

ORIGINAL REPORT

BENEFIT OF OUTPATIENT CARDIAC REHABILITATION IN UNDER-REPRESENTED PATIENT SUBGROUPS

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**Objective:** To assess the effect of outpatient cardiac rehabilitation in important patient subgroups.

**Design:** Prospective cohort study.

**Subjects:** Consecutive patients from March 1999 until July 2003.

**Methods:** This study assessed the results of symptom-limited bicycle stress testing and health-related quality of life (Profil der Lebensqualität Chronisch Kranker) at baseline and after a 3-month rehabilitation program, and complications and drop-outs during outpatient cardiac rehabilitation.

**Results:** Of 1061 patients, 155 (15%) were women and 87 (8%) men aged  $\geq 75$  years, 162 (15%) had diabetes mellitus and 88 (8%) did not speak the local language. Reasons for outpatient cardiac rehabilitation included acute coronary artery disease (87%), valvular heart disease (9%) and congestive heart failure (1%). Mean age was 62 years (standard deviation 11). Patients increased both their age- and body-weight-adjusted workload ( $p < 0.0001$ ) and quality of life ( $p < 0.0001$ ) during the program. Although the initial workload achieved was lower than for normal patients ( $p < 0.0001$ ), it increased in all subgroups during outpatient cardiac rehabilitation ( $p < 0.0001$ ). Baseline quality of life was lower in women, but increased in most dimensions for all subgroups assessed.

**Conclusion:** Important subgroups, such as women, elderly men, diabetic patients and ethnic minorities, are under-represented in outpatient cardiac rehabilitation, although they benefit similarly to other patients. Due to lower baseline quality of life, women may need special medical attention prior to outpatient cardiac rehabilitation.

**Key words:** rehabilitation, coronary artery disease, exercise test, quality of life.

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INTRODUCTION

Contrary to current guideline recommendations, certain subgroups are under-represented in outpatient cardiac rehabilitation (OCR) (1, 2). Specifically, women and elderly men are referred less frequently to cardiac rehabilitation programs despite deriving similar benefit to other patient groups from medical evaluation, prescribed exercise, cardiac risk factor modification, education and counselling (3–6). In addition, since patients with diabetes mellitus have fewer and atypical symptoms when suffering from coronary artery disease, but are at increased risk of further cardiovascular events compared with patients without diabetes mellitus (7, 8), they might benefit from OCR even more than patients without diabetes mellitus.

The reasons for the referral bias in enrolling certain subgroups in OCR are not well understood. Reported causes for non-participation include lack of physician referral, lack of affordability of service, problems with insurance coverage, lack of support from a spouse or other carer, gender-specific attitudes, individual factors, such as anxiety or poor motivation, and logistical and financial limitations (9, 10). In addition, in subgroups such as elderly and diabetic patients more complications may be anticipated after an acute event. It is not known whether these subgroups derive similar benefit from cardiac rehabilitation programs as do non-subgroup patients regarding both physical and psychosocial parameters, i.e. whether cardiac rehabilitation is useful in these populations.

Thus, we consecutively enrolled all patients participating in the local OCR over a 4-year period to assess baseline characteristics at inclusion, complications during rehabilitation, rate and reason for discontinuation of the program, and both physical and psychosocial parameters at the end of the 3-month program in the total population, and to analyse differences between certain subgroups, i.e. women, elderly men, diabetic patients, ethnic minorities, and non-subgroup patients.

METHODS

From March 1999 until August 2003, all patients undergoing the local OCR were enrolled in a prospective cohort study. The OCR of the Department of Cardiology of the University of Basel is an ambulatory rehabilitation program for patients with coronary artery disease, i.e. prior myocardial infarction or angina pectoris with or without revascularization, valvular heart disease, previous cardiac surgery, or congestive heart failure, and consists of medical evaluation, prescribed

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exercise, relaxation, cardiac risk factor modification, education and counselling. While approximately 30% of all patients after cardiac surgery or interventional revascularization at our institution are enrolled in the local OCR, 40% undergo inpatient cardiac rehabilitation at specialized institutions and in another 30% no formal rehabilitation takes place. Patients were referred to OCR based on their preferences or on those of their physicians.

