SPECIAL SUPPLEMENT

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Clinical Insights, Perspectives, and Disease Management

ASSESSMENT OF MEASUREMENT-BASED CARE TO IMPROVE OUTCOMES IN PATIENTS WITH ALLERGIC RHINITIS IN AN OPEN-LABEL, PROSPECTIVE STUDY

Anne K. Ellis, MD, MSc, FRCPC
Paul K. Keith, MD, FRCPC
Jean-Nicolas Boursiquot, MD, FRCPC
Bruno Francoeur, MD
Amin Kanani, MD, FRCPC

ABOUT THE AUTHORS

Anne K. Ellis, MD, MSc, FRCPC

Dr. Anne K. Ellis is a Professor of Medicine and Chair of the Division of Allergy & Immunology at Queen's University. She holds the James H. Day Chair in Allergic Diseases and Allergy Research. She is the Director of the Environmental Exposure Unit and the Allergy Research Unit at Kingston General Hospital. She is the current Vice President of the Canadian Society of Allergy and Clinical Immunology and serves on the Joint Task Force for Practice Parameters, representing the American College of Allergy, Asthma, and Immunology.

Paul K. Keith, MD, FRCPC

Dr. Paul Keith is a Professor of Medicine and Director in the Division of Clinical Immunology and Allergy at McMaster University in Hamilton, ON.

Jean-Nicolas Boursiquot, MD, FRCPC

Dr. Jean-Nicolas Boursiquot completed his medical degree and internal medicine specialty at Université Laval. He then completed postdoctoral training in clinical immunology and allergy at McGill University. He holds a Master's degree in Biomedical Sciences from the University of Montreal and is currently working as an allergist and clinical immunologist at the CHU de Québec, where he also teaches residents in the allergy and immunology program. He was director of the Continuing Professional Development Committee of the Québec Association of Allergists and Immunologists. In 2016, he participated in the adaptation of the "Guide complet des allergies" published by Éditions Edito.

Bruno Francoeur, MD

Dr. Bruno Francoeur is a general practitioner practicing in Trois-Rivières, Québec. He recently joined Syneos Health as an Executive Medical Director. His background includes expertise in family medicine, respiratory disease evaluation (asthma/COPD), evaluation of allergy tests, urticaria evaluation and clinical research. Since 2016, he has participated in numerous phase II to phase IV studies as an investigator, co-investigator and/or assistant medical director. He has also supervised residents during his family medicine internship, while working as an emergency physician.

Amin Kanani, MD, FRCPC

Dr. Amin Kanani is a Clinical Associate Professor in Medicine at the University of British Columbia and the Head of the Division of Allergy and Clinical Immunology at St. Paul's Hospital and University of British Columbia. Dr. Kanani completed his medical degree at McGill University. He then went on to complete Internal Medicine training at UBC and Clinical Immunology and Allergy fellowship training at the University of Toronto. He has held several leadership positions including President of the BC Society of Allergy and Immunology, Board of Directors for the Canadian Hereditary Angioedema Society, and Interim Program Director for the UBC Allergy and Clinical Immunology training program. His clinical and research interests include chronic urticaria, hereditary angioedema and primary immunodeficiency.

Assessment of measurement-based care to improve outcomes in patients with allergic rhinitis in an open-label, prospective study

Anne K. Ellis, MD, MSc, FRCPC • Paul K. Keith, MD, FRCPC • Jean-Nicolas Boursiquot, MD, FRCPC • Bruno Francoeur, MD • Amin Kanani, MD, FRCPC

ABSTRACT

Background

Despite available treatments for allergic rhinitis (AR), patients are often dissatisfied with their treatment and experience uncontrolled symptoms. Measurement-based care is the systematic use of standardized measurements used during office visits to inform treatment decisions. The Improving Symptom Control of Allergic Rhinitis (ICAR) study determined if the assessment and management of AR through measurement-based care could improve patient outcomes.

Methods

ICAR was a real-world, open-label, prospective, multicenter study conducted in Canada between September 2021 and December 2021. Enrolled adult patients (n=503) with AR were categorized as treatment-naïve, uncontrolled despite AR treatment, or requiring a treatment switch due to adverse effects. AR symptoms and symptom control were assessed by the patient using the Rhinitis Control Assessment Test (RCAT) and, by both the patient and the clinician, on a visual analog scale (VAS) at baseline and after 4 weeks of 10 mg daily oral rupatadine.

Results

The majority of patients were uncontrolled (36%) or partially controlled (51%) at baseline, while 20% were treatment-naïve, 32% were uncontrolled despite treatment, and 30% needed treatment switch. At baseline, 66% of patients were taking non-sedating antihistamines, and 78% indicated they were dissatisfied with their treatment.

The overall RCAT score improved by 66%, from an average standard deviation (SD) of 16 (5.2) at baseline to 24 (3.8) at follow-up (P<0.0001). Scores for all individual RCAT items significantly improved (P<0.0001), with a 65% improvement in congestion frequency, a 61% improvement in sneezing frequency, and a 68% improvement in symptom control. Overall RCAT scores significantly improved from baseline by 67% in treatment-naïve patients; 64% in patients uncontrolled despite treatment; 51% in patients needing treatment switch; 55% in patients with asthma; 62% in patients with urticaria; 54% in patients with eczema/atopic dermatitis; 40% in patients with nasal polyps; and 52% in patients with no comorbidities (P<0.0001).

The patient VAS score improved from a mean SD of 6.5 (2.4) units at baseline to 2.6 (2.2) at follow-up; the clinician VAS score improved from 6.6 (2.2) units to 2.0 (2.2).

Conclusion

The ICAR study demonstrated that rupatadine, an antihistamine that also has anti-platelet-activating factor effects, significantly improves AR symptom control when used daily and monitored objectively by measurement-based care.

