

MANAGEMENT OF PATIENTS WITH ALLERGIC RHINITIS IN THE PRIMARY CARE SETTING: A CROSS-SECTIONAL MULTICENTER STUDY IN DAILY PRACTICE (THE MAPRAP STUDY)

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ABSTRACT

Introduction: Allergic rhinitis (AR) is a highly prevalent disease with a great impact on quality of life. The aim of the study was to assess the management of AR in the primary care setting in Spain.

Material and methods: A total of 248 primary care physicians participated in a multicenter cross-sectional survey study and completed a 23-item ad hoc questionnaire.

Results: Ninety-three percent of the participants had more than 10 years of professional experience, excluding residency training. There was consensus in terms of diagnostic criteria: severity according to ARIA criteria (94.3%) and persistent AR if symptoms are present for more than 4 days/week and more than 4 weeks (94.8%). A total of 71.8% had difficulties identifying criteria for referral to specialized care. More than 90% considered that undertreatment was common, 54.5% recognized that their knowledge of the different treatment modalities of AR was insufficient, and 83% stated that management of patients with AR and asthma was difficult. Scientific evidence of efficacy and safety and the prescription of a drug that facilitates adherence were the characteristics with the highest scores in order of importance. Follow-up should be performed by primary care physicians (92%) or by a multidisciplinary team formed by primary care professionals and specialists at the hospital (88.4%).

Conclusions: Patients with AR are adequately managed in primary care but general training deficiencies have been recognized, especially with regard to the combination of AR and asthma. A consensus document defining the criteria for referral of patients with RA to specialists in the hospital should be developed.

Keywords: Allergic rhinitis, primary care, delphi method, asthma.

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Introduction

Rhinitis is an inflammatory process of the nasal mucosa, mediated by anti-IgE antibodies, characterized by anterior or posterior rhinorrhea, sneezing, nasal congestion, itching and/or stinging in the nose. These symptoms must last for two or more consecutive days for more than one hour on most days⁽¹⁾. Allergic rhinitis (AR) is a phenotype of rhinitis and it is one of the most prevalent chronic diseases. In a meta-analysis of 31 studies with more than one million children from 0 to 18 years of

age and from 102 countries, the prevalence of AR was 12.7%⁽²⁾. In the observational, epidemiologic study Alergológica-2005, performed on a sample of 4,991 allergic patients treated by 340 Allergy specialists in Spain, 55.5% of the patients who consulted allergology services for the first time were diagnosed with AR, of whom 65% also had conjunctivitis and 37% asthma⁽³⁾. However, in the Alergológica-2015 study in a population of 2,914 patients, the prevalence of AR was 62%, which represented a significant increase in rhinitis as the reason for consultation compared to previous

data over a 10-year period⁽⁴⁾. AR can be classified according to the seasonal criterion as intermittent or perennial (symptoms present ≤ 4 or >4 days per week for ≤ 4 or >4 consecutive weeks, respectively)⁽⁵⁾, or by severity as mild, moderate and severe, based on the impact on different areas of quality of life according to the modified ARIA classification (m-ARIA)⁽¹⁾ (sleep disorder, disturbance of daily life, sport and leisure activities, and perception of the symptoms as troublesome)^(1, 6). The costs of AR are also high. In a prospective, multicenter, observational study (the FERIN study) of a random sample of AR patients attending allergy outpatient clinics in 101 health centers throughout Spain over 12 months, the cost per patient-year was €2326.70 (direct, €553.80; indirect, €1772.90)⁽⁷⁾. To reduce the impact of AR on patients^(8, 9), as well as on the healthcare system and society, it is essential to improve the understanding and management of this disease to determine the most appropriate treatment, achieve the maximum number of patients with complete recovery, especially in more complex cases of AR associated with rhinosinusitis or asthma^(3, 4, 10) and to reduce the number of cases of chronic rhinosinusitis^(11, 12). To this end, a cross-sectional, multicenter study was carried out with the primary objective of providing updated information on the management of AR in primary care consultations in Spain.

