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Cardiac events after myocardial infarction: Possible effect of relaxation therapy

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Comprehensive cardiac rehabilitation aims primarily at improving quality of life, but an effect on morbidity and mortality may also be expected, especially when changes in behaviour and life-style are induced. The value of relaxation therapy and exercise training in post myocardial infarction (MI) patients was investigated. A group of 90 post MI patients were randomly assigned to either exercise training plus individual relaxation and breathing therapy (treatment A), or exercise training only (treatment B). The occurrence of cardiac events, consisting of cardiac death and of readmission to hospital for unstable angina pectoris, coronary artery bypass grafting (CABG) or recurrent infarction, differed significantly for the two treatment groups in the 2–3 years after infarction. Seven out of 42 patients in treatment group A (17%) experienced a cardiac event, in contrast to 17 out of 46 (37%) patients in treatment group B, (P=0·05, two-tailed). The results suggest that a combination of a behavioural treatment such as relaxation therapy with exercise training is more favourable for the long-term outcome after myocardial infarction than is exercise training alone.

Introduction

A variety of measures may be taken to improve the prognosis of patients surviving myocardial infarction (MI). Treatment or modification of risk factors (smoking, hypercholesterolaemia, hypertension, diabetes, overweight) is considered crucial[1,2]. Also treatment with beta blocking agents improves prognosis[3]. The role of cardiac rehabilitation is controversial in this respect as the evidence of its effect on morbidity and mortality is not conclusive[4–6]. Rehabilitation is often equated with exercise training, and most studies of its secondary preventive value investigated that treatment modality. Its main purpose however, is not physical training, but to improve quality of life and to reduce the effects of psychological as well as physical and social impairment. It may be expected that a multifactorial rehabilitation programme, that improves function and well being, will also influence prognosis in those who adhere to the programme[7,8]. A number of studies have shown a positive effect of behavioural treatment modalities, without exercise, on morbidity and mortality[9–14].

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The question arises therefore whether a combined, multi-factorial approach would be more effective than a single treatment. To our knowledge the additional value of a combined rehabilitation programme in comparison to a single treatment programme has not been studied. In this study the effect of relaxation therapy, additional to a physical exercise training, is investigated. The aim of physical training is basically improved adaptation to increasing levels of physical stress. Relaxation training may be useful to prevent inappropriate effort, counteract its negative effects and promote return to a resting state. Patients who learn to relax may also better adapt to their situation, handle excess effort better and thereby reduce their risk for coronary episodes. The question to be studied is whether MI patients who are taught relaxation technique in the rehabilitation period experience fewer cardiac events over the two years following MI than patients who receive exercise training only and not this therapy.

Materials and methods

PATIENTS

After hospital discharge, MI patients were referred to the rehabilitation regional centre at St Joannes de Deo Hospital, Haarlem, The Netherlands, from several neighbouring hospitals.

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Table 1 Base-line clinical data

Variable	Treatment A	Treatment B	Significance
No. of cases	43	47	—
Age (years)	55·5 (8·4)	54·8 (7·5)	NS
Males	40 (93%)	44 (94%)	NS
History of angina of more than 4 weeks	5 (12%)	9 (19%)	NS
Size of MI:			
unknown	3 (7%)	2 (4%)	
small	10 (23%)	16 (34%)	
medium	18 (42%)	11 (24%)	
large	12 (28%)	18 (38%)	NS
Location of MI:			
anterior	19 (44%)	12 (26%)	
non-anterior	24 (56%)	35 (74%)	NS
Complications of hospital stay			
pump failure	8 (17%)	7 (15%)	NS
cardiac arrhythmias	13 (30%)	17 (36%)	NS
ventricular fibrillation	3 (7%)	5 (11%)	NS
Length of hospital stay (days)	18·3 (4·3)	20·2 (6·0)	NS
Post-infarction angina	14 (33%)	15 (33%)	NS
Medication on discharge:			
beta blockers	10 (23%)	11 (23%)	NS
diuretics	20 (47%)	13 (28%)	NS
anti-anginal	8 (17%)	9 (19%)	NS

Data are reported as events and percentage of cases or as means (SD). Statistical comparison: NS, difference not significant at the 0·05 level. MI, myocardial infarction.

