

The Effectiveness of an Early Rehabilitation Program Using Remote Technologies on an Outpatient Basis in Patients after Surgical Correction of Acquired Valvular Heart Defects

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Abstract:

Purpose of the study: to study the clinical safety and effectiveness of combined rehabilitation, including early rehabilitation with physical training in the hospital and remote rehabilitation using a mobile application on an outpatient basis, in patients after correction of acquired valvular heart disease (AVH) under conditions of artificial circulation.

Material and methods: The study included 68 patients who underwent surgical correction of PPS. Depending on the approach to rehabilitation, patients are divided into two groups: the main group (n=34) and the control group (n=34). In the main group, two subgroups of patients were identified depending on the rehabilitation performed: a subgroup of combined rehabilitation (n=16) with the inclusion of treadmill training at the early hospital stage, at least from the 8th day after surgery for 2 weeks. and remote rehabilitation at the outpatient stage using a mobile application, and a subgroup of remote rehabilitation (n=18) without the use of early treadmill training at the inpatient stage. In the control group, only standard methods of cardiac rehabilitation were used.

Research results: No statistically significant differences were found in the frequency and nature of complications in the early postoperative period. A more pronounced positive dynamics of the functional status of patients from the combined rehabilitation subgroup was demonstrated 24 days after surgery in comparison with patients without the inclusion of early physical training in the rehabilitation program. In the subgroup of combined rehabilitation, there was a more significant increase in the indicators of exercise tolerance ($p = 0.03$) and peak oxygen consumption ($p = 0.04$) in dynamics 24 days after surgery with their further increase ($p = 0.04$; $p = 0.03$) by the 4th month of observation compared with those on the 7th day of the postoperative period, when compared with the dynamics in the remote rehabilitation group. Among patients undergoing combined rehabilitation, there was a higher adherence to regular use of a mobile application for remote rehabilitation than among patients from the remote rehabilitation subgroup - 50% versus 38.8%, respectively ($p = 0.04$).

Conclusion: a rehabilitation program for patients with PPS after surgical correction of the defect, including early moderate-intensity physical treadmill training followed by outpatient remote rehabilitation using a mobile application, demonstrates its safety and effectiveness in the form of a significant improvement in the patient's functional status. At the same time, the early start of physical training is associated with increased adherence to the use of remote rehabilitation technologies in the future.

Key points: acquired heart valve defects, heart surgery, postoperative cardiac rehabilitation, early rehabilitation, remote rehabilitation.

Introduction

Cardiac rehabilitation (CR) is a comprehensive intervention that includes physical training, education, psychological support, a lifestyle modification program, and drug therapy. The main goal of such a program is to improve the physical condition and emotional status, quality of life of patients with pathology of the cardiovascular system [1–3]. Taking into account the clinical and cost-effectiveness of CPG [4], all expert documents (including clinical guidelines) around the world include recommendations for secondary prevention (CP) for patients with chronic cardiovascular diseases who have suffered acute vascular events, as well as cardiac surgery and vessels [5].

It is important to note the fact that the significance of CR in patients who have undergone coronary artery bypass surgery has been convincingly proven, while the effectiveness and features of its implementation in patients with acquired heart defects (HAVs) have not been sufficiently studied [6].

However, CR is not widely available even in highly developed countries and is underused compared to other recommendations, including drug therapy [7, 8].

For the Russian Federation, an urgent problem in the implementation of the CR is the unpreparedness of most cardiac surgical medical institutions to implement rehabilitation programs. There are difficulties in implementing recommendations into clinical practice; the outpatient stage of rehabilitation suffers, which is due to a shortage of personnel, limited time for visiting specialists, insufficient funding and equipment [9].

One of the key factors limiting the use of CR in patient management strategies is the lack of conviction of both doctors and patients in its necessity [10]. Thus, the traditional scheme of patient management after surgical correction of PPS is limited to monitoring laboratory and instrumental parameters and subsequent outpatient observation at the place of residence. As a rule, active rehabilitation measures are not carried out during the hospital period after surgery.

