Applicability of the OPTA Questionnaire for Patients with Stable Ischemic Heart Disease in Indian Clinical Practice: A Cross-sectional, Real-word Evidence Study

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ABSTRACT

Background: Angina is the symptomatic form of stable ischemic heart disease (SIHD). The Optimal Treatment of Angina (OPTA) questionnaire was developed and validated to overcome the lack of a standardized and accurate tool to assess patients' clinical conditions with SIHD. This study aimed to understand the applicability of OPTA in patients with SIHD in routine clinical practice in India.

Materials and methods: In this cross-sectional, single-visit study, 344 patients with SIHD were enrolled. Study endpoints were physicians’ agreement on the applicability of OPTA, the usefulness of OPTA in assessing degree of impairment in daily activities of patients, and its positive predictive value (PPV).

Results: All enrolled patients completed the study. The mean [standard deviation (SD)] age was 56.6 (10.77) years, with a majority of patients being male (69.5%) and on antianginal treatment for >1 year (80.4%). Physicians of all participating patients agreed that the OPTA questionnaire could accurately assess whether treatment received by patients was optimal (100% agreement rate). No or moderate degree of impairment of daily activities was reported by 93.9% and 73.0% of patients for one and two health-related questions, respectively. The PPV and sensitivity of the questionnaire were 88.97% [confidence interval (CI): 87.58%, 90.22%] and 39.33% (CI: 34.01%, 44.85%), respectively.

Conclusion: The OPTA questionnaire showed good agreement regarding health status between physicians and patients and could be used to periodically assess and guide clinical judgment in the management of SIHD in India. Further assessment of the impact of various treatments temporally and in the long term may be warranted.

ORIGINAL ARTICLE

INTRODUCTION

Coronary artery disease (CAD) is a common heart condition that involves atherosclerotic plaque formation in the vessel lumen.⁵ According to the 2019 European Society of Cardiology guidelines, CAD can be categorized as either acute coronary syndrome (ACS) or chronic coronary syndrome (CCS). The most frequently encountered clinical scenarios in patients with suspected or established CCS are (1) patients with suspected CAD and “stable” anginal symptoms and/or dyspnea; (2) patients with new onset of heart failure or left ventricular dysfunction and suspected CAD; (3) asymptomatic and symptomatic patients with stabilized symptoms <1 year after an ACS, or patients with recent revascularization; (4) asymptomatic and symptomatic patients >1 year after initial diagnosis or revascularization; (5) patients with angina and suspected vasospastic or microvascular disease; and (6) asymptomatic subjects in whom CAD is detected at screening.³

Most patients can be given the diagnosis of CCS, also referred to as SIHD, based on a classic history of angina pectoris in the presence of either risk factors for or known atherosclerotic cardiovascular disease.⁴ Angina is classically described as substernal chest pain or discomfort which lasts for <10 minutes. Chest pain in the case of stable angina is often provoked by emotional or physical stress or exercise and is relieved by rest or nitroglycerine.⁴ Stable angina consists of such transient episodes of chest pain over several weeks⁶ and is the symptomatic form of SIHD. SIHD becomes symptomatic when >50% of the luminal diameter is compromised by the plaque. The progression of SIHD to an unstable form could lead to ACS or myocardial infarction.⁵ The incidence of angina rises continuously with age in women, whereas it peaks in men between 55 and 65 years of age before declining.⁷

The 7-item Seattle Angina Questionnaire (SAQ) is a validated disease-specific health status instrument for SIHD with high test-retest reliability, predictive power, and responsiveness.⁶–⁸ The OPTA questionnaire was designed based on the 7-item SAQ tool, with appropriate adaptations catered to the Indian scenario. It was developed by a panel of experienced and leading cardiologists across India and face-validated with 51 patients with SIHD attending cardiology clinics.⁹

The OPTA questionnaire includes five questions on the cardiovascular health status of patients over the past 4 weeks from the date of assessment, including limitation on activities because of angina, frequency of discomfort, frequency of need for emergency medication, effect on the overall enjoyment of life, and views about living with symptoms of angina. This study aims to understand the applicability of the OPTA questionnaire in patients with SIHD in a real-world setting.

METHODS

Study Design

This was a cross-sectional, single-visit study in which patients with SIHD were enrolled at 34 centers from August 2021 to January 2022.

