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# **Analysis of adverse events during a cardiac telerehabilitation program: A single-center study**

**Short title:** Adverse events during cardiac telerehabilitation

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## **INTRODUCTION**

During the COVID-19 pandemic many aspects of patient treatment were transferred to the telemedicine space. That was also 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 that had undergone cardiac telerehabilitation and compare those with and without adverse effects and to confront our results with those of other centers.

## **MATERIAL AND METHODS**

Out of 98 patients enrolled in the cardiac telerehabilitation program between July 30/07/2021 and 30/06/2022, 7 were removed due to their resignation from telerehabilitation and 91 patients were included in the study and analyzed retrospectively.

An adverse event (AE) was defined in the 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, while 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  $\chi^2$  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 years old and the oldest being 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% ( $n = 65$ ) people in the studied group had hypertension, 36.26% ( $N = 33$ ) had obesity (defined as body mass index  $\geq 30$ ) 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), 4% after electrotherapy (resynchronization therapy, implantation of a cardioverter-defibrillator, or cardiac pacemaker). The remaining part was eligible after congestive heart failure, Bentall surgery, non-critical coronary artery occlusion (MINOCA), and pulmonary embolism.

Either AEs or SAEs occurred in 26.37% ( $n = 24$ ) of all patients. AEs occurred among 21 patients, while SAEs were found in 3 patients. The most common AEs included abnormal

blood pressure control (n = 12; 50.00%) and abnormal heart rate (n = 6; 25.00%) of which bradycardia in 4 patients and too fast resting heart rate in 2. In 3 patients (12.50%) there were symptoms of aggravation of heart failure (edema, decrease in exercise tolerance) and arrhythmias in the remaining part (2 of them were attacks of atrial fibrillation, including in 1 a transient disturbance of intraventricular conduction). SAEs included MINOCA myocardial infarction (n = 1; 4.17%) pneumonia after mitral valve replacement surgery requiring intravenous antibiotic administration (n = 1; 4.17%), and symptomatic sinus brady-cardia treated by pacemaker implantation (n = 1; 4.17%).

Taking into consideration the cause of rehabilitation: 19 patients with AE (79.17% of all patients with 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 demographic-clinical profile and 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] show that during outpatient rehabilitation, 8 of 99 patients had AEs (8%) out of which 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 by an overseas center, we learn that out of 162 patients, AEs occurred in as many as 31% of participants — 50 patients. These events were divided into events of mild severity (21/50) and moderate severity (25/50), as well as those unrelated to rehabilitation (42/50) and probably related to it (4/50). The rehabilitation-related group included ankle fracture and soft tissue injuries [4].

In the study by 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), results were reported showing improvements in resting heart rate, activity level, nutritional status, and self-management of cardiovascular disease. No adverse events were described [5].

A publication by Habibović et al. [6] presented the results of cardiac telerehabilitation involving nineteen patients during the COVID-19 pandemic. It did not observe any AEs or SAEs 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 following databases, among others: CINAHL, The Cochrane Library, Embase, in search of randomized controlled trials. Only studies described 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 answering 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 and general practitioners. Of additional importance could be the lack of another option for the doctor and patient at the beginning of the Covid-19 pandemic, only telerehabilitation was possible.

In conclusion, after analyzing the impact of the factors listed in the table on the course of cardiac telerehabilitation, we did not find any differences in incidence of adverse events between groups with and without obesity, hypertension, type 2 diabetes, sex, ejection fraction and age. The research findings presented offer valuable insights for both practitioners already engaged in telerehabilitation and those considering its adoption in their centers.

## **Article information**

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

Tested parameter	Group without adverse events and 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)	P = 0.45

Left ventricular ejection fraction, %	48.40 (8.96)	46.58 (8.18)	<i>P</i> = 0.39
	<b>n (%)</b>		
Female	11 (12.09)	7 (7.69)	<i>P</i> = 0.30
Hypertension	44 (48.35)	21 (23.08)	<i>P</i> = 0.08
Obesity	21 (23.08)	12 (13.19)	<i>P</i> = 0.10
Type 2 diabetes	14 (15.38)	9 (9.89)	<i>P</i> = 0.18