Assessment of Quality of Life With 5 Different Scales in Patients Participating in Comprehensive Cardiac Rehabilitation After Acute Myocardial Infarction

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Background Measures assessing quality of life (QOL) in patients participating in comprehensive cardiac rehabilitation (CCR) have not been established in Japan.

Methods and Results To compare different types of QOL scales and to determine the impact of CCR on QOL in Japanese cardiac patients, 5 different types of questionnaires were assessed in 44 patients participating in CCR after acute myocardial infarction (AMI). After 3-month CCR, peak oxygen uptake ($\dot{V}O_2$, $p < 0.01$), Sick-ness Impact Profile (SIP) total score ($p < 0.05$) and physical function-related QOL scores (Specific Activity Scale (SAS), $p < 0.01$; SIP physical score, $p < 0.01$) significantly improved, whereas psychosocial/mental aspect-related QOL scores (Ministry of Health and Welfare (MHW)-QOL score, SIP psychosocial score, State-Trait Anxiety Inventory, Self-rating Depression Scale) did not change on the average. However, patients with low $\dot{V}O_2$ ($< 21.7 \text{ ml} \cdot \text{min}^{-1} \cdot \text{kg}^{-1}$) showed significant improvements in all scores after CCR, whereas patients with preserved exercise capacity showed improvements only in physical function-related scores (SAS and physical SIP). Furthermore, patients with anxiety and depression showed significant improvements in these respective measures after CCR.

Conclusion In patients with AMI, physical function-related QOL scores improve after a 3-month CCR program, but psychosocial/mental aspect-related QOL scores improve only in those with impaired exercise tolerance or anxiety/depression. Thus, changes in QOL after CCR depend on type of QOL scale used and the baseline status of the patient. In addition, in Japanese cardiac patients MHW-QOL mainly reflects psychosocial/mental aspect-related QOL, as well as overall QOL. (Circ J 2005; 69: 1527–1534)

Key Words: Acute myocardial infarction; Cardiac rehabilitation; Depression; Psychological wellbeing; Quality of life

Comprehensive cardiac rehabilitation (CCR) improves psychological well-being or quality of life (QOL) in patients after acute myocardial infarction (AMI)^{1–4} but because the various QOL scales assess the physical and psychological aspects of QOL differently, it is not fully understood which aspect of QOL is improved by CCR. In addition, it remains unclear which patient group benefits most from CCR in terms of QOL. Furthermore, because most QOL instruments, except for the QOL score of the Ministry of Health and Welfare in Japan (MHW-QOL)^{5,6} were devised in Western countries, their features have not been comparably determined in Japanese cardiac patients. In fact, conflicting results have been reported on the effect of CCR on the MHW-QOL score in Japanese patients after AMI; Yoshida et al reported a significant improvement in the MHW-QOL score⁶ whereas Fujiwara et al reported no significant change⁷.

The effect of CCR on the different aspects of QOL in Japanese patients after AMI using multiple QOL instru-

ments has not been intensively assessed. Accordingly, the purpose of the present study was to use multiple QOL instruments to assess Japanese patients after AMI, to determine the comparative features of the various QOL scales, including the MHW-QOL score, and to clarify the characteristics of the patients who are likely to benefit most from CCR in terms of QOL.

Methods

Subjects

We studied 44 patients who had experienced an AMI (mean age: 58 ± 9 years, range 45–78, male/female: 37/7) and who participated in CCR with exercise training program. All patients gave written informed consent.

The diagnosis of AMI was confirmed by electrocardiographic changes and serum creatine kinase (CK) elevation. Peak serum CK was $3,255 \pm 2,588 \text{ U/L}$. Seven patients (16%) had had a prior myocardial infarction and 2 patients (5%) had congestive heart failure (Killip's class ≥ 2) on admission. All patients underwent cardiac catheterization: 38 patients (86%) had successful percutaneous coronary intervention (PCI), 2 patients (5%) underwent coronary artery bypass grafting (CABG) and 5 patients (11%) with residual myocardial ischemia were medically controlled. Mean left ventricular ejection fraction (LVEF) was $45 \pm 8\%$.

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by left ventriculography 3–4 weeks after the onset of AMI.

