2020-2021

THÈSE

pour le

DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE

Qualification en ANESTHESIE RÉANIMATION

Traduction et validation du questionnaire QoR-15 en français et revue de la littérature sur l'utilisation des échelles de récupération dans la littérature anesthésique

Translation and validation of QoR-15 score in French and systematic review of the use of quality of recovery scales in anaesthesia literature

CAMPFORT MAËVA

Née le 05 FÉVRIER 1993 à CHOLET (49)

Sous la direction de M. LÉGER Maxime

Membres du jury

Monsieur le Professeur LASOCKI Sigismond	Président
Monsieur le Docteur LÉGER Maxime	Directeur
Monsieur le Docteur RINEAU Emmanuel	Membre
Monsieur le Docteur VENARA Aurélien	Membre

Soutenue publiquement le :

17 septembre 2021

FACULTÉ DE SANTÉ

UNIVERSITÉ D'ANGERS

ENGAGEMENT DE NON PLAGIAT

Je, soussignée CAMPFORT Maëva
déclare être pleinement consciente que le plagiat de documents ou d'une partie d'un document publiée sur toutes formes de support, y compris l'internet, constitue une violation des droits d'auteur ainsi qu'une fraude caractérisée.
En conséquence, je m'engage à citer toutes les sources que j'ai utilisées pour écrire ce rapport ou mémoire.

signé par l'étudiant(e) le **20** / **01** / **2021**

LISTE DES ENSEIGNANTS DE LA FACULTÉ DE SANTÉ D'ANGERS

Doyen de la Faculté : Pr Nicolas Lerolle
Vice-Doyen de la Faculté et directeur du département de pharmacie : Pr Frédéric Lagarce
Directeur du département de médecine : Pr Cédric Annweiler

PROFESSEURS DES UNIVERSITÉS

ABRAHAM	Pierre	Physiologie	Département de physiologie et explorations fonctionnelles
ANNWEILER	Cédric	Gériatrie et biologie du vieillissement	Service de gériatrie
ASFAR	Pierre	Médecine intensive - réanimation	Département de Réanimation médicale et de médecine hyperbare
AUBE	Christophe	Radiologie et imagerie médicale	Département de Radiologie
AUGUSTO	Jean-François	Néphrologie	Département de néphrologie-dialyse-transplantation
AZZOUZI	Abdel Rahmène	Urologie	Service d'Urologie
BELLANGER	William	Médecine générale	Département de Médecine Générale
BAUFRETON	Christophe	Chirurgie thoracique et cardiovasculaire	Service de Chirurgie cardiaque
BIGOT	Pierre	Urologie	Service d'Urologie
BONNEAU	Dominique	Génétique	Département de biochimie et génétique
BOURSIER	Jérôme	Gastroentérologie ; hépatologie	Service d'hépatologie-gastroentérologie et oncologie digestive
BOUCHARA	Jean-Philippe	Parasitologie et mycologie	Département de biologie des agents infectieux et pharmaco-toxicologie
BOUVARD	Béatrice	Rhumatologie	Département de rhumatologie
BRIET	Marie	Pharmacologie	Département de biologie des agents infectieux et pharmaco-toxicologie
CALES	Paul	Gastro-entérologie ; hépatologie	Service d'hépatologie-gastroentérologie et oncologie digestive
CAMPONE	Mario	Cancérologie ; radiothérapie	Institut de Cancérologie de l'Ouest Paul Papin
CAROLI-BOSC	François-Xavier	Gastro-entérologie ; hépatologie	Service d'hépatologie-gastroentérologie et oncologie digestive
CHAPPARD	Daniel	Cytologie et histologie	Laboratoire GEROM - IBS
CONNAN	Laurent	Médecine générale	Département de Médecine Générale
COPIN	Marie-Christine	Anatomie et cytologie pathologiques	Département de pathologie cellulaire et tissulaire
COUTANT	Régis	Pédiatrie	Pôle Femme-mère-enfant - fédération de pédiatrie
CUSTAUD	Marc-Antoine	Physiologie	Département de physiologie et explorations fonctionnelles
DE CASABIANCA	Catherine	Médecine générale	Département de Médecine Générale
DESCAMPS	Philippe	Gynécologie-obstétrique	Fédération de Gynécologie obstétrique
D'ESCATHA	Alexis	Médecine et santé au travail	Centre antipoison et de toxicovigilance
DINOMAIS	Mickaël	Médecine physique et de réadaptation	CRRRF les Capucins
DIQUET	Bertrand	Pharmacologie	Département de biologie des agents infectieux et pharmaco-toxicologie
DUBEE	Vincent	Maladies infectieuses	Service des maladies infectieuses et Tropicales et médecine interne
DUCANCELLE	Alexandra	Bactériologie-virologie	Département de biologie des agents infectieux et pharmaco-toxicologie
DUVERGER	Philippe	Pédopsychiatrie	Unité de pédopsychiatrie
FOURNIER	Henri-Dominique	Anatomie	Département de Neurochirurgie
FURBER	Alain	Cardiologie	Service de Cardiologie
GAGNADOUX	Frédéric	Pneumologie	Service de Pneumologie

GARNIER	François	Médecine générale	Département de Médecine Générale
GASCOIN	Géraldine	Pédiatrie	Pôle Femme-mère-enfant - fédération de pédiatrie
GOHIER	Bénédicte	Psychiatrie d'adultes	Département de Psychiatrie d'adultes
GUARDIOLA	Philippe	Hématologie ; transfusion	Service des Maladies du Sang
HAMY	Antoine	Chirurgie générale	Service de Chirurgie Viscérale
HENNI	Samir	Chirurgie vasculaire ; médecine vasculaire	Service de médecine vasculaire
HUNAULT-BERGER	Mathilde	Hématologie ; transfusion	Service des Maladies du Sang
IFRAH	Norbert	Hématologie ; transfusion	Service des Maladies du Sang
JEANNIN	Pascale	Immunologie	Laboratoire d'immunologie et allergologie
KEMPF	Marie	Bactériologie-virologie	Département de biologie des agents infectieux
LACCOURREYE	Laurent	Oto-rhino-laryngologie	Service d'ORL et chirurgie cervico-faciale
LASOCKI	Sigismond	Anesthésiologie-réanimation et médecine péri-opératoire	Pôle d'Anesthésie-réanimation
LEGENDRE	Guillaume	Gynécologie-obstétrique	Pôle Femme-Mère-Enfant - fédération de gynécologie-obstétrique
LEGRAND	Erick	Rhumatologie	Département de Rhumatologie
LERMITE	Emilie	Chirurgie générale	Service de Chirurgie Viscérale
LEROLLE	Nicolas	Médecine intensive - réanimation	Département de Réanimation médicale et de médecine hyperbare
LUNEL-FABIANI	Françoise	Bactériologie-virologie	Département de biologie des agents infectieux et pharmaco-toxicologie
MARTIN	Ludovic	Dermato-vénéréologie	Service de Dermatologie
MAY-PANLOUP	Pascale	Biologie et médecine du développement et de la reproduction	Pôle Biologie
MENEI	Philippe	Neurochirurgie	Département de Neurochirurgie
MERCAT	Alain	Médecine intensive - réanimation	Département de Réanimation médicale et de médecine hyperbare
PELLIER	Isabelle	Pédiatrie	Pôle Femme-Mère-Enfant - Fédération de pédiatrie
PETIT	Audrey	Médecine et santé au travail	Service de santé au travail et pathologies professionnelles
PICQUET	Jean	Chirurgie vasculaire ; médecine vasculaire	Service de Chirurgie vasculaire et thoracique
PODEVIN	Guillaume	Chirurgie infantile	Fédération de pédiatrie - Chirurgie pédiatrique
PROCACCIO	Vincent	Génétique	Département de biochimie et génétique
PRUNIER	Delphine	Biochimie et biologie moléculaire	Département de biochimie et génétique
PRUNIER	Fabrice	Cardiologie	Service de Cardiologie
REYNIER	Pascal	Biochimie et biologie moléculaire	Département de biochimie et génétique
RICHARD	Isabelle	Médecine physique et de réadaptation	CRRRF les Capucins
RODIEN	Patrice	Endocrinologie, diabète et maladies métaboliques	Département d'Endocrinologie, Diabète, Nutrition
ROQUELAURE	Yves	Médecine et santé au travail	Service santé au travail et pathologies professionnelles
ROUGE-MAILLART	Clotilde	Médecine légale et droit de la santé	Service de Médecine légale
ROUSSEAU	Audrey	Anatomie et cytologie pathologiques	Département de pathologie cellulaire et tissulaire
ROUSSEAU	Pascal	Chirurgie plastique, reconstructrice et esthétique	Service de Chirurgie Plastique
ROUSSELET	Marie-Christine	Anatomie et cytologie pathologiques	Département de pathologie cellulaire et tissulaire
ROY	Pierre-Marie	Médecine d'Urgence	Service des urgences
SAVARY	Dominique	Médecine d'Urgence	Service des urgences
SCHMIDT	Aline	Hématologie ; transfusion	Service des Maladies du Sang
TRZEPIZUR	Wojciech	Pneumologie	Département de Pneumologie

UGO	Valérie	Hématologie ; transfusion	Laboratoire d'hématologie
URBAN	Thierry	Pneumologie	Département de Pneumologie
VAN BOGAERT	Patrick	Pédiatrie	Pôle Femme-mère-enfant - fédération de pédiatrie
VERNY	Christophe	Neurologie	Département de Neurologie - Charcot
WILLOTEAUX	Serge	Radiologie et imagerie médicale	Département de Radiologie

Liste des MCU et MCU-PH - Année universitaire 2020-2021

ANGOULVANT	Cécile	Médecine générale	Département de Médecine Générale
BEAUVILLAIN	Céline	Immunologie	Laboratoire d'immunologie
BEGUE	Cyril	Médecine générale	Département de Médecine Générale
BELIZNA	Cristina	Médecine interne	Centre Vasculaire et de la Coagulation
BELONCLE	François	Réanimation	Département de réanimation médicale et médecine hyperbare
BIERE	Loïc	Cardiologie	Service de cardiologie
BLANCHET	Odile	Hématologie ; transfusion	Laboratoire d'hématologie
BRIET	Claire	Endocrinologie, diabète et maladies métaboliques	Service Endocrinologie-Diabète-Nutrition
CAPITAIN	Olivier	Cancérologie ; radiothérapie	Institut de Cancérologie de l'Ouest Paul Papin
CASSEREAU	Julien	Neurologie	Département de neurologie
CHAO DE LA BARCA	Juan-Manuel	Biochimie et biologie moléculaire	Département de biochimie et Génétique
CHEVALIER	Sylvie	Biologie cellulaire	Département de pathologie cellulaire et tissulaire
COLIN	Estelle	Génétique	Département de Biochimie et Génétique
FERRE	Marc	Biologie moléculaire	Département de Biochimie et Génétique
FORTRAT	Jacques-Olivier	Physiologie	Laboratoire d'explorations fonctionnelles vasculaires
HAMEL	Jean-François	Biostatistiques ; informatique méd.	Service de biostatistiques et modélisation
HINDRE	François	Biophysique	Service de Médecine Nucléaire et Biophysique
KHIATI	Salim	Biochimie et biologie moléculaire	Département de biochimie et Génétique
JOUSSET-THULLIER	Nathalie	Médecine légale et droit de la santé	Service de Médecine légale
JUDALET-ILLAND	Ghislaine	Médecine générale	Département de Médecine Générale
KUN-DARBOIS	Daniel	Chirurgie maxillo-faciale et stomatologie	Service de stomatologie et chirurgie. maxillo-faciale
LEBDAI	Souhil	Urologie	Service d'Urologie
LEMEE	Jean-Michel	Neurochirurgie	Département de neurochirurgie
TEXIER-LEGENDRE	Gaëlle	Médecine générale	Département de Médecine Générale
LETOURNEL	Franck	Biologie cellulaire	Département de pathologie cellulaire et tissulaire - Neurobiologie - Neuropathologie
LIBOUBAN	Hélène	Histologie	Laboratoire GEROM
LUQUE PAZ	Damien	Hématologie ; transfusion	Département d'hématologie
MABILLEAU	Guillaume	Histologie	SCIAM
MESLIER	Nicole	Physiologie	Département de Pneumologie
MIOT	Charline	Immunologie	Laboratoire d'immunologie
MOUILLIE	Jean-Marc	Philosophie	Département de Sciences Humaines
PAILHORIES	Hélène	Bactériologie-virologie	Département de Biologie des Agents Infectieux et Pharmaco-toxicologie
PAPON	Xavier	Anatomie	Service de Chirurgie vasculaire et thoracique
PASCO-PAPON	Anne	Radiologie et imagerie médicale	Département de Radiologie
PENCHAUD	Anne-Laurence	Sociologie	Département de Sciences Humaines

PIHET	Marc	Parasitologie et mycologie	Département de Biologie des Agents Infectieux et Pharmaco-toxicologie
PY	Thibaud	Médecine générale	Département de Médecine Générale
POIROUX	Laurent	Sciences infirmières	Bâtiment GIRCI
RAMOND-ROQUIN	Aline	Médecine générale	Département de Médecine Générale
RINEAU	Emmanuel	Anesthésiologie-réanimation	Département d'Anesthésie-Réanimation
SCHMITT	Françoise	Chirurgie infantile	Pôle femme-mère-enfant - fédération de pédiatrie
TESSIER-CAZENEUVE	Christine	Médecine générale	Département de Médecine Générale
VENARA	Aurélien	Chirurgie digestive	Service de Chirurgie viscérale

REMERCIEMENTS

A Monsieur le Professeur LASOCKI Sigismond,
Merci de m'avoir fait l'honneur de présider ce jury de thèse, merci pour tous vos conseils avisés et pour votre disponibilité pour les différentes relectures de protocoles et de manuscrits. Merci pour votre accompagnement tout au long de l'internat, c'est un honneur de pouvoir continuer ma formation à vos côtés.

A Monsieur le Docteur LÉGER Maxime,
Merci d'avoir cru en moi il y a 4 ans pour mener ce projet jusqu'au bout, merci pour ta disponibilité, tes précieux conseils et ton aide sans faille jusqu'à la fin. Ca a été un plaisir de travailler avec toi.

A Monsieur le Docteur RINEAU Emmanuel,
Merci d'avoir accepté d'être membre de ce jury. Merci pour ton aide et tes conseils pour ce travail. Merci d'avoir contribué à ma formation d'anesthésiste-réanimateur.

A Monsieur le Docteur VENARA Aurélien,
Merci d'avoir accepté de juger ce travail.

A mes co-internes,
A Victor, Jonathan, Aurélien, Juliette et Lorine avec qui tout a commencé,
A Cléor, pour les matchs de squash et les session « bloc » pour se détendre après les interminables appels FQoR-15,
A Pierre, Anna, Charlotte, Chloé et Manu pour tous ces moments partagés, entres autres, à la Croix-Montoire.

A tous les anesthésistes-réanimateurs et les équipes rencontrées durant mon internat,
Merci pour votre bienveillance, vos enseignements et vos encouragements, merci pour tout ce que j'ai pu apprendre à vos côtés.

A Morgane, Mathilde et Charline,
Mes copines depuis toujours, nos fous-rires, nos délires, nos petites histoires sont un réel bonheur à chaque fois, j'aimerais tellement qu'on passe plus de temps ensemble.

Au G8,
A Romain, pour tous ces moments partagés depuis l'externat (le « bon » temps où on pliait des enveloppes), les soirées, les descentes et les remontées de pistes plus ou moins enneigées, les plantés de bâtons réussis ... ou pas,
A Perrine, pour ces tournées des caves mémorables, pour ce défi sportif aux Sables, pour les découvertes culinaires à bases de graines et de pois chiches,
A Mathieu et Lucie, pour les (nombreux) déménagements, les barbecues bien garnis, les bonnes glaces (et oui, dans une coupe, ca change tout), plein de bonheur pour la nouvelle vie qui vous attend : les cris et les pleurs ne seront plus seulement dus au Uno …
A Alexis pour cette initiation au ski sur bitume,
A Thibaut, pour cette formidable partie d'apéro-mimes,
J'espère que l'on aura encore plein de bons moments ensemble et qu'un jour on la trouvera cette fameuse piste « Lièvre ».

A mes grands-parents,
A Papy Pierre et Mamie Gigi,
A Papy Eugène et Mamie Madeleine,
De près ou de loin, j'ai toujours une pensée pour vous.

A mes parents,
Merci de me soutenir depuis le tout début, depuis l'époque où je rentrais pour laver mon linge et manger du riz au lait maison, jusqu'à aujourd'hui où je suis plutôt autonome pour le linge mais jamais contre un petit riz au lait fait par maman.
Merci d'être toujours là et d'avoir grandement contribué à faire de moi la personne que je suis aujourd'hui.

REMERCIEMENTS

A Gailord et Valentine,
Mon frère et ma sœur adorés, je suis fière de vous, des adultes que vous êtes en train de devenir. Je vous souhaite tout le bonheur possible pour l'avenir.

A Clément,
Merci d'être là chaque jour, merci pour ton soutien, pour ton amour, merci de me supporter (même quand je fais cuire un œuf au micro-onde), merci de me faire autant rire depuis le tout début.
Merci pour tous ces bons moments passés et à ceux, encore plus délicieux, à venir. Je t'aime.

Liste des abréviations

ASA	American Society of Anesthesiologists
ICC	Intraclass Correlation coefficient
QoR	Quality of Recovery
RCT	Randomized Controlled Trial
SEM	Standard Error of Measurement
SD	Standard Deviation
SORT	Surgical Outcome Risk Tool
PACU	Post-Anesthesia Care Unit
VAS	Verbal Analog Scale

Sommaire

INTRODUCTION

Une procédure chirurgicale, qu'elle soit sous anesthésie générale ou locorégionale, est source de stress et d'anxiété pour les patients. Elle peut aussi provoquer de l'inconfort à toutes les étapes de la prise en charge péri-opératoire, altérant la récupération au décours du geste chirurgical. Différentes complications mineures peuvent se cumuler (e.g. les nausées, les vomissements, la douleur, les troubles du sommeil ou de l'appétit, ou même une limitation de mobilisation) impactant la phase de récupération. Ces derniers éléments sont souvent négligés dans les études cliniques s'intéressant au devenir post-opératoire des patients (1). Néanmoins, ils ont un impact majeur sur le ressenti du patient et vont conditionner le vécu global de l'hospitalisation (2). Il existe actuellement une volonté croissante de la part des médecins impliqués dans les soins péri-opératoires d'améliorer leurs pratiques afin d'optimiser la récupération physique et psychologique, en s'appuyant sur des critères objectifs traduisant le ressenti du patient lui-même.

Dans cet objectif, un questionnaire pluridimensionnel, le QoR-40, a été développé et validé en anglais dans les années 2000 par l'équipe de *P. Myles* pour évaluer la récupération post-opératoire des patients ayant subi une chirurgie sous anesthésie générale (3). Ce questionnaire s'intéresse à 5 dimensions : le confort, le ressenti du patient, sa douleur, sa dépendance envers l'équipe soignante et son bien-être psychologique. En 2013, la même équipe a validé un second questionnaire plus rapidement exécutable (environ 2-3 minutes) : le QoR-15 (4). Il reprend une partie des items de chaque dimension du QoR-40. Ce questionnaire est fiable, sensible, facilement réalisable en pratique clinique, peu contraignant pour le patient et permet d'avoir des informations sur la récupération post-opératoire perçue par le patient lui-même. Le questionnaire peut être rempli par le patient, avec l'aide éventuelle d'une personne tierce, ou même à distance par téléphone (5). Différentes études ont donc utilisé ce questionnaire pour étudier l'impact d'une thérapeutique sur la récupération post-opératoire perçue par le patient, que les procédures aient été réalisées sous anesthésie générale ou locorégionale (6–8).

Le QoR-15 a été depuis validé en anglais puis en danois (9), en chinois (10), en portugais (8), en suédois (11), en italien (12), en coréen (13) et en japonais (14). Une version française du QoR-15 avait aussi été publiée (15). Toutefois, elle ne concerne que des patients opérés sous anesthésie générale avec une seule évaluation à 24 heures postopératoires.

D'autres échelles d'évaluation de la récupération post-opératoire utilisant des critères centrés sur le patient existent et ont été utilisées dans la recherche clinique, que ce soit en critère de jugement primaire ou secondaire.

Certaines sont plus globales que d'autres, comme l'échelle QoR-40, étant pluridimensionnelle dans sa validation psychométrique : une sous-dimension du score peut varier indépendamment des autres dimensions. Cette complexité rend la mesure plus précise, mais perturbe l'interprétation du score global. Par ailleurs, l'exhaustivité du score QoR-40 s'associe à une application en pratique clinique qui est plus compliquée (durée de remplissage plus longue, diminution de la compliance des équipes pour son utilisation systématique). Ainsi, l'utilisation d'échelles plus courtes comme le Postoperative Quality of Recovery Scale (PQRS) (16), l'ObsQoR-11 (17) ou le QoR-15 (4) rendent accessible l'évaluation péri-opératoire des patients sur la qualité de leur récupération. Elles représentent un outil précieux pour standardiser les critères de jugement dans les études s'intéressant au devenir des patients après différentes stratégies analgésiques, chirurgicales ou anesthésiques par exemple. C'est dans cet objectif qu'une conférence de consensus internationale, le groupe Step-COMPAC, a souligné en 2018 l'apport de ces échelles en tant que critère de jugement dans les essais cliniques (18). En effet, la diversité des définitions utilisées pour les complications postopératoires (19), la durée d'hospitalisation, ou même l'utilisation de scores non validés rendent difficilement interprétables, généralisables et réutilisables dans des méta-analyses, les résultats de ces études.

