The Journal of Laryngology & Otology (2007), ***121***, *1151–1155*.

doi:10.1017/S0022215107000059
Printed in the United Kingdom
First published online 19 July 2007

Main Article

Rhinitis symptoms and quality of life in patients with chronic perennial rhinitis treated with desloratadine

H C K Lam, M C F Tong, C A Van Hasselt

Abstract

Objective: To evaluate the outcome and the change in quality of life of patients with chronic rhinitis after treatment with desloratadine.

Study design: A prospective, open-label, non-blinded, non-randomised study of patients in a secondary and tertiary ENT referral centre.

Methods: Chinese patients with chronic rhinitis were recruited. The patients were assessed by a questionnaire that included rhinitis symptoms score and SF-36 health survey components. Endoscopic assessment was performed with a rigid nasoendoscope and scored according to the modified endoscopic appearance score of Lund and Kennedy. A 12-week course of desloratadine 5 mg daily was prescribed. Patients were re-evaluated after treatment. A total of 47 subjects completed the study.

Results: There were significant reductions in median rhinitis symptoms score, from six to five ($p < 0.001$), and in median endoscopic appearance score, from five to three ($p < 0.001$). Patients' general health perception was also improved after treatment ($p = 0.022$).

Conclusion: Desloratadine may be an effective treatment which provides symptomatic relief and improves the quality of life in patients with chronic rhinitis.

Key words: Perennial Allergic Rhinitis; Antihistamines; Desloratadine

Introduction

Chronic rhinitis is a common condition affecting people's quality of life, and it is reported that 10–20 per cent of the population suffer from this problem.[1] Symptoms may range in severity, from mild and temporary to significant and chronic, in different subjects.

The cause of rhinitis can be allergic or non-allergic. Chronic rhinitis is commonly encountered in general and specialist practices in Hong Kong. Patients frequently present with perennial rather than seasonal symptoms. Perennial allergic rhinitis is caused by an immunoglobulin E mediated immunological response to allergens. Allergens in the environment vary in type and quantity, according to the time of year and the geographical location. Commonly encountered allergens include moulds, animal dander, insects and dust mites.

Desloratadine (Aerius™, Schering-Plough, Kenilworth, New Jersey, USA) is a newly released histamine H1 receptor antagonist with additional potent anti-allergic and anti-inflammatory activities. The efficacy of desloratadine in alleviating symptoms and improving the quality of life in patients with seasonal allergic rhinitis has been well demonstrated.[2–4] The present study aimed to evaluate the potential role of this new, potent antihistamine in the treatment of chronic perennial rhinitis.

Methods

Patients over 12 years of age who had been diagnosed with chronic perennial rhinitis in the ENT specialist out-patient clinic of the Prince of Wales Hospital, Hong Kong, were recruited. Patients' rhinitis symptoms were considered chronic if they were sustained for a period of 12 weeks or more. In order to be recruited, patients were also required to score two or more on Lebel and colleagues' rhinitis symptoms score (prior to treatment).[5] Patients already receiving antihistamine or steroid spray for allergic rhinitis were also included, after being subjected to a two-week 'washout' period.

The exclusion criteria included: (1) patients with coexisting nasal conditions other than chronic rhinitis, e.g. nasal polyposis, sinusitis and sinonasal tumours; (2) patients with previous surgery to the nasal cavity or sinuses; (3) patients who were pregnant or nursing; (4) patients taking steroids or other immunosuppressive treatment; (5) patients who had

From the Division of Otorhinolaryngology, Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, NT, Hong Kong.
Accepted for publication: 8 May 2007.

had an upper respiratory tract or sinus infection that required antibiotic therapy within 14 days prior to recruitment, or those who had had a viral upper respiratory tract infection (URTI) within seven days prior to recruitment; (6) patients with a history of hypersensitivity to desloratadine or any of its excipients; (7) patients with any clinically significant metabolic, cardiovascular, immunological, neurological, haematological, gastrointestinal, cerebrovascular or respiratory disease, or any other disorder which, in the judgment of the investigators, might interfere with the study evaluations or affect patient safety.

Informed consent was obtained prior to the start of any protocol-specified procedures, including washout periods for prohibited medication. The study was approved by the clinical research ethics committee.

All included subjects were assigned to receive desloratadine 5 mg once daily for 12 weeks.

