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Adherence

Adherence to and beliefs in lipid-lowering medical treatments: A structural equation modeling approach including the necessity-concern framework

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ABSTRACT

Objective: This study attempts to identify a structure among patient-related factors that could predict treatment adherence in statin patients, especially with regards to the necessity-concern framework.
Methods: 414 Swedish patients using statins completed a questionnaire about their health, treatment, locus of control, perception of necessity-concern and adherence. The data were handled using a structural equation modeling approach.
Results: Patients that reported high perceptions of necessity to treatment seemed to adhere well, and side effects appear to affect adherence negatively. Disease burden, cardiovascular disease experience and high locus of control seem to have mediating effects on adherence.
Conclusion: This study provides support for the hypothesis that health- and treatment-related factors, as well as locus of control factors, are indirectly associated with treatment adherence via their association with mediating factor necessity.
Practice implications: This study highlights the importance of considering patients' beliefs about medications, disease burden, experience of cardiovascular events and locus of control as these factors are associated with adherence behavior to statin treatment. This study also emphasizes more generally the importance of an approach targeting necessity and concern when communicating with and treating patients with lipid-lowering medication.

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death in the industrialized world [1,2]. Dyslipidemia is an important risk factor for CVD, estimated to cause 18% of cerebrovascular disease and 56% of ischemic heart disease [3]. Cholesterol lowering has been the primary goal of therapies aimed at CVD risk reduction, and several randomized studies have demonstrated the benefits of statins (hydroxymethylglutaryl-CoA reductase inhibitors) in the reduction of cardiovascular-related events within high-risk patient groups [4]. Currently, statin drug treatment is one of the most important treatment strategies when managing patients with, or at high risk of, CVD.

Adherence is defined as the extent to which a person's behavior, such as taking medication, following a diet or executing lifestyle changes, corresponds with the recommendations from a health care provider [5]. Poor adherence has been shown to be an important factor for treatment failure when looking at both high cholesterol levels [6] and morbidity [7–9], and, as a result, non-adherence to treatment is considered to be a cardiovascular risk factor [10]. Adherence to long-term pharmacological therapy for chronic illnesses in developed countries averages 50% [5], and for lipid-lowering pharmacological therapies the long-term adherence is poor and declining considerably over time.

In 2003, the World Health Organization (WHO) described adherence as a phenomenon determined by five dimensions: patient-related factors, social and economic factors, health care team and system-related factors, condition-related factors and therapy-related factors [5]. To describe adherence and for the analysis of non-adherence among patients with CVD, hypertension and other long-term therapies, a large number of hypotheses and factors have been proposed [11].

Several models that aim to explain health behavior are based on patients weighing positive and negative perceptions for a treatment or health advice, where the balance directs the behavior. The models that been used in adherence studies are the Health

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Belief Model [12,13], the Transtheoretical Model [14], the Protection Motivation Theory [15,16] and the Self-Regulatory Model (SRM) [17,18]. The SRM proposes that health-related behaviors are cognitive responses influenced by a patient's perception of treatment and emotional response to treatment. These responses can be derived from both manifest symptoms and concern about a health threat, or experience or concern about side effects from a treatment.

Influenced by the earlier models, the necessity-concern framework (NCF) was developed to specifically investigate drug treatment adherence [19]. According to the NCF, a patient's decision regarding adherence is the result of a trade-off between the patient's perceived need for a prescribed treatment (necessity) and their worries about the potential adverse effects as a result (concern). In this study, we chose to assess patients' beliefs using the NCF as it has been used in a broad range of different quantitative studies exploring drug treatment adherence [20–23], especially for cardiovascular diseases [24–27].

Some factors seem to be more related than others. Factors with a high probability of affecting adherence include gender [28], demographics [29,30], patient understanding and perception of medication [5], sickness- and treatment-related factors [31–34], and health locus of control [35]. The health locus of control model is defined by three different dimensions: an individual's sense of control over their health is directly related to their own beliefs and actions (internal); to chance externality (chance); or to the influence of other important persons (powerful others) [36]. There is support for the idea that a person's locus of control is associated with health behavior, mainly in combination with other predictive factors [37]. Qualitative studies suggest that individuals with a strong locus in powerful others might be more adherent to the recommendations of health care professionals [38].