BACKGROUND

Allergic rhinitis (AR) is a common disease characterized by symptoms of nasal congestion, runny nose, sneezing, itchy/watery eyes, and cough. These symptoms can be extremely bothersome to patients, interfering with daily activities, work and sleep, as well as negatively affecting mental health.[1-3] In addition, patients with AR tend to present with comorbid allergic diseases such as asthma, eczema/atopic dermatitis and nasal polyps.[3,4]

The symptoms of AR are the result of a cascade of IgE-mediated events that occur upon exposure to an allergen to which the patient is sensitized. In the early phase of the cascade, the allergen cross-links IgE on the surface of effector cells, triggering the release of immune mediators including histamine, platelet-activating factor (PAF), prostaglandins, and leukotrienes.[5,6] Therefore, first-line treatments for AR include antihistamines (either over-the-counter [OTC] or prescription) and nasal corticosteroids.[7-9] Due to their superior safety profile, second-generation antihistamines such as bilastine, cetirizine, desloratadine, fexofenadine, loratadine, and rupatadine are recommended over first-generation antihistamines (i.e., diphenhydramine, hydroxyzine, chlorpheniramine).[8-10] Rupatadine is the only antihistamine that also has potent anti-PAF effects.[5]

Despite the many available treatments for AR, clinical studies show that patients are often dissatisfied with their AR treatment, and their symptoms may remain uncontrolled.[1,3] Measurement-based care is a relatively new trend in healthcare that involves the systematic use of standardized measurements during office visits, the results of which are used to inform treatment decisions. The quantitative measures typically are in the form of short, validated, patient- and/or clinician-reported rating scales.[11,12] Measurement-based care has been studied primarily for behavioural and mental health issues, where its success has been documented.[12-14] The use of measurement-based care has yet to be studied for the treatment of AR, and its use in this context may be helpful in a real-world setting where symptom assessment is often subjective. The Improving symptom Control of Allergic Rhinitis (ICAR) study was conducted to determine if improving the assessment and management of AR through measurement-based care can lead to improved patient outcomes.

METHODS

Study design

ICAR was a real-world, open-label, prospective, multicenter study conducted in 60 sites across Canada between September 2021 and December 2021. The study was reviewed and approved by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Verbal informed consent to participate in the study was obtained from each patient.

At the baseline visit, information was collected from patients on demographics, comorbidities, disease characteristics, and AR treatment history. Current AR treatment satisfaction was assessed by the question "If you took medication in the past month for your allergies, were your allergy symptoms relieved to your satisfaction?" and by the question "How satisfied are you with your current treatment?" The impact of AR symptoms on health-related quality of life (QOL) was assessed by the Rhinitis Control Assessment Test (RCAT), and an overall AR assessment was determined by both the patient and the clinician on a visual analog scale (VAS).

Patients were then provided four weeks of treatment of 10 mg daily oral rupatadine. Use of all other antihistamines was discontinued; however, patients could continue nasal corticosteroid treatment. At a follow-up visit conducted four weeks later, the RCAT and patient and clinician symptom VAS were repeated.

Patient selection criteria

Patients age 18 years or over with mild, moderate or severe AR were prospectively enrolled in the study. Each patient's AR was categorized as uncontrolled, partially controlled or controlled by physician assessment at baseline. Patients were further categorized as treatment-naïve, uncontrolled despite OTC or prescription AR treatment, or requiring a switch in treatment due to adverse effects. Patient eligibility included both seasonal and perennial AR.

Measurements

The primary study objective was to determine if improving assessment and management of AR through measurement-based care leads to better patient outcomes. The secondary objectives included monitoring the difference between controlled, partially controlled and uncontrolled patients; monitoring previously-treated versus treatment-naïve patients; monitoring the impact of rupatadine on nasal symptoms; and monitoring the physician's symptom assessment vs the patient's symptom assessment.

The frequency of AR symptoms and the impact of symptoms on patients' health-related QOL at baseline and follow-up were assessed by the RCAT. The RCAT is a validated six-item questionnaire that evaluates the frequency of nasal congestion, sneeze, and watery eyes (not related to a cold or the flu) during the previous week.[15] The RCAT also determines how often activities were avoided in the last week because of AR symptoms and how well AR symptoms were controlled in the previous week.

RCAT scores range from 6 to 30, with a score of ≤21 indicating patients are experiencing problems with AR symptom control.[15] An improvement in RCAT score of 2.4 points on a population level and 3 points on an individual level is considered clinically meaningful.[16] The patient's overall AR assessment was determined by the response to the question "How are you feeling today? Think about how troublesome your symptoms have been for the last 24 hours." These were rated on a VAS of 0-10, with 0 being "not troublesome at all" and 10 being "very troublesome." The clinician's overall AR assessment was determined by the response to "classification of allergic rhinitis control" rated on a VAS of 0-10, with 0 being "not troublesome at all" and 10 being "very troublesome." VAS scores of <2 indicated controlled, 2 to 5 indicated partially controlled, and ≥5 indicated uncontrolled.

Data analysis

Results were analyzed primarily by descriptive statistics alone. Data were analyzed by AR patient category (treatment-naïve, uncontrolled despite treatment or switch patients) and by comorbidities. T-tests were conducted to determine statistical differences between baseline and follow-up for each item of the RCAT.

RESULTS

Patient characteristics

A total of 503 patients were enrolled in the study from sites comprising 91% primary care, 8% allergy, and 1% respiratory/sleep medicine. The mean participant age was 43.9 years and 52% of participants were women (**Table 1**). The majority of patients were uncontrolled (36%) or partially controlled (51%) at baseline; 20% were treatment-naïve; 32% were uncontrolled despite treatment, and 30% needed to switch treatment because

Demographic or characteristic	Patients, N=503
Female, n (%)	264 (52)
Age, mean (SD), y	43.9 (17.5)
Physician-assessed AR symptom control, n (%)	
Uncontrolled	179 (36)
Partially controlled	259 (51)
Controlled	40 (8)
Missing data	25 (5)
AR category, n (%)	
Treatment naïve	101 (20)
Uncontrolled by current treatment	160 (32)
Treatment switch needed due to AEs	149 (30)
Not categorized	93 (18)
Province, n (%)	
Ontario	325 (65)
British-Columbia	141 (28)
Quebec	35 (7)
Alberta	2 (0.4)
Comorbidities, n (%)	
None	199 (40)
Asthma	105 (21)
Eczema/atopic dermatitis	103 (20)
Urticaria	27 (5)
Nasal polyps	22 (4)
Missing data	47 (9)
Duration of AR symptoms, y	
Median (IQR)	5 (3-10)
Range	0-46
Current treatments, n (%)	
Nasal corticosteroid	206 (41)
Non-sedating OTC oral antihistamines	171 (34)
Prescription oral antihistamines	161 (32)
Nasal saline	55 (11)
Sedating OTC oral antihistamines	20 (4)
Nasal sprays	15 (3)
Past treatments, n (%)	
Nasal corticosteroid	126 (25)
Non-sedating OTC oral antihistamines	206 (41)
Prescription oral antihistamines	75 (15)
Nasal saline	91 (18)
Sedating OTC oral antihistamines	150 (30)
Nasal sprays	75 (15)
Number of AR medications tried	
Median (IQR)	3 (2-6)
Range	0-17

Table 1. Patient demographics and disease characteristics.
AEs: adverse effects; AR: allergic rhinitis; IQR: interquartile range; OTC: over-the-counter.