Subjects' pre-treatment rhinitis symptoms were assessed after recruitment or after the two-week washout period, where applicable. Pre-treatment symptoms were assessed by the investigators using a questionnaire which covered demographic data and also the rhinitis symptoms score of Lebel *et al.*[5] The rhinitis symptoms score assess the subjective serverity of rhinitis symptoms i.e. sneezing (0–3), nasal discharge (0–3), nasal obstruction (0–3), itchy nose (0–1), itchy ears and palate (0–1) conjuctivitis (0–1). And the total score ranges from zero to 12. The questionnaire also included the Chinese (Hong Kong) version of the Medical Outcomes Study 36-item short form health survey, in order to evaluate patients' health-related quality of life.[6,7]

The Medical Outcomes Study 36-item short form health survey consists of 36 items grouped under 11 questions. Scores for these 36 items are summated into eight multi-item scales: physical functioning; role limitation due to physical problems; body pain; general health; vitality; social functioning; role limitation due to emotional problems; mental health; and one single-item, five-point Likert scale on health transition. The possible scores for each multi-item scale range from zero to 100, with higher scores representing better health status and function.

The pre-treatment endoscopic appearance of the nose was assessed by a 2.7 mm, 0°, rigid nasoendoscope. The endoscopic appearance of the nose was documented using the modified endoscopic appearance score of Lund and Kennedy (Table I).[8]

Patients were required to attend a follow up appointment 12 weeks after treatment. At this appointment, patients' response to therapy, in terms of subjective symptoms, objective nasal endoscopic appearance and health-related quality of life, were reassessed, again using the rhinitis symptoms score of Lebel *et al.*, the modified endoscopic appearance score of Lund and Kennedy,[8] and the Chinese (Hong Kong) version of the Medical Outcomes Study 36-item short form health survey.

Statistical analysis

The results were evaluated and analysed statistically by a medical statistician using the Statistical Package for the Social Sciences version 11.5 computer software (SPSS Inc, Chicago, Illinois, USA). Patients' pre- and post-treatment rhinitis symptoms score, endoscopic appearance score and Medical Outcomes Study 36-item short form health survey results were compared using the Wilcoxon signed rank test. Analysis of the sex predominance and age difference between the study group and the dropout group were performed by chi-square and Mann–Whitney testing, respectively. The two-tailed significant level was taken as 5 per cent.

TABLE I
MODIFIED NASAL ENDOSCOPIC APPEARANCE SCORE[8]

Appearance	Scores	
	Left	Right
Nasal polyp	0–1	0–1
Nasal discharge	0–2	0–2
Mucosal oedema	0–2	0–2
Septal deviation	0–2	
Total	0–12	

Adaptation with permission

Results

From June 2002 to September 2004, a total of 61 patients with chronic rhinitis were recruited. The study was completed over a 30-month period, which was longer than originally expected. This was due to the suspension of non-urgent services in our department during the 2003 Hong Kong outbreak of severe airway and respiratory syndrome.

There were 14 'dropouts' in our study. Of these 14 patients, five were removed from treatment due to subjective discomfort after taking desloratadine. One patient discontinued the study because of significant tiredness and drowsiness. One patient complained of generalised itchiness with no rash; this was considered as hypersensitivity to desloratadine. Another patient suffered from abdominal pain and did not complete the study. Two other patients who suffered from concurrent viral URTI also did not complete the study.

Other than the above, patients' side effects were mild, the commonest being drowsiness ($n = 16$), dry mouth ($n = 6$) and tiredness ($n = 4$).

Forty-seven (77 per cent) patients completed the 12-week study and all the required assessment. All subjects' demographic data, pre-treatment rhinitis symptoms scores and endoscopic appearance scores are summarised in Tables II and III. There were no significant differences between the 47 patients who completed the study and the 14 patients who dropped out, in terms of age, pre-treatment rhinitis symptoms score and endoscopic appearance score. However, there was a significant female predominance (78.6 per cent) in the dropout group.

Of the 47 patients who completed the study, the median age was 34 years, and there were 20 females and 27 males. The pre- and post-treatment rhinitis symptoms scores, endoscopic appearance scores

https://doi.org/10.1017/S0022215107000059 Published online by Cambridge University Press

TABLE II

PATIENTS' DEMOGRAPHIC DATA*

Participants	Completed study	'Dropped out'	*p*
Patients (*n*)	47	14	
Men (*n* (%))	20 (42.6)	11 (78.6)	0.018†
Women (*n* (%))	27 (57.4)	3 (21.4)	

*For the 61 patients recruited. †$p < 0.05$.