L'objectif de cette première étude est donc de traduire et de valider une autre version française du questionnaire QoR-15, le FQoR-15, dans une cohorte comprenant des patients opérés sous anesthésie générale ou locorégionale (y compris une population de chirurgie ambulatoire interrogée par téléphone), avec une évaluation à 24 heures mais aussi à 48 heures postopératoires. Le questionnaire FQoR-15 présente l'intérêt d'être composé de phrases plus construites, rendant facile son application directement auprès du patient, ou même du soignant découvrant le questionnaire.

L'objectif de la seconde étude est de faire un état des lieux de l'utilisation dans la littérature anesthésique des différentes échelles de mesure évaluant la qualité de récupération en tant que critère de jugement primaire ou secondaire dans les études cliniques comparatives dans une population adulte.

L'article 1 a été soumis sous la forme d'un article original, tel que présenté par la suite. Devant la publication récente d'un article similaire, validant également une version française du questionnaire QoR-15 (15), l'article a finalement été publié sous forme de correspondance dans le British Journal of Anaesthesia de juillet 2020 ***(Annexe 2)****. L'article 2 a également été soumis en tant qu'article original et a finalement été accepté sous forme de correspondance dans le British Journal of Anaesthesia d'avril 2021* ***(Annexe 3)****.*

ARTICLE 1

Translation and validation of an alternative French version of the Quality of Recovery -15 score: The FQoR-15.

Maxime Léger[1,2], Maëva Campfort[1], Cléor Cayla[1], Elsa Parrot-Schinkel[2], Sigismond Lasocki[1] and Emmanuel Rineau[1]

[1] Département d'Anesthésie Réanimation, Centre Hospitalier Universitaire d'Angers, Angers, France.

[2] INSERM UMR 1246 - SPHERE, Nantes University, Tours University, Nantes, France.

[3] Centre Hospitalier Universitaire d'Angers, Département de Biostatistiques et Méthodologie, Angers, France.

1. Abstract

Background: The QoR-15 questionnaire is validated to assess the quality of postoperative recovery. There is a need for a French validated version. The objective of this study was to validate a French translation of the QoR-15: the FQoR-15.

Methods: We carried out a translation and cultural development of the QoR-15 in the first phase. Adult patients scheduled for a surgery were prospectively included: they completed the FQoR-15 preoperatively, postoperatively at 24 hours (H24) and 48 hours (H48). The psychometric validation consisted of confirming internal consistency, convergent validity, construct validity, reproducibility, responsiveness, scaling properties, acceptability, and feasibility.

Results: Among the 363 patients included, 301 (83%) patients filled out the questionnaire at all three timepoints. A wide variety of surgeries were performed, including 38% ambulatory surgery. The baseline FQoR-15 score was 124.8 ± 18.2, versus 109.5 ± 22.7 at H24, and 116.6 ± 21.9 at H48. Responsiveness was good at H24 and moderate at H48. The instrument demonstrates excellent internal consistency with Cronbach's coefficients of 0.832 (95%CI from 0.806 to 0.859) at 24 hours, and 0.858 (95%CI from 0.835 to 0.880) at 48 hours. The FQoR-15 is highly correlated with an 11-item general condition score. Construct validity is suitable, including associations with the length of surgery, the length of hospital stays, the severity of the surgery, and occurrence of complications. Reproducibility and standard measurement error are satisfactory.

Conclusions: The FQoR-15 is a validated psychometric questionnaire for evaluating the quality of recovery after surgery in a French-speaking population.

Keywords: Anaesthesia, Perioperative Care, Patient Health Questionnaire, Patient-Reported Outcome Measures.

2. Introduction

Recovery after surgery and anaesthesia (whether general or locoregional) is a multidimensional process, which carries stress, anxiety, pain, and even minor complications (e.g. nausea or vomiting) (20). Unfortunately, the clinical criteria used to evaluate perioperative intervention generally address only a few morbidity parameters, without looking at the overall recovery (21). The use of criteria focused on the patients' overall recovery has become crucial. In a recent international consensus, the SteP–COMPAC group has highlighted the value of post-operative recovery scales (including QoR-15) for standardizing outcomes in perioperative medicine (18). In the 2000s, a multi-dimensional questionnaire – the QoR-40 – has been developed and validated in English to evaluate the postoperative recovery of patients who have undergone surgery under general anaesthesia (3). In 2013, the same team validated a second questionnaire, which can be executed more rapidly (approximately 2-3 min): the QoR-15 (4). This questionnaire appears to be reliable, sensitive, easily achievable in clinical practice. It gives information on post-operative recovery in a unidimensional approach. The patient can complete the questionnaire alone, or with the help of an assessor (even by phone) (5). Different studies have therefore used this questionnaire to evaluate the impact of intervention on the patient's perceived post-operative recovery (7). This questionnaire is validated for both general and regional anaesthesia (6,8).

A systematic review of QoR-15 and its translations confirmed the value of this questionnaire (22). Different translations already exist including Danish (9), Chinese (10), Portuguese (8), and Swedish versions (11).

French is the fifth most widely spoken language in the world, with approximately 280 million people using it regularly (23). One recent version of a French translation has just been published (15), but this study presents some limitations. The authors cannot confirm the unidimensional nature of their scale, and the analysis is limited to the validation at 24 hours in a general surgery population. Furthermore, the authors have constructed their questionnaire based on interviews with an assessor, and these results do not guarantee its understanding and validation if the patient has to fill it out alone.

Our objective was to validate another French version of the QoR-15, the FQoR-15, in a population operated on for a wide variety of surgeries (including ambulatory surgery) to measure the quality of post-operative recovery at 24 hours (H24) and 48 hours (H48).

3. Methods

A French Ethical Research Committees accepted this study (Comité de Protection des Personnes Est-III - registration ID 2019-A011442-55), and we registered the protocol on ClinicalTrials.gov with the identifier NCT03967821. We conducted a monocentric study at Angers University Hospital (France), from July 15th, 2019, to February 19th, 2020. Written consent was waived, but all patients were informed and agreed to the data collection, as requested by the French law (24). The methodology for validating this questionnaire follows the COSMIN guidelines "Consensus-based standards for the selection of health measurement instruments" (25).

3.1. Study population

All participants had to meet the following inclusion criteria: aged ≥ 18 years; agreeing to the use of their data; being French-speaker; being able to understand and complete the FQoR-15 questionnaire at inclusion (alone or with the help of a third party); being admitted to hospital for scheduled surgery. We did not include patients with a significant psychiatric or neurological disorder that compromised cooperation in completing the questionnaire, nor patients undergoing intracranial surgery. Eligible patients were identified at the anaesthesia consultation and included before the surgical procedure.

3.2. Development and pilot testing of the French Quality of Recovery-15: FQoR-15

We translated the English-language QoR-15 questionnaire according to existing recommendations (26,27), after obtaining the authorization of Prof. P. Myles, author of the initial questionnaire. The translation was carried out independently by three investigators fluent in English and French and whose native language is French. We compared and merged these three translated questionnaires to create a pilot version of the questionnaire in French. This pilot version was then translated (French to English) by an independent bilingual translator (forward translation/backward translation method). The pilot questionnaire and the backward translation were pooled among the four translators to produce a single version of the translated questionnaire. About twenty patients and ten nurses with experience in immediate post-operative care completed the translated version to evaluate the

comprehension of the items. We assessed the validity of content (i.e., the degree to which the instrument is an adequate reflection of the construct) during this phase, by qualitative interviews.

This phase enabled us to obtain the definitive version: FQoR-15 **(Annex 1)**. Five subscales composed the score: physical comfort (n=5 items), emotional state (n=4 items), pain (n=2 items), physical independence (n=2 items) and psychological support (n=2 items). If the patient was not able to read the questionnaire himself, a third person could ask the questions orally to the patient. Each item was scored from 0 to 10, and the total score was the full sum (i.e., a total score from 0 to 150, where 0 is the worst recovery score and 150 indicates the best).

3.3. Available data

Patients completed the FQoR-15 questionnaire in the immediate preoperative period (baseline status = H0), 24 (H24) and 48 (H48) hours after surgery. The patient filled out the questionnaire alone if possible, otherwise with the help of an assessor. If the patient had returned home, the assessor interviewed him/her by phone. Assessments at H24 and H48 were our measures of interest.

We collected the following data at baseline: demographic characteristics (weight, height, age, gender), American Society of Anesthesiologists (ASA) status, co-morbidities, smoking status, alcohol consumption, type of anaesthesia and type of surgery planned, as well as its severity according to the SORT score (28). Since the SORT score does not take into account cardiac surgeries, we additionally defined the following surgeries being at higher risk: all cardiac surgeries under cardio-pulmonary bypass, visceral surgeries with laparotomy, thoracic surgeries with thoracotomy, and orthopaedic surgeries with osteosynthesis. Different types of surgery could be included: cardiac, thoracic, vascular, visceral, urological, gynaecological, orthopaedic or otorhinolaryngological. We recorded the duration of surgery, the length of stay in the post-anaesthesia care unit (PACU), as well as the length of hospital stay. At H24 and H48, we noted the minor complications (severe pain with visual analogue assessment > 7, nausea, dyspnoea, confusion, agitation, acute urine retention), as well as those according to the POMS classification (29). Each patient was also asked to rate his/her general condition at each interval (H0, H24 and H48), measured by a verbal analogue scale (VAS) ranging from 0 (very poor general condition) to 10 (best general condition). We designed this evaluation to enable us to make an overall assessment of the criterion validity of the FQoR-15 scale in the absence of another "Gold-Standard" questionnaire.

We timed a subgroup of patients (the first 75 included) to estimate the duration of questionnaire completion. We asked another subset of patients (the first 30 included) to repeat the FQoR-15 questionnaire 30 min later to assess its repeatability.

3.4. The psychometric validation

We conducted a complete psychometric evaluation to validate the FQoR-15 questionnaire (25,30).

- **Content validity** corresponds to the extent to which the items in the questionnaire well represent the concept. We do not discuss the concept of postoperative recovery for which the QoR-15 has already been validated. The translation process has optimized the comprehension and interpretation of the items in French. The target population for the FQoR-15 corresponds to the global population of patients admitted for scheduled surgeries.

- **Internal consistency** is how items measure a single underlying construct. We carried out a factorial analysis to confirm the unidimensionality of the French version of the questionnaire.

- **Criterion validity** refers to the association between the measurement questionnaire and a "gold standard". In the absence of the latter, we tested the convergent validity by comparing the FQoR-15 with the general state verbal analogue score at H24 and H48.

- **Construct validity** corresponds to the consistency on the score of the theoretical impact of modifications on the concept. We tested several hypotheses for this purpose. As in the original validation of QoR-15 (4), we assumed that more than 75% of our assumptions would be confirmed. We assume that FQoR-15 at H24 and H48 is inversely associated with surgical duration, duration in PACU and length of hospital stay. Patients with the least high-risk surgeries, as well as those admitted to the ambulatory track, would have lower scores. Those with postoperative complications would have a lower FQoR-15 score, as well as those operated on under general anaesthesia. The value of the scores should not vary according to age and gender.

- **Reproducibility** implies that repeat testing on stable individuals provides similar answers. The agreement concerns the absolute measurement error, while reliability is the degree to which patients can be distinguished from each other, despite measurement error.

- **Responsiveness** reflects the ability of a questionnaire to detect clinically relevant changes over time.

- We considered **floor** or **ceiling effects** if more than 15% of respondents achieved the lowest or highest possible score (31).

- **Acceptability** and **feasibility** are measures of user-friendliness: the patient recruitment rate, the total participation rate in the three times frames (H0, H24 and H48), and the time taken to complete the questionnaire.

3.5. Statistical Analysis

We had set the sample size at 375 patients for the FQoR-15 validation. It is commonly accepted that the sample size must be 15 to 20 times larger than the number of items in the questionnaire (i.e., 15 items). Assuming 20% of possible lost subjects or missing data, we obtained a total of 375 patients. Furthermore, the threshold of 300 patients seemed to be an acceptable limit for studying the dimensions of a measurement scale (32).

We presented data as mean ± SD, median [interquartile range], number (%). The 95% confidence intervals (95%CI) were obtained by bootstrapping. Associations between quantitative variables were measured using Pearson correlation coefficients. An inter-item correlation matrix is proposed and composed of Pearson correlation coefficients. For comparison between two groups, we used Chi-square tests for categorical variables and Student t-tests for continuous variables. We explored the number of dimensions of the questionnaire by the total percentage variance explained by the first factor, as well as the ratio of variance, explained between the first factor and the second factor. To retain the hypothesis of the unidimensionality of the scale, our criteria was a total percentage of variance greater than 25% or a variance ratio greater than 2. Internal consistency was measured using Cronbach α (33). The objective was to obtain a value between 0.70 and 0.90 (34). Test-retest reliability was measured using the agreement intraclass correlation coefficient (agreement ICC) (35). A value of 0.70 is recommended as a minimum standard for reliability (34). The measurement error was expressed with the standard error of measurement (SEM) (36), including systematic differences (i.e. SEM agreement). Responsiveness was quantified using the Cohen effect size (average change score divided by the SD at baseline) (37) and Standardized response mean (change scores divided by the SD of the change scores) (38).

We rejected the null hypothesis if p-value < 0.05. No procedure for correcting for the multiplicity of statistical tests has been set up, the analyses being carried out for exploratory purposes. For all subjects included, we imputed missing data on items from questionnaires completed at H0, H24 and H48 using multiple imputations with chained equations. Other data were not imputed. We performed all statistical analyses using R software (version 3.6.3).

4. Results

4.1. Description of the population

During the study period, 363 patients were included for the FQoR-15 validation. Finally, 301 patients completed all questionnaires at H0, H24 and H48. The flow chart is depicted in **Figure 1**. Patients' characteristics are summarized in **Table I**. The patient population was between 18 and 94 years of age, with a predominance of males (217 patients, 59.8%). A wide range of scheduled surgeries is represented, from cardiac surgery to gynaecological surgery. A significant proportion of ambulatory surgeries constitutes the population, with 139 (38.3%) procedures.

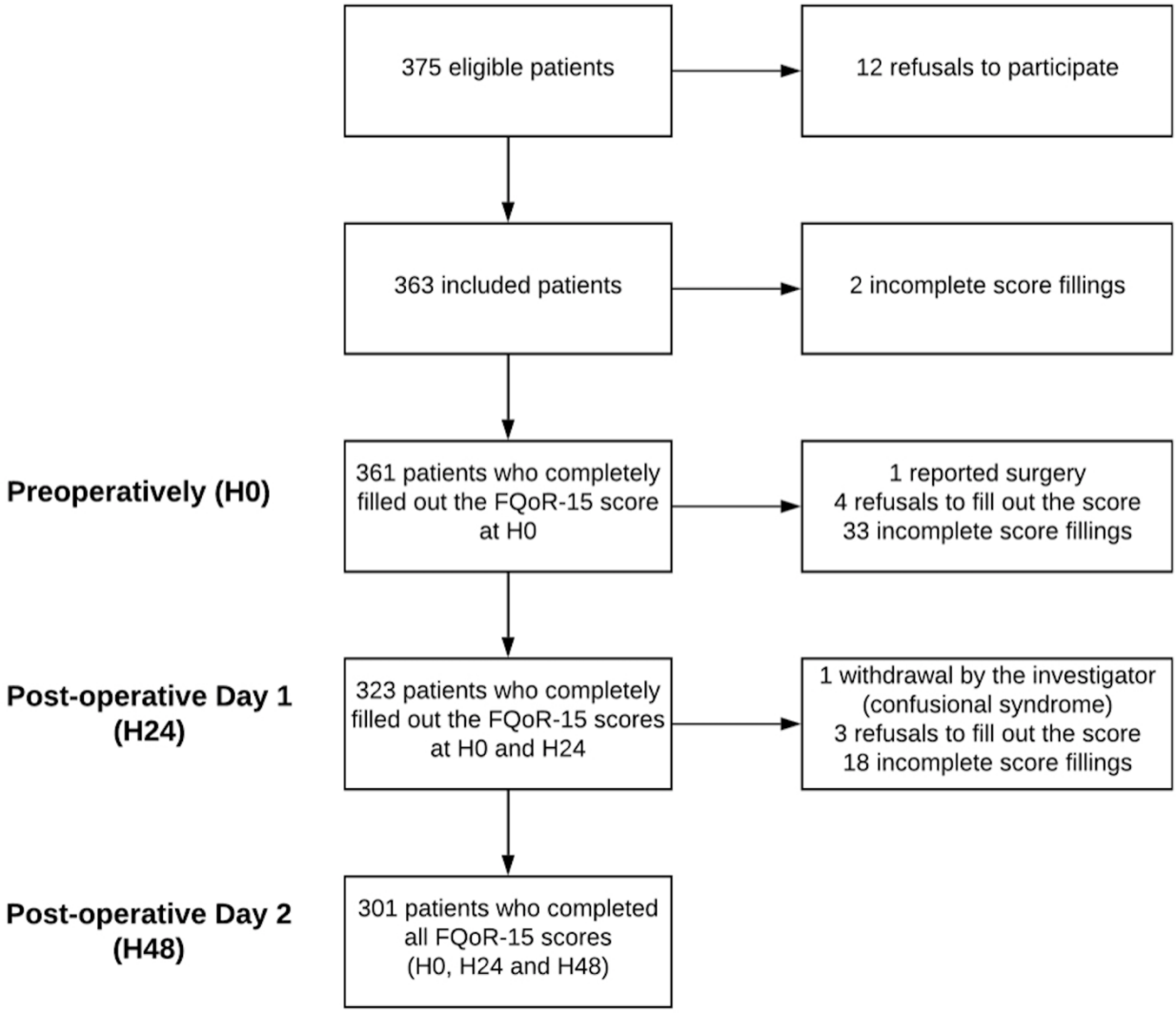

Figure 1. Flow Chart

Table I. The summary table of the patients' characteristics

	Overall (n=363)
Age (years)	57.7 ± 18.2
Weight (kg)	75.2 ± 16.7
Height (cm)	168.6 ± 9.2
Male	217 (59.8)
ASA Status	
1	106 (29.2)
2	177 (48.7)
3	72 (19.8)
4	8 (2.2)
Unit of admission	
Ambulatory	139 (38.3)
Cardiac surgery	33 (9.0)
Gynaecologic surgery	8 (2.2)
Neurosurgery	21 (5.8)
Otorhinolaryngology	10 (2.8)
Orthopaedic surgery	44 (12.1)
Thoracic and Vascular surgery	44 (12.1)
Urologic surgery	27 (7.4)
Visceral surgery	37 (10.2)
High risk surgery	69 (19.0)
SORT Score	0.9 ± 2.5
Type of Anaesthesia (%)	
General	239 (65.8)
General and Locoregional	72 (19.8)
Locoregional	44 (12.1)
Only sedation	8 (2.2)
Patient comorbidities	
Cancer	87 (24.0)
Renal disease	18 (5.0)
Cardiac disease	78 (21.5)
Hepatic disease	11 (3.0)
Pulmonary disease	28 (7.7)
Diabetes	37 (10.2)
Active smoking	78 (21.5)
Addiction history	7 (1.9)
Chronic Alcoholism	23 (6.3)
Questionnaire completion time (min)	3.00 [2.00, 4.00]
FQoR-15 preoperatively	124.8 ± 18.2
FQoR-15 at 24 hours	109.5 ± 22.7
FQoR-15 at 48 hours	116.6 ± 21.9
General Condition Score preoperatively	7.3 ± 1.9
General Condition Score at 24 hours	6.7 ± 2.0

	Overall (n=363)
General Condition Score at 48 hours	7.0 ± 1.8
POMS complication at 24 hours	152 (41.9)
Major complication at 24 hours	
None	211 (58.1)
Cardiovascular	2 (0.6)
Pain	71 (19.6)
Gastrointestinal	20 (5.5)
Infectious	2 (0.6)
Pulmonary	53 (14.6)
Renal	3 (0.8)
Operating site	1 (0.3)
POMS complication at 48 hours	49 (13.5)
Major complication at 48 hours	
None	314 (86.5)
Cardiovascular	3 (0.8)
Pain	23 (6.3)
Gastrointestinal	6 (1.7)
Haematology	2 (0.6)
Infectious	2 (0.6)
Neurologic	1 (0.3)
Pulmonary	11 (3.0)
Renal	1 (0.3)
Operating time (min)	95.0 [70.0, 140.0]
Duration in PACU (min)	107.0 [83.8, 130.0]
Hospital length of stay (day)	1.0 [0.0, 4.0]

4.2. Internal consistency

The heatmap representation of the inter-item correlations of FQoR-15 at H24 is represented in **Figure 2**. The one for the FQoR-15 to H48 is proposed in **Figure 3.** **Table II and III** propose the inter-item correlation tables. The overall average inter-item correlation is 0.260 (95%CI from 0.226 to 0.290) at 24 hours and 0.303 (95%CI from 0.263 to 0.337) at 48 hours. The exploratory analysis confirms the unidimensionality of the FQoR-15, both at H24 (33% variance for the 1st dimension) and H48 (37% variance for the 1st dimension). The scree plot representations are depicted in **Figure 4 and 5**. Cronbach's coefficients are 0.832 (95%CI from 0.806 to 0.859) at 24 hours, and 0.858 (95%CI from 0.835 to 0.880) at 48 hours. These parameters converge to confirm the excellent internal consistency of FQoR-15.

