Safety of Exercise Training for Cardiac Patients

Results of the French Registry of Complications During Cardiac Rehabilitation

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Background: Cardiac rehabilitation is widely recognized as a medical management procedure that reduces mortality, but the cardiovascular safety of exercise training has not been clearly established. Published data are retrospective or outdated, as patient management has substantially progressed in recent years. The aim of this prospective registry was to determine the current complication rate during exercise performed in the course of cardiac rehabilitation.

Methods: This study was conducted by the Functional Evaluation and Cardiac Rehabilitation Working Group of the French Society of Cardiology. During a 1-year period, 65 cardiac rehabilitation centers reported that serious events had occurred during or 1 hour after an exercise stress test or a training session. Severe cardiovascular events were validated by a scientific committee.

Results: A total of 25 420 patients (78% men; mean age, 61.3 years) were included in the study. Initial indications for cardiac rehabilitation were post–cardiac surgery (coronary bypass, 34.3%; valvular surgery, 18.4%); recent percutaneous coronary intervention (21.6%); and other coronary (13.2%) and noncoronary (12.5%) conditions. The study population underwent 42 419 exercise stress tests and 743 471 patient-hours of exercise training. Twenty severe cardiac events were reported: 5 were related to exercise testing and 15 were related to exercise training. The event rate was 1 per 8484 exercise stress tests and 1 per 49 565 patient-hours of exercise training; the cardiac arrest rate was 1.3 per million patient-hours of exercise. Neither fatal complications nor emergency defibrillations were reported.

Conclusion: The frequency of major cardiovascular complications during supervised exercise training in France is quite low.

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AT PRESENT, THE BENEFITS OF comprehensive cardiac rehabilitation have been clearly demonstrated. Cardiac rehabilitation, and in particular exercise training, is recognized to be part of modern management after myocardial infarction or cardiac surgery as well as after a heart failure event. Recent meta-analyses have demonstrated that cardiac rehabilitation reduces overall and cardiac mortality after acute myocardial infarction[1] and in patients with chronic heart failure.[2] However, at least theoretically, exercise testing and training could induce acute cardiac and peripheral modifications, followed by risks of arrhythmias, stent closure, and worsening of angina or heart failure.

Indeed, the benefit-risk ratio of cardiac rehabilitation remains poorly understood; therefore, data concerning the safety of exercise training are scarce and/or outdated. Most previously published studies were single center and/or retrospective. Two major surveys from North America were published in 1978[3] and 1986.[4] In the first of those, the occurrence of cardiac arrest, myocardial infarction, and fatal events was 1 per 32 593, 1 per 232 809, and 1 per 116 402 patient-hours of training, respectively. The second survey reported 1 cardiac arrest per 111 996 hours of training, 1 myocardial infarction per 293 990 hours of training, and 1 death per 783 972 hours of training in a large cohort of an outpatient program. The previous French survey reported 1 death per 70 250 exercise tests and 1 death per 88 500 exercise training sessions.[5] However, since then, medical treatment, as well as interventional and surgical management, has greatly improved and has modified the prognosis of patients referred to cardiac rehabilitation. Also several single-center studies have reported a decrease in the rate of compli-

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Table 1. Characteristics of the Centers

Patients, No./y	<300	300-900	>900
Centers, No. (%)	33 (51)	23 (35)	9 (14)
Exercise tests, No./y	<500	500-1000	>1000
Centers, No. (%)	33 (51)	18 (28)	14 (21)
Patient-hours,* No./y	<5000	5000-10 000	>10 000
Centers, No. (%)	26 (40)	11 (17)	28 (43)

*Mean duration of exercise training by patient times number of patients.

cations.[6,7] More recently, a retrospective study that included 3511 coronary patients showed an overall event rate of 1 per 58 902 patient-hours per year.[8]

The aim of the present study, which was conducted by the Functional Evaluation and Cardiac Rehabilitation Working Group of the French Society of Cardiology, was to evaluate the current risk of severe cardiac complications occurring during exercise testing and training in cardiac rehabilitation in a prospective multicenter registry.

