Development and validation of a French obesity-specific quality of life questionnaire: Quality Of Life, Obesity and Dietetics (QOLOD) rating scale

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S UMMARY

Objective. To develop and validate a new health related quality of life (HRQOL) questionnaire specific to obesity and its management.

Methods. This study was in two parts. The first (Study 1) consisted of the creation of a new tool derived from the American “Impact of Weight on Quality of Life Questionnaire” (IWQOL, 74 items) by adding to it a 17 items specific complementary module. This initial questionnaire (91 items) was reduced so as to obtain a questionnaire adapted to socio-cultural factors of obesity and dietary weight management in France. The objective of the second (Study 2) was to validate this final questionnaire by evaluating its psychometric properties: construction validity, internal reliability, concurrent validity in relation to a generic questionnaire, the SF-12, clinical validity by studying the effects of age, gender and body mass index (BMI), and reproducibility.

Results. The results of Study 1, obtained in 128 obese patients (mean age: 42.5 ± 12.1, BMI: 34.5 ± 2.8 kg/m², women: 83.6%) enabled reduction of the 91 questionnaire items to 36, grouped into 5 dimensions: physical impact, psycho-social impact, sex life, comfort with food and diet experience. Two hundred and twelve patients (mean age: 43.3 ± 12.2, BMI: 35.8 ± 7.4 kg/m², women: 77.7%) were included in Study 2, among whom 75 filled out the questionnaire twice at a one week interval. Analyses enabled verification of the construction validity and internal reliability (Cronbach alpha > 0.7) of the questionnaire as well as its concurrent validity in relation to summarized SF-12 scores and its clinical validity. The “physical impact” dimension was significantly influenced by BMI and age, the dimensions “sex life” and “diet experience” by the factors gender and BMI, while “psycho-social impact” was influenced by the 3 factors cited. Its reproducibility was also deemed satisfactory (intra-class correlation coefficient > 0.8).

Conclusion. This new questionnaire, called the “Echelle Qualité de Vie, Obésité et Diététique (EQVOD)”/“Quality of Life, Obesity and Dietetics (QOLOD)” rating scale is sufficiently reliable and reproducible to be used in clinical practice. It is a simple tool adapted to socio-cultural factors of obesity in France, enabling taking into account of the effects of dietary management on the HRQOL of obese people.

Key-words: Health related quality of life · Obesity · Dietary management.


R ÉSUMÉ

Développement et validation d’un questionnaire français de qualité de vie spécifique de l’obésité : échelle qualité de vie, obésité et diététique (EQVOD)

Objectif. Développer et valider un nouveau questionnaire de qualité de vie lié à la santé (QDV) spécifique de l’obésité et de ses traitements.

Méthodes. Ce travail a été réalisé en 2 parties. La première (étude 1) a consisté à créer un nouvel outil à partir du questionnaire américain “Impact Weight Quality of Life Questionnaire” (IWQOL, 74 items) en lui ajoutant un module complémentaire spécifique de 17 items. Ce questionnaire initial (91 items) a été réduit afin d’obtenir un questionnaire adapté aux facteurs socioculturels de l’obésité et à son traitement diététique en France. La seconde (étude 2) avait pour objectif de valider ce questionnaire final en évaluant ses propriétés psychométriques : validité de construction, fiabilité interne, validité concourante par rapport à un questionnaire générique : le SF-12, validité clinique en étudiant les effets de l’âge, du sexe et de la corpulence, et reproductibilité.

Résultats. Les résultats de l’étude 1, obtenus auprès de 128 patients obèses (âge moyen : 42,5 ± 12,1 ans, indice de masse corporelle (IMC) : 34,5 ± 2,8 kg/m², pourcentage de femmes : 83,6%) ont permis de réduire le questionnaire de 91 items à 36, regroupés en 5 dimensions : impact physique, impact psycho-social, vie sexuelle, bien-être alimentaire et vécu du traitement diététique. Deux cent douze patients (âge moyen : 43,3 ± 12,2 ans, IMC : 35,8 ± 7,4 kg/m², pourcentage de femmes : 77,7%) ont été inclus dans l’étude 2 parmi lesquels 75 ont rempli 2 fois le questionnaire à une semaine d’intervalle. Les analyses réalisées ont permis de vérifier la validité de construction et la fiabilité interne (Cronbach alpha > 0,7) du questionnaire d’une part, ainsi que sa validité concourante par rapport aux scores résumés du SF-12 et sa validité clinique. La dimension « impact physique » est significativement influencée par la corpulence et par l’âge, les dimensions « vie sexuelle » et « vécu de la diététique » par les facteurs sexe et corpulence alors que l’impact psycho-social l’est par les 3 facteurs cités. Enfin, sa reproductibilité a été également jugée satisfaisante (coefficient de corrélation intra-classe > 0,8).

