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Patient-Reported Outcomes

The Development and Validation of a Multidimensional Sum-Scaling Questionnaire to Measure Patient-Reported Outcomes in Acute Respiratory Tract Infections in Primary Care: The Acute Respiratory Tract Infection Questionnaire

Rune Aabenhus, MD, GP, Hanne Thorsen, MD, PhD, Volkert Siersma, PhD, John Brodersen, MD, GP, PhD*

The Research Unit for General Practice and Section of General Practice, Department of Public Health, University of Copenhagen, Copenhagen, Denmark

ABSTRACT

Objective: Patient-reported outcomes are seldom validated measures in clinical trials of acute respiratory tract infections (ARTIs) in primary care. We developed and validated a patient-reported outcome sum-scaling measure to assess the severity and functional impacts of ARTIs. **Methods:** Qualitative interviews and field testing among adults with an ARTI were conducted to ascertain a high degree of face and content validity of the questionnaire. Subsequently, a draft version of the Acute Respiratory Tract Infection Questionnaire (ARTIQ) was statistically validated by using the partial credit Rasch model to test dimensionality, objectivity, and reliability of items. Test of known groups' validity was conducted by comparing participants with and without an ARTI. **Results:** The final version of the ARTIQ consisted of 38 items covering five dimensions (Physical-upper, Physical-lower, Psychological, Sleep, and Medicine) and five single items. All final dimensions were confirmed to fit the Rasch model, thus enabling sum-scaling of responses. The ARTIQ scores in participants with an ARTI were significantly higher than in those without ARTI (known groups' validity). **Conclusion:** A self-administered, multidimensional, sum-scaling questionnaire with high face and content validity and adequate psychometric properties for assessing severity and functional impacts from ARTIs in adults is available to clinical trials and audits in primary care.

Keywords: acute respiratory tract infections, patient-reported outcome, questionnaire, Rasch analysis.

Introduction

Acute respiratory tract infections (ARTIs), which are often divided into upper– and lower–respiratory tract infections, are among the most frequent diseases seen by general practitioners (GPs) [1,2]. The substantial symptomatic and functional impairment caused by these infections constitutes a major public health problem [2].

Symptoms in ARTIs are diverse and often contain elements from the entire respiratory tract. Even individuals infected with the same viral strain display a striking variance in symptoms and the presentation is linked to illness duration [3]. Patient symptoms and clinical signs are often not sensitive enough to discriminate between the different types of ARTIs (such as acute bronchitis from pneumonia). Because of this diagnostic uncertainty, diagnoses in primary care may not always reflect the explicit pathophysiological criteria commonly applied in medical science [4–6]. Hence, the terms rhinitis, sinusitis, and bronchitis, among others, at best indicate the anatomic site most affected at the time of consultation. Accordingly, in a primary care setting, a precise diagnosis is often not possible and symptom-based criteria (e.g., acute cough) are now frequently used as inclusion criteria in pragmatic clinical trials [7,8].

In clinical conditions with no accepted "gold standard," the assessment of new treatment and diagnostic modalities may be better addressed by using a patient-oriented approach [6,9], bypassing the medically defined "gold standard." When assessing treatment effects, cost, and so on of ARTIs in a primary care setting, the vast majority of patients will recover uneventfully with no or few hard end points such as mortality, highlighting the need to measure the direct impact of disease on a patient's daily life. Furthermore, a change in a medical parameter, such as auscultatory abnormalities or the normalization of a C-reactive protein value, may only modestly reflect the patient's own experience of the illness and does not encompass any associated symptoms (e.g., a cough that impacts daily activities or sleep) or

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* *Address correspondence to:* Research Unit for General Practice, University of Copenhagen, Øster Farimagsgade 5, Box 2099, Copenhagen DK -1014 CPH, Denmark.

E-mail: runeaa@sund.ku.dk.

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psychological components (e.g., that individual patients experience different effects on health status despite equal physiological limitations) [10]. This is in line with the recognition that patient-reported outcomes (PROs) are a key component in evaluating health outcomes [11–14].

Several PRO measures have been developed to assess disease-specific conditions such as asthma, pneumonia, chronic obstructive pulmonary disease, and the common cold [15–18] and are valuable in controlled trials with access to further diagnostic workup to ensure certainty in the diagnosis. The instruments available, however, use a single sum score of all parameters: a global score. It can be argued that when assessing different aspects of a disease as experienced by a patient, that is, a biopsychosocial model, the name itself indicates a number of different components that are not directly comparable. Accordingly, a multidimensional approach with several scales may be more suitable. To our knowledge, pragmatic trials intended to reflect everyday routine in primary care treatment of unspecific ARTIs do not have a qualitatively developed, psychometrically validated sum-scaling instrument to measure symptomatic severity and functional impacts in ARTIs *en bloc*.

