ORIGINAL ARTICLES

UDC: 615.065:616.33-008.3
https://doi.org/10.2298/VSP170421123P

Development and validation of a questionnaire for measuring drug-induced nausea

Razvoj i ispitivanje punovažnosti upitnika za merenje mučnine izazvane lekovima

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Abstract

Background/Aim. There are several questionnaires for measuring intensity of nausea after drug administration, but they are either too settings specific (like those measuring chemotherapy-induced nausea), or they were not properly tested for reliability and validity. The aim of this study was to develop and validate a reliable instrument that can measure drug-induced nausea. **Methods.** The cross-sectional study for assessing reliability and validity of a questionnaire was performed. The questionnaire with 5 items and answers according to the Likert's scale was developed during two brainstorming sessions of the research team. Its reliability, validity and temporal stability were tested on the sample of 128 outpatients taking iron salts orally. **Results.** The final version of the Drug-Induced Nausea Scale (DINS) with 5 items showed excellent reliability, both when rated by the investigators (Cronbach's alpha 0.892) and by the patients themselves (Cronbach's alpha 0.897). It was temporally stable, and both divergent and convergent validity tests had very good results. Factorial analysis revealed only one factor, which means that the whole scale is measuring only one phenomenon, intensity of nausea, as was originally intended. **Conclusion.** The DINS is reliable and valid instrument for measuring intensity of drug-induced nausea. Identification of patients with high intensity of drug-induced nausea by this questionnaire will help prescribers to decide whether the therapy should be stopped or the patient switched to less emetogenic therapy.

Key words:
drug therapy; iron; nausea; pharmaceutical preparations; psychometrics; surveys and questionnaires.

Apstrakt

Uvod/Cilj. Do sada je objavljeno nekoliko upitnika za merenje intenziteta mučnine posle primene lekova, ali su oni ili suviše specifični za određenu grupu lekova (npr. oni koji mere mučninu posle primene hemioterapije) ili njihova pouzdanost i punovažnost nisu propisno ispitani. Cilj ove studije je bio da se razvije upitnik za merenje mučnine izazvane lekovima i ispitaju njegova pouzdanost i punovažnost. **Metode.** Studija je bila dizajnirana kao studija preseka za procenu pouzdanosti i validnosti upitnika. Upitnik sa pet pitanja i ponuđenim odgovorima po Likertovoj skali bio je razvijen na dva nestrukturirana sastanka istraživačkog tima. Pouzdanost, punovažnost i stabilnost u vremenu ovog upitnika su ispitani na uzorku od 128 vanbolničkih bolesnika koji su uzimali oralne preparate gvožđa. **Rezultati.** Krajnja verzija Upitnika za mučninu izazvanu lekovima (UMIL) sa pet pitanja je pokazala odličnu pouzdanost, kako kada su upitnike popunjavali istraživači za vreme intervjua sa bolesnicima (Kronbahov alfa koeficijent 0,892), tako i kada su upitnike popunjavali samo bolesnici (Kronbahov alfa koeficijent 0,897). Upitnik je bio stabilan u vremenu, a testovi konvergentne i divergentne punovažnosti su dali vrlo dobre rezultate. Faktorska analiza je otkrila samo jedan faktor, što znači da ceo upitnik meri samo jedan fenomen, intenzitet mučnine, kako je originalno i nemeravano. **Zaključak.** Upitnik UMIL je pouzdan i punovažan instrument za merenje intenziteta mučnine izazvane lekovima. Otkrivanje bolesnika sa visokim stepenom mučnine izazvane lekovima pomoći će propisivačima da odluče da li terapiju treba prekinuti ili preći na manje emetogene lekove.

Ključne reči:
lečenje lekovima; gvožđe; mučnina; lekovi; psihometrija; ankete i upitnici.

Introduction

Drugs have varying potential to induce nausea and/or vomiting. Center for vomiting in medulla oblongata is under the influence of substances from blood, stimulation of nerve endings in gastrointestinal tract and impulses from chemioreceptor zone. Neurotransmitters with significant effect on the center are histamine, acetylcholine, dopamine, 5-hy-

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droxytriptamine, substance P and endogenous cannabinoids [1]. Cytostatic drugs cause nausea in as much as 10% (drugs with low emetogenic potential) to 90% (drugs with high emetogenic potential) patients [2], while opioids cause nausea in 48% of patients when used for treatment of cancer pain and in 27% when used for postoperative pain [3]. Nausea rate after oral administration of iron salts amounts to 11% [4], and it is probably caused by the accumulation of free radicals in gastrointestinal mucosa [5]. Drug-induced nausea is big problem in everyday clinical practice, as many patients are not compliant to the prescribed therapy or discontinue the therapy due to nausea.

