Validation of a short food frequency questionnaire to evaluate nutritional lifestyles in hypercholesterolemic patients

Sophie Béliard a,*, Mathieu Coudert b,c, René Valéro d, Laurie Charbonnier a, Emilie Duchène a, François André Allaert e, Éric Bruckert a

a Department of Endocrinology, hôpital de la Pitié-Salpêtrière, AP-HP, 47-83, boulevard de l’Hôpital, 75013 Paris, France
b EA 3974, Modeling in Clinical Research, University Pierre-et Marie-Curie, 75005 Paris, France
c Department of Biostatistics and Medical Informatics, hôpital de la Pitié-Salpêtrière, 75013 Paris, France
d Department of Nutrition, Metabolic diseases, Endocrinology, La Timone Hospital, 13005 Marseille, France
e Medical evaluation Chair ESC & Dim CHU du bocage, Dijon, France

Abstract

Objectives. – The purpose of our study was to develop and validate a short food frequency questionnaire which could assess the nutritional lifestyles of hypercholesterolemic patients consulting in daily practice. Material and methods. – The questionnaire explores 11 nutrient categories. Hundred and thirty-one patients were recruited for the construct validity and 58 patients for the external validity in La Pitié Hospital, Paris. The reference method used was the diet history. To measure the internal consistency and to test the sensitivity to change on a large scale, the questionnaire was used in an observational study conducted in Spain in 1048 moderate hypercholesterolemic patients. Psychometric analyses included construct validity, internal consistency, test-retest reliability, external validity and sensitivity to change. Results. – Validation of the questionnaire indicated a good internal consistency (Cronbach Coefficient Alpha at 0.69) and test-retest reliability (intraclass correlation coefficient = 0.89). The correlation between the scores of the FFQ and those of the diet history was significant with a Pearson correlation coefficient at 0.3 (P = 0.029). The comparison between the ranking of the patients showed an agreement of 72% with a kappa of 0.48 [0.10; 0.69]. The sensitivity to change was good with a score evolution improving one and four months after nutrition advices: 28.2% of patients ranked in group 1 at inclusion versus 61.3% (P < 0.0001) at one month and 75.2% (P < 0.0001) at four months. Conclusion. – In conclusion, we developed and validated a food questionnaire for hypercholesterolemic patients, which can be used as a therapeutic education tool in daily practice or in clinical research.

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Résumé

Buts/ objectifs. – Le but de notre étude fût de développer et valider un questionnaire de fréquence alimentaire, permettant d’évaluer rapidement les habitudes alimentaires des patients hypercholestérolémiques. Matériel et méthodes. – Le questionnaire explore 11 catégories de nutriments. Cent trente et un patients ont été recrutés pour valider la construction du questionnaire et 58 patients pour la validité externe, à l’hôpital de La Pitié, Paris. La méthode de référence est l’histoire alimentaire. La cohérence interne et la sensibilité au changement furent testées sur 1048 patients d’une large étude observationnelle espagnole. Les analyses psychométriques incluent la validité de la construction, la cohérence interne, la fidélité test-retest, la validité externe et la sensibilité au changement. Résultats. – La validation du questionnaire indique une bonne cohérence interne (coefficient Cronbach alpha à 0.69) et un test-retest fidèle (coefficient de corrélation intraclasse = 0.89). La corrélation entre les scores du questionnaire et ceux de l’histoire alimentaire est significative avec un coefficient de corrélation de Pearson à 0.3 (p = 0.029). La comparaison entre le classement des patients montre un accord de 72 % avec un kappa de 0.48 [0.10; 0.69]. La sensibilité au changement est bonne avec une amélioration significative du score à un et quatre mois après conseils nutritionnels : 28.2 % des patients classés dans le groupe 1 à l’inclusion par rapport à 61.3 % (p < 0.0001) à un mois et 75.2 % (p < 0.0001) à quatre mois. Conclusion. – En conclusion, nous avons validé un questionnaire alimentaire destiné aux patients hypercholestérolémiques, facilement utilisable en pratique quotidienne ou en recherche clinique.