Cardiac Rehabilitation Program

The CCR program consisted of exercise training of moderate intensity and education for 3 months, as previously described^{8–10}. Patients who did not have angina or ischemic changes on ECG at a low level of exercise (200–500 m walking test) were enrolled in the exercise training approximately 10–15 days after AMI. Patients with uncontrolled heart failure and/or angina, multiple organ disorders such as serum creatinine ≥ 2.0 mg/ml, serum transaminase ≥ 40 IU/ml, inflammatory disease or embolic disorders were excluded. The exercise program consisted of walking, bicycling on an ergometer, and aerobic dance sessions of 50–80 min, 3–5 times each week for 3 months. Exercise intensity was determined individually at 50–60% of heart rate reserve (Karvonen's equation, $k=0.5-0.6$)^{11,12} obtained by maximal symptom-limited cardiopulmonary exercise testing (CPX) or at level 13 ("a little hard") of the 6–20 scale perceived rating of exercise (original Borg's score)¹³. The exercise program started with supervised sessions for 2 weeks, followed by home exercise combined with once or twice weekly supervised sessions for the remaining 10 weeks. Home exercise consisted mainly of brisk walking at a prescribed heart rate for 30–60 min 3–5 times per week. There were no adverse cardiac events such as death, AMI, unplanned PCI or CABG, or worsening of heart failure during the 3-month CCR.

Patients were encouraged to attend the education classes, which were held 3 times each week with lectures on coronary artery disease, secondary prevention, diet, smoking cessation, medication, and home exercise given by physicians, nurses, dietitians, pharmacists and exercise instructors. In addition, all patients received individual counseling on exercise prescription, secondary prevention, and daily life activities by a physician and a CCR nurse at the time of hospital discharge and at the end of the CCR program.

CPX

A symptom-limited CPX was performed at the beginning and end of the 3-month CCR.¹⁴ After a 2 min rest on the bicycle ergometer (Examiner, Lode B.V. Groningen-Holland), patients started pedaling at an intensity of 0 W for 1 min (warm-up), then performed an incremental exercise test with a ramp protocol (15 W/min) until exhaustion. During exercise testing, breathed gas was continuously collected to measure oxygen uptake ($\dot{V}O_2$) and carbon dioxide production ($\dot{V}CO_2$) with a gas analyzer AE280 (Minato Medical Electronics, Osaka, Japan). Blood pressure was measured every minute and a 12-lead ECG was continuously monitored during exercise. Patients who showed angina or ischemic ECG changes at the initial exercise test were excluded.

Peak oxygen uptake ($\dot{V}O_{2p}$) was defined as the highest $\dot{V}O_2$ value achieved at peak exercise after reaching the respiratory compensation point. The $\dot{V}O_2$ value at the anaerobic threshold (AT) or ventilatory threshold was determined as the point at which $\dot{V}CO_2$ increased in a nonlinear fashion relative to the rate of $\dot{V}O_2$, according to the time trend of the ratio of minute ventilation ($\dot{V}_E$) and $\dot{V}O_2$ ($\dot{V}_E/\dot{V}O_2$), an abrupt increase in the respiratory exchange ratio, or the V-slope method.^{15,16}

QOL Questionnaires

At the beginning and end of the 3-month CCR program,

all patients answered the 5 types of questionnaires assessing QOL: Specific Activity Scale (SAS), Sickness Impact Profile (SIP), MHW-QOL, State-Trait Anxiety Inventory (STAI) and Self-rating Depression Scale (SDS). SAS is a scale of functional capacity related to daily activities expressed by metabolic equivalents,^{17,18} and SIP comprises 136 items including 12 domains to assess patient behaviors, such as physical disorders (ambulation, mobility, body care and movement), psychosocial disorders (social interaction, alertness behavior, emotional behavior, communication) and other disorders (sleep and rest, eating, work, home management, recreation and pastimes), expressed by the percentage of acquired scores.^{19,20} It has been successfully used in the field of CCR.^{20–22} MHW-QOL has both generic and disease-related scales and mainly assesses the psychosocial and mental aspects of QOL.^{5–7} It comprises 39 items, including 3 domains (2 generic domains and 1 disease-specific domain) for subjective evaluation of health (8 items), social attitude and subjective wellbeing (21 items), and disease-specific conditions (10 items). In the present study we used a total score for the 39 items (so-called "broad sense score") as the MHW-QOL score. STAI is a scale of anxiety and comprises 2 domains of state-anxiety and trait-anxiety, the former representing an anxiety state that a patient faces and the latter mainly representing an anxious personality. Each domain comprises 20 items with 4-point scales.²³ SDS evaluates depression by 20 items with 4-point scales.²⁴ A state of anxiety and/or depression was judged when the percent score of STAI and/or SDS was above 50%. Higher scores indicate a more favorable QOL trait in SAS and MHW-QOL, whereas lower scores indicate a more favorable QOL trait in SIP, STAI and SDS.