TABLE III

PATIENTS' RHINITIS SYMPTOMS SCORES AND ENDOSCOPIC APPEARANCE SCORES*

Patient variable	Median score (IR)	Median score (IR)	*p*
Age (years)	34.0 (22.0, 45.0)	37.0 (28.5, 46.0)	0.466
RSS	6.0 (5.0,7.0)	7.0 (6.0, 8.3)	0.116
EAS	4.0 (5.0, 6.0)	5.0 (2.8, 7.3)	0.589

*For the 61 patients recruited. IR = interquartile range; RSS = rhinitis symptoms score; EAS = endoscopic appearance score

and Medical Outcomes Study 36-item short form health survey results are summarised in Table IV.

After treatment, patients' median rhinitis symptoms score was significantly reduced, from six to five ($p < 0.001$). The median endoscopic appearance score also significantly decreased, from five to three ($p < 0.001$). Further analysis showed that the symptoms which had improved were sneezing ($p < 0.001$), rhinorrhoea ($p < 0.001$) and palatal itchiness ($p = 0.007$). The changes in other symptoms, including nasal obstruction and nose and eye itchiness, were not statistically significant.

Among the eight multi-item scales of the Medical Outcomes Study 36-item short form health survey, the median score for general health perception showed a statistically significant improvement following desloratadine treatment ($p = 0.022$), increasing from 53.5 to 67. The median score for social function increased from 75 to 87.5 after treatment, with a *p* value of 0.054 (i.e. almost, but not quite, statistically significant). There was no statistically significant change in any of the other six multi-item scales (i.e. physical functioning, role limitation due to physical problems, body pain, vitality, role limitation due to emotional problems, and mental health). For the single-item scale on health transition, there was a statistically significant decrease in the median score following treatment; the change in median score was zero, with an interquartile range of −1 to zero ($p = 0.041$).

Discussion

Patients with chronic perennial rhinitis are often treated with nasal steroid sprays.

In the present study, the beneficial effect of desloratadine 5 mg daily in relieving the symptoms of patients with chronic rhinitis may be attributed by its multiple mechanisms of action. In addition, to its antihistaminergic effect, desloratadine has been shown to exhibit anti-inflammatory and anti-allergic effects. It inhibits the new synthesis of allergic mediators, such as Prostaglandin D2 and Leukotriene C4, by mast cells and basophils.[9] It has also been shown to stabilise mast cells and basophils; thus inhibiting the release of preformed mediators of degranulation.[9–11] Desloratadine blocks the effects of pro-inflammatory cytokines which contribute to the inflammatory component of the allergic cascade. These cytokines include interleukin (IL) 4, IL-6, IL-13 and tumour necrosis factor α. Desloratadine has also been shown to inhibit inflammatory chemokines such as Rantes, as well as to inhibit expression of cell adhesion molecules including P-selectin and Intercellular adhesion molecule-1 (ICAM-1).[10,12–14]

However, desloratadine was only shown to be effective in relieving sneezing, rhinorrhoea and palatal itchiness. Like other antihistamines, desloratadine was not shown to have a statistically significant effect in the reduction of nasal obstruction.

After treatment, our patients showed a significant improvement in nasal mucosa status, as demonstrated by comparing their pre- and post-treatment

TABLE IV

PATIENT'S PRE- AND POST-TREATMENT RSS, EAS AND MOS SF-36 RESULTS

Parameter	Score*			*p*
	Pre-treatment	Post-treatment	Change	
RSS	6.0 (5.0, 7.0)	5.0 (3.0, 6.0)	−1.0 (−3.0, 0)	<0.001†
EAS	5.0 (4.0, 6.0)	3.0 (2.0, 5.0)	−1.0 (−3.0, 0)	<0.001†
MOS SF-36				
Physical functioning	95 (85, 100)	95 (85, 100)	0 (−.5.0, 5.0)	0.066
Role – physical	100 (75, 100)	100 (50, 100)	0 (0, 25)	0.951
Role – emotional	100 (66.7, 100)	100 (66.7, 100)	0 (0, 0)	0.346
Social functioning	75 (75, 100)	87.5 (75, 100)	0 (0, 12.5)	0.054
Mental health	72 (60, 88)	72 (56, 80)	0 (−12, 8.0)	0.377
Vitality	65 (45, 70)	55 (50, 75)	0 (−10, 5.0)	0.789
Body pain	80 (61, 100)	74 (52, 100)	0 (−16, 12)	0.466
General health perception	53.5 (34.3, 72)	67 (47, 72)	5.0 (−5.0, 17.3)	0.022†
Health transition	3.0 (3.0, 3.0)	3.0 (2.0, 3.0)	0 (−1.0, 0)	0.041†