Patients, referred on the basis of a diagnosis other than myocardial infarction, were excluded, as well as those for whom more than 3 weeks time had elapsed after hospital discharge. From March–June 1981 and January–July 1982 a total of 90 patients were eligible for the study. The clinical data at entry to the trial are summarized for the two groups in Table 1. Only six women were referred for rehabilitation. Fourteen patients had a history of angina pectoris. Infarction size was classified on the basis of the peak serum enzyme levels, according to the standards of the participating hospitals. In most hospitals an infarction is classified as small when SGOT level is elevated but remains below 60 u l^{-1} whereas the infarction is classified as large when SGOT levels rise above 120 u l^{-1}. In 26 patients the infarction was classified as small, in 29 patients as medium and in 30 as large infarction. For five patients the enzyme levels were not available. Complications of hospital stay, consisting of signs of pump failure (hypotension, cardio-thoracic ratio >50%, pulmonary congestion), occurred in 15 patients (17%). Assessment of ventricular function was not performed routinely in the participating hospitals. Cardiac arrhythmias occurred in 30 patients (33%), eight of whom (9%) had suffered ventricular fibrillation. On average, the patients stayed almost 3 weeks in hospital. Post-infarction angina was present in one-third of the patients.

MEASUREMENTS

At 30 months after infarction, all patients were invited for a follow-up interview at the rehabilitation centre. Information was also obtained from the patient's cardiologist about the occurrence of cardiac events. They were not aware which treatment group their patients belonged to. An event was defined as any cardiovascular re-admission to hospital (unstable angina pectoris, CABG, recurrent infarction) as well as cardiac death. All events reported by the patient were documented with hospital records.

PROCEDURE

After the initial interview for the rehabilitation programme, patients were randomly assigned to either of the two treatment protocols (treatment A: 43, treatment B: 47). Treatment A consisted of a programme of exercise training plus relaxation training. Treatment B consisted of exercise training only.

The exercise training consisted of 5 weeks interval training, once a day for half an hour, on a bicycle ergometer. Training was done in groups of 4 patients supervized by 2 physical therapists. Each patient was exercised up to 70 to 80% of the maximal heart rate attained at pre-training exercise testing.

Relaxation training was given once a week in six individual sessions of one hour and employed mainly a respiratory technique. This is described in detail elsewhere[15,16]. In short, EMG feedback of the frontalis muscle is used for muscle relaxation and combined with instructions for diaphragmatic breathing. The patient learns to achieve a shift in the respiratory pattern, such that inspiration expands both the lower abdomen and the costal margin, without movement in the shoulder region; exhalation is moderated and slow. Consequently, tidal volume increases and respiration rate slows down; respiration becomes more full, involving the trunk as a whole, and requiring less effort. The patient usually feels quieter and calmer. Hyperventilation, if present, decreases. This is practised first in the supine, relaxed position, but also sitting and standing. The patient is asked to practise at home, as a daily routine, and when experiencing chest discomfort.

METHODS OF ANALYSIS

To study the differential effect of exercise training, versus the combined treatment of exercise and individual relaxation and breathing therapy on secondary prevention, the occurrence of cardiac events in the two groups was compared. The outcomes of all randomized patients were analysed, according to the 'intention to treat' principle. The number of patients in whom an event occurred was counted. As some patients experienced more than one event, statistical testing was conducted on those experiencing subsequent events, using Fisher's exact probability test.

Results

As is shown in Table 1, no significant differences between the two groups in base-line clinical characteristics were seen, nor are there trends which consistently favour one treatment group. Thus, it may be assumed that the randomization procedure was successful. In the follow-up period two patients died, one from sudden cardiac death, the other from heart failure, both in the treatment B group. Another nine patients had a recurrent MI, four in treatment A group and five in treatment B group. Coronary bypass surgery was performed on six patients because of severe or unstable angina pectoris, of whom one was in treatment A group and five in B. In treatment B group, one patient was operated shortly after the second infarction. Three patients of treatment A group were readmitted to hospital once, and seven patients of treatment B group were readmitted 12 times to hospital, many because of angina pectoris. Two patients, one in each group, had moved and were lost to follow-up.

Cardiac events occurred in a total of 7 patients in treatment A group and 17 for treatment B (17% and 37%, respectively; see Table 2). The difference is statistically significant (Fisher exact test, $P=0{\cdot}05$,

Table 2 Cardiac events 2 3 years after myocardial infarction

	Treatment A, exercise + relaxation	Treatment B, exercise only	Significance
Subjects without events (%)	35 (83%)	29 (63%)	
Subjects with events (%)	7 (17%)	17 (37%)	$P=0{\cdot}05$*
Lost to follow-up	1	1	
Total	43	47	

*Fisher exact probability test, two-tailed.

