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D.O. Turaev, A.G. Sudenko, S.M. Datsieva

COMPREHENSIVE ASSESSMENT OF THE EFFECTIVENESS OF EARLY REHABILITATION AFTER HEART VALVE SURGERY IN THE STRUCTURE OF CARDIOVASCULAR SURGERY

The purpose of the study. To evaluate the impact of early cardiological rehabilitation on physical function and clinical outcomes in patients after mitral or aortic valve replacement. Materials and methods. The study included 20 patients (12 in the intervention group, 8 in the control group) who underwent elective heart valve surgery. The intervention group received early rehabilitation from day 2 after surgery, including physical activity, walking, and endurance exercises. The assessment was performed before surgery, at discharge, and 6 months later using the SPPB, SF-12, 6MWT, and HADS scales. The analysis was performed in IBM SPSS Statistics 21.0. Results. The patients in the intervention group demonstrated significant improvements in physical function (SPPB), endurance (6MWT), and PCS compared with the control group. SPPB proved to be a statistically significant predictor of readmission (p = 0.017) and mortality (p = 0.006) during 6 months of follow-up. Conclusions. Early cardiac rehabilitation is safe, effective and can be considered as a mandatory stage of treatment for patients after valve replacement. Further studies with an expanded sample are needed to confirm the long-term effectiveness of the program.

Keywords: cardiac rehabilitation, prosthetic heart valves, physical function, six-minute walking test, SPPB, prognosis, early mobilization.

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Introduction. Cardiological rehabilitation (CR) is a multi-level system of secondary prevention, covering physical training, educational modules, psychological support, lifestyle correction and rational drug therapy. It is aimed at restoring physical performance, stabilizing the emotional state and improving the overall quality of life in patients with cardiovascular diseases, including after heart surgery. CR becomes especially relevant for patients who have undergone surgery on the valvular heart apparatus, since it is in this cohort that high risks of postoperative complications and functional limitations are noted [7]. According to international studies, participation in rehabilitation programs can reduce overall mortality by 20-30% and the frequency of repeated hospitalizations by up to 30% [1, 4-6].

Given the high incidence of complications and the need to restore functional activity as soon as possible in this category of patients, the development and implementation of early rehabilitation protocols is of particular importance. In the framework of this study, early cardiac rehabilitation (RCR) refers to the activation of the patient, which begins in the early postoperative period - from the 2nd day after surgical intervention on the heart valves, provided stable hemodynamics. The RCR program includes a gradual increase in physical activity (breathing exercises, exercises for the limbs, walking around the ward and corridor, endurance training under the supervision of a physiotherapist). Unlike standard cardiac rehabilitation, which begins 2-4 weeks after surgery and is performed primarily on an outpatient basis, RCT is aimed at early recovery of physical function and prevention of physical inactivity, skeletal muscle atrophy, thromboembolic complications and psychological maladjustment. The novelty of the program lies in its structured phasing (mobilization - endurance training - individual load selection) and in the use of the SPPB and 6MWT functional scales as objective criteria for recovery dynamics already in the hospital period.

Despite the recognized clinical and economic effectiveness of CP, its implementation and implementation in practice, especially in the context of the treatment of acquired heart defects (CAD), including after valve replacement, still remain fragmentary [23]. Unlike patients after coronary bypass surgery, rehabilitation in patients who have undergone valve surgery has not been studied deeply enough, and protocols are poorly standardized [8,10]. In the Russian Federation, the implementation of the CR is complicated by the lack of specialized departments, poor hospital facilities and a shortage of trained personnel, especially at the outpatient stage, which reduces the coverage and quality of the program [3, 8-10]. In most cases, the management of patients after valvular surgery is limited to follow-up without active rehabilitation support in the early posthospital period, which reduces the potential for recovery and adaptation to physical activity [2].

An additional barrier to the wider implementation of CD is the lack of awareness and motivation on the part of both medical staff and patients themselves [12]. The traditional model of follow-up after heart valve surgery is reduced to occasional visits to the polyclinic with an emphasis on instrumental and laboratory parameters, while a holistic approach to rehabilitation is often absent [20]. In this context, the integration of digital and telemedicine solutions into the outpatient treatment process is becoming increasingly relevant [11]. Current data indicate the high effectiveness of remotely controlled programs: they allow for continuous rehabilitation, reduce the burden on the healthcare system, and increase patient compliance [12, 14, 16, 17].