There are several questionnaires for measurement of nausea intensity after drug administration, usually developed specifically for certan drug groups, like the Chemotherapy-Induced Nausea and Emesis Quality of Life (CINI QOL) questionnaire [6] or the Gastrointestinal Symptom Questionnaire (GSQ) designed to measure nausea after oral drug intake [7] and tested in the patients taking iron salts. Within its program of developing standardized set of the patient-reported outcomes (Patient-Reported Outcomes Measurment Information System – PROMIS) the National Institute of Health in the USA created also the Gastrointestinal Symptom Scales (GSS), and one of them measures nausea caused by either disease or drug [8]. However, these scales are either too settings specific (like CINI QOL), or were not properly tested for reliability and validity after drug administration (like GSQ, or PROMIS GSS-nausea). The reliable and valid questionnaire for measurement of drug-induced nausea as general phenomenon could be an important clinical tool for assesing tolerability of emetogenic drugs and necessity to discontinue therapy or switch to less emetogenic one. If drug-induced nausea is mild, a prescriber could further decrease it through timing intake of the drug with food or giving only one daily dose before going to bed, and in this way preserve potentially very efficient drug for the patient instead of switching to other drugs (which could cause nausea, too). Besides, after adequate explanation and rating of nausea, the patients with a mild form will be more compliant to the prescribed therapy.

The aim of our study was to develop a questionnaire for measurement of intensity of drug-induced nausea and test its reliability and validity on a sample of adult patients taking iron salts orally.

Methods

Design

The study was of a cross-sectional type, and assessed reliability and validity of newly developed questionnaire for measurement of drug-induced nausea (Drug-Induced Nausea Scale – DINS) among outpatients taking iron salts orally.

Construction of the new questionnaire

Developing of the new questionnaire was done according to the guidelines set by Robert F. DeVellis [9], through 8 steps. In the first step (determining object of measurement), drug-induced nausea was chosen as an object of measurement, being one of the most frequent causes of discontinuation of effective drug therapy [10]. The second step, generating an item pool, was conducted through two brainstorming sessions of the authors, one week apart. In the third step (determining format for measurement) each item was constructed in the form of positive statement which should reflect certain element of nausea. Five possible answers were offered for each statement, in the form of Likert's scale: "never", "rarely", "sometimes", "often", and "always". The answers were rated from 1 ("never") to 5 ("always"). Total score of the questionnaire was calculated by summation of answers to individual items. The patients with the total score from 1 to 10 had mild nausea, those from 11 to 20 moderate nausea, and the patients with the score from 21 to 25 severe nausea. The fourth step (revision and correction of the initial pool of items) was made by the three-member expert committee composed of a psychiatrist, a gastroenterologist and a clinical pharmacology specialist employed by the Clinical Center Kragujevac, Serbia. Within the fifth step, one validation item for discovering socially desirable behavior of respondents was included in the questionnaire: "I always try to help other people. "In the sixth step the initial pool of the DINS items was tested on 5 PhD students (at Faculty of Medical Sciences, University of Kragujevac, Serbia) for clarity and comprehension. After the pilot a few minor changes were made, and then the final Serbian version of the DINS was copied and prepared for the reliability testing on the sample of 128 outpatients. The seventh (evaluating the items) and eighth (optimizing the questionnaire length) steps are described below.

Translation and cultural adaptationof supplementary questionnaire for validation purposes of the DINS instrument

The translation and cultural adaptation of the PROMIS-GSS-nausea questionnaire (4 items) was made according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines [11]. Permission for translation of PROMIS-GSS-nausea (version with 4 items) from English to Serbian was granted by the National Institutes of Health Patient Reported Outcomes Measurment Information System. The original scale was first translated into Serbian by two investigators who were Serbian native language speakers (S. Janković and A. Prokić). They translated the scale independently of each other, and then the translations were harmonized to one Serbian version at the meeting of the study investigators. The harmonized Serbian version was then translated back to English by Dr Zan Friscic, native English speaker, citizen of Australia. When translated back to English, Dr Friscic was not aware of the original English version of the PROMIS-GSS-nausea. The back-translation to English was then compared with the original English version by the study investigators and at the new meeting of investigators the final Serbian version of the PROMIS-GSS-nausea was agreed on. The final translation of PROMIS-GSS-nausea into Serbian was then tested on 5 PhD students (at Faculty of

Medical Sciences, University of Kragujevac, Serbia) for clarity and comprehension. After the pilot, a few minor changes were made, and then the final Serbian version of PROMIS-GSS-nausea was copied and prepared for the reliability testing.