METHODS

INCLUSION CRITERIA

The study included data from January 1, 2003, to December 31, 2003. In 2002, a questionnaire for registration was sent to 115 French cardiac rehabilitation centers listed in the directory of the French Federation of Cardiology. The 50 centers that did not respond or provided incomplete data were excluded. Sixty-five centers agreed to take part in the study and provided complete data.

In contrast to practices in other countries, in France patients are generally referred early on to cardiac rehabilitation after an acute cardiac episode, and cardiac rehabilitation programs are conducted on a short-term basis (phase II), ie, either inpatient programs covering approximately 3 to 4 weeks or outpatient programs involving 20 exercise sessions over a period of 4 to 8 weeks. Many of the centers provide a mixed program (inpatient, then outpatient). All patients who were referred to these cardiac rehabilitation centers and who performed at least 1 exercise test and/or at least 1 supervised exercise session were prospectively included in the registry whatever the recognized cardiac rehabilitation indication.[9] Patients who did not perform exercise tests and/or exercise sessions were excluded.

EXERCISE TESTING AND TRAINING

Patients included in a cardiac rehabilitation program had undergone previous cardiac evaluation, including physical examination, echocardiography, and exercise testing. All the exercise stress tests were performed in the cardiac rehabilitation centers under medical supervision by a cardiologist in order to prescribe the target heart rate during exercise training sessions. In some centers, a second exercise test was performed, mainly at the end of the rehabilitation program. The exercise training program may differ between centers but should include calisthenics and bicycle or treadmill endurance exercise training for at least 1 hour per day. Exercise training sessions were supervised by physiotherapists in 93.8% of the centers, by cardiologists in 35.4% of the centers, and by nurses in 41.5% of the centers. Patients were encouraged to reach the target intensity determined by the first exercise stress test. According to French guidelines for cardiac rehabilitation, electrocardiographic (ECG) monitoring is recommended for early exercise training sessions but is not mandatory.[9] The number of patient-hours were calculated as the number of patients times the number of training sessions times the mean duration of each session at each center.

CARDIOVASCULAR EVENTS

Cardiovascular events were defined by 2 main criteria: (1) severity of the event and (2) occurrence of the event during supervision. Therefore, we considered the following to be severe cardiovascular events: chest pain with typical ECG modifications, severe ventricular arrhythmias, syncope, cardiopulmonary arrest, or a clinical condition necessitating cardiopulmonary resuscitation, immediate transfer to a coronary care unit or cardiac surgery, and/or use of intravenous drugs. Any event that occurred during or up to 1 hour after exercise stress testing or a medically supervised exercise training session was considered a cardiovascular complication resulting from exercise testing or training. Efforts such as supervised walking, training, gymnastics, and endurance training (bicycle or treadmill) were included with or without ECG monitoring. Events that occurred at rest or even in corridors (while spontaneously walking) or during nonsupervised efforts (eg, physical training at home between 2 supervised ambulatory sessions) were excluded.

Every 4 months, the cardiologist at each center reported the activity of his or her center and, if appropriate, complications according to the selected criteria. All medical records for patients with reported cardiovascular events were analyzed, and severe events were validated by a scientific committee (board of the Working Group). For these patients, a retrospective risk stratification was performed using French guidelines.[9]

STATISTICAL ANALYSIS

Categorical data, which are presented as number (percentage), were compared using the χ^2 test. Continuous data, which are presented as mean ± SD, were compared using the t test. $P \leq .05$ was considered significant. All analyses were performed using STAT VIEW for Windows (Institute Inc 1992-1998 version 5).

RESULTS

CHARACTERISTICS OF THE CENTERS

Among the 65 cardiac rehabilitation centers, 13 (20%) provided inpatient programs, 24 (37%) provided outpatient programs, and 28 (43%) provided mixed programs. The length of experience of the centers ranged from less than 10 years (n=22) , to 10 to 20 years (n=23), and up to more than 20 years (n=20). The number of patients treated, exercise stress tests, and physical training sessions are summarized in **Table 1**. Electrocardiographic monitoring during endurance training sessions was systematic and continuous in 17 centers (26%); 41 centers (63%) provided intermittent monitoring; 5 centers (8%) provided no monitoring; and data were unavailable for 2 centers.