Materials and methods

Study design

A qualitative, cross-sectional, multicenter, non-randomized, survey-based, qualitative study (MAPRAP study) was designed in the setting of primary care consultations in clinics in Spain. MAPRAP is the acronym of Manejo del Paciente con Rinitis Alérgica en atención Primaria (Management of Patients with Allergic Rhinitis in Primary Care). The primary objective was to study the management of AR in primary care consultations and the secondary objective was to develop consensus recommendations regarding different aspects related to diagnosis, referral criteria, treatment, follow-up, and training needs. The study was based on the Delphi method with two rounds of responses and was conducted over 3 months (the first round from May through June 2019 and the second during the month of September the same year). Since no patient data were collected, the study did not need to be submitted to a clinical research ethics committee and was exempt from the requirement for informed consent.

Participants and procedures

To carry out the study, a scientific committee was established with two specialists, one in Allergology and the other in Family and Community Medicine, with extensive experience in the management of patients with AR in their professional practice. The members of the scientific committee were charged with collaborating in the development of the protocol and the creation of an ad hoc questionnaire. They also coordinated and supervised the conduct and progress of the study, including the review of the results and data analysis. The final questionnaire included 23 items, including the classification of AR (2 items), diagnosis (3 items), referral criteria (2 items), treatment (12 items), current status of AR management (2 items), training needs of specialists (1 item), and follow-up (1 item).

The questions were formulated to be answered on a 5-point Likert scale, including 1 = strongly disagree, 2 = partially disagree, 3 = indifferent, 4 = partially agree, and 5 = strongly agree. It was considered that consensus existed when more than 75% of the participants partially or totally agreed or partially or totally disagreed. In addition, data were collected on the investigator's sociodemographic characteristics, years of practice, participation in research projects, type of health center, and the number of patients seen.

Inclusion criteria were physicians working in primary care who routinely treated patients with AR and who provided care in public and private clinics located nationwide. Participants working in primary care with experience in AR were recruited by means of an invitation leaflet, which detailed the characteristics of the study and provided them with the URL of the platform that included the study questionnaire and the user password. Consent to participate in the study was requested when accessing the questionnaire. Participation was anonymous and voluntary.

Statistical analysis

Since this was a qualitative rather than a quantitative study, the number of researchers selected was not determined based on the probabilistic error^(13, 14). The descriptive analysis of the data included the description of frequencies and percentages for categorical variables and the mean and standard deviation (SD) for quantitative variables. Notwithstanding the ordinal nature of the 5-point Likert scale, in order to facilitate the visual comparison of the various questions in each round

the numerical scores were analyzed by calculating the mean values with 95% confidence intervals (95% CI) for each item. Paired t-tests were used to measure changes in responses between the two rounds.

The continuous variables were compared using Student's t-test for paired data, and the categorical variables using the McNemar or Bowker tests. In addition, it was decided to perform a subanalysis of the data according to the characteristics of the place of work (public or private) and the autonomous communities with the greatest participation. A statistical significance level of 0.05 was accepted. The data were analyzed with the SAS statistical program (Statistical Analysis Systems, SAS Institute, Cary, NC, USA) version 9.1.3 for Windows.

Results

A total of 248 primary care physicians participated in the study, 182 men and 66 women, with a mean (SD) age of 54.5 (8.9) years, from across the country. Catalonia (22.2%), Madrid (16.9%), and Andalusia (14.5%) were the most represented autonomous communities. A total of 93.6% of the participants had more than 10 years of experience in professional practice, excluding the residency training stage. In the last 12 months, 14.1% had taken part in an AR training program and only 2.4% were participating or had participated in a research project on AR. A total of 90.7% were working in urban areas (>15,000 inhabitants). A total of 63% of the participants worked in a private clinic and only 35% in a public clinic, although no differences were detected between them.

With respect to the number of patients seen in the previous week, 61.7% had seen more than 150 patients, and between 2% and 10% of those seen had AR according to 62.1% of the participants and between 11% and 25% according to 32.3%. There were no significant differences between the groups of physicians in public and private practice.

Classification and diagnosis of AR

To assess the control of symptoms and severity, the option of using only symptom intensity was the most frequent (n=130, 52.4%).

Of the 68 participants (27.4%) who reported using scales, the ARIA (Allergic Rhinitis and its Impact on Asthma) scale was the most used (n = 48, 70.5%). For the classification of AR, the mean score was 4.6 (95% CI 3⁽¹⁻⁶⁾). There was consensus in terms of diagnostic criteria: severity according to

the aspects affected (94.3%) and persistent AR if it lasts >4 days/week and >4 weeks (94.8%). In the 15 questions referring to diagnosis, there was consensus in favor of agreement on all the questions posed, with percentages varying between 74.6% (for the item "in patients with AR, the presence of headaches is frequent") and 97.2% (for the item "in the diagnosis of AR, a good anamnesis, seasonality and the pattern of onset can be used") (Table 1). When the numerical scores were analyzed by calculating mean values with the 95% CI, the mean scores for the section on the diagnosis ranged from 3.9 (95% CI 1.8-5.9) to 4.8 (95% CI 3.7-5.9).

