Assessment of patient satisfaction with ebastine fast-dissolving tablets in patients suffering from allergic rhinitis

Objective: The aim of this study was to assess patient satisfaction with ebastine fast-dissolving tablets (FDT) using the Treatment Satisfaction Questionnaire for Medication (TSQM). **Research, design and methods:** This was an international, multicenter, observational study involving patients with at least 1-year history of intermittent allergic rhinitis or persistent allergic rhinitis and who had received a prescription for ebastine FDT (20 mg) in the last 2 months. Investigators collected demographic data, medical history, a completed TSQM questionnaire, and responses regarding perception of onset of action, intensity of rhinitis symptoms, tolerability and their preference compared with previous therapy. **Results:** Validated TSQM questionnaires were collected from 461 patients and the overall ratings for effectiveness, side effects, convenience and global satisfaction were all very high for ebastine FDT. A total of 79% of patients reported a fast or very fast onset of action. On the last day of treatment patients reported a statistically significant ($p < 0.001$) improvement in the intensity and relief of symptoms of allergic rhinitis. A total of 95% of patients reported good or very good tolerability with ebastine FDT. Compared with the patient's experience with previous therapy, ebastine FDT was considered better or much better for: efficacy (81%), tolerability (73%), onset of action (79%) and convenience (94%). A total of 94% of patients indicated that they would like to use ebastine FDT again. **Conclusion:** Ebastine FDT was associated with a very high satisfaction rate and significant relief of rhinitis symptoms and, consequently, patients reported a preference for the FDT formulation over previous antihistamines that they had used.

KEYWORDS: allergic rhinitis ■ ebastine ■ fast-dissolving tablet ■ patient satisfaction ■ Treatment Satisfaction Questionnaire for Medication

Albert Roger[1,†], Josep Fortea[2], M José Plazas[2], Sheila Mora[2] & Maite Artés[1,3]

[†]Author for correspondence:
[1]Centre Roger Barri d´Asmologia i Al.lèrgia, C/ Muntaner 262, 1º pl. 08021, Barcelona, Spain
Tel.: +34 932 092 223
Fax: +34 932 095 154
centre_roger_alergia@comb.es
[2]Almirall SA, Barcelona, Spain
[3]Adelphi Targis, SL, Barcelona, Spain

Allergic rhinitis is a major IgE-mediated chronic respiratory disorder that presents as a complex of nasal, ophthalmic, ear and sinus symptoms such as nasal congestion, nasal itching, rhinorrhea, sneezing and watery/running eyes [1–3]. It is an extremely common condition, which has been estimated to affect more than 15% of the population [4] and it is one of the top ten reasons for patients visiting their general practitioner [101]. While it is not generally considered a life-threatening condition, the negative impact on patient quality of life (QoL) is extensive and can impair the individual's ability to perform in school or the workplace, and therefore represents a global health problem with significant socio–economic costs [5,6].

Allergic rhinitis has traditionally been subdivided, based on time of exposure, into seasonal and perennial disease. This subdivision is not perfect since there are many examples that fall outside of these definitions. For example, there are places where pollens and moulds are perennial allergens (e.g., grass pollen allergy in parts of the USA) and some symptoms of perennial disease are not always present all year round [7]. In 2001, the Allergic Rhinitis and its Impact on Asthma (ARIA) workshop group, in collaboration with the WHO, introduced a new classification system for allergic rhinitis based on the duration of symptoms and their severity [7].

The disease is classified as either intermittent allergic rhinitis (IAR; symptoms are present for less than 4 days per week or for less than 4 weeks) or persistent allergic rhinitis (PAR; symptoms are present for more than 4 days per week and for longer than 4 consecutive weeks) and the severity is categorized as either mild (all of the following items should be present: normal sleep; no impairment of daily activities, sport or leisure; no impairment of work or school; and no troublesome symptoms) or moderate to severe (one or more of the following items should occur: abnormal sleep; impairment of daily activities, sport or leisure; impaired work or school; or troublesome symptoms). This new classification recognizes that allergic rhinitis is a significant chronic respiratory disease and supports a stepwise approach to therapy in which second-generation antihistamines such as ebastine are an important component [8].

Ebastine, a potent and selective H_1-receptor antagonist, has been shown to be effective and well tolerated in the management of the

future medicine part of fsg

symptoms associated with allergic rhinitis, allergic conjunctivitis and chronic idiopathic urticaria (CIU) when administered orally once daily [9–13]. Results of a meta-analysis concluded that 2 weeks' treatment with ebastine was associated with a good efficacy profile and decreased mean rhinitis symptoms scores relating to nasal discharge, nasal congestion, nasal itching, sneezing and total eye symptoms compared with baseline values [14].

From the patient's perspective, rapid relief of allergic symptoms and the return to normal routines would be an ideal property for an antihistamine used in the treatment of rhinitis. In this regard, a new fast-dissolving tablet (FDT) formulation of ebastine has been developed, using lyophilized powder, and has recently been launched in several markets. When ebastine FDT is placed in the mouth, the freeze-dried structure immediately disintegrates, releasing the drug, which dissolves or disperses in the saliva. The saliva containing the dissolved or dispersed drug is then swallowed and the drug is absorbed in the normal way. Bioequivalence studies have confirmed that the ebastine FDT 10 mg and 20 mg tablets disintegrate significantly more rapidly than conventional tablets administered at the same dosages [15].