POPULATION

The 65 centers treated 25 420 patients during the year of the registry. The mean age was 61.3 years; 78% of pa-

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Table 2. Complications During Exercise Stress Testing

Patient No./ Sex/Age, y	Pathologic Findings	Complications	Results
1/M/57	MI and stent; heart failure EF = 40%	Final exercise test result: negative; pulmonary edema	Intravenous therapy
2/M/49	RCA stent >1 mo; stopped taking antiplatelet agents	Baseline test result: angina and ECG ischemia	New lesion; new RCA stent
3/M/46	Inferior MI >1 mo; RCA stent	Baseline test result: negative; "vagal" cardiac arrest at recovery period	Successful CPR
4/M/44	Inferior MI >1 mo; LAD stent	Baseline test result: angina and ECG ischemia	Diagonal branch stenosis; medical treatment
5/M/66	Inferior MI; LAD and CX stents	Baseline test result: angina and ECG ischemia	LAD stent closure; new angioplasty

Abbreviations: CPR, cardiopulmonary resuscitation; CX, circumflex artery; ECG, electrocardiographic; EF, ejection fraction; LAD, left anterior descending; MI, myocardial infarction; RCA, right coronary artery.

Table 3. Complications During Physical Training Sessions

Patient No./ Sex/Age, y	Pathologic Findings	LVEF, %	Revascularization	RS	Complication	Action or Place	Results
1/M/70	Angina	U	C	U	NSVT	Cycling	Medical treatment
2/M/66	Angina; CX stent	60	I	L	Chest pain	Cycling	Restenosis: PCI
3/M/68	Angina; CA stent	60	I	M	Chest pain	Cycling	Other stenosis
4/M/49	Inferior AMI; CA stent	49	C	M	NSVT	Gymnasium	ICD
5/F/41	Inferior AMI; CA stent	65	C	L	Chest pain	Cycling	Stent closure: PCI
6/M/50	Inferior AMI; CA stent	55	C	L	NSVT	Cycling	Medical treatment
7/F/63	Inferior AMI; CX + RCA stent	50	C	M	Chest pain	Walking	Pericarditis
8/M/58	Anterior AMI; LAD stent	30	C	H	Chest pain	Cycling	Restenosis: PCI
9/M/81	Anterior AMI; LAD stent	25	I	H	CA	Walking	AVB: PM
10//M/62	Anterior AMI; LAD stent	40	I	M	Chest pain	Walking	Other stenosis: PCI
11/M/53	Anterior AMI; LAD stent	58	I	L	Chest pain	Cycling	Other stenosis: PCI
12/F/53	Anterior AMI; LAD stent	50	I	L	Chest pain	Cycling	Stent closure: PCI
13/M/63	Aortic valve replacement	60	NA	L	SVT	Gymnasium	Medical treatment
14/M/79	Aortic valve replacement	75	NA	H	Heart failure	Gymnasium	Medical treatment
15/M/48	Aortic surgery	64	NA	U	Weakness	Cycling	Tamponade: surgery

Abbreviations: AMI, acute myocardial infarction; AVB, atrioventricular block; C, complete; CA, cardiac arrest; CPR, cardiopulmonary resuscitation; CX, circumflex; H, high; I, incomplete; ICD, implantable cardioverter defibrillator; L, low; LAD, left anterior descending; LVEF, left ventricular ejection fraction; M, moderate; NA, not available; NSVT, nonsustained ventricular tachycardia; PCI, percutaneous coronary intervention; PM, pacemaker; RCA, right coronary artery; RS, risk stratification; SVT, sustained ventricular tachycardia; U, unknown.

tients were men and 22% were women. These patients performed 42 419 exercise stress tests and 743 471 patient-hours of exercise training. The available data for initial cardiac diseases in 63 centers (23 575 patients) included the following: 8079 patients who had undergone a recent coronary artery bypass graft (<1 month earlier); 5089 patients who had undergone a recent percutaneous coronary intervention (PCI); 3116 coronary patients without recent revascularization; 4350 patients who had undergone recent valve surgery; and 2941 other noncoronary patients.