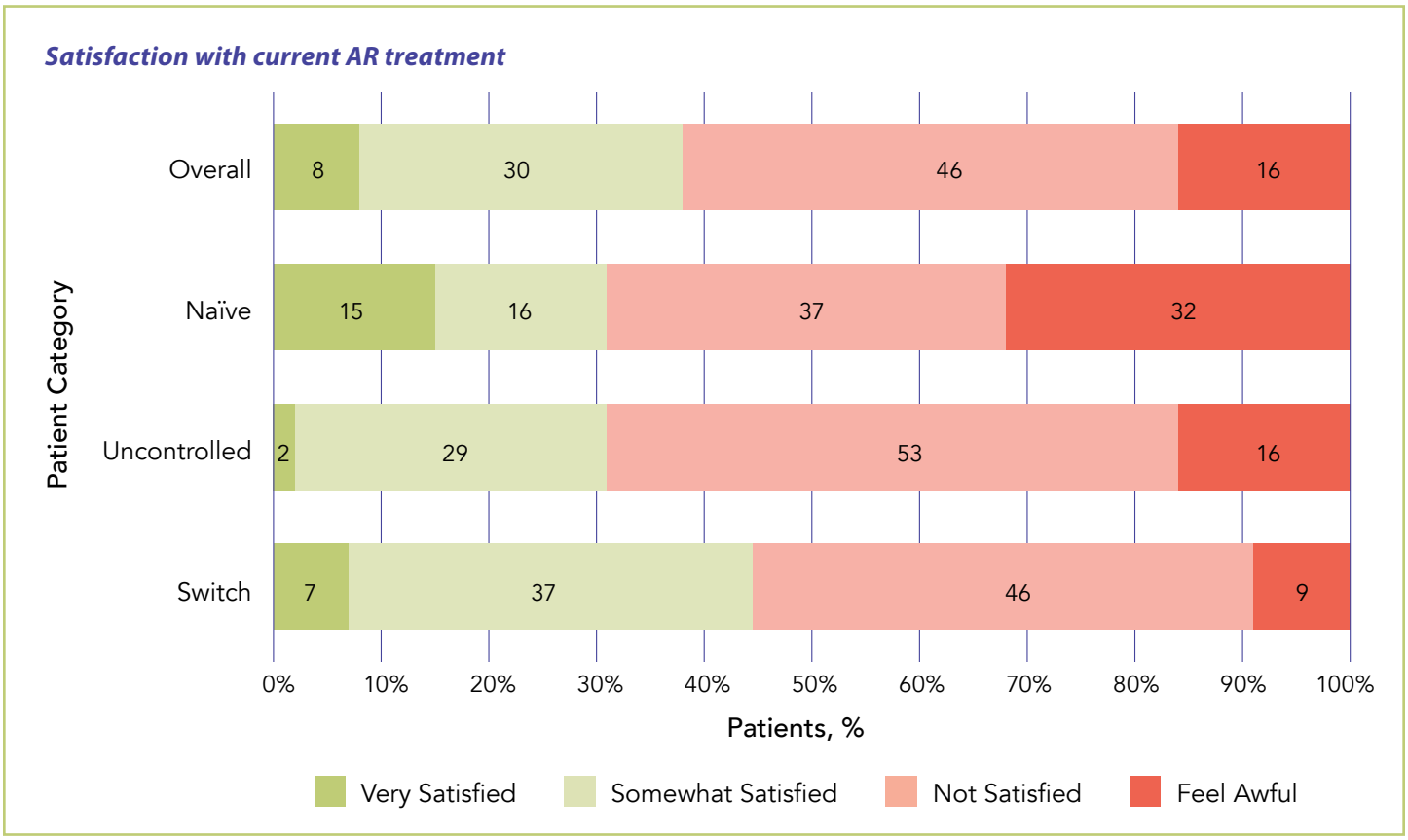

Figure 1. Baseline assessment of patient satisfaction with current AR treatment.

