Original article

Developmentand Validation of a Questionnaire about Patient Knowledge of Adverse Effects of Statins

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SUMMARY

Statins are drugs that are well tolerated, but considering their extensive use, there are still concerns regarding their safety. Knowledge of patients about the side effects of statins has not been adequately studied, although timely recognition of the AES is of vital importance for improving the quality of patient care and reducing morbidity and suffering. The aim of this study was to develop and test a questionnaire for measuring the knowledge of patients about statin therapy about adverse effects of statins (AES).

This two-center cross-sectional study was conducted during the period from March 1, 2015 to April 1, 2016, taking place in pharmacies from the city of Belgrade and at the Department of Internal Medicine, Clinical Center in Kragujevac, Serbia. The study included 300 patients and 20 pharmacists.

The questionnaire showed satisfactory internal consistency, with Cronbach's alpha of 0.898, good construction and homogeneity of questions. After splitting the questionnaire to two parts at random, Cronbach's alphas were 0.834 and 0.842 for the both parts, respectively. Exploratory factorial analysis revealed two domains. The patients rated their knowledge of the side effects of statins 52.7±19.9 on the visual analogue scale.

Based on the results of this study, we believe that this questionnaire could be a useful tool for testing the knowledge of patients about adverse effects of statins and help physicians to identify patients with insufficient knowledge who should be additionally informed about it.

Key words: questionnaire, statins, adverse effects

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INTRODUCTION

Lovastatin, simvastatin, pravastatin, atorvastatin, etc. ("the statins") are 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors, which are used in the treatment of hypercholesterolemia (HH) (1). They also have an important role in primary and secondary prevention of cardiovascular diseases (2), in reducing the rate of cardiovascular events from 25% to 45% (3). It was shown that 48.1% of patients with HH in 2008 were treated with statins (4), so no wonder they are referred to as top-selling prescription drugs in the USA and worldwide (5, 6). It has been proved that benefits of using statin therapy significantly exceed their risks (2). Statins are drugs that are mostly well tolerated, and therefore inappropriately considered to have minimal adverse effects (AEs) (7, 8).

The main adverse effects of statins (AES) are gastrointestinal symptoms (8%), myopathy and musculoskeletal pain (7%), rhabdomyolysis (0.005%), which is a rare but serious adverse effect (9-12), and elevated liver enzymes (3). Liver failure in the United States occurs in 0.5-1 /100,000 persons per year and kidney damage in 0.5% (13). The US Agency for Food and Drug Administration (FDA) announced that use of statins can lead to cognitive impairment and increased risk of diabetes (3). Other AEs are: headache, rash (1), peripheral neuropathy (12 /100,000 in the US) (13), cataract, erectile dysfunction, and venous thromboembolism (14). There is a growing concern about their safety among health professionals, especially after withdrawal of cerivastatin from the market in 2001 (15). Sound knowledge of patients about (AES) is critical for early recognition of potentially serious AEs and timely cessation of further intake of these drugs. The study in Nigeria showed that the patients' knowledge about AEs of drugs is associated with sex, education, and employment status (P <0.05), and that only 55.1% of the examined patients knew AEs of medicines they used and 88.1% of respondents answered that they should contact a doctor if any adverse effect occurs (16).

The knowledge of patients about AES has not been adequately studied, although the recognition of the AEs is of vital importance for improving the quality of patient care and reducing morbidity and suffering of the patient (8, 17). Measuring patients' knowledge about AES with a scale will enable the identification of previously unrecognized AES, their characterization and identification of predisposing factors in patients (18, 19). There are publications that indicate that damage due to the AEs is much greater than the utility of statins, which indicates the vitality of this topic (8, 20).

The aim of this study was to develop and test reliability and validity of the questionnaire designed to measure the knowledge of patients' on statin therapy about AEs of the drugs they were taking.

MATERIALS AND METHODS

Construction of the questionnaire

Development of the questionnaire for assessing patients' knowledge about AES of statins (QPK-AES) was carried out in a standardized manner, using the accepted methodology for the development and validation of a questionnaire.

