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Variability and reliability of the French version of the Quality of Recovery-40

Questionnaire (QoR-40)

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Abstract:

Introduction: The quality of recovery- 40 (QoR-40) is a 40-item questionnaire. It is widely used and validated in English language for non-major surgery. Its objective is to collect information about quality of recovery in the postoperative period. However, a French version of the QoR-40 has not yet been established. The objective of this study was to develop a French version of QoR-40.

Patients and Methods: The translation procedure was established according to Beaton's recommendations to create a French version of QoR-40. 181 patients were enrolled, and each completed the questionnaire the day after surgery, and 6 hours later, and 15 days later. The QoR-40 was compared to morphine consumption in recovery room, and to visual analogue scale. The method of validation for QoR-40 included internal consistency, test-retest reliability, effect size and level of responsiveness.

Results: 99% of patients answered the full questionnaire at day one. Cronbach's alpha for the global QoR-40 at day one was 0.83. For the total QR40 total score, Lin's concordance coefficient was 0.78 (95%CI [0.70; 0.86]). The sensitivity to change was determined in 39 patients for an effect-size equals 0.56 (95%CI [0.11; 1.02]).

Conclusion: The French version of QoR-40 seems to be valid, reliable, and acceptable as the original English Version

Keywords: Quality of Recovery 40; French; Post-operative recovery; Questionnaire

Introduction

Quality of recovery after anaesthesia is an important measure of the early postoperative health status of patients. Focusing on a limited number of aspects of patient's recovery (i.e. pain and postoperative nausea and vomiting) leads to narrow vision and other sources of patient discomfort might not be considered. Of course, the overall quality of recovery after surgery and anaesthesia should be defined from the patient's perspective. Among all the scores proposed in the literature to measure a patient's global health status after surgery, the 40-item quality-of-recovery scale (the QoR-40) is the most used and validated (1). The QoR-40 is a simple, valid, reliable, and responsive instrument (2). It is a 40 items questionnaire providing a global score across five dimensions: patient support, comfort, emotions, physical independence, and pain. Each item is rated on a 5-point Likert scale, giving a global QoR-40 score ranging from 40 to 200, representing, respectively, very poor to excellent quality of recovery.

QoR-40 has already been translated in several languages including Thai, Arabic, Iranian, Korean (3-6). So far, the French version of QoR-40 has not been validated. Therefore, the aim of the study was to develop a French version of QoR-40 questionnaire by translation and cultural adaptation and to assess the validity and the reliability of the French questionnaire

Patients and methods

1- Translation procedure

The translation procedure was performed based on the Beaton's and Bullinge's recommendations to create a French version of the QoR-40 comparable to the original English version (7). In the first step, and after obtaining the authorization of Pr Myles, two French native bilingual translators (CM and EF) independently translated the QoR-40 into French. Afterwards, a third French native bilingual translator (MV, the initial project manager)

compared the two translations and checked for inconsistency and adapted the vocabulary. Any discrepancies and differences were resolved by discussion, and finally a consensus version was reached. The next step was a backward translation, the French version was translated into the original English language. The translator was a native English speaker (MH). The authors verified good concordance of English and French versions and checked for grammatical mistakes.

2-Ethics

The validity and the reliability of the French questionnaire was then assessed in a multicentre prospective observational study in 2 tertiary teaching hospitals in France (Clermont-Ferrand and Rennes). The study was approved by the ethics committee of the French Society of Anaesthesia Intensive Care and Perioperative Medicine (SFAR) (Comité D'Ethique en Anesthésie Réanimation- CERAR- ref IRB 0010254-2018-025).

3-Protocol

Adult patients 18 years of age scheduled for elective general surgery under general anaesthesia were included. The non-inclusion criteria were inability to speak or write French, day-case surgery, inability to understand the questionnaire, patients scheduled for major surgery (cardiac, aortic, hepatic, pancreatic, gastric, intracranial), ASA score of 4.

The study aims were explained to eligible patients the day before surgery, before signing an informed consent. Patients orally answered to the questionnaire when asked by an investigator (A.H in Rennes and C.M in Clermont-Ferrand) 3 times: day one after surgery twice and 6 hours apart to evaluate the test/retest phase and a third time by phone 15 days after surgery to evaluate sensitivity to change.