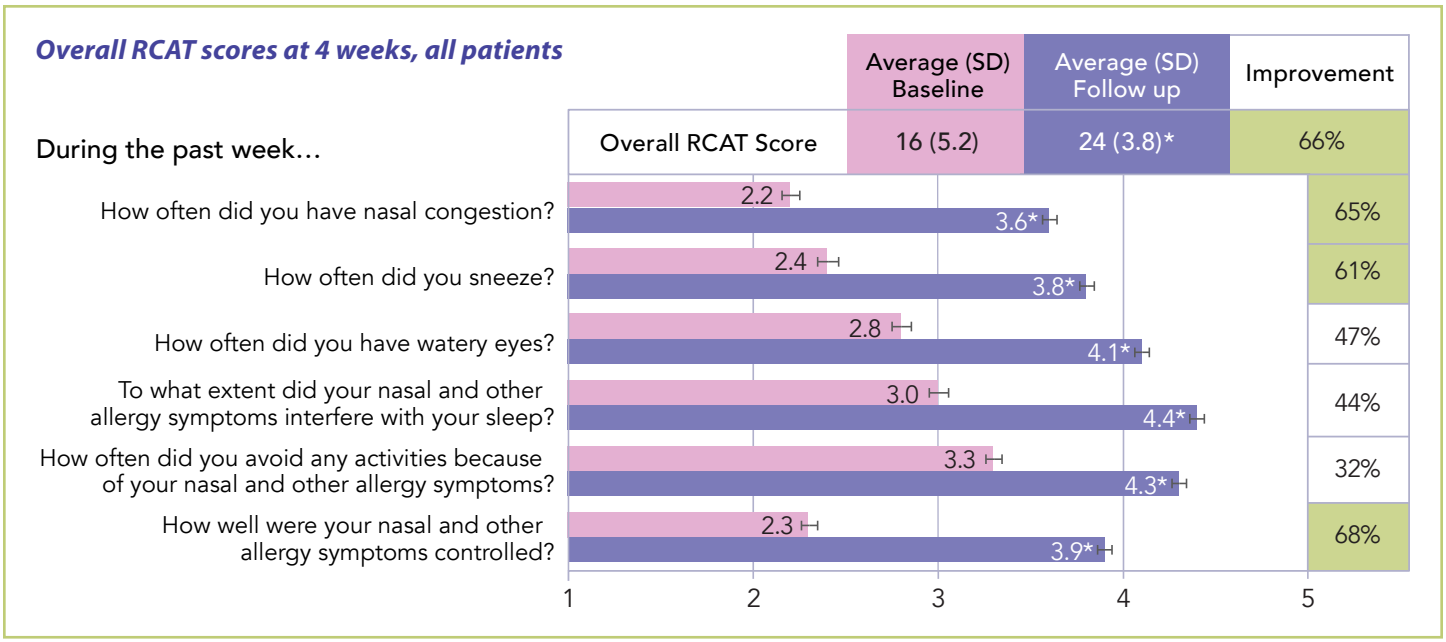

Figure 2. RCAT results at baseline and after 4 weeks of rupatadine treatment. *P<0.0001 vs baseline. Error bars represent standard deviation.

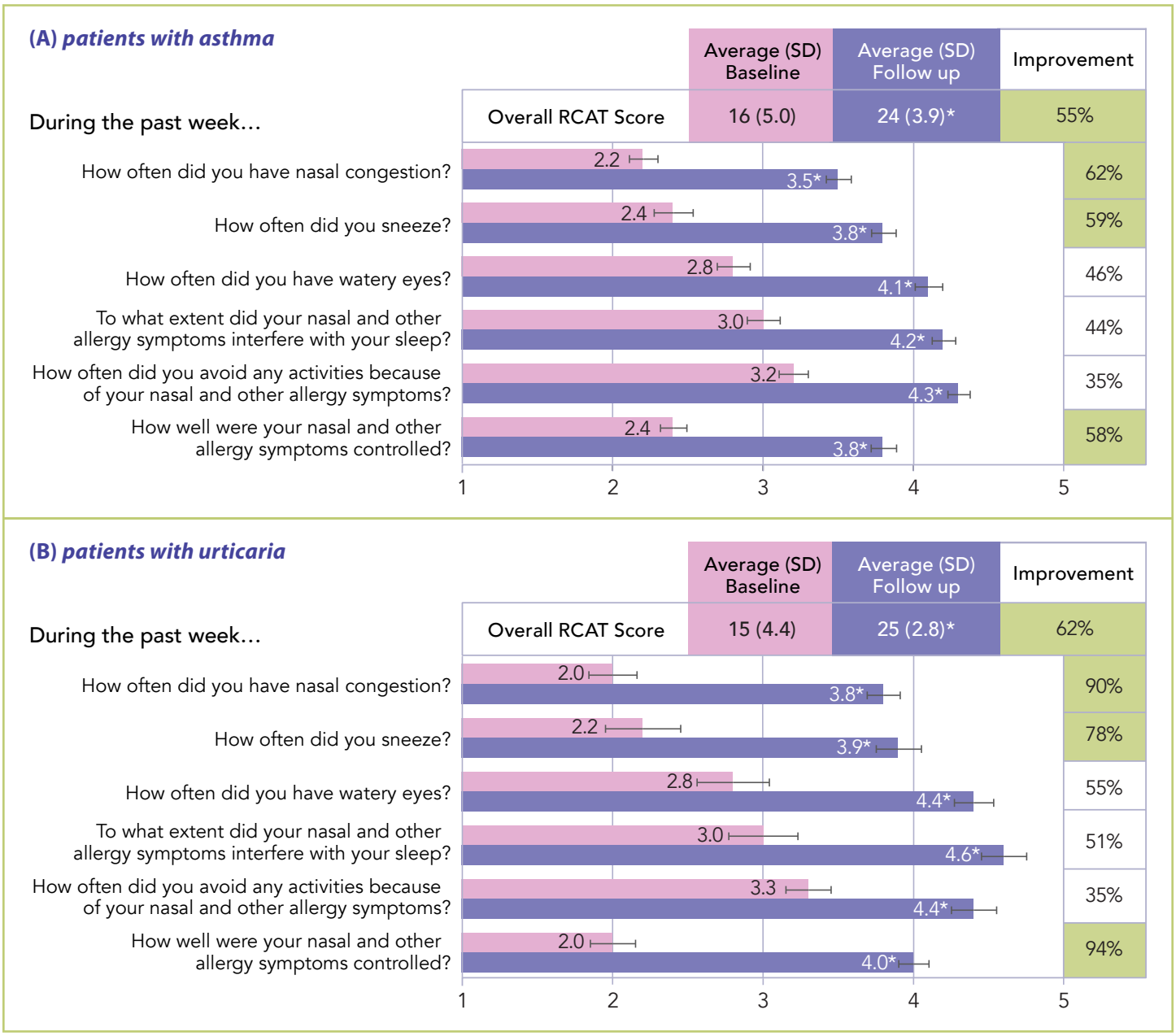

Figure 3. RCAT results at baseline and after 4 weeks of rupatadine treatment in **(A)** patients with asthma and **(B)** patients with urticaria. *P<0.0001 vs baseline. Error bars represent standard deviation.

of adverse effects (**Table 1**). The most common comorbidities were asthma (21%) and eczema/atopic dermatitis (20%). A total of 66% of patients were taking non-sedating antihistamines (34% OTC and 32% prescription) and 41% were taking nasal corticosteroids (**Table 1**). Patients reported having tried a median of three AR medications (**Table 1**).

Overall, 78% of patients indicated that they were dissatisfied with their treatment in the previous month; 62% of patients were either "not satisfied" or "feel awful" at baseline with their current treatment (**Figure 1**). Treatment-naïve patients tended to rate at the extremes of treatment satisfaction vs the patients uncontrolled despite treatment or patients needing treatment switch with 15% reporting they were "very satisfied," yet 32% reporting they "feel awful" (**Figure 1**). Satisfaction with treatment was generally similar across comorbidities, although a slightly greater number of patients with urticaria or nasal polyps reported "not satisfied" or "feel awful" (**Supplemental Figure S1**).

