Pharmacologie médicale
Bordeaux PharmacoEpi
CIC Bordeaux CIC1401

Oralair® real-world treatment pattern from a French cohort study.

P Blin [1], P Demoly [2], M Drouet [3], S Lignot-Maleyran [1], H Maizi [1], S Lorrain [1], R Lassalle [1], C Droz-Perroteau [1], N Moore [1,4] et M Molimard [4,5]

[1] Bordeaux PharmacoEpi, INSERM CIC1401, Université de Bordeaux, Bordeaux, France – [2] CHRU de Montpellier, Montpellier, France – [3] CHU d'Angers, France – [4] INSERM U1219, Bordeaux France – [5] CHU de Bordeaux, Bordeaux, France

Abstract

Background: Allergic rhinitis (AR) has been reported to affect between 20% and 40% of the world population. Oralair® obtained indication for the treatment of grass pollen allergic rhinitis with or without conjunctivitis in adults, adolescents and children (above the age of 5) with clinically relevant symptoms, confirmed by a positive skin test and/or a positive titre of specific grass pollen IgE.
Objectives: The French Health Technology Assessment agency requested a post-authorisation cohort study to describe Oralair® real-world treatment pattern and patients characteristics.
Methods: Patients with an initiation of Oralair® before pollen season in 2015, were included in a cohort study and followed by allergy specialists to the end of the pollen season.
Results: Ninety allergy specialists included 280 adults and 203 children, with a mean age of 33.8 years and 11.8 years at inclusion, 49.6% men and 63.5% boys, age of onset of AR = 15.2 (±10.2) and 4.0 (±2.9) years, 87.1% and 83.7% with conjunctivitis, 41.4% and 34.3% asthma, 87.9% and 85.2% of AR classified as persistent during the year before, 98.6% and 92.6% as moderate-severe (ARIA classification). Overall, all conditions of Oralair® indication were respected for 82.5% of adults and 85.7% of children. A skin test was performed for all patients. Oralair® was started 3-5 months before pollen season for 85.1% of patients and continued during pollen season for most patients with a mean duration of 2.5 months. Treatment was discontinued early (<2 months) in 11.3% of adults and 10.1% of children, generally because of an adverse event (83.7%). At the end of follow-up, AR during pollen season was classified as intermittent for 75.0% of adults and 85.7% of children, and mild severe for 61.8% and 66.0%. The following symptoms reported during the year before were no longer reported during the 2015 pollen season: nasal congestion for 52.6% of patients, rhinorrhoea for 50.1%, repeated sneezing for 48.9%, conjunctivitis for 48.4% and nasal pruritus for 47.8%.
Conclusions: This study shows that the conditions of Oralair® prescriptions by allergy specialists followed the indication recommendations well, and were associated with an improvement of AR severity observed for more than 3 patient out of 5, with a resolution of main previous AR symptoms for about half of the patients.

Conflict of Interest Statement

This study was performed at the request of the French Health Authorities, supported by an unconditional grant from Stallergènes, and supervised by an independent expert Scientific Committee. It was designed, conducted, and analyzed independently by the Bordeaux PharmacoEpi Platform, CIC Bordeaux CIC1401 of the Bordeaux University. This study was registered with the European Medicine agency's EUPAS registry (www.encepp.eu), under study number EUPAS9358. The funder assisted as an observer to all the meetings of the study scientific committee. The funder did not have any role in study protocol, data acquisition, management or analysis.

Background

Allergic rhinitis (AR) has been reported to affect between 20% and 40% of the world population. Oralair® obtained indication for the treatment of grass pollen allergic rhinitis with or without conjunctivitis in adults, adolescents and children (above the age of 5) with clinically relevant symptoms, confirmed by a positive skin test and/or a positive titre of specific grass pollen IgE. The French Health Technology Assessment agency requested a post-authorisation cohort study to describe Oralair® real-world treatment pattern.

Objectives

➢ **Primary objective:**
To describe Oralair® real-world treatment pattern.

➢ **Secondary objectives:**
- To describe characteristics of patients treated with Oralair® ;
- To describe characteristics of prescribing physicians;
- To describe frequency of discontinuation and the reasons for them;
- To describe compliance rate for the treatment;
- To describe frequency of adverse effects.