4-Data collection

At each participating centre, the following data were collected by two investigators

(AH and CM): Age, gender, ASA score, type and duration of surgery, perioperative opioid

treatment and morphine consumption at day one were retrieved. The QoR-40 data were also collected:

- Part A includes comfort state (4 items), emotional state (3 items), physical independence (5 items) and patient support (6 items) and makes a total of 90 points.
- Part B includes comfort state (8 items), emotional state (6 items), patient support (1 item), and pain (7 items) and makes a total of 110 points. All items are rated on a five-points Likert scale from one (worst) to five (best). The total score was computed by summing all items. The minimum and maximum possible score were 40 and 200, respectively.

5- Statistical analysis

According to Terwee et al. a minimum of 160 patients were needed to conduct to evaluate the internal consistency: "The number of subjects included in a factor analysis is a matter of debate. Rules-of-thumb vary from four to 10 subjects per variable, with a minimum number of 100 subjects to ensure stability of the variance-covariance matrix". A minimum of 50 to 60 patients were needed to conduct the test/retest phase (evaluation of reliability), and a minimum of 30 to 50 were necessary to conduct the sensitivity to change analysis (8).

According to these considerations and to recruitment, it was proposed inclusion during 6 months.

The statistical analyses used in this study were those usually used in studies to validate scales (8). In addition to descriptive statistics, the following psychometric properties of the QoR-40 scale were explored using Stata Software (StataCorp, College Station, US).

(i) *Acceptability*: Data quality was considered satisfactory if more than 95% of the scale data were fully computable. Score range, closeness of mean to median, floor and ceiling effects, and skewness of score distributions were also analysed.

(ii) *Internal consistency* was determined through Cronbach's alpha coefficient (minimum accepted value: 0.70); the item homogeneity coefficient (criterion value: ≥ 0.30); and the item-total correlation corrected for overlap (criterion value: ≥ 0.30).

(iii) *Reproducibility*: The Lin's concordance coefficient was used to determine the test-retest reliability of the QUIP-RS scale. Values ≥ 0.70 were deemed satisfactory (9).

(iv) *Hypotheses testing*: Regarding convergent validity, relationships between QoR-40 scale score, other quantitative measures of psychological disorders and PD-related measures were studied using correlation coefficient (Pearson or Spearman, according to statistical distribution) (10).

(v) *The external validity* in comparison to QoR-40 scale was explored using correlation coefficients when items of QoR-40 scale were considered as quantitative outcomes, and usual statistical tests (ANOVA or Kruskal-Wallis tests) when items of QoR-40 scale were considered as categorical outcomes.

Results

Between May and October 2018, 181 patients were included in this study. Subject characteristics are presented Table 1.

Data on the internal consistency of the QoR-40 scale are displayed on Table 2. Cronbach's alpha coefficient was 0.83 [0,79; 0,87].

Detailed results for QoR-40 questionnaire at day one are shown in Table 3. Time to complete the questionnaire was 5 +/- 1 minutes.

The results for the data quality and acceptability of the QoR-40 scale are displayed in Figure 1. Fully computable data were obtained for 99% of the sample. The total score of QoR-40 was 166 ± 16 , with a minimum value at 68 (1/181, 0.6%) and a maximum at 197 (1/181, 0.6%) for a possible range between 40 and 200 points.

The item-rest correlation are ranged from 0.09 and 0.55 (appearance and well-being respectively) and are presented in table 2. Inter-items correlations are represented graphically with a color-coded heatmap in figure 2.

Test-retest reliability was determined in 96 patients. For the total QoR-40 total score, Lin's concordance coefficient was 0.78 (95%CI [0.70; 0.86]). The concordance coefficient for items was higher than 0.4, except for "shaking or twitching" and "feeling confused" (respectively 0.4 and 0.39), both in Part B. These results are presented Figure 3

The correlation between QoR-40 and morphine consumption at day one was weak to moderate ($r=-0.11$, $p=0.14$), contrary to QoR-40 and visual analogue scale ($r=-0.30$, $p<0.0001$). The sensitivity to change was determined in 39 patients. The total score at J0 was 165.8 ± 14.8 and 173.9 ± 13.8 at J15 ($p=0.001$), for an effect-size equals 0.56 (95%CI [0.11; 1.02]). The sensitivity to change for each dimension is presented figure 4.