*Score data are presented as median plus interquartile range. †$p < 0.05$. RSS = rhinitis symptoms score; EAS = endoscopic appearance score; MOS SF-36 = Chinese (Hong Kong) version of Medical Outcomes Study 36-item short form health survey

https://doi.org/10.1017/S0022215107000059 Published online by Cambridge University Press

endoscopic appearance scores. This endoscopic assessment provided additional evidence of the clinical efficacy of desloratadine. However, a single post-treatment endoscopic assessment may not have accurately represented the status of the nasal mucosa over the whole treatment period. Moreover, objective nasal mucosa status did not necessarily correlate with patients' subjective symptoms, which were of greater clinical importance.

In this study, the health-related QOL quality of life of patients with chronic rhinitis was assessed using the Chinese (Hong Kong) version of the Medical Outcomes Study 36-item short form health survey. Many health-related QOL measures have been developed in Western countries, and only a few are applicable to the Hong Kong Chinese population. At present, the Medical Outcomes Study 36-item short form health survey is the only health-related QOL measure that has been validated and normalised for Chinese adults in Hong Kong.[8,15] The Medical Outcomes Study 36-item short form health survey is a generic measure of health status and is applicable to various diseases. However, there are limitations with the use of this tool in assessing our patients with chronic rhinitis. For example, the multi-item scales for bodily pain, mental health, and role limitation due to emotional problems are unlikely to be significantly affected in our patients.

- **This study aimed to evaluate the outcome and the change in the quality of life of patients with chronic rhinitis after treatment with desloratadine**
- **Desloratadine was shown to be an effective and safe treatment in Hong Kong Chinese patients with chronic perennial rhinitis**
- **There was significant improvement in the rhinitis symptoms, the endoscopic nasal appearance and the health-related quality of life in these patients**
- **Although the post-treatment results of this study were encouraging, the study was an open-label study and the results could thus have been potentially biased as subjects and clinicians were not blinded**

Our patients reported an improvement in their quality of life following desloratadine treatment, as reflected in the statistically significant increase in the median score for general health perception, from 53.5 to 67. The median score for social function was also increased post-treatment, from 75 to 87.5 ($p = 0.054$). These two improvements may be intuitively interpreted as representing improved general well-being and reduced social inconvenience, once rhinitis symptoms were controlled. However, a larger sample size is probably needed in order to draw conclusions regarding the effect of desloratadine on social functioning.

There was a marginally significant change ($p = 0.041$) in the single-item scale for health transition, which aimed to assess patients' perception of their overall health status, compared with one year previous. However, the change of score was zero, with an interquartile range of -1 to zero. We also found that the mean pre- and post-treatment scores for health transition were respectively 3.1 and 2.9. These observations suggest a deterioration in patients' QOL regarding health transition; however, the change was small and did not reach the lower levels of the scale. There were no changes in the median scores for physical function, role limitation due to emotion problems, role limitation due to physical problems, or mental health. Although the median scores for vitality and body pain decreased from 65 to 55 and from 80 to 74 post-treatment, respectively, these changes were not statistically significant ($p = 0.789$ and $p = 0.466$, respectively).

In our study, patients were not assessed with skin or blood tests in order to determine their allergic status. Further, independent analysis of allergic and non-allergic groups may provide new and interesting information concerning the treatment of chronic rhinitis with desloratadine.

It should be noted that there were limitations to our study. Although the post-treatment results of our subjects were encouraging, the study was an open-label study, and results could therefore have been biased due to lack of subject and clinician blinding. Moreover, the beneficial effects of treatment may be partially attributed to a placebo effect, in the absence of a control group.