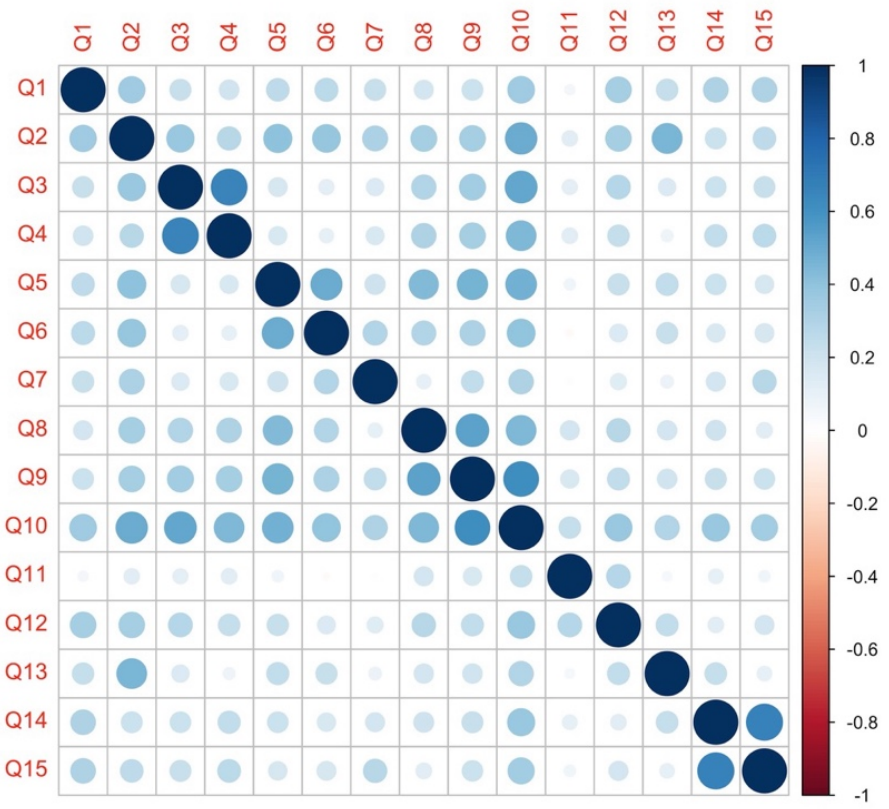

Figure 2. Heatmap at H24

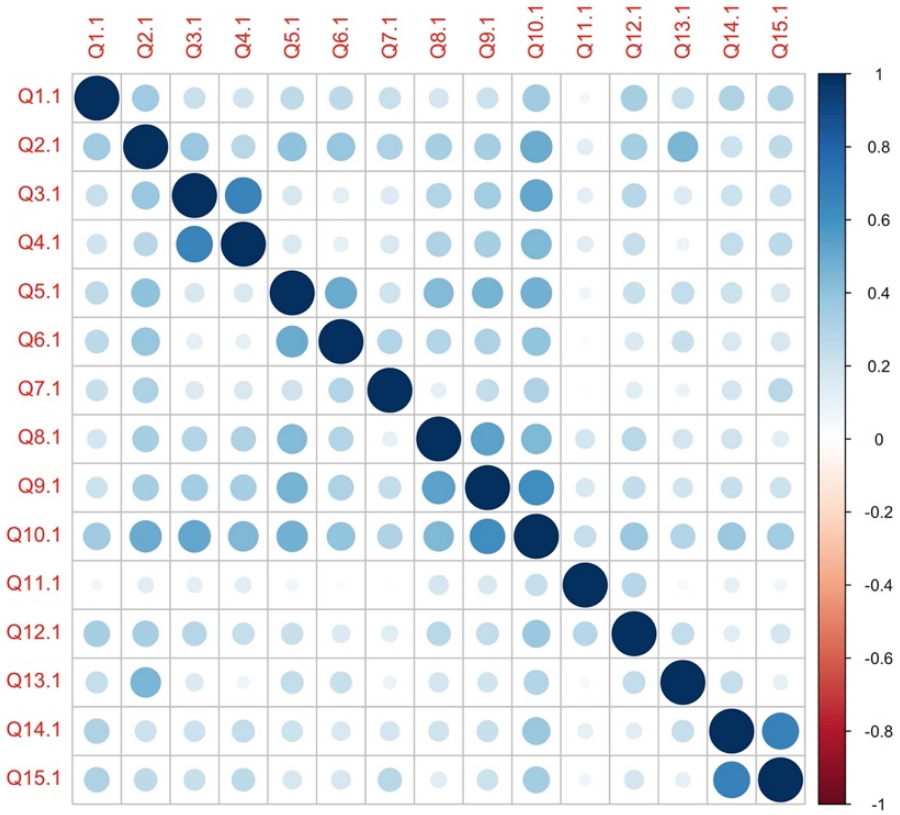

Figure 3. Heatmap at H48

Table II. The inter-item correlation table for FQoR-15 at 24 hours

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15
Q1		0.352	0.223	0.193	0.256	0.268	0.227	0.181	0.218	0.360	0.053	0.334	0.230	0.308	0.308
Q2	0.352		0.377	0.274	0.402	0.388	0.315	0.337	0.334	0.500	0.121	0.330	0.451	0.219	0.258
Q3	0.223	0.377		0.655	0.177	0.117	0.153	0.300	0.342	0.513	0.114	0.285	0.151	0.213	0.222
Q4	0.193	0.274	0.655		0.167	0.104	0.163	0.303	0.333	0.450	0.122	0.232	0.072	0.248	0.260
Q5	0.256	0.402	0.177	0.167		0.492	0.203	0.433	0.468	0.478	0.067	0.230	0.246	0.215	0.170
Q6	0.268	0.388	0.117	0.104	0.492		0.294	0.292	0.315	0.392	-0.022	0.160	0.226	0.170	0.179
Q7	0.227	0.315	0.153	0.163	0.203	0.294		0.104	0.242	0.300	0.018	0.131	0.082	0.182	0.276
Q8	0.181	0.337	0.300	0.303	0.433	0.292	0.104		0.538	0.446	0.184	0.278	0.189	0.201	0.125
Q9	0.218	0.334	0.342	0.333	0.468	0.315	0.242	0.538		0.611	0.168	0.243	0.191	0.222	0.212
Q10	0.360	0.500	0.513	0.450	0.478	0.392	0.300	0.446	0.611		0.234	0.371	0.298	0.373	0.346
Q11	0.053	0.121	0.114	0.122	0.067	-0.022	0.018	0.184	0.168	0.234		0.284	0.045	0.110	0.066
Q12	0.334	0.330	0.285	0.232	0.230	0.160	0.131	0.278	0.243	0.371	0.284		0.243	0.122	0.183
Q13	0.230	0.451	0.151	0.072	0.246	0.226	0.082	0.189	0.191	0.298	0.045	0.243		0.237	0.107
Q14	0.308	0.219	0.213	0.248	0.215	0.170	0.182	0.201	0.222	0.373	0.110	0.122	0.237		0.665
Q15	0.308	0.258	0.222	0.260	0.170	0.179	0.276	0.125	0.212	0.346	0.066	0.183	0.107	0.665	

Table III. The inter-item correlation table for FQoR-15 at 48 hours

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15
Q1		0.448	0.300	0.336	0.511	0.436	0.313	0.267	0.324	0.398	0.082	0.212	0.147	0.244	0.280
Q2	0.448		0.486	0.422	0.492	0.456	0.309	0.363	0.365	0.560	0.111	0.266	0.390	0.303	0.246
Q3	0.300	0.486		0.613	0.392	0.273	0.279	0.300	0.387	0.576	0.118	0.271	0.150	0.268	0.287
Q4	0.336	0.422	0.613		0.440	0.289	0.236	0.353	0.357	0.493	0.163	0.303	0.170	0.296	0.284
Q5	0.511	0.492	0.392	0.440		0.501	0.312	0.476	0.442	0.466	0.107	0.300	0.167	0.332	0.293
Q6	0.436	0.456	0.273	0.289	0.501		0.426	0.276	0.335	0.470	0.132	0.210	0.223	0.295	0.281
Q7	0.313	0.309	0.279	0.236	0.312	0.426		0.114	0.176	0.255	-0.024	0.053	0.132	0.317	0.395
Q8	0.267	0.363	0.300	0.353	0.476	0.276	0.114		0.594	0.522	0.264	0.284	0.158	0.284	0.214
Q9	0.324	0.365	0.387	0.357	0.442	0.335	0.176	0.594		0.687	0.220	0.267	0.133	0.228	0.211
Q10	0.398	0.560	0.576	0.493	0.466	0.470	0.255	0.522	0.687		0.192	0.412	0.292	0.423	0.359
Q11	0.082	0.111	0.118	0.163	0.107	0.132	-0.024	0.264	0.220	0.192		0.376	0.068	0.029	0.029
Q12	0.212	0.266	0.271	0.303	0.300	0.210	0.053	0.284	0.267	0.412	0.376		0.228	0.273	0.229
Q13	0.147	0.390	0.150	0.170	0.167	0.223	0.132	0.158	0.133	0.292	0.068	0.228		0.211	0.167
Q14	0.244	0.303	0.268	0.296	0.332	0.295	0.317	0.284	0.228	0.423	0.029	0.273	0.211		0.674
Q15	0.280	0.246	0.287	0.284	0.293	0.281	0.395	0.214	0.211	0.359	0.029	0.229	0.167	0.674	

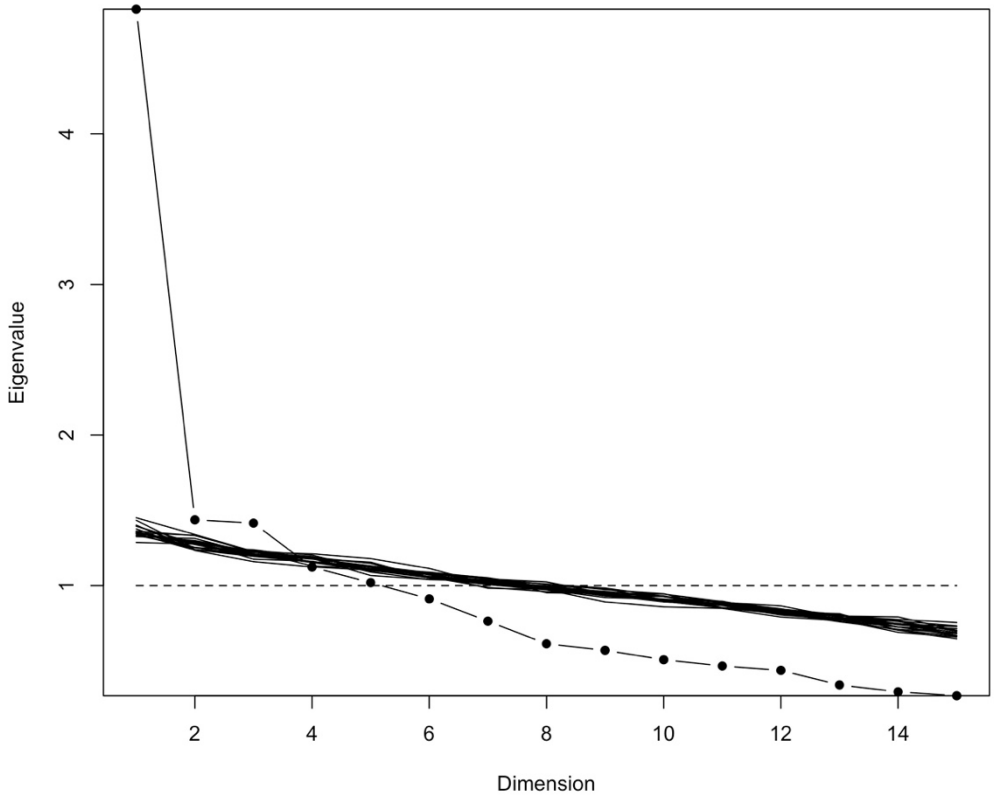

Figure 4. Scree plot representation of FQoR-15 at 24 hours

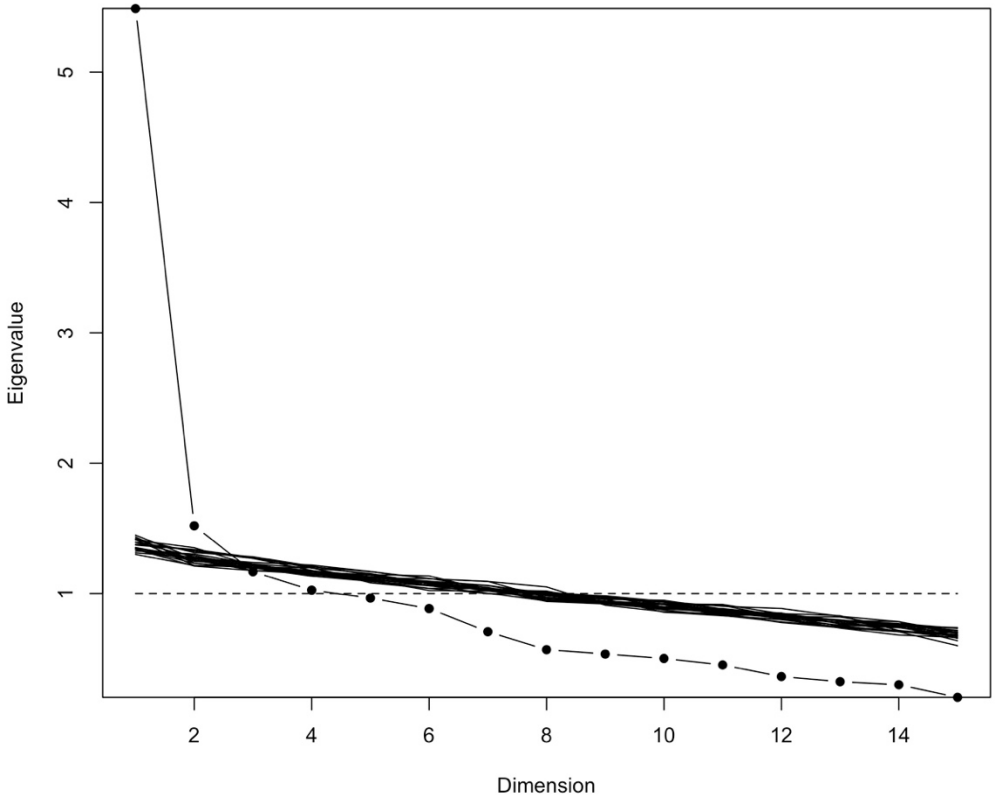

Figure 5. Scree plot representation of FQoR-15 at 48 hours

4.3. Convergent validity

The FQoR-15 and general condition scores are highly correlated with a coefficient of 0.53 (95%CI from 0.45 to 0.60) at H0, 0.63 (95%CI from 0.57 to 0.69) at H24 and 0.67 (95%CI from 0.60 to 0.72) at H48.

4.4. Construct validity

The results of the assumptions tested on the FQoR-15 are reported in **Table IV**. In total, we confirmed 80% of our assumptions, both at the FQoR-15 assessment at 24 and 48 hours. Besides, regarding the completion time, we verified that it was correlated with age (Pearson's coefficient of 0.27 (95%CI from 0.04 to 0.46), but not associated with gender (mean time for women of 3.5 ± 1.3 min versus 3.2 ± 1.4 min for men, p=0.43). There was also an association between filling time and the risk status of the surgery: 4.0 ± 1.4 min for high-risk surgeries versus 3.1 ± 1.3 min for the others, p=0.018. All these confirmations construct the validity of the FQoR-15.

Table IV. The summary table of tested assumptions (constructed validity) on the FQoR-15 score at 24 and 48 hours

Assumptions	FQoR-15 at 24 hours	FQoR-15 at 48 hours	Confirmed
Negative association between surgical duration and FQoR-15	-0.38 (95%CI from -0.47 to -0.29)	-0.40 (95%CI from -0.48 to -0.30)	X
Negative association between PACU duration and FQoR-15	0.00 (95%CI from -0.11 to 0.11)	-0.02 (95%CI from -0.12 to -0.09)	
Negative association between length of hospital stay and FQoR-15	-0.39 (95%CI from -0.48 to -0.30)	-0.42 (95%CI from -0.50 to -0.33)	X
Negative association between SORT score and FQoR-15	-0.09 (95%CI from -0.20 to 0.02)	-0.04 (95%CI from -0.15 to 0.07)	
No association between patient's age and FQoR-15	0.09 (95%CI from -0.02 to 0.19)	-0.03 (95%CI from -0.13 to 0.08)	X
Negative association between high-risk surgery and FQoR-15 (high-risk surgeries versus the others)	99.8 ± 25.1 vs 112.1 ± 21.4, p<0.001	105.1 ± 24.4 vs 118.9 ± 20.7, p<0.001	X
Positive association between ambulatory surgery and FQoR-15 (ambulatory surgeries versus the others)	118.0 ± 19.2 vs 104.5 ± 23.1, p<0.001	124.3 ± 18.1 vs 112.0 ± 22.7, p<0.001	X
Negative association between general anaesthesia and FQoR-15 (general anaesthesia versus the others)	108.3 ± 23.1 vs 117.1 ± 18.5, p=0.003	115.7 ± 22.0 vs 122.8 ± 19.6, p=0.018	X
Negative association between occurrence of POMS complications and FQoR-15 (at least one complication versus none)	98.6 ± 23.5 vs 117.5 ± 18.3, p <0.001	94.4 ± 23.8 vs 120.2 ± 19.5, p<0.001	X
No association between patient's gender and FQoR-15 (Women versus Men)	110.5 ± 22.5 vs 108.9 ± 22.8, p=0.512	117.7 ± 20.9 vs 115.9 ± 22.6, p=0.430	X

Tests of quantitative variables based on Pearson's correlation coefficient. Tests of binary qualitative variables based on Student tests.

4.5. Reproducibility

When we compared the questionnaires completed with a 30-minutes time difference, we calculate an agreement ICC of 0.96 (95%CI from 0.91 to 0.98). The SEM is 4.18 (95%CI from 3.12 to 6.33). The FQoR-15 confirms its excellent reliability and acceptable SEM.

4.6. Responsiveness

Preoperatively, the mean FQoR-15 score was 124.8 ± 18.2, versus 109.5 ± 22.7 at 24 hours, and 116.6 ± 21.9 at 48 hours. The distribution of scores in the three times is illustrated in **Figure 6**. The change in FQoR-15 from baseline to H24 and H48 confirms the excellent responsiveness of the score. At H24, Cohen's effect size for the FQoR-15 is 0.84 with a standardized response mean of 0.70. All items decrease in value between baseline and postoperatively, except for items 6 (ability to communicate with family and friends) and 7 (the feeling of support from the health care team). **Table V** summarizes the responsiveness between baseline and H24. The score increased between H24 and H48, assuming the dynamics of recovery and confirming responsiveness following the surgical assault. Responsiveness between baseline and H48 are presented in **Table VI**.