Table 1: Subject characteristics

Number of subjects	181
Sex, Women	114 (63%)
Age, Year	55.7 ± 16.6
ASA score	
1	63 (35%)
2	80 (44%)
3	38 (21%)
Type of surgery	
Maxillo-facial surgery	12 (7%)
Minor orthopaedic surgery	5 (3%)
Major orthopaedic surgery	56 (31%)
Spine surgery	20 (11%)
Proctologic surgery	4 (2%)
Colorectal surgery	28 (15 %)
Wound abdominal surgery	7 (4%)
Bariatric surgery	5 (3%)
Biliary surgery	5 (3%)
Urologic surgery	6 (3%)
Plastic surgery	7 (4%)
Peripheral vascular surgery	4 (2%)
Gynaecologic surgery	22 (12%)
Duration of surgery, min	90 [60; 130]
Intraoperative opioids	
Sufentanyl,	141 (78%)
Remifentanyl	36 (18%)
Opioid free anaesthesia	4 (2%)

Table 2: Internal consistency criteria

	Item-rest correlation	N	Item-test correlation	Average Inter item correlation	Alpha
Breathe easily	0,1286	181	0,1961	0,1133	0,8329
Good sleep	0,3372	181	0,3976	0,1094	0,8273
Enjoy food	0,2334	180	0,2982	0,1113	0,8301
Feel rested	0,5056	181	0,556	0,1062	0,8226
Well-being	0,546	181	0,5936	0,1055	0,8214
In Control	0,4783	181	0,5306	0,1067	0,8233
Comfortable	0,5076	181	0,558	0,1062	0,8225
Normal speech	0,32	181	0,3811	0,1097	0,8277
Brush teeth	0,2893	180	0,3522	0,1102	0,8285
Appearance	0,0891	181	0,1573	0,1141	0,8339
Able to write	0,1992	181	0,265	0,112	0,831
Return to work	0,3501	179	0,4098	0,1091	0,8268
Communicate with staff	0,3625	181	0,4216	0,1089	0,8265
Communicate with family	0,2867	181	0,3493	0,1103	0,8286
Support from doctors	0,3377	181	0,3981	0,1093	0,8272
Support from nurses	0,3746	181	0,4331	0,1086	0,8262
Support from friends	0,2267	181	0,2915	0,1114	0,8302
Able to understand instructions	0,2135	180	0,279	0,1117	0,8306
Nausea	0,4629	180	0,5162	0,107	0,8238
Vomiting	0,3389	180	0,3991	0,1094	0,8272
Dry- retching	0,4182	180	0,4742	0,1079	0,825
Feeling restless	0,1343	180	0,2017	0,1132	0,8327
Shaking	0,1928	180	0,2593	0,1121	0,8312
Shivering	0,1347	179	0,2031	0,1132	0,8327
Cold	0,2423	181	0,3073	0,1112	0,8299
Dizzy	0,3896	181	0,4477	0,1084	0,8258
Bad Dreams	0,1858	181	0,2522	0,1123	0,8314
Anxious	0,3824	181	0,4409	0,1085	0,826
Angry	0,2797	181	0,343	0,1105	0,8289
Depressed	0,4664	181	0,5194	0,107	0,8237
Alone	0,3239	181	0,3852	0,1096	0,8277
Difficulty falling asleep	0,3383	180	0,3985	0,1093	0,8272
Confused	0,1921	179	0,258	0,1121	0,8312
Moderate pain	0,1601	180	0,2269	0,1127	0,8321
Severe pain	0,3197	179	0,3806	0,1097	0,8277
Headache	0,2468	180	0,3108	0,1111	0,8297
Muscle pain	0,2376	179	0,3018	0,1112	0,83
Back Ache	0,2458	179	0,3097	0,1111	0,8298
Sore Throat	0,275	180	0,338	0,1105	0,8289
Sore Mouth	0,3365	180	0,3968	0,1094	0,8273

Table 3: QoR-40 at Day one

Variable	P25	Median	P75
Part A/90 point (n=181)	70	75	81
Comfort Part A/20 point (n= 181)	13	15	17
Emotions Part A/ 15 points (n=181)	10	12	14
Physical Independence/ 25 points (n=181)	17	21	22
Patient Support Part A/ 30 points (n=181)	27	30	30
Part B/ 110 points (n= 181)	88	94	98
Confort Part B /40 points (n=181)	34	36	37
Emotions Part B/ 30 points (n= 181)	24	26	28
Patient Support Part B /5 points (n=179)	4	5	5
Pain /35 points (n=181)	25	28	31

