Validation of a Patient-reported Outcome (PRO) Measure and a Clinician-reported Outcome (CRO) Measure to Assess Satisfaction with Pharmacologic Stress Agents for Single-photon Emission Computed Tomography (SPECT) Myocardial Perfusion Imaging (MPI)

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ABSTRACT

Purpose: The objective of this study was to develop and validate clinician and patient measures of satisfaction for pharmacologic stress agents (PSAs) used in single-photon emission computed tomography myocardial perfusion imaging procedures.

Methods: Two questionnaires were developed: the Clinician Satisfaction and Preference Questionnaire (CSPQ) and the Patient Satisfaction and Preference Questionnaire (PSPQ). Items were developed, and the content validity of the questionnaires was ensured by participants' involvement in the item generation (5 clinician and 18 patient face-to-face concept elicitation interviews) and item modification phases (5 clinician and 10 patient face-to-face cognitive debriefing interviews). Psychometric validation of the satisfaction component of the questionnaires was conducted in a sample of 9 clinicians and 90 patients.

Findings: After initial patient interviews and cognitive interviews, two 8-item instruments were developed with each containing an optional PSA preference question. The PSPQ assessed patients' receptiveness and satisfaction with the PSA that they received. The CSPQ assessed clinicians' satisfaction with the time and ease of PSA preparation, administration, and monitoring of the PSA. The optional preference question in both instruments assesses preference among PSAs. In a multicenter observational study of 88 patients and 9 clinicians, the PSPQ Preparation and Reaction to Agent scales elicited reliability coefficients of 0.90 and 0.87, respectively. In addition, the test-retest reliability was acceptable for all PSPQ scales (intraclass correlation coefficient range, 0.73–0.86). Concurrent validity with the Treatment Satisfaction Questionnaire for Medication (TSQM) indicates low-to-moderate correlations between the Effectiveness, Convenience, and Global Satisfaction scales of the TSQM with the PSPQ Satisfaction with Administration, Satisfaction with Effects, and Overall Satisfaction items (range, 0.46–0.78). Analysis of the CSPQ found that both the Preparation and Reaction to Agent subscales indicated strong internal consistency (α = 0.98 and 0.99, respectively).

Implications: The PSPQ and CSPQ were developed and validated with rigorous methods. The instruments and their domains found strong internal consistency and good test-retest reliability. These questionnaires, when used as measures of treatment satisfaction in clinical trials, real-world observational studies, or by clinicians in their own laboratories, may help patients and clinicians better understand the impact of single-photon emission computed tomography myocardial perfusion imaging pharmacologic stress testing. (*Clin Ther*. 2016;38:1141–1150)
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Key words: clinician-reported outcome, CRO, patient-reported outcome, PRO, satisfaction, stress agents.

Accepted for publication February 20, 2016.
http://dx.doi.org/10.1016/j.clinthera.2016.02.024
0149-2918/$ - see front matter

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INTRODUCTION

Patient-reported outcomes from clinical trials offer insight into the impact of disease on health-related quality of life, including treatment satisfaction.[1] Individual and overall ratings of satisfaction reflect the patient perspective and help to facilitate treatment options that may minimize patient burden.[2] Patient satisfaction is a highly relevant outcome because side effects, inconvenience, and complications associated with testing may affect clinical outcomes.[1,2] An example of a diagnostic test in which patient satisfaction is influential is myocardial perfusion imaging (MPI).

Single-photon emission computed tomography (SPECT) MPI stress testing is a noninvasive imaging procedure that can be used for the diagnosis, prognosis, and assessment of treatment effectiveness in cardiovascular disease, including myocardial scarring or infarction.[3] Dynamic exercise is the stress technique of choice in the assessment of patients when coronary artery disease is suspected or known; however, utilization is limited by patients' ability to exercise to an acceptable workload (eg, at least 85% of the maximum predicted heart rate and 5 metabolic equivalents). Pharmacologic stress is an alternative to dynamic exercise for patients with comorbidities, such as chronic obstructive pulmonary disease, peripheral vascular disease, obesity, arthritis, neuromuscular disease, or age-related generalized reconditioning, all of which can limit patients' ability to undergo exercise stress testing.[4] The pharmacologic stress procedure has the advantages of speed, reliability, and reproducibility. However, disadvantages include that it is not possible to monitor the adequacy of stress, and it is not equivalent to the physiologic stress experienced by the patient in everyday life. Despite its disadvantages, approximately one-half of MPI stress tests in the United States are performed with a pharmacologic stress agent (PSA).[5]

MPI with pharmacologic stress testing, although noninvasive, is burdensome for the patient; patients taking a pharmacologic agent must abstain from caffeine-containing foods and beverages and some medications for a minimum of 12 hours before the test. The procedure itself is time consuming for both the patient and laboratory staff in addition to the requirement, as with exercise stress testing, of the presence of a health care professional current in immediate life support for the duration of the procedure.

To better understand the impact (ie, time spent for the test, ease of use, resource allocation, burden of test administration) of MPI pharmacologic stress testing, from the perspective of both patients and clinicians, 2 questionnaires were developed: the Patient Satisfaction and Preference Questionnaire (PSPQ) and the Clinician Satisfaction and Preference Questionnaire (CSPQ). These questionnaires measure satisfaction with and preference for PSAs used in the SPECT MPI procedure from the perspective of the patients and the cardiologists, technologists, or technicians ("clinicians"). The content validity of the questionnaires (ie, their ability to capture concepts that are important and comprehensive for the respondent) was ensured by participants' taking part in an item-generation phase (18 patient and 5 clinician face-to-face concept elicitation interviews) and item modification (10 patient and 5 clinician face-to-face cognitive debriefing interviews).[6]

The objective of this study is to document and report on the psychometric performance of the satisfaction portions of these 2 newly developed questionnaires with data collected during a US, multicenter, observational study.

METHODS

Instrumentation

The PSPQ is a self-report measure of a patient's satisfaction with and preference for drugs that induce cardiovascular stress by increasing blood flow through the arteries of the heart during a cardiac nuclear stress test. It consists of 8 items that address the following: Preparation (3 items), Reaction to Agent (2 items), Satisfaction with Administration (1 item), Satisfaction with Effects (1 item), and Overall Satisfaction (1 item). The PSPQ also includes an optional item for use in a clinical trial to assess patient preference between 2 stress agents. The PSPQ is based on an 11-point numeric scale, with items measuring the Preparation and Reaction to Agent domains range from 0 (not at all) to 10 (extremely bothered), with higher positive scores indicating a higher level of bother. Items that measure the domains of Satisfaction with Administration, Satisfaction with Effects, and Overall Satisfaction range from −5 (extremely dissatisfied) to 0 (neither satisfied or dissatisfied) to 5 (extremely satisfied), with higher positive scores indicating a higher level of satisfaction. This scoring format was determined in the development of the measures to denote the distributional shift from positive to negative outcomes. The questionnaire concerns patients' reactions

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