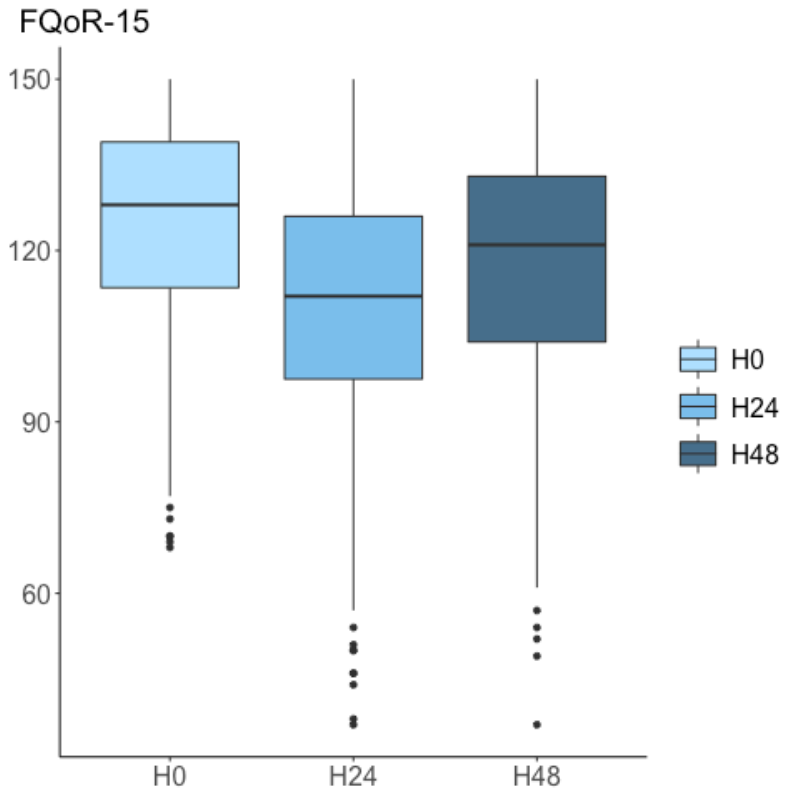

Figure 6. Boxplot representing the distribution of scores at H0, H24 and H48

Table V. Mean changes and responsiveness between baseline and H24

FQoR-15 items	Preoperative	At H24	Mean change*	% Change from baseline	Cohen effect size	Standardized Response Mean
1. Breathing	9.2 ± 1.8	8.9 ± 1.9	0.32 (0.13 to 0.56)	3.3	0.17	0.15
2. Food	8.4 ± 2.2	7.1 ± 2.5	1.28 (1.01 to 1.55)	15.5	0.59	0.49
3. Rest	6.6 ± 3.5	4.9 ± 3.2	1.71 (1.35 to 2.17)	25.8	0.49	0.41
4. Sleep	8.2 ± 3.0	7.1 ± 3.2	1.06 (0.65 to 1.45)	13.4	0.36	0.27
5. Hygiene	9.6 ± 1.5	9.0 ± 2.4	0.66 (0.41 to 0.94)	6.2	0.45	0.26
6. Communication	6.3 ± 3.4	7.8 ± 3.2	-1.53 (-1.91 to -1.16)	-23.8	0.45	0.42
7. Support	8.3 ± 2.8	8.7 ± 2.6	-0.39 (-0.69 to -0.13)	-4.8	0.14	0.14
8. Return to work	9.1 ± 1.8	7.8 ± 2.8	1.29 (0.98 to 1.62)	14.3	0.71	0.44
9. Feeling in control	7.2 ± 2.5	6.2 ± 2.7	1.00 (0.69 to 1.36)	13.9	0.40	0.32
10. Well-being	6.4 ± 2.9	5.5 ± 3.0	0.97 (0.63 to 1.36)	14.1	0.34	0.27
11. Moderate pain	9.6 ± 1.4	7.1 ± 3.5	2.49 (2.14 to 2.88)	26.0	1.75	0.72
12. Severe pain	9.8 ± 0.9	9.2 ± 1.8	0.62 (0.44 to 0.85)	6.1	0.72	0.32
13. Nausea/vomiting	9.5 ± 1.2	9.4 ± 1.2	0.08 (-0.07 to 0.23)	1.1	0.07	0.06
14. Anxiety	8.0 ± 3.0	4.3 ± 3.4	3.64 (3.24 to 4.03)	46.2	1.22	0.97
15. Depressed	8.5 ± 2.4	6.5 ± 2.7	2.02 (1.71 to 2.36)	23.5	0.86	0.64
Total	124.7 ± 18.2	109.5 ± 22.7	15.23 (13.02 to 17.46)	12.2	0.84	0.70

** Mean changes with their 95% confidence intervals in parentheses.*

Table VI. Mean changes and responsiveness between baseline and H48

FQoR-15 items	Preoperative	At H48	Mean change*	% Change from baseline	Cohen effect size	Standardized Response Mean
1. Breathing	9.2 ± 1.8	9.1 ± 1.5	0.04 (-0.17 to 0.22)	1.1	0.02	0.02
2. Food	8.4 ± 2.2	7.4 ± 2.4	0.98 (0.74 to 1.23)	11.9	0.45	0.41
3. Rest	6.6 ± 3.5	5.6 ± 3.1	1.06 (0.62 to 1.49)	15.2	0.30	0.25
4. Sleep	8.2 ± 3.0	7.5 ± 3.1	0.66 (0.27 to 1.1)	8.5	0.22	0.17
5. Hygiene	9.6 ± 1.5	9.1 ± 2.3	0.54 (0.29 to 0.81)	5.2	0.37	0.22
6. Communication	6.3 ± 3.4	8.2 ± 3.0	-1.89 (-2.34 to -1.5)	-30.2	0.56	0.47
7. Support	8.3 ± 2.8	8.8 ± 2.5	-0.48 (-0.8 to -0.19)	-6.0	0.18	0.16
8. Return to work	9.1 ± 1.8	8.2 ± 2.5	0.89 (0.65 to 1.14)	9.9	0.49	0.38
9. Feeling in control	7.2 ± 2.5	7.1 ± 2.4	0.16 (-0.17 to 0.43)	1.4	0.06	0.05
10. Well-being	6.4 ± 2.9	6.7 ± 2.7	-0.26 (-0.62 to 0.09)	-4.7	0.09	0.07
11. Moderate pain	9.6 ± 1.4	8.3 ± 2.6	1.31 (1.07 to 1.58)	13.5	0.92	0.52
12. Severe pain	9.8 ± 0.9	9.3 ± 1.6	0.43 (0.28 to 0.62)	5.1	0.50	0.26
13. Nausea/vomiting	9.5 ± 1.2	9.4 ± 1.2	0.08 (-0.07 to 0.22)	1.1	0.07	0.06
14. Anxiety	8.0 ± 3.0	5.1 ± 3.2	2.83 (2.49 to 3.19)	36.3	0.95	0.82
15. Depressed	8.5 ± 2.4	6.8 ± 2.8	1.77 (1.41 to 2.08)	20.0	0.75	0.59
Total	124.7 ± 18.2	116.6 ± 21.9	8.12 (6.11 to 10.09)	6.5	0.44	0.40

** Mean changes with their 95% confidence intervals in parentheses.*

4.7. Scaling properties

The FQoR-15 has excellent scaling properties both at H24 and H48. We note no ceiling or floor effect. Histograms representing the distribution of FQoR-15 score at baseline, H24 and H48 are provided in the **Figure 7**. At H24, the 25th, 50th and 75th centiles are 98, 112 and 126.

4.8. Acceptability and feasibility

The flow chart confirms the acceptability of patients to complete this questionnaire. 97% of the eligible population agreed to participate in the study, with 99% of them completing the baseline questionnaire entirely, 89% completing the baseline and H24 FQoR-15, and 83% fill out the questionnaire at all three timelines. The average time to fully complete the questionnaire is 3.3 ± 1.3 min, with a range of 1 to 7 min.

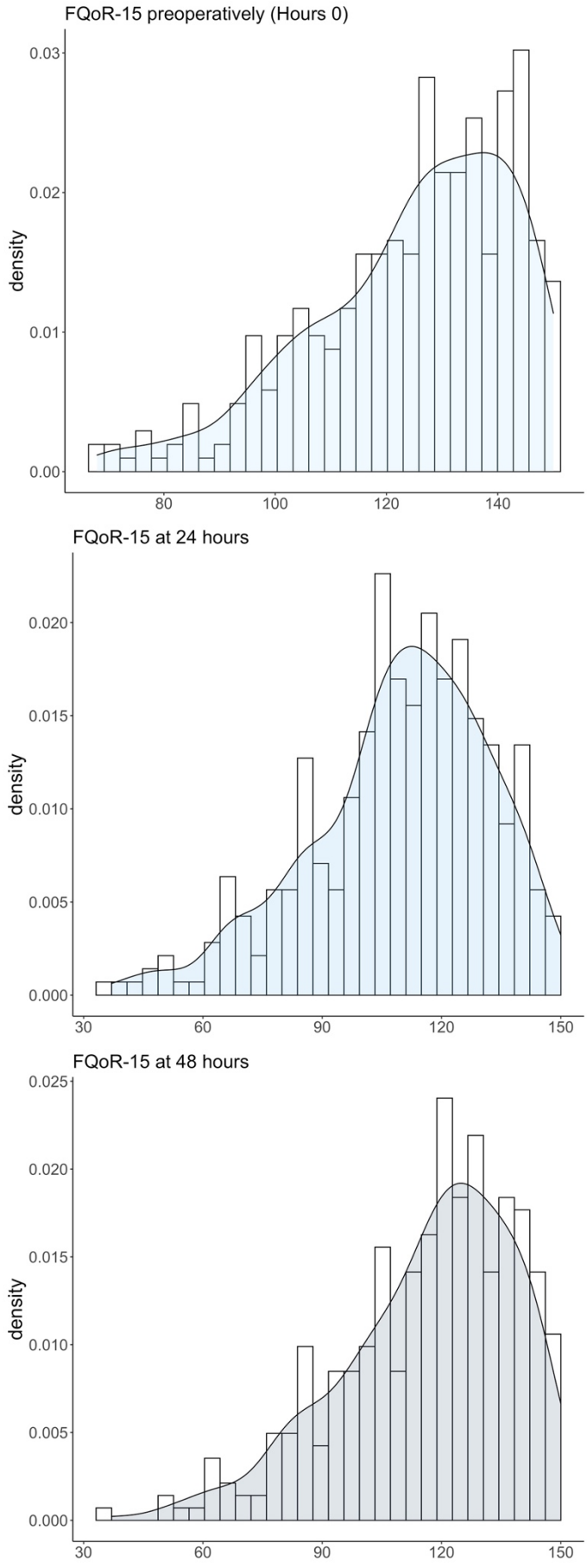

Figure 7. Histograms of FQoR-15 scores at H0, H24 and H48

5. Discussion

This study consisted of the development and prospective validation of a French translation of the QoR-15, a 15-item questionnaire on post-operative recovery. The FQoR-15 questionnaire obtained after translation and cross-cultural development following the guidelines (26,27), confirms its psychometric qualities. We have confirmed that the FQoR-15 is a one-dimensional measuring instrument allowing us to approach the concept of post-operative recovery in the French-speaking population.

Another recent version of the French translation of QoR-15 has just been published, the QoR-15F (15). Our version, the FQoR-15, was developed in parallel with the QoR-15F. When we look at the linguistic construction of the FQoR-15, we find a substantial similarity with that of QoR-15F. It is necessary to note that we build the items in our translation around complete sentences that may facilitate comprehension if the patient has to complete the questionnaire alone, or if it has to be completed by an unexperienced assessor. We felt it necessary to propose an alternative questionnaire at least on this point. Furthermore, we believe that the target population for the use of this tool is the entire operated population under general or loco-regional anaesthesia. It seemed to us essential to study a wide range of surgeries in order to highlight the generalizability of this score. We had approximately 38% of ambulatory surgeries, for which patients were contacted by phone. We thus confirm the use of this score by phone, as it had been performed in other validation (4–6,9,10). To continue in this concern for generalizability, we decided to select various patient criteria, as well as different anaesthesia options. Even in the context of loco-regional anaesthesia, the use of FQoR-15 seems relevant.

Beyond this other French version, there are several validations of the QoR-15 in different languages, allowing us to compare the results of our psychometric validation (22).

Both in the original study and various other validations (4,5,8,15), we find an excellent internal consistency with Cronbach's coefficients remaining above 0.8. Besides, FQoR-15 makes it possible to effectively discriminate patients with the weakest recovery, without observing a threshold or ceiling effect. The responsiveness of the FQoR-15 is assessed using the Cohen effect size, and standardized response mean. These two values are higher than 0.8 at 24 hours, confirming broad responsiveness, and suggesting a strong ability to detect a clinically relevant change in the quality of recovery (39). We can classify the recovery quality according to the value of the QoR-15 (40), and it is the same for the FQoR-15. The responsiveness between the baseline and 48-hour values remains confirmed but in a more moderate way and can be explained by the proportion of ambulatory surgery which could have already fully recovered from their surgery at 48 hours. The construct validity of the FQoR-15 is

ensured by verifying 80% of the pre-established assumptions. Moreover, just like the other French version, we find a negative correlation with the duration of surgery, the duration of hospitalization, the risk of surgery, and the occurrence of complications (15). Convergent validity is also excellent with a Pearson's correlation coefficient of 0.63 at H24 and 0.67 at H48 with an 11-item general condition rating scale. We could not use a Gold-Standard scale, which does not exist to evaluate postoperative recovery, nor could we rely on the QoR-40 score (3), for which many items are collinear.

Unlike the recently published French version, we propose an estimation of the SEM at 4.18, which is globally in agreement with the other existing validations (22). The minimal clinically important difference for QoR-15 is estimated at 8.0 (6). We also studied the structural validity of our questionnaire, confirming its unidimensionality at both H24 and H48.

To evaluate postoperative recovery, we preferred to choose the QoR-15 score among others because it takes advantage of the rigorous psychometric development of the QoR-40, but with more interesting feasibility (41). This feasibility is essential to obtain the participation of patients, but also that of the nursing staff. We can print this questionnaire on a single page, in order to facilitate its use as an outcome in trials. QoR-15 is one of the six recommended endpoints for the evaluation of patient comfort in clinical trials according to the Standardized Endpoints in Perioperative Medicine (StEP) initiative (18). Besides, QoR-15 monitoring is recommended by the American Society for Enhanced Recovery to improve clinical care (42). It is important to remember that this scale is especially useful for assessing acute recovery, the measurement time window of which is dependent on the severity of surgical aggression. However, this instrument suffers from the lack of evaluation of cognitive status, which remains a component of postoperative recovery (especially for older patients), and that it was not constructed to evaluate the dynamics of recovery over time.

We can point out some limitations to our study. First, we have studied a wide variety of surgeries, but we did not include emergency surgeries. The use of FQoR-15 in this subpopulation needs to be validated. Second, the estimation of SEM could be affected by a small size of the test-retest population. Thirdly, we note a post-operative improvement for items 6 (communication) and 7 (support), without impacting the evolution of the total score. We can explain this point by the fact that the patients filled in the questionnaires just before surgery. We could have proposed to complete the questionnaire during the anaesthesia consultation, further away from the surgery. This observation should nevertheless guide us to improve communication and support during our preoperative period.

6. Conclusion

Our study validates an alternative version of the French translation of the QoR-15 to measure postoperative recovery, the FQoR-15. This scale verifies all the psychometric parameters necessary for its use by the patient himself, in a wide range of surgery. We recommend the use of this measurement instrument in a French-speaking population, whether for clinical studies or the optimization of care.

ARTICLE 2

Postoperative quality of recovery measurements as endpoints in comparative anaesthesia studies: a systematic review

Maxime Léger[1,2], Maëva Campfort[1], Cléor Cayla[1], Sigismond Lasocki[1] and Emmanuel Rineau[1]

[1] Département d'Anesthésie Réanimation, Centre Hospitalier Universitaire d'Angers, Angers, France.

[2] INSERM UMR 1246 - SPHERE, Nantes University, Tours University, Nantes, France.

1. Abstract

Study objective: Different scales have been developed and translated for measuring the postoperative quality of recovery (QoR). Their use is recommended as patient-centred outcomes. We aimed to systematically review the use of QoR scale as an endpoint in comparative anaesthesia studies.

Design: We systematically searched MEDLINE from January 01st, 1900, to October 30th, 2020, to identify comparative studies evaluating perioperative interventions with a QoR measurement. Three reviewers independently assessed eligibility and extracted data.

Setting: The inclusion criteria were comparative studies in the field of anaesthesia, with the measurement of QoR as an endpoint in an adult population.

Measurements: We collected the type of applied QoR scale, the publication, study and population characteristics, and the types of aneasthesia and surgery included in these studies.

Main results: Of the 339 screened records, 148 (43.7%) comparative studies were included, including 127 (85.8%) randomized controlled trials. The most commonly used scales were the QoR-40 (63 studies, 42.6%), the 9- items QoR (41 studies, 27.7%) and the QoR-15 (22 studies, 14.9%) scores. Throughout the years, the number of comparative studies using a QoR scale increased, with among those considering these scores as primary endpoints, 30.9% of studies before 2018 versus 58.7% from 2018. A wide variety of surgical specialties was represented. Patients were included in countries all over the world, with a predominance of English-speaking countries.

Conclusion: Our review highlights the increasingly and internationally widespread use of postoperative QoR scales to evaluate perioperative outcomes in the field of anaesthesia. The most applied scales were the 9-item QoR, QoR-40 and QoR-15 scores.

Keywords: Anaesthesia, Perioperative Care, Patient Health Questionnaire, Patient- Reported Outcome Measures, Systematic Review, Postoperative Recovery.

2. Introduction

Recovery after surgery and anaesthesia (whether general or locoregional anaesthesia) is a multidimensional process, which carries stress, anxiety, pain, and even minor complications (e.g. nausea or vomiting) (20). Unfortunately, clinical criteria used to evaluate perioperative intervention generally address only a few morbidity parameters, without looking at the overall recovery (43). The usual endpoints include complications that may be observed by clinicians, as the length of stay or the long-term survival. Perioperative adverse events have inconsistent definitions across studies, making it difficult to reproduce and/or compare the different results (19). Beyond this, the current objective is to focus on the evaluation of perioperative interventions on what the patient experienced (i.e., patient-centred outcome measures, PCOMs), rather than on doctors' perceptions of success (44,45). The use of criteria focused on patients' overall recovery has thus become crucial. In a recent international consensus, the SteP–COMPAC group has highlighted the value of postoperative recovery scales for standardizing outcomes in perioperative medicine (18).

The 9-item quality of recovery (QoR) score was one of the first scales developed to evaluate the postoperative QoR (46). In the 2000s, a multidimensional questionnaire – the QoR-40 – has been validated to evaluate the overall QoR on five dimensions (physical comfort, emotional status, physical independence, psychological support, and pain). In 2013, the same team validated the QoR-15 scale which simplified the evaluation, with a shorter completion time, a unidimensional psychometric structure, and an improved responsiveness (4). In parallel, other scales have also been developed such as the postoperative quality of recovery scale (PQRS) (16), or the ObsQoR-11 score for a post-partum use (17). The latest literature reviews on the subject did not address all existing scales, or were not systematic (7,22,47). In addition, many studies using these scales have since been published, necessitating a more up-to-date assessment of the use of QoR scales in clinical anaesthesia research.

Our objective was to evaluate the use of early QoR scale as an endpoint in comparative studies in the field of anaesthesia. The secondary objective was to specifically investigate the use of QoR scales in randomized controlled trials (RCTs). We assumed that QoR scores were increasingly being used as a primary endpoint.

3. Methods

This systematic review was registered (PROSPERO registration number CRD42020211561) and is reported following the Preferred Reporting Items for Systematic Reviews and Meta- Analyses (PRISMA) statement (48).

3.1. Searching strategy

We searched MEDLINE via PubMed® from January 1, 1900, to October 31, 2020, to identify all published comparative studies using a QoR scale as an endpoint (primary or secondary). We focused on the anaesthesia literature, and we selected 24 anaesthesiology journals with the highest impact factors. We used different search terms addressing the QoR, or the use of one of the most popular scales (i.e., QoR score, QoR-40, QoR-15, ObsQoR and the postopQRS) in the title or abstract. The complete search strategy and the list of the selected anaesthesiology journals are presented in **Annex 4 and 5**, respectively.

3.2. Eligibility criteria

The inclusion criteria for considering an article were: comparative study (randomized controlled trial, or prospective or retrospective cohorts), with the use of a scale to measure the QoR as an endpoint, and the assessment of an intervention in the field of anaesthesia (i.e., an invasive procedure such as surgery, interventional radiology, or endoscopy). We focused on human studies involving adults (age > 15 years old). We did not include systematic reviews, meta-analyses, case reports, study protocols, editorial or other comments.

3.3. Study Selection and Data collection

One reviewer (M.L.) screened the titles and abstracts to exclude ineligible articles (neither a comparative study nor an analysis performed on an adult population). Using a piloted electronic data extraction form, three reviewers (M.L., M.C., and C.C.) extracted data independently from the full text of all potentially eligible articles. All extracted data were cross-checked by another reviewer of the group (M.L., M.C., and C.C.). All discrepancies were resolved by the third reviewer who did not participate in the initial collection or cross-checking. For each eligible article, we confirmed the study design (comparative study) while ensuring that it involved an adult population. We focused on the endpoints, and we reported the use of a scale to measure the early QoR (in the

seven days after the surgery), detailing the type of scale. Scores assessing satisfaction, immediate post-anaesthetic recovery, quality of life or psychomotor test were not considered. Articles that did not meet these criteria were excluded. Among excluded articles, for the purpose of a qualitative evaluation, we collected data from studies that validated the original or translated versions of QoR scales as well as from those that validated existing scales on other populations.

The list of included studies and the list of excluded non-comparative studies (for qualitative evaluation) are detailed in **Annex 6 and 7**, respectively.

3.4. Available data

For each included article, we detailed the article information (authors, title, journal of publication, year of publication, study design and the country in which the inclusions were done). We also specified whether the study protocol was registered in a registry. We extracted data concerning the QoR scale (i.e., name of scale, name of the original version of the scale, language used in the study, the different time frames of measurement). We examined whether the QoR score was considered as a primary or secondary outcome. When the QoR scale was a primary outcome, we specified at which timeline the QoR was measured, whether the primary endpoint was statistically significant, and whether the analysis of the primary endpoint required baseline measurement (for value difference analysis or statistical adjustment). For each included article, we collected information concerning the study population (i.e., the number of analysed subjects, the mean age, and the proportion of women), the type of surgical procedure, the type of anaesthesia, and the type of intervention studied. For precision, we considered all types of intervention related to locoregional anaesthesia (e.g., drug, device, dose- comparison) in the category "locoregional anaesthesia".