Given the prevalence of allergic rhinitis and the fact that it can involve longer-term treatment in patients with PAR or requires frequent intervention in patients with IAR, it is important that drug therapy is well-accepted by the patient. This not only includes having confidence with respect to the efficacy and safety of the treatment, but also satisfaction with the formulation *per se* so that compliance with therapy does not become a problem. The aim of the current study was to use the validated Treatment Satisfaction Questionnaire for Medication (TSQM) to assess individual satisfaction and experience following treatment with ebastine FDT (20 mg) in patients with IAR and PAR. In addition, for patients who had been treated for allergic rhinitis before, we evaluated their perception of the new FDT formulation and compared this with their experience with previous antihistamine therapy.

To assess effectiveness, side effects, convenience and global satisfaction with ebastine FDT we used the TSQM psychometric test. The scales employed within this test have been shown to have good internal consistency as indicated by Cronbach's α coefficients more than 0.80 for all of the dimensions evaluated [16]. The TSQM is a general scale that has proven useful for measuring treatment satisfaction in diseases such as arthritis, asthma, major depression, Type I diabetes, lipid disorders, hypertension, migraine and psoriasis. However, to our knowledge, it has never been used in patients with allergic rhinitis. Given the importance of patient-reported outcomes in allergic rhinitis, TSQM would appear to be an appropriate tool for estimating treatment satisfaction in this setting [17–19].

Patients & methods

This was an international, multicenter, observational assessment of the level of patient satisfaction with ebastine FDT (20 mg) in individuals with at least a 1-year history of IAR or PAR. Patients of either sex, aged 18–65 years, were treated with ebastine FDT (20 mg) once daily for the management of IAR or PAR. Only those who had taken the drug for at least 2 weeks over a 2-month period, and who had signed an informed consent form, were eligible to enter the final analysis. The diagnosis of allergic rhinitis was confirmed by a positive skin prick test or using a specific IgE test.

Investigators from 43 centers (six from Belgium, 17 from Mexico and 20 from Spain) were involved in the study, and it was conducted according to European and Mexican local law and regulation. The study was submitted for approval to the relevant Ethics Committees. Data Confidentiality was maintained according to EU Data Privacy Directive 95/46/EC and HIPPA Rules for US trials.

All participating patients completed questionnaires to record the following:

- Satisfaction/experience with ebastine FDT using the TSQM;
- An assessment of therapy and their willingness to continue with its use;
- Perception of the speed of onset of action;
- Evaluation of tolerability;
- Evaluation of patient preference;
- An assessment of intensity and relief of clinical symptoms.

The TSQM was completed in the local language and the questionnaire was developed from the English version using the principles of good practice for the translation and cultural adaptation of patient-reported outcome measures [20].

At the time of the interview the following were also recorded: demographic data, medical history and a physical examination.

The TSQM questionnaire includes 14 items covering the following dimensions: 'side effects' (five items), 'effectiveness' (three items), 'convenience' (three items) and 'global satisfaction' (three items). The TSQM contains two types of questions: those requiring a 'yes/no' answer and others requiring the patient to respond on a five- or seven-point Likert scale. The TSQM is scored by dimensions, with the minimum score for each dimension being zero and the maximum being 100. Higher scores correspond to greater satisfaction with medication.

The patient's perception of onset of action was evaluated in relation to the response to the question: "Taking into account how long it took to relieve your symptoms, how would you rate the onset of action of the study medication" (very fast, fast, regular, slow or very slow).

The intensity of clinical symptoms of allergic rhinitis were recorded on the first and last days of treatment by asking questions relating to their severity (i.e., none, mild, moderate or severe) and likewise for symptom relief (no relief, mild relief, moderate relief, great relief or total relief/no symptom at all).

The number of days ebastine FDT was used over a 2-month period was recorded and patients were included in one of the following four groups: 7–15 days, 16–30 days, 31–45 days or 46–60 days.

Overall tolerability with the study medication was evaluated and rated by the investigator (very good, good, regular, bad or very bad), and also by asking the patient general open safety questions.

For patients with previous experience of using an oral antihistamine their treatment preference was assessed by asking a series of questions regarding how well ebastine FDT compared with previous treatment with respect to efficacy, tolerability, onset of action and convenience (much better, better, the same, worse or much worse).

Statistical analyses

The minimum sample size needed for this study was estimated from information regarding the psychometric validation of the TSQM (primary variable) [16]. Using a standard deviation of 22.6, which was obtained during the psychometric validation of the TSQM scale, and an α risk of 5%, it was calculated that 161 valid patients were required per group (IAR and PAR) to estimate the TSQM with a precision of 3.5 units. Assuming that 20% of the data would be incomplete or invalid, a total sample size of 200 patients or more per group was therefore considered necessary to scientifically assess patient satisfaction using the TSQM. The valid population for analysis was defined as those patients meeting the inclusion/exclusion criteria and who completed the TSQM questionnaire. The safety population consisted of all patients taking at least one dose of ebastine FDT.

Assessments were undertaken for the global population, as well as the IAR and PAR subgroups, and descriptive analyses were completed for demographic characteristics (gender and age) and clinical history (comorbidities, concomitant medication and allergic symptoms). Frequency tables were computed for nominal variables, and central trend and dispersion statistics for continuous variables. Patient satisfaction with medication was assessed by estimating the 95% interval of the mean score for each TSQM dimension, and a one-way analysis of variance (ANOVA) was used to compare differences. Differences in symptom intensity and relief between the first and last days of treatment were evaluated using the Bowker test and correlations between symptom intensity and TSQM were evaluated using the Spearman correlation coefficient. The perception of onset of action, the use of medication, symptom intensity and symptom relief, patient preferences and use of concomitant medication were assessed using frequency tables, with results expressed as percentages.