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* Corresponding author.
E-mail address: sophie.beliard@psl.aphp.fr (S. Béliard).
1. Introduction

Cardiovascular diseases (CVD) are the first cause of mortality in developed and developing countries. All studies of cardiovascular risks imply that the most important risk factor is abnormal lipid levels [1]. In the Interheart study, where 15,152 cases with acute myocardial infarction and 14,820 controls were enrolled, Yusuf et al. show that 53.8% of myocardial infarction can be put down to hypercholesterolemia [2]. Furthermore, there is a direct link between the decrease of low density lipoprotein (LDL) cholesterol and the decrease of CVD [3]. In a meta-analysis of randomized trials of cholesterol lowering with statins, Law et al. demonstrated that a reduction of 1.8 mmol/l of LDL-cholesterol reduces the risk of ischemic heart diseases by about 60% [3]. The first choice of treatment in hypercholesterolemic patients is to modify the diet [4,5]. Although drug therapy is often prescribed specially for patients at moderate or high cardiovascular risk, dietary changes are recommended for all individuals.

The main difficulty of the setting up of a nutritional therapy is that it requires a nutritional evaluation of the food intake. To conduct this evaluation, four main groups of methods may be used [6,7]: food diary, the 24-hour dietary recall, diet history and the food frequency questionnaire (FFQ). Each method has advantages and disadvantages [8]. In the food diary all food intakes are recorded during a given period (usually 3 or 7 days) specifying their quantities and/or photographs of servings. It provides accurate information on foods consumed but the method is cumbersome for the patient and is time consuming (several hours) for the diettitian who is in charge of analyzing the data [9]. The 24-hour dietary recall involves the record of all foods and beverages consumed within 24 hours that preceded the interview. It must be renewed because of the intra-individual variation of food intake [8]. The diet history is a detailed retrospective description of the usual distribution of food consumptions. It takes nearly half an hour and requires a dietitian [10]. The last method, the FFQ, describes usual food consumptions. It takes nearly half an hour and requires a dietitian [10]. The last method, the FFQ, describes usual food consumption. Patient has only to indicate on a predetermined list of food which nutrients he eat and their quantities [11]. They are simple, inexpensive, rapid and well adapted to the classification of subjects according their nutritional habits [12]. By cons, their preparation requires validation studies and calibration to ensure their consistency and most of them are hardly exhausting [13,14].

The purpose of our work was to develop and validate a short self-questionnaire, which could assess the nutritional lifestyles of hypercholesterolemic patients consulting in daily practice: the NLSChol questionnaire.

2. Patients and methods

2.1. Development of the NLSChol questionnaire

The items were elaborate in agreement with recommendations for a Desirable Lipid Profile [4,5]: to limit the intake of saturated fat to less than 7%, trans fat to less than 1% of energy and cholesterol to less than 300 mg per day by choosing lean meats and selecting fat-free or low-fat dairy products, to consume a diet rich in vegetables and fruits, to consume fish especially oily fish, at least twice a week, to minimize the food with added sugar. The questionnaire explores 11 nutrients category giving direct or indirect information on the lipid statute of food consumed. Saturated fat consumed was explored with items on fat meat, butter and hard margarines, cream, cheese, milk and derived products, processed meals and cakes. Unsaturated fat consumed was explored with items on vegetable oils and soft margarines. Indirect informations on lipid consumed were explored with items on fish or sea products, fruits and vegetables, bread and carbohydrates and consumption of products with phytosterols. At the end of the questionnaire, a score was calculated ranging from 0 points to 33 points and the patient was ranked in one of the three purposed categories: 1: “less than 10: my diet improves my cholesterol level”, 2: “from 11 to 18: my diet is not optimal for my cholesterol level”, 3: “19 or more: my diet increases my cholesterol level”. The questionnaire is in Appendix 1.