3.5. Statistical analysis

We presented data as mean ± SD or median [interquartile range] of continuous variables according to their graphical distribution, and the number of occurrences with proportions represented as percentages (%) for categorical variables. For comparison between two groups, we used Chi-square tests for categorical variables (Fisher exact test if necessary), and Student t-tests for continuous variables (Wilcoxon tests if the graphical distribution was asymmetrical). No procedure for correcting the multiplicity of statistical tests has been set up, the analyses being carried out for exploratory purposes. All tests of significance were two-tailed, and we rejected

the null hypothesis if p-value < 0.05. We performed all statistical analyses using R software, version 3.6.3 (http://www.Rproject.org; the R Foundation for Statistical Computing, Vienna, Austria).

4. Results

4.1. Overall characteristics

Of the 339 screened records, 148 (43.7%) comparative studies were included. The flow chart of included studies is provided in **Figure 8**. The median sample size was 89.5 [65.5 – 135.0], while the median age was 50.0 [42.4 – 56.4] years old and the median proportion of women was 63.7% [47.7% – 100.0%]. The main characteristics of the included studies are presented in **Table VII**. More information regarding the characteristics of these studies (e.g., country of inclusion, type of anaesthesia or surgery) is provided in **Table VIII**. Of these comparative studies, 127 (85.8%) were RCTs. For the other studies, 16 (76.2%) were prospective cohorts, 4 (19.0%) were post hoc analyses, and one study (4.8%) had a before/after design. The first uses of a scale to measure the quality of postoperative recovery in a comparative study dated back to the early 2000s, and their use had only increased in recent years. Besides, the publication of comparative studies using a QoR scale had considered these scores more and more as primary endpoints throughout the years (**Figure 9**).

Different types of postoperative QoR scales were used as an endpoint. Those most commonly used in the anaesthesia literature were the QoR-40 (63 studies, 42.6%), the 9-item QoR (41 studies, 27.7%) and the QoR-15 (22 studies, 14.9%) scores. The included studies covered a wide variety of surgical specialties, with gynaecological and obstetrical surgery accounting for a quarter. Five studies concerned the field of gastroenterology (endoscopic procedure), but we found no study on interventional radiology. The main modality of anaesthesia was general anaesthesia that could be combined with locoregional analgesia. Locoregional anaesthesia alone accounted for only 7.5% of the included studies (**Table VIII**). Forty studies (27%) studied specifically an outpatient population. Except for obstetrical studies, none specified the inclusion of emergency surgery. The countries in which patients were included were from all over the world, with a predominance of English-speaking countries (**Table VIII**).

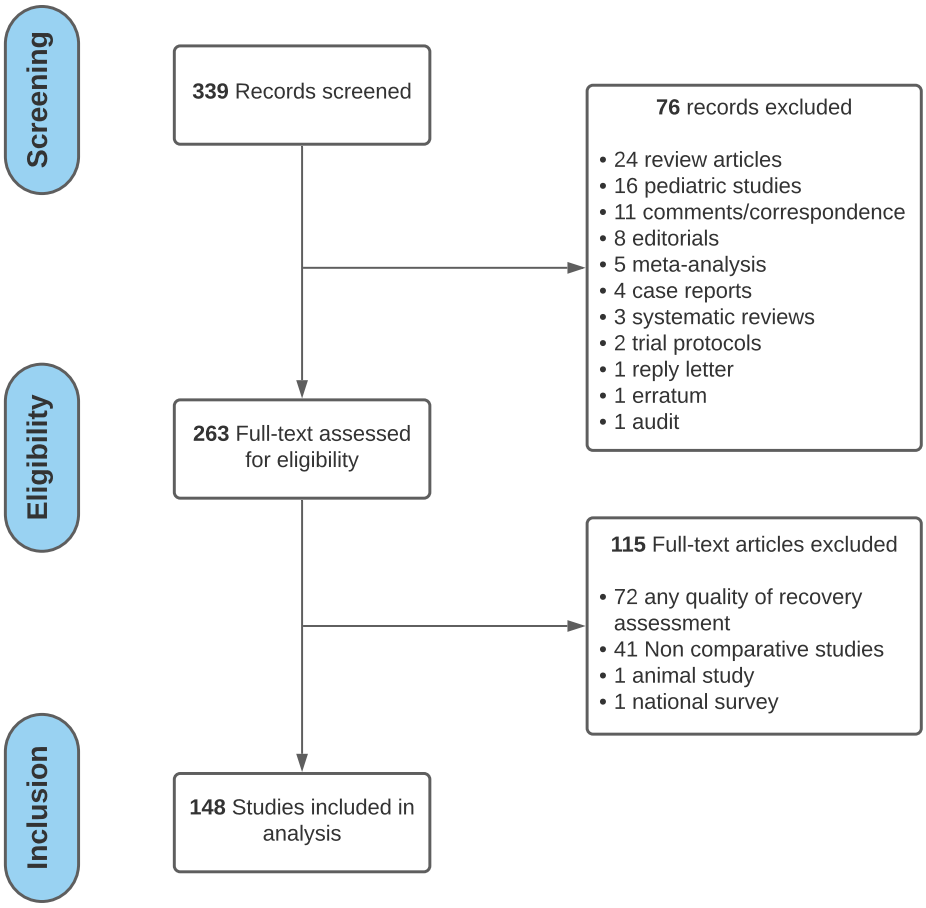

Figure 8. Flow chart of the review

Table VII. Main characteristics of the included studies

Characteristics	Included studies (n=148)	RCTs (n=127)	Other designs (n=21)	p-value
Publication years				0.082
2000 - 2002	6 (4.1)	6 (4.7)	0 (0.0)	
2003 - 2005	9 (6.1)	9 (7.0)	0 (0.0)	
2006 - 2008	14 (9.5)	13 (10.2)	1 (4.8)	
2009 - 2011	18 (12.2)	16 (12.6)	2 (9.5)	
2012 - 2014	25 (16.9)	20 (15.7)	5 (23.8)	
2015 - 2017	25 (16.9)	17 (13.4)	8 (38.1)	
2018 - 2020	51 (34.5)	46 (36.2)	5 (23.8)	
Type of QoR scale				
Numerical scale	9 (6.1)	9 (7.1)	0 (0.0)	
ObsQoR-11	2 (1.4)	2 (1.6)	0 (0.0)	
PQRS	11 (7.4)	4 (3.1)	7 (33.3)	
QoR Score (9 items)	41 (27.7)	35 (27.6)	6 (28.6)	
QoR-15	22 (14.9)	18 (14.2)	4 (19.0)	
QoR-40	63 (42.6)	59 (46.5)	4 (19.0)	
Primary endpoint	66 (44.6)	52 (40.1)	14 (66.6)	0.050
Surgical specialities				0.037
Cardiac and Thoracic	16 (10.8)	13 (10.2)	3 (14.3)	
Ear, Nose and Throat	7 (4.7)	6 (4.7)	1 (4.8)	
Gastroenterology	5 (3.4)	3 (2.4)	2 (9.5)	
General and Urological	28 (18.9)	28 (22.0)	0 (0.0)	
Gynaecological and Obstetrical	36 (24.4)	34 (26.8)	2 (9.5)	
Multiple specialities	23 (15.5)	16 (12.6)	7 (33.3)	
No specified	6 (4.1)	6 (4.7)	0 (0.0)	
Ocular	1 (0.7)	1 (0.8)	0 (0.0)	
Orthopaedic and Spinal	22 (14.9)	16 (12.6)	6 (28.6)	
Plastic	4 (2.7)	4 (3.1)	0 (0.0)	
Type of studied intervention				<0.001
Endoscopic or surgical techniques	6 (4.1)	0 (0.0)	6 (28.6)	
Locoregional anaesthesia	37 (25.0)	37 (29.1)	0 (0.0)	
Medical device	18 (12.2)	15 (11.8)	3 (14.3)	
Medicament (except local anaesthetics)	77 (52.0)	71 (55.9)	6 (28.6)	
Other protocol	5 (3.4)	4 (3.1)	1 (4.8)	
Population comparison	5 (3.4)	0 (0.0)	5 (23.8)	

RCTs, Randomized Controlled Trials; PQRS, Postoperative Quality Recovery Scale; QoR, Quality of Recovery

Table VIII. Detailed characteristics on included studies

Characteristics	Included studies (n=148)	RCTs (n=127)	Other designs (n=21)	p-value
Journal				0.065
Anesth Analg	36 (24.3)	36 (28.3)	0 (0.0)	
Anesthesiology	16 (10.8)	13 (10.2)	3 (14.3)	
J Clin Anesth	13 (8.8)	12 (9.4)	1 (4.8)	
Br J Anaesth	12 (8.1)	9 (7.1)	3 (14.3)	
Eur J Anaesthesiol	9 (6.1)	8 (6.3)	1 (4.8)	
Acta Anaesthesiol Scand	8 (5.4)	4 (3.1)	4 (19.0)	
BMC Anesthesiol	8 (5.4)	7 (5.5)	1 (4.8)	
Can J Anesth	8 (5.4)	8 (6.3)	0 (0.0)	
Anaesth Intensive Care	7 (4.7)	6 (4.7)	1 (4.8)	
Anaesthesia	6 (4.1)	5 (3.9)	1 (4.8)	
J Cardiothorac Vasc Anesth	5 (3.4)	3 (2.4)	2 (9.5)	
Minerva Anestesiol	5 (3.4)	4 (3.1)	1 (4.8)	
Reg Anesth Pain Med	4 (2.7)	3 (2.4)	1 (4.8)	
Pain Med	3 (2.0)	2 (1.6)	1 (4.8)	
J Clin Monit Comput	2 (1.4)	2 (1.6)	0 (0.0)	
J Neurosurg Anesthesiol	2 (1.4)	2 (1.6)	0 (0.0)	
Clin J Pain	1 (0.7)	0 (0.0)	1 (4.8)	
Eur J Pain	1 (0.7)	1 (0.8)	0 (0.0)	
Int J Obstet Anesth	1 (0.7)	1 (0.8)	0 (0.0)	
Pain Physician	1 (0.7)	1 (0.8)	0 (0.0)	
Anaesth Crit Care Pain Med	0 (0.0)	0 (0.0)	0 (0.0)	
Curr Opin Anaesthesiol	0 (0.0)	0 (0.0)	0 (0.0)	
J Anesth	0 (0.0)	0 (0.0)	0 (0.0)	
Pain	0 (0.0)	0 (0.0)	0 (0.0)	
Country				0.001
USA	46 (31.1)	41 (32.3)	5 (23.8)	
Australia	27 (18.2)	18 (14.2)	9 (42.9)	
China	16 (10.8)	16 (12.6)	0 (0.0)	
Canada	12 (8.1)	11 (8.7)	1 (4.8)	
South Korea	8 (5.4)	8 (6.3)	0 (0.0)	
Brasil	6 (4.1)	6 (4.7)	0 (0.0)	
Turkey	5 (3.4)	5 (3.9)	0 (0.0)	
Netherlands	4 (2.7)	4 (3.1)	0 (0.0)	
Sweden	4 (2.7)	3 (2.4)	1 (4.8)	
Germany	3 (2.0)	3 (2.4)	0 (0.0)	
Japan	3 (2.0)	3 (2.4)	0 (0.0)	
Egypt	2 (1.4)	2 (1.6)	0 (0.0)	
France	2 (1.4)	1 (0.8)	1 (4.8)	
Ireland	2 (1.4)	2 (1.6)	0 (0.0)	
Multicentre	2 (1.4)	0 (0.0)	2 (9.5)	
Belgium	1 (0.7)	1 (0.8)	0 (0.0)	
India	1 (0.7)	1 (0.8)	0 (0.0)	
Nepal	1 (0.7)	1 (0.8)	0 (0.0)	
Portugal	1 (0.7)	0 (0.0)	1 (4.8)	
Republic of Korea	1 (0.7)	1 (0.8)	0 (0.0)	
UK	1 (0.7)	0 (0.0)	1 (4.8)	

Table VIII (continued). Detailed characteristics on included studies

Characteristics	Included studies (n=148)	RCTs (n=127)	Other designs (n=21)	p-value
Measurement timelines				
Baseline	56 (38.1)	45 (35.7)	11 (52.4)	0.225
Postoperative H6	3 (2.0)	2 (1.6)	1 (4.8)	0.905
Postoperative H12	4 (2.7)	3 (2.4)	1 (4.8)	1.000
Postoperative H24	122 (83.0)	102 (81.0)	20 (95.2)	0.194
Postoperative H48	48 (32.7)	40 (31.7)	8 (38.1)	0.747
Postoperative H72	37 (25.2)	9 (42.9)	28 (22.2)	0.081
Type of anaesthesia				0.691
General anaesthesia	125 (85.0)	106 (84.1)	19 (90.5)	
Locoregional anaesthesia solely	11 (7.5)	10 (7.9)	1 (4.8)	
Sedation	5 (3.4)	4 (3.2)	1 (4.8)	
Various	6 (4.1)	6 (4.8)	0 (0.0)	
Surgical specialities				0.037
Cardiac	7 (4.7)	6 (4.7)	1 (4.8)	
Ear, Nose and Throat	7 (4.7)	6 (4.7)	1 (4.8)	
Gastroenterology	5 (3.4)	3 (2.4)	2 (9.5)	
Gynaecological	30 (20.3)	29 (22.8)	1 (4.8)	
Multiple specialities	23 (15.5)	16 (12.6)	7 (33.3)	
No specified	6 (4.1)	6 (4.7)	0 (0.0)	
Obstetrical	6 (4.1)	5 (3.9)	1 (4.8)	
Ocular	1 (0.7)	1 (0.8)	0 (0.0)	
Orthopaedic and Spinal	22 (14.9)	16 (12.6)	6 (28.6)	
Plastic	4 (2.7)	4 (3.1)	0 (0.0)	
Thoracic	9 (6.1)	7 (5.5)	2 (9.5)	
Visceral, Digestive and Urological	28 (18.9)	28 (22.0)	0 (0.0)	
Type of hospital admission				0.258
Inpatient	69 (46.6)	61 (48.0)	8 (38.1)	
Outpatient	40 (27.0)	36 (28.3)	4 (19.0)	
ICU	7 (4.7)	6 (4.7)	1 (4.8)	
Various	32 (21.6)	24 (18.9)	8 (38.1)	

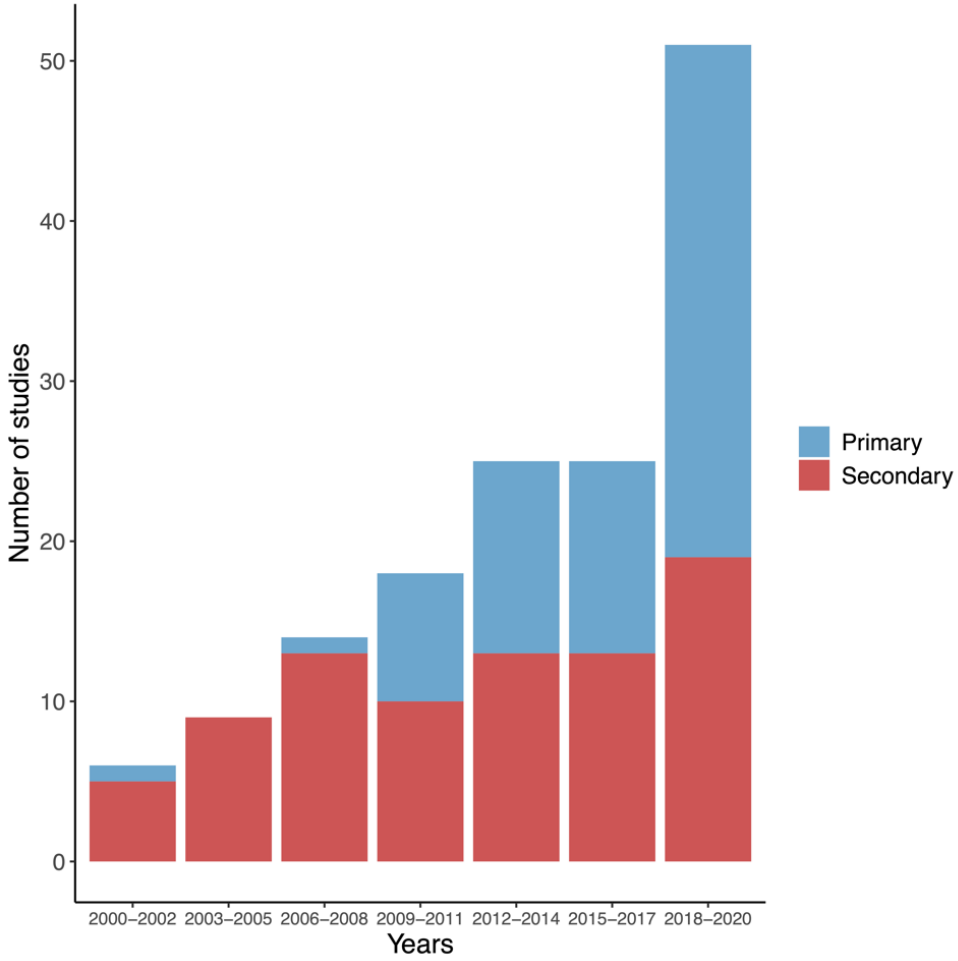

Figure 9. Barplot representing studies using QoR scales as primary or secondary endpoints through years

4.2. Randomized controlled trials characteristics

The same international trend in the geographical distribution of studies was observed for RCTs. **Figure 10** represents the geographical distribution of countries where patients were included in published RCTs using a QoR scale as an endpoint. **Table IX** describes the characteristics of RCTs stratified according to the endpoint's hierarchy (primary versus secondary). Fifty-two RCTs used a QoR scale as the primary endpoint. Most of these studies preferred either the 9- item QoR, QoR-15 or QoR-40 scores, with the recent increased use of the QoR-15 and QoR- 40 scores (**Figure 11**). The majority of surgical specialties have been evaluated by these three scales (**Figure 12**). No surgical specialty seemed to prefer a specific scale predominantly.

Of the studies using QoR measurement as the primary endpoint, 39 (75%) measured QoR at 24 hours after surgery. In these studies, the statistical analysis concluded to a significant difference in the primary endpoint for 31 of them (59.6%). Of the studies using QoR score as the primary endpoint and for which a preoperative measurement was performed, most employed this measure solely to describe the population (24 studies, 75%).

