Validation of App and Phone Versions of the Control of Allergic Rhinitis and Asthma Test (CARAT)

Jácome C1,2, Pereira AM2,3, Almeida R1,2, Amaral R1,4, Correia MA3, Mendes S1, Vieira-Marques P1, Ferreira JA5, Gomes J5, Vidal C6, López Freire S6, Méndez Breu P6, Arrobas A7, Valério M7, Chaves Loureiro C8, Santos LM1, Couto M1, Araujo L1, Todo Bom A9, Azevedo JP9, Cardoso J10, Emílio M10, Gerardo R10, Lozoya C11, Pinto PL12, Castro Neves A13, Pinto N12, Palhinha A14, Teixeira F15, Ferreira-Magalhães M15, Alves C14, Coelho D16, Santos N15, Menezes F16, Gomes J16, Cidraís Rodrigues JC17, Oliveira G17, Carvalho J18, Rodrigues Alves R18, Moreira AS19, Costa A19, Abreu C20, Silva R20, Morête A21, Falcão IF21, Marques ML22, Câmara R23, Cálux MJ24, Bordalo D25, Silva D26, Vasconcelos MJ26, Fernandes RM27,28, Ferreira R27,28, Freitas F29, Lopes F30, Almeida Fonseca J31, INSPIRERS group

1Center for Health Technology and Services Research (CINTESIS), Faculty of Medicine, University of Porto, Porto, Portugal
2Department of Community Medicine, Information and Health Decision Sciences (MEDCIDS), Faculty of Medicine, University of Porto, Porto, Portugal
3Allergy Unit, Instituto and Hospital CUF, Porto, Portugal
4Dept. of Cardiovascular and Respiratory Sciences, Porto Health School, Polytechnic Institute of Porto, Porto, Portugal
5Serviço de Imunoalergologia, Centro Hospitalar Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal
6Serviço de Alergia, Complejo Hospitalario Universitario de Santiago, Santiago De Compostela, Spain
7Serviço de Pneumologia, Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal
8Serviço de Pneumologia, Hospital Santa Marta, Centro Hospitalar Universitário de Lisboa Central, Lisboa, Portugal
9Serviço de Imunoalergologia, Hospital Amato Lusitano, Unidade Local de Saúde de Castelo Branco, Castelo Branco, Portugal
10Serviço de Imunoalergologia, Hospital de Dona Estefânia, Centro Hospitalar Universitário de Lisboa Central, Lisboa, Portugal
11Serviço de Pediatria, Centro Materno Infantil do Norte, Centro Hospitalar Universitário do Porto, Porto, Portugal
12Serviço de Pneumologia, Hospital Nossa Senhora do Rosário, Centro Hospitalar Barreiro Montijo, Barreiro, Portugal
13Serviço de Imunoalergologia, Hospital do Divino Espírito Santo, Ponta Delgada, Portugal
14Serviço de Pediatria, Hospital da Senhora da Oliveira, Guimarães, Portugal
15Serviço de Imunoalergologia, Hospital São Pedro de Vila Real, Centro Hospitalar De Trás-os-Montes E Alto Douro, Vila Real, Portugal
16Serviço de Imunoalergologia, Hospital Infante D. Pedro, Centro Hospitalar Baixo Vouga, Aveiro, Portugal
17Serviço de Imunoalergologia, Centro Hospitalar Universitário do Porto, Porto, Portugal
Assessment of asthma control is recommended where possible [1]. The Control of Allergic Rhinitis and Asthma Test (CARAT) is a patient-reported outcome measure commonly used to assess asthma control in clinical practice [2-4]. It includes 10 questions answered on a 4-point Likert scale that address upper and lower airway symptoms, sleep disturbances, limitations of activity, and the need to increase medication over a 4-week period [5]. CARAT is frequently administered paper during medical visits, although digital versions are available through websites [6] and mobile apps [7,8].