Results

All 508 patients (mean age 35.5 years, 62.3% females, 274 IAR and 234 PAR) recruited into the study were evaluated for safety. However, 47 patients were excluded from the efficacy analysis primarily (n = 45) as a result of taking prohibited medication. Thus, the final efficacy population was 461 patients: 251 in the IAR group (98 from Spain, 137 from Mexico and 16 from Belgium) and 210 in the PAR group (80 from Spain, 113 from Mexico and 17 from Belgium).

With regard to the use of the study medication, nearly half of the study patients (49.2%) took ebastine FDT for 16–30 days, 20.6% for 7–15 days, 12.1% for 31–45 days, 11.7% for 46–60 days and 6.3% for more than 60 days. There were no statistically significant differences between the IAR and PAR groups with regards the number of days that ebastine FDT was taken. TSQM results were analyzed according to the four dimensions: effectiveness, side effects, convenience and global satisfaction (Figure 1).

For the 'effectiveness' dimension IAR patients achieved higher overall scores than did PAR patients. Generally, there were no statistically

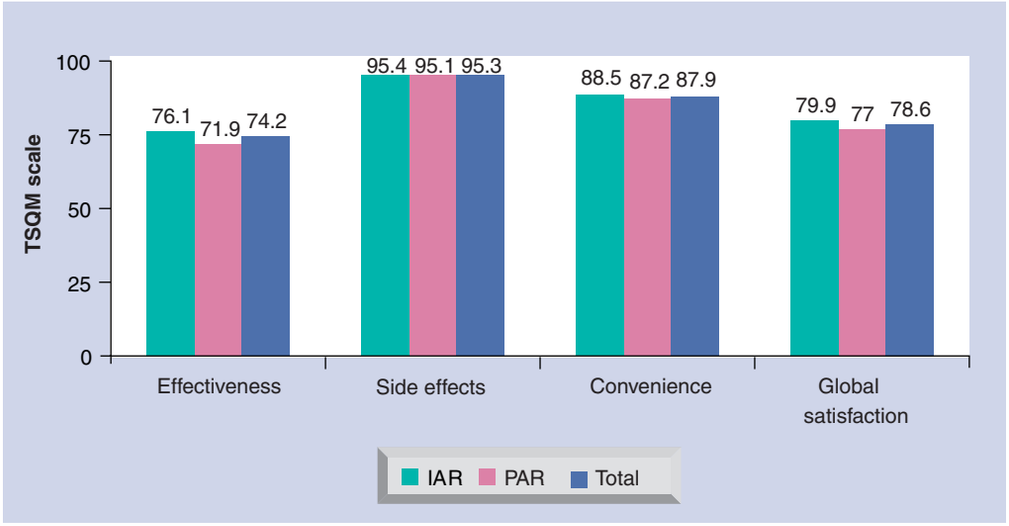

Figure 1. Treatment Satisfaction Questionnaire for Medication scale. Results by dimension. IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis; TSQM: Treatment Satisfaction Questionnaire for Medication.

significant differences in the results categorized according to the number of days that ebastine FDT had been taken, except in the IAR group where higher scores were recorded for patients who had taken ebastine FDT for 46–60 days compared with patients who had taken the antihistamine for 16–30 days ($p = 0.024$). The results by country showed no significant differences in the Spanish or Belgium populations, whereas in the Mexican population effectiveness ratings were significantly higher in patients who had consumed ebastine FDT for 46–60 days compared with those who had taken the antihistamine for 16–30 days ($p = 0.006$ for the global group and $p = 0.014$ for the IAR group) and who had consumed ebastine FDT for 46–60 days compared with those who had taken the antihistamine for 7–15 days ($p < 0.001$ for the global group and $p = 0.007$ for the IAR group).

With regards to the 'side effects' dimension, there were no statistically significant differences in tolerability in any of the analyses (i.e., in the global, IAR and PAR study populations, by country or by length of treatment).

For the 'convenience' dimension, the overall scores were generally very high (~90 out of 100) and there were no significant differences between the IAR or PAR groups. With regard to the analysis of duration of treatment, patient perception was higher in the global population for those in the 16–30-day group compared with those in the 7–15-day group ($p = 0.012$). Likewise in the IAR group patient perception of convenience was higher in patients who took the drug for 46–60 days compared with those who took it for 7–15 days ($p = 0.004$). The results by country showed no significant differences in the Spanish or Belgium populations. However, in the Mexican population the perception of convenience with ebastine FDT treatment was generally higher in patients who had taken the antihistamine for longer periods. For example, in the global population, patients who had taken ebastine FDT for 46–60 days rated it significantly more highly than patients who had taken it for 7–15 days ($p < 0.001$) or 16–30 days ($p = 0.006$). Similarly, statistically significant results were noted in the IAR group with patients who took the drug for 46–60 days rating it most highly ($p < 0.001$ vs 7–15 days).

Finally, with regards to the 'global satisfaction' dimension, there were no differences in ratings based on length of treatment in the global or PAR populations, but patients with IAR taking ebastine FDT for 46–60 days had a significantly ($p = 0.004$) higher rating than patients taking the drug for 16–30 days. The results by country showed no significant differences in the Spanish and Belgian populations. However, Mexican patients who took ebastine FDT for 46–60 days rated the treatment significantly higher ($p < 0.001$ vs 7–15 days and $p = 0.003$ vs 16–30 days) in the global group and ($p < 0.001$ vs 7–15 days and $p = 0.009$ vs 16–30 days) in the IAR group.

