Chapter 8

Outcome of Exercise Training alone and in Combination with Relaxation Therapy after Myocardial Infarction: what Patients benefit from these Treatments?

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The predictability of the outcome of two rehabilitation programmes was studied, aerobic conditioning alone and in combination with individual relaxation therapy. Myocardial infarction patients were randomly assigned to either exercise training (n=80) or a combination of exercise training and relaxation therapy (n=76). The outcome was assessed through a composite criterion, based on exercise testing.

By using logistic regression analysis, the predictive value of baseline variables of clinical information, exercise data and psychosocial variables to identify patients whose training was successful, was investigated. For exercise as single treatment, predictor variables for training success turned out to be predominantly exercise data and clinical information (correct classification: 76%). For the treatments jointly, psychosocial information had incremental value in predicting, beyond clinical and exercise data. With all data sets combined, 91% of the patients were identified correctly. The prediction rules shared only one variable (Type A behaviour), in opposite direction.

This study supports the usefulness of prediction analysis for divergent forms of cardiac rehabilitation. The relaxation therapy modifies the effects of the determinants of training success. Validation is needed to develop a reliable tool to identify patients for whom exercise training is indicated and those for whom additional relaxation therapy is indicated.

Introduction

Predictability of the efficacy of physical exercise training in cardiac rehabilitation has been investigated in a few studies where exercise training constituted the only or main type of treatment (1-4). The aim of this study is to predict the outcome of training for two different types of treatment. Exercise training as a single treatment, is contrasted to a more comprehensive treatment, consisting of exercise and individual relaxation therapy (5). Comparison of the outcome of the two treatments in a previous analysis showed, that relaxation therapy enhanced the effectiveness of rehabilitation (5-7). However, this leaves the question unanswered as to what patients, in particular, will benefit from this comprehensive treatment, which is more expensive and time-consuming than exercise training alone.

The main objective of this study is to investigate the predictability of the training outcome for the two treatments separately, on the basis of initial medical, psychosocial and exercise data.

Patients and Methods

Patients. After discharge, cardiac patients from various hospitals are referred to the regional rehabilitation centre at St. Joannes de Deo Hospital, Haarlem, The Netherlands. A total of 156 myocardial infarction (MI) patients were admitted to the study and were randomly assigned to one out of two treatment protocols. Patients, with a diagnosis other than MI, e.g. coronary artery bypass graft surgery, and patients who needed psychosocial help were excluded from the study. There were 147 men and 9 women. Median age was 56, their age ranging from 36 to 76. Tables 1 and 2 summarize clinical data upon entry for the two treatments, according to the training outcome.

Table 1. Predictor variables for training success: clinical information and exercise testing

	Exercise training success			Exercise + relaxation success		
	no (N=43)	yes (N=37)	p	no (N=34)	yes (N=42)	p
sex (women; %)	4	0	0.08	3	2	ns
	(9)	(0)		(8)	(5)	
Clinical data						
pre infarction						
anginal medication	7	1	0.05	2	3	ns
(%)	(16)	(3)		(6)	(7)	
previous infarction	7	3	ns	2	4	ns
(%)	(16)	(8)		(6)	(10)	
non-cardiac morbidity	16	22	0.08	14	20	ns
(%)	(37)	(60)		(41)	(48)	
infarction						
small	14	13		5	15	
(%)	(33)	(35)		(15)	(36)	
medium	13	13	ns	15	16	0.03
(%)	(30)	(35)		(44)	(38)	
large	16	11		14	11	
(%)	(37)	(30)		(41)	(26)	
heart failure	9	4	ns	9	5	ns
(%)	(21)	(11)		(27)	(12)	
post infarction						
beta blockers (%)	14	12	ns	10	10	ns
	(33)	(30)		(29)	(24)	
diuretics (%)	10	10	ns	16	11	0.09
	(23)	(27)		(47)	(26)	
glucosides (%)	7	3	ns	8	5	ns
	(16)	(8)		(24)	(12)	
Exercise testing						
work capacity (in percent of normal)	90	84	ns	93	87	0.01
	(22.8)	(16.7)		(15.3)	(14.5)	
heart rate resting	82.2	77.1	ns	84.4	76.9	0.06
	(19.4)	(14.6)		(17.8)	(14.3)	
Watt=60	104.5	98.7	ns	108.7	98.5	0.02
	(19.6)	(14.8)		(16.8)	(17.5)	
maximal systolic blood pressure	154.4	156.2	ns	155.2	162.0	ns
	(19.1)	(23.1)		(20.2)	(26.0)	
ST abnormalities	10	11	ns	8	19	0.08
(%)	(23)	(30)		(24)	(45)	
arrhythmias	10	1	0.007	3	3	ns
(%)	(23)	(3)		(9)	(7)	