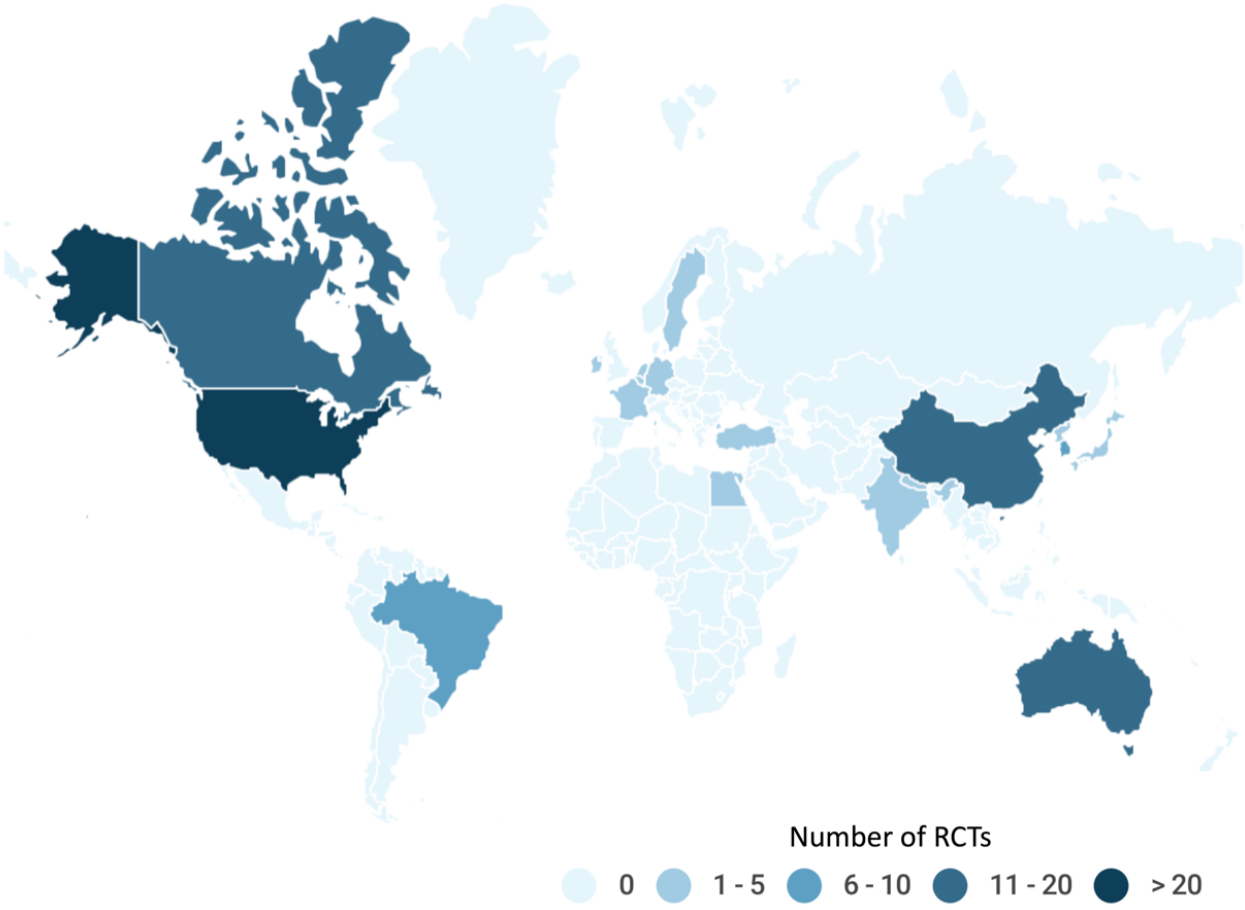

Figure 10. Geographical distribution of RCTs included in the review

Table IX. Main characteristics of included randomised trials stratified according to the QoR measurement as primary or secondary endpoints

Characteristics	Primary endpoint (n=52)	Secondary endpoint (n=75)	p-value
Sample size (n)	79.5 [63.8 – 116.5]	87.0 [62.0 – 117.0]	0.870
Age (years old)	51.7 [42.6 – 56.1]	46.5 [41.3 – 56.6]	0.286
Women (%)	64.5 [47.9 – 100.0]	67.5 [49.3 – 100.0]	0.840
Protocol registration	44 (84.6)	33 (44.6)	<0.001
Type of QoR scale			<0.001
Numerical Scale	0 (0.0)	9 (12.0)	
ObsQoR-11	0 (0.0)	2 (2.7)	
PQRS	3 (5.8)	1 (1.3)	
QoR Score	2 (3.8)	33 (44.0)	
QoR-15	10 (19.2)	8 (10.7)	
QoR-40	37 (71.2)	22 (29.3)	
Measurement timelines			
Baseline	32 (61.5)	13 (17.6)	<0.001
Postoperative H6	0 (0.0)	2 (2.7)	0.638
Postoperative H12	1 (1.9)	2 (2.7)	1.000
Postoperative H24	49 (94.2)	53 (71.6)	0.003
Postoperative H48	16 (30.8)	24 (32.4)	0.998
Postoperative H72	12 (23.1)	16 (21.6)	1.000
Studied Intervention			0.080
Locoregional anaesthesia	17 (32.7)	20 (26.7)	
Medical device	1 (1.9)	14 (18.6)	
Medicament (except local anaesthetics)	32 (61.5)	39 (52.0)	
Other protocol	2 (3.8)	2 (2.7)	

PQRS, Postoperative Quality Recovery Scale; QoR, Quality of Recovery

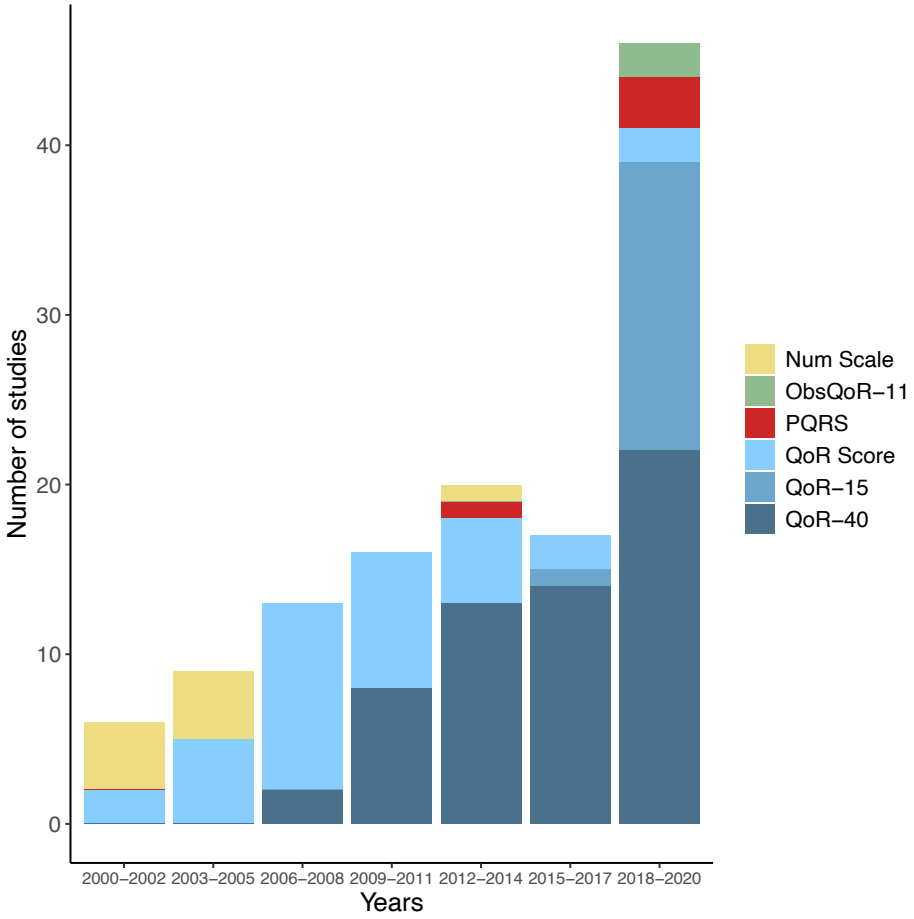

Figure 11. Barplot representing the distribution of use of each QoR scale through years

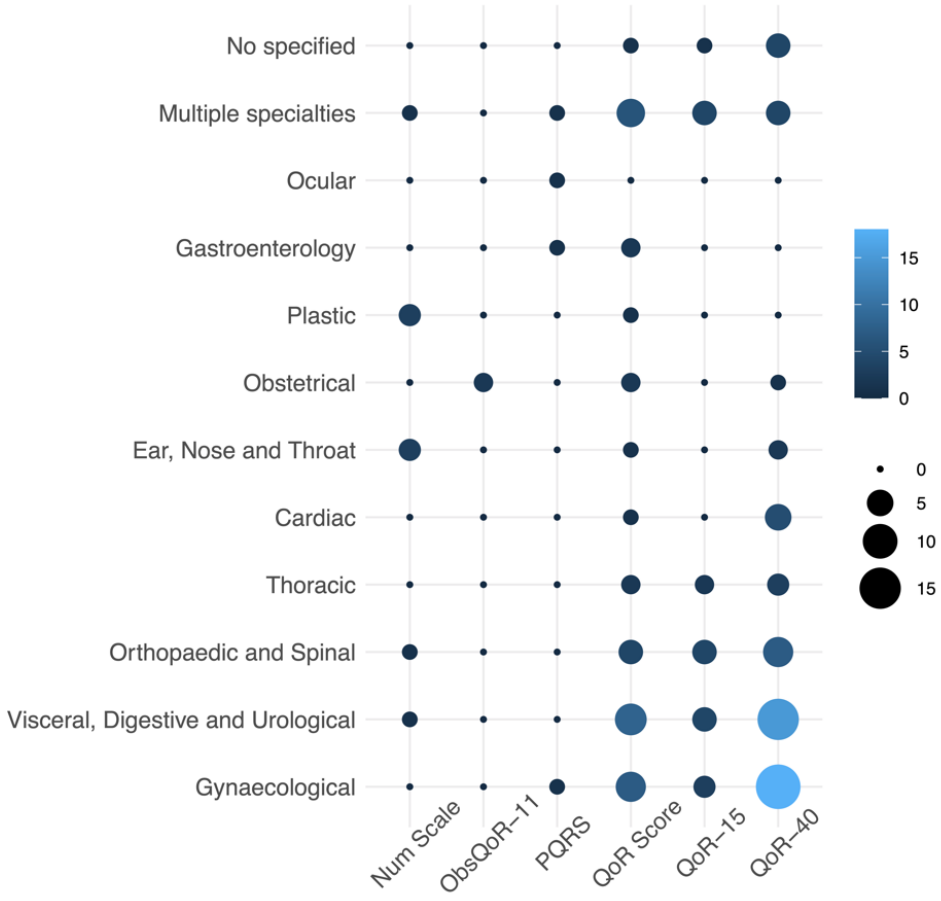

Figure 12. Distribution of each QoR scale' use according to surgical specialty

4.3. Qualitative evaluation of non-comparative studies

Among the 41 non-comparative excluded studies, 5 (12.2%) were the initial development of QoR scales (9-items QoR, QoR-40, QoR-15, ObsQoR-11 scores and PQRS), while 12 (29.3%) studies focused on existing scale translation. More than half of the psychometric translation validations concerned the QoR-15 score. Thirteen other studies (31.7%) investigated the association of postoperative QoR with another parameter (e.g., satisfaction, quality of life, walking ability, fatigue, sleep quality). Nine (22.0%) studies validated an existing QoR scale on another population or by a different mode of administration. One study looked at the minimal clinically important difference for the 9-item QoR, QoR-15 and QoR-40 scores.

5. Discussion

Our systematic review shows an increase in the use of QoR scales in the postoperative phase over the last decade. Initially mostly used as secondary endpoints, these scales have been more recently used as primary endpoints.

The most commonly used scales were the 9-item QoR Score, the QoR-40, and the QoR-15 scores. The recent validation of the ObsQoR-11 score (17), and its new version (i.e., ObsQoR- 10 score) (49), will probably favor their use for the evaluation of interventions in obstetric. PQRS has also been developed and used in clinical trials, without psychometric evaluation or external validation (7). PQRS is based on a dichotomous scoring system in which the postoperative return to a patient's previous baseline value allows to assess the adequate recovery (16). We noted that this scale was employed in only four RCTs, and its use as an endpoint is not proposed by recent consensus (18,42). We did not consider the Surgical Recovery Index (50), nor the Surgical Recovery Scale (51), that assess longer-term recovery.

One of the strengths of global QoR scales is that they integrate several components of the patient's recovery, without emphasizing one (e.g., opioid pain reduction at the cost of adverse effects). QoR values are correlated with patient satisfaction (52), postoperative pain and quality of sleep (53), or even longer-term quality of life (54,55), supporting the construct validity of the measurement. It is also important to note that QoR scales are different from satisfaction scales even though their values are correlated (52). Different scales exist for assessing postoperative satisfaction (56). The multiple psychometric validations of QoR scales on different populations and at different timeframes ensure that we obtain a quantitative, standardized, reliable and reproducible measure of health status after surgery and anaesthesia. As with any measurement, one must remain critical about the size of the effect and its clinical interest. For the QoR Score and its variants, the minimal clinically important differences (MCID), which are here the minimal change in the score corresponding to a perceptible change in health status, have already been determined (6).

Different types of interventions have been studied, in many surgical specialties or even endoscopic procedures, highlighting the broad scope of application of QoR scores. Surgical specialties using a QoR scale ranged, for instance, from cardiac surgery with a postoperative stay in the intensive care unit to outpatient plastic surgery.

Although measurement of QoR is validated at different time points, the most common time frames encountered was 24 hours and 48 hours after surgery. This observation confirms the interest of these scales for the evaluation of early QoR (47). Meanwhile, expert recommendations suggest preoperative measurement of QoR to obtain a baseline value (57), less than half of the included RCTs in our review had performed a baseline measurement.

This is understandable due to the difficulty of assessing recovery before the invasive procedure is performed, and to answer to questions that are unsuitable in a preoperative outpatient assessment (e.g., evaluation of the ability to get support from doctors and nurses).

In our review, we noted that QoR assessments were mainly conducted by self-administered questionnaires completed alone, or face-to-face with an investigator (who may help or not the patient), or even by phone interview. At present, few investigators assessed QoR through the internet via e-mail or mobile app (58).

The use of this type of scale predominates in Anglo-Saxon countries (especially Australia, the United States and Canada), but psychometric validations of different translations of QoR scales allow for broader use in comparative trials worldwide. However, as global disparities persist, we recommend validating QoR scale translations and their use as an endpoint for evaluating perioperative interventions.

Our review has several limitations. Our selection of journals was limited to the English language, and we could not consider publications in Asian literature. Similarly, we focused our search in the field of anaesthesia literature, and we did not review published studies in generalist or surgical journals. Similarly, due to the limitation of the research field to anaesthesia, our qualitative evaluation of the non-comparative studies does not represent all the translations currently validated and published. We also focused on the use of QoR scales in adults, although a field of evaluation also exists in children. Finally, we mainly considered scales evaluating early QoR, but some authors also developed scales to evaluate longer-term recovery. Clinicians can broaden a long-term assessment with the use of the number of days alive and at home up to 30 days after surgery (DAH30) (59), or disability-free survival (60).

6. Conclusion

Our review highlights the increasingly and internationally widespread use of postoperative QoR scales to evaluate a perioperative procedure in the field of anaesthesia. Recently, the most applied scales were the 9-item QoR, QoR-40 and QoR-15 scores. We recommend further translation and validation of these scales to support their usefulness as an endpoint for perioperative intervention assessment.

DISCUSSION

Les données psychométriques du FQoR-15 sont excellentes. La consistance interne est très bonne avec un coefficient de Cronbach supérieur à 0,70. Le questionnaire FQoR-15 est unidimensionnel avec une variance supérieure à 25% que ce soit à 24 ou à 48 heures. La validité construite du questionnaire est également très intéressante avec plus de 75% des hypothèses d'association entre le FQoR-15 et la condition du patient qui sont confirmées. La taille d'effet de Cohen traduit l'excellente sensibilité du test. La reproductibilité du FQoR-15, sa fiabilité et sa facilité de réalisation en pratique clinique en font un très bon questionnaire afin d'évaluer la qualité de récupération postopératoire. Ainsi, à l'instar des autres versions traduites, le FQoR-15 conserve les performances psychométriques initialement décrites avec le QoR-15 (4,5,8,9,15).

Une des forces des échelles de qualité de récupération est l'évaluation du patient dans sa globalité, en prenant en compte différents aspects de sa récupération, et sans se focaliser sur un seul critère comme la « douleur » par exemple. Elles permettent d'obtenir un meilleur reflet de l'expérience péri-opératoire vécue par le patient. Or, c'est bien ce critère qui doit être une des cibles privilégiées dans les études comparant différentes stratégies anesthésiques. En effet, la qualité de récupération postopératoire est associée à la satisfaction des patients concernant les soins qu'ils ont reçu (52), à la douleur postopératoire et à la qualité du sommeil (53), mais aussi à la qualité de vie à long terme (55).

De plus, ne prendre en compte que les complications péri-opératoires au sens médical, comme elles sont décrites dans les diverses classifications (61,62), est vraiment très restrictif. En effet, nous pouvons imaginer un patient en l'absence de symptômes justifiant une ré-hospitalisation ou même l'instauration d'un traitement mais ne pouvant pas être en mesure de reprendre une activité professionnelle ou des activités habituelles du fait d'une fatigue intense par exemple. Ces aspects de la récupération vont avoir un impact social mais aussi économique pour le patient lui-même, ainsi que pour la société (40,63). La considération globale de la récupération du patient permet ainsi de comparer différentes stratégies anesthésiques et/ou chirurgicales et leur impact sur le bien-être médical et socio-économique du patient lors de la phase postopératoire.

Nous avons choisi de nous intéresser au questionnaire QoR-15 car il garde les performances psychométriques du QoR-40 développé quelques années auparavant, tout en présentant une meilleure applicabilité en pratique clinique avec un temps de réalisation de 3 à 4 minutes en moyenne. De plus, la différence minimale ayant un intérêt clinique a été précédemment décrite comme étant égale à 8 (6). D'ailleurs, l'utilisation du QoR-15 fait partie des 6 critères de jugement à intégrer dans les essais cliniques afin d'améliorer le vécu du patient selon le

groupe StEP-COMPAC (18). Il est également recommandé par la société américaine de réhabilitation améliorée après une chirurgie, afin d'améliorer la prise en charge des patients (42).

A la lumière de ces recommandations récentes, il nous semblait donc nécessaire de vérifier comment les échelles évaluant la qualité de récupération sont utilisées dans la littérature anesthésique et si leur emploi se majore, notamment en tant que critère de jugement principal.

Notre revue systématique révèle que le nombre d'études comparatives utilisant une échelle de qualité de récupération comme critère de jugement est croissant avec une utilisation de plus en plus fréquente comme critère de jugement primaire : 30,9% des études avant 2018 contre 58,7% depuis 2018. Les échelles les plus utilisées sont les échelles QoR-40 (63 études, 42,6%), 9-item QoR (41 études, 27,7%) et l'échelle QoR-15 (22 études, 14,9%). Les patients inclus proviennent du monde entier, mais de façon prédominante des pays anglophones non européens (États-Unis 46 études, Australie 27 études, Canada 12 études). Les échéances de mesure les plus utilisées sont à 24 et 48 heures postopératoires (83.0% et 32.7% respectivement).

La validation récente du score ObsQoR-11 (17), mis à jour en ObsQoR-10 (49,64), va favoriser l'utilisation des échelles de qualité de récupération en obstétrique. En ce qui concerne la pédiatrie, un seul score a été validé par une équipe suédoise (65), mais son utilisation dans la littérature reste anecdotique. Ces échelles n'ont pas encore été validées pour la chirurgie en urgence. A noter également, que ces échelles ne permettent pas une évaluation cognitive, qui est pourtant un pan important de la récupération postopératoire, notamment chez les patients âgés.

Il faut donc poursuivre les traductions, adaptations culturelles et validations de ces différentes échelles afin de pouvoir étendre leur utilisation à tous les pays, y compris non-anglophones, d'harmoniser les critères de jugements de la littérature anesthésique et ainsi de faciliter l'interprétation et la comparaison des résultats.

Afin d'encore améliorer la compréhension du FQoR-15 par les patients, nous avons mis à jour le FQoR-15 en ajoutant des icônes de visage à l'échelle numérique (Annexe 8).

CONCLUSION

Notre étude permet de valider la traduction française du questionnaire QoR-15 pour évaluer la récupération post-opératoire avec des données psychométriques intéressantes pour un large panel de chirurgies (allant de la chirurgie cardiaque à la chirurgie ophtalmologique, en passant par la chirurgie gynécologique), y compris la chirurgie ambulatoire et l'anesthésie locorégionale. Son utilisation nous semble aussi pouvoir être appliquée aux autres procédures réalisées sous sédations, comme les endoscopies ou la radiographie interventionnelle. Le questionnaire FQoR-15 est donc utilisable pour des études cliniques comparant des stratégies péri-opératoires pour l'optimisation des soins auprès du patient. Toutefois, son utilisation dans le cadre de la chirurgie en urgence n'a pas encore été étudiée à ce jour.

Les échelles évaluant la qualité de récupération postopératoire sont de plus en plus utilisées dans la littérature, que ce soit en tant que critère de jugement primaire ou secondaire. Leur utilisation est surtout localisée dans les études réalisées dans les pays anglophones non-européens. Toutefois, elles sont actuellement sous-utilisées dans les essais cliniques malgré leur facilité de réalisation avec les moyens de communication modernes (e.g., les applications sur smartphone). Ainsi, l'utilisation de ces échelles centrées sur le patient doit encore s'élargir, notamment dans tous les protocoles d'essais cliniques comparant différentes stratégies péri-opératoires afin d'optimiser leurs standardisation et généralisabilité.

Bibliographie

1. Tevis SE, Kennedy GD. Postoperative complications and implications on patient-centered outcomes. J Surg Res. mai 2013;181(1):106-13.

2. Moerman N. Recollections of general anaesthesia: a survey of anaesthesiological practice. Acta Anesthesio Scand. 1992;5.

3. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S. Validity and reliability of a postoperative quality of recovery score: the QoR-40. Br J Anaesth. janv 2000;84(1):11-5.

4. Stark PA, Myles PS, Burke JA. Development and Psychometric Evaluation of a Postoperative Quality of Recovery ScoreThe QoR-15. Anesthesiol J Am Soc Anesthesiol. 1 juin 2013;118(6):1332-40.

5. Chazapis M, Walker EMK, Rooms MA, Kamming D, Moonesinghe SR. Measuring quality of recovery-15 after day case surgery. Br J Anaesth. févr 2016;116(2):241-8.

6. Myles PS, Myles DB, Galagher W, Chew C, MacDonald N, Dennis A. Minimal Clinically Important Difference for Three Quality of Recovery Scales. Anesthesiology. juill 2016;125(1):39-45.

7. Myles PS. Measuring quality of recovery in perioperative clinical trials. Curr Opin Anaesthesiol. août 2018;31(4):396-401.

8. Sá AC, Sousa G, Santos A, Santos C, Abelha FJ. Quality of Recovery after Anesthesia: Validation of the Portuguese Version of the « Quality of Recovery 15 » Questionnaire. Acta Med Port. oct 2015;28(5):567-74.

9. J K, M EH, R S, J V, I G. Translation and validation of the Danish version of the postoperative quality of recovery score QoR-15. Acta Anaesthesiol Scand. 1 août 2015;59(7):912-20.

10. Bu X-S, Zhang J, Zuo Y-X. Validation of the Chinese Version of the Quality of Recovery-15 Score and Its Comparison with the Post-Operative Quality Recovery Scale. Patient - Patient-Centered Outcomes Res. 1 juin 2016;9(3):251-9.

11. Lyckner S, Böregård I-L, Zetterlund E-L, Chew MS. Validation of the Swedish version of Quality of Recovery score -15: a multicentre, cohort study. Acta Anaesthesiol Scand. août 2018;62(7):893-902.