Based on their physical capacity achieved in the baseline stress test and the previously assessed left ventricular ejection fraction, patients were divided into 3 groups; A, B and C. Group A comprised patients with a good maximal physical capacity, i.e. achieving  $\geq 1.5$  W/kg. Group B comprised patients with impaired maximal physical capacity, i.e. achieving  $< 1.5$  W/kg, but with a left ventricular ejection fraction of  $\geq 35\%$ . Group C comprised patients with an impaired maximal physical capacity, i.e. achieving  $< 1.5$  W/kg and a left ventricular ejection fraction  $< 35\%$ . For groups A and B, OCR was divided into 2 phases; a build-up and consolidation phase. The build-up phase consisted of 4 weeks of intense rehabilitation with daily activities in the afternoon including education, counselling, physical training, and relaxation, whereas the consolidation phase was less intense but lasting for another 8 weeks with biweekly physical activities in the afternoon; participation in the consolidation phase was optional for patients in groups A and B. In both groups, physical training consisted of mixed activities for a duration of 1–2 h including endurance training at 60–80% of the maximal heart rate achieved at the baseline exercise test or a rate of perceived exercise of 5/10 to 6/10, strength training, and co-ordination training. OCR in group C consisted of a 12-week course of physical training 3 times a week in the mornings (either interval or steady-state bicycle training) and education once a week during one afternoon. For group C, physical training was limited to endurance training and co-ordination training. Compliance with the training sessions was very good ( $> 90\%$ ).

In all patients data were available at inclusion and completion of the 3-month program. Parameters assessed at baseline included demographic data, reason for rehabilitation, risk factors and medication. Prior to enrolment, left ventricular ejection fraction was assessed either by coronary angiography, echocardiography, myocardial perfusion single-photon emission computed tomography, or radionuclide ventriculography. Except for drop-outs, a symptom-limited bicycle stress test (ramp protocol) in groups A and B, or a spiroergometry in group C was performed both at inclusion and completion of the program; spiroergometry was performed as routine assessment at our heart failure clinic. Furthermore, complications during the program, abortion of the program, and the duration of the participation of each patient in the program were assessed. Complications were defined as unexpected events due to cardiac or non-cardiac reasons leading to therapeutic interventions including hospitalization and, eventually, discontinuation of the program. Non-medical reasons for discontinuation were defined as discontinuation of the OCR due to neither cardiac nor non-cardiac reasons.

Quality of life (QoL) was assessed at both inclusion and completion of the program using the Profil der Lebensqualität Chronisch Kranker (PLC) questionnaire (11). This generic questionnaire was created to assess time-related changes in health for most of the chronic/degenerative diseases and was selected for this study because of the heterogeneous nature of the patient cohort, its broad range of aspects, and the fact that it represents an instrument specifically developed for a German-speaking cohort. The PLC questionnaire measures QoL on the physical, emotional and social levels, and consists of 40 questions that assess 6 dimensions of health, including physical capacity, psychological functioning, positive mood, negative mood, social functioning and social well-being, and has been validated (12). All scales range from 0 to 4, with higher scores depicting a better performance.

Diabetes mellitus was defined as an established diagnosis of diabetes mellitus, or receiving treatment for hyperglycaemia. The ethnic minority subgroup included patients of varying non-local ethnicity or race, and was defined as the population who did not speak the local language, i.e. German. This population traditionally represents an important

sub-segment in our working population and usually originates from Southern and South-eastern Europe and the Near East. The different subgroups were not mutually exclusive.

For this study, primary end-points were achieved workload and QoL after 3 months; secondary end-points were complications during the program and cessation of the program. For all patients, follow-up time was equal to the duration of the OCR, i.e. 3 months.

