Nechwatal RM[1]

Cardiac Rehabilitation after Surgical and Transcatheter Valve Replacement and Repair

Kardiale Rehabilitation nach chirurgischem oder interventionellem Klappenersatz und Klappenrekonstruktion

REVIEW

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Summary

› **The benefits of rehabilitation** following coronary artery surgery have been well documented but only three controlled trials following valve surgery with a total of 295 patients have been published to date. These studies have demonstrated similar benefits from exercise training with an increase in VO_2 or work capacity at short term and up to 12 months after surgery. Insufficient data exist about a rise in quality of life (QOL) and about return to work which tended only to be facilitated. A multidisciplinary rehabilitation program should be offered for patients undergoing valve surgery. Besides exercise training and psychological counseling patients should be educated about anticoagulation, including drug interaction and self-management if appropriate, about the recognition of important symptoms and about the elements of a healthy lifestyle.

› **In TAVI patients,** several well designed and controlled trials show that rehabilitation in these elderly patients with higher comorbidities is safe and leads to improvement of exercise capacity and improvement in disability favoring home discharge with more independent life at home.

› **Further research** is needed in patients after cardiac valve surgery to address the question of mortality benefits, as well as quality of life, cost effectiveness and return to work.

KEY WORDS:
Rehabilitation, Cardiac Valve, Mortality, Work Capacity, Quality Of Life

Zusammenfassung

› **Trotz langjähriger Erfahrung und Praxis** in der Rehabilitation von Patienten nach operativer Korrektur von Herzklappenfehlern liegen nur wenig kontrollierte Studien bei diesem Patientenkollektiv vor. Bis 2018 wurden nur drei prospektive, randomisierte Studien mit kleiner Patientenzahl veröffentlicht. Hierbei zeigte sich eine Verbesserung der Belastungskapazität in Watt oder der maximalen Sauerstoffaufnahme mit quantitativ ähnlichem Zugewinn wie bei KHK-Patienten. Widersprüchliche Daten liegen zur Verbesserung der Lebensqualität vor, die in einer kontrollierten Studie nicht verbessert wurde. In neuerer Zeit finden sich mehrere retrospektive Studien, die für den Kombinationseingriff Klappenersatz + Bypass einen Überlebensvorteil nach Reha zeigen. Insgesamt fehlen Daten hinsichtlich Patientenedukation und psychologischen Interventionen, der sozialmedizinische Verlauf -"Return to work"- wurde durch die Reha in einer Studie nur tendenziell verbessert.

› **Deutlich besser** ist die Datenlage bei der Gruppe der älteren TAVI-Patienten mit gleichzeitiger Multimorbidität. Hier zeigt sich, dass ein Rehaprogramm die Belastbarkeit steigern und die Entlassung in die häusliche Umgebung und die Vermeidung von Pflege fördern kann. Reha hilft dabei die körperliche Unabhängigkeit, Mobilität und funktionelle Belastungskapazität wiederzuerlangen und sollte daher in dieser Patientengruppe empfohlen werden.

› **Es gibt zu wenige Outcome-Studien** nach Klappenersatz und Rehabilitationsbehandlung. Weitere prospektive Studien insbesondere zur Mortalität, Lebensqualität, Kosteneffektivität und beruflicher Wiedereingliederung sind notwendig.

SCHLÜSSELWÖRTER:
Rehabilitation, Herzklappen, Mortalität, Belastungskapazität, Lebensqualität

Introduction

Valvular heart disease is not uncommon in Western countries with a prevalence of 2.5% and it increases with age to 13.3% in the 75 years and older group (28). It limits exercise capacity as well as daily activities and restricts quality of life. If necessary, surgical valve replacement or valve reconstruction are the surgical procedures of choice. In recent years interventional procedures such as TAVI and mitral clip have evolved both technically and procedurally thus increasing the number of interventions for specific patient populations.

The reintegration and participation in daily life after valve surgery often represents a physical, psychological and not least social challenge.