12. Picconi E, Iacobucci T, Adducci E, Gualtieri E, Beccia G, Sollazzi L. Translation and validation of the Italian version of the postoperative quality of recovery score QoR-15. Minerva Anestesiol [Internet]. juill 2020 [cité 15

mars 2021];86(7). Disponible sur: https://www.minervamedica.it/index2.php?show=R02Y2020N07A0787

13. Kim D, Kim JK, Yeo J. Translation and Validation of the Korean Version of the Postoperative Quality of Recovery Score QoR-15. Wang H-X, éditeur. BioMed Res Int. 9 oct 2020;2020:1-7.

14. Nakatani S, Ida M, Tanaka Y, Okamoto N, Wang X, Nakatani H, et al. Translation and validation of the Japanese Version of the Quality of Recovery-15 Questionnaire. J Anesth [Internet]. 24 mars 2021 [cité 6 mai 2021]; Disponible sur: http://link.springer.com/10.1007/s00540-021-02921-z

15. Demumieux F, Ludes P-O, Diemunsch P, Bennett-Guerrero E, Lujic M, Lefebvre F, et al. Validation of the translated Quality of Recovery-15 questionnaire in a French-speaking population. Br J Anaesth. 14 avr 2020;

16. Royse CF, McKay RE, Hannallah R. Development and Feasibility of a Scale to Assess Postoperative Recovery. Perioper Med. 2010;14.

17. Ciechanowicz S, Setty T, Robson E, Sathasivam C, Chazapis M, Dick J, et al. Development and evaluation of an obstetric quality-of-recovery score (ObsQoR-11) after elective Caesarean delivery. Br J Anaesth. janv 2019;122(1):69-78.

18. Myles PS, Boney O, Botti M, Cyna AM, Gan TJ, Jensen MP, et al. Systematic review and consensus definitions for the Standardised Endpoints in Perioperative Medicine (StEP) initiative: patient comfort. Br J Anaesth. avr 2018;120(4):705-11.

19. Bruce J, Russell EM, Mollison J, Krukowski ZH. The measurement and monitoring of surgical adverse events. Health Technol Assess [Internet]. 2001 [cité 21 janv 2021];5(22). Disponible sur: https://www.journalslibrary.nihr.ac.uk/hta/hta5220/

20. Lee L, Tran T, Mayo NE, Carli F, Feldman LS. What does it really mean to « recover » from an operation? Surgery. févr 2014;155(2):211-6.

21. Neville A, Lee L, Antonescu I, Mayo NE, Vassiliou MC, Fried GM, et al. Systematic review of outcomes used to evaluate enhanced recovery after surgery. Br J Surg. févr 2014;101(3):159-70.

22. Kleif J, Waage J, Christensen KB, Gögenur I. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. Br J Anaesth. janv 2018;120(1):28-36.

23. What are the top 200 most spoken languages? [Internet]. Ethnologue. 2018 [cité 10 avr 2020].

Disponible sur: https://www.ethnologue.com/guides/ethnologue200

24. Toulouse E, Masseguin C, Lafont B, McGurk G, Harbonn A, A Roberts J, et al. French legal approach to clinical research. Anaesth Crit Care Pain Med. 2018;37(6):607-14.

25. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res Int J Qual Life Asp Treat Care Rehabil. mai 2010;19(4):539-49.

26. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. J Clin Epidemiol. avr 2015;68(4):435-41.

27. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 15 déc 2000;25(24):3186-91.

28. Protopapa KL, Simpson JC, Smith NCE, Moonesinghe SR. Development and validation of the Surgical Outcome Risk Tool (SORT). BJS Br J Surg. 2014;101(13):1774-83.

29. Bennett-Guerrero E, Welsby I, Dunn TJ, Young LR, Wahl TA, Diers TL, et al. The use of a postoperative morbidity survey to evaluate patients with prolonged hospitalization after routine, moderate-risk, elective surgery. Anesth Analg. août 1999;89(2):514-9.

30. Terwee CB, Bot SDM, Boer MR de, Windt DAWM van der, Knol DL, Dekker J, et al. Quality criteria are proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60:34-42.

31. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res Int J Qual Life Asp Treat Care Rehabil. août 1995;4(4):293-307.

32. Rouquette A, Falissard B. Sample size requirements for the internal validation of psychiatric scales. Int J Methods Psychiatr Res. déc 2011;20(4):235-49.

33. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika. 1951;16:297-334.

34. Nunnally J, Bernstein I. Psychometric theory. 3rd ed. New York: McGraw-Hill; 1994.

35. McGraw KO, Wong SP. Forming inferences about some intraclass correlation coefficients. Psychol Methods. 1996;1(1):30-46.

36. Stratford P. Reliability: consistency or differentiating among subjects? Phys Ther. avr

1989;69(4):299-300.

37. Kazis LE, Anderson JJ, Meenan RF. Effect sizes for interpreting changes in health status. Med Care. mars 1989;27(3 Suppl):S178-189.

38. Mcdowell I, Newell C. Measuring health: A guide to rating scales and questionnaires, 2nd ed. [Internet]. 1987 [cité 23 avr 2020]. Disponible sur: https://www.semanticscholar.org/paper/Measuring-health%3A-A-guide-to-rating-scales-and-2nd-Mcdowell-Newell/b956cbd326629a99235ede1a5118476653d41aaa

39. Kirshner B, Guyatt G. A methodological framework for assessing health indices. J Chronic Dis. 1985;38(1):27-36.

40. Kleif J, Gögenur I. Severity classification of the quality of recovery-15 score—An observational study. J Surg Res. 1 mai 2018;225:101-7.

41. Bowyer A, Jakobsson J, Ljungqvist O, Royse C. A review of the scope and measurement of postoperative quality of recovery. Anaesthesia. 2014;69(11):1266-78.

42. Abola RE, Bennett-Guerrero E, Kent ML, Feldman LS, Fiore JF, Shaw AD, et al. American Society for Enhanced Recovery and Perioperative Quality Initiative Joint Consensus Statement on Patient-Reported Outcomes in an Enhanced Recovery Pathway. Anesth Analg. 2018;126(6):1874-82.

43. Neville A, Lee L, Antonescu I, Mayo NE, Vassiliou MC, Fried GM, et al. Systematic review of outcomes used to evaluate enhanced recovery after surgery: Outcomes used to evaluate enhanced recovery after surgery. Br J Surg. févr 2014;101(3):159-71.

44. Shulman M, Myles P. Measuring perioperative outcome. 2016;29(6):6.

45. Kalkman CJ, Kappen TH. Patient-centered Endpoints for Perioperative Outcomes Research. Anesthesiology. 1 mars 2015;122(3):481-3.

46. Myles PS, Bs M, Hunt JO, Nightingale CE, Fletcher H, Beh T, et al. Development and Psychometric Testing of a Quality of Recovery Score After General Anesthesia and Surgery in Adults. ANESTH ANALG. 1999;8.

47. Myles PS. More than just morbidity and mortality – quality of recovery and long-term functional recovery after surgery. Anaesthesia [Internet]. janv 2020 [cité 21 janv 2021];75(S1). Disponible sur: https://onlinelibrary.wiley.com/doi/abs/10.1111/anae.14786

48. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA Statement for

Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration. PLoS Med. 21 juill 2009;6(7):e1000100.

49. Sultan P, Kormendy F, Nishimura S, Carvalho B, Guo N, Papageorgiou C. Comparison of spontaneous versus operative vaginal delivery using Obstetric Quality of Recovery-10 (ObsQoR-10): An observational cohort study. J Clin Anesth. août 2020;63:109781.

50. Talamini MA, Stanfield CL, Chang DC, Wu AW. The surgical recovery index. Surg Endosc. 1 avr 2004;18(4):596-600.

51. Paddison JS, Sammour T, Kahokehr A, Zargar-Shoshtari K, Hill AG. Development and Validation of the Surgical Recovery Scale (SRS). J Surg Res. mai 2011;167(2):e85-91.

52. Myles PS, Reeves MDS, Anderson H, Weeks AM. Measurement of Quality of Recovery in 5672 Patients after Anaesthesia and Surgery. Anaesth Intensive Care. juin 2000;28(3):276-80.

53. Wu C, Rowlingson A, Partin A, Kalish M, Courpas G, Walsh P, et al. Correlation of Postoperative Pain to Quality of Recovery in the Immediate Postoperative Period. Reg Anesth Pain Med. nov 2005;30(6):516-22.

54. Myles PS, Hunt JO, Fletcher H, Solly R, Woodward D, Kelly S. Relation between Quality of Recovery in Hospital and Quality of Life at 3 Months after Cardiac Surgery. Anesthesiology. 1 oct 2001;95(4):862-7.

55. Myles PS, Viira D, Hunt JO. Quality of Life at Three Years after Cardiac Surgery: Relationship with Preoperative Status and Quality of Recovery. Anaesth Intensive Care. avr 2006;34(2):176-83.

56. Barnett SF, Alagar RK, Grocott MPW, Giannaris S, Dick JR, Moonesinghe SR. Patient-Satisfaction Measures in Anesthesia. Anesthesiology. 1 août 2013;119(2):452-78.

57. Jammer I, Wickboldt N, Sander M, Smith A, Schultz MJ, Pelosi P, et al. Standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome (EPCO) definitions. Eur J Anaesthesiol. févr 2015;32(2):88-105.

58. Jaensson M, Dahlberg K, Eriksson M, Nilsson U. Evaluation of postoperative recovery in day surgery patients using a mobile phone application: a multicentre randomized trial. Br J Anaesth. nov 2017;119(5):1030-8.

59. Myles PS, Shulman MA, Heritier S, Wallace S, McIlroy DR, McCluskey S, et al. Validation of days at home as an outcome measure after surgery: a prospective cohort study in Australia. BMJ Open. août 2017;7(8):e015828.

60. Shulman MA, Myles PS, Chan MTV, Wallace S. Measurement of Disability-free Survival after Surgery. Perioper Med. 2015;13.

61. Bennett-Guerrero E, Welsby I, Dunn TJ, Young LR, Wahl TA, Diers TL, et al. The Use of a Postoperative Morbidity Survey to Evaluate Patients with Prolonged Hospitalization After Routine, Moderate-Risk, Elective Surgery. ANESTH ANALG. 1999;6.

62. Dindo D, Demartines N, Clavien P-A. Classification of Surgical Complications: A New Proposal With Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. août 2004;240(2):205-13.

63. Bowyer A, Royse C. The importance of postoperative quality of recovery: influences, assessment, and clinical and prognostic implications. Can J Anesth Can Anesth. févr 2016;63(2):176-83.

64. Ciechanowicz S, Howle R, Heppolette C, Nakhjavani B, Carvalho B, Sultan P. Evaluation of the Obstetric Quality-of-Recovery score (ObsQoR-11) following non-elective caesarean delivery. Int J Obstet Anesth. août 2019;39:51-9.

65. Bramhagen A-C, Eriksson M, Ericsson E, Nilsson U, Harden S, Idvall E. Self-reported post-operative recovery in children: development of an instrument: PRiC - post-operative recovery in children. J Eval Clin Pract. avr 2016;22(2):180-8.

Table des matières

Table des figures

Table des tableaux

Table des annexes

Validation of an alternative French version of the Quality of Recovery-15 Score: the FQoR-15

Maxime Léger*, Maëva Campfort, Cléor Cayla, Elsa Parot-Schinkel, Sigismond Lasocki and Emmanuel Rineau

Angers, France

*Corresponding author. E-mail: maxime.leger@chu-angers.fr

Keywords: patient-reported outcome; perioperative care; postoperative recovery; quality of recovery; questionnaire

Editor—Recovery after surgery and anaesthesia is associated with stress, anxiety, pain, and even minor complications.[1] The Standardised Endpoints in Perioperative Medicine—Core Outcome Measures in Perioperative and Anaesthetic Care group has highlighted the value of postoperative recovery scales for standardising outcomes in perioperative medicine.[2] The Quality of Recovery (QoR)-40 score was developed in English to measure the quality of postoperative recovery,[3] and the same team validated the QoR-15 score that can be executed more rapidly.[4] Different translations of the QoR-15 questionnaire exist, including a recent version in French.[5] Our objective was to validate this French version of the QoR-15, the FQoR-15, in a population undergoing a variety of surgeries, including ambulatory surgery, to measure the quality of postoperative recovery at 24 h (H24) and 48 h (H48). The French Ethical Research Committees accepted the study (NCT03967821).

We conducted a monocentric study at Angers University Hospital (Angers, France) from July 2019 to February 2020. Written consent was waived, but all patients were informed and agreed to the data collection, as required by French law.[6] Methods followed the guidelines of the Consensus-Based Standards for the Selection of Health Measurement Instruments.[7] Participants had to meet the following inclusion criteria: age ≥18 yr, French speaker, able to understand and complete the FQoR-15 questionnaire at inclusion (alone or with the help of a third party), and admitted to a hospital for scheduled surgery. We did not include patients with significant psychiatric or cognitive disorders, or patients undergoing intracranial surgery. Cardiac, thoracic, vascular, visceral, urological, gynaecological, orthopaedic, and otorhinolaryngological surgeries were included. Translation of the English-language QoR-15 questionnaire was carried out independently by four investigators fluent in English and French according to existing recommendations following the forward translation/backward translation method.[8] This enabled us to obtain the definitive version: FQoR-15 (Supplementary material). Each item is scored 0 to 10, and the total score is the sum (overall score from 0 to 150, where 0 is the worst and 150 is the best recovery score).

Patients completed the FQoR-15 questionnaire in the immediate preoperative period (baseline, H0), and at 24 h (H24) and 48 h (H48) after surgery. Patients filled out the questionnaire alone if possible, otherwise with the help of an assessor. If the patient had returned home, the assessor interviewed him/her by phone. Each patient was asked to rate his/her general condition at each interval, measured by a VAS ranging from 0 (deplorable general health) to 10 (best general health). At H24 and H48, we noted complications according to the postoperative morbidity survey classification.[9] We timed patients to estimate the duration of completion. We asked patients to repeat the FQoR-15 questionnaire 30 min later to assess repeatability. Psychometric validation consisted of confirming internal consistency, convergent validity, construct validity, reproducibility, responsiveness, scaling properties, acceptability, and feasibility.[7,10] Of 363 patients included for the FQoR-15 validation, 301 patients completed all questionnaires at H0, H24, and H48. Patient characteristics are summarised in Table 1. A significant proportion of procedures (139; 38.3%) were ambulatory surgeries.

The exploratory analysis confirmed the unidimensionality of the FQoR-15, both at H24 and H48; Cronbach's coefficients were 0.832 (95% confidence interval [CI]: 0.806–0.859) at H24, and 0.858 (95% CI: 0.835–0.880) at H48. The FQoR-15 and general condition scores correlated with coefficients of 0.53 (95% CI: 0.45–0.60) at H0, 0.63 (95% CI: 0.57–0.69) at H24, and 0.67 (95% CI: 0.60–0.72) at H48. We also found associations between FQoR-15 score and duration of surgery, length of stay, type of anaesthesia (general *vs* regional), risk of surgery, ambulatory status, and occurrence of complications. Preoperatively, the mean FQoR-15 scores were 125 (18) *vs* 110 (23) at H24, and 117 (22) at H48. The score increased between H24 and H48, consistent with the dynamics of recovery and confirming responsiveness after surgery. We noted no ceiling or floor effect both at H24 and H48. When we compared the questionnaires completed with a 30 min time difference, we calculated an intra-class agreement coefficient of 0.96 (95% CI: 0.91–0.98) with standard error of the mean of 4.18 (95% CI: 3.12–6.33). Patient follow-up confirmed acceptability to complete the questionnaire, and 97% of eligible patients agreed to participate, with 99% of them entirely completing the baseline questionnaire and 83% completing the questionnaire at all three time points. The average time to complete the questionnaire was 3.3 (1.3) min. Additional data are included in the Supplementary material.

Despite a few differences with QoR-15F, we built the items around complete sentences in the FQoR-15. This syntax may facilitate comprehension if the patient has to complete the

Table 1 Patient characteristics. Data are presented as mean (standard deviation), median [inter-quartile range], and number (%). *High-risk surgeries: cardiac surgeries with cardiopulmonary bypass, visceral surgeries with laparotomy, thoracic surgeries with thoracotomy, and orthopaedic surgeries with osteosynthesis. FQoR-15, French version of the Quality of Recovery-15; POMS, postoperative morbidity survey.

	Overall (*n*=363)
Age (yr)	60 [44, 71]
Weight (kg)	75.2 (16.7)
Height (kg)	168.6 (9.2)
Male	217 (59.8)
American Society of Anesthesiologists physical status	
1	106 (29.2)
2	177 (48.7)
3	72 (19.8)
4	8 (2.2)
Unit of admission	
Ambulatory	139 (38.3)
Cardiac surgery	33 (9.0)
Gynaecological surgery	8 (2.2)
Neurosurgery	21 (5.8)
Otorhinolaryngology	10 (2.8)
Orthopaedic surgery	44 (12.1)
Thoracic and vascular surgery	44 (12.1)
Urological surgery	27 (7.4)
Visceral surgery	37 (10.2)
High-risk surgery*	69 (19.0)
Type of anaesthesia	
General	239 (65.8)
General and loco-regional	72 (19.8)
Loco-regional	44 (12.1)
Only sedation	8 (2.2)
Patient co-morbidities	
Cancer	87 (24.0)
Renal disease	18 (5.0)
Cardiac disease	78 (21.5)
Hepatic disease	11 (3.0)
Pulmonary disease	28 (7.7)
Diabetes mellitus	37 (10.2)
Active smoking	78 (21.5)
Addiction history	7 (1.9)
Chronic alcoholism	23 (6.3)
Questionnaire completion time (min)	3.00 [2.00, 4.00]
FQoR-15 preoperatively	125 (18)
FQoR-15 at 24 h	110 (23)
FQoR-15 at 48 h	117 (22)
General condition score preoperatively	7 (2)
General condition score at 24 h	6.7 (2.0)
General condition score at 48 h	7.0 (1.8)
POMS complication at 24 h	152 (42)
None	211 (58)
Cardiovascular	2 (0.6)
Pain	71 (20)
Gastrointestinal	20 (5)
Infectious	2 (0.6)
Pulmonary	53 (15)
Renal	3 (0.8)
Operating site	1 (0.3)
POMS complication at 48 h	49 (14)
None	314 (86)
Cardiovascular	3 (0.8)
Pain	23 (6)
Gastrointestinal	6 (2)
Haematological	2 (0.6)
Infectious	2 (0.6)
Neurological	1 (0.3)
Pulmonary	11 (3)
Renal	1 (0.3)

Table 1 Continued

	Overall (*n*=363)
Operating time (min)	95.0 [70.0, 140.0]
Duration in PACU (min)	107.0 [83.8, 130.0]
Hospital length of stay (day)	1.0 [0.0, 4.0]

questionnaire alone, or if it has to be completed by an unexperienced assessor. We believe that the target population for use of this tool is all surgical patients under general or loco-regional anaesthesia. It was important to study a wide range of surgeries to highlight the generalisability of this score, including ambulatory surgeries. Thereby, we confirmed use of this score by telephone calls. Our study validates all the psychometric parameters of the FQoR-15 score for measuring quality of recovery in a wide range of surgeries, whether for clinical studies or the optimisation of care.

Acknowledgements

The authors thank the participating patients and the doctors at Angers University Hospital for their investment in this study.

Declarations of interest

The authors declare that they have no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.05.052.

References

1. Lee L, Tran T, Mayo NE, Carli F, Feldman LS. What does it really mean to 'recover' from an operation? *Surgery* 2014; **155**: 211–6
2. Myles PS, Boney O, Botti M, et al. Systematic review and consensus definitions for the Standardised Endpoints in Perioperative Medicine (StEP) initiative: patient comfort. *Br J Anaesth* 2018; **120**: 705–11
3. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S. Validity and reliability of a postoperative quality of recovery score: the QoR-40. *Br J Anaesth* 2000; **84**: 11–5
4. Stark PA, Myles PS, Burke JA. Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15. *Anesthesiology* 2013; **118**: 1332–40
5. Demumieux F, Ludes P-O, Diemunsch P, et al. Validation of the translated Quality of Recovery-15 questionnaire in a French-speaking population. *Br J Anaesth* 2020; **124**: 761–7
6. Toulouse E, Masseguin C, Lafont B, et al. French legal approach to clinical research. *Anaesth Crit Care Pain Med* 2018; **37**: 607–14
7. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010; **19**: 539–49

8. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* 2000; **25**: 3186–91
9. Bennett-Guerrero E, Welsby I, Dunn TJ, et al. The use of a postoperative morbidity survey to evaluate patients with prolonged hospitalization after routine, moderate-risk, elective surgery. *Anesth Analg* 1999; **89**: 514–9
10. Terwee CB, Bot SDM, de Boer MR, et al. Quality criteria are proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007; **60**: 34–42

doi: 10.1016/j.bja.2020.05.052
Advance Access Publication Date: 9 July 2020

CORRESPONDENCE

Postoperative quality of recovery measurements as endpoints in comparative anaesthesia studies: a systematic review

Maxime Léger[1,2,*], Maëva Campfort[1], Cléor Cayla[1], Sigismond Lasocki[1] and Emmanuel Rineau[1]

[1]Département d'Anesthésie Réanimation, Centre Hospitalier Universitaire d'Angers, Angers, France and [2]INSERM UMR 1246, SPHERE, Nantes University, Tours University, Nantes, France

*Corresponding author. E-mail: maxime.leger@chu-angers.fr, Twitter: @mxmleger

Keywords: patient-centred outcome; perioperative medicine; quality of postoperative recovery; recovery; surgery; systematic review

Editor—Recovery after surgery and anaesthesia is a multidimensional process that carries stress, anxiety, pain, and even minor complications.[1] Clinical evaluation of perioperative intervention generally addresses only some morbidity parameters without looking at the overall recovery.[2] These evaluations should focus on what the patient experienced (i.e. patient-centred outcome measures) rather than on doctors' perceptions of success.[3] Several scales have been developed and validated to measure the quality of postoperative recovery (QoR) (e.g. the 9-item QoR,[4] QoR-40,[5] QoR-15,[6] ObsQoR-11 scores,[7] or even the postoperative quality of recovery scale[8]). In a recent international consensus, the SteP–COMPAC group has highlighted the value of these postoperative recovery scales for standardising outcomes in perioperative medicine.[9] Our objective was to evaluate the use of early QoR scales as an endpoint in comparative studies in the field of anaesthesia.