AR assessment at baseline

At the baseline visit, patients reported that their most bothersome AR symptoms were congestion/stuffed nose (68%), followed by sneezing (37%); runny nose (30%), itchy/watery eyes (23%); sore throat/cough (11%); and sleep disturbance (8%). The overall

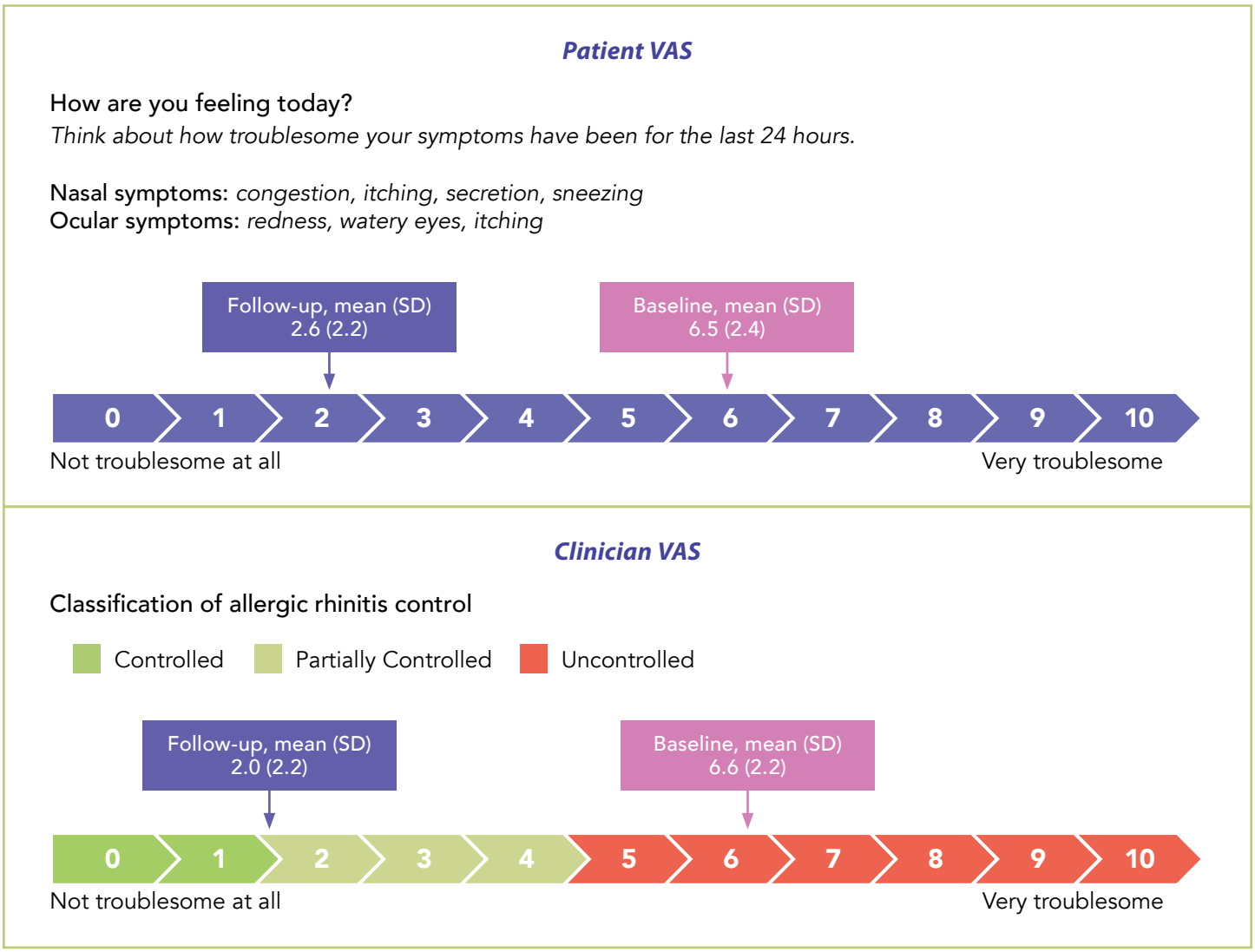

Figure 4. Patient- and clinician-assessed VAS scores at baseline and after 4 weeks of rupatadine treatment.
SD: standard deviation; VAS: visual analog score.

average (SD) RCAT score was 16 (5.2) at baseline (**Figure 2**). Individual RCAT item scores indicated that patients frequently had nasal congestion and that AR symptoms had been poorly controlled in the previous week (**Figure 2**). Similar baseline RCAT results seen in the overall patient population were observed in the treatment-naïve patients (RCAT=17) and patients needing treatment switch (RCAT=17), whereas AR symptoms were higher in the patients who were uncontrolled despite treatment (RCAT=14; Supplemental Figure S2). Baseline RCAT was similar among patients with asthma (RCAT=16); eczema/atopic dermatitis (RCAT=16); urticaria (RCAT=15); or no comorbidities (RCAT=16), and was numerically higher (i.e., fewer symptoms) for patients with nasal polyps (RCAT=18) (**Figure 3** and **Supplemental Figure S3**).

At baseline, the patient mean (SD) VAS score was 6.5 (2.4) and the clinician VAS score was 6.6 (2.2; **Figure 4**), indicating poorly controlled symptoms perceived by both patients and clinicians.

AR assessment after four weeks of treatment

After four weeks of treatment, the overall RCAT score improved by 8 points to an average (SD) of 24 (3.8), corresponding to a 66% improvement (P<0.0001; **Figure 2**). Scores for all the individual RCAT items significantly improved (P<0.0001), with a 65% improvement in congestion frequency, a 61% improvement in sneezing frequency, and a 68% improvement in symptom control assessment (**Figure 2**). Overall RCAT scores improved from baseline by 67% in treatment-naïve patients, 64% in patients who were uncontrolled despite treatment, and 51% in patients needing treatment switch (all P<0.0001; **Supplemental Figure S2**). Scores for all the individual RCAT items significantly improved in all patient

categories (all P<0.0001), and improvements were particularly notable (≥57%) for congestion frequency, sneezing frequency, and symptom control in all patient categories (**Supplemental Figure S2**). The improvement in symptom control was 86% in the treatment-naïve patients and 77% in the patients who were uncontrolled despite treatment. Overall RCAT scores improved from baseline by 55% in patients with asthma and 62% in patients with urticaria (P<0.0001; **Figure 3**). In patients with urticaria, congestion frequency improved by 90% and symptom control improved by 94%. Overall RCAT scores also improved by 54% in patients with eczema/atopic dermatitis, 40% in patients with nasal polyps, and 52% in patients with no comorbidities (P<0.0001; **Supplemental Figure S3**).

