Adverse events during a cardiac telerehabilitation program: A single-center study

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DOI: 10.33963/v.phj.101403

Received:
February 21, 2024

Accepted:
July 1, 2024

Early publication date:
July 9, 2024

INTRODUCTION

During the COVID-19 pandemic, many aspects of patient treatment were transferred to the realm of telemedicine. Such was the case with cardiac rehabilitation, for which a form of remote monitoring was the only one available for cardiac patients at our center during this period [1]. During cardiac telerehabilitation (CTR), some participants were found to have abnormal test results or measurements that required modification of pharmacotherapy and, in some cases, hospitalization in another department.

The purpose of this study was to assess the demographic and clinical profile of patients who had undergone cardiac telerehabilitation, and to compare patients with and without adverse effects, and to analyze our results against those of other centers.

MATERIAL AND METHODS

Out of 98 patients enrolled in the cardiac telerehabilitation program between July 30, 2021 and June 30, 2022, 7 were removed due to their withdrawal from telerehabilitation, meaning that 91 patients were included in the study and analyzed retrospectively.

An adverse event (AE) was defined in this study as the finding of an abnormal test/measurement result (e.g., blood pressure, heart rate) requiring a change in pharmacotherapy but without hospitalization in another department. A serious adverse event (SAE) was defined as the occurrence of a situation requiring interruption of the improvement program and/or hospitalization in another department.

CTR was conducted in accordance with the guidelines of the Working Group on Cardiac Rehabilitation of the Polish Society of Cardiology. Electrocardiogram, blood pressure and body weight of patients participating in the remote improvement program were controlled using a telemedicine platform manufactured by Pro-PLUS S.A. Poland.

Statistical analysis was performed using Statistica v.13 software and included the Student's T test and χ^2 test. For expected values with n <10, Yates correction was applied. The significance level alpha was set at 0.05.

RESULTS AND DISCUSSION

CTR participants were predominantly in the seventh decade of life, with the youngest patient in the study group being 41 and the oldest 91. The average age of participants was 64.34 (10.91) years; mean (standard deviation). The group had an ejection fraction of 47.92% (8.75); mean (standard deviation). 80.22% (n = 73) of all patients were male. 71.43% (n = 65) of the studied group had hypertension, 36.26% (n = 33) had obesity (defined as body mass index ≥30 kg/m^2), and 25.27% (n = 23) were diagnosed with diabetes.

The vast majority of patients participating in the improvement program were those with chronic coronary syndrome. 74% were enrolled after primary coronary angioplasty, 10% after myocardial surgical revascularization, 5% after mitral and aortic valve replacement (by surgery or transcatheter aortic valve replacement respectively), and 4% after electrotherapy (resynchronization therapy, implantation

Table 1. Evaluation of relevance of tested parameter on occurrence of adverse events (n = 91)

Tested parameter	Group without adverse events or serious adverse events (n = 67)	Group with adverse events or serious adverse events (n = 24)	*P*-value
	Mean (SD)		
Age, years	63.82 (11.16)	65.79 (10.25)	0.45
Left ventricular ejection fraction, %	48.40 (8.96)	46.58 (8.18)	0.39
	n (%)		
Female	11 (12.09)	7 (7.69)	0.30
Hypertension	44 (48.35)	21 (23.08)	0.08
Obesity	21 (23.08)	12 (13.19)	0.10
Type 2 diabetes	14 (15.38)	9 (9.89)	0.18

of a cardioverter-defibrillator, or cardiac pacemaker). The remaining patients were eligible after congestive heart failure, Bentall surgery, non-critical coronary artery occlusion (MINOCA), or pulmonary embolism.

