Real-world 5-Grass pollen tablet pattern from a French cohort study

EUROPEAN ACADEMY OF ALLERGY & CLINICAL IMMUNOLOGY

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Disclosure

In relation to this presentation, I declare the following, real or perceived conflicts of interest:

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Revision

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Background

- Allergic rhinitis (AR) reported to affect between 20% and 40% of the world population.

- The studied **5-Grass pollen tablet obtained indication** for the treatment:

  ✓ of grass pollen AR,

  ✓ 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.

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Objectives

- The French Health Technology Assessment agency requested a study.
- **Primary objective** was to describe 5-Grass pollen tablet real-world treatment pattern
- **Secondary objectives** were to describe :
  - ✓ characteristics of patients treated with 5-Grass pollen tablet (sociodemographic and medical data),
  - ✓ characteristics of prescribing physicians,
  - ✓ frequency of discontinuations and the reasons for them,
  - ✓ compliance rate for the treatment,
  - ✓ frequency of adverse effects.

Methods

- **Prospective cohort study** in France conducted by Bordeaux PharmacoEpi plateform (Bordeaux, France).

- Inclusion by allergy specialists of patients (adults and children) with an **initiation of the 5-Grass pollen tablet** before pollen season in 2015.

- **Follow-up** to the end of pollen season.

- **Case Report Forms** completed by the physicians
  - ✓ at the inclusion (before pollen season),
  - ✓ during the follow-up in case of consultation,
  - ✓ at the end of the follow-up (end of pollen season).

- **Self-administered questionnaires** completed by patients
  - ✓ at the inclusion (patient needs questionnaire),
  - ✓ at the end of the follow-up (patient benefit questionnaire).

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Results: Characteristics of prescribing physicians

- 90 participating physicians (inclusion of 1 patient at least in the study period).

- Mean age of 54.2 (± 7.5) years.

- 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.

Results: Characteristics of patients

- 483 included patients (280 adults and 203 children)

	Children n = 203	Adults n = 280	Total n = 483
Male gender, n (%)	129 (63.5)	139 (49.6)	268 (55.5)
Mean age at inclusion, years (±SD)	11.8 (3.4)	33.8 (10.9)	24.5 (13.9)
Non smoker, n (%)	200 (98.5)	206 (73.6)	406 (84.1)
Urban area, n (%)	88 (43.3)	167 (59.6)	255 (52.8)
Mean age at the first allergic rhinitis, years (±SD)	7.8 (3.3)	18.6 (9.9)	14.1 (9.5)
Allergic rhinitis with conjunctivitis, n (%)	170 (83.7)	244 (87.1)	414 (85.7)

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Results: Characteristics of patients (2)

	Children n = 203	Adults n = 280	Total n = 483
At least one other allergic symptom, n (%)	113 (55.7)	137 (48.9)	250 (51.8)
Asthma	84 (41.4)	96 (34.3)	180 (37.3)
Eczema	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	200 (98.5)	279 (99.6)	479 (99.2)
Titre of specific grass pollen IgE	113 (55.7)	143 (51.1)	256 (53.0)
Mean age of onset of allergic rhinitis, years (±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)

Results: Allergic rhinitis treatments

- 5-Grass pollen tablet was started **3-5 months before pollen season** for 85.1% of patients (82.9% of adults and 88.2% of children).

- Treatment continued during pollen season for most patients.

- 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%)).

- **All conditions** of the 5-Grass pollen tablet indication **were respected** for 82.5% of adults and 85.7% of children:

  ✓ treatment initiation at least 3 months before pollinic season,
  ✓ >5 years of age,
  ✓ clinically relevant symptoms,
  ✓ diagnostic confirmed by at least one specific test.

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Results: 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 the studied 5-Grass pollen tablet.

- 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.

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Results: Allergic rhinitis symptoms evolution

Between pollen season 2014 and 2015:

- Persistent symptoms ➔ **intermittent symptoms**: 64.6% of adults, 71.9% of children.

- Moderate-severe AR ➔ **mild AR**: 60.4% of adults, 60.1% of children.

- **Symptoms improvement** for 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 56.8% of adults, 46.8% of children,

  ✓ rhinorrhea: for 52.1% of adults, 47.3% of children,

  ✓ conjunctivitis: for 49.6% of adults, 46.8% of children,

  ✓ repeated sneezing: for 49.3% of adults, 45.8% of children.