For patients who have undergone heart valve surgery using artificial circulation (IC), a combined approach to

TURAEV Diyorbek Oybek ugli – student of the First Pavlov State Medical University of St. Petersburg, email: turaev.diyor@mail.ru; **SUDENKO Anastasia Gennadievna** – student of the First Pavlov State Medical University of St. Petersburg, email: a.sudenochka@gmail.com; **DATSIEVA Saida Magomedovna** – Candidate of Medical Sciences, assistant of the Department of Polyclinic Therapy, Dagestan State Medical University, datsievas83@mail.ru

rehabilitation based on continuity between inpatient and outpatient stages is of particular importance [24]. The use of telemedicine technologies at the third stage of the treatment ensures the maintenance of habits formed in a hospital setting, promotes better adaptation to physical activity, reduces anxiety and increases adherence to prescribed therapy [20]. However, in Russia, the experience of implementing such models is still limited to pilot projects, which requires a comprehensive assessment of their effectiveness, especially in the group of patients after surgical interventions on heart valves [8]. In this regard, further research is needed to optimize protocols, standardize remote solutions, and form a unified approach to early rehabilitation of this category of patients.

Thus, the aim of the study is to evaluate the clinical effectiveness of the early hospital stage of cardiac rehabilitation in patients after prosthetic heart valves, with an emphasis on the dynamics of physical function, quality of life and frequency of adverse outcomes in comparison with standard management without an active rehabilitation program.

Materials and methods. The present study was conducted as part of a prospective follow-up at the Clinical Hospital named after Peter the Great, St. Petersburg. The required sample size for comparing two independent groups was calculated using the MedCalc statistical package (version 20.1; MedCalc Software Ltd, Belgium), with the parameters: significance level α = 0.05, test power 80% and expected effect size 0.7. According to calculations, the minimum number of patients in each group should have been at least 18 a person taking into account possible retirement. As part of the pilot phase, 20 patients who underwent elective heart valve surgery between January 2022 and March 2024 were included in the study (Fig.1).

The clinical characteristics of the included patients are presented taking into account the genesis and volume of the valvular lesion. Among the 20 examined patients, patients with rheumatic (n = 11; 55%) and degenerative (n = 6; 30%) malformation predominated, less often with infectious endocarditis (n = 3; 15%). The majority of patients had isolated damage to one valve (mitral - 60%, aortic - 40%), while a two-valve lesion occurred in 3 (15%) of the examined patients.

Prior to surgery, all patients underwent a standard echocardiographic assessment with the determination of the main hemodynamic parameters: left ventricular ejection fraction (LVEF), terminal diastolic volume (CDV), terminal systolic volume (CSF), average pressure gradient on the valve and the degree of regurgitation. The average LVEF before surgery was 55 ± 6%, after surgical correction - 58 ± 5%, which indicates the preserved systolic function of the myocardium. At the time of the start of rehabilitation (2-3 days after surgery), the patients of both groups did not differ in age, gender, type of prosthetics (mechanical or biological valve), LV ejection fraction and frequency of concomitant diseases.

The early cardiological rehabilitation program was developed by the authors taking into account the adapted recommendations of the European Society of Cardiology [15] and the national clinical protocols of the Russian Ministry of Health [23]. The rehabilitation was carried out in stages and included three consecutive blocks:

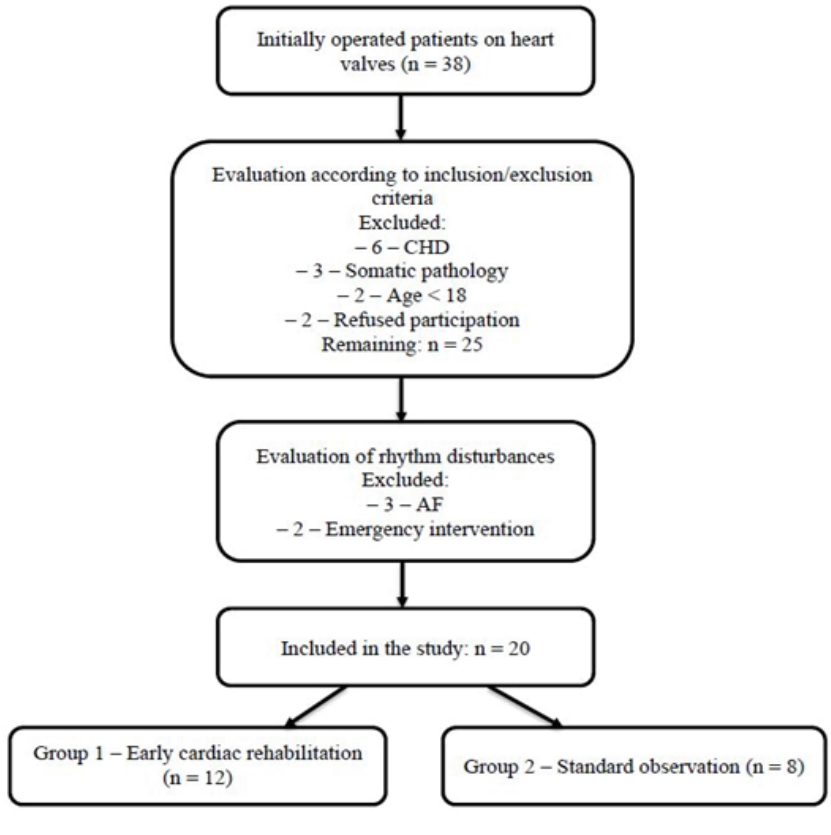
1. The stage of early mobilization is the beginning of the patient's activation on the 2-3 day after surgery; breathing exercises, passive and active limb movements, and gradual verticalization were performed under the supervision of a physiotherapist.

2. The exercise tolerance training stage was carried out on days 4-7 and included metered walks around the ward and corridor, exercises for coordination of movements and light isotonic loads with a gradual increase in walking distance to 400-500 m.

3. The stage of functional adaptation was carried out before discharge and was aimed at teaching the patient self-control of heart rate, blood pressure and saturation, the formation of individual recommendations for the outpatient stage and a gradual return to everyday activity.

All classes were conducted under constant monitoring of heart rate, blood pressure and blood oxygen saturation. A distinctive feature of the program was its early and phased structure, ensuring continuity between the hospital and outpatient stages of rehabilitation. Unlike standard schemes, which assume the onset of activation 2-4 weeks after surgery, the developed model allowed recovery to begin in the early postoperative period, which helps to prevent physical inactivity, thromboembolic complications and reduce anxiety in patients.

The study included 12 patients who underwent mitral or aortic valve replacement followed by an early stage of rehabilitation, and 8 patients who were under standard supervision without an active rehabilitation program. It should be noted that in the main group, an early hospital cardiorehabilitation program was conducted, implemented directly in the hos-



Flow chart of inclusion and exclusion of patients in the early cardiac rehabilitation program

pital and aimed at gradually activating the patient starting on the 2nd day after surgery. The term "remote" in the diagram (Fig. 1) it is used in a technical sense and implies the continuity of stages between hospital and subsequent outpatient follow-up, but not remote rehabilitation in a telemedicine format.

The selection was carried out by a cardiologist with experience in the field of postoperative management. Inclusion criteria: patients over the age of 18 who underwent elective mitral or aortic valve replacement, with preserved LV ejection fraction > 50%, stable hemodynamics and the ability to perform physical exercises under the supervision of specialists. Exclusion criteria: the presence of severe coronary heart disease, decompensated chronic heart failure, severe somatic and neurological diseases that interfere with physical activity, permanent or paroxysmal atrial fibrillation, emergency or repeated surgical interventions, refusal to participate in the study.

The control group included patients undergoing standard postoperative follow-up without a structured physical rehabilitation program. Unlike the main group, these patients did not receive daily sessions with a physical therapy instructor or a physiotherapist. Rehabilitation measures in this group were limited to the general recommendations of the attending cardiologist on the regime of physical activity, prevention of thromboembolic complications and control of hemodynamic parameters.

At the hospital stage, they received only basic consultations on the principles of gradual expansion of the motor regime and performing the simplest breathing exercises without individual selection of the load. The active development of the steps of motor activity (verticalization, metered walks, endurance exercises) was not carried out under the supervision of physical therapy specialists. At the outpatient stage, the patients of the control group were under the medical supervision of a cardiologist, without specialized physical rehabilitation. Thus, the main difference between the groups was the presence of a personalized multi-stage physical activation program in the main group and the limitation of standard advisory supervision in the control group.