To date, how these (and other) factors are related to adherence and non-adherence for patients with CVD has not been fully explored, and there is little information available regarding how strong the influence of these factors is on adherence in adjusted models. This study attempts to identify a structure among factors regarding demographic, health and treatment factors, locus of control, NCF and adherence in patients using statins. The aim is to present a model that describes the relationships between the central variables and a measurement structure that possibly predicts adherence within patient groups at high risk of CVD.

2. Methods

For this study, a cross-sectional study design was applied. A total of 600 postal questionnaires were distributed in May 2009 to the 28 operating pharmacies within the county of Uppsala in central Sweden. The number of questionnaires distributed to each pharmacy was proportional to the number of previous statin prescription sales. The employees of each pharmacy were instructed to invite every patient who visited the pharmacy for the preparation of their statin prescription. There were no inclusion criteria other than the statin prescription requisite, and no exclusion criteria. Patients agreeing to participate, after receiving oral and written information about the study by the pharmacist, were handed a questionnaire to take home and complete, and then return by post. The number of patients declining to participate was registered for control of non-participants. The first page of the questionnaire contained precise information on the purpose of the study. Completed questionnaires were returned anonymously in a prepaid envelope. All questionnaires returned within three months were included in the study. A total of 697 statin users were asked to participate: 109 declined to participate and 588 questionnaires were handed out (one pharmacy failed to distribute their questionnaires). Questionnaires were returned by 414 individuals, making the response rate of the distributed questionnaires 70.4% (414/588) and the overall response rate 59.4% (414/697).

2.1. Measures in questionnaires

The questionnaire contained a total of 76 questions. The main data types and measures that were included were:

Demographic data: This was collected using questions that assessed the respondent's gender, age, occupation and educational level, including compulsory school, secondary school (or equivalent) and university.

Health-, disease- and treatment-related factors: Data were collected using a list of 14 common health problems (used as a cumulative measure of disease burden and number of health problems), cardiovascular disease experience (myocardial infarction and/or angina), perceived satisfaction with treatment explanations made by a physician, and time on statin treatment; these questions have been used earlier [39]. Experiences or worries of side effects and difficulties swallowing solid doses can affect adherence negatively [34], and data were assessed by the question: Do you experience any of this unpleasantness when taking your statins? (a) Yes, I feel that I have trouble swallowing tablets, (b) Yes, I feel that I encounter unpleasant side effects from them, (c) No, I do not feel any unpleasant reactions related to my treatment. The variable was scored as a count variable.

Health locus of control: These data were measured using the Multidimensional Health Locus of Control (MHLC) 18-item test [36]. MHLC is a measurement instrument that includes three six-point Likert scales: Internal (MHLC-I), Chance externality (MHLC-C) and Powerful others (MHLC-PO). The different scales, or levels, were analyzed separately. In this study, the MHLC scales were treated as index only in the correlation matrix.

Beliefs about medicines: Results were measured using NCF based on the Beliefs about Medicines Questionnaire-Specific (BMQ-S) [19]. BMQ-S is a validated 10-item test instrument which assesses beliefs about perceived medication necessity and perceived medication concerns on five-point Likert scales. BMQ is a two-scale construction and is also available to use as an index. In this study, the index was only used in the correlation matrix. The BMQ questionnaire has been translated into Swedish, with a back translation approved by the original author of the questionnaire, and has been previously used in Sweden [40–43].

Medication adherence: These data were self-reported using the Morisky scale of adherence (MSA) in a four-item form [44]. The MSA is a count variable and the first question is: "Do you ever forget to take your medicine?". The Morisky scale was originally designed to evaluate medication adherence in hypertensive patients, but has subsequently been found to be reliable in a variety of adherence studies [45,46]. In previous statin studies, the MSA used was binary, with only two categories [47]. Patients who answered "no" to all questions were categorized as highly adherent, while patients who answered "yes" to at least one question were categorized as having low adherence. This categorization system is consistent with what was used when developing the original scale, as well as how it has been used in several adherence studies [47,48].

2.2. Method of data analysis

The Statistical Package for the Social Sciences version 19 (Chicago, IL, USA) was used for descriptive statistics, factor analysis, to measure the variance inflation factor (VIF), and Chi-square and Mann–Whitney *U* tests. WarpPLS vs. 2.0 was used for structural equation modeling (SEM) analysis with the partial least squares (PLS) estimation technique [49]. SEM is a combination of