Original Research

Development of an adverse-event coping scale (AECS) using item response theory

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Abstract

Background: Adverse drug events (ADEs) cause significant morbidity and mortality to patients. A brief questionnaire asking patients how they coped with such problems could be a useful tool for providing timely interventions.
Objective: The aim of this study was to develop an adverse-event coping scale (AECS) to measure patients' coping responses to their ADE.
Methods: Data were collected from subjects recruited from community pharmacies. Psychometric analyses based on item response theory (IRT) were performed to calibrate items and assess reliability. Convergent validity was evaluated by testing *a priori* formulated hypotheses about expected correlations between the coping scores and other related scales.
Results: A total of 140 patients participated in this study by answering the developed items. Confirmatory factor analysis supported a one-dimensional item bank with 11 items. The developed scale was reliable with the reliability coefficient of 0.82. Coping scores were positively correlated with seriousness of the ADE and health literacy, but not coping self-efficacy. Overall, results suggest that the score reflects problem magnitude and coping effort rather than coping efficacy.
Conclusion: A high score on the AECS indicates an ADE serious enough to prompt a patient to invest substantial efforts to cope with it. The final AECS item bank and its short-form can help clinicians better understand their patients' ADE-coping efforts.
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Introduction

Medication-related problems (MRPs) are serious and urgent health problems, causing significant morbidity, mortality, and economic burden to patients. More than 200,000 deaths were attributed to MRPs in 2005, and annual direct MRP-related costs were estimated to be in excess of $177 billion in the United States.[1,2] Among MRPs, patients' experiences of adverse effects have been consistently reported as one of the foremost reasons for non-adherence to medication, resulting in negative health outcomes to patients, including poor quality of life, high risk of hospitalization, and increased healthcare costs.[3–8] This suggests that a substantial opportunity exists for improving patients' outcomes by improving adverse drug event (ADE) management.

To optimize medication use, many physicians ask patients about their ADEs during office visits. However, some physicians avoid discussing patients' adverse responses to prescribed medication.[9] A significant discrepancy may sometimes exist between patients' perceived ADEs and physicians' evaluations of ADEs.[10] In addition, patients may consider their ADEs to be under their control, modify their treatment regimen independent of their physicians, and hesitate to discuss their actions with their physicians. Therefore, if problems occurred, physicians' asking patients not about the problem, but whether and how they coped with those problems could be an alternative approach to improve ADE management. For example, dose adjustments or a substitute treatment can be offered if the physician is aware of ADEs. Physicians can also dissuade patients from using maladaptive coping (e.g., independently modifying their treatment regimen without informing physicians) and encourage skillful and adaptive coping.

With the purpose of providing information to guide interventions to manage ADEs, Johnson and Neilands developed an instrument, the Side Effect Coping questionnaire (SECope), which measured patients' coping with ADEs.[11] The SE-Cope was shown to be valid and reliable among patients with HIV.[11] Recently, De Smedt et al applied the SECope to patients with heart failure after adding two items based on cognitive interviews.[12] The SECope consists of 20 items grouped into five subscales: positive emotion-focused coping, social support seeking, non-adherence, information seeking, and taking side effect medications. The items address two forms of coping behavior: *emotion-focused coping* which serves to regulate the negative emotions associated with the problem and *problem-focused coping* which aims at solving or managing the problem. In this study, problem-focused items were highlighted rather than emotion-focused items in the SECope since patients could consider ADEs as controllable by modifying their treatment regimen.[12] When the problem involves a controllable aspect, it has been generally recognized that this calls for a greater proportion of active and instrumental problem-focused coping than other types of coping.[13] In the previous studies using the SE-Cope, there was a lack of information on how precisely each item measured an individual's coping level across the full spectrum of patient's coping with ADEs. By employing item response theory (IRT), the relationship between a patient's coping level and the probability of endorsing the individual item can be explored. Because the IRT model analyzes psychometric properties at the item level, it can inform the relationship between the respondent's coping level and responses to each item. The item information function from IRT analyses measures the latent trait (in this case, patients' coping level) precisely with a minimum number of items.

The objective of this study was to develop an adverse-event coping scale (AECS) that clinicians could use in their patient population to receive patients' immediate feedback on their coping with ADEs. Based on IRT, items were calibrated and reliability was assessed. Validity was evaluated by testing *a priori* formulated hypotheses about expected correlations between the coping scale and other related scales.

Methods

Development of an item pool

Nine items were derived from among the problem-focused SECope items. Emotion-focused coping items were excluded and problem-focused SECope items with similar meanings were combined and reworded to reduce participant response burden. Discussions were then held to assess the content gaps with four pharmacy faculty, one medicine faculty, and one clinical psychologist. Based on the discussions, seven new items were created resulting in a total of 16 items in the initial item pool for the main analysis. The response options of the 16-item pool