COMPLICATION RATES

Among the 44 reported events, 20 were validated by the scientific committee. Of the 22 rejected events, 9 were not in accordance with the item "severity," while in the 15 others, the event occurred outside of a supervised effort. Finally, 14 centers reported 20 complications. Two of the complications were taken care of on site, and 18 patients required immediate transfer to acute care units.

During exercise stress tests, 5 events occurred (**Table 2**), all in patients who had undergone a recent PCI with stent implantation. The event rate was 1 per 8484 exercise stress tests. Three patients had angina with ischemic ECG changes during the baseline exercise test: 1 case was caused by stent closure; in the other 2 cases, a new coronary angiogram showed coronary stenosis that had not been previously treated. The other events were not directly linked to the recent stent implantation. In 1 case, cardiac arrest by "vagal reflex" occurred during the recovery period but quickly responded to short cardiopulmonary resuscitation; in another case, acute pulmonary edema that occurred during a stress test with negative results required intravenous drug treatment.

During exercise training sessions, 15 events occurred (**Table 3** and **Figure**), representing an event rate of 1 per 49 565 patient-hours. These cardiac events affected 12 patients with coronary disease, 8 of whom experienced chest pain. The results of 6 baseline exercise tests were normal, with medication including 1 or 2 antiplatelet agents, β-blockers, and statins. In 1 patient, chest pain was in keeping with pericarditis demon-

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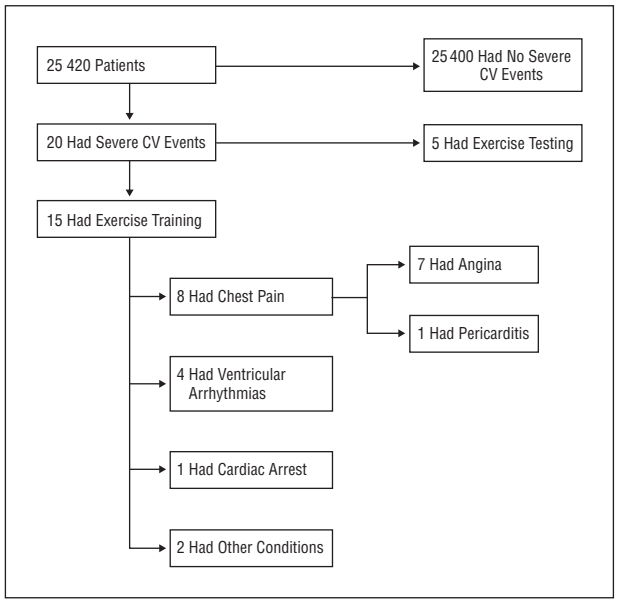

Figure. Overall diagram of events. CV indicates cardiovascular.

strated by echocardiography. In 7 patients, the association of clinical angina with ECG modifications justified a new coronary angiogram. These angiograms showed stent closures in 2 patients (at day 9 and >1 month after implantation), restenosis in 2 patients, and a previously untreated coronary lesion in 3 patients. Of these 7 patients, 6 required PCI and new stenting (2 patients with stent closures, 2 patients with restenosis, and 2 patients with previously incomplete revascularization); 1 patient did not undergo coronary intervention, but his medical treatment was reinforced. Retrospective analysis of their risk stratification showed high risk in 1 patient, moderate risk in 2 patients, and low risk in 4 patients.

Three ventricular arrhythmias were reported: 1 required an implantable cardioverter defibrillator and 2 required medical treatment adjustment. One patient experienced cardiac arrest due to a third-degree atrioventricular block while walking outside in a supervised session; he was promptly resuscitated and transferred for a pacemaker implantation. The three noncoronary patients who experienced a cardiovascular event during exercise training had undergone aortic valve replacement or aortic surgery: 1 had cardiac tamponade that required urgent surgical treatment;1 had nonsustained ventricular tachycardia that required medical treatment; and 1 had a severe acute heart failure episode.