An assessment of the correlation between the intensity of symptoms and TSQM ratings using the Spearman correlation coefficient demonstrated a weak relationship between these two parameters. This is despite the fact that the majority of symptoms were significantly improved by the end of treatment.

Concerning the perception of onset of action of ebastine FDT, the majority of patients in the global group reported a fast (52.8%) or very fast (26.3%) onset of action and this was also the case for the IAR and PAR subgroups (Figure 2). In terms of rank order the percentage of patients who reported a fast or very fast onset of action was 66.7, 76.5 and 82.7%, in Belgium, Spain and Mexico, respectively. Interestingly, virtually all of the patients indicated that they would like to use ebastine FDT in the future (94, 95 and 94%, in the global, IAR and PAR groups, respectively). In Spain and Mexico, the percentage of patients wanting to use the product again was in excess of 90% for all groups whereas in Belgium the rates were slightly lower, but still exceeded 75%.

Results relating to the intensity of rhinitis symptoms on the first and last days of the study are presented in Table 1. Statistically significant improvements were recorded for all symptoms on the last day of treatment. Sneezing and rhinorrhea were reduced in 87% of patients, while itching, nasal obstruction and ocular pruritus were lower in 83, 76 and 68% of subjects, respectively.

The level of symptom relief with ebastine FDT was significantly higher by the final day of treatment (Table 2). Statistically significant improvements were observed for all symptoms following treatment with ebastine FDT: relief from sneezing, rhinorrhea, itching, nasal obstruction and ocular pruritus was recorded in 74, 70, 66, 64 and 64% of patients, respectively.

An evaluation of patient's preference regarding ebastine FDT compared with their previous experience with other oral antihistamines demonstrated that it was always rated higher in the global population. Efficacy was rated as much better or better by 81% of patients, tolerability was rated as much better or better by 73% of patients, onset of action was rated as much better or better by 79% of patients, and finally convenience of treatment was rated as much better or better by 94% of patients (Figure 3). Ebastine FDT was also rated as much better or better for the IAR and PAR subgroups of patients, and for each country population (Spain, Mexico and Belgium).

Overall tolerability with the ebastine FDT was rated as very good or good in 95% of those treated (68 and 27%, respectively). The findings were very similar in the IAR (70 and 25%, respectively) and PAR (65 and 30%, respectively) populations (Figure 4). An analysis by country demonstrated that the tolerability of ebastine FDT was rated very good or good in greater than 90% of patients for all groups treated in Spain, Mexico and Belgium. In the safety evaluation, 8% of patients reported an adverse event related to ebastine therapy. The most frequent reported adverse events were sleeping disorders (6% of patients) and dry mouth or dry mucosa (2%).

Discussion

There is little doubt that allergic rhinitis results in significant impairment of QoL. In addition to classical symptoms such as sneezing, nasal pruritus, congestion and rhinorrhea, it is recognized that allergic rhinitis can profoundly impact many aspects of everyday life and patients may be affected by poor sleeping patterns, emotional problems, impairment of physical and mental functioning, and disturbances in daily activities [1,21]. As such, it is a common chronic condition that has a significant negative impact on general health, comorbid illnesses, and productivity. The socio–economic costs are enormous.

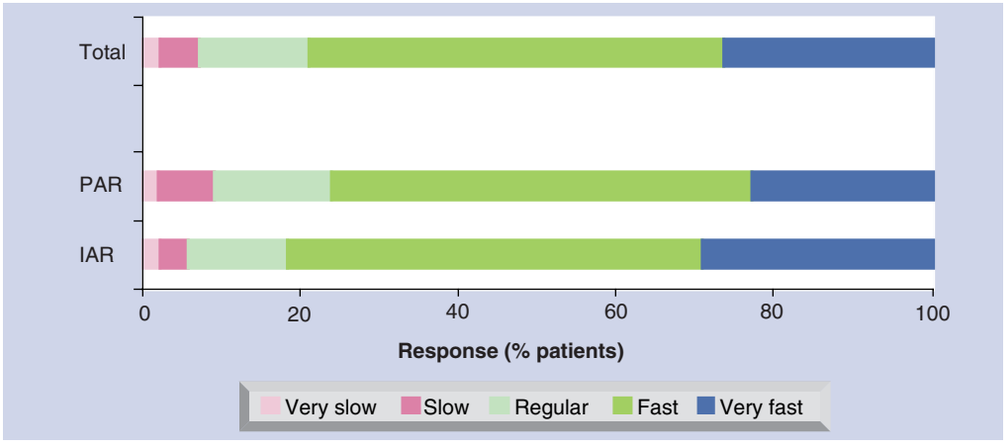

Figure 2. Assessment of the patient's perception of onset of action.
IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis.

According to current ARIA guidelines second-generation antihistamines represent a first-line treatment option for patients with allergic rhinitis [22]. When prescribing oral antihistamines, healthcare providers need to consider not only the clinical efficacy and possible side effects associated with treatment, but also the potential to improve QoL [1,6,23,24]. Despite numerous treatment options available to the physician, it is enlightening that 60% of all allergic rhinitis patients in a recent Asthma and Allergy Foundation of America (AAFA) survey responded that they were 'very interested' in finding a new medication and 25% were 'constantly' trying different medications to find one that 'works' [19]. To alleviate their condition, patients are frequently self-adjusting their treatment regimen of over-the-counter and prescription medications because of a lack of efficacy, deterioration of efficacy, lack of 24-h relief and/or bothersome side effects [5].