Questionnaire items	Agree ^a n (%)	Indifferent ^a n (%)	Disagree ^a n (%)
1. In patients with moderate/severe rhinitis, the presence of asthma should be ruled out	234 (94.3)	3 (1.2)	11 (4.4)
2. In Primary Care, the combination of ASTHMA and allergic rhinitis is common, although it is not usually considered for its diagnosis and management	196 (79.1)	5 (2.0)	47 (19.0)
3. The presence of food allergy is frequent in patients with allergic rhinitis	193 (77.8)	42 (16.9)	13 (5.2)
4. Many patients with allergic rhinitis have an associated dry cough, even if asthma is not detected	227 (91.5)	8 (3.2)	13 (5.2)
5. Early diagnosis of allergic rhinitis is essential since its management varies significantly depending on the intensity and duration of exposure to the allergen responsible	239 (96.3)	2 (0.8)	7 (2.8)
6. The concurrence of nasal and ocular symptoms makes the diagnosis of allergic rhinitis more likely	237 (95.6)	3 (1.2)	8 (3.2)
7. A family history of allergy makes the diagnosis of allergic rhinitis more likely	225 (90.7)	13 (5.2)	10 (4.0)
8. The presence of seasonal symptoms is a clinical finding of high diagnostic value in allergic rhinitis	240 (96.8)	2 (0.8)	6 (2.4)
9. In patients with allergic rhinitis, the presence of headaches is common	185 (74.6)	34 (13.7)	29 (11.7)
10. Daytime drowsiness is an additional problem, which should be assessed in patients with allergic rhinitis	202 (81.4)	28 (11.3)	18 (7.2)
11. The use of diagnostic imaging techniques is of little value in allergic rhinitis	197 (79.4)	19 (7.7)	32 (12.9)
12. In the diagnosis of AR, we can use a thorough anamnesis: family and personal history	241 (97.2)	1 (0.4)	6 (2.4)
13. In the diagnosis of AR, we can use seasonality and the pattern of onset	241 (97.2)	1 (0.4)	6 (2.4)
14. In the diagnosis of AR, we can use associated symptoms (itchy eyes)	238 (96.0)	3 (1.2)	7 (2.8)
15. We can use triggers in the diagnosis of AR	237 (95.6)	3 (1.2)	8 (3.2)

Table 1: Diagnosis of allergic rhinitis (AR).

^aLikert scale score 4-5: agree, 3: indifferent, 1-2: disagree.

Referral criteria

There was consensus that it would be helpful to have a consensus document that clearly defines the criteria for referral of allergic rhinitis from primary care consultations (87.5%), as well as to increase the number of check-ups until symptom control is

achieved (82.2%), increase doses (81.5%), switch to another drug (86.7%), combine drugs (93.2%), and refer to a specialized consultation (84.7%) in AR that is poorly controlled in primary care.

There was no consensus (71.8%) about the statement that they sometimes felt it was difficult to identify criteria for referral of patients with AR from primary care. The mean scores ranged from 3.6 (95% CI 2.1-5.2) to 4.5 (95% CI 3.1-5.8).

Treatment

The results obtained in this section of the questionnaire are described in Table 2. There was consensus on most questions. No agreement was reached on the following items: the existence of overtreatment in the absence of severity criteria (72.9%), the consideration of whether patients are receiving appropriate treatment (71.3%), I would like to explain if I had more time to do so (67.7%), and the options for prescribing drugs may vary according to the autonomous communities (61.3%).

Among the barriers to prescription, no consensus was reached on the presence of insufficient knowledge of the various treatments (54.4%) and lack of time in primary care consultations (54.4%). The participants also disagreed that they were unfamiliar with the technique of nasal spray use (70.2%), that the patient's opinion was of little relevance when prescribing a treatment (68.5%), and that working conditions did not allow the patient's preferences to be considered (68.5%). Although mention was made of the variability in prescribing among physicians in the different autonomous communities, there were no significant differences in the percentages of responses between physicians in Catalonia, Madrid, or Andalusia ($P=0.145$). The scientific evidence of efficacy and safety, the prescription of a drug that facilitates patient compliance, and experience of personal use were the characteristics with the highest scores in order of importance (Figure 1). In the treatment block, the mean score ranged from 1.4 (95% CI 1-3.1) to 4.9 (95% CI 4.1-5.6).