OCCURRENCE OF CARDIAC EVENTS DURING EXERCISE TRAINING; CHARACTERISTICS OF PATIENTS AND CENTERS

Cardiac events occurred during different types of exercise sessions. During bicycle endurance training sessions, 6 cases of angina pectoris, 2 cases of ventricular arrhythmias, and 1 case of cardiac tamponade were registered. During supervised walking training, 2 cases of angina pectoris and 1 case of cardiac arrest occurred, while during gymnastics, 2 cases of ventricular arrhythmias and 1 case of heart failure occurred.

Table 4. Characteristics of the Centers and Rate of Complications

Characteristics	No. of Centers	Rate of Complications During Training Sessions*	*P* Value
Size			
Small (≤300 patients/y)	33	0.12 ± 0.30	.13
Large (>300 patients/y)	32	0.03 ± 0.72	
Experience, y			
≤10	22	0.03 ± 0.12	.43
>10	43	0.09 ± 0.26	
Monitoring			
Continuous	17	0.09 ± 0.25	.77
Other	46	0.07 ± 0.22	

*The rate of complications is expressed as the percentage of the number of events divided by the number of patients in each center.

Table 4 shows that neither the small size of the centers, nor their shorter length of experience, nor ECG monitoring influenced the rate of events. We also noted that compliance with the prescribed target heart rate during training sessions had been respected by all patients who experienced a serious event. In our study, and based on the French recommendations,[9] we were able to retrospectively classify 13 patients who had experienced a cardiovascular event: 3 were classified as being at high risk; 4, at moderate risk; and 6, at low risk.

COMMENT

This national prospective registry revealed that the rate of cardiovascular complications during exercise and training in cardiac rehabilitation patients was very low. Our results provide up-to-date information on the safety of exercise in cardiac patients, and they confirm the speculated decreasing risks observed over the last decades.

RISKS ASSOCIATED WITH EXERCISE TESTS

Exercise tests performed before or during cardiac rehabilitation represent a low risk for patients. In post–myocardial infarction patients, previously published data showed that the incidence of fatal cardiac events was 0.03%; that of nonfatal myocardial infarction and unsuccessfully resuscitated cardiac arrest was 0.09%; and that of complex ventricular arrythmias was 1.4%.[10] An analysis of published surveys on cardiac rehabilitation that included both coronary and noncoronary patients revealed complication rates of 0.8 to 5.6 per 10 000 exercise tests and death rates of 0 to 5 per 100 000 exercise tests.[11] In similar fashion, in our study, the risk of severe cardiovascular events was 1.2 per 10 000 tests, while no deaths occurred during exercise testing. We should note that the main complication we encountered was cardiac ischemia in patients with previous stent implantation. However, and despite the short term between the time of PCI and exer-

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cise testing, most of the ischemic episodes were related to a previously untreated coronary lesion.

RISKS ASSOCIATED WITH PHYSICAL TRAINING SESSIONS

Unaccustomed, vigorous physical exertion is related to the triggering of acute myocardial infarction and cardiac arrest. In 1 review, Foster and Porcari[12] reported a risk of major complications during exercise of approximately 10 per million patient exercise hours (cardiac arrests and myocardial infarctions). However, according to the "risk-protection paradox," the risk decreases with increasing levels of regular physical training.[13-15]

Exercise training for cardiac patients represents a particular situation, because the patients have previously undergone appropriate risk stratification and the exercise prescription is personalized and monitored. Obviously, patients with known heart disease are at greater risk of sudden death or myocardial infarction during vigorous exercise than healthy individuals. In line with this, the average rate of major cardiovascular complications in outpatient cardiac rehabilitation programs has been estimated at 1 in 60 000 participant-hours.[10]

Indeed, during the period in which the 5 studies were carried out, including ours, fatal and overall risk showed a continuing decrease. The rates of cardiac arrest were, respectively, 30.6,[3] 8.9,[4] 6.8,[7] 5.9,[8] and 1.3 (in our registry) per million patient-hours. Neither fatalities nor myocardial infarctions occurred in our study. The fact that no myocardial infarction was reported could be explained by an interventionist approach by cardiologists who, very early on, transferred patients with chest pain after recent stenting. Among these patients, 6 PCIs were required; it is possible that this invasive strategy could have avoided as many as 6 myocardial infarctions (ie, 1/123 912 patient exercise hours). However, pharmacological, interventional, and surgical management improvements over time for coronary patients seem to be the main explanation for the lower risk incurred by our patients.