The main purpose of the current study was to evaluate patient satisfaction with ebastine FDT (20 mg) using the generic and validated TSQM questionnaire [20]. Overall results for ebastine FDT on the TSQM were very favorable compared with results from a previously published study that involved 344 outpatients suffering from a number of different pathologies and treated with different drugs over a 4-week period [25]. The earlier study had a similar distribution of patients with acute and chronic disorders and, as in the current study, the majority of patients were still receiving treatment for their underlying disease. Whilst historical comparisons are fraught with problems it is encouraging that for all dimensions the satisfaction scores for ebastine FDT were higher than those previously reported [25]. Thus, the overall satisfaction score was 78.6 versus 72.1 while the scores for effectiveness (74.2 vs 69.0), side effects (95.3 vs 93.6), and convenience (87.9 vs 81.4) all favored ebastine FDT.

Table 1. Intensity of symptoms of allergic rhinitis on the first and last days of treatment with ebastine fast-dissolving tablets.

Symptoms	Categories	First day			Last day		
		IAR (n [%])	*PAR (n [%])*	*Total (n [%])*	*IAR (n [%])*	*PAR (n [%])*	*Total (n [%])*
Sneezing	Missing	0	2	2	3	2	5
	None	15 (6)	10 (4.8)	25 (5.4)	157 (63.3)	113 (54.3)	270 (59.2)
	Mild	53 (21.1)	34 (16.3)	87 (19)	70 (28.2)	74 (35.6)	144 (31.6)
	Moderate	117 (46.6)	89 (42.8)	206 (44.9)	19 (7.7)	20 (9.6)	39 (8.6)
	Severe	66 (26.3)	75 (36.1)	141 (30.7)	2 (0.8)	1 (0.5)	3 (0.7)
Rhinorrhea	Missing	0	1	1	2	2	4
	None	8 (3.2)	2 (1)	10 (2.2)	153 (61.4)	104 (50)	257 (56.2)
	Mild	44 (17.5)	35 (16.7)	79 (17.2)	67 (26.9)	79 (38)	146 (31.9)
	Moderate	124 (49.4)	86 (41.1)	210 (45.7)	26 (10.4)	21 (10.1)	47 (10.3)
	Severe	75 (29.9)	86 (41.1)	161 (35)	3 (1.2)	4 (1.9)	7 (1.5)
Nasal obstruction	Missing	0	1	1	1	1	2
	None	16 (6.4)	13 (6.2)	29 (6.3)	114 (45.6)	71 (34)	185 (40.3)
	Mild	55 (21.9)	42 (20.1)	97 (21.1)	96 (38.4)	92 (44)	188 (41)
	Moderate	111 (44.2)	82 (39.2)	193 (42)	30 (12)	45 (21.5)	75 (16.3)
	Severe	69 (27.5)	72 (34.4)	141 (30.7)	10 (4)	1 (0.5)	11 (2.4)
Itching	Missing	1	7	8	2	5	7
	None	22 (8.8)	12 (5.9)	34 (7.5)	166 (66.7)	122 (59.5)	288 (63.4)
	Mild	52 (20.8)	40 (19.7)	92 (20.3)	64 (25.7)	65 (31.7)	129 (28.4)
	Moderate	103 (41.2)	83 (40.9)	186 (41.1)	16 (6.4)	15 (7.3)	31 (6.8)
	Severe	73 (29.2)	68 (33.5)	141 (31.1)	3 (1.2)	3 (1.5)	6 (1.3)
Ocular pruritus	Missing	3	13	16	4	13	17
	None	64 (25.8)	49 (24.9)	113 (25.4)	193 (78.1)	140 (71.1)	333 (75)
	Mild	65 (26.2)	47 (23.9)	112 (25.2)	42 (17)	47 (23.9)	89 (20)
	Moderate	67 (27)	55 (27.9)	122 (27.4)	9 (3.6)	7 (3.6)	16 (3.6)
	Severe	52 (21)	46 (23.4)	98 (22)	3 (1.2)	3 (1.5)	6 (1.4)

IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis.

Table 2. Level of symptom relief in patients with allergic rhinitis on the first and last days of treatment with ebastine fast-dissolving tablets.