Current status of AR management and training needs

The participants concurred that the management of mild/moderate and moderate/severe AR in primary care was adequate and that it was more complicated to manage patients with AR and associated asthma (Figure 2). The mean score for this block was 3.9 (95% CI 2.6-5.3). As regards training needs, there was a broad consensus ($n=233$, 94%) that new

training programs were needed to manage patients with AR more efficiently in primary care.

Questionnaire items	Agree* n (%)	Indifferent* n (%)	Disagree* n (%)
1. There is an observable proportion of patients with allergic rhinitis who are overtreated despite not meeting the severity criteria	181 (72.9)	21 (8.5)	46 (18.5)
2. There is an observable proportion of patients with allergic rhinitis who are undertreated despite meeting the severity criteria	226 (91.1)	11 (4.4)	11 (4.4)
3. I believe that, in general, patients are receiving adequate treatment	177 (71.3)	25 (10.1)	46 (18.5)
4. The use of combined treatment in certain patients with allergic rhinitis in primary care could lead to greater compliance by rapidly improving their symptoms	242 (97.6)	4 (1.6)	2 (0.8)
5. The use of combination therapy in selected patients with allergic rhinitis in primary care may be a cost-effective measure	231 (93.1)	12 (4.8)	5 (2.0)
6. I explain the correct nasal spray technique to my patients	230 (92.8)	8 (3.2)	10 (4.0)
7. I am not very familiar with the application technique of nasal sprays	64 (25.8)	10 (4.0)	174 (70.2)
8. I consider it unnecessary to give explanations	22 (8.8)	7 (2.8)	219 (88.4)
9. If I had more time, I would like to give an explanation	168 (67.7)	33 (13.3)	47 (18.9)
10. The choice of treatment in AR should be made according to the severity and/or duration of symptoms	194 (78.2)	3 (1.2)	51 (20.6)
11. The mainstays of AR treatment are based on avoiding trigger factors	244 (98.4)	0	4 (1.6)
12. The mainstays of AR treatment are based on pharmacological management	244 (98.4)	2 (0.8)	2 (0.8)
13. The mainstays of AR treatment are based on educating patients about their condition and treatment	244 (98.4)	3 (1.2)	1 (0.4)
14. The mainstays of AR treatment are based on immunotherapy	187 (75.4)	41 (16.5)	20 (8.1)
15. I believe that the primary care physician's options for prescribing drugs for allergic rhinitis may vary in different autonomous communities	152 (61.3)	74 (29.8)	22 (8.8)
16. When prescribing a treatment according to the patient's characteristics, I take the possibility of pregnancy into consideration	239 (96.4)	5 (2.0)	4 (1.6)
17. When prescribing a treatment according to the patient's characteristics, I take the associated comorbidities into consideration	245 (98.8)	1 (0.4)	2 (0.8)
18. When prescribing a treatment according to the patient's characteristics, I take the patient's age into consideration	212 (85.5)	26 (10.5)	10 (4.0)
19. When prescribing a treatment according to the patient's characteristics, I take polymedicated patients into consideration	232 (93.5)	10 (4.0)	6 (2.4)
20. When prescribing a treatment according to the patient's characteristics, I take the clinical response to previous treatments into consideration	246 (99.2)	1 (0.4)	1 (0.4)
21. When prescribing a treatment according to the patient's preferences, I take his/her occupation into consideration	229 (92.3)	13 (5.2)	6 (2.4)
22. When prescribing a treatment according to the patient's preferences, I take his/her lifestyle into consideration	218 (87.9)	24 (9.7)	6 (2.4)
23. When prescribing a treatment according to the patient's preferences, I take his/her leisure activities into consideration	211 (85.1)	30 (12.1)	7 (2.8)
24. When prescribing a treatment, I consider the patient's preferences to be of little relevance	64 (25.8)	14 (5.6)	170 (68.5)
25. When prescribing a treatment, my working conditions prevent me from taking the patient's preferences into consideration	58 (23.4)	20 (8.1)	170 (68.5)
26. Topical intranasal corticosteroids are highly effective and are considered the first line of treatment in moderate/severe AR	196 (79.0)	3 (1.2)	49 (19.8)
27. One of the barriers to prescribing is insufficient knowledge of the various treatments for AR among primary care physicians	135 (54.4)	18 (7.3)	95 (38.3)
28. One of the barriers to prescribing is the price of this type of treatment for AR	195 (78.6)	26 (10.5)	27 (10.9)
29. One of the barriers to prescribing is therapeutic inertia	225 (78.6)	24 (9.7)	29 (11.7)
30. One of the barriers to prescribing is the lack of time in primary care consultations	135 (54.4)	40 (16.1)	73 (29.4)
31. Educating the patient to avoid exposure to allergens helps control AR	223 (90.0)	0	25 (10.0)
32. Patients who go directly to the pharmacy for over-the-counter treatment often fail to adequately assess the severity of their AR	221 (89.1)	1 (0.4)	26 (10.5)