After four weeks of treatment, the patient VAS score improved 3.9 units to a mean (SD) score of 2.6 (2.2) and the clinician VAS score improved 4.6 units to a mean (SD) score of 2.0 (2.2; **Figure 4**), indicating partially controlled symptoms.

DISCUSSION

The symptoms of AR impact patients across multiple domains and can significantly affect their daily lives. The AR patient journey typically includes self-treating with OTC medications, often resulting in unsuccessful symptom control and treatment dissatisfaction.[1,3] Tracking symptom control and patient responses to treatment over time can be difficult as objective measures of AR symptoms are not typically conducted in real-world clinical settings. The measurement-based care used in the ICAR study quantitatively demonstrated that the second-generation antihistamine rupatadine improved bothersome AR symptoms for patients who were naïve to treatment, who were uncontrolled despite treatment, who needed to switch from current treatment, and who had various allergy-related comorbidities. The concise and easy-to-complete RCAT and VAS provided objective indicators of symptom control that can easily be implemented into daily practice.

Improvement in the RCAT score from baseline after four weeks of rupatadine treatment was statistically significant and exceeded the 2.4 point difference for a clinically meaningful improvement.[15] The items on the RCAT that were the worst at baseline (e.g., frequency of nasal congestion and how well symptoms were controlled) were the items that improved the most. The 65% improvement in the frequency of nasal congestion was encouraging as oral antihistamines generally have only a small effect on congestion.[16] Vascular permeability induced by PAF contributes to nasal congestion,[17] and the anti-PAF effect of rupatadine may have played a role in mitigating this symptom. Congestion was improved by 90% in patients with urticaria. Chronic urticaria can be associated with markers of airway mucosal inflammation,[18] thus, the substantial improvement in nasal congestion in this group could also be related to the anti-PAF effect of rupatadine. Clinical benefits were also demonstrated in patients with asthma, eczema/atopic dermatitis and nasal polyps, and the presence of these comorbidities did not diminish the response to treatment. The improvement in patients with nasal polyps was not quite as robust as the other comorbidities; however, AR in patients with nasal polyps is traditionally harder to treat. In addition, according to the RCAT scores, AR symptoms in the patients with nasal polyps were not as severe at baseline as in the other groups and therefore had less room for improvement. The anti-PAF action of rupatadine may also explain the improvement in AR symptoms in patients who were already using other antihistamines (e.g., uncontrolled despite treatment and needing treatment switch patient categories).

One other real-world study of second-generation antihistamines for AR has been conducted in Canada.[19] In this open-label study, patients rated seasonal AR symptoms during the spring-summer allergy season on a 0-3 scale at baseline and after 7 days of desloratadine treatment.[19] Half of the patients were being treated with AR medications at baseline, yet individual (including congestion) and overall symptom scores significantly improved after desloratadine treatment. Although the study did not evaluate measurement-based care per se, it did demonstrate the same principal as ICAR, namely, that an objective measure of symptoms could be used to track the effect of AR treatment in real-world practice.

One particular strength of the ICAR study is that its timing indicates that patients likely had perennial AR, which is typically more difficult to treat than seasonal AR. The study was limited by its open-label, non-controlled design. In addition, few or no patients were included from some of the Canadian provinces; therefore, the results may not be generalizable across all of Canada.

The ICAR study demonstrated that using rupatadine, a dual-acting antihistamine and anti-PAF agent, significantly improves symptom control when used daily and monitored objectively by measurement-based care. Incorporating assessment and management tools (measurement-based care) may help better determine the impact of symptoms on patients' quality of life.

CORRESPONDENCE

Dr. Anne K. Ellis
Email: ellis.anne@kingstonhsc.ca

DECLARATIONS

Ethical approval and consent to participate

The study was reviewed and granted ethical clearance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

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Authors' contributions

A.K. Ellis was the Chair of the study Steering Committee and obtained the ethics review. P. Keith, J-N. Boursiquot, B. Francoeur, and A. Kanani were members of the study Steering Committee. All authors interpreted the data, critically reviewed the manuscript, and approved the manuscript for submission.

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FINANCIAL DISCLOSURES

A.K. Ellis has participated in advisory boards for ALK-Abelló, AstraZeneca, Aralez, Bausch Health, Circassia Ltd, GlaxoSmithKline, LEO Pharma, Johnson & Johnson, Merck, Mylan, Novartis, Pediapharm and Pfizer, has been a speaker for ALK, Aralez, AstraZeneca, Bausch Health, Boehringer-Ingelheim, CACME, Meda, Medexus, Mylan, Merck, Novartis, Pediapharm, Pfizer, The ACADEMY, and Takeda. Her institution has received research grants from AstraZeneca, Bayer, LLC, Circassia Ltd, Green Cross Pharmaceuticals, GlaxoSmithKline, Sun Pharma, Merck, Novartis, Pfizer, Regeneron and Sanofi. She has also served as an independent consultant to Allergy Therapeutics, Bayer, LLC, Ora Inc., and Regeneron in the past.

P. Keith has participated in advisory boards for ALK-Abelló, AstraZeneca, Aralez, Bausch Health, CSL Behring, GlaxoSmithKline, LEO Pharma, Novartis, Medexus, Pfizer and Sanofi, has been a speaker for ALK, AstraZeneca, Bausch Health, Meda, Medexus, Novartis, Sanofi and Takeda. His institution has received research grants from CSL Behring, AstraZeneca, and Takeda.

J-N. Boursiquot has served as a speaker for Medexus, Pfizer, Bausch Health, and Stallergenes and on advisory boards for CSL Behring, Takeda, and Bausch Health.

B. Francoeur has served as a speaker, consultant, or investigator for Covis Pharma, Valeo Pharma, AstraZeneca Canada, GlaxoSmithKline, Organon, Novartis, Pfizer, Sanofi-Aventis, Bellus Health, Roche, and Regeneron.

A. Kanani has participated in advisory boards for AstraZeneca, Aralez, Bausch Health, CSL Behring, Novartis, Medexus, and Sanofi, and has been a speaker for AstraZeneca, Bausch Health, Aralez, Medexus, Novartis, and Takeda.