The rehabilitation program began on the second day after surgery and included activation in the ward, endurance exercises and walking, gradually brought up to 500 m, under the supervision of physiotherapists. The control group received only basic medical supervision and recommendations for secondary prevention. Functional and psychological indicators were assessed in three stages: before surgery, at discharge, and after six months. Standardized tools were used for the assessment: SPPB (Short Physical Performance Battery) - a short battery of physical performance tests, SF-12 (Short Form-12 Health Survey) - a quality of life questionnaire including physical (PCS) and mental (MCS) components, 6MWT (Six-Minute Walk Test) - a six-minute walking test, and HADS (Hospital Anxiety and Depression Scale) - a scale of anxiety and depression. The main assessment tools were the SPPB, SF-12 (PCS and MCS) scales, the 6-minute walking test, and the HADS Anxiety/Depression scale. Statistical analysis was performed using IBM SPSS Statistics 21.0, adjusted for distorting factors, including age, gender, and type of surgery. The Shapiro–Wilk criterion was used to assess the normality of the data distribution. Quantitative indicators were compared between two independent groups using the Student's t-test (with a normal distribution) or the Mann-Whitney U–test (with an abnormal distribution). To analyze the dynamics within the groups, a variance analysis with repeated measurements (Repeated Measures ANOVA) was used. Categorical variables were compared using the χ2-test. The effect of functional indicators (SPPB, 6MWT, SF-12) on the risk of readmission and mortality was assessed using binary logistic regression. The results are presented as an average value ± standard deviation; the differences were considered statistically significant at $p < 0.05$.

All participants have given written informed consent to participate. The study protocol was approved by the Local Eth-

Table 1

Demographic and clinical characteristics of the study participants

Indicator	Intervention group (n = 12)	Control group (n = 8)	t (χ^2)	p
Gender, n (%)	Men – 8 (66.7%) / Women – 4 (33.3%)	Men – 5 (62.5%) / Women – 3 (37.5%)	0.13	0.72
Age, years (M ± SD)	58.6 ± 5.1	57.3 ± 4.7	0.42	0.68
BMI, kg/m2 (M ± SD)	24.1 ± 2.3	23.9 ± 2.6	0.36	0.72
Systolic blood pressure, mmHg (M ± SD)	142 ± 11	144 ± 12	0.78	0.44
Diastolic blood pressure, mmHg (M ± SD)	86 ± 8	85 ± 9	1.01	0.31
Total cholesterol, mmol/l (M ± SD)	4.5 ± 1.0	4.6 ± 1.1	0.72	0.47
Presence of symptoms before surgery, n (%)	10 (83.3)	7 (87.5)	0.11	0.74
Type of affected valve, n (%)				
– Aortic	6 (50.0)	5 (62.5)		
– Mitral	3 (25.0)	2 (25.0)		
– Double valve lesion	3 (25.0)	1 (12.5)		
Arterial hypertension, n (%)	8 (66.7)	6 (75.0)	0.09	0.76
Hypercholesterolemia, n (%)	5 (41.7)	4 (50.0)	0.18	0.67
LV ejection fraction after surgery, % (M ± SD)	51 ± 9	52 ± 10	0.84	0.41

Note: The data is presented as M ± SD (mean ± standard deviation) or n (%). There were no statistically significant differences between the groups in terms of the main demographic and clinical characteristics ($p > 0.05$).

Table 2

Dynamics of indicators of physical and mental state of patients in groups at different stages of observation