Conclusion. Ce nouveau questionnaire, nommé Echelle Qualité de Vie, Obésité et Diététique (EQVOD), nous paraît suffisamment fiable et reproductible pour être utilisé en pratique clinique. C’est un outil simple adapté aux facteurs socioculturels de l’obésité en France, qui permet de prendre en compte les effets des traitements diététiques sur la qualité de vie des sujets obèses.

Mots-clés : Qualité de vie liée à la santé · Obésité · Traitement diététique.

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Obesity is an increasingly common disorder in industrialised countries [1] and is a veritable health care problem, due to the extent of its complications, particularly mechanical, metabolic and vascular [2, 3]. It is also a chronic disease which is difficult to treat. Since it is almost always impossible to obtain recovery, it is important to ensure management of associated co-morbidities. In this setting, the concept of “Health Related Quality of Life” (HRQOL) is especially significant [4]. While it is difficult to obtain and above all maintain large weight loss, it is at the very least essential to try to improve the quality of life of obese patients [4, 5]. Health care professionals’ guidelines specify that such improvement should form part of the treatment objectives and end-points of clinical trials [2, 6].

Studies concerning the QOL of obese patients are hence increasing in number [4, 5]. However, HRQOL is a complex notion and difficult to measure. According to Schipper [7], improving the HRQOL of patients involves reducing the functional repercussions of the disease and its treatments, as they perceive them. Measurement implies the availability of reliable and validated tools, adapted to the community concerned. These tools or questionnaires are either generic, i.e. usable regardless of the disease concerned, or specific to a given disease. All studies concerning the HRQOL of obese patients show that it is impaired, and all the more so when obesity is severe [8-10]. Most of the first studies used generic questionnaires, sometimes with the association of specific modules. A number of specific questionnaires for use in obese patients have been developed recently [9, 11-19], including the “Impact of Weight on Quality of Life” (IWQOL), created in the United States for use at all stages of the disease [11]. This latter questionnaire consists of 74 items grouped in 8 dimensions: health, social and interpersonal relations, work, mobility, self esteem, sexuality, everyday activities and comfort with food.

No specific questionnaire in French being available at the start of our research, we decided to develop and validate a specific questionnaire usable in clinical trials in France. The IWQOL questionnaire was used as a base after translation into French using the recommended methodology [20]. We also wished to take into account not only the perception of food [11, 12], but also diet experience, which is another aspect of the HRQOL of obese patients, never studied directly by existing questionnaires.

Development and validation of this new tool, called the “Echelle Qualité de Vie, Obésité et Diététique (EQVOD) / “Quality of Life, Obesity and Dietetics Rating Scale (QOLOD)” required two stages. The first (Study 1) involved enrichment of the IWQOL by creating new items. This questionnaire was then reduced so as to obtain a fast questionnaire specific to obesity, and taking into account the effects of its dietary treatment. The objective of the second (Study 2) was to validate this final questionnaire by evaluating its psychometric properties: construction validity, internal reliability, concurrent reliability, clinical validity and reproducibility.

Patients and methods

Study 1: development of QOLOD rating scale questionnaire

Study design and methods

The preliminary phase of this work was to question 31 obese patients about the relations between their quality of life and excess weight. It was a qualitative evaluation using traditional face to face interviews with patients. This enabled identification among them of shared preoccupations poorly identified by the French translation of the IWQOL questionnaire: attitude to food, difficulties adhering to the diet (“diet experience”), feelings of guilt and shame, and functional handicap related to low back pain. An additional module of 17 items was created in order to cover these specific points. The questionnaire thus obtained (IWQOL and specific module) consisted of 91 items. It was felt preferable to reduce it, since it is not easy to administer a long questionnaire in clinical research due to the lack of availability of physicians and patients and the difficulty for patients participating in a long procedure, especially when repeated [21].

Once created, the questionnaire had to be validated by comparing it with another, already validated, measure of HRQOL. This was the generic Short-Form 12 (SF-12) [22, 23] which was used as the external criterion for the validation phase, despite it never being used in obese patients. The SF-12 was chosen for the following reasons: it is a generic questionnaire, validated, available in French, easy to use and administer to patients and widely used. The SF-12 consists of 12 items grouped in 2 summary scores (physical and psychological): it is also derived from the Short-Form-36 (SF-36), already used in cohorts of obese patients [4, 5, 8, 9, 18].

Patients

Patients, who had presented for treatment of their obesity were enrolled and monitored by general practitioner or specialist investigators. Patients included were to be of both sexes, aged between 18 and 65 years and had a BMI between 30 and 40 kg/m². Those with obesity of endocrine origin, as those with uncontrolled hypertension, type 1 diabetes, mental disease or linguistic problems were excluded. Sociodemographic and medical data were collected by the investigators. Patients filled out the QOLOD and SF-12 questionnaires alone. Investigators were to note all information concerning obesity of patients, and particularly date of onset, weight variations, as well as the presence or not of concomitant diseases such as type 2 diabetes, hypertension, and angina or sleep apnoea. They were also to evaluate for each patient the handicap related to obesity on a 5 point scale.
Statistical analysis

Socio-demographic and medical data were described by expressing qualitative variables as the number and percentage of answers to each modality and quantitative variables as their mean and standard deviation.