Figure 1a

Red Curve: Floor effect of each item of part A of QoR-40 questionnaire (percentage of patients responding most favourably to the item)

Black cure: Ceiling effect of each item of part A of QoR-40 questionnaire (percentage of patients responding most negatively to the item)

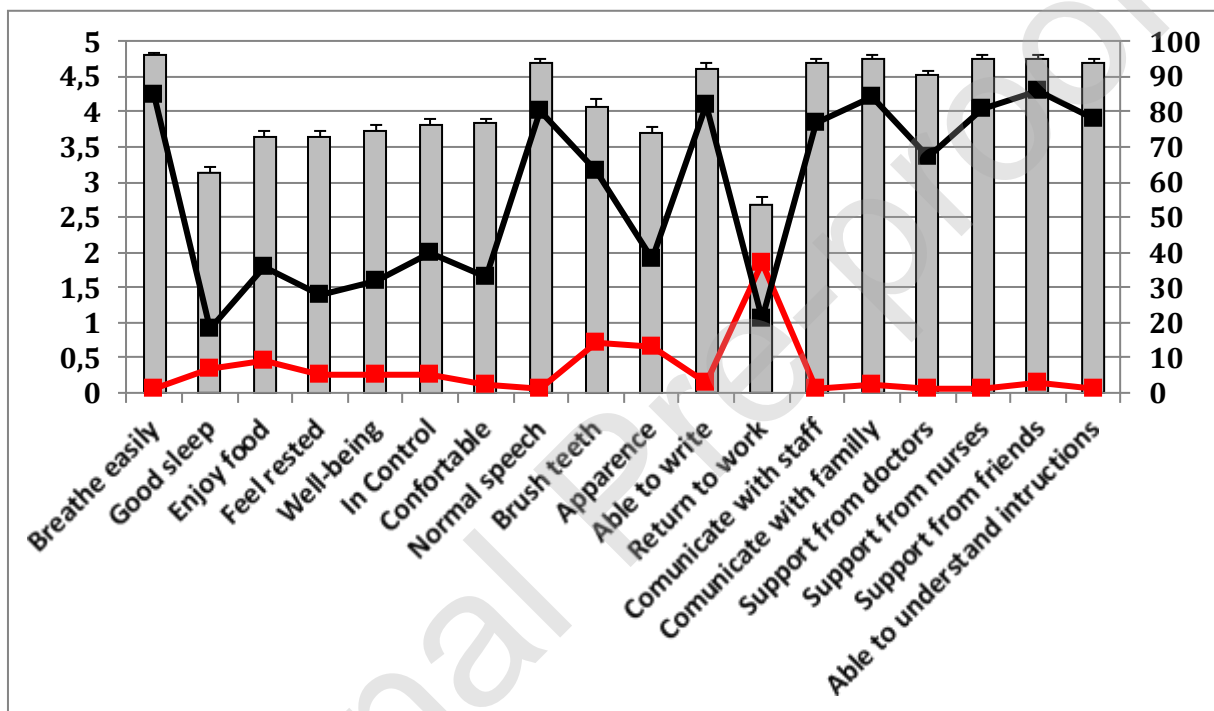
Histogram: Mean response of the item (on a five-point Likert scale- from 0 "none of the time" to 5 "all the time")