Designing QPK-AES began by searching bibliographic databases (PubMed, SciIndex). After that, three focus groups (FGs) were formed, on the basis of recommendations used in the construction of other questionnaires for the measurement of knowledge. Focus groups consisted of 5 physicians, 5 pharmacists and 5 patients on statin therapy (21). The aim of the FGs was creation of the initial pool of questions, and this process resulted in 24 questions.

The database of questions for QPK-AES was then reviewed by the same FGs. The aim of the review was the selection of relevant, clear and objective questions for the questionnaire. The review ended with 15 questions which were comprised by the final instrument. Pilot testing of the questionnaire was performed with 7 pharmacists and 30 patients on statin therapy, by the same researcher, to evaluate the clarity and comprehension (22). The results of the pilot testing were not taken into account when processing data for the validation of the questionnaire.

QPK-AES questionnaire (Figure 1) contains 15 statements (questions) that test patients' knowledge about the side effects of statins. On each statement, patients may respond by circling one of 7 possible answers. We used the Likert scale with 7 answers: 1-completely disagree, 2- moderately disagree, 3-partially disagree, 4-neither agree nor disagree, 5-partially agree, 6-moderately agree, and 7-completely agree. The statements were both affirmative and negative, in order to minimize the tendency of respondents to answer always by circlingthesame letter.

Figure 1. **The questionnaire for assessing patients' knowledge about the adverse effects of statins (QPK-AES).** The answers to each of the 15 questions were rated as the following: 1 - "completely disagree", 2 - "disagree", 3 - "partially disagree", 4 - "neither agree nor disagree", 5 - "partially agree", 6 - "agree" and 7 - "completely agree". Total score for a patient was obtained by summation of the scores for the eight questions.

Please answer the following statement about adverse effects of the drug you are taking by encircling the number in front of the answer you consider the most appropriate. For each statement there is only one correct answer.

1. The treatment with statins can cause serious adverse effects
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree
    6. agree
    7. completely agree

2. Statins can cause muscle weakness, above all
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree
    6. agree
    7. completely agree

3. Difficult muscle damage can be the result of statin therapy
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree
    6. agree

        7. completely agree

4. Sudden muscular pain can develop as a result of statin usage
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree
    6. agree
    7. completely agree

5. Liver damage can occur from the use of statins
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree
    6. agree
    7. completely agree

6. The use of statins may lead to an increased risk for diabetes
    1. completely disagree
    2. disagree
    3. partially disagree
    4. neither agree nor disagree
    5. partially agree

6. agree

7. completely agree

7. The use of statins can affect mental activity

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

8. Statins may cause lungs dysfunction

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

9. Statins may affect the occurrence of erectile dysfunction

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

10. Cataract is a rare adverse effect of statins

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

11. Rash may appear as a result of the use of statins

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

12. Statin therapy has an effect on increased blood clotting in the veins

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

13. Nerve damage can be an adverse effect of statin therapy

1. completely disagree

2. disagree

3. partially disagree

4. neither agree nor disagree

5. partially agree

6. agree

7. completely agree

14. Death may occur due to the serious adverse reactions to the statin therapy

    1. completely disagree

    2. disagree

    3. partially disagree

    4. neither agree nor disagree

    5. partially agree

    6. agree

    7. completely agree

15. Adverse reactions to statins should be treated without doctors assistance

    1. completely disagree

    2. disagree

    3. partially disagree

    4. neither agree nor disagree

    5. partially agree

    6. agree

    7. completely agree

The questionnaire also included the question for discovering patients who were motivated by social desirability when answering.

Besides the QPK-AES, we also used a socio-demographic survey, designed to obtain information about clinical and demographic characteristics of the patients. The variables to be measured by this questionnaire were: age (the data was divided into four groups: 18-29 years of age, 30-49, 50-65, and over 65 years), gender (male and female), education level (years of schooling were divided into five groups: ≤4, 8, 12, 16, ≥17), level of monthly income (wages), main diagnosis, comorbidity, and duration of statin therapy (22, 23).