Data are reported as events and percentages of cases or as means (SD).

Table 2. Predictor variables for training success: psychosocial information

	Exercise training success no (N=43)	yes (N=37)	p	Exercise + Relaxation success no (N=34)	yes (N=42)	p
Interview						
working (%)	24 (56)	27 (73)	0.10	17 (50)	33 (79)	0.03
infarction experience						
seriously ill (%) 1)	18 (58)	17 (57)	ns	14 (56)	12 (35)	ns
prolonged pain (%)	21 (49)	20 (54)	ns	12 (35)	17 (41)	ns
expects full recovery of activities (%), 1)	22 (73)	22 (71)	ns	21 (88)	20 (63)	0.05
expects to cope differently with work (%)	6 (14)	5 (14)	ns	1 (3)	7 (17)	0.06
attributed cause infarction						
tension (%)	11 (26)	10 (27)	ns	6 (18)	14 (33)	0.10
stressors (%)	15 (35)	11 (30)	ns	8 (24)	20 (48)	0.05
Questionnaires						
JAS (Type A)	102.8 (20.1)	110.8 (20.5)	0.09	109.7 (18.9)	112.9 (19.2)	ns
sleep quality	7.3 (3.0)	7.6 (1.9)	ns	8.2 (2.0)	6.8 (2.5)	0.01
daytime nap (quarter of hours)	4.2 (1.4)	3.8 (1.8)	ns	4.1 (1.7)	3.2 (1.6)	0.06
anxiety-trait	35.3 (10.7)	35.5 (9.3)	ns	35.9 (8.6)	39.1 (9.5)	ns
well-being	27.5 (7.1)	27.0 (7.5)	ns	27.2 (6.9)	24.0 (7.0)	0.05
invalidity feelings	25.1 (6.0)	24.1 (6.4)	ns	25.8 (6.2)	25.8 (6.0)	ns

Data are reported as events and percentages of cases or as means (SD).
1) n=117; JAS: Jenkins Activity Scale.

Procedure. Clinical base-line data and medical history were obtained from the referring cardiologist. Upon entry, patients were interviewed to obtain psychosocial information and they were asked to participate in the study. After informed consent, they completed additional psychological questionnaires. All patients participated in a physical conditioning programme. In addition, half of them were randomly assigned to individual relaxation therapy. Graded exercise testing was performed on a bicycle ergometer before and after physical training, supervised by the cardiologist. He also assessed medication usage.

Exercise testing. After an adaptation period on the bicycle, the test was started with a 1-minute period of cycling at 60 cycles a minute without load, then for two minutes at 60 Watts. The test was continued by increasing the workload with 30 Watts every two minutes until symptoms limited the patient to continue or until the physician terminated the test. The occurrence of angina pectoris, ST-abnormalities and arrhythmias were noted. ST-abnormalities mostly consisted of ST-depressions greater than 2mm, horizontal or downsloping, occurring during or immediately after the test. Arrhythmias were coded as single premature ventricular contractions or as complex (groups or runs or multifocal or frequent premature ventricular complexes, bigeminy or ventricular tachycardia). A bipolar ECG lead (CM5) was taken during the last half-minute before the work load was increased. Blood pressure was taken before the test and at maximum work load.

