The Allergic Rhinitis and its Impact on Asthma (ARIA) score of allergic rhinitis using mobile technology correlates with quality of life

The MASK study

Bousquet, J; Arnavelhe, S; Bedbrook, A; Fonseca, J; Morais Almeida, M; Todo Bom, A; Annesi-Maesano, I; Caimmi, D; Demoly, P; Devillier, P; Siroux, V; Menditto, E; Passalacqua, G; Stellato, C; Ventura, M T; Cruz, A A; Serpa, F S; da Silva, J; Larenas-Linnemann, D; Rodriguez Gonzalez, M; Cabañas, M T Burguete; Bergmann, K C; Keil, T; Klimek, L; Mösges, R; Shamai, S; Zuberbier, T; Bewick, M; Price, D; Ryan, D; Sheikh, A; Anto, J M; Mullol, J; Valero, A; Haahtela, T; Valovirta, E; Fokkens, W J; Kuna, P; Samolinski, B; Bindslev-Jensen, C; Eller, E; Bosnic-Anticevich, S; O’Hehir, R E; Tomazic, P V; Yorgancioglu, A; Gemicioglu, B; Bachert, C; Hellings, P W; Kull, I; Melén, E; MASK study group

Published in:
Allergy

DOI:
10.1111/all.13307

Publication date:
2018

Document version:
Accepted manuscript

Citation for published version (APA):

Go to publication entry in University of Southern Denmark's Research Portal

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The ARIA score of allergic rhinitis using mobile technology correlates with quality-of-life: The MASK study

J Bousquet, MD (1, 2), S Arnavielhe, PhD (3), A Bedbrook, BSc (1), J Fonseca, MD (4), M Morais Almeida, MD (5), A Todo Bom, MD (6), I Annesi-Maesano, PhD (7), D Caimmi, MD (8), P Demoly, MD (8), P Devillier, MD (9), V Siroux, PhD (10), E Menditto, PhD, (11), G Passalacqua, MD (12), C Stellato, MD (13), M T Ventura, MD (14), AA Cruz, MD (15), FS Serpa, MD, (16) J da Silva, MD, (17) D Larenas-Linnemann, MD, (18) M Rodriguez Gonzalez, MD, (19) MT Burguete Cabañas, MD, (20), KC Bergmann, MD (21), T Keil, MD (22), L Klimek, MD (23), R Mösges, MD (24), S Shamai, MD, (24) T Zuberbier, MD (21), M Bewick, MD, (25), D Price, MD (26), D Ryan, MD (27), A Sheikh, MD (28), JMAnto, MD (29), J Mullol, MD (5), A Valero, MD (30), T Haashtela, MD (31), E Valovirta, MD (30), WJ Fokkens MD, (32), P Kuna, MD (33), B Samolinski, MD, C Bindslev-Jensen, MD (34), E Eller, MD (34), S Bosnic-Anticevich, PhD (35), RE O’Hehir MD, (36), PV Tomazic, MD (37), A Yorgancioglu, MD, (38) B Gemicioglu, MD, (39), C Bachert, MD (40), PW Hellings, MD (41), I Kull, PhD, (42), E Melén, MD (42), M Wickman, MD (43), M van Eerd (44), G De Vries, PhD (44), and the MASK study group

1. MACVIA-France, Contre les MAladies Chroniques pour un Vieillissement Actif en France European Innovation Partnership on Active and Healthy Ageing Reference Site, Montpellier, France.
2. INSERM U 1168, VIMA : Ageing and chronic diseases Epidemiological and public health approaches, Villejuif, Université Versailles St-Quentin-en-Yvelines, UMR-S 1168, Montigny le Bretonneux, France
4. Center for Health Technology and Services Research- CINTESIS, Faculdade de Medicina, Universidade do Porto; and Allergy Unit, CUF Porto Instituto & Hospital, Porto, Portugal.
5. Allergy Center, CUF-Descobertas Hospital, Lisboa, Portugal.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/all.13307
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6. Imunoalergologia, Centro Hospitalar Universitário de Coimbra and Faculty of Medicine, University of Coimbra, Portugal.


8. CHRU de Montpellier, Sorbonne Universités, UPMC Paris 06, UMR-S 1136, IPLESP, Equipe EPAR, F-75013 Paris, France.

9. Laboratoire de Pharmacologie Respiratoire UPRES EA220, Pôle des Maladies Respiratoires, Hôpital Foch, Suresnes Université Versailles Saint-Quentin, France.

