

Patient-reported outcomes: validation of the French Quality of Recovery-15 score in cardiac surgery

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	1	Patient reported outcomes: validation of the quality of recovery-15 score in cardiac
1 2	2	surgery
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11 12	8	Short Title: Patient reported outcome in cardiac surgery
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	24 25 26 27 28 29 30 31 32 33	Corresponding author: Grégoire LE GAC, Hôpital Pontchaillou Grégoire LE GAC, Hôpital Pontchaillou, Département d'Anesthésie-Réanimation et Médecine Péri-Opératoire, 2 rue Henri Le Guilloux, 35033 Rennes Cedex 9, France. Tel.: +33.2.99.28.91.53; Fax: +33.2.99.28.24.21; E-mail: <u>Gregoire.le.gac@chu-rennes.fr</u> Keywords: patient-reported outcomes, cardiac surgery, perioperative medicine, quality of recovery, critical care.
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The increasing number of individuals undergoing surgical procedures has made the improvement of postoperative recovery a major global health concern¹⁻³. The 15-item Quality of Recovery (QoR-15) score, introduced in 2012^{4, 5}, is one example of a patient-centred outcome measure designed for perioperative medicine. This score has been validated in the French language^{6, 7}. However, the QoR-15 has not been validated in the setting of cardiac surgery, which involves invasive procedures under cardiopulmonary bypass (CPB), followed by systematic admission in the intensive care unit (ICU)⁸ with a moderate to high rate of complications^{9, 10}. This study aimed to validate the French version of the QoR-15 score in a cohort of cardiac surgical patients.

This prospective observational cohort study (NCT05684354) received ethical approval (Ethic Committee CPP Est IV, France; 22.01827.000088; 07/22/2022). Oral informed consent was obtained from all participating patients prior to inclusion, following oral and written information provided either the day before or on the morning of the surgery. We included all consecutive adult patients scheduled for cardiac surgery under CPB. Adults subject to legal protection or undergoing non-elective surgery were not included. We used the French version of the QoR-15⁶. The preoperative QoR-15 was performed at baseline, either the day before or on the morning of the surgery. All patients were admitted to the cardiothoracic ICU for a minimum of 24 hours immediately following surgery, and subsequently transferred to the cardiothoracic surgery ward. To account for this post-operative management and to assess the overall patient stay, the postoperative QOR-15 was measured after ICU discharge in the cardiothoracic surgery ward on the 7th postoperative day. If a patient was discharged before day 7, or had an extended ICU stay, the QOR-15 was conducted on the day of, or the day before, discharge. Patients completed the questionnaire independently, but assistance from one of the investigators was available if needed. Based on previous studies^{5,6}, the primary outcome was the convergent validity (accuracy) of the QoR-15 score in measuring the quality of postoperative recovery. Patients were asked to evaluate their global postoperative recovery using a Visual Analog Scale (VAS) ranging from 0 to 100, where 0 indicated the worst possible recovery and 100 the best⁵. Secondary outcomes included construct validity, reliability (consistency of the scale), responsiveness (ability to detect clinically important changes), and feasibility (practical applicability of the scale). Further details on study design, inclusion and exclusion criteria, data collection and sample size calculation are available as Supplementary Data.

Over a three-month period in 2022, 189 patients were identified as eligible, with 146 ultimately included in the study (Supplementary Figure 1). Patient and perioperative characteristics are reported in Table 1. The distribution of surgical procedures was as follows: 18 (12%) aortic surgeries, 53 (36%) coronary artery bypass grafting surgeries (CABG), 55 (38%) valvular surgeries, and 20 (14%) mixed surgeries (valvular and CABG). The median duration of CPB

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was 105 [82, 135] minutes (n=146). The mean change between preoperative and
postoperative QoR-15 was -12 (23) (n=137). The distribution of the postoperative QoR-15 is
shown in Supplementary Figure 2 and a detailed breakdown of each item and the mean
change in QoR-15 from preoperative to postoperative period are reported in Supplementary
Table 1. The mean global postoperative recovery assessment was 59 (20) (n=145).