2.2. Patients’ interviews

Patients were recruited in the “Cardiovascular Diseases Prevention Unit” in La Pitié Hospital, Paris. This study was conducted in accordance with the Declaration of Helsinki, and an informed consent was obtained from all patients. The inclusion criteria were to be at least 18 years of age, to have at least one cardiovascular risk factor and to give and informed consent to study participation. There were none exclusion criteria. Patients first lonely completed the FFQ, calculated their score and ranked themselves in one of the three categories purposed. The study was conducted in four distinct populations: population A: 131 patients were recruited in our “Cardiovascular Diseases Prevention Unit” for the construct validity, population B: 58 patients were recruited in the same center for the external validity, population C: 1048 moderate hypercholesterolemic patients were recruited in a nationwide observational study conducted in Spain. These latter patients were advised to improve their cardiovascular lifestyle and to take phytosterol supplemented, so this database was used to test the sensibility to change; it was also used to confirm the internal consistency on a large scale. The population D was represented by 20 patients recruited in our “Cardiovascular Diseases Prevention Unit” who should not change their dietary habits between two visits.

2.3. Psychometric analyses of the questionnaire

2.3.1. Internal validity (construct validity and internal consistency)

According to good practice for the construct of such an evaluation tool [11–13], we followed different stages: patients’ interviews and the writing of a first draft whose patient understanding and handling was tested. This study was first conducted in 131 hypercholesterolemic patients (population A). They were asked to complete the questionnaire and their answers were analyzed to describe and study:
2.3.2. External validity (reliability, external validation, sensibility to change)

2.3.2.1. Reliability. The reliability of the questionnaire was studied in a group of 20 patients who were asked to fill out the questionnaire at two successive visits 30 days apart, without changing their eating habits (population D). The Intraclass Correlation Coefficient (ICC) was used to quantify the reliability (intra-individual reproductibility). The absence of retest effect was quantified by comparing visits V1 and V30 with a paired Wilcoxon rank score.

2.3.2.2. External validation. The reference method used was the diet history conducted by a trained dietitian on a sample of 58 patients (population B). The patient was asked to first complete the questionnaire and then was interviewed by the dietitian who has no access to the results of the studied questionnaire (blind evaluation). The results were analyzed using the simplified Ciqual food composition table [15] and the Dieta software. Using these different tools, the dietitian was able to describe the total energy intake, the carbohydrate and fat intake, the plant sterol intake, daily consumption of fruits and vegetables and the weekly consumption of fish. At the end of the interview, the dietitian ranked the patients according to the AHA recommendations and the European recommendations on diet for a desirable lipid profile [45] in three categories: group (1) “my diet improves my cholesterol level”, group (2) “my diet is not optimal for my cholesterol level”, group (3): “my diet increases my cholesterol level”. The external validity was first evaluated by analysing the correlation between the score of the FFQ and the score obtained with the diet history using a Pearson correlation coefficient. The concordance between NLSChol classification and dietitian classification was analyzed using kappa concordance coefficient.

2.3.2.3. Sensibility to change. We analyzed sensibility to change after the validation process of the questionnaire. The population C (1048 hypercholesterolemic patients to whom their practitioner has advised nutritional lifestyle modification and a regular consumption of Danacol®) was used. NLSChol classification of the patients were compared before and after 4 months of follow-up using paired Wilcoxon rank in order to verify its sensibility to change under effect of nutritional recommendations.

3. Results

3.1. Internal validity of the NLSChol self-administered questionnaire

We first recruited 131 patients for the construct validity (population A). The patients were 60.9±15.5 years old, 72 were men and 59 women and a large majority of them (76.4%) had already been given dietary advice. Their body mass index was 26.9±6.5 kg/m², and 75.5% were hypercholesterolemic, 37.4% were hypertensive, 19.8% had a hypertriglyceridemia and 13% had type 2 diabetes.

Some amendments regarding the presentation of the questionnaire were made. The wording of some questions was changed like the title “salty pie” was changed by the word “quiche” more familiar to patients. Central tendency and edge effects were also studied by the description of the distribution of answer to each question. Item order biases were also identified and the order of the question in the questionnaire was modified. For example, in the first issue the question concerning hard margarine was before plant sterols and some patients consuming plant sterols margarine answered hard margarine rather plant sterols. Both issues have been inverted and the error disappeared. The redundancy between all questions was studied and the highest correlation coefficient between questions was of 0.5. Therefore no question has been eliminated from the questionnaire due to redundancy.