The development of technologies for remote monitoring of cardiac patients is becoming increasingly important. This method is also applicable in the field of CR in outpatient settings. The use of a remote method as part of the third outpatient stage of postoperative rehabilitation of patients is becoming a relevant solution [11], taking into account the available data on the comparability and even advantages in terms of safety and effectiveness of supervised home training and rehabilitation programs in a medical facility [12–15]. However, in the Russian Federation, the experience of using telemedicine technologies for remote rehabilitation of patients with cardiovascular diseases, and especially in a cohort of cardiac surgery patients, is still limited to single studies [11, 15].

In turn, for people who have undergone cardiac surgery under conditions of cardiopulmonary bypass (CPB), the use of a combined rehabilitation program using remote rehabilitation technologies at the outpatient stage is primarily aimed at maintaining the continuity of the CR program formed in the hospital and increasing adherence to the methods recommended upon discharge secondary prevention.

Purpose of the study: to study the clinical safety and effectiveness of combined rehabilitation, including early rehabilitation with physical training in the hospital and remote rehabilitation using a mobile application on an outpatient basis, in patients after correction of PPS under IR conditions.

Material and methods

The study included 68 patients who underwent surgical correction of PPS under cardiopulmonary bypass (median age 59.0 [45.0; 68.75] years). All patients signed voluntary informed consent to participate in the study. The study was performed in accordance with the standards of Good Clinical Practice and the principles of the World Medical Association Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects.” The study protocol was approved by the local ethics committee of the Research Institute of the KPSSZ (protocol No. 10 of December 23, 2022).

Inclusion criteria:

- voluntary informed consent of the patient to participate in the study;
- verified diagnosis of PPS of non-infectious origin;
- isolated correction of mitral valve disease or in combination with correction of the aortic/tricuspid valve under cardiopulmonary bypass;
- age from 35 to 75 years;
- The patient has a smartphone with the Android operating system.
- Non-inclusion criteria:
 - the presence of unstable angina in the postoperative period;
 - acute conditions for 6 months. before surgery and in the early postoperative period (myocardial infarction, acute cerebrovascular accident, pulmonary embolism, decompensation of heart failure);
 - genesis of acquired heart valve disease associated with infective endocarditis;
 - expressed by disturbances of cardiac rhythm and conduction;
 - reduced (less than 40%) left ventricular ejection fraction;
 - the presence of other somatic diseases that impede the implementation of rehabilitation measures;
 - the patient's initial reluctance to participate in the distance rehabilitation program.

All patients underwent a general clinical examination upon admission, a preliminary assessment of inclusion and exclusion criteria at the preoperative stage, and then also on the 5th day after surgery. A 6-minute walk test was performed at least on the 6th day after surgery. At least on the 7th day after surgery, patients underwent a stress test (spiroveloergometry, SVEM) to determine the parameters of peak oxygen consumption (VO_{2peak}) and exercise tolerance (PET).

After performing SVEM using randomization, the patients were divided into two groups of 34 people - the main group and the control group, depending on the approach to rehabilitation. In the main group, two subgroups of patients were identified depending on the rehabilitation components used: a subgroup of combined rehabilitation (n=16) with the inclusion of early physical training on the treadmill at the inpatient stage and remote rehabilitation at the outpatient stage, and a subgroup of remote rehabilitation (n=18) without using early treadmill training at a stationary stage.

Patients of the combined rehabilitation subgroup (n=16) in the early postoperative period, starting from at least 8 days after correction of valvular pathology, underwent early physical inpatient rehabilitation in the form of daily treadmill training for 14 days, with their continuation during the second inpatient stage rehabilitation. Exercise intensity during early inpatient rehabilitation was defined as 60% of VO_{2peak} . Each workout consisted of a warm-up (5 min), a main period and a cool-down (5 min). Warm-up and cool-down consisted of walking at a slow pace. The duration of the main training period was increased daily depending on the patient's condition. The methodology for early training at the stationary stage is described in previously published works [16, 17]. No complications were reported during the stress test and subsequent early rehabilitation training. There was no increase in cardiac and coronary insufficiency, cardiac rhythm and conduction disturbances, or hemodynamic disturbances. Clinically, the patients' exercise tolerance was satisfactory.