Data collection – population and the sample

The final Serbian versions of the both new (DINS) and translated (PROMIS-GSS-nausea) questionnaires were tested for reliability on the outpatients who visited community pharmacies in Osečina, western Serbia. The visits took place during the year 2016. The inclusion criteria were the oral intake of iron salts for at least two weeks, literacy and age over 18. The exclusion criteria were previous gastrectomy, cognitive disorders (score at Mini-Mental State Examination below 24), mood disorders and mental retardation. The sample of the patients was of consecutive nature, i.e., all patients who visited community pharmacies during the study period (and satisfied inclusion and exclusion criteria) were offered the questionnaire. During the first encounter, the questionnaires were completed in two ways: at first, by the investigators who were questioning the patients, and second, by the patients themselves. At the second encounter, two weeks later, the patients were repeatedly interviewed by the study investigators who completed the same questionnaires again. The study was approved by the Ethics Committee of Clinical Center Kragujevac, Serbia. The patients were treated with due respect and care, according to the principles stated in Declaration of Helsinki.

Data analysis

Reliability testing

Reliability of the questionnaire was tested by three methods. First, internal consistency was determined through calculation of Cronbach's alpha for the questionnaire as a whole. Second, the questionnaire was divided by split-half method to two parts with the same number of questions, and Cronbach's alpha was calculated for each of the parts. Using the alphas for both parts, number of questions in each part and average correlation between the 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 [12]. Third, for each question mean score and their variances were calculated in order to check their suitability for measurement of whole extent of nausea severity.

Factorial analysis

Principal component analysis of the questionnaire was made in order to discover principal factors [13]. The principal component analysis groups the items of a scale to a smaller number of principal components which describe most of the variance of the responses to the scale items. Each of the principal components identified covers part of the variance in the data, and they are not correlated between themselves. The components (factors) covering maximal variance are kept, while the otherswith small amount of variance are discarded. The amount of variance covered by each component is measured by its eigenvalue. First, suitability of the questionnaire and sample for factorial analysis was tested by the 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 the eigenvalues had to be greater than 1.0, and using the Scree-plot (the extracted factors were above the "elbow" of the graph). Second, 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. The following was reported for the extracted factors: loadings, eigenvalues, and percentage of variance explained. The extracted factors were then named accordingly. All calculations were performed by the SPSS statistical software, version 18.0.

Validity

The content validity of the questionnaire was evaluated by an independent panel of three experienced clinicians at the Clinical Center Kragujevac, Serbia: psychiatrist, gastroenterologist and clinical pharmacology specialist.

The criterion validity was tested by three methods: comparison of the DINS scores when the questionnaire was completed by the investigators and by the patients themselves, convergent validity testing by comparison of the DINS score with the PROMIS-GSS-nausea score, and the divergent validity testing by comparison of the DINS score with the score of the Intolerance of Uncertainty (IU) questionnaire. The permission to use the Intolerance of Uncertainty questionnaire in Serbian language (which measures intolerance of uncertainty in everyday life and was previously validated in Serbian population) was granted by the Associated Professor, Ljiljana Mihić, psychologist, the University of Novi Sad, Serbia [14]. The correlations between scores on the questionnaires were calculated and presented in Multimethod, multi-trait matrix. All calculations were performed by the SPSS statistical software, version 18.0.

Temporal stability

Temporal stability of the DINS and the PROMIS-GSS-nausea results was tested by second completion of the questionnaires by the investigators who repeatedly interviewed the patients two weeks after the first encounter. The patients were invited to the second encounter by phone.

Results

The first version of the DINS questionnaire contained 5 questions, which after the pilot and minor adjustments was tested on the sample of 128 outpatients: mean age 45.8 ± 13.5 years, male/female ratio 16/112 (12.5%/87.5%), education elementary school/high school/university = 26.6%/51.6%/21.6%, place of residence, urban/rural = 83/45 (64.8%/35.2%), and all patients except 2 (1.6%) were prescribed with oral iron for treatment of anemia. Thirty-eight patients (29.7%) were taking iron salts before meal, 7 (5.5%) during meal, 68 (53.1%) after meal and remaining 15

(11.7%) did not take care about the timing of drug intake. Seventy patients (54.7%) were previously introduced with the gastrointestinal adverse effects of iron preparations, and the remaining 58 patients (45.3%) were not. Sixteen patients (12.5%) did have previous experience with nausea after oral drug intake, and the remaining 112 (87.5%) did not. Finally, 53 (41.4%) patients suffered from at least one chronic non-contagious disease, and 75 (58.6%) did not.