Care was taken during psychometric reduction of the number of items to preserve the dimensions of the initial questionnaire (IWQOL): health, social life, work, mobility, self-esteem, sex-life, everyday activities and eating. Successive factorial analyses [principal components analyses (PCA)] were used to eliminate the least pertinent items and retest the model until a clinically and statistically consistent factorial structure was obtained. Items suppressed were those in which: (1) 20 % or more of patients had not answered; (2) 50 % or more of patients had answered checking one or other of the anchor responses (e.g. not at all or always) resulting in the emergence of a distribution with a “ceiling” or “floor” effect; (3) the item was poorly correlated with other items of its dimension (multitrait analysis): the convergent validity of this item with its own dimension was insufficient (correlation coefficient < 0.4); the discriminant validity of the item was not met (correlation with other items of its dimension less than that seen with another dimension).

Each item of the IWQOL questionnaire and additional model was graded from 1 to 5 (1: always/enormously; 2: often/a lot; 3: sometimes/moderately; 4: rarely/a little; 5: never/not at all). A score was then calculated for each dimension by adding together its constituent items. Scores obtained by adding up answers graded from 1 to 5 of all items per dimension were transformed to convert the lowest and highest score possible to 0 and 100 respectively. Hence the higher the score, the better the quality of life.

Evaluation of the concurrent validity of a questionnaire involves study of the equality between the scales of the questionnaire concerned and scores of another questionnaire. Here, links between the dimensions of the new questionnaire and scores of the physical and psychological components of the SF-12 were analysed using Spearman’s correlation coefficients (ICC) which were to be more than the recommended minimum threshold of 0.8 [27]. Patients deemed stable, were compared by calculation of intra-class correlation coefficients (ICC) [26] which were to be more than the recommended minimum threshold of 0.8 [27].

Patients

Selection criteria were the same as those of Study 1, except BMI which could vary from 25 to more than 40 kg/m².

Statistical analysis

The scoring method used was the same as that used in Study 1. Validity of the construction of the reduced questionnaire was verified by principal component analysis and multitrait analysis [24]. The objective was to confirm that grouping of questionnaire items clearly reflected the hypothesis of constructions determined by the authors during the first study. Internal reliability of the various items of the new questionnaire was evaluated by calculation of Cronbach’s alpha coefficient [25]. This coefficient enabled verification of the consistency of grouping of items in each dimension.

The clinical validity of the questionnaire was also verified, i.e. meeting the hypothesis that it should give different results in distinct cohorts identified by their different characteristics. By symmetry, these results should be well correlated with the different levels of a given characteristic in the cohort explored. Here, the clinical pertinence of the questionnaire (clinical validity) was evaluated according to data recommended in the literature [14]. The following hypotheses were tested: HRQOL was to be less in older patients, women and the most corpulent patients (grouped into 4 categories according to their BMI: 25-29.9 kg/m²; 30-34.9 kg/m²; 35-39.9 kg/m²; 40 kg/m²). Analysis of HRQOL scores according to BMI used multivariate analysis adjusted for the age and gender of patients, so as to take into account differences on HRQOL inherent to factors other than obesity.

As far as reproducibility is concerned, scores obtained when the questionnaire was filled out twice by patients deemed stable, were compared by calculation of intra-class correlation coefficients (ICC) [26] which were to be more than the recommended minimum threshold of 0.8 [27]. Patients deemed stable were those whose weight had not changed (to the nearest kilogram) or who felt that their state of health or HRQOL had remained the same between the two administrations of the questionnaire (questionnaire directly asked to the patient).

Results

Study 1: development of QOLOD questionnaire

Characteristics of population

Mean age of the 128 patients included was 42.5 ± 12.1. The majority were women (83.6%), most often living with a partner (63.3%) and 52.3% were office workers. Clinical profiles are shown in Table 1. Most patients had one or more obes-
ity-related diseases and a handicap considered to be moderate to very severe. More than half of the patients (57.8%) were on a diet but only 3.1% of patients were taking medications to lose weight. Obesity had existed on average for 14 years (from 1 to 50), 41.4% of patients were losing weight, 43% had stable weight and 15.6% had recently gained weight.

Acceptability of questionnaire

One hundred and twenty one patients returned their completed questionnaire. The mean number of missing items was 1.5 per patient (1.4%) and seventy four patients (61.2%) completed the questionnaire fully.