The aim of this study was to develop and validate a PRO questionnaire with high face and content validity and adequate psychometric properties to measure the severity and functional impact of an ARTI in adults to determine the impact of the infection itself and to evaluate the success or failure of therapeutic trials in primary care.

Methods

The study was composed of 1) a literature and qualitative study to ensure face and content validity of the PRO (phase 1 and 2, respectively) and 2) a test of the PROs' psychometric properties (phase 3).

Phase 1: Item Generation

A list of all domains (physical, social, psychological, sleep, etc.) that might be affected during an ARTI and their corresponding symptoms was generated by reviewing other questionnaires covering specific ARTI diseases, looking at guidelines, and consulting colleagues. A first draft version of the questionnaire was constructed.

Phase 2: Face and Content Validity

Interviews

The qualitative study aimed to expand our knowledge of the symptomatic and functional impact of an ARTI. The participating GPs identified patients who agreed to participate and scheduled an interview no later than 48 hours after inclusion. The participants were assigned to focus group or single interviews to ensure adequate concept elicitation and cognitive assessment. The goals of this phase were 1) to elicit participants' experiences with ARTIs for item generation and 2) to verify the comprehensiveness and patient understanding of the questionnaire. We choose to conduct both single and focus group interviews to secure different views and dynamics in generating input on the questionnaire. All interviews took place at the Research Unit for General Practice. No payment was given to interviewees.

Single interviews

The single interviews lasted approximately 30 minutes. The purpose of these interviews was to understand which dimensions of the subjects' lives were affected and how this was experienced. During the interview, the subject completed the draft version of the questionnaire and was interviewed item by item to ascertain relevance and comprehension.

Focus group interviews

The group interviews lasted approximately 2 hours and were audio-recorded. The focus group first engaged in an open-ended discussion about symptoms and functional impairments in an ARTI. Then, the participants completed the draft version of the questionnaire and discussed the instructions, item wording, and ease of completion.

Timeline of qualitative study

We had a focus group session followed by single interviews. This procedure was then repeated. The first half of the qualitative study was mainly on concept elicitation; the second part focused more on cognitive assessment of the questionnaire, the corresponding wording of items, and response categories.

Analysis of interviews (focus and single)

R.A. conducted all interviews. H.T. was a comoderator in the focus groups. After each interview, R.A. and H.T. analyzed data and the draft version of the questionnaire was changed according to relevant input. The draft version of the questionnaire was successively used in the next interviews until further interviews gave no additional information, and the participants completed the questionnaire without problems or misunderstandings of the wording or meaning [19]. Items were worded according to participants' suggestions.

Phase 3: Psychometric Properties

Recruitment and participants

The psychometric properties of the final version of the questionnaire were tested in subjects with and without an ARTI who consulted their GP. Fifteen GPs were invited to enroll 20 subjects with and 20 subjects without an ARTI (scheduled for consultations and without complaints of fever or ARTI symptoms). All ARTI diagnoses were made solely on clinical grounds. Subjects were excluded if they were younger than 18 years or unable to communicate in Danish.

Statistical Analyses

Rasch analysis

Many PROs consist of ordinal response categories measuring the severity of the latent health trait (e.g., functional ability, pain, or happiness) as perceived by the respondent. When summing raw scores of items in a scale, however, an assumption of unidimensionality is made, that is, that the items in the questionnaire describe different aspects of the same construct (dimension), allowing raw scores of the items to be added together [20,21]. Rasch models are tests for unidimensionality in the sense that they investigate whether responses from persons can be listed according to item difficulty, from lowest to highest, in a probabilistic Guttmann pattern [22,23]. Items with poor fit to a Rasch model may be excluded in an iterative process, with one item removed at a time and model fit reestimated accordingly. When items fit a Rasch model, objective (invariant) measurement is obtained. Moreover, Rasch models can also test whether one or more items possess uniform or nonuniform differential item functioning (DIF), indicating that an item has unequal function in different subgroups, for example, sex, age, and diagnostic groups, and thereby disturbs the invariant measurement [23]. They also estimate whether response categories function as intended [24,25], that is, that an ordinal ranking of the response categories is obtained.

The pairwise estimation procedure implemented in the software program RUMM2030 was used to estimate item parameters in the partial credit Rasch model for dichotomous and polytomous items [26]. The overall fit of the model and scales was assessed by