This systematic review was registered (PROSPERO registration number CRD42020211561). We searched MEDLINE via PubMed from January 1, 1900 to October 31, 2020 to identify all published comparative studies using a QoR scale as an endpoint (primary or secondary). We focused on the anaesthesia literature, and selected the 24 anaesthesiology journals with the highest impact factors. We applied different search terms addressing the QoR or the use of one of the most popular scales in the title or abstract. The complete search strategy and list of the selected anaesthesiology journals are presented in the Supplementary material. Inclusion criteria for considering an article were: comparative study using a scale to measure the QoR as an endpoint, and assessing an intervention in the field of anaesthesia. We focused on human studies involving adults (age >15 yr old). We did not include systematic reviews, meta-analyses, case reports, study protocols, editorials, or other comments. One reviewer (ML) screened the titles and abstracts to exclude ineligible articles. Three reviewers (ML, MC, and CC) extracted data independently from the full text of all potentially eligible articles. Another reviewer of the group cross-checked all extracted data. All discrepancies were resolved by the third reviewer, who did not participate in the initial collection or cross-checking. We focused on the endpoints, and reported the use of a scale to measure the early QoR, detailing data concerning the QoR scale. We detailed article information including authors, title, journal of publication, year of publication, study design, and the country in which the patients were included. We collected information concerning the study population, the type of surgical procedure, the type of anaesthesia, and the type of intervention studied. The list of included studies, list of excluded non-comparative studies, and the flow chart are detailed in the Supplementary material.

Of 339 screened records, 148 (43.7%) comparative studies were included. The median sample size was 89.5 (65.5–135.0), while the median age was 50.0 (42.4–56.4) yr and the median proportion of women was 63.7% (47.7–100.0%). The main characteristics of the included studies are presented in Supplementary material. Among the included studies, 127 (85.8%) were RCTs. For the other studies, 16 (76.2%) were prospective cohorts, four (19.0%)

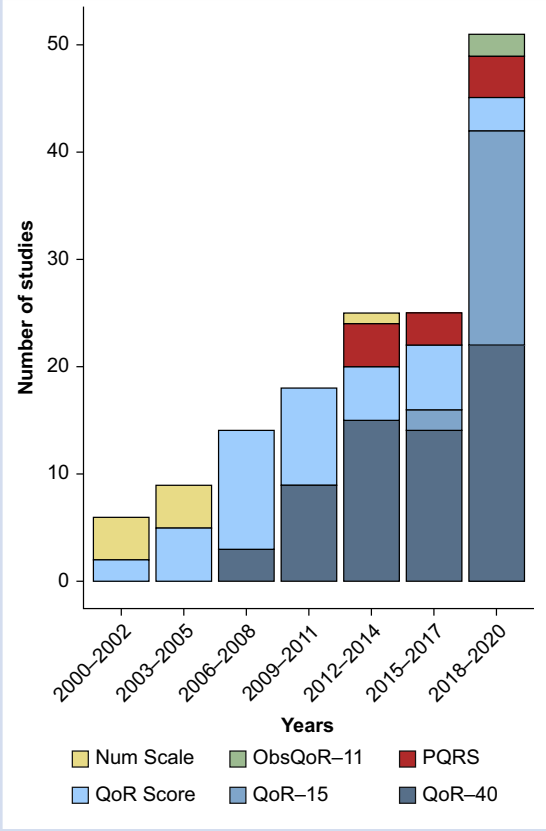

Fig 1. Time representation of the use of a postoperative recovery quality scale as an endpoint in comparative studies according to the type of QoR scale. Num Scale, numerical scale; PQRS, postoperative quality recovery scale; QoR, quality of postoperative recovery.

were *post hoc* analyses, and one (4.8%) had a before/after design. The first uses of a QoR scale in a comparative were in the early 2000s, and their use has only increased in recent years (Fig. 1). The QoR scores most commonly used as endpoints were the QoR-40 (63 studies, 42.6%), the 9-items QoR (41 studies, 27.7%), and the QoR-15 (22 studies, 14.9%). Figure 1 highlights the recent increased use of the QoR-15 and QoR-40 scores. The included studies covered a wide variety of surgical specialities, with gynaecological and obstetrical surgery accounting for 25%, general surgery for 18.9%, and orthopaedic surgery for 14.9% (see Supplementary material). The majority of surgical specialities have been evaluated by the 9-items QoR, the QoR-40, and the QoR-15 scores. Five studies concerned gastroenterology (endoscopic procedures), but we found no study on interventional radiology. Four studies used the ObsQoR-11 score to assess postpartum QoR. The main modality of anaesthesia was general anaesthesia that could be combined with locoregional analgesia (85.0%), whereas locoregional anaesthesia alone represented 7.5% of the studies. Forty studies (27%) studied specifically an outpatient population. The studies were conducted in countries around the world, with a predominance of non-European English-speaking countries (USA, 46 studies; Australia, 27 studies; Canada, 12 studies; more detailed information in Supplementary material). Several European countries reported less than three studies with the use of a QoR scale (e.g. Germany, France, UK). The most frequently used measurement timelines were H24 (83.0%) and H48 (32.7%), with 68 studies (45.9%) measuring QoR at multiple timelines. Only seven studies (4.7%) measured QoR at 1 month or more. It is probably preferable to use quality of life scales at this time.

Fifty-two RCTs (35.1%) used a QoR scale as the primary endpoint. Among them, 39 RCTs (75%) measured QoR at 24 h after surgery. The statistical analysis concluded that there was a significant difference in the primary endpoint for 31 (59.6%).

One of the strengths of global QoR scales is that they integrate several components of patient recovery without emphasising one (e.g. opioid pain reduction at the cost of adverse effects). The multiple psychometric validations of QoR scales on different populations and at different timeframes ensure a quantitative, standardised, reliable, and reproducible measure of health status after surgery and anaesthesia. A few limitations restrain the diffusion of these scales: the psychometric validation of translations is complex, filling in the survey may require time and external help, and their use is difficult for patients with cognitive problems or who do not speak the appropriate language.

Despite the increasing use of QoR scales in anaesthesia over the past decade, our review shows that these scales are still under-used as primary endpoints in RCTs. Few studies have used these recovery scales in the countries of the European continent so far. We recommend further translation and validation of these scales to support their usefulness as an endpoint for perioperative intervention assessment.

Authors' contributions

Designed the study: ML, MC, CC, ER
Carried out the review and selection of the included studies, and acquired the data: ML, MC, CC
Conducted the statistical analysis: ML
Wrote the first draft of the manuscript: ML, MC, CC, ER
Made substantial contributions to the conceptual design and revised the final version of the manuscript: SL
Contributed to conception and design, acquisition of data, or analysis and interpretation of data; drafted the article or revised it critically for important intellectual content; approved the final version; and agreed to be accountable for all aspects of the work thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: all authors.

Declarations of interest

ML was the developer of a validated version of the French translation of the QoR-15 (FQoR-15). No other competing interests declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2021.03.008.

References

1. Lee L, Tran T, Mayo NE, Carli F, Feldman LS. What does it really mean to "recover" from an operation? *Surgery* 2014; **155**: 211–6
2. Neville A, Lee L, Antonescu I, et al. Systematic review of outcomes used to evaluate enhanced recovery after surgery. *Br J Surg* 2014; **101**: 159–70
3. Kalkman CJ, Kappen TH. Patient-centered endpoints for perioperative outcomes research. *Anesthesiology* 2015; **122**: 481–3
4. Myles PS, Hunt JO, Nightingale CE, et al. Development and psychometric testing of a quality of recovery score after general anesthesia and surgery in adults. *Anesth Analg* 1999; **88**: 83–90
5. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S. Validity and reliability of a postoperative quality of recovery score: the QoR-40. *Br J Anaesth* 2000; **84**: 11–5
6. Stark PA, Myles PS, Burke JA. Development and psychometric evaluation of a postoperative quality of recovery score the QoR-15. *Anesthesiology* 2013; **118**: 1332–40
7. Ciechanowicz S, Setty T, Robson E, et al. Development and evaluation of an obstetric quality-of-recovery score (ObsQoR-11) after elective Caesarean delivery. *Br J Anaesth* 2019; **122**: 69–78
8. Royse CF, Newman S, Chung F, et al. Development and feasibility of a scale to assess postoperative recovery: the post-operative quality recovery scale. *Anesthesiology* 2010; **113**: 892–905
9. Myles PS, Boney O, Botti M, et al. Systematic review and consensus definitions for the Standardised Endpoints in Perioperative Medicine (StEP) initiative: patient comfort. *Br J Anaesth* 2018; **120**: 705–11

doi: 10.1016/j.bja.2021.03.008

FQoR-15

PARTIE A

Comment vous êtes-vous senti au cours des dernières 24 heures ?

Veuillez entourer le chiffre qui correspond le mieux à votre ressenti pour chaque item.

(0 à 10, 0 = Jamais et 10 = Tout le temps)

1. Vous êtes-vous senti capable de respirer facilement ?
2. Vous êtes-vous senti capable d'apprécier vos repas ?
3. Vous êtes-vous senti reposé ?
4. Avez-vous réussi à bien dormir ?
5. Vous êtes-vous senti capable de faire votre toilette tout seul ?
6. Vous êtes-vous senti capable de communiquer avec votre famille et vos amis ?
7. Avez-vous ressenti un soutien de la part de l'équipe soignante ?
8. Vous êtes-vous senti capable de retourner travailler ou de faire vos activités habituelles chez vous ?
9. Vous êtes-vous senti en pleine possession de vos moyens ?
10. Vous êtes-vous senti bien ?

Jamais → *Tout le temps*
0 1 2 3 4 5 6 7 8 9 10

PARTIE B

Avez-vous eu au cours des dernières 24 heures …

Veuillez entourer le chiffre qui correspond le mieux à votre ressenti pour chaque item.

(0 à 10, 10 = Jamais et 0 = Tout le temps; Attention à l'inversion des chiffres !)

11. Une douleur modérée ?
12. Une douleur importante ?
13. Des nausées ou des vomissements ?
14. De l'inquiétude ou de l'anxiété ?
15. Un sentiment de tristesse ou de déprime ?

Jamais → *Tout le temps*
10 9 8 7 6 5 4 3 2 1 0

Annexe 4. Searching strategy

#1 Selection of studies which evaluated the concept of recovery quality or used potential scales of measurement

"quality of recovery"[Title/Abstract] OR "recovery quality"[Title/Abstract] OR "quality recovery"[Title/Abstract] OR "QoR"[Title/Abstract] OR "QoR-15"[Title/Abstract] OR "QoR-40"[Title/Abstract] OR "obsQoR"[Title/Abstract] OR "postopQRS"[Title/Abstract] OR "post-operative recovery"[Title/Abstract]

#2 Selection of the top journals in the field of anesthesiology

"Anesthesiology"[Journal] OR "Br J Anaesth"[Journal] OR "Anesth Analg"[Journal] OR "Anaesthesia"[Journal] OR "Reg Anesth Pain Med"[Journal] OR "J Neurosurg Anesthesiol"[Journal] OR "Eur J Anaesthesiol"[Journal] OR "Can J Anaesth"[Journal] OR "Acta Anaesthesiol Scand"[Journal] OR "Minerva Anestesiol"[Journal] OR "J Clin Monit Comput"[Journal] OR "Curr Opin Anaesthesiol"[Journal] OR "Paediatr Anaesth"[Journal] OR "Int J Obstet Anesth"[Journal] OR "J Cardiothorac Vasc Anesth"[Journal] OR "BMC Anesthesiol"[Journal] OR "Anaesth Intensive Care"[Journal] OR "J Clin Anesth"[Journal] OR "J Anesth"[Journal] OR "Anaesth Crit Care Pain Med"[Journal] OR "Pain"[Journal] OR "Clin J Pain"[Journal] OR "Eur J Pain"[Journal] OR "Pain Med"[Journal] OR "Pain Physician"[Journal]

#3 No publication date restriction

"1900/01/01"[Date - Publication] : "2020/10/31"[Date - Publication]

#1 AND #2 AND #3

339 RESULTS

Annexe 5. Selected anaesthesiology journals for the review

Acta Anaesthesiologica Scandinavica (Acta Anaesthesiol Scand)
Anaesthesia and Intensive Care (Anaesth Intensive Care)
Anesthesiology (Anesthesiology)
Anesthesia & Analgesia (Anesth Analg)
Anaesthesia (Anaesthesia)
BMC Anesthesiology (BMC Anesthesiol)
British Journal of Anaesthesia (Br J Anaesth)
Canadian Journal of Anesthesia (Can J Anaesth)
Current Opinion in Anaesthesiology (Curr Opin Anaesthesiol)
European Journal of Anaesthesiology (Eur J Anaesthesiol)
European Journal of Pain (Eur J Pain)
International Journal of Obstetric Anesthesia (Int J Obstet Anesth)
Journal of Anesthesia (J Anesth)
Journal of Cardiothoracic and Vascular Anesthesia (J Cardiothorac Vasc Anesth)
Journal of Clinical Anesthesia (J Clin Anesth)
Journal of Clinical Monitoring and Computing (J Clin Monit Comput)
Journal of Neurosurgical Anesthesiology (J Neurosurg Anesthesiol)
Minerva Anestesiologica (Minerva Anestesiol)
Pain (Pain)
Pain Medicine (Pain Med)
Pain Physician Journal (Pain Physician)
Pediatric Anesthesia (Paediatr Anaesth)
Regional Anesthesia & Pain Medicine (Reg Anesth Pain Med)
The Clinical Journal of Pain (Clin J Pain)

FQoR-15

Comment vous êtes-vous senti au cours des dernières 24 heures ? (Veuillez entourer)

(0 à 10, **0 = Jamais** *[Vraiment faible]* et **10 = Tout le temps** *[Excellent]*)

1. Vous êtes-vous senti capable de respirer facilement ?
2. Vous êtes-vous senti capable d'apprécier vos repas
3. Vous êtes-vous senti reposé ?
4. Avez-vous réussi à bien dormir ?
5. Vous êtes-vous senti capable de faire votre toilette tout seul ?
6. Vous êtes-vous senti capable de communiquer avec votre famille et vos amis ?
7. Avez-vous ressenti un soutien de la part de l'équipe soignante ?
8. Vous êtes-vous senti capable de retourner travailler ou de faire vos activités habituelles chez vous ?
9. Vous êtes-vous senti en pleine possession de vos moyens ?
10. Vous êtes-vous senti bien ?

Jamais — *Tout le temps*

0 1 2 3 4 5 6 7 8 9 10

Avez-vous eu au cours des dernières 24 heures … (Veuillez entourer)

(10 à 0, **10 = Jamais** *[Excellent]* et **0 = Tout le temps** *[Vraiment faible]*)

11. Une douleur modérée ?
12. Une douleur importante ?
13. Des nausées ou des vomissements ?
14. De l'inquiétude ou de l'anxiété ?
15. Un sentiment de tristesse ou de déprime ?

Jamais — *Tout le temps*

10 9 8 7 6 5 4 3 2 1 0

CAMPFORT Maëva

Traduction et validation du questionnaire QoR-15 en français et revue de la littérature sur l'utilisation des échelles de récupération dans la littérature anesthésique

RÉSUMÉ

Introduction : L'utilisation de critères de jugement centrés sur le patient est recommandée pour représenter au mieux leur vécu et leur récupération dans les études anesthésiques. Différentes échelles ont été développées, validées et traduites pour mesurer la qualité de récupération postopératoire (QoR). Notre objectif était de traduire et de valider l'échelle QoR-15 en français puis de faire une revue systématique de l'utilisation d'échelle de QoR comme critère de jugement dans des études cliniques comparatives publiées dans la littérature anesthésique.
Matériels & méthodes : Après accord du comité de protection des personnes, l'étude prospective a été conduite de juillet 2019 à février 2020 au CHU d'Angers. Les patients inclus ont complété le questionnaire avant l'intervention chirurgicale, à 24 heures et à 48 heures après la chirurgie. Pour la revue de la littérature, nous avons fait une recherche systématique dans MEDLINE, comprenant les articles publiés entre le 1er janvier 1900 et le 30 octobre 2020, parmi une sélection de 24 revues d'anesthésie. Les critères d'inclusions étaient : les études comparatives réalisées chez l'adulte, utilisant une échelle de QoR comme critère de jugement.
Résultats : 301 patients ont été inclus pour la validation du score FQoR-15, avec un large panel de chirurgies représentées. Le FQoR-15 fait preuve d'une excellente cohérence interne (coefficient de Cronbach > 0.8), avec une bonne réponse aux changements. Le score est inversement corrélé à la durée de la chirurgie et à la durée d'hospitalisation. Il est inversement associé à la survenue de complications (p<0.001). 148 (43,7%) études comparatives ont été inclues dans notre revue systématique, dont 127 (85,8%) essais randomisés contrôlés. Les échelles les plus utilisées sont les échelles QoR-40 (n=63), 9-item QoR (n=41) et l'échelle QoR-15 (n=22). Le nombre d'études est croissant, avec une utilisation de plus en plus fréquente en tant que critère de jugement primaire. Les patients inclus proviennent du monde entier, mais de façon prédominante des pays anglophones non européens (États-Unis n=46, Australie n=27, Canada n=12).
Conclusion : Le FQoR-15 est un questionnaire psychométrique validé pour évaluer la qualité de la récupération après une intervention chirurgicale programmée dans une population francophone. L'utilisation des échelles de QoR comme critère de jugement est croissante dans la littérature anesthésique. Toutefois, elles restent sous-utilisées dans les études cliniques interventionnelles malgré leur simplicité de réalisation.

Mots-clés : Anesthésie, FQoR-15, QoR-15, qualité de récupération, QoR, traduction, validation, revue, QoR-40, 9-item QoR, ObsQoR-11, ObsQoR-10, PQRS

Translation and validation of QoR-15 score in French and systematic review of the use of quality of recovery scales in anaesthesia literature

ABSTRACT

Introduction: The use of patient-centred outcomes is recommended for a better representation of their lives and their recovery in anaesthesia literature. Different scales were developed, validated and translated for measuring quality of postoperative recovery (QoR). Our goal was to translate and validate a French version of QoR-15; and perform a systematic review of QoR scales used as outcomes in comparative clinical studies published in anaesthesia.
Materials & methods: After ethics committee agreement, the prospective study was conducted from July 2019 to February 2020 in Angers University Hospital. Enrolled patients have completed the form before the surgery, at 24 hours and 48 hours after the surgery. Concerning the review, we did systematic research on MEDLINE, including publications between 1st January 1900 and 30th October 2020, among a selection of 24 anaesthesia journals. Inclusion criteria were comparative studies interested in adult population and using a QoR scale as outcome.
Results: 301 patients were included for the validation of the FQoR-15 score with a large panel of represented surgeries. FQoR-15 has an excellent internal consistency (Cronbach's coefficient > 0.8), with an acceptable responsiveness. The score is conversely correlated to surgical duration, to length of hospital stay and to complications occurrence (p<0.001). 148 (43,7%) comparative studies were included for the review, with 127 (85,8%) randomized controlled trials. The most frequent scales were QoR-40 (n=63), 9-item QoR (n=41) and QoR-15 score (n=22). The use of postoperative QoR scales is increasing, with a more frequent application as primary outcome. Included patient are coming from all over the world, but mostly from non-European English-speaking countries (United-States n=46, Australia n=27, Canada n=12).
Conclusion: FQoR-15 is a psychometric score validated for postoperative QoR evaluation in elective surgery for French-speaking patients. The use of QoR scales as outcomes in anaesthesia studies is increasing. However, these scales are underutilized in interventional clinical studies despite their ease of application.

Keywords: Anaesthesia, FQoR-15, QoR-15, quality of recovery, QoR, translation, validation, review, QoR-40, 9-item QoR, ObsQoR-11, ObsQoR-10, PQRS

FACULTÉ DE SANTÉ
UNIVERSITÉ D'ANGERS