A first official recommendation for the rehabilitation of valve patients was published by ›

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CORRESPONDING ADDRESS:
Dr. Robert Michael Nechwatal
Rehaklinik Heidelberg Königstuhl
Fachklinik für Herz- Kreislauf , Gefäße und Lungenkrankheiten
Kohlhof 6, 69117 Heidelberg
✉: robert.nechwatal@rehaklinik-koenigstuhl.de

the European Society of Cardiology in 2005 that was essentially based on studies in coronary disease and heart failure (5). The guideline draws particular attention to the need for high-quality medical care in the first few weeks after surgery, the significant reduction in hospital stays after cardiac surgery in recent years, and the fact that more and more elderly and multimorbid patients have become involved.

Methods

A systematic review to assess the effects of cardiac rehabilitation programs after surgical or trancatheter interventions for heart valve reconstruction or replacement was conducted. The search was executed by the following databases: MEDLINE, EMBASE, COCHRANE LIBRARY and ClinicalTrials.gov. Included were studies that investigated in- or outpatient rehabilitation as a multidisciplinary approach or merely exercise based intervention. All retrospective and prospective published studies as cohort studies or case controlled and randomized controlled studies were assessed. The effects of exercise based rehabilitation on patient outcomes, including mortality and morbidity and quality of life as well as cost effectiveness and return to work were evaluated.

Determinants of Valvular Heart Disease and Comorbidities

Patients with valvular disease suffer from limitation of exercise capacity and are frequently deconditioned. Especially in elder patients, daily life activities and independence are jeopardized. Following heart surgery patients are often troubled with impaired quality of life, depression, anxiety, or posttraumatic stress reactions (8).

Accompanying illness has a negative impact on early and late survival after surgery such as impairment of renal function as well as coronary, cerebrovascular and peripheral artery disease (2, 33). The type of valve lesion that leads to surgery is also of prognostic importance: whether there is an acute destruction of the valve like in endocarditis or a chronic lesion progressing over many years like degenerative or rheumatic disease, the presence of a combined valve lesion or mere insufficiency.

Hemodynamic improvement after valve replacement depends on the extent of preoperative impairment, LV function and the specific valve lesion. Exercise capacity is dependent on ejection fraction, severity of the valve disease, pulmonary resistance, presence of cardiac arrhythmias such as atrial fibrillation and the type of valve replacement. The time to reach the maximum load capacity can range from a few weeks after uncomplicated aortic valve replacement with preserved ejection fraction up to several months, especially if the mitral valve is involved, with higher grade aortic insufficiency and depressed cardiac function (16

Aortic stenosis is the most common primary valve disease leading to surgery or catheter intervention with a growing prevalence due to the ageing population. Early elective surgery is indicated in all symptomatic patients with severe aortic stenosis because of their dismal spontaneous prognosis and in asymptomatic patients with depressed LV function or who develop symptoms during exercise testing (3). Before aortic valve replacement, most patients are classified in NYHA class III (17, 27) and the average improvement after surgery at six months without cardiac rehabilitation is one class (17, 26, 27).

In chronic, hemodynamically significant aortic regurgitation a long period of left ventricular remodelling occurs prior to the development of left ventricular dysfunction and exercise capacity and peak oxygen consumption are well preserved (3). After aortic valve replacement in patients with significant regurgitation a decrease in peak VO_2 was observed from six to 49 months postoperatively representing an impaired aerobic capacity (15).

An alternative to aortic valve replacement constitutes the replacement with the patient´s own pulmonary valve as an autograft the so called Ross-operation. The pulmonary valve, in turn, is replaced during the same procedure with an allograft or stentless xenograft. The Ross procedure is mainly for younger patients who are still growing, women desiring to have children and adults under 65 years of age who decline to receive a mechanical prosthesis because they do not want to be orally anticoagulated. Patients undergoing the Ross operation tend to be much younger (mean age 40.6 years) (11). In a study with 26 adolescents with a median age of 15.7 years after 17.4 months exercise performance was within the normal range of a healthy age and sex matched population, despite sedentary lifestyles (21).

There is only limited information regarding the effect of mitral valve surgery in patients with chronic MR on exercise capacity (13, 16, 26). Le Tourneau (46) investigated the functional effects of surgical correction of mitral regurgitation by mitral valve replacement or repair in the absence of cardiac rehabilitation. Mitral regurgitation correction did not lead to an overall improvement of peakVO_2 in either valve repair or replacement; these results were confirmed by Kim (18).