Psychological questionnaires. (1) Heart Patients Psychological Questionnaire, for measuring the well-being of cardiac patients (8), consisted of four scales: (a) Well-being, (b) Feelings of invalidity, (c) Displeasure, (d) Social Inhibition; (2) Anxiety measured by STAI in two modes: State and Trait anxiety (9); (3) Sleeping habits, consisting of questions about hours of sleep, daytime nap and about quality of sleep (10); (4) Functional symptoms, consisting of complaints, not typical of angina pectoris. In addition, two questionnaires referred to the pre-infarction period: (5) Jenkins Activity Scale (JAS), for Type A behaviour (11); (6) Maastricht Questionnaire, for vital exhaustion and depression (12).

Rehabilitation. Physical exercise training consisted of five weeks of interval training on a bicycle ergometer, once a day, for half an hour. Training was given in groups of four patients, supervised by two physical therapists. Each patient was exercised up to 70 to 80 % of the maximal heart rate (Karvonen method) attained at the pre-training exercise test.

Relaxation training was given once a week in six individual one hourly sessions. The relaxation therapy was provided by five experts. Several proce-dures for active and passive relaxation were applied, with a respiratory tech-nique (13) as a core. The aim was for the patient to become aware of a more relaxed way of breathing so that he would be able to recognize and elicit this. EMG Feedback of the frontalis muscle was used for muscle relaxation and for monitoring unnecessary inspiratory effort. The patient learned to observe and elicit a "shift" in his respiratory pattern, in such a way that inspiration expanded both the lower abdomen and the costal margin, expiration was moderated and slow. Manual techniques and audible lip-breathing were applied to elicit breathing movements involving the trunk as a whole and requiring fewer effort. This was practised first in the supine position, to induce passive relaxation, but later also sitting up and standing ("active relaxation").

The rehabilitation programme did not have a structured form of patient education. At the patients' request information was given and questions were answered by the rehabilitation staff.

Outcome-criterion: training benefit. In order to obtain a single measure indicating the efficacy of physical training, changes in measurements obtained at exercise testing pre and post training, were integrated into a composite criterion for "training benefit". This criterion was used to trichotomize the patients as follows: a. patients with little or no change, b. patients who improved (success) or c. patients who deteriorated (failure). The criterion was an operationalisation of the primary purpose of exercise training to improve physical fitness and lower the threshold for myocardial ischaemia. The predictability of success and failure on this criterion proved satisfactory (14). For the present analysis, patients with success were distinguished from those without. "Success" implied an improved physical condition which could be attributed to exercise. The procedure is discussed in detail elsewhere (5). In short, the measurements were ranked according to their clinical relevance: 1) exercise-induced signs of cardiac dysfunction (ST-abnormalities, angina pectoris, complex ventricular arrhythmias), 2) maximal work load, 3) heart rate and 4) systolic blood pressure response (see figures 8.2 and 8.3). At each level, a patient could be assigned to success or failure when a significant change in a particular measurement had taken place. For cardiac signs, a negative change had priority over a positive one. Levels 2 - 4 represented physical fitness. This procedure allowed for dropouts to be included and classified as far as possible on the basis of the reason for not completing the programme. Thus, following the intention to treat principle, all randomised subjects could be classified.

Statistical analyses were made of the two treatments separately. Since this reduced the number of subjects for each analysis, the outcome categories were collapsed into a dichotomy. Patients with a positive outcome (success) were compared to those with no change or with a negative outcome (no success).

Univariate association with the baseline characteristics as predictor variables was tested with chi square for contingencies, in case of variables of nominal or ordinal level, and with student's t test in case of variables of interval level.