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SUPPLEMENTAL MATERIAL

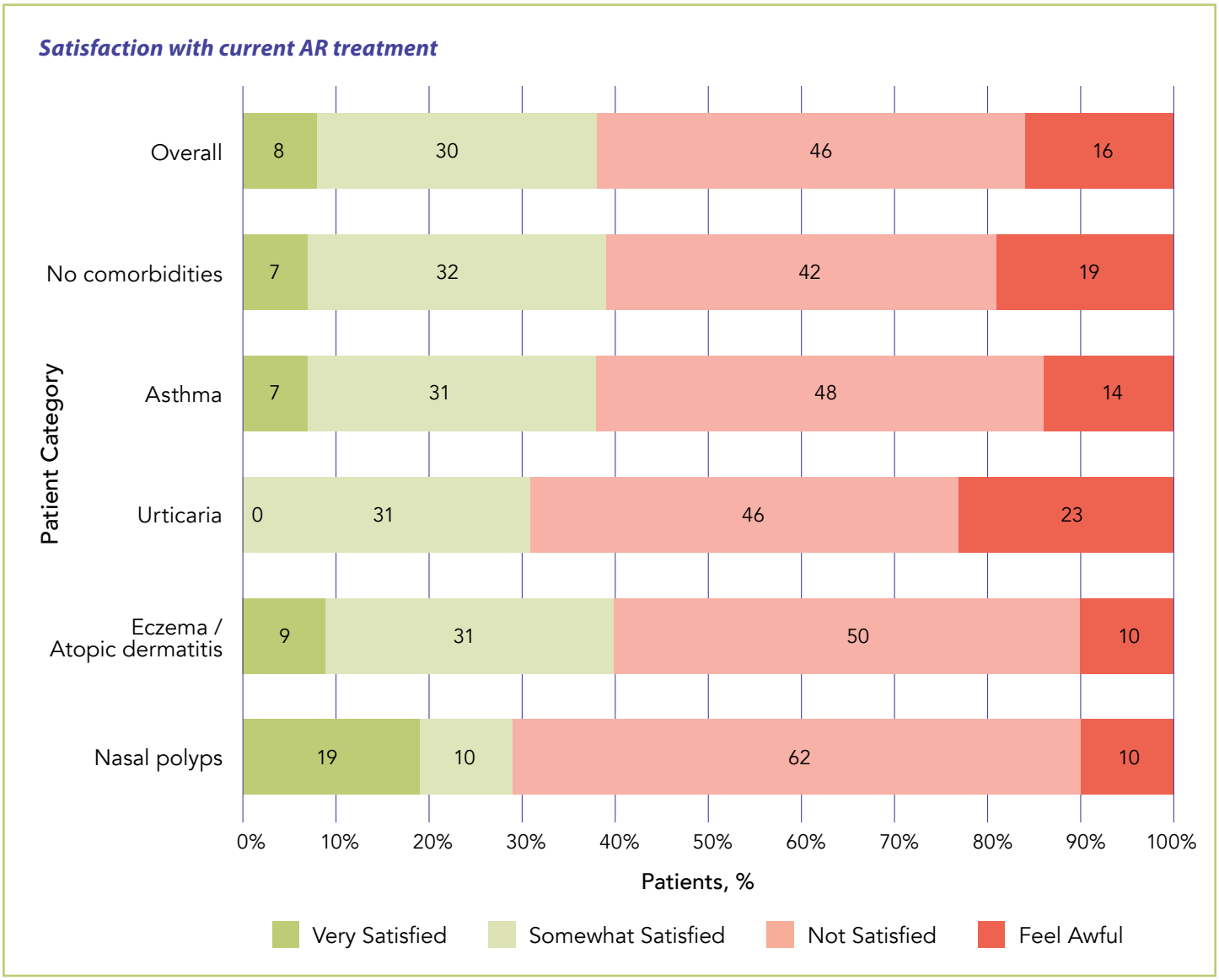

Figure S1. Baseline assessment of patient satisfaction with current AR treatment by comorbidity.