Table 2: Treatment of allergic rhinitis (AR).

*Likert scale score 4-5: agree, 3: indifferent, 1-2: disagree.

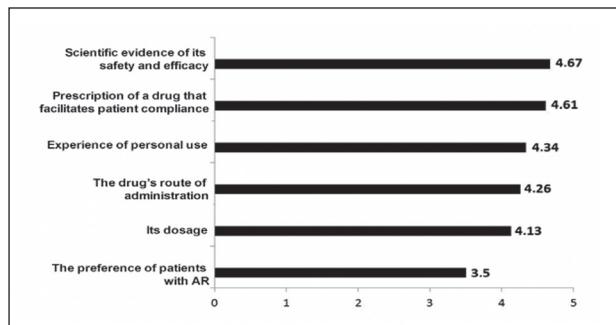


Figure 1: Characteristics that influence the prescription of one type of treatment over another in allergic rhinitis in primary care (1: least important, 5: most important).

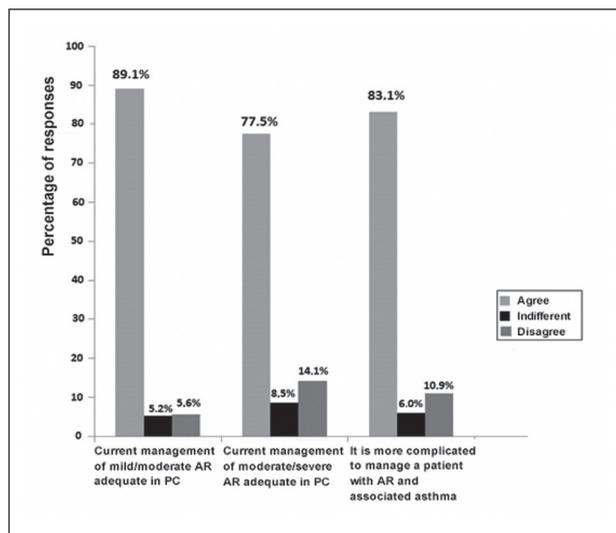


Figure 2: Current status of the management of allergic rhinitis in the primary care setting in Spain.

Post-treatment follow-up

In the four questions in this block (Table 3), there was consensus in two, specifically that follow-up should be carried out by primary care physicians (92.0%) or by a multidisciplinary team that included primary care physicians and hospital specialists (88.4%). The mean for these questions was 4.4 (95% CI 3.0-5.8). Follow-up by allergists or otolaryngologists only met with agreement in 41.1% and 20.2% of the cases, respectively. The mean scores were 3.0 (95% CI 1.24-4.75) and 2.6 (95% CI 1.1-4.1), respectively.

Questionnaire items	Agree* n (%)	Indifferent* n (%)	Disagree* n (%)
Follow-up should be carried out by:			
Primary care physicians	228 (92.0)	13 (5.2)	7 (2.8)
Allergists	169 (41.1)	35 (16.5)	44 (42.3)
Otorhinolaryngologists	115 (20.2)	53 (21.4)	80 (58.9)
A multidisciplinary team including primary care physicians in coordination with hospital specialists	219 (88.3)	12 (4.8)	17 (6.8)

Table 3: Post-treatment follow-up.

*Likert scale score 4-5: agree, 3: indifferent, 1-2: disagree.