Symptoms	Categories	First day			Last day		
		IAR (n [%])	*PAR (n [%])*	*Total (n [%])*	*IAR (n [%])*	*PAR (n [%])*	*Total (n [%])*
Sneezing	Missing	0	1	1	0	1	1
	No relief	14 (5.9)	18 (9.1)	32 (7.4)	3 (1.3)	2 (1)	5 (1.2)
	Mild relief	48 (20.3)	49 (24.9)	97 (22.4)	11 (4.7)	11 (5.6)	22 (5.1)
	Moderate relief	77 (32.6)	54 (27.4)	131 (30.3)	30 (12.7)	27 (13.7)	57 (13.2)
	Great relief	87 (36.9)	60 (30.5)	147 (33.9)	65 (27.5)	66 (33.5)	131 (30.3)
	Total relief	10 (4.2)	16 (8.1)	26 (6)	127 (53.8)	91 (46.2)	218 (50.3)
Rhinorrhea	Missing	0	0	0	3	1	4
	No relief	15 (6.2)	18 (8.7)	33 (7.3)	4 (1.7)	4 (1.9)	8 (1.8)
	Mild relief	56 (23)	58 (28)	114 (25.3)	14 (5.8)	20 (9.7)	34 (7.6)
	Moderate relief	74 (30.5)	55 (26.6)	129 (28.7)	29 (12.1)	27 (13.1)	56 (12.6)
	Great relief	83 (34.2)	58 (28)	141 (31.3)	69 (28.8)	57 (27.7)	126 (28.3)
	Total relief	15 (6.2)	18 (8.7)	33 (7.3)	124 (51.7)	98 (47.6)	222 (49.8)
Nasal obstruction	Missing	0	0	0	2	0	2
	No relief	34 (14.5)	29 (14.8)	63 (14.6)	15 (6.4)	8 (4.1)	23 (5.4)
	Mild relief	67 (28.5)	69 (35.2)	136 (31.6)	31 (13.3)	34 (17.3)	65 (15.2)
	Moderate relief	75 (31.9)	46 (23.5)	121 (28.1)	45 (19.3)	49 (25)	94 (21.9)
	Great relief	43 (18.3)	42 (21.4)	85 (19.7)	68 (29.2)	46 (23.5)	114 (26.6)
	Total relief	16 (6.8)	10 (5.1)	26 (6)	74 (31.8)	59 (30.1)	133 (31)
Itching	Missing	1	1	2	2	1	3
	No relief	10 (4.4)	15 (7.9)	25 (6)	4 (1.8)	7 (3.7)	11 (2.6)
	Mild relief	40 (17.6)	41 (21.6)	81 (19.4)	12 (5.3)	11 (5.8)	23 (5.5)
	Moderate relief	63 (27.8)	42 (22.1)	105 (25.2)	27 (11.9)	22 (11.6)	49 (11.8)
	Great relief	97 (42.7)	73 (38.4)	170 (40.8)	59 (26.1)	52 (27.4)	111 (26.7)
	Total relief	17 (7.5)	19 (10)	36 (8.6)	124 (54.9)	98 (51.6)	222 (53.4)
Ocular pruritus	Missing	1	1	2	3	1	4
	No relief	11 (6)	15 (10.2)	26 (7.9)	6 (3.3)	4 (2.7)	10 (3)
	Mild relief	36 (19.7)	36 (24.5)	72 (21.8)	13 (7.2)	9 (6.1)	22 (6.7)
	Moderate relief	45 (24.6)	30 (20.4)	75 (22.7)	17 (9.4)	19 (12.9)	36 (11)
	Great relief	70 (38.3)	43 (29.3)	113 (34.2)	40 (22.1)	32 (21.8)	72 (22)
	Total relief	21 (11.5)	23 (15.6)	44 (13.3)	105 (58)	83 (56.5)	188 (57.3)

IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis.

In many patients with allergic rhinitis, symptoms of the disease can be particularly bothersome and rapid relief is an important clinical objective. Consequently, a fast onset of action would be advantageous and would represent an important clinical benefit for patients, and this should be taken into account by physicians and other healthcare professionals who provide treatment advice for patients with rhinitis [17,26,27]. Patient perception of a faster onset of action with ebastine FDT has been documented in both a cross-sectional, multicenter study conducted in IAR and PAR patients who were consumers of oral antihistamines and who changed to ebastine FDT during the previous week, and also in an international study assessing the preferred attributes of ebastine FDT in patients with an allergic disorder [28,29]. In these studies ebastine FDT was perceived by patients as having a fast onset of action, thus increasing their satisfaction with treatment. Similar findings were demonstrated in the present study, where 79% of the patients considered ebastine FDT better or much better owing to its fast onset of action.

The combination of high ratings for all aspects related to convenience, together with the high levels of overall satisfaction and the fast onset of action attributed to the product clearly explain the reason why almost all patients were interested in continuing treatment with ebastine FDT. These results are consistent with findings from previous studies with ebastine FDT [28–30]. For example, the acceptance and preference for the new fast-dissolving formulation was