Stepwise logistic regression analysis was used to predict the outcome based on sets of variables. Predictions were first made using four sets: 1) medical history and hospital records, 2) interviews, 3) exercise testing and 4) psychological questionnaires, with all sets taking age and gender into account (see appendix). Missing values were assigned to a middle category in the case of discrete variables and to the means in the case of interval variables. Next, selected variables from the different subsets were combined, with the exception of incomplete interview variables. The criterion for inclusion of variables was $p < 0.10$ and for exclusion $p > 0.15$. The performance of the resulting logistic function is expressed through its classification rates.

In view of the relatively small number of subjects, the variables selected in the final analysis are presented with their regression coefficients and the coefficients/standard error. A value of > 2.0 on this latter measure indicates that the level of statistical significance of the contribution of the variable < 0.05.

Results

A total of 156 patients was admitted to the study, 80 of whom participated in exercise training as a single treatment, and 76 underwent additional individual relaxation therapy. The treatments did not differ in baseline characteristics (tables 1 and 2). Three patients had previous coronary artery bypass grafting, 16 patients had experienced recurrent infarction and 26 patients had a history of angina pectoris. The infarction size was classified according to the patients' peak serum enzyme levels. In

47 patients the infarction was regarded as small, in 49 patients as medium and in 52 as large. Of eight patients, the enzyme levels were not available; they were included in the medium category. In-hospital signs of heart failure (hypotension, cardio-thoracic ratio > 50%, pulmonary congestion) were present in 27 patients (17%). Post-infarction angina was present in one third of the patients. Beta blockers were used by 45 patients.

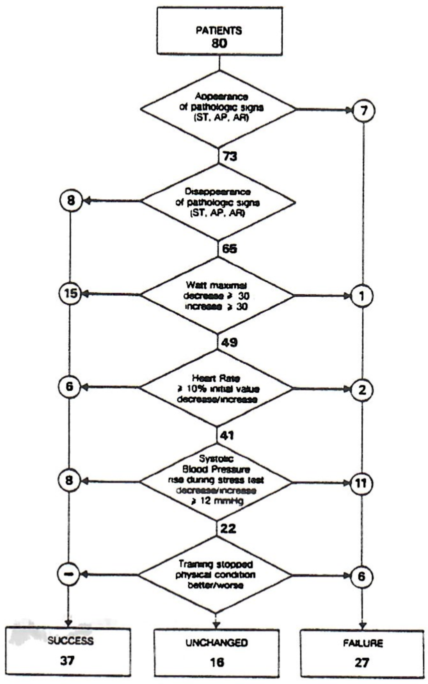

Figure 8.2: Flow chart to decide success or failure of exercise training for **exercise as sole treatment.**

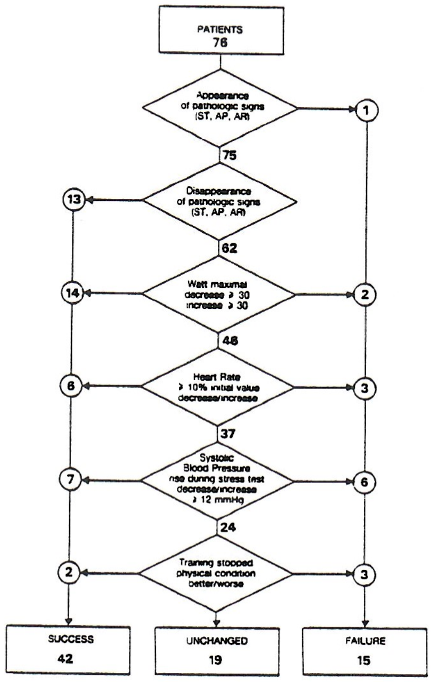

Figure 8.3: Flow chart to decide success or failure of exercise training **for relaxation therapy and exercise training jointly.**

ST: ST-segment depression; AR: complex ventricular arrhythmia;
AP: Angina pectoris; all three induced by exercise (see Methods)