Indicator	Intervention Group (Basic)	Intervention Group (Extract)	Intervention group (6 months)	Control group (Basic)	Control group (Extract)	Control group (6 months)	F / p
SPPB	8.65 ± 1.40	9.88 ± 1.15	10.09 ± 1.42	8.52 ± 1.59	8.91 ± 1.22	8.73 ± 1.65	4.61 / 0.018
PCS	41.20 ± 5.11	50.10 ± 7.92	52.02 ± 7.64	40.75 ± 5.04	44.30 ± 6.88	45.11 ± 6.95	4.88 / 0.021
The ISS	46.90 ± 6.82	49.50 ± 6.31	51.10 ± 7.44	47.30 ± 6.94	48.10 ± 6.99	47.85 ± 7.90	1.11 / 0.317
6MW (m)	305.10 ± 52.88	355.00 ± 58.40	412.00 ± 61.21	306.55 ± 54.33	315.40 ± 57.20	365.10 ± 52.80	6.42 / <0.001
HADS-A	5.18 ± 1.10	5.00 ± 1.24	5.05 ± 1.61	4.89 ± 1.19	4.96 ± 1.08	5.00 ± 1.54	0.48 / 0.667
HADS-D	4.70 ± 1.42	4.80 ± 1.19	4.61 ± 1.12	4.85 ± 1.48	4.81 ± 1.05	4.55 ± 1.18	0.03 / 0.981

Note: The values are average ± standard deviation. SPPB is a battery of short physical characteristics; PCS is a summary of the physical component; HADS is a hospital scale of anxiety and depression, MCS is a summary of the mental component; 6MWT is a 6-minute walking test.

ics Committee of the Clinical Hospital. Peter the Great (Protocol No. 3 dated 15.01.2022) in accordance with the principles of the Helsinki Declaration.

Results. The study included 20 patients after heart valve surgery, of whom 12 were randomized to the early cardiac rehabilitation group, and 8 to the standard management control group. During the 6 months of follow-up, one patient dropped out of the control group for reasons unrelated to the intervention. Generalized demographic and clinical characteristics are presented in the table (Table 1).

The average age of the patients was 58.6 ± 5.1 years in the intervention group and 57.3 ± 4.7 years in the control group. Men dominated in both groups, accounting for 66.7% and 62.5%, respectively. All participants had diagnosed acquired heart valve defects, the most common of which were aortic valve stenosis (40%) and mitral regurgitation (30%). 91.7% of patients in the intervention group and 87.5% in the control group successfully completed the study. There were no statistically significant differences in the initial demographic and clinical parameters between the two groups, which indicates a correct random sample.

The results of the repeated analysis of variance revealed a statistically significant improvement in physical function (SPPB) over time, while the growth rate was more pronounced in the early rehabilitation group ($F = 8.11$; $p = 0.004$). There was also a significant difference between the average SPPB scores in the intervention and control groups ($F = 4.92$; $p = 0.017$), which indicates the advantage of rehabilitation intervention. A posteriori analysis showed that participants undergoing the cardiac rehabilitation program showed a more significant improvement in physical status both at discharge (average difference = 1.23 ± 1.74; $p = 0.009$; effect size = 0.41) and after 6 months (average difference = 1.44 ± 2.15; $p = 0.031$; effect size = 0.37) compared with the control group (Table 2).

The calculation of Cohen's d coefficient for comparing intergroup differences in SPPB showed values of 0.74 at discharge and 0.65 after 6 months, indicating a moderate but clinically significant effect of the intervention over both the short and long term.

The regression analysis assessed the impact of clinical, demographic, and functional characteristics on readmission and mortality in patients (n = 20) who underwent heart valve surgery. The logistic model included age, gender, type of surgery, as well as functional status indicators (SPPB, PCS, and 6MWT) measured after undergoing an early stage of cardiological rehabilitation (Table 3).

To assess the factors associated with death, a separate logistic model was constructed ($\chi2$ (6) = 11.84, $p = 0.041$, Nagelkerke R2 = 0.278). Of all the variables, the statistically significant predictor of mortality was the SPPB index (B = 0.891, $p = 0.006$, OR = 0.411; 95% CI: 0.205–0.788), which emphasizes the importance of physical function in predicting patient survival after cardiac surgery (Table 4).

Table 3

Results of logistic regression for predictors of readmission

The predictor	B	p	OR	95% ДИ
Age	0.054	0.245	1.056	0.958–1.165
Gender (male)	-0.227	0.551	0.797	0.377–1.684
Type of surgery	0.137	0.382	1.147	0.842–1.563
SPPB	-0.728	0.017	0.483	0.265–0.878
PCS	-0.091	0.118	0.913	0.812–1.026
6MWT	-0.005	0.067	0.995	0.989–1.001