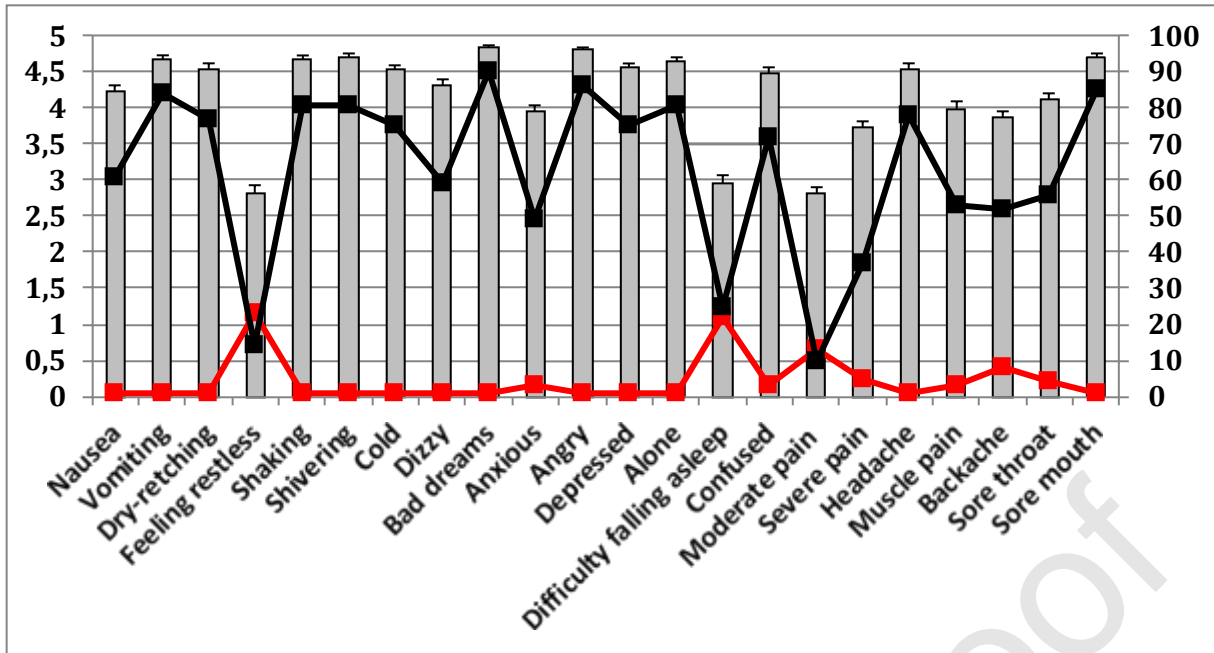
Figure 1b

Red Curve: Floor effect of each item of part B of QoR-40 questionnaire (percentage of patients responding most favourably to the item)

Black cure: Ceiling effect of each item of part B of QoR-40 questionnaire (percentage of patients responding most negatively to the item)

Histogram: Mean response of the item (on a five-point Likert scale- from 0 "none of the time" to 5 "all the time")





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Figure 2 : Collor-coded heatmap describing QoR-40 inter- items correlations