Training outcome. In 139 patients exercise testing results were available before and after training. They have been described in detail elsewhere (5). In short, in both treatments there was a modest training response: maximal work load increased and heart rate at a given work load decreased. Heart rate reduction was more pronounced for patients who participated in relaxation therapy. There was no effect on blood pressure, although there were large individual changes. Exercise-induced signs of cardiac dysfunction remained relatively stable, except for a remarkable decrease in ST-depression in patients who underwent relaxation therapy: it was present in 24 patients and disappeared in half of the cases, whereas it appeared anew in one patient. For exercise training as a single treatment, ST-depression was initially present in 20 patients, it disappeared in four patients and appeared in another five. The difference between treatments was statistically significant. Seventeen patients did not complete their training. Fifteen were classified as unsuccessful because of dropping out: nine had to stop because of cardiac problems and six for non-cardiac reasons. Two patients stopped rehabilitation because they became fully active again: they were classified as successful. There was no significant change in medication during rehabilitation, probably because the programme covered only a short period of time.

Out of 80 patients who participated in exercise as a single treatment, the training outcome was successful for 37 (46%) according to the composite criterion and for 43 it was unsuccessful; for 27 (33%) the outcome was negative and for 16 (21%) there was no change (figure 8.2). Out of 76 patients who underwent relaxation therapy for 42 (55%) the outcome was positive and for 34 patients it was not successful; only for 15 (20%) the outcome was negative and for 19 (25%) there was no change (figure 8.3). Thus, for more patients who underwent relaxation therapy the outcome was positive and for a few the training outcome was negative. The difference in failure was statistically significant: the odds ratio for failure was 2.07 (95% confidence interval: 1.002 - 4.28) for exercise training in comparison to the combined treatment.

Exercise training. Univariately, few base-line characteristics were predictive of the outcome (tables 1 and 2). Female patients, those who used anti-anginal medication before infarction or who showed arrhythmias during exercise testing, were unsuccessful. On the other hand, patients who worked before infarction, those who had a history of one or more non-cardiac diseases and those who scored higher on Type A behaviour, tended more often to have a positive outcome.

Multivariate analysis showed that three of the four sets of variables (clinical, exercise testing and psychological questionnaires) had a limited ability to identify successful patients (table 3). Interview variables, including work status, had no predictive ability. With all data sets combined, 76% of the patients were classified correctly. Type A behaviour, anginal medication before infarction and exercise-induced ventricular arrhythmias, were variables with high differential qualities (table 4). A low initial work capacity was also conducive to success.

47 patients the infarction was regarded as small, in 49 patients as medium and in 52 as large. Of eight patients, the enzyme levels were not available; they were included in the medium category. In-hospital signs of heart failure (hypotension, cardio-thoracic ratio > 50%, pulmonary congestion) were present in 27 patients (17%). Post-infarction angina was present in one third of the patients. Beta blockers were used by 45 patients.

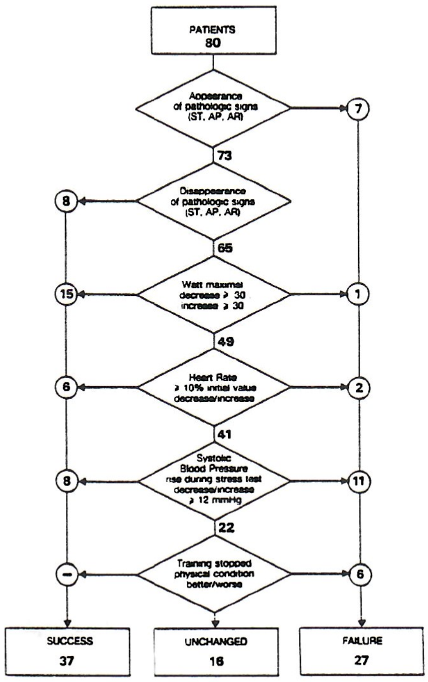

Figure 8.2: Flow chart to decide success or failure of exercise training for **exercise as sole treatment.**