The COVID-19 pandemic led the European Respiratory Society to recommend the use of phone screening to monitor patients with asthma [9] in order to minimize face-to-face contacts. Therefore, clinicians need to rely on CARAT (digital or phone versions), which can be used outside medical facilities to gain insight into patients’ health status and enable better strategic planning during the period between visits. Currently, 4 apps include CARAT (questions on 10 consecutive screens with bullet-point responses) [7,8], and their usefulness is increasingly reported [10,11]. An app version of CARAT with 1-week recall has been validated [7], and another was used in an interventional study with adolescents [12]. However, the app version has yet to be validated taking into account the 4-week recall period. A previous study applying CARAT by phone showed its feasibility, but not its validity [13].

CARAT administered through a mobile app or phone interview is a convenient alternative to the paper version. Yet, before widespread implementation, we need to ensure these versions are equally reliable and valid. We compared the psychometric properties of 3 versions of CARAT (paper, phone, and app) in patients with asthma.

We analyzed data collected between March 2018 and January 2020 from prospective observational studies conducted by the authors about the feasibility of the InspirerMundi app [14]. Patients were recruited during a medical visit at 23 secondary care centers in Portugal and Spain. Patients were included if they had persistent asthma, were aged ≥13 years, were able to use apps, had access to a mobile device with Internet, and had been prescribed inhaled controller medication. During medical visits, physicians reported patients’ asthma treatment, asthma control according to the Global Initiative for Asthma guidelines [1], number of exacerbations, and number of unscheduled medical visits.

Patients filled in a sociodemographic and clinical questionnaire, including the paper version of CARAT (pCARAT) and were invited to complete CARAT in the following days using the InspirerMundi app (mCARAT). After approximately 1 week (3-10 days), the responses for CARAT were collected through a telephone interview (tCARAT) (Supplementary Figure S1). A total of 144 patients participated in the studies, although the only patients analyzed were those who completed the 3 versions within 10 days. For each version of CARAT, the total score (CARAT-T, 0-30), upper airway score (CARAT-UA, 0-12), and lower airway score (CARAT-LA, 0-18) were calculated. Good disease control was defined as scores >24 on CARAT-T, >8 on CARAT-UA, and ≥16 on CARAT-LA. The internal consistency (Cronbach α), convergent validity (Spearman correlation, rs), reliability (intraclass correlation coefficient [ICC]), and agreement (% agreement, Cohen κ) were determined.

Sixty-seven patients with a median (IQR) of 20 (17-33) years were analyzed (Supplementary Table S1). mCARAT was completed on the same day as pCARAT by 85% of patients (median, 0 [0-2] days), while tCARAT was completed after a median of 6 (5-7) days. The median total score was 20 (16-23) for pCARAT, 20 (18-24) for mCARAT, and 22 (18-26) for tCARAT. The median CARAT-UA and CARAT-LA scores were 5 (4-8) and 15 (12-17) in pCARAT, 6 (4-8) and 15 (12-17) in mCARAT, and 7 (4-8) and 16 (13-17) in tCARAT, respectively.

The internal consistency of the CARAT scores was good (pCARAT, α=0.71-0.79; mCARAT, α=0.72-0.81; and tCARAT, α=0.71-0.80). The scores obtained with pCARAT were significantly correlated with the mCARAT scores (rs=0.64-0.82) and tCARAT scores (rs=0.55-0.64). The correlation between mCARAT and tCARAT scores was also significant (rs=0.59-0.69) (Supplementary Table S2). Differences in CARAT-T between methods were significantly correlated with the time interval between the assessments (rs=0.22, Supplementary Figure S2).

The relative test-retest reliability of the CARAT scores was acceptable for all versions, although better for pCARAT-mCARAT (ICC2.1=0.65-0.85) and mCARAT-tCARAT (ICC2.1=0.71-0.76) in comparison with pCARAT-tCARAT (ICC2.1=0.59-0.71). There was reasonable agreement between versions, with bias close to zero and reasonable limits of agreement. Slightly better agreement was seen for pCARAT-mCARAT than for tCARAT-mCARAT and pCARAT-tCARAT (Figure, Supplementary Figure S3).