Data acquisition and statistical analysis was performed using KarData® software (kaSoft Development Kaufmann, Münsingen, Switzerland). Descriptive statistics are presented as means and standard deviation or as percentages. Categorical variables were compared using the  $\chi^2$  test. Continuous variables were compared using the Student's *t*-test. All *p*-values were 2-sided and considered statistically significant if  $\leq 0.05$ .

## RESULTS

The total population comprised 1061 patients of whom 155 (15%) were women, and 87 (8%) men, aged  $\geq 75$  years, 162 (15%) had diabetes mellitus and 88 (8%) were not able to communicate in the local language.

In the total cohort, the vast majority of patients entered OCR because of coronary artery disease, i.e. prior myocardial infarction or angina pectoris (Table I). Most patients completed the build-up phase, whereas less than two-thirds completed both parts of the rehabilitation program. Patients achieved a mean workload of 79% of the expected age- and body-weight-adjusted value, in the baseline exercise stress test. The exercise stress test at the end of the rehabilitation program was performed in 887 (84%) patients. During the final stress test most patients were able to increase their physical ability and achieved a workload of 100% of the expected value. Overall, the increase in workload between inclusion and completion of the rehabilitation program was significant ( $p < 0.0001$ ). During rehabilitation, as much as 17% of patients suffered from complications (Table II). Regarding QoL, all dimensions increased during rehabilitation except for social well-being, which remained constant (Table III).

Compared with men, women were entering OCR less often because of angina pectoris, but more often because of congestive heart failure; of note, women entered OCR less often after coronary artery bypass graft surgery compared with men. Cardiovascular risk factors were similar in women as in men, except for current smoking which was more prevalent in women (Table I). Compared with men, women less often completed the build-up phase and both phases of the rehabilitation program, but more often only completed the consolidation phase. Achieved workload during exercise stress test at both OCR inclusion and completion was lower than in men, but the increase in workload between inclusion and completion of the rehabilitation program was significant ( $p < 0.0001$ ). The occurrence of cardiac complications was similar in women and men, but lead more often to discontinuation of the program. By contrast, non-cardiac complications occurred less often but were not more frequently a reason for discontinuation of the program compared with men. Non-medical reasons for discontinuation were more frequent in women than in men (Table II). Compared with the total population, baseline QoL

Table I. Baseline characteristics. Results are given in % unless stated otherwise.

	All patients (n = 1061)	Women (n = 155)	Elderly men (n = 87)	Diabetes mellitus (n = 162)	Ethnic minority (n = 88)
Age (years, mean (SD))	62 (11)	63 (11)	79 (3)****	65 (9)****	55 (13)****
LVEF (mean (SD))	55 (13)	54 (13)	55 (16)	54 (14)	52 (13)*
History of hypertension	57	55	61	72	43
History of dyslipidaemia	71	74	66	74	71
History of diabetes mellitus	15	12	18	100****	22*
History of smoking	43	40	33	40	41
Current smoking	19	32**	5****	17	19
Family history of coronary artery disease	33	40	18*	100****	21
Reason for rehabilitation					
Coronary artery disease	87	85	87****	80**	73****
Angina pectoris	18	13*	21	16*	32**
Prior myocardial infarction	68	72	64	64	59
PCI	49	47	26	43	32
CABG	15	7****	20	19	7****
PCI/CABG combined	5	3***	5	6	9****
Valvular heart disease	9	7	7	8	9
Congestive heart failure	1	2****	1	3****	8****
Medication					
Acetylic salicylic acid	81	84	74	78	81
Warfarin (Coumadin)	18	15	24	22	17
Beta-blockers	90	90	86*	90	91
ACE-inhibitors	44	50	49	59	55
Statins	79	77	70	75	82

\* $p \leq 0.05$  (subgroup vs non-subgroup patients), \*\* $p \leq 0.01$ , \*\*\* $p = 0.001$ , \*\*\*\* $p < 0.0001$

LVEF: left ventricular ejection fraction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft surgery; ACE: angiotensin-converting enzyme; SD: standard deviation.

was lower regarding physical capacity, psychological functioning, and both positive and negative mood, but not for social functioning and well-being, which were similar; contrary to men, only physical capacity and positive mood increased during rehabilitation, whereas all other dimensions remained constant (Table III).