Studies on the Impact of Rehabilitation on Mortality, Exercise Capacity, Quality of Life, Return to Work and Cost Effectiveness

Studies regarding cardiac rehabilitation in valve disease are scarce. Most data are derived from retrospective cohort studies or prospective but uncontrolled studies.

In a retrospective cohort study, De Vries evaluated the health insurance data of about 22% of the population in the Netherlands (>3.3 Million people). The mean follow-up was 4 years with a minimum of 180 days. Cardiac rehabilitation was associated with a significant benefit on mortality for patients with bypass (CABG) and/or valve surgery, with no difference seen between the single bypass surgery or a combination bypass + valve intervention (HR=0.55, 95% CI 0.42-0.74). Furthermore this survival benefit was independent of age as well as type of valve surgery (7).

Goel published similar results in a monocentric, retrospective study with a mean follow-up of 6.8 years after rehabilitation in combined heart valve and bypass surgery. Rehabilitation was associated with a significant reduction in mortality (HR 0.48, p=0.009), the effect being more pronounced in mitral valve defects (HR 0.24, 95% CI, 0.08-0.77) (12). By contrast Pack in a retrospective study of the Mayo Clinic did not find any effect on survival (29).

Savage addressed the question of whether a rehabilitation program would increase exercise capacity differently in bypass and valve patients, all of whom underwent classic sternotomy. Peak oxygen uptake increased by 19.5% from 17.4±4.4 to 20.8±5.5ml/kg/min (p<.0001) after a mean of 23.6±11.7 workouts. There was no difference between the two groups: heart valve patients increased load capacity as patients with bypass surgery alone or if bypass and a valve procedure were performed simultaneously (38).

Table 1

Results of the three prospective randomized studies on rehabilitation after valve replacement; abbreviations: N=number, M=male, F=female, m=month.

AUTHOR	PATIENTEN (N=) M/F	REHAB SESSIONS	INCREASE EXERCISE PERFORMANCE	FOLLOW UP	OTHER
Sire 1987 (44)	44 36m/8f Isolated aortic valve implantation Mean age 45,5 yrs	4 weeks, 4 hours daily	Cumulated work in KJ at 6 and 12 months improved by 38 % (6 m) and 37% (12 m)	2, 6 and 12 months	Return to work 81% to 65% n.s.
Lin 2004 (19)	104 Mitral valve replacement 57 m/ 47 f Mean age 31,3 yrs	20 to 30 minutes per session 2 to 3 times weekly over a 3 month period	(4.98±0.41) to (4.21±0.53) METs,(P 0.05); after 3 months (8.67±0.74) METs to (6.86±0.63) METs,(P 0.01).	3 months	incidence of pulmonary complication 8% training 24% control (P 0.05)
Sibilitz 2016, 2017 (42, 43)	147 36.76% male, mean age 62 years, aortic (62%), mitral (36%) or tricuspid/ pulmonary surgery (2%)	12 weeks exercise and monthly psycho-educational consultations	VO_2 peak at 4 months (24.8 ml/kg/min vs 22.5 ml/kg/min, p=0.045) No effect after 12 months (43)	4 and 12 months	Short Form-36 Mental Component Scale at 6 months 53.7 vs 55.2 points n.s. Increase in self-reported non-serious adverse events (11/72 vs 3/75, p=0.02)

In mitral valve repair patients Meurin showed that exercise testing performed 21±10 days after surgery allowed to prescribe an exercise aerobic training driven by the measured heart rate at the anaerobic threshold that improved peakVO_2, peak power, peak oxygen puls and chronotropic reserve significantly (22).

In a prospective cohort study with registry data from the CopenHeart survey 292 patients who participated in exercise based cardiac rehabilitation were more likely to be active at a moderate to high physical activity level than non-participants (OR 1,52, 95%CI 1.03 to 2.24). (20). Patients with a moderate to high physical activity level had a reduced risk of mortality compared to those with a low physical activity level (HR 0.19; 95% CI 0.05 to 0.70).

Only three randomized and controlled trials on rehabilitation after heart valve surgery between 1987 and 2016 were published with a total of 295 patients (19, 42, 44), one being fully published only in Chinese (19) (table 1). In all three trials exercise capacity could be improved significantly. In the recent Copen Heart VR study (42) peak oxygen uptake was significantly increased by exercise training -two thirds with aortic valve replacement – from 22.5 to 24.8mlO2/kg/min. All presented studies though are heterogenic, including several valvular pathologies intermixed. A positive effect on aerobic capacity was seen with training programmes ranging from 4 to 16 weeks in length and the follow-up ranging from 3 (19) to 12 months (42, 44).