The study was conducted in accordance with the ethical principles laid down by the Declaration of Helsinki ICH-E6 R2 “Good Clinical Practice” guidelines, and New Drugs and Clinical Trials 2019. The trial was prospectively registered on Clinical Trials Registry-India (CTRI/2021/07/035263) on 29 July 2022.

Written informed consent was obtained from all patients before enrolment. Before administering the questionnaire to patients, all investigators had to grade each patient’s overall condition based on their clinical judgment as good, moderate, or severe.
The investigators or their qualified designees conducted all assessments. Baseline demographic information such as age, gender, and duration of the disease was recorded for all patients.

**Eligibility Criteria**

Male and female patients aged >18 years with a confirmed history of SIHD documented in their medical records who had completed at least 10 years of school education, and who were on medical therapy for at least the past 3 months were included in the study. Patients with a history of coronary artery bypass grafting within the past 6 months, patients with a history of ACS and/or percutaneous transluminal coronary angioplasty within the past 6 months, and those deemed unsuitable by the investigator for participation in the study were excluded.

**Study Endpoints and Assessments**

The OPTA questionnaire consisted of five questions, each with three options as described below: 

**Question 1:** patient’s opinion on day-to-day activities in the past 4 weeks being (1) extremely limited, (2) moderately limited, or (3) not limited at all. 

**Question 2:** frequency of chest pain/tightness/discomfort/angina experienced by the patient over the past 4 weeks at assessment to be (1) ≥4/week, (2) ≤3/week, or (3) 0/week. 

**Question 3:** average frequency of nitroglycerine (short-acting nitrate) taken for chest pain, tightness, or angina over the past 4 weeks by the patient to be (1) ≥4/week, (2) ≤3/week, or (3) 0/week. 

**Question 4:** patient’s opinion on limitation to the enjoyment of life over the past 4 weeks due to chest pain, chest tightness, or angina to be (1) extremely limited, (2) moderately limited, or (3) not limited at all. 

**Question 5:** patient’s opinion on having to live with chest pain, chest tightness, or angina the way it was right now as (1) not satisfied, (2) somewhat satisfied, or (3) mostly satisfied.

Patients’ responses were recorded, and health status was categorized as good, moderate, or severe (not good) using the following predetermined cut-offs: (1) good, if patients chose response C for at least four out of five questions; (2) moderate, if patients chose response C for at least three out of five questions; and (3) severe, if patients chose response C for at least two out of five questions.

This categorization of OPTA responses was compared with investigators’ clinical judgment of the patient’s health condition as good, moderate, or severe, and the proportion of true positives (TP), false positives (FP), true negatives (TN), and false negatives (FN) were computed to determine the sensitivity, specificity, PPV, negative predictive value (NPV), FP rate (FPR), and FN rate (FNR) of the OPTA questionnaire.

Sensitivity was calculated as the number of TP/(number of TP + number of FN) PPV of the questionnaire was the percentage of patients with a positive OPTA result who actually had the disease. NPV was the percentage of patients with a negative OPTA result who actually did not have the disease. FPR is the probability that a positive result will be given when the true value is negative. FNR is the probability that the test missed a TP.

Based on these assessments, the following study endpoints were defined: (1) the proportion of physicians in agreement that the OPTA questionnaire appropriately assessed whether treatment received by the patients was optimal; (2) the proportion of patients choosing options B alone (moderate impairment of activities), C alone (no impairment of activities), or B or C for any of the five questions; and (3) PPV of the OPTA questionnaire.

**Statistical Analysis**

No formal sample size calculation was performed for this study. This study planned to enroll approximately 500 patients with SIHD. COVID-19 restrictions caused a delay in achieving the original sample size, and the study was terminated after 344 participants were enrolled. All continuous variables were summarized as mean and SD, while categorical data were summarized as frequency and percentage.

PPV was calculated as the number of TP/(number of TP + number of FP). Thus, the PPV of the OPTA questionnaire denoted the percentage of patients who were accurately labeled per clinicians’ assessment. Statistical analysis was performed using R software Version 4.1.