Reduction of number of items

No item was eliminated from the acceptability criterion (all filled out by at least 80% of patients). In contrast, 14 were withdrawn because they showed a “floor” effect. Items were withdrawn and dimensions defined during each principal components analysis, the new questionnaire then being tested to verify its construction validity. Eight repeated analyses were necessary to select pertinent items and obtain a consistent factorial structure. Scales defined in the initial questionnaire were completely transformed with the exception of the sex life and comfort with food dimensions. The final questionnaire thus obtained (Tab II) consisted of 36 items grouped in 5 dimensions: physical impact (11 items), psycho-social impact (11 items), sex life (4 items), comfort with food (5 items) and diet experience (5 items).

Concurrent validity

The score obtained for the physical impact dimension of the obesity-specific HRQOL questionnaire was highly correlated with the SF-12 physical score (Spearman’s correlation coefficient, $r = 0.72$, $P = 0.0001$); in the same way, the psychological score (psychological impact dimension) was highly correlated with the SF-12 psychic score ($r = 0.64$, $P = 0.0001$). In contrast, other dimensions of the specific questionnaire were less well correlated with the SF-12 physical and psychological scores, though some correlations were statistically significant (data not shown).

Study 2: Evaluation of psychometric properties and reproducibility of questionnaire

Characteristics of population

Mean age of the 212 patients included in the validation study was $43.3 \pm 12.2$. The majority were women (77.7%), most often living with a partner (68.2%), and working full or

<table>
<thead>
<tr>
<th>Table I</th>
<th>Clinical characteristics of obese patients included in Study 1 (reduction in number of items) and Study 2 (validation of psychometric properties and reproducibility).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1 (N = 128)</td>
<td>Study 2 (Validation (N = 210))</td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td></td>
</tr>
<tr>
<td>Age*</td>
<td>42.5 ± 12.1</td>
</tr>
<tr>
<td>Men/Women**</td>
<td>16.4%/83.6%</td>
</tr>
<tr>
<td>Weight (kg)*</td>
<td>94.1 ± 10.8</td>
</tr>
<tr>
<td>Height (m)*</td>
<td>1.65 ± 0.07</td>
</tr>
<tr>
<td>BMI (kg/m²)*</td>
<td>34.5 ± 2.8</td>
</tr>
<tr>
<td>Obesity duration (years)*</td>
<td>14.0 ± 9.8</td>
</tr>
<tr>
<td>Obesity duration (years)***</td>
<td>10 [7, 20]</td>
</tr>
<tr>
<td>Concomitant disease</td>
<td>Presence**</td>
</tr>
<tr>
<td>Treatment of obesity</td>
<td>Medication**</td>
</tr>
<tr>
<td>Obesity-related handicap estimated by investigator**</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td>Slight</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>Very severe</td>
</tr>
</tbody>
</table>

*mean and standard deviation
**frequency (%)
***median [quartile 1; quartile 3]
part time in 55.9% of cases. Clinical characteristics are shown in Table I. Patients had a mean BMI equivalent to that of Study 1.

**Acceptability of questionnaire**

Two hundred and twelve patients filled out their questionnaire at one visit. The mean number of missing data was 0.57 (1.59%) per patient and 165 patients (77.8%) completed the questionnaire in full. Results were similar to those obtained in Study 1, indicating good acceptability of this tool as well as good understanding of its constituent items.

**Construction validity and internal reliability of final questionnaire**

A final principal components analysis (PCA) of the 36 items limited to 5 factors confirmed that items were in general well distributed in the pre-supposed dimensions, and especially those concerning the physical impact, comfort with food and diet experience dimensions. Items of the sex life dimension joined those of the psychological impact dimension on the first axis of the PCA, which could possibly be explained by the strong link between psychological state and sex life.
Multitrait analysis enabled verification of the 5 dimension structure of the questionnaire (Tab III). All items were better correlated with their own dimension than with other dimensions, indicating excellent discriminant validity, and all met the convergent validity criterion with their dimension (correlation coefficient 0.4).

All Cronbach’s alpha coefficients were above 0.7, hence confirming the good internal reliability of the questionnaire (Tab IV). The distribution of scores was also deemed satisfactory in that no ceiling or floor effect was seen (< 20%) except for the “sex life” dimension (19.9%).

Clinical validity

Hypotheses enabling verification of the clinical validity of the questionnaire were tested (Tab V). Elderly patients reported that they were more physically affected by their obesity than younger patients (P < 0.05), but their psychological scores were significantly higher (P < 0.05). Women had a more impaired quality of life than men from a psychological and sexual standpoint, and tolerated diets less well (P < 0.05). With the exception of the comfort with food score, all other scores varied significantly according to the severity of obesity (P < 0.05).
Reproducibility

Clinical characteristics of the 75 patients who completed the questionnaire twice at a one week interval were similar to those of the Study 1 patients (Tab I). Most patients lived with a partner (69.3 %) and 40.0% of them were office workers. Most were women (73.3 %). Three different criteria were used to establish the clinical stability of patients. Analyses concerned 69, 46 and 51 patients respectively, according to the criterion chosen to evaluate the stability of weight, health and quality of life of the patients. Scores increased between the two administrations of the questionnaire, indicative of an improvement in HRQOL. However, variations in scores were not statistically significant in the

Table III
Results of multitrait analysis (36 items, 5 dimensions).