All patients completed also the visual-analog scale (VAS). This scale was used to determine the overall knowledge about the AES. Knowledge was marked on the 10 cm line, where they were asked to put a cross on, depending on the level of their knowledge. The knowledge was then measured by measuring the distance from the left end of the VAS (equal to 0) to the cross. The distance was then quantified into values from 0 to 100, where 0 indicates the minimum knowledge and 100 the maximum knowledge of AES (28, 29).

Besides the QPK-AES and VAS, the patients completed another validated survey, Short welfare scale (KSB), for which we obtained adequate permission from the author V. Jovanović (30). It was used for testing divergent validity since it measures the phenomenon opposite to knowledge.

The study was approved by the Ethics Committee of the Clinical Center in Kragujevac, and all participants gave written consent before completing the questionnaire. The patients were treated with due respect and care, according to the principles stated in the Declaration of Helsinki.

Population and the sample

This two-center cross-sectional study was conducted in the period from March 1, 2015 to April 1, 2016 in the pharmacies in the city of Belgrade and the Department of Internal Medicine, Clinical Center in Kragujevac.

The study included two cohorts: 300 patients and 20 pharmacists.

The first cohort (development cohort) consisted of patients who used statin therapy. The second cohort (validation cohort) included pharmacists (25-27).

Criteria for inclusion in the development cohort were: age over 18 and statin intake more than six months prior to completing the questionnaire. Exclusion criteria were: mentally retarded patients, illiterate persons, patients with dementia, and those who refused to fill out the questionnaire.

Reliability testing

Reliability of the questionnaire was tested by three methods. Firstly, internal consistency was determined through calculation of Cronbach's alpha for the questionnaire as a whole. Cronbach's alpha is the most commonly used objective measure of internal consistency. It varies from 0 to 1, and shows the extent to which all the ingredients of the test measure the same concept. For an instrument with variables with a nominal/ordinal outcomes (such as a 1-7 Likert scale), it is acceptable to obtain Cronbach's alpha values above 0.7 (21, 22). Secondly, the questionnaire was divided randomly into two parts with the same number of questions, and Cronbach's alpha for each part was

calculated. Using the alphas for both parts, number of questions in each part and average correlation between questions in both parts of the original questionnaire, the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula (6). Thirdly, for each question mean score and its variance were calculated in order to check their suitability for the measurement of the whole spectrum of knowledge.

Factorial analysis

Exploratory factorial analysis of the questionnaire was made in order to discover the principal factors. Firstly, suitability of the questionnaire and sample for factorial analysis was tested by Kaiser-Meyer-Olkin measure of sampling adequacy and by the Bartlett's test of sphericity. Then, the factors were extracted at first without rotation, with conditions that eigenvalues had to be greater than 1.5, using a Scree plot (the extracted factors were above the "elbow" of the graph). Secondly, referent axes were rotated orthogonally, by the varimax method, and another extraction of the factors was made, using the same criteria as for the unrotated solution. Extracted factors were then named accordingly.

Validity

As already mentioned, content validity of the questionnaire was tested by the three focus groups. Convergent criterion validity could not have been tested, since the gold standard for the measurement of patients' knowledge about adverse reactions to statins was not available. Convergent and divergent validity was investigated by examining its relationship with other scales, mostly similar or completely different. Given that there were no validated scales for measuring the knowledge of patients, the VAS was used (28). Correlation between scores on the QPK-AES and VAS and KSB were calculated. Also, the correlation between two cohorts was assessed. All calculations were performed by SPSS statistical software, version 18.0 (31).

RESULTS

Study sample

The study included 320 subjects, from the territory of Kragujevac and Belgrade. Of all respondents, 58.5% were male and 41.5% were female. Average age

was 58.41 +/- 12.036 years, a range of 25 to 87 years. An average number of years of schooling was 11.52 +/- 3.597 with a minimum of 0 and a maximum of 25 years spent in school. The mean value of VAS was 52.7 +/- 19.9.

Reliability analysis

Results of the questionnaire in the study sample showed satisfactory internal consistency, with Cronbach's alpha of 0.898. When the questionnaire was divided by the split-half method to two parts, Cronbach's alphas were 0.834 and 0.842 for the both parts, respectively; the value of Spearman-Brown coefficient for the questionnaire as a whole calculated from the split-half method by the Spearman-Brown "prediction" formula was 0.801. Mean score, its variance, kurtosis and skewness were calculated for each question, and are shown in the Table 1.