**RESULTS**

**Patient Disposition and Baseline Characteristics**

A total of 344 patients were screened and enrolled in this study across 34 study sites in India. The mean (SD) age of the study population was 56.6 (10.77) years, and the majority of patients were male (n = 239; 69.5%; Table 1).

**Physicians’ Agreement on the Applicability of the OPTA Questionnaire**

In this study, investigators of all the enrolled patients agreed that the OPTA questionnaire could accurately assess that the treatment received by patients was optimal.

**Usefulness of OPTA Questionnaire in assessing Degree of Impairment in Daily Activities**

Table 2 summarizes the responses chosen by patients for any of the five questions. The majority of the patients chose options B or C for one question (93.9%); the proportion of patients choosing these options for two, three, four, and five questions were 73.0%, 59.9%, 49.7%, and 29.4%, respectively.

**Predictive Value of the OPTA Questionnaire**

The OPTA questionnaire’s sensitivity, specificity, and PPV were determined based on TP and FP and TN and FN values. A high PPV of 88.97% (87.58%, 90.22%) was obtained for OPTA with a sensitivity of 39.33% (34.01%, 44.85%) and specificity of 0% (0.00%, 20.59%).

**DISCUSSION**

The objective of the present cross-sectional, questionnaire-based study was to understand the applicability of the OPTA questionnaire.
Real-world Applicability of the OPTA Questionnaire

in patients with SIHD in a real-world setting in India. Investigators of all patients who participated in the survey agreed that the questionnaire could accurately assess that the treatment received by patients was optimal. Furthermore, the degree of impairment in daily activities as experienced by patients was reflective of the real-world setting, considering that 93.9% of patients reported good status for one question, and the proportions sequentially declined for two, three, four, or five questions. A PPV of 88.97% with a sensitivity of 39.33% and specificity of 0% for the OPTA questionnaire indicates that there is a high level of agreement between physicians and their patients about individual health status. The OPTA questionnaire, which is a shorter derivation of the SAQ, was developed according to the Indian setting of literacy, compliance, and level of routine physical activities considering that SAQ is a detailed questionnaire that requires daily diary documentation by the patient and may be cumbersome in the Indian setting. Thus, the current applicability findings further corroborate the previous content validation of OPTA by a panel of six experts and face validation by 51 patients.

The OPTA questionnaire can be considered a simple checklist-like tool for screening angina and further formulating a treatment plan for managing a suspected case of angina. It also helps clinicians in risk stratification, which generally follows a sequential order: clinical evaluation, resting electrocardiogram/echocardiogram, and stress and imaging tests to document inducible ischemia. Optimum management depends on the grading of angina symptoms, that is, stable angina can be treated by medications noninvasively, whereas unstable high-risk patients can be selected, and timely revascularization can be administered for better prognosis and reduced morbidity and mortality.

In this study, the investigators’ agreement with the OPTA questionnaire’s assessment of the patient’s clinical condition and treatment and PPV affirm its applicability in the real-world setting in India for SIHD. Quick administration of the OPTA questionnaire can help in risk stratification, referral, and timely management, especially in India, where patients need to be referred to tertiary care centers from peripheral rural areas without cardiologists or medical facilities. Its brevity, validity, and high predictive value can assure accurate assessment and, therefore, can be used as a standard yardstick to assess the clinical condition of SIHD. Further translations in local languages are warranted to widen the reach and simplicity of the questionnaire administration in India.

This study had certain limitations: due to COVID-19 restrictions, the planned recruitment target was not achieved, leading to a smaller sample size. The cross-sectional, single-visit study design limited future follow-up of patients’ clinical condition and the impact of treatment. Hence, the applicability of OPTA in long-term clinical condition assessment has not been established. A long-term study with follow-up visits would help in assessing the temporal applicability of the OPTA questionnaire.

**Author Contributions**

All authors were involved in the conception and development of the study and interpretation of data. PB Jayagopal, Bhupesh Shah, Bishwa Bhushan Bharti, and Jayapal Vidhyadharan were involved in data acquisition and analysis. All authors reviewed and approved the final draft of the manuscript before submission.

**Conflicts of Interest**

PB Jayagopal, Bhupesh Shah, Bishwa Bhushan Bharti, and Jayapal Vidhyadharan received research grants from Abbott for participation in the study. Greeshma Upendra is an employee of Abbott.

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