Data Analysis

Data were analyzed in 3 steps. First, data for exercise capacity and QOL were compared between the 2 time points (ie, before and after the 3-month CCR) in the whole group of patients. Second, to assess the influence of baseline exercise capacity on the improvement in QOL scores after CCR, QOL data were compared between the 2 time points in the subgroups of preserved and impaired exercise capacity. Because the average $\dot{P}\dot{V}O_2$ measured by CPX at the beginning of the CCR was 21.7 ± 1.7 ml·min⁻¹·kg⁻¹, patients were divided into 2 groups according to their initial $\dot{P}\dot{V}O_2$ value: Low $\dot{P}\dot{V}O_2$ group ($\dot{P}\dot{V}O_2 < 21.7$ ml·min⁻¹·kg⁻¹, $n=22$) and Preserved $\dot{P}\dot{V}O_2$ group ($\dot{P}\dot{V}O_2 \geq 21.7$ ml·min⁻¹·kg⁻¹, $n=22$). Finally, QOL data were compared between the 2 time points in the subgroups with and without initial anxiety (STAI score $\geq 50\%$ or $< 50\%$, respectively) and with and without initial depression (SDS score $\geq 50\%$ or $< 50\%$, respectively).

Statistical Analysis

All values are expressed as mean $\pm$ SD. The paired t-test was used to compare paired variables before and after CCR within a group. Comparisons between groups were made by unpaired t-test. Statistical analysis was performed using StatView software (Abacus, Cupertino, CA, USA). A p-value less than 0.05 was considered statistically significant.

Results

Changes in Exercise Capacity and QOL Scores in the Whole Group

As shown in Table 1, which summarizes the baseline

Table 1 Characteristics of 44 Patients After Acute Myocardial Infarction

	Total (n=44)	Preserved $\dot{V}O_2$ group (n=22)	Low $\dot{V}O_2$ group (n=22)	p value
Age (years)	58±10	57±11	59±9	NS
Sex (M/F)	37/7	20/2	17/5	NS
Hypertension	21 (48%)	12 (55%)	9 (41%)	NS
Hyperlipidemia	18 (41%)	10 (45%)	8 (36%)	NS
Diabetes mellitus	12 (27%)	6 (27%)	6 (27%)	NS
Obesity (BMI ≥26 kg/m ²)	10 (23%)	4 (18%)	6 (27%)	NS
Smoking	23 (52%)	14 (64%)	9 (41%)	NS
Family history	9 (20%)	4 (18%)	5 (23%)	NS
Killip class ≥2 (numbers)	2	0	2	NS
PCI/CABG/none	38/2/5	18/1/3	20/1/2	NS
peak CK (IU/ml)	3,255±2,588	3,009±1,986	3,384±2,796	NS
LVEF (%)	44.5±8.2	45.9±6.6	42.9±9.6	<0.05
$\dot{V}O_2$ (ml·kg ⁻¹ ·min ⁻¹)	21.7±4.9	24.7±3.6	18.1±3.8	<0.001

Values are mean ± SD. P values for comparisons between Preserved $\dot{V}O_2$ and Low $\dot{V}O_2$ groups.

$\dot{V}O_2$, peak oxygen uptake; Preserved $\dot{V}O_2$ group, patients whose baseline $\dot{V}O_2$ values were equal to or above average ($\dot{V}O_2$ ≥21.7 ml·kg⁻¹·min⁻¹); Low $\dot{V}O_2$ group, patients whose baseline $\dot{V}O_2$ value were below average ($\dot{V}O_2$ <21.7 ml·kg⁻¹·min⁻¹); BMI, body mass index; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; CK, serum concentration of creatine kinase; LVEF, left ventricular ejection fraction.