Additionally, on the 5th day after surgical correction of PPS, a mobile application developed at the Research Institute of CPSSZ for remote rehabilitation of patients after heart surgery was installed on a personal smartphone [18]. Information about the mobile application and its sections is given in our previously published study [11]. After completing the early rehabilitation stage, an individual outpatient rehabilitation plan for 4 months was drawn up using a mobile application, including

physical therapy (physical therapy) and dosed walking with individually selected training parameters. Additionally, each patient in the combined rehabilitation group was given a fitness bracelet (SunWind SW 30) for use at home to monitor the distance traveled per day, the dynamics of heart rate, and arterial blood oxygen saturation. Its use was recommended to the patient daily for 4 months, except at night. Using a mobile bracelet application, the doctor assessed the tolerability of the training and its safety on a daily basis.

In the remote rehabilitation group (n=18) at the inpatient stage, rehabilitation did not include early treadmill training and was limited to respiratory rehabilitation, exercise therapy and dosed walking. Upon completion of the inpatient phase, just like patients in the combined rehabilitation group, a mobile application was installed with the development of an individual plan for 4 months, and they were also given a fitness bracelet.

In the control group (n=34), only standard CR methods were used, including early mobilization, respiratory rehabilitation, exercise therapy and dosed walking with a gradual expansion of motor activity. The control group was observed by a cardiologist at the place of residence as part of the third outpatient stage of rehabilitation; patients were given recommendations on maintaining a healthy lifestyle and performing daily physical activity.

Upon completion of the second inpatient stage of rehabilitation (after 24 days), all patients underwent a standard clinical and instrumental examination, 6-minute walk test, SVEM, and transthoracic echocardiography (EchoCG). After 4 months After surgery, a similar examination was carried out with the exception of the 6-minute walk test. After 4 months After the operation, the functional status of the patients was analyzed: the safety of the training performed on an outpatient basis, the patients' adherence to the recommended remote rehabilitation program using a mobile application.

Statistical analysis was carried out using the Statistica 10.0 program (Statsoft, USA). Quantitative indicators are presented as median and lower and upper quartiles (Me [Q1; Q3]). When assessing differences in quantitative indicators, nonparametric Mann-Whitney tests (with two comparison groups) and Kruskal-Wallis tests (with three comparison groups, followed by post-hoc comparison using the Mann-Whitney test) were used. Qualitative indicators are represented by the frequency distribution of the characteristic. To assess differences in qualitative indicators, Pearson's χ^2 test was used. The critical level of statistical significance was taken to be 0.05.

Research results

The patients did not differ significantly in the main preoperative parameters, as well as in the frequency of persistence of atrial fibrillation on the 7th day after surgery, or the functional class of heart failure. In the early hospital postoperative period, the frequency and structure of complications were analyzed. The total number of postoperative complications during the hospital period was taken as a combined end point (Table 3). During the hospital period, no significant differences were found in the frequency and nature of complications in the subgroups of the main group and the control group.

The 6-minute walk test scores in the two rehabilitation subgroups after 24 days were significantly higher than in the control group. At the same time, a more pronounced positive dynamics of the functional status of patients from the combined rehabilitation subgroup was noted 24 days after the operation (by the time of completion of the second inpatient stage of rehabilitation) in comparison with patients without the inclusion of early physical training in the rehabilitation program.

In the subgroups of combined and remote rehabilitation, higher indicators of functional status were observed, assessed by the results of SVEM by the 4th month of observation than in the control group. In the combined rehabilitation group, there was a more significant increase in the parameters of physical fitness ($p=0.03$) and VO_{2peak} ($p=0.04$) in dynamics 24 days after surgery with their further increase ($p=0.04$; $p=0.03$) by the 4th month of observation compared with those on the 7th day of the postoperative period when compared with the dynamics in the remote rehabilitation group (see figure).