A positive correlation was observed between the postoperative QoR-15 score and the global postoperative recovery assessment, with a Pearson coefficient of 0.48 (95% confidence interval [0.34–0.59]; p<0.001). The correlation between Δ QoR-15 (difference between pre and postoperative QoR-15) and the global recovery assessment was similar, with a Pearson coefficient of 0.47 (95% CI [0.32-0.59]; p<0.001). Inter-item correlation matrix is presented in Supplementary Table 2 and showed a strong correlation between each item. A significant negative association was found between the postoperative QoR-15 score the duration of CPB (r=-0.09; p=0.038), ICU length-of-stay (LOS) (r=-2.11; p=0.034), duration of pleural chest tube use (r=-3.80; p=0.015), and the total dose of morphine use (r=-0.20; p = 0.006). There was no significant association between the postoperative QoR-15 score and the type of surgery, surgical revision, atrial fibrillation, mediastinal chest tube drainage duration (p=0.895), acute renal failure (p=0.791), pulmonary oedema, atelectasis and the hospital LOS. The postoperative QoR-15 was higher in the group with a high global recovery assessment (VAS≥70) compared to the group with a low global recovery assessment (VAS<70), with 124 (16) and 113 (22), respectively (p=0.005). There was no statistical difference in preoperative QoR15 between groups with high or low global recovery assessment, with 129 (15) and 130 (16) respectively, (p=0.512). Similarly, no significant difference was found between patient with or without postoperative complication in preoperative QoR-15 (131 (14) vs 129 (16); p=0.558) or postoperative QoR-15 (122 (20) vs 116 (21) p=0.116). The completion rate was 94% (n=138) for the preoperative QoR-15 questionnaire and 99% (n=145) for the postoperative questionnaire. Internal consistency, measured by Cronbach's alpha, was 0.872. Cohen's effect size and standardized response mean are reported in Supplementary. Table 1.

This study demonstrated that the QoR-15 score is a valid, responsive, reliable, and feasible tool for assessing overall quality of recovery in cardiac surgery patients. However, its validity and responsiveness were lower compared to previous studies conducted in the general surgery population, including minor and intermediate surgeries, where the QoR-15 demonstrated stronger validity and responsiveness^{5, 6}. This variation can be attributed to the delayed assessment during hospitalization, necessitated by the initial admission to the cardiothoracic ICU. The single-centre nature of this study may limit the generalization of the results, highlighting the need for further evaluation in other cardiac surgery centres.

⁵/₅₈ 109 In conclusion, the QoR-15 scale demonstrated acceptable levels of validity, reliability, ⁵⁹/₆₀ 110 responsiveness, and feasibility in the assessment of postoperative recovery among cardiac ⁶¹ 111 surgery patients. While these findings support the routine application of QoR-15, the

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- 112 development of a patient-centred outcome measure tailored for cardiac surgery patients could
- 113 be a valuable progression.

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Authors' contributions: GLG,ML,NN conceived the study and elaborated the analysis plan . GLG, AM, ML contributed to the investigation and data collection, performed the statistical analysis, analyzed and interpreted the data . EF, CC, CE and HB contributed to the 4 118 investigation. GLG, AM and NN drafted the manuscript, which was revised for important intellectual content by EF, CC, CE and HB. All authors approved the final work and agree to б be accountable for all aspects of the research and for the accuracy and integrity of the work. 9 121 11¹ 122 Funding : None ¹² 123 14 124 **Declaration of interests:** ₁₆ 125 GLG declares no competing interests. ML declares no competing interests. **127** AM received payments made to his institution from i-SEP for consulting fees, and from LFB, ₂₁ 128 Aguettant, Viatris and Pfizer for lecture fees EF declares no competing interests. 24 130 CB declares no competing interests. **131** CE declares no competing interests. HB declares no competing interests. ²⁹ 133 NN declares no competing interests. ACCEPTED MANUSCRIPT / CLEAN COPY