J Investig Allergol Clin Immunol 2021; Vol. 31(3): 270-273
Disease was not controlled in 81% of patients based on pCARAT, in 78% based on mCARAT, and in 67% based on tCARAT. Agreement in the CARAT-T control classification was higher for tCARAT and mCARAT (81%; \( \kappa = 0.52 \) [95%CI, 0.30-0.74]) than for pCARAT and mCARAT (76%; \( \kappa = 0.28 \) [95%CI, 0.01-0.55]) and for pCARAT and tCARAT (72%, \( \kappa = 0.28 \) [95%CI, 0.04-0.52]). Uncontrolled UA and LA symptoms were present in 81% and 58% of patients based on pCARAT, in 76% and 36% based on mCARAT, and in 76% and 55% based on tCARAT. The agreement for classification of control according to CARAT-UA and CARAT-LA (75%-85%; \( \kappa = 0.51-0.64 \)) followed the same pattern as CARAT-T.

Comparison of paper and app versions yielded better results, followed by app and phone versions and, lastly, by paper and phone versions. This finding is likely related to the time interval between the assessments rather than to the collection method. Most patients answered the app version on the same day they filled in the paper version, while the phone version was collected 1 week later. During this period and considering the possible effect of the medical visit (and related interventions), patients may experience changes in their symptoms or in other CARAT-assessed domains or may perceive them differently. A previous study showed that recent weeks play a more prominent role in the assessment of control than the initial weeks, considering the 4-week recall period [7]. In an additional analysis (Supplementary Table S2) with patients answering the 3 versions within 7 days, slightly better results were found than for those answering with a 10-day interval. Nevertheless, agreement between the paper and app versions was noticeably better for both intervals. It is possible that the slightly larger differences observed between tCARAT and the other versions may also be associated with the distinct nature of the phone interview, which involves an interviewer, in comparison with patients’ self-completion in the paper and app versions. Future studies should collect the 3 methods over a shorter period (<48 hours) and in a random order to clarify this possibility.

Regardless of the collection method, the internal consistency of the CARAT scores was above the 0.7 threshold [15]. In addition, the correlation coefficients between the CARAT scores obtained were found to be moderate [7]. Since most ICCs were above 0.7 [15], we can rely on the test-retest reliability of CARAT using all 3 methods. The only ICCs that were below this cut-off were CARAT-T and CARAT-UA between the paper and phone versions and CARAT-UA between the paper and app versions, probably because of the high variability of UA symptoms in our sample.

This study was based on a small sample, mostly of adolescents/young adults followed in secondary care. Future studies should include an adequately powered sample of patients with an extended age range also recruited from primary care. This study showed that both mHealth and phone versions of CARAT are acceptable tools for assessment of disease control in adolescents and young adults with persistent asthma.

Acknowledgments

We thank the participants and centers involved in the Inspirers project. The authors would like to acknowledge all members of the INSPIRERS group (https://paceit.med. up.pt/sample-page/inspirers-group/). They also acknowledge Mundipharma-Portugal for supporting the dissemination of the InspirerMundi application.

Funding

This work was funded by ERDF (European Regional Development Fund) through the opera-tions POCI-01-0145-FEDER-029130 (“mINSPIRE—mHealth to measure and improve adher-ence to medication in chronic obstructive respiratory diseases - generalisation and evaluation of gamification, peer support and advanced image processing technologies”) and cofunded by COMPETE2020 (Programa Operacional Competitividade e Internacionalização), Portugal 2020, and by Portuguese Funds through FCT (Fundação para a Ciência e a Tecnologia).

Conflicts of Interest

The authors declare that they have no conflicts of interest.