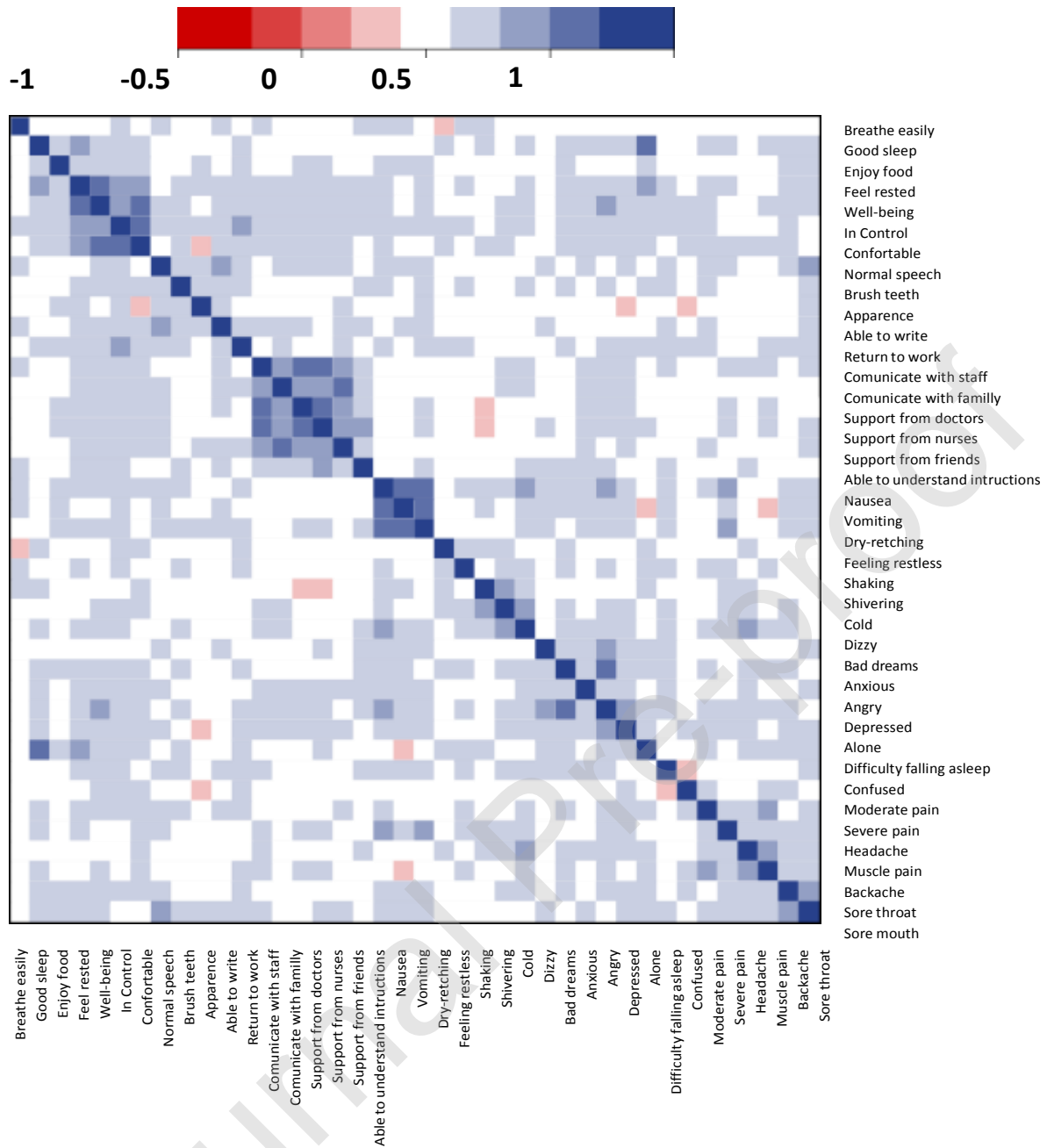


Figure 3a and 3b. Lin's concordance coefficient for QoR-40 re-test items.