Table 2 Exercise Capacity and QOL Scores Before and After Comprehensive Cardiac Rehabilitation in All Patients

	Before CCR	After CCR	p value
Peak R	1.26±0.12	1.24±1.0	NS
$\dot{V}O_2$ (ml·kg ⁻¹ ·min ⁻¹)	21.7±1.7	24.7±2.6	<0.01
$\dot{V}O_2$ at AT (ml·kg ⁻¹ ·min ⁻¹)	11.8±2.3	13.1±2.5	<0.01
SAS (METs)	4.5±1.7	5.3±0.7	<0.05
SIP (% scores)			
Total	7.9±5.6	5.5±4.9	<0.05
Physical disorders	7.2±3.1	1.5±1.6	<0.01
Psychosocial disorders	6.0±4.4	5.8±7.4	NS
Other disorders	11.5±7.5	10.6±8.4	NS
MHW-QOL (scores)	57.4±12.7	58.6±20.5	NS
STAI (% scores)			
Total	49.3±10.9	46.9±13.2	NS
State-anxiety	48.2±11.7	45.3±12.2	NS
Trait-anxiety	49.7±12.0	47.1±12.3	NS
SDS (% scores)	45.3±9.5	43.4±7.9	NS

Values are mean ± SD.

QOL, quality of life; CCR, comprehensive cardiac rehabilitation; Peak R, respiratory exchange ratio at peak exercise; $\dot{V}O_2$, peak oxygen uptake; AT, anaerobic threshold (or ventilatory threshold); SAS, specific activity scale; METs, metabolic equivalents; SIP, sickness impact profile; MHW-QOL, QOL score of the Ministry of Health and Welfare in Japan; STAI, state-trait anxiety inventory; SDS, self-rating depression scale.

Fig 1. Comparisons of exercise capacity and quality of life (QOL) scores before and after 3-month comprehensive cardiac rehabilitation (CCR) in all 44 patients. $\dot{V}O_2$, peak oxygen uptake; SAS, Specific Activity Scale; SIP total, Sickness Impact Profile total score; MHW-QOL, Ministry of Health and Welfare QOL broad sense score; OM, baseline values (before CCR); 3M, values after 3-month CCR program. *p<0.05 and **p<0.01 compared with baseline values.

Table 3 Exercise Tolerance and QOL Related Scores Change in Subgroups

	Preserved $\dot{V}O_2$ group (n=22)			Low $\dot{V}O_2$ group (n=22)		
	Before CCR	After CCR	p value [#]	Before CCR	After CCR	p value [#]
$\dot{V}O_2$ ($\text{ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$)	24.7 $\pm$ 3.6	27.5 $\pm$ 5.0	<0.01	18.1 $\pm$ 3.8**	21.3 $\pm$ 5.4**	<0.01
$\dot{V}O_2$ at AT ($\text{ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$)	13.2 $\pm$ 1.8	14.5 $\pm$ 2.3	0.05	10.2 $\pm$ 1.7	11.6 $\pm$ 1.8	<0.05
SAS (METs)	5.0 $\pm$ 1.7	5.6 $\pm$ 1.9	<0.05	3.9 $\pm$ 1.5*	4.9 $\pm$ 1.3	<0.05
SIP (% scores)						
Total	7.7 $\pm$ 5.8	6.0 $\pm$ 4.8	<0.05	8.1 $\pm$ 5.6	4.1 $\pm$ 5.2	<0.05
Physical disorders	6.9 $\pm$ 7.9	0.8 $\pm$ 1.7	<0.01	6.8 $\pm$ 5.8	2.1 $\pm$ 3.4	<0.01
Psychosocial disorders	6.2 $\pm$ 6.9	6.6 $\pm$ 7.6	NS	4.8 $\pm$ 5.5	2.7 $\pm$ 5.6	<0.05
Other disorders	10.5 $\pm$ 6.2	10.6 $\pm$ 8.1	NS	12.7 $\pm$ 8.8	8.6 $\pm$ 7.9	<0.05
MHW-QOL (scores)	61.0 $\pm$ 8.1	60.3 $\pm$ 10.8	NS	53.1 $\pm$ 10.0**	56.6 $\pm$ 9.3	<0.05
STAI (% scores)						
Total	47.7 $\pm$ 10.1	47.9 $\pm$ 15.3	NS	51.2 $\pm$ 11.8	45.7 $\pm$ 10.3	<0.05
State-anxiety	47.9 $\pm$ 10.3	47.6 $\pm$ 17.0	NS	49.6 $\pm$ 13.2	44.4 $\pm$ 10.3	<0.05
Trait-anxiety	47.6 $\pm$ 11.1	48.3 $\pm$ 14.7	NS	52.7 $\pm$ 12.6	46.9 $\pm$ 11.2	<0.05
SDS (% scores)	42.3 $\pm$ 7.0	43.6 $\pm$ 10.7	NS	49.2 $\pm$ 10.5*	44.4 $\pm$ 6.7	<0.05