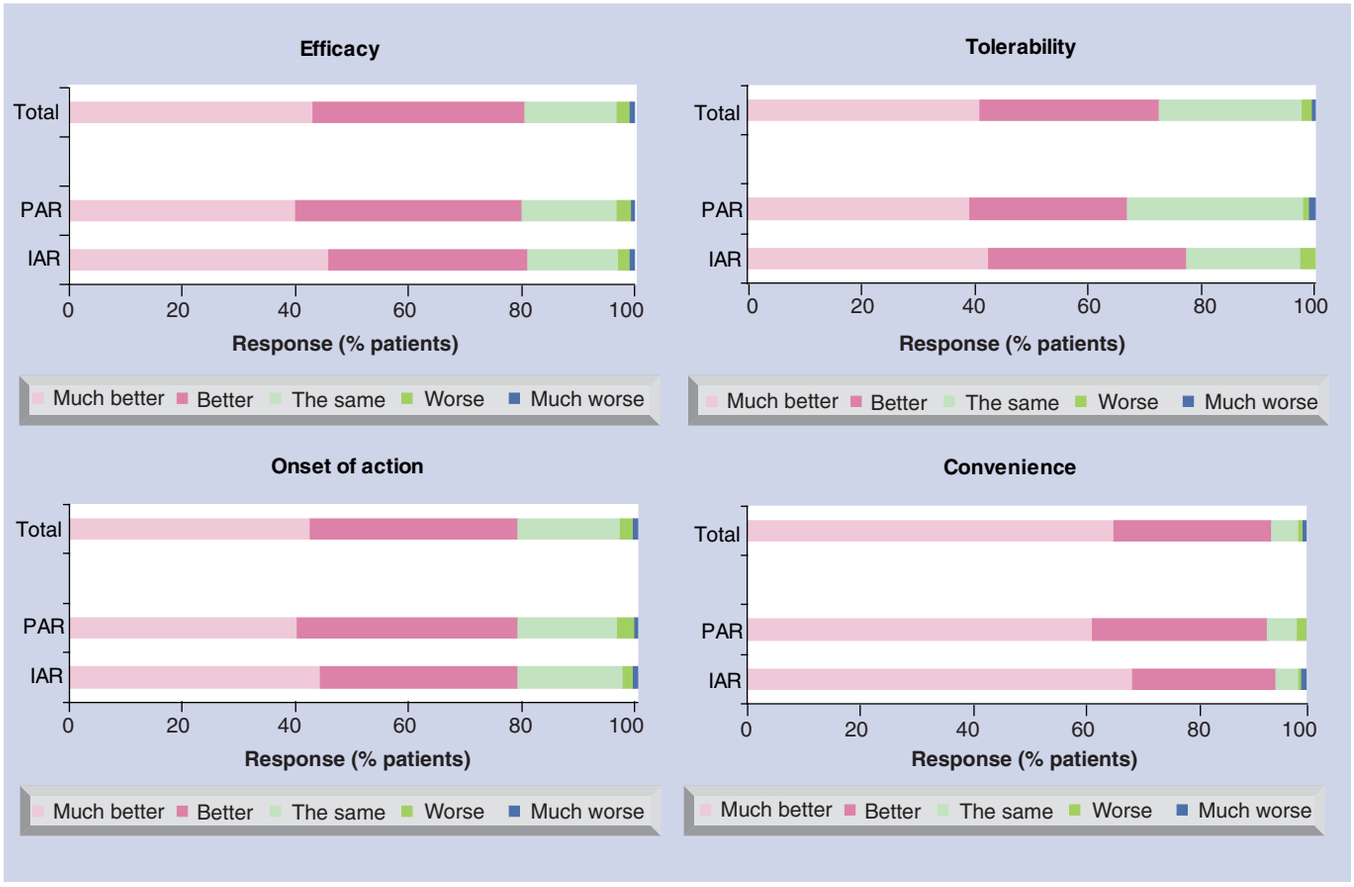

Figure 3. Assessment of the patient's preference for ebastine fast-dissolving tablets over previous therapy.
IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis.

evaluated in an international market research study using placebo formulations of ebastine FDT and the conventional product, and highlighted a clear preference of subjects for the FDT formulation (83%) in all the countries analyzed (64.3% in Germany, 88.7% in Italy and 96.5% in Mexico) [30].

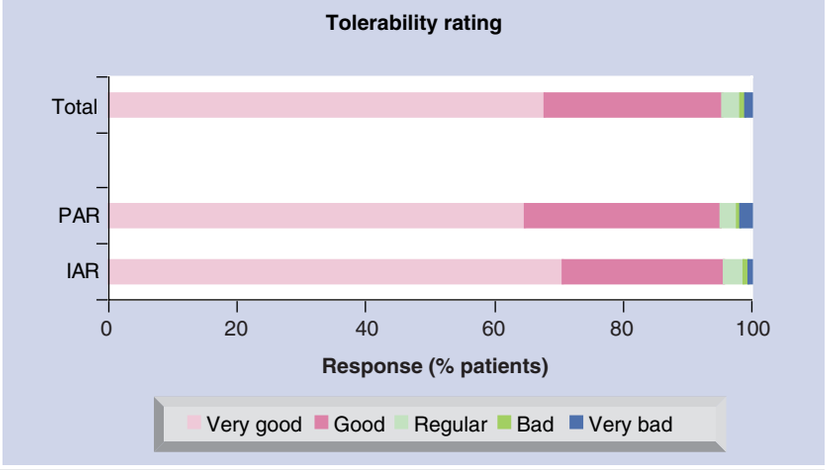

Figure 4. Overall tolerability of ebastine fast-dissolving tablets.
IAR: Intermittent allergic rhinitis; PAR: Persistent allergic rhinitis.

In conclusion, the new ebastine FDT formulation was rated very highly by patients with IAR or PAR as reflected by significantly improved satisfaction and convenience ratings on the TSQM at the end of treatment, and these were associated with a marked reduction in the severity of rhinitis symptoms. This resulted in the new formulation being preferred by the patients included in this study over antihistamines that they had previously used, and an overall positive reaction regarding wanting to use ebastine FDT to treat future episodes of allergic rhinitis.

Acknowledgements

We are very grateful to all physicians from Belgium, Mexico and Spain who participated in this study and without whose dedication this survey would not have been possible. The authors thank Steve Clissold PhD, Content Ed Net, Madrid for editorial assistance with the manuscript.

Financial & competing interests disclosure

Josep Fortea, M José Plazas and Sheila Mora are full-time employees of Almirall SA and Maite Artés is a full time employee of Adelphi Targis. This work was funded by

Almirall SA. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Bibliography

1 Lehman JM, Blaiss MS: Selecting the optimal oral antihistamine for patients with allergic rhinitis. *Drugs* 66(18), 2309–2319 (2006).

2 Rosenwasser LJ: Treatment of allergic rhinitis. *Am. J. Med.* 113(Suppl 9A), 17S–24S (2002).

3 Schoenwetter WF: Allergic rhinitis: epidemiology and natural history. *Allergy Asthma Proc.* 21(1), 1–6 (2000).

4 Picado C, Rinitis: Asma bronquial. In: *Medicina Interna*. Farreras, Rozman (Eds). Elsevier, Amsterdam, The Netherlands (2004).

5 Nathan RA: The burden of allergic rhinitis. *Allergy Asthma Proc*. 28(1), 3–9 (2007).

6 Blaiss MS: Quality of life in allergic rhinitis. *Ann. Allergy Asthma Immunol.* 83(5), 449–454 (1999).

7 Bousquet J, Van Cauwenberge P, Khaltaev N; ARIA Workshop Group; World Health Organization: Allergic rhinitis and its impact on asthma. *J. Allergy Clin. Immunol.* 108(5), S147–S334 (2001).