Either an AE or SAE occurred in 26.37% (n = 24) of all patients. AEs occurred in 21/24 patients, and SAEs in the other three. The most common AEs included abnormal blood pressure (n = 12; 50%) and abnormal heart rate (n = 6; 25%) of which bradycardia in 4 patients and too fast resting heart rate in 2. In 3/24 patients (12.5%) there were symptoms of aggravation of heart failure (edema, decrease in exercise tolerance) and arrhythmias in the remainder (2 of them were attacks of atrial fibrillation, including in 1 a transient disturbance of intraventricular conduction). SAEs comprised MINOCA myocardial infarction (n = 1; 4.17%), pneumonia after mitral valve replacement surgery requiring intravenous antibiotic administration (n = 1; 4.17%), and symptomatic sinus bradycardia treated by pacemaker implantation (n = 1; 4.17%).

Turning to the cause of rehabilitation: 19 patients with an AE (79.17% of all patients with an AE) were rehabilitated because of pPCI compared to pPCI being the cause of rehabilitation for 49; 73.13% patients without AE. The rest of the AE patients were after CRT, PE, CHF and MINOCA.

Statistical analysis showed no association between the demographic-clinical profile and the incidence of adverse events in cardiac telerehabilitation in the study cohort (Table 1).

The percentage of patients with SAEs during CTR at our center clearly exceeds the percentage of such patients described by other centers analyzing this issue in Poland.

In the study by Korzeniowska-Kubacka et al. [2], no SAEs were observed during hybrid cardiac rehabilitation. Single extrasystoles of supraventricular and ventricular origin were diagnosed in 14.9% of patients. There were no patients who dropped out of CTR after its initiation [2]. The results published by Piotrowicz et al. [3] showed that during outpatient rehabilitation, 8/99 (8%) patients had AEs, of whom 3 required intensification of treatment (1 due to poor rate control during atrial fibrillation and 2 due to elevated cardiac pressure), 2 developed lumbosacral back pain, 1 developed a respiratory infection, and 2 patients were unable to attend exercise sessions due to random events [3].

On the other hand, analyzing the study by Maddison et al. [4], conducted outside Poland, we learn that out of 162 patients, AEs occurred in as many as 50, i.e., 31% of participants. These events were divided into events of mild (21/50) and moderate severity (25/50), as well as into those unrelated to rehabilitation (42/50) and those probably related to it (4/50). The rehabilitation-related group included ankle fracture and soft tissue injuries [4].

Bryant et al. [5], describing a study involving patients who completed a 12-week telerehabilitation program immediately after coronary artery bypass surgery (patients were still in the subacute phase), reported improvements in resting heart rate, activity level, nutritional status, and self-management of cardiovascular disease. No adverse events were described [5].

Habibović et al. [6] presented the results of cardiac telerehabilitation involving 19 patients during the COVID-19 pandemic. They did not observe any AE or SAE, although four patients expressed dissatisfaction with the online form of rehabilitation [6].

Stefanakis et al. [7] conducted a study to investigate the incidence and severity of adverse events occurring during home-based cardiac rehabilitation. They searched the CINAHL, Cochrane Library, and Embase databases for randomized controlled trials. Only studies in English that analyzed the incidence of AEs/SAEs as a primary or secondary endpoint were selected. Five studies reported on the incidence of adverse events, only one of which reported serious adverse events related to exercise during home-based cardiac rehabilitation. The incidence of serious adverse events in the study sample (n = 808) was estimated at 1 per 23.823 patients per hour of exercise.

In addressing the question of why there were more adverse events in our study than in the cited works from Polish centers, it is worth noting that, as in the foreign center, a very sensitive criterion for the diagnosis of AE was established in our study, including both those apparently related to the rehabilitation process and random chance events.

In part, the emergence of numerous adverse events was also influenced by the onset of the pandemic period,

which resulted in a deterioration of medical control by family doctors. Of additional importance could be the lack of another option for the doctor and patient at the beginning of the pandemic, when only telerehabilitation was feasible.

In conclusion, after analyzing the impact of the factors listed in Table 1 illustrating the course of cardiac telerehabilitation, we did not find any differences in the incidence of adverse events between groups regardless of obesity, hypertension, type 2 diabetes, sex, ejection fraction, or age. Our findings offer valuable insights for both practitioners already engaged in telerehabilitation and those considering its adoption in their centers.

Article information

Conflict of interest: None declared.

Funding: None.

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