Speaking about patients' adherence to remote rehabilitation, it is important to note that it was in the combined rehabilitation group that adherence to using the mobile application was slightly higher than in the remote rehabilitation group. Thus, when analyzing adherence after 4 months. after inclusion in the rehabilitation program, it was revealed that in the combined rehabilitation group, 13 (81.2%) of 16 patients used a mobile application for remote rehabilitation, while in the remote rehabilitation group - 14 (77.8%) of 18 patients ($p > 0.05$).

At the same time, from the subgroup of combined rehabilitation, only 8 (50%) patients at least 5 times a week for 4 months. used the "Dosed Walking" and "Therapeutic Exercises" sections of the application, while 5 (31.2%) patients used the application irregularly (the median number of visits to the physical rehabilitation sections was 7 [5; 10] times) during the entire observation period, 3 (18.7%) patients did not use the application. 5 (31.2%) patients received consultations with a cardiologist via chat. In turn, in the remote rehabilitation subgroup at least 5 times a week for 4 months. 7 (38.8%) people were engaged, which turned out to be significantly less than in the subgroup of combined rehabilitation ($p = 0.04$). The application was also used irregularly by 7 (38.8%) patients in this subgroup. The application was not used by 4 (22.2%) patients. 3 (16.6%) patients received consultations via chat, which is also significantly less than in the combined rehabilitation subgroup ($p = 0.04$).

In the combined rehabilitation subgroup, adherence to using a fitness bracelet for home workouts was also assessed. Two (12.5%) patients did not use a fitness bracelet, did not perform recommended home workouts, and did not use the remote rehabilitation application. Eight (50%) patients used a fitness bracelet, performing recommended exercises 5 times a week, 5 (31.2%) patients used a fitness bracelet, performing workouts no more than 2 times a week, 1 (6.2%) patient used bracelet, but did not perform the recommended exercises as part of home workouts.

When assessing the safety of home workouts and the role of fitness bracelets in assessing safety, heart rhythm disturbances such as atrial fibrillation were recorded in one patient using a fitness bracelet. This allowed him to promptly seek help from a cardiologist to resolve the issue of cardioversion. One patient had rhythm variability, a tendency to tachycardia, and increased blood pressure, which was accompanied by complaints of shortness of breath during measured walking; Taking into account the patient's complaints, the cardiologist promptly adjusted the therapy and training regimen. According to the fitness bracelet, two patients showed a tendency to tachycardia, and subsequently the cardiologist also adjusted the therapy.

Discussion

Methods of secondary prevention, namely non-pharmacological interventions, should be considered as a key link in terms of not only increasing life expectancy, but also the patient's physical and social activity and quality of life. One of the components in the management of patients after surgery is an individually developed secondary prevention/rehabilitation program. Considering the staffing limitations of rehabilitation services in all countries and the lack of clear recommendations for non-drug management of such patients, it is advisable to plan CR programs in clinics that perform surgical correction and have the most experience in monitoring such patients [11].

The INVOLVE study describes predictors of readmissions in patients undergoing valve surgery, justifying the need for an individualized approach [19]. An intensive, individually planned CR program in a valvular heart disease clinic reduced the composite endpoint of readmissions and/or death to 23% (compared to 37% in the control group). In addition, economic analysis showed that in the group with intensive CR, the total costs per patient with PPS undergoing cardiac surgery were 883 euros less than those in the control group ($p < 0.001$) [20].

To date, the basic principles of CR have been developed for patients with coronary artery disease, primarily those who have suffered acute coronary syndromes, as well as for cardiac surgical patients, in particular, those undergoing direct myocardial revascularization [2, 21]. Postoperative rehabilitation of patients who have undergone cardiac surgery has common features for all patients undergoing sternotomy and bypass. However, the structure and content of the rehabilitation

program, the timing of its start depend on the pathology of the heart and blood vessels, and for the cohort of patients with PPS, the effectiveness and features of post-operative rehabilitation with physical training have not been sufficiently studied [6].

In addition to the first and second stages of inpatient rehabilitation, the third - outpatient - stage is also important, which in the Russian Federation most often consists of observation by a therapist at the place of residence with the absence of selected home training programs, much less control over their tolerance. Current trends dictate conditions for improving approaches to outpatient monitoring of patients using remote technologies [11].