8 Bousquet J, Van Cauwenberge P, Khaled NA *et al.*: Pharmacologic and anti-IgE treatment of allergic rhinitis (ARIA) update (in collaboration with GA2LEN). *Allergy* 61, 1086–1096 (2006).

9 Ratner P, Hampel F Jr, Gispert J: Efficacy of ebastine in the control of nasal congestion associated with allergic rhinitis. *Methods Find. Exp. Clin. Pharmacol.* 25(2), 111–115 (2003).

10 Bousquet J, Gaudaño EM, Palma Carlos AG, Staudinger H: A 12-week, placebo-controlled study of the efficacy and safety of ebastine, 10 and 20 mg once daily, in the treatment of perennial allergic rhinitis. Multicentre Study Group. *Allergy* 54(6), 562–568 (1999).

11 Picado C, Cadahia A, Cistero A *et al.*: Ebastine in perennial allergic rhinitis. *Ann. Allergy* 67(6), 615–618 (1991).

12 Van Cauwenberge P, De Belder T, Sys L: A review of the second-generation antihistamine ebastine for the treatment of allergic disorders. *Expert Opin. Pharmacother.* 5(8), 1807–1813 (2004).

13 Frank H Jr, Gillen M, Rohatagi SS *et al.*: A double-blind, placebo-controlled study of the efficacy and safety of ebastine 20 mg once daily given with and without food in the treatment of seasonal allergic rhinitis. *J. Clin. Pharmacol.* 42(10), 1097–1104 (2002).

14 Ratner P, Falques M, Chuecos F *et al.*: Meta-Analysis of the efficacy of ebastine 20 mg compared with loratadine 10 mg and placebo in the symptomatic treatment of seasonal allergic rhinitis. *Int. Arch. Allergy Immunol.* 138(4), 312–318 (2005).

15 Salva M, Carreño B, Pintos M *et al.*: Phase I, single dose, open-label, randomized, crossover bioequivalence studies of ebastine 10 and 20 mg regular tablets versus 10 and 20 mg fast-dissolving tablets in healthy male volunteers. *J. Invest. Allergol. Clin. Immunol.* 14(4 Suppl. 1), S5 (2004).

16 Atkinson MJ, Sinha A, Hass SL *et al.*: Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease. *Health Qual. Life Outcomes* 2(1), 12 (2004).

17 Scadding GK, Richards DH, Price MJ: Patient and physician perspectives on the impact and management of perennial and seasonal allergic rhinitis. *Clin. Otolaryngol. Allied Sci*. 25(6), 551–557 (2000).

18 Ricard N, Kind P, Christian S *et al.*: Link between patient preferences and treatment outcomes in seasonal allergic rhinitis: an empiric investigation. *Clin. Ther*. 21(1), 268–277 (1999).

19 Juniper EF: Rhinitis management: the patient's perspective. *Clin. Exp. Allergy* 28(Suppl 6), 34–38 (1998).

20 Wild D, Grove A, Martin M *et al.*: Principles of good practice for the translation and cultural adaptation process for Patient-Reported Outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health* 8, 94–104 (2005).

21 Bachert C: Quality of life: improvement due to treatment. *Clin. Exp. All. Rev.* 2, 73–78 (2002).

22 Bousquet J, Lund VJ, van Cauwenberge P *et al.*: Implementation of guidelines for seasonal allergic rhinitis: a randomized controlled trial. *Allergy* 58(8), 733–741 (2003).

23 Marple BF, Fornadley JA, Patel AA *et al.*: Keys to successful management of patients with allergic rhinitis: focus on patient confidence, compliance, and satisfaction. *Otolaryngol. Head Neck Surg.* 136(6 Suppl.), S107–S124 (2007).

24 Meltzer EO: Quality of life in adults and children with allergic rhinitis. *J. Allergy Clin. Immunol.* 108(1 Suppl.), S45–S53 (2001).

25 Atkinson MJ, Kumar R, Cappelleri JC, Hass SL: Hierarchical construct validity of the treatment satisfaction questionnaire for medication (TSQM version II) among outpatient pharmacy consumers. *Value Health* 8(Suppl. 1), S9–S24 (2005).

26 Greisner WA: Onset of action for the relief of allergic rhinitis symptoms with second-generation antihistamines. *Allergy Asthma Proc*. 25(2), 81–83 (2004).

27 Bousquet J: Rapid symptom relief in rhinitis. *Clin. Exp. Allergy* 29(Suppl. 1), 25–29 (1999).

28 Roger A, Fortea J, Artés M, Montilla L: Perception of the onset of action with ebastine in fast dissolving tablet formulation in patients with allergic rhinitis. Presented at: *IV Congreso de Atención Farmacéutica (IV Congress of Pharmaceutical Care)*. Valencia, Spain, 3–5 November 2005.

29 Roger A, J Fortea, M Artés, L Montilla: Preferred attributes of the new fast dissolving tablet (FDT) formulation of ebastine in patients with allergy. *J. Outcomes Res.* 10, 13–22 (2006).

30 Roger A, Fortea J, Artés M, Montilla L: Acceptability and preference of the placebo fast dissolving tablet vs placebo regular tablets of ebastine in consumers of oral antihistamines with allergic rhinitis. *Pharmaceutical Care (Spain)* 7(Special Edition), 157 (2005).

Website

101 AAAAI, The Allergy Report. Accessed October 2007. www.aaaai.org