Conflicting data can also be found in terms of improving quality of life. Uncontrolled studies found a positive effect on the quality of life of patients undergoing rehabilitation (13). In a nonrandomized case controlled study an increase of quality of life, exercise tolerance and the anaerobic threshold was found. Moreover there was a positive correlation between the improvement rating of quality of life and the change in peak VO_2 (47). In the controlled CopenHeart VR study, on the other hand, 147 patients were randomized to receive 12 weeks of physical training after valve surgery and monthly psychoeducational intervention. However, the SF 36 did not change significantly after 4 months (42).

One study was identified that examined occupational rehabilitation after medical rehabilitation (44). However, despite a trend towards improved „return to work“, the difference was not significant after 12 months: 81% in the rehabilitation group compared to 65% in the control group returned to work. There was a high risk of bias because in both groups the percentage of so called white and blue collar workers was not equally distributed.

Hansen conducted a randomized controlled controlled cost-effectiveness study in Denmark. A positive tendency in cost savings was seen, suggesting the likelyhood of rehabilitation being cost-effective, outweighing the extra costs of cardiac rehabilitation (14). But only low risk patients with a mean ejection fraction of 55% and 74% with NYHA class I and II were included - a fact that may explain the lack of significance (14).

Rehabilitation Following Percutaneous Replacement of Heart Valves (TAVI) and Mitral Clip Procedure

In recent years improved valve technologies with fewer complications such as permanent AV block III and paravalvular leaks have led to a 20-fold increase since 2008 with a total of 48,353 TAVI procedures that have been performed in Germany (9).

Several controlled studies were published regarding rehabilitation after TAVI.

Russo examined 78 TAVI and 80 patients with conventional aortic valve replacement, all of them octogenerians not differing neither in age, gender or duration of rehabilitation. ›

Although TAVI patients had more comorbidities, rehabilitation was safe either after TAVI or surgical valve replacement with no difference in exercise capacity (37).

Pressler conducted a small, randomized controlled trial of 30 TAVI patients. The maximum oxygen uptake increased by 3.7 ml/min kg, as well as the muscle strength in all five major muscle groups investigated. The same was true for the sum scales of the quality of life questionnaires (Kansas City Cardiomyopathy Questionnaire) proving that structured strength-endurance training can be safely and effectively used even in patients with a median age of 81 years (31).

Tarro Genta was able to show in 65 TAVI patients that rehabilitation significantly improved both the Barthel Index and the the Morse assessment instrument for the tendency to fall, although TAVI patients were rated as inferior regarding ejection fraction, Barthel, comorbidity and Morse index. TAVI patients tolerated less physical effort and had a lower 6-minute walk capacity compared to patients with conventional surgical valve valve replacement, but there was a significant improvement in walking distance. Rehabilitation in addition to improving exercise capacity, led to an improvement in daily activities and a reduction in the tendency to fall, which could facilitate discharge at home (45).

In a meta-analysis of 5 trials with 292 TAVI patients, the 6-minute walk test and the Barthel Index were found to improve significantly as they did after surgical aortic valve replacement (36).

The mitralclip procedure with edge to edge reconstruction provides a catheter-based alternative for multimorbid patients with more severe mitral regurgitation. In the German transcatheter mitral valve interventions registry (TRAMI registry) including 749 patients between 2010 and 2013, median age was 76 years, 89.0% had NYHA functional classes III or IV and 33.7% showed an EF of <30%.

There was a high rate of comorbidities like coronary artery disease (78.1%), prior myocardial infarction (27.9%), previous stroke (10.6%), atrial fibrillation (44.1%), Diabetes mellitus (31.4%), COPD (22.3%) and renal failure (65.5%) (32). At one year after MitraClip implantation, 63.3% of patients pertained to NYHA functional classes I or II (compared with 11.0% at baseline), and self-rated health status (on EuroQuol visual analogue scale) also improved significantly. Importantly, a significant proportion of patients regained complete independence in self-care (independence in 74.0 vs. 58.6% at baseline, P=0.005), but no information was given which percentage attended a rehabilitation program (32). Although there are no specific studies on the effectiveness of rehabilitation after mitralclip procedure such a program seems to be usually warranted both because of heart failure and multimorbidity (39).