Table 4

Results of logistic regression for mortality predictors

The predictor	B	p	OR	95% ДИ
Age	0.078	0.202	1.081	0.963–1.212
Gender (male)	-0.313	0.478	0.731	0.299–1.785
Type of surgery	0.106	0.428	1.112	0.843–1.578
SPPB	-0.891	0.006	0.411	0.205–0.788
PCS	-0.073	0.188	0.93	0.828–1.045
6MWT	-0.004	0.082	0.996	0.989–1.002

Discussion. Unlike traditional programs implemented at late stages, the early rehabilitation model we used assumed activation from the 2nd day after surgery, which made it possible to shorten recovery time and increase exercise tolerance. This protocol can be considered as a modified hospital version of postoperative rehabilitation based on the principle of early activation of patients after valvular interventions. The results obtained demonstrate the effectiveness of implementing the principle of early activation in patients after surgical correction of valvular heart defects. Upon discharge, and especially after 6 months of follow-up, patients undergoing the rehabilitation program showed significant improvements in physical function (SPPB), six-minute walking distance (6MWT), and physical quality of life (PCS) compared with the standard follow-up group. These results are consistent with the conclusions presented in Xue et al. [24], which also noted a significant advantage of early RCR in patients after heart valve surgery, especially in terms of restoring endurance and physical activity.

At the same time, the present study recorded a moderate but clinically significant difference on the SPPB scale between the groups (Cohen's d = 0.74 at discharge and 0.65 after 6 months), which is comparable to the effects described in the studies of Truong et al. [21] and Ennis et al. [14], which also used individualized mobilization programs in hospital settings. However, unlike most studies, including the study by Gach et al. [16], our work focused specifically on patients after valve replacement, rather than after interventions for coronary heart disease, which makes the results especially valuable for this subgroup.

An interesting difference in our work is the use of functional scales (SPPB and 6MWT) as primary outcomes, followed by modeling the effect of these variables on clinical events. Thus, according to the results of logistic regression, only the level of physical function (SPPB) turned out to be a statistically significant predictor of both re-hospitalization and mortality within 6 months ($p = 0.017$ and $p = 0.006$, respectively). This confirms the conclusions of Pelliccia et al [17] and Ambari et al. [12], which emphasize the role of assessing physical endurance as a criterion for risk stratification and an indicator of the effectiveness of rehabilitation measures.

The practical significance of the study is to confirm the benefits of early initiation of RCT in patients after prosthetic heart valves. Given the continuing shortage of outpatient rehabilitation centers in Russia and the shortage of specialized personnel [1, 8], the data from our study can be used as the basis for recommendations on mandatory hospital activation of patients on the second day after surgery. This is also consistent with the approaches reflected in ESC Guidelines [17], which emphasize the role of continuity between inpatient and outpatient stages of RCT.

However, it is necessary to take into account the limitations of the present study. Firstly, it is a small sample size (20 patients), which is due to the pilot nature of the work. Secondly, the follow-up was limited to 6 months, and it is impossible to judge long-term outcomes. Thirdly, despite random randomization, it is impossible to completely exclude the influence of external factors. Also, the rehabilitation program was implemented in one center, which limits the extrapolation of data to a wide population. In the future, it is advisable to conduct multicenter studies involving a larger number of patients and a long follow-up period to confirm the stability of the effects obtained.

Thus, this study confirms that the implementation of early cardiac rehabilitation in patients after surgical interventions on heart valves is associated with improved physical function, quality of life, and a reduced risk of adverse outcomes in the near future. The introduction of the hospital stage of RCT should be considered as an essential component of the comprehensive management of cardiac surgery patients.

Conclusion. As part of a pilot prospective observational study, the effectiveness of the early activation program for patients after mitral or aortic valve replacement was confirmed. Participation in the rehabilitation program from the second day after surgery contributed to a more pronounced improvement in physical function, the six-minute walking distance, and the physical component of quality of life by the time of discharge, as well as 6 months after the intervention. Analysis of logistic models showed that the level of physical activity (on the SPPB scale) was associated with a lower risk of re-hospitalization and death.

Despite the limited sample size, the results demonstrate the practical importance of introducing an early stage of rehabilitation directly in a hospital setting. The program can be recommended for inclusion in the standard of patient management after valve replacement as a way to increase the effectiveness of the recovery period. Large-scale randomized trials with a multicenter design and a long follow-up period are needed to verify the data obtained.

The authors declare that there is no conflict of interest.

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