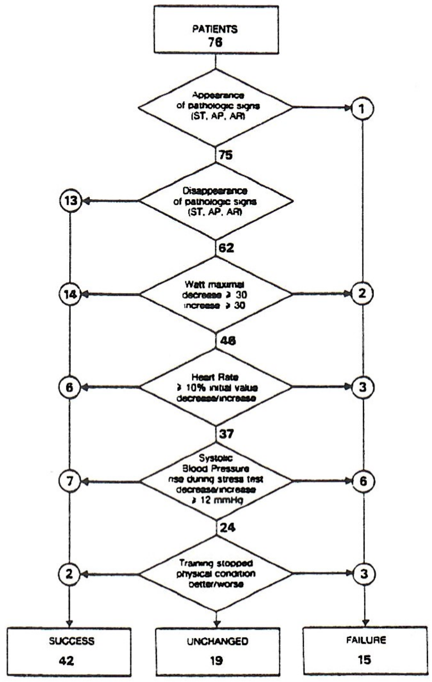

Figure 8.3: Flow chart to decide success or failure of exercise training **for relaxation therapy and exercise training jointly.**

ST: ST-segment depression; AR: complex ventricular arrhythmia;
AP: Angina pectoris; all three induced by exercise (see Methods)

Table 3. Performance of predictor variables on training success for exercise training

Performance rates	Sets of predictor variables				
	A Cli-nical	C Exer-cise	D Psycho-logical	A+C	All
Classification rates correctly (%) classified	54	57	64	63	76
sensitivity (%)	97	97	78	95	84
specificity (%)	16	23	51	35	70
True Pos (%)	50	52	58	56	71
True Neg (%)	88	91	65	88	83

A: anginal medication pre infarction; C: arrhythmia; D: Type A behaviour; A+C: anginal medication pre infarction, arrhythmia; All: see table 4.

Table 4. Prediction of training success for exercise training: all data.

Variable	regression coefficient	coefficient/s.e.
1) morbidity pre	0.74	1.90
2) anginal medication pre	-2.95	-2.36
3) work capacity (%)	-0.03	-1.81
4) arrhythmia	-2.44	-2.25
5) Type A behaviour	0.05	2.66
constant	-4.15	-1.61

Training success: value 1, no success: value 0.
1) number of major non-cardiac diseases in anamnesis; 2) present=1, absent=0; 4) complex=2, single=1, absent=0 (see under Methods); pre: before myocardial infarction;

Relaxation therapy and exercise training combined. Univariate analyses showed that several medical and exercise variables, as well as psychosocial variables had predictive power for training outcome (tables 1 and 2). For more patients with a small infarction the outcome was positive, as well as for patients with initial ST-depression, a low heart rate or a low work capacity. More patients who worked before infarction, completed the training successfully. Also subjective appraisal was important: most patients, who expected to cope with their work differently in the future, had a positive outcome. More patients who attributed the myocardial infarction to stressors were successful, as well as patients who did not expect to fully resume their activities. The outcome was often more positive for patients with a less optimal sleep quality, those who took shorter daytime naps and those who did not feel very well.

With logistic regression analyses, the four data-sets had a variable predictive ability (see table 5). Medical information had the lowest ability (59%) to classify the outcome correctly. Combining the data sets in the final analysis enhanced the performance substantially, although incomplete interview variables were excluded. Work status and ST-abnormalities had the highest predictive ability, followed by heart rate at 60 Watts and sleeping quality (see table 6). With all data sets, 91% of the patients could be classified correctly.