<table>
<thead>
<tr>
<th>Item</th>
<th>Physical impact</th>
<th>Psychological impact</th>
<th>Sexual Impact</th>
<th>Comfort with food</th>
<th>Diet experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>0.69 *</td>
<td>0.47</td>
<td>0.32</td>
<td>0.16</td>
<td>0.33</td>
</tr>
<tr>
<td>Q2</td>
<td>0.55 *</td>
<td>0.43</td>
<td>0.30</td>
<td>0.03</td>
<td>0.37</td>
</tr>
<tr>
<td>Q3</td>
<td>0.57 *</td>
<td>0.36</td>
<td>0.33</td>
<td>0.03</td>
<td>0.30</td>
</tr>
<tr>
<td>Q4</td>
<td>0.64 *</td>
<td>0.40</td>
<td>0.36</td>
<td>0.00</td>
<td>0.26</td>
</tr>
<tr>
<td>Q5</td>
<td>0.65 *</td>
<td>0.61</td>
<td>0.48</td>
<td>0.16</td>
<td>0.42</td>
</tr>
<tr>
<td>Q6</td>
<td>0.70 *</td>
<td>0.58</td>
<td>0.33</td>
<td>0.20</td>
<td>0.38</td>
</tr>
<tr>
<td>Q7</td>
<td>0.59 *</td>
<td>0.41</td>
<td>0.22</td>
<td>0.04</td>
<td>0.25</td>
</tr>
<tr>
<td>Q8</td>
<td>0.72 *</td>
<td>0.50</td>
<td>0.48</td>
<td>0.14</td>
<td>0.32</td>
</tr>
<tr>
<td>Q9</td>
<td>0.72 *</td>
<td>0.46</td>
<td>0.51</td>
<td>0.11</td>
<td>0.28</td>
</tr>
<tr>
<td>Q10</td>
<td>0.75 *</td>
<td>0.52</td>
<td>0.43</td>
<td>0.07</td>
<td>0.32</td>
</tr>
<tr>
<td>Q11</td>
<td>0.73 *</td>
<td>0.60</td>
<td>0.45</td>
<td>0.17</td>
<td>0.36</td>
</tr>
<tr>
<td>Q12</td>
<td>0.54</td>
<td>0.76 *</td>
<td>0.45</td>
<td>0.05</td>
<td>0.39</td>
</tr>
<tr>
<td>Q13</td>
<td>0.52</td>
<td>0.68 *</td>
<td>0.49</td>
<td>0.06</td>
<td>0.39</td>
</tr>
<tr>
<td>Q14</td>
<td>0.61</td>
<td>0.67 *</td>
<td>0.48</td>
<td>0.04</td>
<td>0.43</td>
</tr>
<tr>
<td>Q15</td>
<td>0.56</td>
<td>0.77 *</td>
<td>0.46</td>
<td>0.06</td>
<td>0.45</td>
</tr>
<tr>
<td>Q16</td>
<td>0.47</td>
<td>0.60 *</td>
<td>0.27</td>
<td>0.25</td>
<td>0.45</td>
</tr>
<tr>
<td>Q17</td>
<td>0.33</td>
<td>0.45 *</td>
<td>0.30</td>
<td>0.00</td>
<td>0.21</td>
</tr>
<tr>
<td>Q18</td>
<td>0.47</td>
<td>0.75 *</td>
<td>0.43</td>
<td>0.12</td>
<td>0.52</td>
</tr>
<tr>
<td>Q19</td>
<td>0.46</td>
<td>0.79 *</td>
<td>0.45</td>
<td>0.03</td>
<td>0.45</td>
</tr>
<tr>
<td>Q20</td>
<td>0.40</td>
<td>0.64 *</td>
<td>0.36</td>
<td>0.14</td>
<td>0.60</td>
</tr>
<tr>
<td>Q21</td>
<td>0.49</td>
<td>0.69 *</td>
<td>0.45</td>
<td>0.11</td>
<td>0.44</td>
</tr>
<tr>
<td>Q22</td>
<td>0.51</td>
<td>0.58 *</td>
<td>0.39</td>
<td>0.28</td>
<td>0.48</td>
</tr>
<tr>
<td>Q23</td>
<td>0.43</td>
<td>0.50</td>
<td>0.75 *</td>
<td>-0.04</td>
<td>0.28</td>
</tr>
<tr>
<td>Q24</td>
<td>0.57</td>
<td>0.56</td>
<td>0.77 *</td>
<td>0.08</td>
<td>0.38</td>
</tr>
<tr>
<td>Q25</td>
<td>0.43</td>
<td>0.51</td>
<td>0.82 *</td>
<td>-0.06</td>
<td>0.34</td>
</tr>
<tr>
<td>Q26</td>
<td>0.43</td>
<td>0.41</td>
<td>0.80 *</td>
<td>-0.01</td>
<td>0.28</td>
</tr>
<tr>
<td>Q27</td>
<td>0.18</td>
<td>0.20</td>
<td>0.03</td>
<td>0.75 *</td>
<td>0.32</td>
</tr>
<tr>
<td>Q28</td>
<td>0.06</td>
<td>0.08</td>
<td>-0.05</td>
<td>0.72 *</td>
<td>0.23</td>
</tr>
<tr>
<td>Q29</td>
<td>0.08</td>
<td>0.04</td>
<td>-0.10</td>
<td>0.81 *</td>
<td>0.26</td>
</tr>
<tr>
<td>Q30</td>
<td>0.05</td>
<td>0.08</td>
<td>-0.06</td>
<td>0.82 *</td>
<td>0.31</td>
</tr>
<tr>
<td>Q31</td>
<td>0.21</td>
<td>0.21</td>
<td>0.12</td>
<td>0.73 *</td>
<td>0.39</td>
</tr>
<tr>
<td>Q32</td>
<td>0.28</td>
<td>0.36</td>
<td>0.16</td>
<td>0.47</td>
<td>0.55 *</td>
</tr>
<tr>
<td>Q33</td>
<td>0.27</td>
<td>0.40</td>
<td>0.27</td>
<td>0.31</td>
<td>0.63 *</td>
</tr>
<tr>
<td>Q34</td>
<td>0.42</td>
<td>0.44</td>
<td>0.35</td>
<td>0.16</td>
<td>0.55 *</td>
</tr>
<tr>
<td>Q35</td>
<td>0.25</td>
<td>0.47</td>
<td>0.21</td>
<td>0.12</td>
<td>0.44 *</td>
</tr>
<tr>
<td>Q36</td>
<td>0.41</td>
<td>0.51</td>
<td>0.34</td>
<td>0.24</td>
<td>0.61 *</td>
</tr>
</tbody>
</table>