Table 3 Total number of cardiac events after myocardial infarction

	Treatment A, exercise + relaxation ($N=43$)	Treatment B, exercise only ($N=47$)
Readmission to hospital		
Unstable angina pectoris	3	12
Bypass operation	1	5
Recurrent infarction	4	5
Death	0	2
Total Events	8	24

two-tailed). Some individuals experienced more than one event; the total number of events (see Table 3) is, therefore, higher than the number of subjects with events. The difference between treatment groups A and B exists for all events, but not to the same degree. The occurrence of unstable angina pectoris and CABG, in particular, is more frequent in group B. Mortality is very low, 0% in group A and 4·3% in group B. However, the number of patients is too small to test the difference for the classes of events separately.

Discussion

These data suggest that the inclusion of individual relaxation and breathing therapy in an exercise rehabilitation programme reduces the occurrence of cardiac events and decreases hospital readmissions. Although the results must be interpreted with great caution, they are intriguing. The following considerations are important:

(1) The study involved a selected group of MI patients, referred for cardiac rehabilitation. Mortality is quite low, as in other studies[10,11], probably because the seriously ill are already excluded. Cardiac events occurred less frequently than was expected[10,17]. It is therefore quite remarkable that a significant difference in cardiac events between treatments was seen in this study where the control group also received rehabilitation.

(2) The treatment groups do not differ significantly in base-line characteristics. Anterior infarction, which would affect prognosis unfavourably, has occupied more often in treatment group A (44% *vs* 26%). However, this would only strengthen the result. On the other hand, a large infarction was more frequent in treatment group B (38% *vs* 28%). The use of beta-blocking agents, which improve prognosis, is the same for both treatments (both 23%), as well as the presence of post-infarction angina pectoris (both 33%). It seems therefore that the randomization procedure has been successful and that the results cannot be explained by biased allocation of patients of the treatments.

However, the natural course of ischaemic heart disease is dependent on many risk factors; uneven distribution of these among the two treatment groups cannot be excluded, especially with the small number of patients involved. Firm conclusions cannot therefore be drawn from this study. Also, it is not known whether relaxation would be effective as an independent factor, or through reduction of risk factors[18].

(3) The end-points in the study were not predefined. The indications for hospital readmission or CABG may differ among the clinicians involved. There is little change of a treatment bias in this respect, however, as the cardiologists were not aware of the forms of rehabilitation treatment. Nonetheless, the difference between the treatments is greatest for angina pectoris, both as a cause for hospital admission and for CABG. One possibility is that patients who learned to relax were better able to cope with anginal pain. If that idea is correct, the results show a reduction in symptoms, but not necessarily an effect on the natural course of the disease. In a future study, the end-points will have to be considered separately as well.

To summarize the results of this study: it suggests that relaxation and breathing therapy influence cardiac events after myocardial infarction. This result is remarkable in view of the fact that (1) the control group also underwent rehabilitation, (2) the study group already had a fairly good prognosis and (3) the intervention was limited to a two-months rehabilitation period. The stability of this result should be investigated in a replication study, specifically designed for long term outcome on morbidity and mortality. If the effect holds, the implication will be that relaxation therapy has secondary preventive value for MI patients.

For future research, three points should be emphasized. Secondary preventive measures should not be limited to the convalescence phase, but extend beyond the first year after MI[8]. If the influence of relaxation therapy on the natural history of ischaemic heart disease is to be studied, the therapy ought to be continued, and its application assessed, in the same way as compliance with

medication or the presence of risk factors are monitored. An example is the recurrent coronary prevention project, which aims at reduction of 'coronary prone' (type A) behaviour in post-MI patients. In that study the intervention group meetings continued monthly for $4\frac{1}{2}$ years, after an initial higher frequency, and its efficacy in changing behaviour was assessed[19]. Patients with reduced type A behaviour had a far lower recurrence rate than those whose behaviour remained unchanged[13]. It is important therefore to apply criteria for relaxation success and ability.

Secondly, the beneficial effect of relaxation therapy may not apply to all patients equally. It is to be expected that patients who experience benefit in the short term are more motivated to continue the practice of relaxation[15]. Possibly, some categories of patient are more apt to find benefit, as for instance, those who approach the exercise programme in an over-zealous manner[14], or who are unable to undergo physical training. The selection criteria for referral to an exercise training programme may not be the same as the criteria for relaxation therapy. Also, patients with a risk of the development of angina, or with a possible indication for CABG may be especially selected for this therapy.

Finally, the integration of relaxation therapy in rehabilitation can take several forms. As a psychophysiological technique, it can be included in a behavioural treatment[11,13,14], but also be part of the exercise training, for instance during the warm up and/or cool down phases. To study the value of relaxation technique as a treatment modality, we chose individual lessons. Breathing technique is especially difficult to teach in groups. On the other hand, motivation will be enhanced when relaxation is also integrated in the other rehabilitation procedures.

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