Validation of a French version of the DHEQ - Quality of Life Questionnaire in Relation to Oral Health and Dentin Hypersensitivity

11/06/2024

1. Study protocol

1.1. Expected duration of participation of individuals

All participants (n=216) will be invited to a 45-minute visit (test). A second visit will be organized for the 60 patients randomly selected for a 15-day retest.
The maximum duration of participation is therefore 15 days.

1.2. Description of the acts performed on the persons (description of each visit)

Visit 1 (Test): Patients will be seen by the local investigator/examiner who will assess the eligibility of patients according to the inclusion and non-inclusion criteria described above.

HD group
- Clinical examination performed to confirm the diagnosis of HD (Schiff score on the air jet test ≥1);
- Air jet test: determination of the Schiff score (score ≥1) and the EVA score;
- Self-administration of DHEQ-fr, GOHAI and OHIP questionnaires.

Control group
- Clinical examination performed to confirm the absence of HD;
- Self-administration of DHEQ-fr, GOHAI and OHIP questionnaires.

Visit 2 (Retest)

HD Group and Control
- Self-administration of DHEQ-fr questionnaires.

1.3. Description of the general logistical organization of the trial

Patient recruitment will be done in three centers (Odontology Department of Clermont-Ferrand, Bordeaux and Lyon), after informing all practitioners and practicing students about the present study and the need to refer patients with HD symptoms to the local investigator.
A local co-investigator/examiner will conduct visits to all patients at the investigator center in which they practice; His senior will ensure methodological and administrative supervision of the Investigator Center in which he works.
The principal investigator and the biostatistician will take charge of the data analysis.

1.4. Study samples and biological analyses

No samples will be taken during this study. No biological analysis will be performed during this study.

2. Statistical analysis plan

2.1. Data Analysis Method

2.1.1. General

The statistical analysis will be carried out with the Stata software (version 15, StataCorp, College Station), considering a first-kind bilateral risk of error of 5%.

The sample will be described by associated numbers and percentages for categorical variables and by mean and standard deviation or median and interquartile range for quantitative variables, with respect to their statistical distribution. Normality will be studied by the Shapiro-Wilk test and/or histogram. Graphical representations will be associated with the analyses as much as possible.

Patients will be described and compared between groups at baseline according to the following variables: compliance with eligibility criteria, epidemiological characteristics and clinical characteristics.

A description of the deviations from the protocol, the patients distributed according to these deviations and the causes of abandonment will also be carried out.

The initial comparability of the two arms will be assessed on the main characteristics of the participants and potential factors associated with the primary outcome. Any difference between the two groups on one of these characteristics will be determined according to clinical considerations and not just statistical ones. Comparisons between groups will be made systematically (1) without adjustment and (2) by adjusting for factors whose distribution could be unbalanced between groups despite the matching.

2.1.2. Statistical analyses

The validation of the DHEQ-fr will consider the study of psychometric properties according to the following plan:

The measure of **acceptability** will be based on the calculation of missing data at the item level and for the overall score; the scale will be considered applicable if the conditions of use show that the cost of implementation is modest, that the acceptability by patients and the medical community is high, and that the time to pass is low.

The **fidelity** of the instrument will be assessed according to two criteria:

- *Internal consistency* will be assessed by calculating the Cronbach alpha coefficient (Kuder-Richardson α_k) and will be studied against the usual recommendations described as follows: $\alpha k \geq 0.9$ excellent; $0.9 > \alpha k \geq 0.8$ correct; $0.8 > \alpha k \geq 0.7$ acceptable; $0.7 > \alpha k \geq 0.6$ moderate; $0.6 > \alpha k \geq 0.5$ low; and $0.5 < \alpha k$ not acceptable.
- *Test-retest reproducibility*, the ability to produce comparable responses when the measure is repeated while the individual's condition remains stable, will be assessed by calculating the intensity of agreement (for items of a quantitative nature: Lin's coefficient of agreement and for items of a categorical nature: agreement rate: for each item, percentage of identical responses during the test and retest and the Kappa coefficient of agreement (denoted k) compared to the following recommendations: no agreement ($k<0.2$), low agreement (k 0.2 to 0.4), moderate agreement (k 0.4 to 0.6), substantial agreement (k 0.6 to 0.8), or excellent agreement ($k> 0.8$). The overall score will be compared in a test-retest situation by the paired

Student's test in addition to the correlation coefficient (Pearson or Spearman with regard to the statistical distribution) and the Lin concordance coefficient. A graphical representation of Bland and Altman will complete these analyses.

Internal **structure validity** explores the coherence of the internal layout of the questionnaire. This validity will be evaluated by studying the following parameters: for items of a categorical nature: proportion of patients for each of the modalities of each item ('difficulty', denoted p), variance of each item (denoted p(1-p)), 'item-score' correlations (so-called biserial point correlation coefficient, i.e. correlation between a dichotomous variable and a quantitative variable) and multi-trait matrix of correlation coefficients (inter-item and item-dimension) for the items of a quantitative nature.
A factor analysis will allow us to study the relationships between the modalities of each of the items.
These analyses will be complemented by an item response theory approach; specifically, a Rasch model analysis will be implemented to study the internal structure of the AHS, taking into account inter and intra item variability. The following indicators will be calculated, among others: one-dimensionality, item difficult, DIF (Differential Item Functioning), reliability alpha (PSI: person separation index), fit (overall, outfit, infit).

The DHEQ-fr scores of patients in the HD group will be compared to those of the "control" group by Student's t-test or Mann-Whitney test if the conditions for the application of the t-test are not met. Homoscedasticity will be studied by Fisher-Snedecor test. Results will be expressed in terms of effect sizes and 95% confidence intervals.

The study of the relationships between variables of a quantitative nature (DHEQ-fr, GOHAI, OHIP-49 and 14) will be analyzed by estimation of correlation coefficients (Pearson or Spearman, with regard to the statistical distribution).

2.1.3. Method of accounting for missing, unused or invalid data

A sensitivity analysis will be conducted to measure the impact of missing data and determine the most appropriate imputation method. Complete and missing samples will be compared for key socio-demographic and clinical characteristics, as will test and retest samples.
Additional analyses will then be carried out according to the statistical nature of the missing data (missing at random or not).

2.1.4. Interim analyses

An intermediate analysis will be carried out as part of a Master II thesis. Inclusions will be continued during this period as there is no risk to participants.