Table 5. Performance of predictor variables on training success for exercise and relaxation

Performance rates	Sets of predictor variables						
	A Clini-cal	B Inter-view	C Exer-cise	D Psycho-logical	A+C	A+C+D	All
correctly (%) classified	59	78	72	62	78	87	91
sensitivity (%)	74	79	91	69	88	91	91
specificity (%)	41	77	50	53	65	82	91
True Pos (%)	61	80	69	64	76	86	93
True Neg (%)	44	74	81	58	82	88	89

A: infarction size; B: age, work status, infarction pain, illness experience, doubt of diagnosis, expected recovery, cause MI tension; C: work capacity, heart rate 60 Watts, maximal blood pressure, ST-abnormality; D: sleeping quality; A+C: hypertension medication before MI, heart rate 60 Watts, ST-abnormality, beta-blockers, diuretics, systolic blood pressure; A+C+D: hypertension medication pre MI, heart failure, beta-blockers, heart rate 60 Watts, maximal blood pressure, ST-abnormality, sleeping quality, well-being, invalidity feelings; All: see table 6.

Table 6. Prediction of training success for exercise + relaxation: all data

Variable	regression coefficient	coefficient/s.e.
1) infarction size	-1.09	-1.91
2) beta blockers post	-2.17	-1.91
3) glucosides post	-2.55	-2.16
4) hypertension med pre	-1.45	-2.64
5) heart rate W60	-0.09	-2.73
6) ST-abnormality	4.21	3.42
7) Type A behaviour	-0.09	-2.24
8) sleeping quality post	-0.55	-2.65
9) well-being	-0.12	-1.84
10) work status	-1.53	-3.00
constant	34.63	3.81

Training success: value 1, no success: value 0.
1) small = 1, medium = 2, large = 3; 2,3,4,6) present = 1, absent = 0; 10) full time = 1, part time = 2, none = 3; pre: before myocardial infarction; post: after infarction

Discussion

The results indicate that for patients participating in exercise training as a single treatment, the physical outcome is predictable to a moderate degree, whereas training success is highly predictable for patients who participate in a more comprehensive type of rehabilitation. The limited predictability of the outcome for exercise as a single treatment (76% correctly classified) is in line with other studies (1,3,4). For the combined treatment, more base-line variables were of predictive value, especially psychosocial variables, and the resulting overall predictability was discernibly higher (91% correctly classified).

Few authors evaluated the outcome of exercise training in terms of success and failure instead of average changes in exercise parameters (1,14,15). Hammond et al., as well as Uniken Venema-van Uden, obtained results similar to those in this study: only about half of the patients referred for cardiac rehabilitation, actually benefit from exercise training, in the sense that they improve in exercise testing measurements. It means that, for the other patients, intensive training is not suitable and aerobic conditioning is not a proper therapeutic goal. These patients may nevertheless benefit from rehabilitation, for instance in a psychosocial sense (6), and they may even be in special need of it, but other treatment forms will have to be found, e.g lighter exercises, group sessions for relaxation and stretching exercises, group discussion, patient education, etc (16).

Since this study was primarily designed as a randomised clinical trial of relaxation therapy, the prognostic characteristics of the two treatment groups were basically the same (5). The difference in predictability may therefore be attributed to the nature of the treatment. Thus, when relaxation therapy is added to an exercise training programme, the probability of a training success is slightly higher and the effects of the determinants of training success are modified. In other words, some patients benefit from exercise as a single treatment, whereas others benefit from the more comprehensive approach. Possibly, relaxation improves the context of the exercise training (7), the motivation of the patient, or his arousal level, each of which may facilitate a training effect.

The conclusions seem justified that 1) exercise training is not suitable for all patients, referred to a cardiac rehabilitation programme; 2) it is possible to predict for what patients training will be successful, on the basis of clinical and exercise data and psychosocial information; 3) relaxation therapy modifies the effects of the determinants of training success. These findings have important implications for rehabilitation. They support the idea that rehabilitation should be tailored to the individual, in order to reach a greater number of patients more effectively and to save unnecessary effort (1,17,18).