Conclusion

In our study, desloratadine was shown to be an effective and safe treatment in Hong Kong Chinese patients with chronic perennial rhinitis. This drug significantly improved patients' rhinitis symptoms, endoscopic nasal appearance and health-related QOL. Desloratadine may therefore be recommended as a treatment for patients with chronic perennial rhinitis.

Acknowledgement

This study was partially supported by a grant from the Schering-Plough Corporation (Hong Kong).

References

1 Naclerio R, Solomon W. Rhinitis and inhalant allergens. *JAMA* 1997;**278**:1842–8
2 Berger WE, Schenkel EJ, Mansfield LE. Desloratadine Study Group. Safety and efficacy of desloratadine 5mg in asthma patients with seasonal rhinitis and nasal congestion.. *Ann Allergy Asthma Immunol* 2002;**89**:485–91
3 Bachert C. Decongestant efficacy of desloratadine in patients with seasonal allergic rhinitis. *Allergy* 2001;**56 (suppl 65)**:14–20
4 Corren J, Salmun LM. Quality of life in patients with seasonal allergic rhinitis is improved with desloratadine. *Allergy* 2000;**5**:193–4
5 Lebel B, Bousquet J, Morel A, Chanal I, Godard P, Michel FB. Correlation between symptoms and the threshold for release of mediators in nasal secretions during nasal challenge with grass-pollen grains. *J Allergy Clin Immunol* 1988;**5**:869–77

6 Ware JE, Snow KK, Kosinski M, Gandek B. *SF36 Health Survey – Manual and Intrepretation Guide*. Boston: The Health Institute, 1993
7 Lam CLK, Gandek B, Ren XS, Chan MS. Tests of scaling assumptions and construct validity of the Chinese (HK) version of the SF-36 health survey. *J Clin Epidemiol* 1998;**51**:1139–47
8 Lund VJ, Kennedy DW. Quantification for staging sinusitis. The Staging and Therapy Group. *Ann Otol Rhinol Laryngol (Suppl)* 1995;**167**(suppl):17–21
9 Genovese A, Patella V, De Crescenzo G, De Paulis A, Spadaro G, Marone G. Loratadine and Desethoxylcarbonyl-loratadine inhibit the immunological release of mediators from human Fc epsilon RI+ cells. *Clin Exp Allergy* 1997; **27**:559–67
10 Lippert U, Kruger-Krasagakes S, Moller A, Kiessling U, Czarnetzki BM. Pharmacological modulation of IL-6 and IL-8 secretion by the H1-antagonist decarboethoxy-loratadine and dexamethasone by human mast and basophilic cell lines. *Exp Dermatol* 1995;**4**:272–6
11 Kleine-Tebbe J, Josties C, Frank G, Stalleicken D, Buschauer A, Schunack W *et al*. Inhibition of IgE- and non-IgE-mediated histamine release from from human basophil leukocytes in vitro by a histamine H1-antagonist, desethoxycarbonyl-loratadine. *J Allegy Clin Immunol* 1994;**93**:494–500
12 Vignola AM, Crampette L, Mondain M, Sauvere G, Czarlewski W, Bosquet J *et al*. Inhibitory activity of loratadine and descarboethoxyloratadine on expression of ICAM-1 and HLA-DR by nasal epithelial cells. *Allergy* 1995;**50**: 200–3
13 Geha RS, Meltzer EO. Desloratadine: A new, nonsedating, oral antihistamine. *J Allergy Clin Immunol* 2001;**107**: 751–62
14 Molet S, Gosset P, Lassalle P, Czarlewski W, Tonnel AB. Inhibitory activity of loratadine and descarboxyethoxylor-atadine on histamine-induced activation of endothelial cells. *Clin Exp Allergy* 1997;**27**:1167–74
15 Lam CLK, Lauder IJ, Lam TP, Gandek B. Population based norming of the Chinese (HK) version of the SF-36 health survey. *Hong Kong Practitioner* 1999;21:460–70

Address for correspondence:
Dr Henry Chuen Kwong Lam,
Division of Otorhinolaryngology,
Department of Surgery,
The Chinese University of Hong Kong,
Prince of Wales Hospital,
Shatin, NT, Hong Kong.

Fax: (852) 26466312
E-mail: henrycklam@yahoo.com.hk

Dr H C K Lam takes responsibility for the integrity of the content of the paper.
Competing interests: None declared