Values are mean $\pm$ SD.

[#]Comparisons were made by paired t-test before and after CCR within the group; *p<0.05, **p<0.01 compared with corresponding values in the Preserved $\dot{V}O_2$ group.

Abbreviations as in Table 2.

Fig 2. Changes in representative quality of life (QOL) scores before and after 3-month comprehensive cardiac rehabilitation program in patients with preserved and impaired exercise capacity. Patients with preserved exercise capacity showed improvements in Specific Activity Scale (SAS) and Sickness Impact Profile (SIP) physical score, but not in SIP psychosocial and Ministry of Health and Welfare (MHW)-QOL scores, whereas patients with impaired exercise capacity showed improvements in all 4 scores. SIP physical, SIP physical disorder score; SIP psychosocial, SIP psychosocial disorder score; Preserved, preserved exercise capacity group (peak $\dot{V}O_2 \geq 21.7 \text{ ml}\cdot\text{min}^{-1}\cdot\text{kg}^{-1}$); Low, impaired exercise capacity group (peak $\dot{V}O_2 < 21.7 \text{ ml}\cdot\text{min}^{-1}\cdot\text{kg}^{-1}$). *p<0.05 and **p<0.01 compared with baseline values.

clinical characteristics of the 2 groups with preserved and impaired exercise capacity, there were no significant differences except for LVEF and $\dot{V}O_2$. Table 2 and Fig 1 summarize the data for exercise capacity and QOL scores before and after the 3-month CCR. The respiratory exchange ratio at peak exercise was sufficiently high both before and after CCR, suggesting that the measured $\dot{V}O_2$ values are reliable. After 3 months of CCR, $\dot{V}O_2$ (+13.8%, p<0.01), $\dot{V}O_2$ at AT (+11.0%, p<0.01) and SIP total score (−30.4%, p<0.05) improved significantly, as did the SAS (+17.8%, p<0.05) and SIP physical disorder score (−79.2%, p<0.01), both representing QOL related to physical function. However, other QOL scores such as the SIP score for psychosocial disorders and other disorders, MHW-QOL, STAI and SDS, all representing QOL related to psychosocial or mental function, did not change after 3 months of CCR.

Changes in QOL Scores in the Subgroups With Preserved and Impaired Exercise Capacity (Table 3, Fig 2)

In the Preserved $\dot{V}O_2$ group, $\dot{V}O_2$ (+11.3%, p<0.01), $\dot{V}O_2$ at AT (+9.8%, p=0.05), SIP total score (−22.1%, p<0.05), and physical function-related QOL scores (ie, SAS (+12.0%, p<0.05) and SIP physical disorder score (−88.4%, p<0.01), significantly improved after CCR, but there was no significant change in the psychosocial and mental aspect-related QOL scores (ie, SIP psychosocial disorder score, SIP other disorder score, MHW-QOL, STAI, and SDS). In contrast, the Low $\dot{V}O_2$ group showed significant improvements in $\dot{V}O_2$ (+17.7%, p<0.01), $\dot{V}O_2$ at AT (+13.7%, p<0.05), SIP total score (−49.4%, p<0.05), and both physical function-related QOL (SAS +25.6%, p<0.05; SIP physical disorder score −69.1%, p<0.01) and psychosocial/mental aspect-related QOL scores after CCR (SIP psychosocial disorder score −43.8%, p<0.05; MHW-QOL +6.7%, p<0.05;