Prediction analysis appears to be a useful tool in tailor-made rehabilitation. Validation of the results of this study on a larger sample is required in order to apply the prediction rules. The number of predictor variables is relatively high for the number of subjects involved. Nevertheless, all variables selected were statistically significant ($p < 0.10$) and most of them were significant at the 0.05 level (regression coefficient/standard error > 2.0). If predictability remains high in a replication study, application will result in two estimates of the probability of training success. These can be utilised for future patients as a a tool to identify those for whom training will be successful, either with or without relaxation. A substantial difference between the two estimates can be considered an argument in assigning the patient to the treatment with the greatest probability of success, also taking other factors (cost, manpower, patient's motivation) into account.

Acknowledgments

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Appendix A. Variables used as predictors in the stepwise logistic regression analysis.

CLINICAL: before infarction
hypertension
exercise habits
smoking
angina pectoris
coronary bypass surgery
previous infarction
non-cardiac morbidity
cardiac medication:
- beta-blockers
- digoxin
- diuretics
- anti-anginal
- anti-arrhythmic
- anti-hypertensive

CLINICAL: hospital
infarction size
infarction location
mild heart failure
medication at discharge
- beta-blockers
- digoxin
- diuretics
- anti-anginal drugs
- anti-arrhythmic drugs

angina pectoris at discharge

INTERVIEW
marital status
work status
job level
infarction appraisal:
- pain experience
- illness experience
- doubt of diagnosis

view of future
wishes early start of rehabilitation
expectation of activity resumption
cause of MI clear
attributed cause of MI:
- stress
- external
- risk factors
- psychic

EXERCISE TESTING
weeks after hospital discharge
maximal work load
work capacity (%)
maximal heart rate
resting heart rate
heart rate at Watt=60
resting diastolic blood pressure
resting systolic blood pressure
maximal systolic blood pressure
systolic pressure rise
chest pain
ST-abnormalities
arrhythmias

PSYCHOLOGIC QUESTIONNAIRES
sleep quality (pre and post MI)
daytime nap (pre and post MI)
vital exhaustion pre MI
Type A (JAS) pre MI
functional complaints
sense of well-being
feelings of invalidity
displeasure
anxiety state (STAI-S)
anxiety trait (STAI-T)

JAS: Jenkins Activity Scale; MI: Myocardial Infarction; STAI: State Trait Anxiety Inventory.

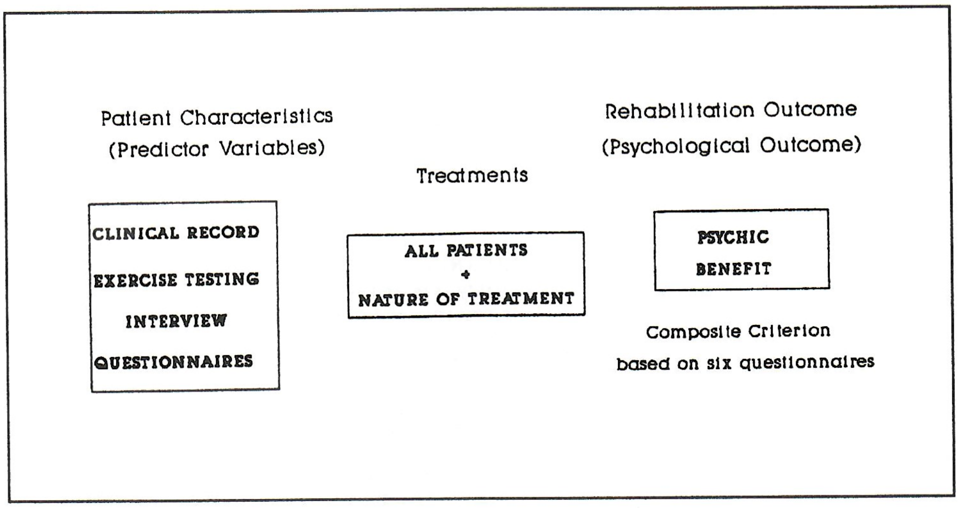

Figure 9.1.
Predicting Psychic Outcome