Our study touched upon two fundamentally new aspects of postoperative rehabilitation for patients with PPS: studying the effect of a 14-day course of personalized physical training as part of the inpatient rehabilitation phase, starting at least 8 days after surgery, as well as studying the safety and effectiveness of remote rehabilitation programs with monitoring of the implementation of selected home workouts as part of the outpatient stage.

Previous clinical studies assessing the effect of physical exercise initiated within 1 month after heart valve surgery have shown its positive impact on patients' quality of life and exercise tolerance [22–26], safety and no negative impact on outcome operations [17]. Previously, we also proved the safety and effectiveness of early physical rehabilitation with moderate-intensity aerobic exercise for patients after surgical correction of mitral valve defects, starting at least 8 days after surgery in an uncomplicated postoperative period [18]. This study demonstrated the importance of the continuity of stages of postoperative rehabilitation, which began in the early postoperative period and continues after discharge from the hospital at home.

In the group with standard CR methods at the inpatient stage, the additional use of remote monitoring of home exercises at the outpatient stage influenced the improvement of the patient's functional status. However, more pronounced dynamics of functional status over 4 months. after surgery, she was observed in the combined rehabilitation group, where early physical training was used in the hospital and home training under remote control on an outpatient basis. Thus, in the combined rehabilitation group there was a more significant increase in the indicators of physical activity ($p = 0.03$), VO_{2peak} ($p = 0.04$) already 24 days after surgery, with a further increase by the 4th month of observation at the end of the remote outpatient phase rehabilitation ($p=0.04$; $p=0.04$).

Patients undergoing combined rehabilitation also showed better adherence to regular use of a mobile application for remote rehabilitation than patients in the distance rehabilitation group. This can be explained by the start of physical training in the combined rehabilitation group during the inpatient stage, which probably provided additional motivation for maintaining this physical regime and attitude of the patient after discharge. Moreover, a detailed discussion in the hospital with the patient about the prospects for physical activity as part of future home workouts (dosed walking and exercise therapy using the application) and familiarizing the patient with the application program in advance could also be an incentive to perform the recommended amount of physical training within both inpatient and outpatient stage of rehabilitation. The use of fitness bands in the combined rehabilitation group may also have contributed to increased patient adherence and engagement.

There are still a large number of “blank spots” in assessing the effectiveness of the CR program for patients with heart defects. Many researchers state the need to conduct numerous studies assessing the effectiveness and safety of such programs, the importance of creating individually oriented programs taking into account the patient's pre-existing phenotype. It is important to evaluate not only the classic effects of any intervention (deaths, readmissions), but also clinical outcomes such as the persistence (occurrence) of atrial fibrillation, heart failure, pericardial and pleural effusion, and typical postoperative complications. In addition, the criterion for the effectiveness of such programs should be social factors, including the duration of temporary disability and the absence of disability [27]. In addition, it is necessary to develop and implement measures to increase motivation and awareness of new approaches to CR for both patients and doctors.

Limitations of the study. When assessing the effectiveness of the developed comprehensive rehabilitation program, the contribution of the patient's comorbid pathology, the nature of damage to the heart valves, the type of prosthesis and the extent of surgery for PPS were not taken into account.

Conclusion

The inclusion of patients with PPS after surgical correction of the defect in a rehabilitation program, including early physical treadmill training of moderate intensity followed by outpatient remote rehabilitation using a mobile application, demonstrates its safety and effectiveness in the form of a significant improvement in the patient's functional status. At the same time, the early start of rehabilitation activities, including physical training, is associated with increased adherence to the use of remote rehabilitation technologies in the future. In turn, the use of remote methods of rehabilitation after surgical correction of PPS is a safe, effective and, for most patients, a comfortable method of CR on an outpatient basis. Remote technologies in the Kyrgyz Republic make it possible to adjust the physical activity performed under the control of its subjective tolerance and heart rate, identifying dangerous heart rhythm disturbances, helping to increase patients' motivation to exercise.

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