10. INSERM, Université Grenoble Alpes, IAB, U 1209, Team of Environmental Epidemiology applied to Reproduction and Respiratory Health, Université Joseph Fourier, Grenoble, France.

11. CIRFF, Center of Pharmacoeconomics, University of Naples Federico II, Naples, Italy.

12. Personalized Medicine Clinic Asthma & Allergy, Humanitas University, Humanitas Research Hospital, Rozzano, Milan, Italy.

13. Department of Medicine, Surgery and Dentistry "Scuola Medica Salernitana", University of Salerno, Salerno, Italy.

14. University of Bari Medical School, Unit of Geriatric Immoallergology, Bari, Italy.

15. ProAR – Nucleo de Excelencia em Asma, Federal University of Bahia, Brasil and GARD Executive Committee, Brazil.

16. Asthma Reference Center, Escola Superior de Ciencias da Santa Casa de Misericordia de Vitoria, Brazil.

17. Allergy Service, University Hospital of Federal University of Santa Catarina (HU-UFS), Florianopolis, Brazil.

18. Center of Excellence in Asthma and Allergy, Hospital Médica Sur, México, Mexico.

19. Mexico City, Mexico.

20. Centro Médico Zambrano Hellion, Monterrey, Mexico.

21. Comprehensive Allergy-Centre-Charité, Department of Dermatology and Allergy, Charité - Universitätsmedizin Berlin; Global Allergy and Asthma European Network (GA²LEN), Berlin, Germany.

22. Institute of Social Medicine, Epidemiology and Health Economics, Charité - Universitätsmedizin Berlin, Berlin, and Institute for Clinical Epidemiology and Biometry, University of Wuerzburg, Germany.

23. Center for Rhinology and Allergology, Wiesbaden, Germany.

24. Institute of Medical Statistics, Informatics and Epidemiology, Medical Faculty, University of Cologne, Germany.

25. iQ4U Consultants Ltd, London, UK.

26. Observational and Pragmatic Research Institute, Singapore, Optimum Patient Care, Cambridge, UK, and Academic Centre of Primary Care, University of Aberdeen, Aberdeen, UK.

27. Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, UK.

28. Director, Asthma UK Centre for Applied Research, Centre of Medical Informatics, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Edinburgh, UK.

29. ISGloBAL, Centre for Research in Environmental Epidemiology (CREAL), Barcelona; IMIM (Hospital del Mar Research Institute); CIBER Epidemiología y Salud Pública (CIBERESP), & Universitat Pompeu Fabra (UPF), Barcelona, Spain.

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Short title: Quality of life in rhinitis using a mobile application

Funding source

Unrestricted educational grant from Meda, European Union Development and Structural funds (Région Languedoc Roussillon), MACVIA-LR
Corresponding author

Professor Jean Bousquet

CHU Montpellier, 371 Avenue du Doyen Gaston Giraud, 34295 Montpellier Cedex 5, France   Tel +33 611 42 88 47   jean.bousquet@orange.fr

Abstract

Mobile technology has been used to appraise allergic rhinitis control but more data are needed. In order to better assess the importance of mobile technologies in rhinitis control, the ARIA (Allergic Rhinitis and its Impact on Asthma) score ranging from 0 to 4 of the Allergy Diary was compared with EQ-5D (EuroQuol) and WPAI-AS (Work Productivity and Activity Impairment in allergy) in 1,288 users in 18 countries. This study showed that quality-of-life data (EQ-5D visual analogue scale and WPAI-AS Question 9) are similar in users without rhinitis and in those with mild rhinitis (scores 0-2). Users with a score of 3 or 4 had a significant impairment in quality-of-life questionnaires.

Key words: rhinitis, EQ-5D, ARIA, MASK, WPAI-AS

Abbreviations

AHA: Active and Healthy Aging
AR: allergic rhinitis
ARIA: Allergic Rhinitis and its Impact on Asthma
EIP on AHA: European Innovation Partnership on Active and Healthy Ageing (DG CONNECT, DG Santé)
EQ-5D: EuroQuol
ICT: information and communications technology
MACVIA: Contre les MALadies Chroniques pour un VIellissement Actif
MASK: MACVIA-ARIA Sentinel NetworK
MAFEIP: Monitoring and assessment framework for the EIP on AHA
QOL: Quality of life
Q9: Question 9 of WPAI-AS
SF-36: Short Form 36 questions

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VAS: visual analogue scale

WPAI-AS: Work Productivity and Activity Impairment in allergy

Introduction

Measures of allergic rhinitis (AR) control include symptom scores, patients’ self-administered visual analogue scales (VAS), objective measures of nasal obstruction, a recent modification of the ARIA severity classification, or patients’ reported outcomes such as QOL or scores with several items (1, 2). Mobile technology has been used to appraise AR control (3, 4). More information is however needed to fully understand the importance of these novel approaches.