The internal consistency was calculated on the answers to the NLSChol in a large cohort of 1048 hypercholesterolemic patients (population C). They were 56±12 years old and 56.9% of them were female. At inclusion day their total cholesterol was 2.5±0.3 g/l, their HDL-cholesterol 0.54±0.2 g/l, their LDL-cholesterol 1.6±0.3 g/l and their triglycerides 1.5±0.6 g/l. The value of the Cronbach Coefficient Alpha calculated on 1048 questionnaires was 0.69.

3.2. External validity of the NLSChol self-administered questionnaire

3.2.1. Test-Retest reliability

At the first period, patients were distributed as follow: group 1 (my diet improves my cholesterol level): 35%, group 2 (my diet is not optimal for my cholesterol level): 55.0% and group 3 (my diet increases my cholesterol level): 10%. At the second period, these percentages became respectively 40.0%, 50% and 10%. Overall 85% of patients were belonging to the same group at the two periods, two patients went from group 2 to group 1 and one patient had the inverse evolution. The Intraclass Correlation Coefficient of the score of the FFQ was 0.89. Comparison of medians between the two evaluations showed no significant difference (P = 0.52); which means that no retest effect was found.

3.2.2. External validation of the NLSChol self-administered questionnaire

The external validation was performed in the population B (58 patients recruited in the department of Cardiovascular Diseases Prevention). These patients were 58±16 years old,
Nutritional Lifestyle score evolution.

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>1 month later</th>
<th>4 months later</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>My diet improves my cholesterol level</td>
<td>296</td>
<td>28.2</td>
</tr>
<tr>
<td>My diet is not optimal for my cholesterol level</td>
<td>658</td>
<td>62.8</td>
</tr>
<tr>
<td>My diet increases my cholesterol level</td>
<td>94</td>
<td>9.0</td>
</tr>
<tr>
<td>Total</td>
<td>1048</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The sensibility to change was studied in 1048 hypercholesterolemic patients. At inclusion, 28.2% of patients were ranked in group (1): my diet improves my cholesterol level. At one month after nutritional advices, 61.3% of patients were ranked in the group (1) ($P<0.0001$). At 4 months after nutritional advices, 75.2% of patients were ranked in the group (1) ($P<0.0001$).

35 were men and 23 women and a large majority of them (74.5%) had already been given dietary advice. Their body mass index was $27 \pm 8 \text{kg/m}^2$, and 77.9% were hypercholesterolemic, 32.2% were hypertensive, 18.6% had a hypertriglyceridemia and 8.8% had type 2 diabetes. Statistical calculations were made only on the 53 completed questionnaires. The Pearson correlation coefficient between the scores of the FFQ and those of the diet history was 0.30 ($P=0.0329$). The comparison between the classification of patients by the dietician and their classification resulting from the NLSChol score showed an agreement of 72% with a kappa of 0.48 [0.10; 0.69]. The Bowker’s test of symmetry was not significant ($P=0.84$).

3.2.3. Sensitivity to change

The sensibility to change was studied in the population C describes above. The Cronbach test was performed on the NLSChol component at the inclusion period and showed a value of 0.69. All patients received advices for nutritional lifestyle modifications by their practitioner. The Nutritional Lifestyle score evolution improved from the first month and continues in the fourth reaching respectively 61.3% ($P<0.0001$) and 75.2% ($P<0.0001$) of patients in which the diet improved their cholesterol level versus 28.2% at inclusion (Table 1).

4. Discussion

We have constructed and validated a self-administered FFQ, which may help hypercholesterolemic patients to assess whether their diet is adequate to current recommendations. Indeed, properly validated instruments for rapid self-assessment of compliance with dietary recommendations in hypercholesterolemic patients are lacking. So there is a need for instruments with proven reliability and validity.

We carefully followed all important steps to construct and validate the questionnaire [13,14]. The NLSChol showed a quite good internal consistency with a Cronbach Coefficient Alpha at 0.69. Similar results were obtained with other self-administered FFQ [16–18]. Furthermore, high reproducibility was demonstrated with an Intraclass Correlation Coefficient at 0.89. Additionally, the NLSChol allowed detecting recent changes in diet. Indeed, the sensibility to change studied in 1048 patients 1 month and 4 month after nutritional recommendations was good with 28.2% of patients which were ranked in the group 1 (my diet improves my cholesterol level) at inclusion, 61.3% at one month and 75.2% at the fourth month.