In elderly men, mean age by definition was higher in this group than in other patients. The reason for OCR was more often coronary artery disease compared with the rest of the cohort. Elderly men were less often current smokers, less often

had a family history of premature coronary artery disease and less often had dyslipidaemia, and less often were treated with beta-blockers compared with other patients (Table I). Achieved workload during exercise stress test at both OCR inclusion and completion was lower than in the rest of the cohort; however, the increase in workload between inclusion and completion was significant ( $p < 0.0001$ ) and the achieved workload at the end of the rehabilitation consisted of 99% of the expected value. Cardiac complications occurred more frequently in elderly men compared with younger men and women, but were not more

Table II. Achieved baseline and post-rehabilitation workload, complications and discontinuation. Results are % unless stated otherwise.

	All patients (n = 1061)	Women (n = 155)	Elderly men (n = 87)	Diabetes mellitus (n = 162)	Ethnic minority (n = 88)
Pre-rehabilitation test workload (W)	123 (38)	86 (24)***	100 (23)***	109 (33)***	117 (36)***
Mean (SD) % maximum	79 (20)	73 (19)	79 (20)	71 (17)	71 (21)
Post-rehabilitation test workload (W)	156 (49)	105 (28)***	126 (26)***	137 (43)***	133 (39)***
Mean (SD) % maximum	100 (25)	89 (22)	99 (21)	89 (23)	81 (26)
Discontinuation of rehabilitation					
Build-up phase	93	85****	100***	100****	94
Consolidation phase	7	15****	0***	0***	6
Both phases	59	53	46	44	60
Complications					
Cardiac	8	9	13***	17***	15****
Non-cardiac	9	6**	6*	8	13
Discontinuation					
Cardiac reason	1	3***	1	6***	2***
Non-cardiac reason	5	5	6	6*	13****
Non-medical reason	5	8****	4***	5	6

\* $p < 0.01$  (subgroup vs non-subgroup patients), \*\* $p < 0.001$ , \*\*\* $p < 0.0001$ .

SD: standard deviation.

Table III. Quality of life (Profil der Lebensqualität Chronisch Kranker Questionnaire). All values are means (standard deviation (SD)). All scales range from 0 to 4. The questionnaire was not applicable to the ethnic minority subgroup.

Dimensions	All patients (n = 1061)			Women (n = 155)			Elderly men (n = 87)			Diabetes mellitus (n = 162)		
	Baseline	3 months	p	Baseline	3 months	p	Baseline	3 months	p	Baseline	3 months	p
Physical	2.19	2.88		2.00	2.71		2.35	2.83		2.15	2.78	
Capacity	(0.76)	(0.70)	< 0.0001	(0.73)***	(0.64)	< 0.0001	(0.69)*	(0.55)	0.0018	(0.67)	(0.68)	< 0.0001
Psychological	2.64	2.98		2.50	2.79		2.73	3.12		2.62	2.93	
Functioning	(0.63)	(0.60)	< 0.0001	(0.62)**	(0.57)	0.052	(0.53)	(0.47)	0.0007	(0.60)	(0.56)	0.070
Positive	2.19	2.54		2.04	3.32		2.30	2.59		2.16	2.42	
Mood	(0.70)	(0.72)	< 0.0001	(0.69)*	(0.68)	0.021	(0.49)	(0.51)	0.0084	(0.61)	(0.66)	0.34
Negative	2.85	3.14		2.69	2.87		2.87	3.23		2.82	3.10	
Mood†	(0.78)	(0.74)	< 0.0001	(0.79)*	(0.75)	0.36	(0.69)	(0.60)	0.017	(0.75)	(0.73)	0.054
Social	2.60	2.99		2.58	2.95		2.62	3.05		2.55	2.93	
Functioning	(0.84)	(0.60)	< 0.0001	(1.42)	(0.66)	0.29	(0.64)	(0.55)	0.0013	(0.69)	(0.58)	0.011
Social Well-being	3.16	3.19	0.75	3.09	3.09	0.43	3.18	3.22	0.92	3.16	3.10	0.69
	(0.62)	(0.64)		(0.71)	(0.69)		(0.57)	(0.54)		(0.59)	(0.66)	

\* $p < 0.05$  (subgroup vs non-subgroup patients), \*\* $p < 0.02$ , \*\*\* $p < 0.01$ .