MASK-rhinitis (MACVIA-ARIA Sentinel NetworK for allergic rhinitis), an ICT system centred around the patient (5), is one of the implementation tools of the B3 Action Plan of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) (6). A mobile phone app (Allergy Diary) central to MASK-rhinitis belongs to the Fondation Partenariale FMC VIA-LR (Ministry of Education and Research, France). App users are asked to complete a short demographic questionnaire, EQ-5D (7-10) and WPAI-AS (11, 12), thus providing baseline characteristics of their disease. The Allergy Diary has been launched in 21 countries (3, 4). It was found to be an easy and effective method of assessing symptoms of AR and work productivity. The ARIA score is also available in the Allergy Diary adding the four components of the impact of AR (sleep, work and school performance, daily activities and bothersome symptoms).

The ARIA score of the Allergy Diary was compared with QOL scores of EQ-5D (7-10) and WPAI-AS (11, 12).

Methods

Design of the study

A cross-sectional study on a self-selected population was carried out from June 1, 2016 to June 1, 2017. EQ-5D (7-10) and/or WPAI-AS (11, 12) questionnaires are only available in some countries and not all of the Allergy Diary users filled in these questionnaires as they are optional. All users filled in the ARIA score. The ARIA score was compared with the EQ-5D visual analogue scale (VAS) and Question 9 (degree allergy affected regular activities) of the WPAI-AS.

The study is reported according to STROBE.

Setting and users

All consecutive users from June 1, 2016 to June 1, 2017 who answered the questions of the EQ-5D (7-10) and/or WPAI-AS (11, 12) were included in the study in 18 countries. Some demographic characteristics (age, sex, country and language) were recorded. The App was used by people who found it on Internet, Apple App store, Google Play store or any other way. A few users were clinic patients that were asked by their physicians to use the app. However, due to anonymisation of data, no specific information was gathered.

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Allergy Diary

The app collects information on AR symptoms experienced (nasal and ocular), disease type (intermittent/persistent), how symptoms impact users’ lives, and type(s) of AR treatment used (Table 1 online). The system has been deployed in 21 countries and in 16 languages (translated and back-translated, culturally adapted and legally compliant).

Ethics

The Allergy Diary is CE1 registered but not considered by the Ethical Committee of the Cologne hospital of the MHRA (Medicines and Healthcare products Regulatory Agency - GOV.UK) as a medical device as it does not give any recommendations concerning treatment or diagnosis. The terms of use, translated into all languages and customized according to each country’s legislation, allow the use of the results for research purposes. The data are anonymized except for geolocalized data that are never totally anonymous. An Independent Review Board approval was not needed.

Outcomes

The ARIA score was calculated using the four Q4 questions of the Allergy Diary which include impact on daily activities, work and sleep and troublesome symptoms (Table 1 online). Each of the 4 items was ascribed a score of 1 (“Yes”) or 0 (“No”). The total ARIA score ranged from 0 (no impairment) to 4 (severe impairment).

The electronic form of the EQ-5D-5L questionnaire (https://euroqol.org) was applied in the 10 available languages (Danish, Dutch, English, Finnish, French, German, Italian, Polish, Portuguese, Spanish) (Online supplement 1) and we assessed the global VAS level and mobility impairment as this was an absent domain in the assessment of AR impairment.

The electronic form of the WPAI-AS questionnaire was applied in the 10 available languages (same as above for EQ-5D) (11, 12) according to the package obtained from Reilly and associates (www.reillyassociates.net/WPAI_General.html). The percentage of impairment due to allergy for daily activities (Q9) was the outcome used. (Online supplement 2).

Classification of users

Users with any positive answer to Q4 (Table 1 online) were classified as “rhinitis” (score 0-4). Those with a score of zero were classified as “no rhinitis” if they had no symptom (Q3, Table 1 online). Those with a positive answer were classified as “rhinitis” (score 0).