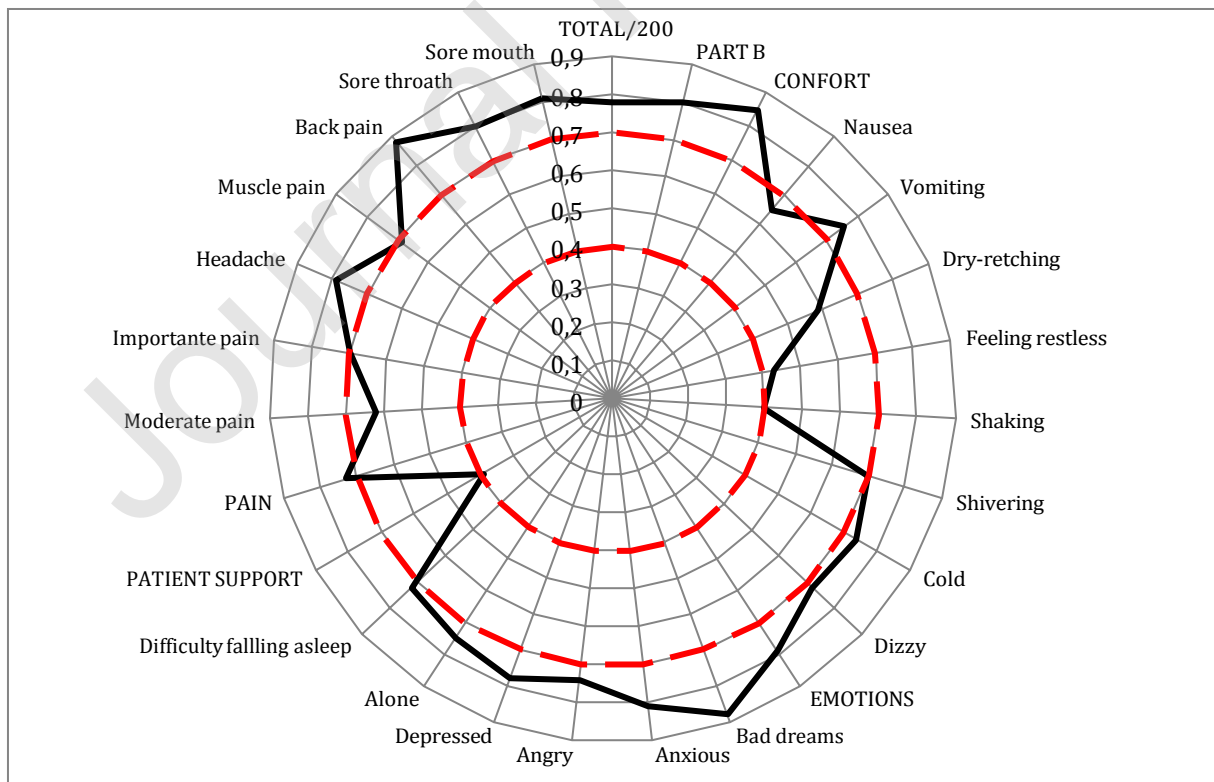
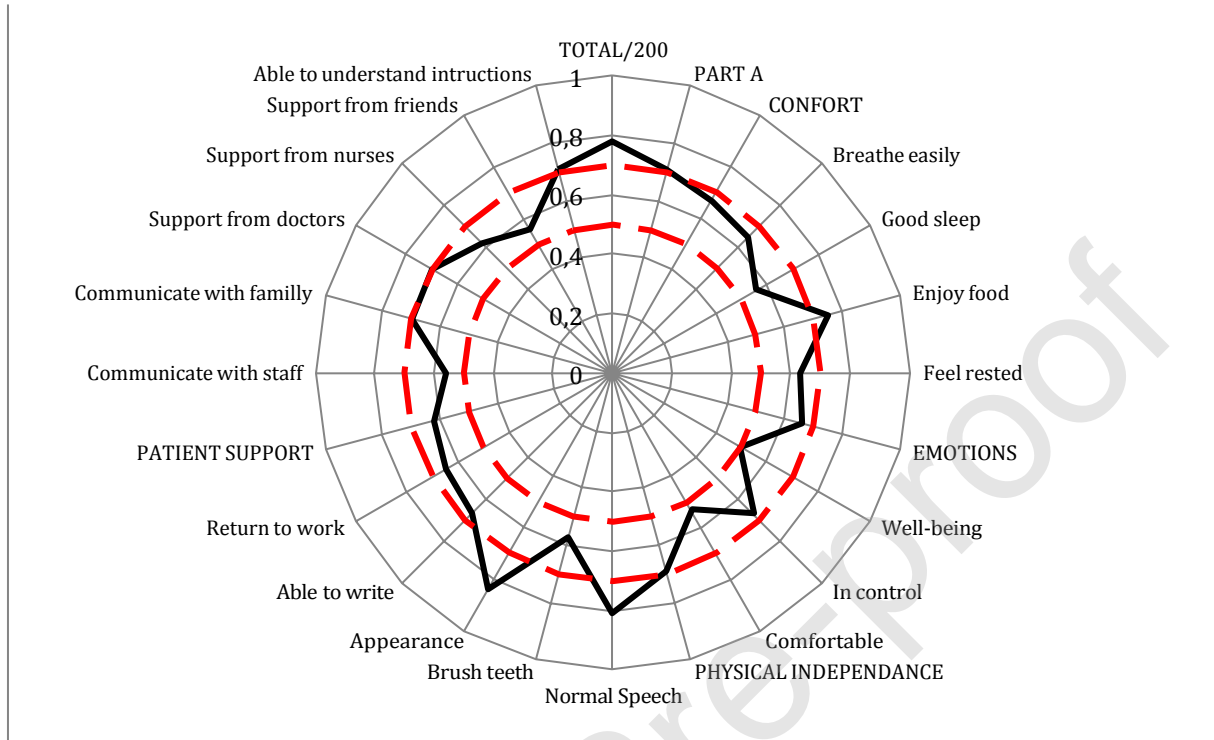
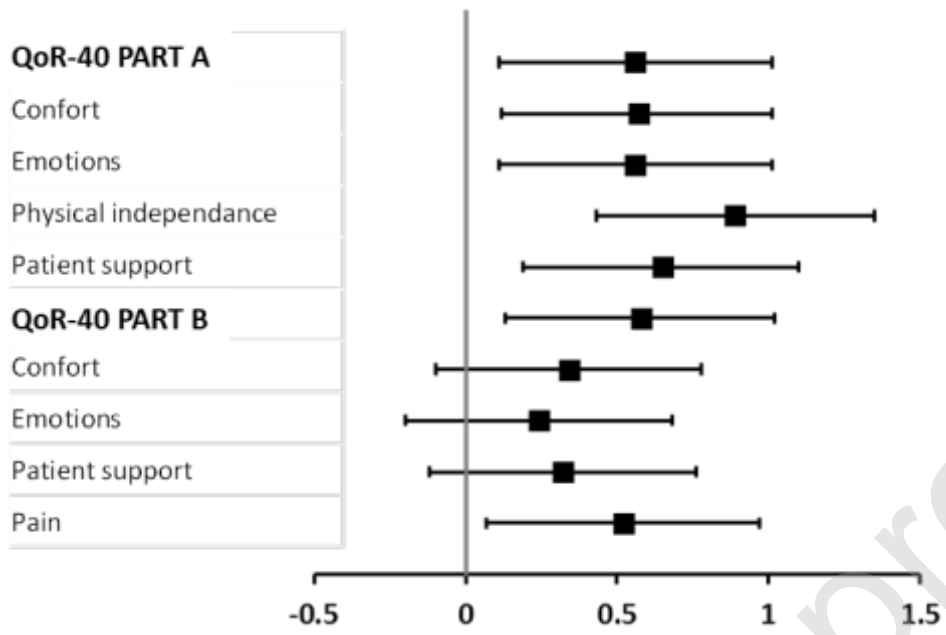