Method

➢ Prospective cohort study in France conducted by Bordeaux PharmacoEpi platform (Bordeaux, France).
➢ Inclusion by allergy specialists of patients (adults and children) with an initiation of Oralair® before pollen season in 2015.
➢ Follow-up to the end of pollen season.

Results

Characteristics of prescribing physicians and patients

➢ **90 participating physicians**: mean age of 54.2 (± 7.5) years with more of women (sex ratio of 0.55). Liberal activity for more than 95.6% of the physicians. More than 9 about 10 specialists indicating an experience in allergic diseases.

➢ **483 included patients** (280 adults, 203 children). Characteristics of patients and allergic rhinitis are presented in Table 1.

Table 1: Characteristics of patients and rhinitis

	Children n = 203	Adults n = 280	Total n = 483
Gender, n (%)			
Male	129 (63.5)	139 (49.6)	268 (55.5)
Age (years)			
Mean (± SD)	11.8 (3.4)	33.8 (10.9)	24.5 (13.9)
Smoker, n (%)			
Non	200 (98.5)	206 (73.6)	406 (84.1)
Urban area, n (%)	88 (43.3)	167 (59.6)	255 (52.8)
Age at the first allergic rhinitis (years)			
Mean (± SD)	7.8 (3.3)	18.6 (9.9)	14.1 (9.5)
Type of allergic rhinitis, n (%)			
With conjunctivitis	170 (83.7)	244 (87.1)	414 (85.7)
At least one other allergic symptoms, n (%)	113 (55.7)	137 (48.9)	250 (51.8)
Asthma	84 (41.4)	96 (34.3)	180 (37.3)
Eczama	32 (15.8)	30 (10.7)	62 (12.8)
Food allergy	14 (6.9)	16 (5.7)	30 (6.2)
Hives	6 (3.0)	12 (4.3)	18 (3.7)
≥1 specific grass pollen test, n (%)	203 (100.0)	280 (100.0)	483 (100.0)
Skin test, n (%)	200 (98.5)	279 (99.6)	479 (99.2)
Titre of specific grass pollen IgE, n (%)	113 (55.7)	143 (51.1)	256 (53.0)
Onset of allergic rhinitis (years)			
Mean (± SD	4.0 (2.9)	15.2 (10.2)	10.5 (9.7)
Persistence of symptoms* (ARIA classification), n (%)			
Persistent	173 (85.2)	246 (87.9)	419 (86.7)
Severity of allergic rhinitis* (ARIA classification), n (%)			
Moderate-severe	188 (92.6)	276 (98.6)	464 (96.1)

*During the last pollen season (2014)

Allergic rhinitis treatments

➢ Oralair® was started **3-5 months before** pollen season 2015 for 85.1% of patients (82.9% of adults, 88.2% of children).
➢ Mean duration of the treatment of **2.5 months**.
➢ At the first day of the beginning of the pollen season, 88.8% of patients were under Oralair®. This percentage was stable until 45 days then decreased gradually.
➢ Treatment **was discontinued early** (<2 months) in 11.3% of adults and 10.1% of children (generally because of an adverse event (83.7%)).
➢ All conditions of the **Oralair® indication were respected** for 82.5% of adults and 85.7% of children:
- Treatment initiation at least 3 months before pollen season;
- >5 years of age;
- Clinically relevant symptoms;
- Diagnostic confirmed by at least one specific test.

Adverse events and adverse effects

➢ 255 adverse events reported: **25.3%** of the patients with **1 adverse event at least.**
➢ Among the 255 adverse events, 8.1% considered by the physician as linked to Oralair®.
➢ 20.3% of the patients with at least one Adverse Effect (AE), 4 patients reported one severe AE at least (4 expected et 1 unexpected): discontinuation of the treatment as a result, and patient recovers.

Allergic rhinitis symptoms evolution

➢ Between pollen season 2014 and 2015 :
- Allergic rhinitis symptoms were classified **persistent to intermittent** for 67.7 % of patients (64.6% of adults, 71.9 % of children).
- Allergic rhinitis was classified **moderate/severe to mild** for 60.2% of patients (60.4% of adults, 60.1 % of children).
- **Symptoms improvement** for 67.5% (67.9% of adults, 67.0% of children).
- **Symptoms** reported during the year before **no longer reported during** the 2015 pollen season: nasal congestion for 52.6% of patients (56.8% of adults, 46.8% of children), rhinorrhoea for 50.1% (52.1% of adults, 47.3% of children), repeated sneezing for 48.9% (49.3% of adults, 45.8% of children), and conjunctivitis for 48.4% (49.6% of adults, 46.8% of children).

