille D, Simpson B, et al. A comparison of effects of triamcinolone acetonide aqueous nasal spray, oral prednisone, and placebo on adrenocortical function in male patients with allergic rhinitis. J Allergy Clin Immunol 1996; 98:32–38.
26 Nayak AS, Ellis MH, Gross GN, Mendelson LM, Schenkel EJ, Lanier BQ, et al. The effects of triamcinolone acetonide aqueous nasal spray on adrenocortical function in children with allergic rhinitis. J Allergy Clin Immunol 1998; 101(Pt 1):157–162.
27 Oztürk F, Yüceüzürek AV, Kurt E, Ünlü HH, Ilker SS. Evaluation of intraocular pressure and cataract formation following the long-term use of nasal corticosteroids. Ear Nose Throat J 1998; 77:846–848. 50–51
28 Ernst P, Baltzan M, Deschênes J, Suisa S. Low-dose inhaled and nasal corticosteroid use and the risk of cataracts. Eur Respir J 2006; 21:1168–1174.
29 Garbe E, LeLorier J, Boivin JF, Suisa S. Inhaled and nasal glucocorticoids and the risks of ocular hypertension or open-angle glaucoma. JAMA 1997; 277:722–727.
30 McBryde CE, Ensrud KE, Bender E, Genant HK, Yu W, Griffith JM, Niewoehner DE. Association between corticosteroid use and vertebral fractures in older men with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1998; 157(Pt 1):704–709.
31 Leone FT, Fish JE, Szefler SJ, West SL. Systematic review of the evidence regarding potential complications of inhaled corticosteroid use in asthma: collaboration of American College of Chest Physicians, American Academy of Allergy, Asthma, and Immunology, and American College of Allergy, Asthma, and Immunology. Chest 2003; 124:2329–2340.
32 Schoetzl EP, Menzel ML. Nasal sprays and perforation of the nasal septum. JAMA 1985; 253:2046.
33 Cervin A, Andersson M Intranasal steroids and septum perforation – an overlooked complication? A description of the course of events and a discussion of the causes. Rhinology 1998; 36:128–132.