Discussion

This multicenter study conducted on a large sample of 248 primary care professionals representing all the autonomous communities presents current data on the challenges of managing patients with AR in daily practice. It is of note that more than 93% of the participants had more than 10 years of experience in professional practice, but with no specific interest in AR or recent training in this condition, which avoids the information bias derived from a collective of both experts and non-experts. Ninety-one percent of the participants worked in urban areas, so the results obtained might vary with a greater representation of rural areas.

Furthermore, the professionals were assigned large quotas of patients (62% had seen more than 150 patients in the previous week), although only 2-10% consulted for AR. The diagnostic criteria for AR were satisfactory and slightly more than half of the professionals used symptom intensity to assess the severity of AR. The ARIA scale was the most widely used method, with scant representation of the visual analog scale (VAS) (only 8%), despite it being an accurate, simple, and reproducible tool. In patients categorized according to the ARIA guidelines⁽¹⁾, several studies have described VAS cut-off points lower than 5 and higher than 6 to classify the severity of mild and moderate/severe AR, respectively^(15, 16). There was consensus on increasing doses, switching to another drug, increasing check-ups, and referral for a specialized consultation in the absence of response to treatment. It should be noted that the participants concurred on the need for a consensus document that explicitly defines the criteria for referral to specialists, mainly allergology and/or otorhinolaryngology specialists. Improving the referral system between the different levels makes it possible to organize and structure the whole care process for patients with AR in order to maintain continuity of care⁽¹⁷⁾.

More than 90% of the participants believed that there is a notable percentage of undertreated AR patients. This opinion coincides with data from previous studies. In a random sample of 10,877 Danish individuals between 14 and 44 years of age, 1,149 manifested symptoms of asthma or rhinitis, of which 50% of asthmatics and 83% of subjects with moderate/severe rhinitis were undertreated⁽¹⁸⁾. In a sample of 166 school-aged children with asthma and rhinitis, only 33% received adequate treatment for their rhinitis⁽¹⁹⁾. Moreover, inadequate treatment

of AR is a risk factor for comorbidity, including the development of asthma^(20, 21). In this regard, 83% of the participants considered it complicated to manage a patient with AR and asthma.

With respect to nasal sprays, the participants reported problems with delivery techniques; they also believe it is necessary to instruct the patient but they do not have the necessary time and, in addition, they themselves are not very familiar with the techniques. It has also highlighted the shortage of time in general and to explain the correct handling of nasal devices, as well as to consider the patient's preferences when agreeing on the treatment. More than 50% of the participants acknowledged having insufficient knowledge about the various treatments, indicating the need for training on the treatment of AR in the primary care setting. When it came to selecting the treatment, what the physicians valued most was the scientific evidence regarding efficacy and safety and that it would facilitate patient compliance. For patient follow-up, there was agreement that it should be carried out by primary care physicians or by a multidisciplinary team comprising primary care physicians and hospital specialists. There was no agreement regarding the role of the allergist or otorhinolaryngologist in the exclusive follow-up.

These results should be interpreted with certain limitations in mind, especially the fact that the selection of the participants was not random, which compromises the representative nature of the participants with respect to the collective of primary care physicians in the country. The aim of the survey was to provide information on the current management of AR in daily practice in the primary care setting. Despite the inherent limitations of information based on the opinion of the physicians surveyed and the strength of the Delphi method used, the availability of such information is important for designing effective strategies to improve the long-term outcomes of patients with AR. It should be noted that surgical aspects (e.g. decongestion of hypertrophic turbinates) were not evaluated. In this respect, radiofrequency turbinate reduction is an effective treatment option in patients suffering from turbinated hypertrophy in association with Eustachian tube dysfunction⁽²²⁾.

Conclusions

This study, based on a survey of primary care physicians using the Delphi method on different relevant aspects of the management of AR, provides

a cross-sectional view regarding the perception of a significant group of professionals in our setting of one of the most prevalent conditions, which has a great impact on quality of life and a high economic cost. It should be emphasized that patients with AR are well-managed in the primary care setting.

At the same time, there is a lack of training in general, but especially in patients with both AR and asthma. The availability of a consensus document defining the referral criteria would be of great help, as would an increase in training activities on the treatment of AR in primary care.

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Conflict of interest:

CCS has acted as a consultant for Mylan and AstraZeneca; received lecture fees from AstraZeneca, GSK, Mylan, and MSD; and benefited from research or training grants from Roxall, Novartis, AstraZeneca, and Sanofi. ETC has received lecture fees from AstraZeneca, GSK, and Esteve.

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