Differences in Rehabilitation of Patients after Valve Replacement Versus Coronary Patients

The actual exercise prescription for patients with recent valve replacement or repair is the same used for CABG surgery patients (24). However, the physical activity of these patients may have been more restricted for an extended period of time prior to the surgical intervention. Early after valvular surgery, the spontaneous exercise capacity improvement is weak and consequently, the resulting low functional capacity may require these patients to initiate with exercise in a conservative fashion (1). Exercise intensities may vary according to the patient´s needs using interval training such as in heart failure patients (25) or a steady state modus in the light or light to moderate domains and it should be supervised by the target heart rate and the rate of perceived exertion (Borg scale). Heart rate is often higher than after coronary artery bypass grafting because of absence of systematic betablocking therapy and higher incidences of atrial fibrillation and no formula allows the calculation of the heart rate at the anaerobic threshold, which is often used as a target during the training sessions (24).

In addition patients with valve surgery are undergoing more frequently minimally invasive lateral thoracotomy than coronary patients because of mitral edge to edge repair. This patient group in comparison with conventional cardiac operation shows a tendency to suffer less pain as in median sternotomy strain causes bony friction due to mobilization (48). It is still emphasised that patients after sternotomy should completely refrain from upper extremity aerobic exercise training 4-6 weeks post-surgery to ensure the stability of the sternum (24). But no guideline exists for specific training modalities including upper limb training after sternotomy. In a survey 78% of 50 clinics interviewed provided also strength training (40).

Although multidisciplinary components have not been systematically investigated it is widely accepted that contemporary cardiac rehabilitation is a complex intervention. Besides functional aerobic training, flexibility, equilibrium and strength training are also considered fundamental. Additional interventions may also include breathing and coughing exercises and vocational evaluation advice. But no less important are educational counseling regarding adherence to medication (such as anticoagulation in mechanical valves and atrial fibrillation), symptom monitoring, nutrition advice, risk factor control, psychosocial counseling and relaxation training as well as counseling on endocarditis prophylaxis. Individually tailored multidisciplinary programmes are needed to maintain patients' autonomy and to empower them in meeting challenges of their everyday life.

Differences in the rehabilitation of TAVI patients with regard to conventional valve surgery arise considering age and the presence of multimorbidity. In TAVI patients the group of 80 to 90 years predominate with 58,1%, 5,4% of patient being more than 90 years old (6). Leading a life on their own with a possible discharge at home should be a priority objective of rehabilitation for this patient group. Exercise-based cardiac rehabilitation in TAVI patients is leading to significant improvements in exercise tolerance, walking capacity, muscle strength and quality of life, and reduces frailty (10,31, 37,45). As a result, official position statements promote the implementation of exercise-based cardiac rehabilitation after TAVI (34). Although exercise testing is part of the guideline recommendations of international societies in cardiac rehabilitation (23), there may be only half of the patients able to perform the bicycle stress test (10). The bicycle stress test thus seems to be an inadequate testing tool – the six minutes walk test being more appropiate for TAVI patients characterised by several comorbidities.

It is evident that cardiac rehabilitation should be individualized, organised in accordance with patient's everyday life and can be delivered as an inpatient or outpatient program. In practice no studies addressed the issue of superiority of any of these both programs.There is little doubt that multimorbid

octogenarians with TAVI should follow a supervised inpatient program, whereas in conventional valve surgery often the combined approach of hospital based followed by a period of home based exercise was used (19, 42, 44). An increase in self-reported non-serious adverse events (11/72 vs 3/75, p=0.02) was only reported in one home based exercise program (42).

Finally we do not know how the optimal follow-up after rehabilitation should look like. Exercise-based cardiac rehabilitation after heart valve surgery positively impacts VO2 peak after 4 months, but recently no long term benefit was found after 12 months (43). Therefore future guidelines should also include regular assessments in the follow up. Further randomised clinical trials are needed in order to assess the impact of rehabilitation on patient-relevant outcomes, including morbidity and mortality, cost effectiveness, return to work and quality of life in valvular patients.

Conflict of Interest

The author has no conflict of interest.

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