Fig 3. Changes in anxiety (STAI) and depression (SDS) scores before and after 3-month comprehensive cardiac rehabilitation (CCR) program in patients with normal and impaired mental function. Anxiety scores (STAI: State-Trait Anxiety Inventory) and depression scores (SDS: Self-rating Depression Scale) improved after CCR only in patients with impaired STAI score and impaired SDS score at baseline. OM, baseline values (before CCR); 3M, values after 3-month CCR. *p<0.05 and **p<0.01 compared with baseline values.

Table 4 Correlation Matrix of Different Types of QOL Scores

	$\dot{V}O_2$	$\dot{V}O_2$ at AT	SAS	SIP total	SIP physical	SIP psychosocial	STAI	SDS
MHW-QOL	0.14	0.21	0.49***	0.36***	0.27*	0.38***	0.77***	0.69***
$\dot{V}O_2$		0.74***	0.29**	0.01	0.08	0.09	0.07	0.09
$\dot{V}O_2$ at AT			0.32**	0.14	0.20	0.01	0.04	0.18
SAS				0.35**	0.32**	0.30**	0.37***	0.43***
SIP total					0.74***	0.81***	0.31**	0.25*
SIP physical						0.40***	0.12	0.18
SIP psychosocial							0.37***	0.28**
STAI								0.73***

Correlation coefficients and their statistical significance are presented.

Data both before and after 3-month comprehensive cardiac rehabilitation for all 44 patients were included for regression analysis.

Abbreviations as in Table 2. *p<0.05, **p<0.01, ***p<0.001.

STAI -10.7%, p<0.05; SDS -9.8%, p<0.05).

Changes in Anxiety and Depression (Fig 3)

When the patients were divided into 2 groups according to the initial STAI score $\geq$ or <50%, 22 patients (50.0%) with STAI score $\geq$ 50% (ie, anxiety state) showed a significant improvement after CCR (58.2 $\pm$ 6.1 to 53.0 $\pm$ 9.3, p<0.05), but the remaining 22 patients with initial STAI score <50% (ie, normal) showed no significant change. When the patients were divided into 2 groups according to the initial SDS score $\geq$ or <50%, 12 patients (27.3%) with SDS score $\geq$ 50% (ie, depressive state) showed a significant improvement in SDS score after CCR (58.2 $\pm$ 4.4 to 49.7 $\pm$ 6.4, p<0.01), but the remaining 32 patients with initial SDS score <50% (ie, normal) showed no significant change.

Correlations Between MHW-QOL and Other QOL Scores (Table 4)

The MHW-QOL score significantly correlated with SAS (r=0.49, p<0.001) and SIP total score (r=0.36, p<0.001), indicating that MHW-QOL represents the overall QOL of cardiac patients. Intriguingly, the MHW-QOL score correlated very tightly with the SIP psychosocial disorder score (r=0.38, p<0.001), STAI (r=0.77, p<0.001) and SDS (r=0.69, p<0.001), but less tightly with the SIP physical disorder score (r=0.27, p<0.05) and not significantly with $\dot{V}O_2$ (r=0.14, NS) or $\dot{V}O_2$ at AT (r=0.21, NS). These findings suggest that in cardiac patients MHW-QOL mainly reflects the psychosocial and mental aspects of QOL rather than physical aspects.

Discussion

The major findings of the present study are that (1) exercise capacity and physical function-related QOL scores (ie, SAS and SIP physical disorder score) significantly improved, whereas psychosocial and mental aspect-related QOL scores (SIP psychosocial disorder score, MHW-QOL, STAI, and SDS) did not change in the whole patient group participating in the 3-month CCR program after AMI, (2) patients with impaired exercise capacity at baseline showed significant improvements in all QOL scores including both physical function-related scores and psychosocial and mental aspect-related scores, whereas patients with preserved exercise capacity showed improvements only in physical function-related QOL scores, (3) patients with anxiety or depression at baseline showed an improvement in each score after CCR, whereas those without anxiety or depression showed no change, and finally, (4) the MHW-QOL score correlated more tightly with psychosocial/mental function-related QOL scores rather than with physical function-related aspects.