Figure 4: Effect size of each dimension of QoR-40.

Discussion

Our study demonstrated a good validity and reliability of our French Version of the Quality of Recovery-40 Questionnaire with a Cronbach's alpha of 0.83 [0,79; 0,87]. QoR-40 could be used for French patients after general anaesthesia.

Few tools are available in current practice to evaluate global recovery after general anaesthesia. As example, SF-36 was validated for cardiac surgery (11), SF-8 for ambulatory knee surgery (12) and SF- MPQ-2 for non-specific acute pain (13). To date, the QoR-40 is the only validated score providing information about comfort, emotion, and pain after surgery. The acceptability of the French version of the QoR-40 was excellent (179 over 181 patients answered every 40 items of the questionnaires, and there were few missing datas for the two other patients). A ceiling effect was observed because a proportion of patients did not experience the highest score on some items ("return to work", "feeling restless" and "falling asleep"), which is coherent with clinical events one day after surgery. Internal consistency parameters met the standard criteria; variables of the QoR-40 were positively correlated even if the strength of relationship was low to moderate.

Regarding Test/retest and construct validity, Lin's concordance coefficient test was 0.78 for total QoR-40 questionnaire, suggesting a substantial concordance. All coefficients were above 0.4, except two items, "shaking or twitching" and "feeling confused" (respectively 0.4 and 0.39). The explication could be a translation mistake, or for the second item, a real confusion. It may be a bias of the study.

Reproductibility was excellent for the item "physical independence" of part A, moderate for global part A and B, "comfort part A", "emotions part A", "patient support part A" and "pain part B"; and weak for "comfort part B", "emotions part B" and "patient support part B".

In our study, we choosed to evaluate sensitivity to change 15 days after surgery because we hypothesised that most of the postoperative perturbations should have return to normal at

this time. Effect size showed a moderated sensitivity to change for both Part A et B of the questionnaire. Surprisingly, this indicator was never evaluated in the other validation QoR-40 papers.

Correlation between QoR-40 and morphine consumption at day one were weak to moderate, while Myles *and al.* reported a good convergent validity (2). Several explanations can be evocated: there was several differences between the populations of our studies: our population was older, and repartition of surgeries were different -more general surgery in Myles's study and more orthopaedic and ENT surgery in our study- then we can evocate cultural differences in pain evaluation between Anglo Saxon and French populations. This enhances the fact that QoR-40 is a use full toll to evaluate the quality of recovery, which is not reduced to the evaluation of pain in the recovery room.

Moreover, French validation of QoR-40 could be useful in program of enhanced rehabilitation after surgery.

Time to complete the questionnaire was about five minutes, which seems relevant in the context. Same durations were found in the literature (6, 14). Equivalent durations were found in a summary version of QoR-40, the QoR-15 (with 15 items questionnaire), supporting using QoR-40 in routine clinical practice (15, 16).

Our study has several limitations. First, our population is predominantly female, and composed for 45% of orthopedic and spine surgery. Then, we did not report marital and education status of our population, which could have been relevant in the context. Finally, contrary to other papers, we did not evaluate correlation between QoR-40 and an other questionnaire of quality of life, like Short-Form-36 (SF-36) (6, 14).

Conclusion

We propose that the French version of QoR-40 is a valid, reliable, and acceptable to evaluate quality of recovery for French speaking patients after general anaesthesia. It could be a very relevant criterion for studies to come up.

Conflict of interest: none

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