➢ Patients treatment benefits before and after pollen season are described in Figure 1 (A self-administered questionnaire was completed by patients at the inclusion and at the end of the follow-up).

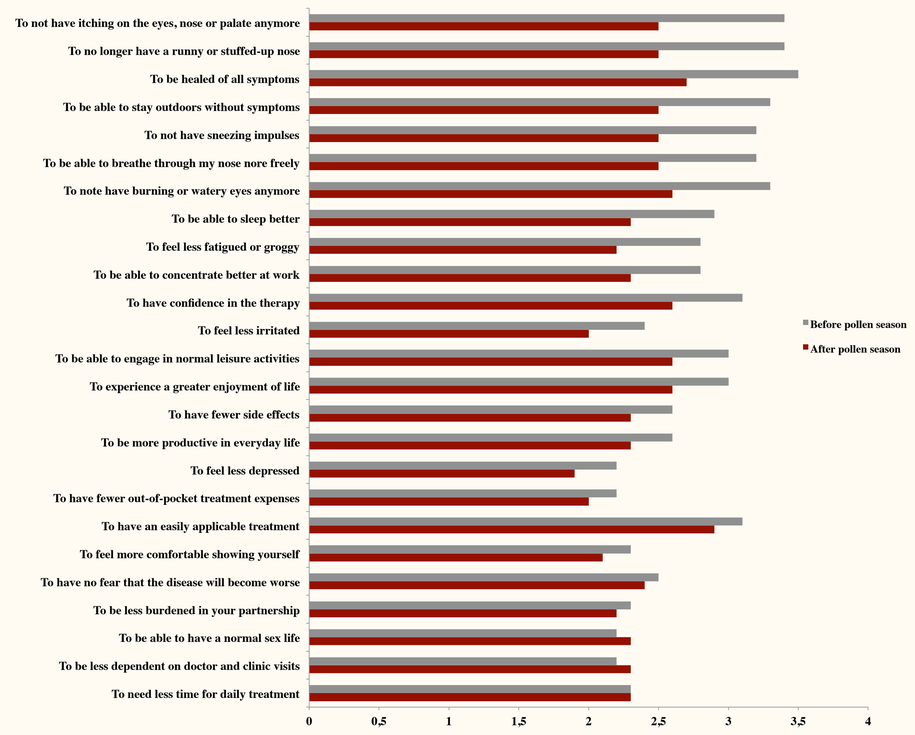

Figure 1: Patients treatment benefits before and after the pollen season

➢ Global score of patient-relevant benefit is presented in Table 2.

Table 2: Global score of patient-relevant benefit

	Children n = 203	Adults n = 280	Total n = 483
Patient Benefit Index (BFI)*			
Number (missing)	193 (10)	263 (17)	456 (27)
Mean (±SD)	2.2 (1.0)	2.3 (0.9)	2.3 (1.0)
Median	2.3	2.4	2.3
[p25% - p75%]	[1.7;3.0]	[1.7;3.1]	[1.7;3.0]
[Min - Max]	[0.0;4.0]	[0.0;4.0]	[0.0;4.0]
Relevant benefit of treatment, n (%)**			
No (BFI < 1)	25 (13.0)	25 (9.5)	50 (11.0)
Yes (BFI ≥ 1)	168 (87.0)	238 (90.5)	406 (89.0)

** BFI is computed by dividing each rating on the need item (Patient needs questionnaire=PNQ) by the sum of all ratings in the PNQ, and multiplying this fraction with the respective benefit rating (Patient Benefit Questionnaire=PBQ). The PFI is the sum of these products and ranges from 0 « No benefit » to 4 « Maximum benefit »;*
*** Among patients with a calculated BFI.*

Conclusion

- **All conditions of Oralair® indication were respected for more than 8 patients about 10 (82.5% of adults and 85.7% of children).**
- **The allergic rhinitis severity is improved for more than 3 patients about 5 (persistent to intermittent for 67.7% and moderate/severe to mild for 60.2%).**