	134	References		
	135			
1	136	1.	Weiser TG, Haynes AB, Molina G, et al. Estimate of the global volume of surgery in	
2	137		2012: an assessment supporting improved health outcomes. Lancet Lond Engl.	
4	138		2015;385 Suppl 2:S11. doi:10.1016/S0140-6736(15)60806-6	
5 6		_		
7 8	139	2.	Abola RE, Bennett-Guerrero E, Kent ML, et al. American Society for Enhanced Recovery	
9	140		and Perioperative Quality Initiative Joint Consensus Statement on Patient-Reported	
10 11	141		Outcomes in an Enhanced Recovery Pathway. <i>Anesth Analg</i> . 2018;126(6):1874-1882.	
12 13	142		doi:10.1213/ANE.000000000002758	
14	143	3.	Khan MS, Butler J. Stability of Changes in Health Status: Next Step in Comprehensively	
15 16	144		Assessing Patient-Reported Outcomes. JAMA. 2022;328(10):923-924.	
17 18	145		doi:10.1001/jama.2022.13551	
19				
20 21	146	4.	Myles PS, Shulman MA, Reilly J, Kasza J, Romero L. Measurement of quality of	
22 23	147		recovery after surgery using the 15-item quality of recovery scale: a systematic review	
24	148		and meta-analysis. Br J Anaesth. 2022;128(6):1029-1039. doi:10.1016/j.bja.2022.03.009	
26	149	5	Stark PA Myles PS Burke IA Development and psychometric evaluation of a	
27 28	150	0.	postoperative quality of recovery score: the QoB-15 Apesthesiology 2013:118(6):1332-	
29 30	151		1340 doi:10.1097/ALN.0b013e318289b84b	
31	101			
32 33	152	6.	Demumieux F, Ludes PO, Diemunsch P, et al. Validation of the translated Quality of	
34 35	153		Recovery-15 questionnaire in a French-speaking population. Br J Anaesth.	
36	154		2020;124(6):761-767. doi:10.1016/j.bja.2020.03.011	
37 38	455	-		
39 40	155	7.	Leger M, Campfort M, Cayla C, Parot-Schinkel E, Lasocki S, Rineau E. Validation of an	
41 42	156		alternative French version of the Quality of Recovery-15 Score: the FQOR-15. Br J	
43	157		Anaestn. 2020;125(4):e345-e347. doi:10.1016/j.bja.2020.05.052	
44 45	158	8.	Almashrafi A, Elmontsri M, Aylin P. Systematic review of factors influencing length of stay	
46 47	159		in ICU after adult cardiac surgery. BMC Health Serv Res. 2016;16:318.	
48	160		doi:10.1186/s12913-016-1591-3	
49 50				
51 52	161	9.	Welsby IJ, Bennett-Guerrero E, Atwell D, et al. The association of complication type with	
53	162		mortality and prolonged stay after cardiac surgery with cardiopulmonary bypass. Anesth	
54 55	163		Analg. 2002;94(5):1072-1078. doi:10.1097/00000539-200205000-00004	
56 57	164	10.	Fischer MO, Brotons F, Briant AR, et al. Postoperative Pulmonary Complications After	
58 59	165		Cardiac Surgery: The VENICE International Cohort Study. J Cardiothorac Vasc Anesth.	
60	166		2022;36(8 Pt A):2344-2351. doi:10.1053/j.jvca.2021.12.024	
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		Characteristics	All patients (N=146)		
		Age (year)	69 [62, 73]		
1		Male sex;	113 (77)		
∠ ג		BMI	27 [24, 31]		
4		Diabetes	33 (23)		
5		Hypertension	81 (55)		
6		Smoker	13 (9)		
7		ASA score	10 (0)		
8		2	5 (3)		
10		2	124 (85)		
11		3	17 (12)		
12		4 Destancestive Characteristics	17 (12)		
13			22 (22)		
14		Cardiac pacing	30 (20)		
15 16		Dobutamine support	17 (12)		
17		Surgical revision	22 (15)		
18		Total morphine in ICU (mg)	22 [9; 44]		
19		QoR-15 score			
20		Preoperative QoR-15	133 [121, 143]; N=138		
21		Postoperative QoR-15	112 [104, 134]; N=145		
22		Postoperative QoR-15 measurement (days)	7 [6, 9]; N=145		
24		Postoperative complications			
25		Atrial fibrillation	60 (41)		
26		Postoperative myocardial infarction	0(0)		
27		Pulmonary oedema	48 (33)		
20 29		Cardiac arrest	0 (0)		
30		Ventricular Tachycardia	O(0)		
31			O(0)		
32		Ploural offusion drainage	3 (2)		
33			3 (2) 0 (6)		
34 35			9 (0)		
36		Atelectasis	27 (18)		
37		Pneumonia	2 (1)		
38		Sepsis	5 (3)		
39		HIT	5 (3)		
40 41		Acute renal failure	2(1,4)		
42		Stroke	3 (2)		
43		Gastrointestinal bleeding	2 (1)		
44		Pleural chest tube drainage duration (days)	2 [1, 6]		
45		Mediastinal chest tube drainage duration (days)	2 [2, 3]		
46		ICU LOS (days)	2 [2, 3]		
48		Hospital LOS (days)	8 [7, 12]		
49		In-hospital mortality	0 (0)		
50		One-month mortality	0 (0)		
51	168	Qualitative parameters: Number (%).	(
52 53	169	Quantitative parameters: Median linterquartile rand	ael		
54 55	170	BMI (Body Mass Index), ASA (American Society of	Anesthesiologists), CBP (Cardio		
56	171 Pulmonary Bypass). ICU (Intensive Care Unit). HIT (Heparin-Induced Thrombocyton				
57 58	172	LOS (Length of Stay), QoR-15 (quality of recovery-15)			

Table 1: Patient demographic and clinical characteristics

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Supplementary Material

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