Mean score of the DINS was 8.6 ± 5.1 (range from 5 to 25). There were no significant differences in severity of nausea (the DINS score) according to the sex (females 8.6 ± 5.1, males 8.3 ± 4.7, $p = 0.781$), education (elementary school 8.9 ± 4.5, high school 8.7 ± 5.3, higher education 8.3 ± 4.4, $p = 0.910$) or place of living (urban 8.6 ± 5.4, rural 8.5 ± 4.4, $p = 0.962$) of the study participants.

Reliability testing

After testing the original 5 items from the questionnaire, and examining results of correlation matrix, mean values, variance, skewness and kurtosis of distributions of responses for each of the items, none of the items was removed, leaving final version of the DINS questionnaire with 5 items. Criteria for removing the items were extreme means, near zero variances and correlation coefficients with a majority of other items below 0.2. Cronbach's alpha of the final version with 5 items was 0.892, when the scale was rated by the investigators. The mean values of responses, standard deviations, skewness and kurtosis for each item of the DINS are shown in Table 1. After division of the DINS questionnaire by the split-half method, the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula, and its value was 0.834. When the scale was rated by the patients themselves, Cronbach's alpha was 0.897.

Cronbach's alpha of the PROMIS-GSS-nausea questionnaire with 4 items was 0.739, when the scale was rated by the investigators. After division of the PROMIS-GSS-nausea questionnaire by the split-half method the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula, and its value was 0.662. When the scale was rated by the patients themselves, Cronbach's alpha was 0.737.

Factorial analysis

Factorial analysis of the DINS was made by the principal components method. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.815 and the Bartlett's test of sphericity was significant ($p = 0.000$). Only one factor was extracted, explaining in total 70.1% of variance and with eigenvalue 3.503.

Factorial analysis of the PROMIS-GSS-nausea questionnaire was made also by the principal components method. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.614 and the Bartlett's test of sphericity was significant ($p = 0.000$). Only one factor was extracted, explaining in total 56.22% of variance and with eigenvalue 2.249.

Validity

Construct validity of the questionnaire was confirmed by the panel of experts, who also helped with slight rephrasing of the questions.

Divergent criterion validity was tested through non-parametric correlation between scores of the DINS scale (when it was rated by an investigator and by the patients themselves) and scores of the IU scale (when it was rated by investigator and by patients themselves). The convergent criterion validity was tested through the non-parametric correlation between the scores of the DINS scale (when it was rated by an investigator and by the patients themselves), the scores of the PROMIS-GSS-nausea scale (when it was rated by an investigator and by the patients themselves). The correlation coefficients between the DINS and the IU scales and between the PROMIS-GSS-nausea and the IU scales were below 0.2 and were statistically insignificant. The non-parametric correlation was chosen due to the non-normal distribution of some of the scores. The Spearman's correlation coefficients are shown in the Multi-trait, multi-method matrix (Table 2).

Table 1

Mean values, standard deviation, skewness and kurtosis of responses to the items of DINS questionnaire (the responses are rated from 1 to 5 on a Likert scale).

Item	Mean response	Standard deviation	Skewness	Kurtosis
Did you feel nausea during drug therapy?	1.97	1.386	1.157	-0.084
During drug therapy, did you feel nausea always in the same time during a day?	1.89	1.399	1.338	0.319
During drug therapy, how often you could not perform your daily activities due to nausea?	1.71	1.243	1.641	1.404
Was your appetite decreased due to nausea during drug therapy?	1.36	.858	2.651	6.599
Did you feel an urge to vomit during drug therapy?	1.63	1.100	1.746	2.083

DINS – drug-induced nausea scale.

Table 2

Multi-trait, multi-method correlation matrix (non-parametric Spearman's coefficients)

Parameter	DINS score, rated by an investigator	DINS score, rated by a patient	PROMIS-GSS-nausea score, rated by an investigator	PROMIS-GSS-nausea score, rated by a patient	IU score, rated by an investigator	IU score, rated by a patient
DINS score, rated by an investigator	1	0.956**	0.765**	0.765**	0.131	0.126
DINS score, rated by a patient	0.956**	1	0.757**	0.759**	0.127	0.123
PROMIS-GSS-nausea score, rated by an investigator	0.765**	0.757**	1	0.961**	0.052	0.037
PROMIS-GSS-nausea score, rated by a patient	0.765**	0.759**	0.961**	1	0.018	0.013
IU score, rated by an investigator	0.131	0.127	0.052	0.018	1	0.972**
IU score, rated by a patient	0.126	0.123	0.037	0.013	0.972**	1

****significant correlation at $p < 0.001$.**
DINS – Drug Induced Nausea Scale. PRMIS-GSS – Patient-Reported Outcomes Measurement Information System Gastrointestinal Symptom Scale; IU – Intolerance of Uncertainty.