References

1. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for prevention, diagnosis and management of COPD. URL: https://goldcopd.org/gold-reports/. 2020.
2. Calderón MA, Casale TB, Demoly P. Validation of Patient-Reported Outcomes for Clinical Trials in Allergic Rhinitis: A Systematic Review. The Journal of Allergy and Clinical Immunology: In Practice. 2019;7:1450-61.e6.
3. Azevedo P, Correia de Sousa J, Bousquet J, Bugalho-Almeida A, Del Giacco SR, Demoly P, et al. Control of Allergic Rhinitis and Asthma Test (CARAT): dissemination and applications in primary care. Prim Care Respir J. 2013;22:112-6.

4. van der Leeuw S, van der Molen T, Dekhuijzen PN, Fonseca JA, van Gemert FA, Gerth van Wijk R, et al. The minimal clinically important difference of the Control of Allergic Rhinitis and Asthma Test (CARAT): cross-cultural validation and relation with pollen counts. NPJ Prim Care Respir Med. 2015;25:14107.

5. Fonseca JA, Nogueira-Silva L, Morais-Almeida M, Azevedo L, Sa-Sousa A, Branco-Ferreira M, et al. Validation of a questionnaire (CARAT10) to assess rhinitis and asthma in patients with asthma. Allergy. 2010;65:1042-8.

6. Control of Allergic Rhinitis and Asthma Test [Available from: http://www.caratnetwork.org/.

7. Flokstra-de Blok BMJ, Baretta HJ, Fonseca JA, van Heijst E, Kollen BJ, de Kroon J, et al. Control of Allergic Rhinitis and Asthma Test with 1-week recall: Validation of paper and electronic version. Allergy. 2018;73:2381-5.

8. Jácome C, Almeida R, Teixeira J, Vieira-Marques P, Vilaça R, Fernandes J, et al., editors. Inspirers: An app to measure and improve adherence to inhaled treatment. International Conference e-Health; 2017; Lisbon.

9. European Respiratory Society. COVID-19 and asthma. URL: https://www.ersnet.org/the-society/news/covid-19-and-asthma (accessed on 27.05.2020). 2020.

10. Pereira AM, Jacome C, Almeida R, Fonseca JA. How the Smartphone Is Changing Allergy Diagnostics. Curr Allergy Asthma Rep. 2018;18:69.

11. Mazzoleni S, Turchetti G, Ambrosino N. The COVID-19 outbreak: From "black swan" to global challenges and opportunities. Pulmonology. 2020;26:117-8.

12. Kosse RC, Bouwy ML, Belitzer SV, de Vries TW, van der Wal PS, Koster ES. Effective Engagement of Adolescent Asthma Patients With Mobile Health–Supporting Medication Adherence. JMIR Mhealth Uhealth. 2019;7:e12411.

13. Sá-Sousa A, Amaral R, Morais-Almeida M, Araújo L, Azevedo LF, Bugalho-Almeida A, et al. Asthma control in the Portuguese National Asthma Survey. Pulmonology. 2015;21:209-13.

14. Jácome C, Guedes R, Almeida R, Teixeira JF, Pinho B, Vieira-Marques P, et al. mINSPIRERS - Estudo da exequibilidade de uma aplicação móvel para medição e melhoria da adesão à medicação inalada de controlo em adolescentes e adultos com asma persistente. Protocolo de um estudo observacional multicêntrico. Revista Portuguesa de Imunologia e Allergologia. 2018;26:47-61.

15. Mokkink LB, Prinsen CA, Patrick DL, Alonso J, Bouter LM, Vet HCd, et al. COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs): user manual. URL: https://www.cosmin.nl/wp-content/uploads/COSMIN-syst-review-for-PROMs-manual_version-1_feb-2018.pdf. 2018.

Manuscript received June 20, 2020; accepted for publication August 20, 2020.

Cristina Jácome
Center for Health Technology and Services Research, Faculty of Medicine, University of Porto, Rua Dr. Plácido da Costa, Porto 4200-450, Portugal.
E-mail: cjacome@med.up.pt