Previous Studies

Many previous studies have demonstrated the benefits of CCR for QOL in patients after AMI,^{1-4,6,7,20-22} but most have used only 1 or 2 QOL instruments and assessed changes in QOL scores after CCR in the whole group. In other words, few studies have investigated which aspect of QOL (physical, psychosocial or mental aspects) is most improved by CCR, which QOL instruments are most sensitive to changes occurring during CCR, and what type of patients obtain the

greatest benefit from CCR after AMI. In fact, Jolliffe et al noted in their meta-analysis that it was not possible to combine the data from studies reporting health-related QOL as an outcome, because 18 different instruments were used in the 11 randomized studies reporting it as an outcome.²⁵ Shephard et al also noted that there were few direct comparisons between different types of QOL instruments!

One direct comparison was made by Taylor et al, who utilized 3 generic QOL instruments, including SIP, to assess changes in QOL over time in 88 patients after AMI, and found that all 3 QOL instruments had modest sensitivity.²⁶ Smith et al²⁷ compared 4 QOL instruments, including the Medical Outcome Study 36-item Short Form Survey (SF-36);²⁸ in 22 cardiac patients before and after CCR, and found that only 1 of the SF-36 subscales, vitality, significantly improved over time, from which they concluded that all 4 QOL measures lacked sensitivity to change. In Japan, where most QOL questionnaires invented in Western countries and written in English cannot be directly applied to Japanese patients, comparative assessments of the different QOL instruments during CCR has not been done so far. Yoshida et al studied the MHW-QOL, STAI and SDS in patients with AMI participating in 2-week hospitalized CCR, but did not analyze correlations among the measures.⁶ Seki et al also investigated SF-36, STAI and SDS in elderly patients with coronary artery disease participating in phase III CCR, but did not analyze correlations among the measures.²⁹ Thus, the optimal QOL test instrument or the best method of interpreting the resultant scores there has not been established!

Present Study

In the present study, we compared 5 different QOL instruments in Japanese patients participating in a 3-month CCR program with supervised exercise training and education after AMI. This enabled us to analyze which aspect of QOL improves after CCR and what type of patients gain the greatest improvement in QOL from CCR after AMI. In addition, we were able to determine the nature of the Japan-invented MHW-QOL by assessing the correlations between MHW-QOL and other established QOL scales.

Improvement in QOL After CCR

The present study has shown that P $\dot{V}O_2$, SAS, SIP total score and SIP physical disorder score significantly improved, whereas the SIP psychosocial disorder score, MHW-QOL, STAI, and SDS did not change in the whole patient group after CCR, which indicates that overall the physical function-related QOL scores improved, but the psychosocial and mental aspect-related QOL scores did not. Therefore, not all aspects of QOL (or all types of QOL scores) necessarily improve after CCR in patients with AMI.

Many previous studies have demonstrated an improvement in physical function-related QOL after CCR;^{4,20,30–32} but the improvement in mental/psychosocial aspect-related QOL has been inconsistent; some studies have reported a significant improvement;^{20,30–33} and others have not.^{34–36} For example, Sledge et al³⁰ and Tyni-Lenne et al³¹ reported significant improvements in all areas of QOL (overall, physical, and psychosocial scores) in an 8-week CR program in cardiac patients, whereas Worcester et al³⁵ and Daumer et al³⁶ reported no significant difference in the psychosocial and mental aspects of QOL between an exercise training group and a control group. Recently, Izawa et

al³⁷ using SF-36;²⁸ reported significant improvements in the physical function-related SF-36 subscales (ie, physical functioning, role-physical, general health) but not in the mental function-related subscales (ie, social functioning, role-emotional, mental health) after CCR in patients with AMI. Thus, whether or not QOL improves after CCR in cardiac patients appears to depend on the aspect of QOL and the type of QOL instrument.