Temporal stability

The DINS scale showed excellent temporal stability: when rating (by an investigator) was repeated on the same patients two weeks later, the correlation between the scores (Spearman's coefficient) was 0.965 ($p < 0.001$). Cronbach's alpha after the repeated rating was 0.901.

The PROMIS-GSS-nausea scale also showed excellent temporal stability: when rating (by an investigator) was repeated on the same patients two weeks later, the correlation between the scores (Spearman's coefficient) was 0.947 ($p < 0.001$). Cronbach's alpha after the repeated rating was 0.742.

Discussion

The final version of the DINS scale with 5 items showed excellent reliability, both when rated by the investigators and the patients themselves. It was temporally stable, and both divergent and convergent validity tests had very good results. The factorial analysis revealed only one factor, which means that the whole scale was measuring only one phenomenon, intensity of nausea, as was originally intended. The DINS scale was also more reliable than the previously validated PROMIS-GSS-nausea scale.

Although the PROMIS-GSS-nausea scale was used for measuring intensity of nausea in a variety of gastronitestinal diseases, showing high ability to discriminate between the subtle changes in the nausea intensity [15], it was not previously used to measure drug-induced nausea. In our study, it showed necessary level of reliability for this purpose, but the DINS surpassed it by far with its high Cronbach's alpha around 0.9.

Since nausea and vomiting are particularly severe in the patients receiving chemotherapy, it is not surprising that the largest number of instruments for measuring drug-induced vomiting was specifically developed in this area. Recent systematic review has found seven instruments for measuring chemotherapy-induced nausea, retching and vomiting [16]. A majority of these instruments cover three key domains (nausea, vomiting and retching) and are prepared in several forms which are adjusted for three different phases of nausea-vomiting-retching phenomenon: anticipatory, acute and delayed. Our instrument DINS was focused on nausea domain, which is usually the only one present when the patients take less emetogenic drugs other than cytostatics [17]. Therefore, the DINS should not be used for the measurement of chemotherapy induced nausea, retching and vomiting, but for estimation of nausea caused by less emetogenic drugs prescribed to outpatients.

Although limited to the measurement of nausea, the items from the DINS instrument cover essential aspects of this phenomenon, which could be also applied to vomiting and retching: occurrence (item 2), duration (item 1) and severity (items 3,4 and 5) [17]. The Gastrointestinal Symptom Questionnaire by Pereira et al. [7] also covered these aspects of nausea, but the answers to questions had only three modalities, "mild", "moderate" and "severe", limiting discriminative power of the scale. Although in their study, Pereira et al. [7] did not measure internal consistency of their questionnaire, most likely it would not be too high, since the questionnaire related only to condition of a patient on the day of rating, and misses chronicity as important aspect of drug-induced nausea. We also would like to point out that the second question (During drug therapy, did you feel nausea always in the same time during a day?) could be better formulated in a way which would take into account timing of a drug intake during the day (e.g., During drug

therapy, did you feel nausea always after its administration?) in order to capture causality between intake of a drug and emergence of nausea. However, this new formulation would have to be tested in a future study.

Main limitations of this study were non-homogenous nature of the study sample, i.e., some of the patients had previous experience with nausea after oral drug intake, some did not, and female sex was largely predominant, due to higher incidence of iron-deficiency anemia. This non-homogeneity could be responsible for somewhat wider dispersion of the patients' responses. Besides, the patients were taking only one drug (iron salts) which causes nausea, so the results could be drug type – specific, and may not apply to nausea caused by other drugs. Future studies with the same questionnaire should be conducted on several patient subgroups which are taking other emetogenic drugs in order to get complete insight into its functionality.

Conclusion

In conclusion, the DINS is a reliable and valid instrument for measuring intensity of drug-induced nausea. Identification of patients with high intensity of drug-induced nausea by this questionnaire will help prescribers to decide whether the therapy should be stopped or the patient switched to less emetogenic therapy.

Acknowledgements

The authors are grateful to Dr Zan Frisčić, MD, specialist of orthopedic surgery and native English language speaker, who helped with backward translation from Serbian to English of the PROMIS-GSS-nausea scale. The authors also thank to Associated Professor Ljiljana Mihić, psychologist, University of Novi Sad, Serbia, for giving permission to use the Intolerance of Uncertainty questionnaire for testing divergent validity of the DINS scale.

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Received on April 21, 2017.
Revised on August 21, 2017.
Accepted on September 11, 2017.
Online First September, 2017.