Pearson Item-Scale Correlations. Items were grouped in 5 dimensions: physical impact, psycho-social impact, sexual impact, comfort with food, diet experience.
*Item-scale correlation corrected for overlap (relevant item removed from its scale for correlation).
Table IV
Internal reliability of questionnaire specific to obesity: Cronbach's alpha coefficient and percentage answers for extreme options in Studies 1 and 2.

<table>
<thead>
<tr>
<th>Study</th>
<th>Dimensions</th>
<th>Number analysed</th>
<th>Cronbach's alpha coefficient</th>
<th>% answer to option noted 1(a)</th>
<th>% answer to option noted 5(b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Physical impact</td>
<td>201</td>
<td>0.91</td>
<td>1.5</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Psycho-social impact</td>
<td>201</td>
<td>0.92</td>
<td>0.0</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>Sex life</td>
<td>201</td>
<td>0.90</td>
<td>2.0</td>
<td>19.9(c)</td>
</tr>
<tr>
<td></td>
<td>Comfort with food</td>
<td>201</td>
<td>0.90</td>
<td>3.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Diet experience</td>
<td>201</td>
<td>0.78</td>
<td>1.5</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>Physical Impact</td>
<td>72</td>
<td>0.92</td>
<td>2.8</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Psycho-social Impact</td>
<td>72</td>
<td>0.92</td>
<td>0.0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sex life</td>
<td>69</td>
<td>0.92</td>
<td>1.4</td>
<td>19.7(c)</td>
</tr>
<tr>
<td></td>
<td>Comfort with food</td>
<td>72</td>
<td>0.89</td>
<td>2.8</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Diet experience</td>
<td>70</td>
<td>0.72</td>
<td>0.0</td>
<td>0</td>
</tr>
</tbody>
</table>

(a)Floor effect
(b)Ceiling effect
(c)Sexual desire felt: has little physical difficulty during sexual relations, derives pleasure from sexual relations.

Table V
Description of quality of life scores (mean ± standard deviation) according to clinical characteristics of obesity in the 210 patients included in the second study.