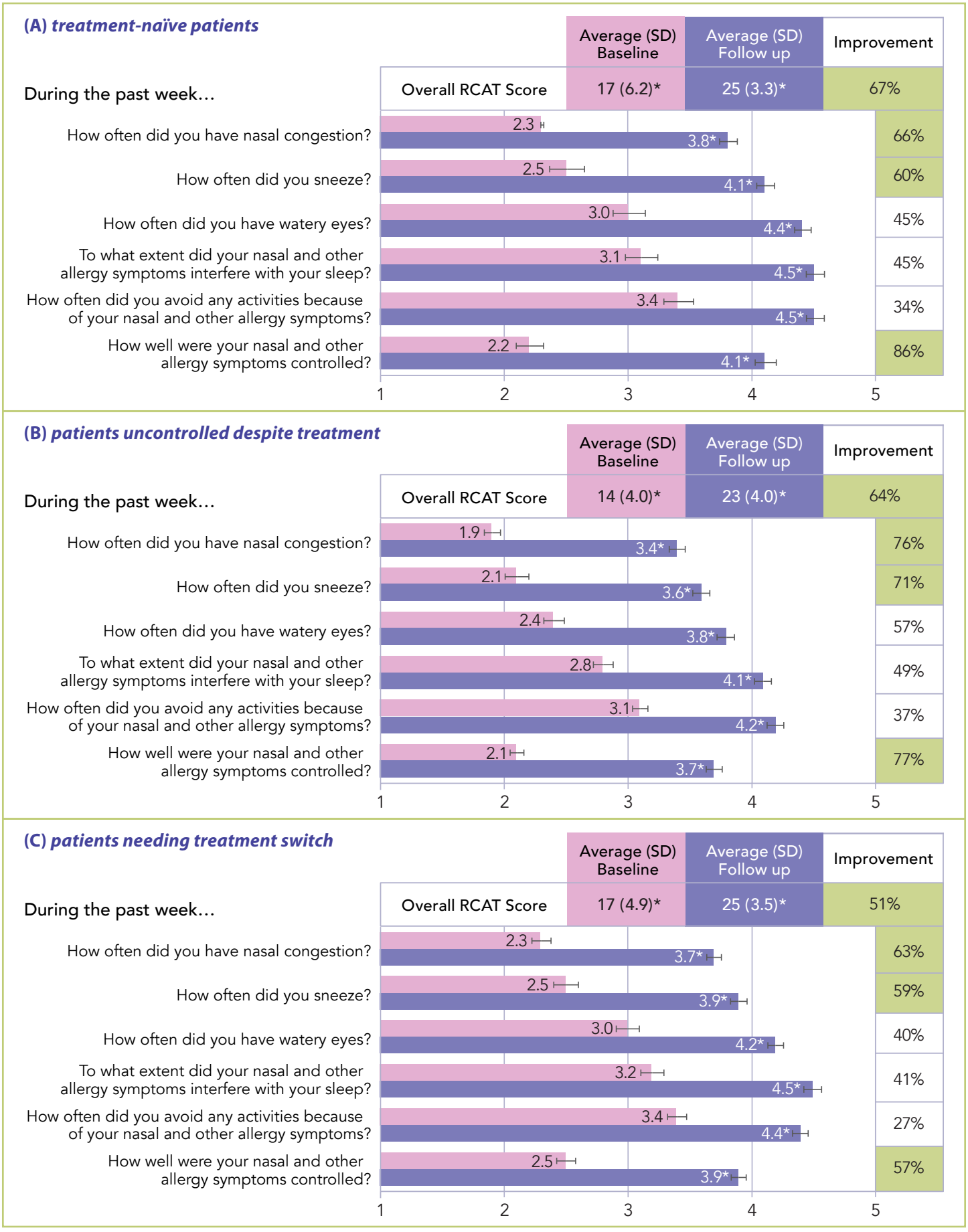

Figure S2. RCAT results at baseline and after 4 weeks of rupatadine treatment in **(A)** treatment-naïve patients (n=101), **(B)** patients uncontrolled despite treatment (n=160), and **(C)** patients needing treatment switch due to adverse effects (n=149). *P<0.0001 vs baseline. Error bars represent standard deviation.

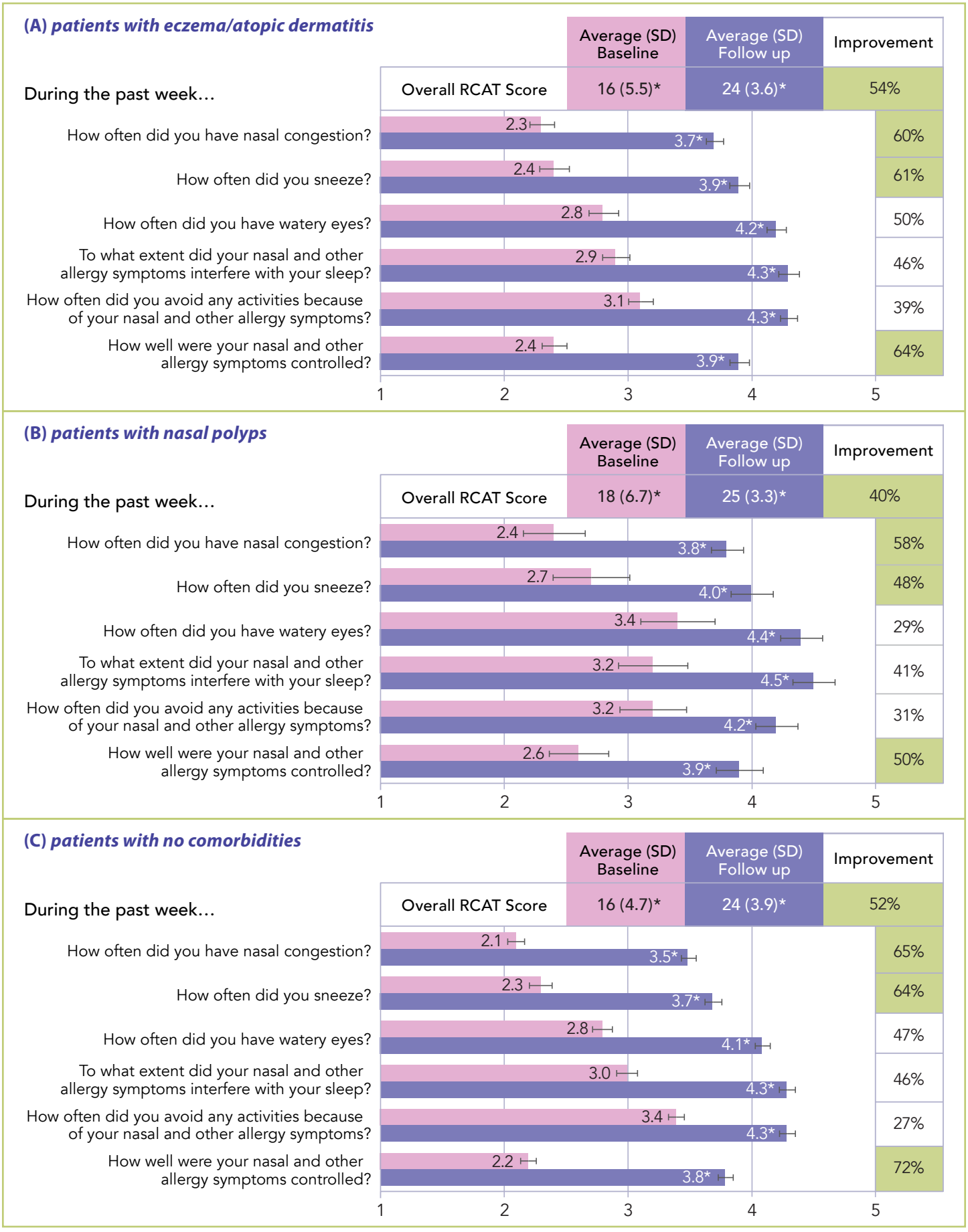

Figure S3. RCAT results at baseline and after 4 weeks of rupatadine treatment in (**A**) patients with eczema/atopic dermatitis, (**B**) patients with nasal polyps, and (**C**) patients with no comorbidities. *P<0.0001 vs baseline. Error bars represent standard deviation.

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SPECIAL SUPPLEMENT

ASSESSMENT OF MEASUREMENT-BASED CARE TO IMPROVE OUTCOMES IN PATIENTS WITH ALLERGIC RHINITIS IN AN OPEN-LABEL, PROSPECTIVE STUDY

Anne K. Ellis, MD, MSc, FRCPC
Paul K. Keith, MD, FRCPC
Jean-Nicolas Boursiquot, MD, FRCPC
Bruno Francoeur, MD
Amin Kanani, MD, FRCPC