Among interventional management improvements over the last decades, stenting during angioplasty procedures and widespread use of primary stenting in acute myocardial infarction are clearly the most important. In France, 85% of angioplasty procedures include stent implantation.[16] Obviously, this population requires specific supervision, even though the risk of stent closure would appear to be very low. For example, if we extrapolate the percentage of stenting in France to our own population of PCI patients, we calculate a risk of stent closure during exercise of 0.07%, in accordance with other recent publications.[17-19] Furthermore, even when stent closure occurred during or just after a training session, the onset of the thrombotic process was probably earlier.[20,21]

Cardiovascular risk due to exercise training after cardiac surgery has been poorly studied. The cardiac events that occur most frequently during exercise testing or training after cardiac surgery are cardiac arrhythmias.[22] Surprisingly, in our study, patients with recent surgical revascularization did not have severe complications. Our results are in accordance with an earlier short-term randomized study in which no cardiovascular complications occurred during the training program.[23] It is probable that cardiac evaluation before exercise testing and training led to the exclusion of high-risk patients.

The most common complication that occurs after valve surgery is supraventricular arrhythmia, which was not taken into account in our study.[24] In our study, only a few patients who had undergone aortic valve surgery had experienced a severe cardiovascular event. Further investigations may be needed to evaluate cardiovascular events in a postsurgical population.[25]

CAN WE PREDICT THE RISK OF COMPLICATIONS DURING EXERCISE?

Several guidelines permit risk stratification, but the criteria are commonly derived from research concerning factors associated with an increased risk of morbidity and mortality in the general population.[26] Thus, it is not clear whether the overall risk and the risk during exercise training are similar. Moreover, the usefulness of this risk stratification in the cardiac rehabilitation population is controversial. Franklin et al[7] reported a risk stratification strategy developed by the American Association of Cardiovascular and Pulmonary Rehabilitation. Conversely, Vongvanich et al,[6] using the same criteria, reported a poor risk stratification. In agreement with the latter work, in our retrospective analysis using French criteria, we were unable to correctly predict the risk of complications during exercise training.

The value of ECG monitoring during exercise training sessions for limiting cardiac complications is controversial. In the study of Haskell,[3] ECG monitoring was associated with a lower risk. In contrast, our results are in agreement with those of Van Camp and Peterson,[4] who did not find any difference between continuous or intermittent monitored programs and nonmonitored programs.

Finally, although risk stratification remains necessary at the beginning of a rehabilitation program, the occurrence of a severe cardiac event seems to be difficult to predict in most cases. This difficulty emphasizes the role of the cardiologist in the prescription and supervision of cardiac rehabilitation sessions.

LIMITATIONS OF THE STUDY

Our study had some limitations related to registry methodology. The prospective data in our registry were not complete because they were not reported patient by patient in real time, but rather, center by center. Prior registration of every center and reports issued every 4 months should attenuate the risk of missing data.

We had no indication of medical treatment in the overall population, nor of the modalities of physical training, but there was a consensus based on national recommendations,[9,27] and individual analysis of patients with complications showed adequate medical coverage. The fine line between a complication, its causes, and its detection and treatment may exist; indeed, some events such as postoperative pericarditis complications or

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heart failure are not directly related to effort, and in such cases medical supervision could lead to earlier diagnosis. Furthermore, it is more advantageous to close a stent during exercise stress testing or during a medically supervised training session than to do so at home.

The selected population did not represent all patients in rehabilitation, because some patients initially admitted to the center may have presented a contraindication to physical training and would thus have been excluded from our registry. The registry included only exercise-related complications, and the rate of events that may have occurred during the same period but outside the time of exercise is not known. Therefore, further studies involving other analytical problems (eg, potential predictors of adverse cardiac events or postsurgical complications) may be warranted.

In summary, the risk of cardiac events during exercise testing and training appears to be very low at present, but such events seem difficult to predict. Our results concern supervised exercise training, but they should induce cardiac patients to be more active and to practice physical activity on a regular basis.[28]

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