Factorial analysis

Kaiser-Meyer-Olkin test confirmed sampling adequacy with its value of 0.856 (which exceeds the recommended value of 0.6) and the Bartlett's test of sphericity was highly significant (x^2 = 2039.058; df = 78; p < 0.001). After orthogonal rotation there were two factors with similar loadings (6.288 and 2.146), the first of them having 5 items, and the second 10 items. The first factor is comprised of questions about potentially dangerous AES for which physicians warn the patients, while the second factor contains the questions about AES for which patients are usually not warned. Cronbach's alpha for the first factor was 0.839, and for the second factor 0.817.

Validity

Content validity of the questionnaire was analyzed and confirmed by the three FG. Based on their opinions questions were clear, understandable, accurate, and relevant and on a scale from 1 to 5, all scored 4 or 5 points. Correlation coefficient (ρ =- 0.242) calculated between scores of patients and pharmacists showed that there was an expected, significant difference in the level of knowledge about the AES between the two groups. The divergent validity was confirmed with KSB scale as correlation coefficient was low (ρ = -0.117). Convergent validity was high, as correlation coefficient between VAS and QPK-AES scores was ρ=0.253.

Table 1. **Distribution characteristics of the questions after surveying 300 patients**

Question	Average score the patients achieved for each question	Standard deviation	Skewness	Kurtosis
1	4.13	2.053	-0.052	-1.260
2	4.30	1.962	-0.164	-1.088
3	4.06	1.969	0.001	-1.048
4	4.11	2.015	-0.042	-1.188
5	5.38	1.768	-1.038	0.125
6	4.26	1.949	-0.201	-1.071
7	3.89	1.897	-0.053	-0.975
8	3.21	1.813	0.645	-0.359
9	3.69	1.749	0.033	-0.703
10	3.83	1.662	0.010	-0.370
11	4.87	2.087	-0.535	-0.957
12	3.65	1.821	0.096	-0.780
13	3.73	1.659	0.164	-0.585
14	3.60	1.982	0.203	-1.071
15	4.27	1.964	0.189	-1.104

DISCUSSION

Based on these results, the QPK-AES scale showed high reliability, good structure and homogeneity. Factorial analysis revealed two domains (subscales, factors).

The first factor (five questions) is dedicated to the side effects, that due to their potential seriousness stand out from the rest, and for which are physicians warned to inform the patients and instruct them to read the "Warnings" summary of product characteristics. Therefore, this factor can be called "Adverse effects of statins that medical workers warn about". The internal consistency of this factor is high (Cronbach's coefficient of 0.839, and explains 41.919% of variability).

The most common and most recognizable adverse effect of statins is muscle damage. It range from muscle pain, nausea and possible rhabdomyolysis. Meta-analysis of randomized double-blind, placebo-controlled studies showed an increased incidence of myositis patients on statins compared to those who received placebo (OR 2:56, 95% CI 1.12-5.85) (31). Patients who use statins have the incidence of myopathy from 0.1% to 0.2%, while the incidence increases from 1% to 7% if they also take other medicines (5). Rhabdomyolysis is an adverse effect of statins which is the most feared by doctors because it can lead to the release of haemoglobin, haemoglobinuria, renal tubular blockage and possibly kidney failure. Meta-analyses showed no significant increase in its incidence since statins were introduced into clinical practice (1:59 OR, 95% CI 0.54-4.70) (32). Liver damage occurs infrequently, but FDA recommends that patients check the level of liver enzymes prior to statin use and if there are symptoms of liver damage (1).

Another factor obtained by analysing QPK-AES is named "Adverse effects of statins that medical professionals do not alert about", and contains 10

questions. This factor explains 56.226% of the variance. Issues that are covered by this factor relate to the impact of statins on the occurrence of diabetes mellitus, lung function, psychological activity, rash, death, occurrence of erectile dysfunction, cataract, increased blood clotting in the veins, and nerve damage. These are the side effects of statins, which occur very rarely (6) and because of that, medical professionals typically do not warn patients to them individually. However, these side effects can have serious consequences or they can reduce the quality of life of patients markedly, so it is important that patients are aware of the possibility and the exact probability of their occurrence.