†an increase in this scale is equivalent to a decrease of negative mood (reciprocal rating).

often a reason for discontinuation of the program. In contrast, non-cardiac complications occurred less frequently in elderly men compared with other patients, but were not more often a reason for discontinuation of the program. Non-medical reasons for cessation were less frequent in elderly men than in the rest of the cohort (Table II). Compared with the rest of the cohort, physical capacity was lower in elderly men, but changes in QoL were similar with all dimensions increasing during rehabilitation, except for social well-being, which remained constant (Table III).

Patients with diabetes mellitus were older than patients without, and had all a family history of premature coronary artery disease. Reason for rehabilitation was less often coronary artery disease, but more often congestive heart failure compared with non-diabetic patients (Table I). Achieved workload during the exercise stress test at both OCR inclusion and completion was lower than in patients without diabetes mellitus, but the increase in workload between inclusion and completion was significant ( $p < 0.0001$ ). Cardiac complications occurred more frequently in patients with diabetes mellitus compared with patients without and were more often a reason for discontinuation of the program. Similarly, non-cardiac complications occurred more frequently in patients with diabetes mellitus compared with patients without, but were not more often a reason for discontinuation of the program. Non-medical reasons for cessation were as frequent in patients with diabetes mellitus as in patients without (Table II). Compared with non-diabetic patients, QoL was not different in diabetic patients. Physical capacity and social functioning increased during rehabilitation, whereas all other dimensions remained constant (Table III).

Patients not able to communicate in the local language were younger than others, and were more likely to be diabetic. Reason for rehabilitation was less often coronary artery disease, but more often congestive heart failure. Left ventricular ejection fraction was lower in this subgroup than in other patients (Table I). There was no difference in the duration of OCR in

patients who did not speak the local language compared with other patients. Achieved workload during the exercise stress test at both OCR inclusion and completion was lower than in patients able to communicate in the local language. However, the increase in workload between inclusion and completion was significant ( $p < 0.0001$ ), but the achieved workload at the end of the rehabilitation consisted of only 80% of the expected value. Cardiac complications occurred more frequently in the ethnic minority subgroup compared with other patients and were more often a reason for discontinuation of the program. In contrast, non-cardiac complications occurred similarly in the ethnic minority subgroup compared with the other patients, but were more often a reason for discontinuation of the program. Non-medical reasons for discontinuation were as frequent in patients not able to speak the local language as in other patients (Table II). Because patients in the ethnic minority were not able to speak and read German, but questionnaires were available in this language only, no data are available regarding QoL in this subgroup.

## DISCUSSION

Cardiac rehabilitation after myocardial infarction and cardiac surgery or in congestive heart failure is a class I indication (2, 13, 14). Important aims of cardiac rehabilitation include secondary prevention of coronary artery disease to reduce the risk of future cardiovascular events or cardiac death (15), and beneficial effects of OCR on both outcome (16) and cost-effectiveness (17) have been shown before.

Just recently, pooled data showed a considerable underrepresentation of women, elderly people, and ethnic minorities (16). In our cohort, the percentage of women and men  $\geq 75$  years of age was low, paralleling the fact that both women and elderly people often are under-represented in clinical trials (18–20). As a comparator, in previous randomized trials at our institution in symptomatic coronary artery disease the percent-

age of women was between 21% and 44% and the percentage of patients > 75 years of age was 20% (21, 22) being double the numbers shown in this report. Thus, our findings corroborate a previous report showing that enrolment of women in OCR are particularly low after myocardial infarction and coronary artery bypass grafting (5). On the other hand, it has been shown that cardiac rehabilitation is safe and effective for elderly coronary patients, and it was concluded that these individuals should be routinely referred to, and vigorously encouraged to attend, cardiac rehabilitation programs following major coronary events (23). These findings have been further corroborated in our study, where women and elderly men generally achieved a lower physical ability after rehabilitation, but were able to increase their workload and their QoL similarly to the total population.