Patient Characteristics Predicting Improved QOL After CCR

In the present study, patients with impaired exercise capacity at baseline showed significant improvements in all QOL scores, including both physical function-related QOL scores and psychosocial and mental aspect-related QOL scores, whereas patients with preserved exercise capacity showed improvements only in physical function-related QOL scores. A potential explanation for this new finding is that there might be a “ceiling effect” (ie, patients with lower initial values have a greater improvement)¹ because the low exercise capacity group in the present study tended to have worse QOL scores at the beginning of CCR (Table 3). In support of this, Lavie et al reported that elderly patients with coronary artery disease had a lower baseline P $\dot{V}O_2$ value, but a greater improvement in QOL score (SF-36), after CCR than younger patients;³⁸ although Oldridge et al reported that higher exercise tolerance at baseline predicts a greater improvement in the quality of well-being in patients with AMI participating in CCR.³⁹ The reason for this discrepancy is unclear, and further studies are necessary to address this issue.

The present study also demonstrated that patients with anxiety or depression at baseline showed a significant improvement in each score after CCR, whereas those without showed no change. This finding is in accordance with Oldridge et al³⁹ who stated that a poor baseline health-related QOL was the predominant predictor of improved generic and specific health-related QOL after CCR. Likewise, Milani et al showed that depressed patients exhibited a greater improvement in psychosocial/mental aspect-related QOL than did normal patients.⁴⁰ Again, this finding may well be explained by the ceiling effect! Taken together, the findings suggest that an improvement in QOL after CCR depends not only on the type of QOL instrument but also on the patient characteristics at baseline, and that patients with impaired QOL, anxiety, or depression at baseline should be strongly recommended to participate in CCR with an expectation of greater improvements than patients without these problems.

QOL Instruments for Japanese Cardiac Patients

Although MHW-QOL was originally invented in Japan, no study to date has systematically compared it with other established QOL instruments in patients with AMI participating in CCR. The present study has demonstrated that MHW-QOL reflects overall QOL, as indicated by a significant correlation with SIP total score, but that it mainly represents psychosocial/mental aspect-related QOL rather than physical aspect-related QOL, as indicated by the tight correlations with SIP psychosocial score, STAI and SDS (Table 4).

Recently, SF-36 (Japanese version) has become used more frequently in the field of CCR.^{29,37} In fact, a recent review of generic health-related QOL instruments⁴¹ suggests that the SF-36 health survey is the most commonly

used of the generic QOL instruments reviewed.⁴² However, some studies have raised a concern that SF-36 may not be sufficiently sensitive to measure the changes in QOL following CCR in cardiac patients.^{27,43} Because a perfect QOL instrument for cardiac patients has not been established in Japan, further studies are needed to comparatively assess multiple QOL instruments and to invent a more appropriate QOL instrument for Japanese cardiac patients.

Study Limitations

First, because the present study did not have a control group not participating in CCR, it is unclear whether the improvement in QOL observed is attributable to the favorable effect of CCR or the natural course after AMI. However, the purpose of the present study was to compare different types of QOL instruments rather than to examine the efficacy of CCR on QOL in patients with AMI. To determine whether CCR improves QOL in Japanese patients after AMI, a prospective randomized study will be needed.

Second, the present study did not employ SF-36;²⁵ however, as mentioned before, it remains unclear whether SF-36 is the most appropriate instrument to assess QOL in Japanese patients participating in CCR after AMI. Further studies are needed to directly compare the usefulness and validity of various QOL instruments, such as MHW-QOL, SIP, and SF-36, in Japanese patients participating in CCR.

Third, the present study assessed changes in QOL in a relatively short-term (ie, 3 months) CCR program. Assessment of the effects of a longer term CCR on QOL in patients with AMI may also be necessary. Finally, because the present study included only a small number of elderly (6 patients (14%) >70 years of age) and female patients (7 (16%) female patients), the present results cannot be directly applied to such specific populations.

Conclusion

In patients with AMI, physical function-related QOL scores improve after 3-month CCR, whereas psychosocial and mental aspect-related QOL scores improve only in those with impaired exercise tolerance or impaired mental function at baseline. Thus, changes in QOL after CCR depend on the type of QOL scales and the patient's baseline status of physical and mental function. In addition, the present study demonstrated for the first time that MHW-QOL mainly reflects psychosocial/mental aspect-related QOL, as well as overall QOL, in Japanese cardiac patients.

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