For the external validation, the FFQ’s scores and the diet history’s scores were well correlated with a Pearson correlation coefficient at 0.30 ($P=0.029$). When we first compared the ranking in the three groups, the agreement was quite good (68% of agreement) and the level of agreement was relatively moderate with a kappa of 0.48 [0.28; 0.67]. However, the bounds of the ranking were more drastic in the NLSChol questionnaire than those of the diet history (Table 2). So we changed the bounds of the questionnaire to improve the agreement of ranking: the first bounds were: group 1: 0 to 7 points, group 2: 8 to 15, group 3: 16 or more points; the modified bounds were: group 1: 0 to 10, group 2: 11 to 18, group 3: 19 or more points. With these last bounds, the level of agreement improves from 68% to 72% and the kappa remained at 0.48 [0.10; 0.69]. Furthermore, the Bowker’s test of symmetry was not significant ($P=0.84$) with the new bounds.

Table 1
Nutritional Lifestyle score evolution.

Table 2
Evolution of the ranking’s bounds of the NLSChol questionnaire.
the new bounds, which indicates that the NLSChol score and the dietician had the same propensity to select categories. This moderate level of agreement between the FFQ and the diet history underlines the fact that the evaluation of a dietician remains subjective. It is therefore important to develop standardized tools for clinical studies in which the intervention of a dietician is not required. Only five patients on 58 (8.6%) did not answer to at least one question of the questionnaire, which is an acceptable threshold of no response for this kind of self-administered questionnaire.

FFQ described in the literature provide a precise quantitative description of food intakes, but they are time consuming and required the help of a dietician for the interview and the interpretation, so they are difficult to implement in a daily practice. Contrary to them, this self-administered questionnaire aims to evaluate the main dietetic errors of the patients, requires little time to complete (less than 5 min), can be done without any help and the cost is low. The NLSChol questionnaire is short and explores 11 nutrients category giving direct or indirect information on the lipid statute of food consumed. But, the excessive consumption of saturated fat, the absence of consumption of fruits and vegetables or fish, are very good indicator of nutritional imbalance. In the same way, the daily consumption of plants sterols shows knowledge of dietary principles and an effort to change eating habits. In routine practice, the objective would let patient in the worse category to ask their doctors for more advice.

A short FFQ for cardiovascular prevention has been already construct and published in 1995 by a French team [19,20]. However, the final score was complicated to calculate (with intermediate scores for saturated fatty acids, mono-unsaturated fatty acids, Ω-3 and Ω-6 poly-unsaturated fatty acids) and should be done by a dietician and not by the patient himself. Contrary to this FFQ, the NLSChol score can be calculated and interpreted by the patient himself. Furthermore, the validity of their FFQ (comparison with the results of a diet history) was tested on a population of healthy subjects [19]. Indeed, the subjects recommended for the validation study should be representative of the main study target population [13,14], which is, in our study, patient with hypercholesterolemia. Another short FFQ for the assessment of fat intakes in hypercholesterolemic patients was validated in a Finnish population [21]. But their questionnaire was used and interpreted in an interview situation. Furthermore, the reproducibility was not tested. Finally, our NLSChol questionnaire approximates the MEDFICTS dietary assessment questionnaire used in the USA to assess the adherence to the Adult Treatment panel III (Third Report to the NCEP, 2002) Therapeutic Lifestyle Changes [22,23]. Actually, MEDFICTS (Meat, Eggs, Dairy, Fried food, fat in Baked goods, Convenience foods, fats added at the Table, and Snacks) is a brief dietary questionnaire (20 items), focused on fat intakes, which can be auto-administrated and used as a free tool for proper cardiovascular assessment. In this American FFQ the patient calculates his score and ranks himself in one of the three groups to assess adherence to the Therapeutic Lifestyle Changes diet recommended by the ATPIII [24], as in our NLSChol questionnaire.