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Results: Patients treatment benefits
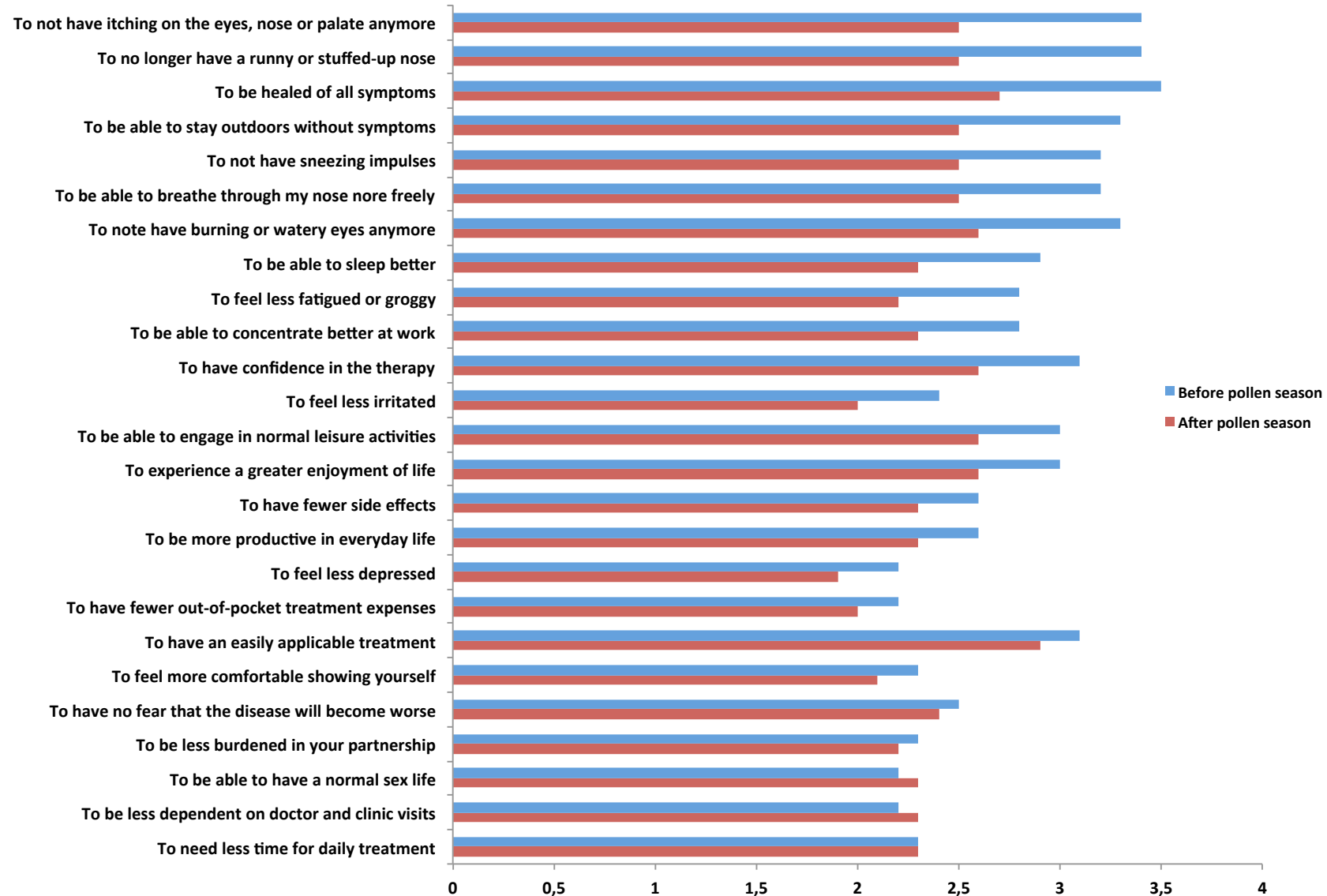
Results: Global score of patient-relevant benefit

	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.

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Conclusion

This study shows that:

- **All conditions** of the 5-Grass pollen tablet 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%).

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