Statistical methods and analyses

Some users filled in EQ-5D or WPAI-AS more than once for a single day. The first data were then used. A non-Gaussian distribution was found for some of the data (Shapiro-Wilk test). However, EQ-5D data are usually reported in means and SD. Since the number of observations was large, we used parametric analyses.
Results

Users
Of the 12,179 registered users, 1,287 filled in the EQ-5D questionnaire and 1,028 the WPAI-AS questionnaire (Table 2 online). Among the 843 users who filled in both questionnaires, there were 507 women (60%) and 336 men (40%), with a mean (± SD) age of 35 ± 14 years.

Main results
Similar levels of EQ-5D VAS and WPAI-AS Q9 were found for users with no rhinitis and for those with an ARIA score of 0 to 2. There was a significant reduction of EQ-5D VAS levels and a significant increase of WPAI-AS Q9 levels in users with an ARIA score of 3 or 4 (Table 1).

The repartition of users for both EQ-5D and WPAI-AS (Figure 1) shows that impairment occurred significantly more commonly for ARIA scores of 3 and 4 than for ARIA scores of 0-3. There were from 12 to 16% of users with an EQ-5D VAS level ≥60 in ARIA scores 0-2 whereas the level increased to 26 and 27% in users with an ARIA score of 3 or 4. There were from 19 to 31% of users with a Q9 ≥50 in ARIA scores of 0-2 whereas the level increased to 51 and 53% in users with an ARIA score of 3 or 4.

Discussion
This pilot study using mobile technology showed that QOL data (EQ-5D VAS and WPAI-AS Q9) are similar in users without rhinitis as in those with mild rhinitis (scores 0-2). Users with a score of 3 or 4 had a significant impairment in QOL.

Strengths and limitations
The strengths and limitations of this study are those of mobile technology lengthily discussed previously (3, 4). In particular, there is a lack of patient characterization that is impossible using an App. However, every observational study we have performed using the Allergy Diary has confirmed its interest and was able to identify users with a severe disease. It is likely that mobile technology will become a very important tool for the understanding and management of AR.

One specific problem of the study is that there are more countries with EQ-5D or WPAI-AS reporting than translations in the App. It is not known which translations were employed by users.

In this study, we did not perform sub-analyses assessing the importance of symptoms or other factors. We did not investigate the treatments received. As this is a pilot study, these analyses will be carried out once the number of users will have increased.
**Generalizability**

The EQ-5D scores observed in the study accord with those of previous studies (8, 10). Users with an ARIA score of 3 to 4 have a level similar to asthmatic patients with uncontrolled asthma (13, 14). Because of the equal weighing score of ARIA, it is difficult to know whether these differences may be due to specific symptoms (e.g. sleep). EQ-5D is a MAFEIP (Monitoring and assessment framework for the EIP on AHA) tool (15) and the present study is in line with the EIP on AHA. This is another important finding since the Transfer of Innovation of the Allergy Diary is an EIP on AHA scaling up project (16).

One of the major findings of the study is the very similar results with both tools supporting the use of the ARIA score to assess AR control using mobile technology. The WPAI-AS scores observed in the study are lower than those reported in patients selected by physicians (11, 17-19). This is because many users have mild rhinitis whereas in clinical trials or in patients selected by physicians AR is usually more severe.

This study also suggests that, in real life, there is a phenotype of severe AR that needs to be considered in terms of public health and cost savings since the severe form causes disability. This phenotype is in focus in the Finnish Allergy Program (20).

<table>
<thead>
<tr>
<th>ARIA score</th>
<th>EQ-5D VAS</th>
<th></th>
<th>WPAI-AS Q9</th>
<th></th>
</tr>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>m ± sd</td>
<td>N</td>
<td>m ± sd</td>
</tr>
<tr>
<td>No rhinitis</td>
<td>48</td>
<td>80.0±19.0</td>
<td>49</td>
<td>27.5±25.5</td>
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<tr>
<td></td>
<td>83</td>
<td>77.0±21.3&lt;sup&gt;a&lt;/sup&gt;</td>
<td>71</td>
<td>29.9±27.3&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
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<td>308</td>
<td>20.4±22.1</td>
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<td>67.7±23.0&lt;sup&gt;c&lt;/sup&gt;</td>
<td>168</td>
<td>45.8±27.7&lt;sup&gt;n&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

*p<sub>a/b</sub>&lt;0.0001, p<sub>a/c</sub>&lt;0.0001, p<sub>d/e</sub>&lt;0.0001, Student’s t test*
Figure 1: Repartition of users depending on EQ-5D visual analogue scale (A) and WPAI-AS Q9 (B)

References


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