<table>
<thead>
<tr>
<th>Number analysed</th>
<th>Physical impact</th>
<th>Psycho-social Impact</th>
<th>Impact on sex life*</th>
<th>Comfort with food</th>
<th>Diet experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-demographics characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 30</td>
<td>42</td>
<td>68.0 ± 16.6</td>
<td>57.9 ± 22.9</td>
<td>77.4 ± 22.4</td>
<td>59.5 ± 17.0</td>
</tr>
<tr>
<td>30-40</td>
<td>41</td>
<td>56.2 ± 19.5</td>
<td>47.0 ± 23.0</td>
<td>63.6 ± 29.1</td>
<td>57.9 ± 23.8</td>
</tr>
<tr>
<td>40-50</td>
<td>56</td>
<td>51.1 ± 23.7</td>
<td>58.5 ± 25.0</td>
<td>66.8 ± 30.6</td>
<td>56.4 ± 23.8</td>
</tr>
<tr>
<td>&gt; 50</td>
<td>71</td>
<td>56.6 ± 25.0</td>
<td>62.2 ± 24.7</td>
<td>67.5 ± 28.8</td>
<td>52.7 ± 24.5</td>
</tr>
<tr>
<td>ANCOVA**</td>
<td>-</td>
<td>0.0054</td>
<td>0.0380</td>
<td>0.2899</td>
<td>0.3199</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>47</td>
<td>61.8 ± 23.1</td>
<td>73.3 ± 23.0</td>
<td>80.0 ± 23.3</td>
<td>56.4 ± 25.0</td>
</tr>
<tr>
<td>Female</td>
<td>164</td>
<td>56.03 ± 22.4</td>
<td>52.9 ± 22.4</td>
<td>65.2 ± 28.9</td>
<td>56.1 ± 22.2</td>
</tr>
<tr>
<td>ANOVA</td>
<td>-</td>
<td>0.0821</td>
<td>&lt; 0.0001</td>
<td>0.0017</td>
<td>0.8567</td>
</tr>
<tr>
<td>Classification of overweight according to BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30 kg/m²</td>
<td>36</td>
<td>72.4 ± 15.1</td>
<td>73.0 ± 16.4</td>
<td>81.88 ± 18.7</td>
<td>56.1 ± 22.2</td>
</tr>
<tr>
<td>30-35 kg/m²</td>
<td>84</td>
<td>57.1 ± 21.9</td>
<td>55.5 ± 25.6</td>
<td>66.84 ± 27.8</td>
<td>57.5 ± 21.3</td>
</tr>
<tr>
<td>35-40 kg/m²</td>
<td>47</td>
<td>54.4 ± 23.5</td>
<td>59.3 ± 21.2</td>
<td>68.7 ± 28.5</td>
<td>55.3 ± 23.3</td>
</tr>
<tr>
<td>40 kg/m²</td>
<td>44</td>
<td>48.4 ± 22.8</td>
<td>46.5 ± 22.6</td>
<td>61.77 ± 32.6</td>
<td>54.7 ± 26.0</td>
</tr>
<tr>
<td>ANCOVA**</td>
<td>-</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
<td>0.0109</td>
<td>0.9254</td>
</tr>
</tbody>
</table>

Scores vary from 0 to 100. A higher score indicates a better perceived HRQOL. ANCOVA was used for help in analyses.

* Nine missing patients for sex life dimension.
** Multivariate analysis adjusted for patient's age and gender.

Discussion

Development of new weight management strategies using or not obesity medications must be based upon clini-
Psychometric theory does not provide statistical rules to calculate the sample size needed for a development and validation study. In this case, it is important to note that, the structure of the IWQOL was already known and consequently analysis was not “fully” exploratory. Although the number of patients is low in study 1, the results on the structure of the questionnaire were validated in study 2 in an independent population. The decisions taken regarding sample size were based on the rule of 5/10 patients per (new) item. A higher number of subjects might better guarantee the validity of the five dimensions that we have identified.

Acceptability of the initial questionnaire was felt to be good, the number of non-returned questionnaires and the number of unanswered questions being small, no doubt because of the interest shown by patients in questioning of this sort [29]; hence no item was eliminated on the basis of the acceptability criterion. In contrast, fourteen items were withdrawn because they had a “floor” effect of more than 50%. Other items were taken out with the help of results obtained by exploratory factorial analyses. These enabled identification of five dimensions providing different information on the impact of obesity and its treatment on the HRQOL of obese people: physical impact, psychological impact, sex life, and comfort with food and diet experience. Items retained covered those areas of HRQOL affected by obesity and its treatments, which were felt to be essential. These dimensions being very different, it was decided not to summarise them by a global score, in contrast to what was done with the brief version of the IWQOL [13], which explores the following dimensions: physical impact, self esteem, sex life, public distress, work.

Particular attention was paid to the two dimensions concerning comfort with food and diet experience since we feel that they represent a major therapeutic challenge. Only items 1, 2, 3, 7 and 9 of the “comfort with food” dimension of Kolotkin et al. [11] were retained, such as to render this dimension more homogeneous and keep the notion of eating with pleasure. The dimension diet experience has been created to assess the constraints of treatment during its two phases i.e. to achieve weight loss and to maintain healthy weight. It would also seem interesting to be able to study this aspect of HRQOL in cases of weight regain or of weight cycling. The same applies to people with binge eating or eating disorders [30, 31] and in the presence of restraint eating [32, 33]. This could also offer a better approach to the problem of divergence between patient weight loss goal and the physician’s proposals. Patients could choose more sustainable and realistic goals, so as to be able to also improve their HRQOL regarding comfort with food and diet experience. It is finally possible that anti-obesity drugs may have different effects on HRQOL according to their mode of action. For example, central acting anti-obesity drugs might have a favourable effect on both these dimensions, but this still remains to be demonstrated. Our QOLOD questionnaire is hence original in this area, all the more since these dimensions were withdrawn from the new short version of Kolotkin’s IWQOL-lite [13]. The comfort with food scale was discarded when the questionnaire was reduced for use in clinical research in the United States [13, 14].