Comparing the scores of the first and second factors, it has been shown that the first factor has a higher score than the second (29.8> 21.9). This result indicates that patients have greater knowledge on the questions from the first domain, precisely because physicians warn them on these AES. The questionnaire actually divides questions into those that patients are more familiar with and the issues that are less familiar. In the process of health care, it is vital for patient to be directly acquainted with all clinically significant adverse effects, or to the instructions where they can read the patient information section. After that, health workers should check how much information they have adopted, by using this or any other questionnaire Patient knowledge of adverse effects of drugs (AEDs) is important because higher awareness leads to a reduction of AEs, the number of hospitalizations, morbidity and costs. Previous studies have shown that patient knowledge of AEDs is often insufficient (33). It has been shown that patients with the help of VAS rated NSAILs

as drugs with low risk of AEs (2.1, 0.7-4.9), where they did not know that bleeding from the upper parts of GIT is significant adverse effect of NSAILs (3.8, 0.9-6.0), while doctors assessed the same adverse effect with higher grade - 7.0 (6.2-7.5). In the same study, the patients knew much more about warfarin and aspirin AES, than about the AEs of NSAILs (34). In our study, patients rated their knowledge about the side effects of statins with the score 52.7±19.9on VAS.

The main limitation of this study is that it was not possible to perform retesting of patients after 15-30 days and thus determine the temporal stability of the questionnaire. The reason for this is that patients were tested on several different locations, including different hospitals and pharmacies, so it was not possible to find and examine again. The other limitation of our study was lack of "gold standard" for the measurement of patients' knowledge about adverse effects of statins. Yet, we demonstrated high reliability of the QPK-AES, which should be additionally tested in future studies.

CONCLUSIONS

Based on the results of this study, we believe that this questionnaire is a useful tool for testing the knowledge of patients on adverse effects of statins and it can be of great importance for improving the quality of treatment of these patients and reducing the harmful consequences of adverse effects of statins.

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Dizajn i validacija upitnika za procenu znanja bolesnika o neželjenim dejstvima statina

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SAŽETAK

Statini su lekovi koji se dobro tolerišu i s obzirom na njihovu veliku upotrebu, još uvek postoje brige o njihovoj bezbednosti. Znanje bolesnika o neželjenim dejstvima statina nije do sada adekvatno ispitivano iako je rekognicija neželjenih dejstava od vitalnog značaja za poboljšanje kvaliteta brige o bolesniku smanjenjem morbiditeta i patnje bolesnika. Cilj ovog rada bio je da razvije i testira validirani pouzdan upitnik koji bi merio znanje bolesnika koji su naterapiji statinima o njegovim neželjenim dejstvima.

Ova multicentrična studija preseka je sprovedena u perioduod 01.03.2015. do 01.04.2016. u apotekama na teritoriji grada Beograda i na Klinici za internu medicinu Kliničkog centra u Kragujevcu. Studijom je obuhvaćeno 300 bolesnika i 20 farmaceuta.

Skala „Znanjebolesnika o neželjenim dejstvima statina" pokazala je visoku pouzdanost sa vrednošću Kronbahovog koeficijenta od 0.898, dobru konstrukciju i homogenost pitanja. Prilikom nasumičnog deljenja upitnika na dva dela, vrednosti alfe su bile 0.834 i 0.842. Eksplorativna faktorska analiza je ukazala na postojanje dva faktora. Bolesnici su svoje ukupno znanje o neželjenim dejstvima statina ocenili sa 52.7± 19.9 na vizuelno-analognoj skali.

Na osnovu rezultata ove studije, verujemo da bi ovaj upitnik mogao biti korisno sredstvo za ispitivanje znanja bolesnika o neželjenim dejstvima statina i možepomoći lekarima da identifikuju bolesnike sa nedovoljnim znanjem koji bi trebalo da se dodatno informišu.

*Ključne reči:*upitnik, statini, neželjena dejstva