However, this study presents some limitations. The first one is that the NLSChol was constructed for French and Spanish hypercholesterolemic patients who have globally the same food habits. Further studies are needed to validate it in other countries with different food habits. Secondly, we did not study if changes in the score of the NLSChol can predict changes in total or LDL cholesterol levels.

In conclusion, we constructed and validated a short self-administered FFQ for hypercholesterolemic patients. The NLSChol questionnaire is a therapeutic education tool, easy to use in daily practice and in clinical study. It can also be used to circumvent recent changes in diet.

Disclosure of interest

Dr Béliard declares no conflict of interest in relation to the work described. Pr Bruckert declares the following conflict of interest: fees for presentations and participation to scientific boards of Danone. Pr F.A. Allaert is consulting for the Research center Cen Nutriment.

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Appendix 1. The NLSChol questionnaire: self-administered food frequency questionnaire for evaluating the nutritional lifestyle of hypercholesterolemic patients.

<table>
<thead>
<tr>
<th>FOOD CATEGORY</th>
<th>PORTION SIZE</th>
<th>CIRCLE THE QUANTITY CONSUMED PER WEEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatty meats or cooked meat (except low fat ham)</td>
<td>100 g or 1 sausage or 6 slices of salami</td>
<td>6 or more 3 to 5 1 to 2 0 to 1</td>
</tr>
<tr>
<td>Fish and seafood</td>
<td>No. of times per week</td>
<td>0 1 2 3 or more</td>
</tr>
<tr>
<td>Processed foods (pizza, “away food”, quiche, quick served restaurants etc. . .)</td>
<td>No. of times per week</td>
<td>5 or more 3 to 4 2 to 3 &lt;1</td>
</tr>
<tr>
<td>Products enriched in plant sterols</td>
<td>1 portion (20 g of margarine, 2 yogurts, 1 dairy speciality)</td>
<td>0 to 3 3 to 4 5 to 6 7 or more</td>
</tr>
<tr>
<td>Butter or whole-fat cream or lard or hard margarines</td>
<td>1 knob or 10-15 g or 1 soup spoon</td>
<td>7 or more 5 to 6 3 to 4 0 to 3</td>
</tr>
<tr>
<td>Full fat dairy desserts, full fat milk, full fat yogurts, cream desserts</td>
<td>1 portion or equivalent (1 cake or 6 biscuits)</td>
<td>7 or more 5 to 6 3 to 4 0 to 3</td>
</tr>
<tr>
<td>Biscuits, cakes or ice cream</td>
<td>1 portion or equivalent (1 cake or 6 biscuits)</td>
<td>5 or more 3 to 4 2 to 3 0 to 1</td>
</tr>
<tr>
<td>Fruits, cooked or raw vegetables</td>
<td>1 portion (1 fruit, fruit juice 100% or pure juice, 1 plate of vegetables)</td>
<td>0 to 2 2 to 3 3 to 4 5 or more</td>
</tr>
<tr>
<td>Bread, starches (pasta, rice, potatoes, etc.), cereals</td>
<td>1 portion (50 g of bread or 1 plate of pasta, rice or potatoes)</td>
<td>0 to 2 2 3 4 or more</td>
</tr>
<tr>
<td>Mature cheese</td>
<td>30 g (1/8 of a camembert)</td>
<td>3 or more 2 1 0 to 1</td>
</tr>
<tr>
<td>Vegetable oil (sunflower, olive, soft margarine)</td>
<td>1 portion (1 soup spoon or 10 g of margarine)</td>
<td>0 to 1 1 2 3 or more</td>
</tr>
<tr>
<td>Calculate your score</td>
<td>Insert the number of boxes circled and Calculate!</td>
<td></td>
</tr>
</tbody>
</table>

Calculate your score:

Insert the number of boxes circled and Calculate!

\[
\text{Score} = (\text{Multiply by 3}) + (\text{Multiply by 2}) + (\text{Report}) - (\text{Not report})
\]

Interpret your score:

Score 0 to 10 points: my diet improves my cholesterol level.
Score 11 to 18: my diet is not optimal for my cholesterol level.
Score 19 or more: my diet increases my cholesterol level.

References