In patients with diabetes mellitus, an exercise program improves exercise performance which usually is impaired compared with age-matched controls (24, 25). In the present study, patients with diabetes mellitus benefited from rehabilitation similarly to the total cohort regarding both physical ability and QoL, which is in accordance with previous reports (26, 27). However, in our study the percentage of diabetic patients was both lower than in previous analyses performed at our institution, which demonstrated a prevalence between 19% and 22% (21, 22), and lower than what one could expect based on previous studies, i.e. approximately 25% (26, 28).

The evidence regarding the inclusion of ethnic minorities in clinical trials is unclear, since most authors do not report the ethnicity or language skills of their patients. A recently published study demonstrated that the exclusion of ethnic minorities is based primarily on language, whereas eligible patients, i.e. patients able to communicate in the local language, were enrolled in similar proportions irrespective of their ethnicity (29). In our study, ethnic minority was defined accordingly based on the inability to communicate in the local language. The percentage of patients in this group was low based on the average percentage of non-Swiss residents in our country that reaches approximately 20% of the total population. Therefore, it can be assumed that ethnic minority patients are excluded from participation in OCR based on their inability to speak the local language. As the other subgroups, these patients derived similar benefit from cardiac rehabilitation, although the achieved work capacity was lower than in other groups. This might be due to the higher rate of congestive heart failure as the reason for rehabilitation and the consecutively lower ejection fraction in this group. However, due to the lack of a validated questionnaire in the respective mother language, QoL could not be assessed in these patients.

The risk of a cardiac complication during OCR is very low (30). However, the occurrence of complications in elderly people and diabetic patients is thought to be higher than in the normal population. In our analysis, cardiac complications occurred more frequently in both elderly men and diabetic patients compared with the total cohort. Of note, cardiac complications were not more often a reason for discontinuation of the program in elderly men, but were in diabetic patients.

The rate of occurrence of cardiac complications was similar in women to that in the total cohort, but lead more often to discontinuation of the program, which might be explained by differences in pain or disease perception (31). In the ethnic minority, cardiac complications occurred more frequently compared with the total cohort and were more often a reason for discontinuation of the program, possibly due to a lower left ventricular ejection fraction at inclusion and a higher rate of diabetic mellitus.

Cardiovascular events lead to a loss of QoL, i.e. lack of self-confidence, depression and social isolation. In turn, depression and social isolation lead to an increased rate of cardiac mortality (32–35). In our analysis, all subgroups increased their QoL in most dimensions numerically, although sample sizes were too low in some populations to yield statistical significance. Of note, women had a lower QoL at inclusion in the OCR, which might be explained by differences of disease-perception between the sexes.

As a limitation, the maximal follow-up duration of this analysis was 3 months, which is too short to assess the whole spectrum of complications and late outcome of the studied population. Furthermore, no QoL assessment was possible in the ethnic minority due to lack of validated outcome measures in the respective mother language; other questionnaires were not chosen due to the lack of comparability with the other study groups. Finally, some subgroups consisted of rather small numbers, which might have precluded some final conclusions.

In conclusion, subgroups such as women, elderly men, diabetic patients and ethnic minorities are under-represented in OCR programs, although – in contrast to widely prevailing prejudice – they benefit from a rehabilitation program regarding both physical ability and QoL similarly to the normal population, despite a somewhat higher risk profile and a slightly elevated complication and drop-out rate. Special efforts need to be made regarding a better inclusion rate of minorities into OCR programs. The lower QoL in women at inclusion in OCR may need special attention to care-givers prior to rehabilitation.

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