Methods used to verify the internal reliability [27, 34] and external reliability or reproducibility [26] of the final questionnaire obtained are those recommended in the literature. Results obtained, close to those of Kolotkin et al. [11, 12] with IWQOL were deemed satisfactory (Cronbach’s alpha coefficient between 0.68 and 0.95: ICC varying between 0.68 and 0.93).

As far as reproducibility is concerned, the interval of a week adopted between the two administrations was sufficiently long to allow patients to forget at the time of the second administration their answers at the first, and sufficiently short for patients to be considered stable, especially concerning their weight (+1 kg), and they had not experienced too many events capable of modifying their HRQOL (e.g. bereavement, job loss). Analysis results showed the good reproducibility of questionnaire scores, regardless of the dimension considered (Tab VI). However, a slight (between 1.8 and 5.6 points) but general improvement in quality of life was seen between the first and second administration. This could be due to a widely described phenomenon: the Hawthorne effect [35–37], defined as the tendency of a study cohort to modify its behaviour because of the interest shown in it.

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Intra-class correlation coefficients according to 3 stability criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stable weight (n = 69)</td>
</tr>
<tr>
<td>Physical impact</td>
<td>0.895</td>
</tr>
<tr>
<td>Psycho-social impact</td>
<td>0.903</td>
</tr>
<tr>
<td>Sex life</td>
<td>0.883</td>
</tr>
<tr>
<td>Comfort with food</td>
<td>0.788</td>
</tr>
<tr>
<td>Diet experience</td>
<td>0.813</td>
</tr>
</tbody>
</table>

Table VI
Reproducibility of answers to questionnaires specific to obesity after two administrations at an interval of one week: Intra-class correlation coefficients (ICC).
Concurrent validity of the questionnaire was also verified and found to be satisfactory, the physical and psychological dimensions of the questionnaire being respectively more correlated with the physical and psychological dimensions of the SF-12 questionnaire.

Clinical validity of the questionnaire was analysed by evaluating the effect of age, gender and BMI. Age did influence HRQOL scores: the oldest patients felt better in psychological terms than the youngest. In contrast, their physical scores were worse. In their study, Kolotkin et al. [11] attributed the better HRQOL perceived from a psychological standpoint by elderly patients to the fact that they are generally less concerned by their physical appearance than young people. We feel that in addition to less concern for their physical appearance, the elderly better accept obesity-related handicaps than young people. This is found in other diseases, e.g. intermittent claudication, where authors talk about patients becoming “accustomed” [41]. In contrast, age-related physical problems are worsened by obesity, which explains why physical or everyday activity dimensions, according to questionnaires, were more impaired in the elderly. The impact of pain on quality of life in the elderly has already been stressed in many other studies [42, 43]. Women were more affected by their obesity than men. A difference between scores obtained in men and women is very often described in HRQOL studies, regardless of the disease involved [38, 39]. This has already been reported in many publications on obese patients [4, 11] and it is usually explained by different susceptibility of women to obesity [40]. Effects of an increased BMI have been confirmed for the dimensions: physical, psychological, sex life and diet experience. The same findings have emerged from several previous studies [8-11]. It is nevertheless interesting to note that whatever the severity of obesity, comfort with food of patients did not change, as has already been reported by Kolotkin et al. [11]. Clinically, it seems clear that the vast majority of obese patients like to eat, regardless of their corpulence. It would be interesting to study the effects of psychological factors, such as depression.

The next stage will be to evaluate the sensitivity of the EQVOD/QOLOD questionnaire to the change in weight obtained during dietary or drug treatment, in order to validate its usefulness as an evaluation criterion or endpoint in clinical research. A special study of this aspect is currently under way.

In conclusion, the quality of life questionnaire developed in this study consists of 36 items grouped in 5 dimensions: physical impact, psycho-social impact, sex life, and comfort with food and diet experience. The concepts measured by these 5 dimensions are very different and some are specific to the EQVOD/QOLOD, notably regarding the dimension “diet experience”. The EQVOD/QOLOD is valid and reliable. It is intended for use in clinical trials in French-speaking countries. Its cultural adaptation to other European countries could also be envisaged.

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References


34. Fletcher RH, Fletcher SW, Wagner EH. Clinical Epidemiology, The essentials. Williams & Wilkins, Baltimore, Maryland, 1984, 127-52.


