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PACEMAKER IMPLANTATION IN ACTIVE COVID-19 PATIENTS: EXPERIENCE OF A CITY HOSPITAL

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Aim. To analyze the experience of a multidisciplinary hospital in the implantation of pacemaker (PM) in patients with COVID-19, to evaluate predictors and the incidence of complications and adverse outcomes.

Methods. One-hundred twenty five patients with active COVID-19 underwent PM implantation/replacement during the period from 04/01/2020 to 11/30/2021 at the Department of Cardiovascular Surgery of the City Multidisciplinary Hospital, reprofiling to provide medical care to patients with COVID-19. The presence of SARS-CoV-2 virus was confirmed by a positive result of the polymerase chain reaction performed the day before the procedure.

Results. Median age of patients was 81 [73-86] years. Indications for PM in most cases were atrioventricular block of II-III degrees (n=71, 56.8%), sick sinus syndrome (n=30, 24%). The PM was replaced in 20 (16%) patients. Of the 125 patients in the study survey, the 30-day complication rate was 12%, and the 180-day mortality rate was 16.8%.

Conclusion. Patients with active COVID-19 had an increased level of complications and mortality rates after PM implantation/replacement. It is necessary to take these risks into consideration to better select patients with active COVID-19 infection.

Key words: COVID-19; pacemaker implantation; atrioventricular block; sick sinus syndrome; complications; mortality

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Coronavirus infection COVID-19 is caused by an RNA-containing severe acute respiratory syndrome coronavirus SARS-CoV-2 of the Coronaviridae family. Since the end of 2019, the COVID-19 pandemic has affected more than 500 million people worldwide and has resulted in more than 6 million deaths [1]. In Russia, the total number of infected as of April 2022 reached 18 million cases with 368 thousand deaths registered [2]. The main clinical manifestations of COVID-19 are respiratory disorders, however, cardiovascular complications, including cardiac arrhythmias, are also found among those infected [3]. According to several international multicenter studies, about 18.3% of hospitalized patients with COVID-19 had arrhythmias. The most common was sinus tachycardia because of a combination of causes (hypoperfusion, fever, hypoxia, agitation) [4]. In general, atrial tachyarrhythmias were observed in 70% of these patients, various types of bradyarrhythmias were diagnosed in 20% [5]. The pathophysiological mechanisms of arrhythmias associated with COVID-19 are not yet fully understood. Hypoxia, circulating pro-inflammatory factors, and metabolic disturbances may be possible direct arrhythmogenic factors. Also, patients with active viral infection may develop acute coronary syndrome or acute myocarditis, which can cause various cardiac arrhythmias. Another arrhythmogenic factor are some medications. For example, hydroxychloroquine, which was actively used at the beginning of the pandemic as a therapy, affects intracellular pH, leading to electrolyte imbalance, cardiotoxicity, and QT prolongation. Azithromycin can also prolong the QT interval and cause life-threatening ventricular tachycardias [6].

Against the backdrop of the COVID-19 pandemic, there has been a deterioration in the quality of medical care for patients with bradyarrhythmia. Several studies conducted in 2020 report a significant decrease in the number of cardiac implantable electronic devices (CIEDs) implanted worldwide [7-9]. Possible reasons include both organizational (re-profiling of some hospitals to provide care to

patients with coronavirus infection, restrictions in the work of electrophysiological departments, especially at the beginning of the pandemic), and psychological (the patient's fear of becoming infected when seeking medical help).

To streamline the organization of specialized care for patients with heart rhythm disorders, in May 2020, the Heart Rhythm Society, the American College of Cardiology and the American Heart Association published a consensus document with recommendations for conducting electrophysiological procedures during the COVID-19 pandemic. The document was based mainly on expert opinion, since at that time there were not enough published data on the management of patients with COVID-19 infection complicated by cardiac arrhythmias [10]. In 2021, an international multicenter study was conducted based on data obtained from 53 centers in 13 countries (Russia is not represented in the study), which analyzed the implantation / replacement of CIED (in addition to traditional pacemakers (PMs), cardioverter-defibrillators, cardiac resynchronization devices and wireless pacemakers were also considered) performed on 166 patients with active coronavirus infection. The study demonstrated higher rates of complications and adverse outcomes after surgery compared to pre-pandemic data. As an explanation, the authors identified two global factors. The first is related to the clinical course of COVID-19 infection, the high level of comorbidity of patients and their advanced age, the use of corticosteroids and anticoagulants in the treatment, as well as elevated levels of C-reactive protein (CRP) in patients with active COVID-19 infection. The second important value, according to the authors, could have a «human» factor. The use of personal protective equipment, according to the study, caused discomfort to the surgeon and forced him to complete the operation faster, which could affect its quality, and the risk of infection in close contact with a patient with COVID-19 led to psychological stress [11].

However, despite existing publications, to date there are no clinical guidelines governing the management of patients with COVID-19 who require high-tech medical care, in particular pacemaker implantation. It is not clear how safe "early" surgery is, performed before the development of possible autoimmune complications of the infection, or whether delayed intervention is advisable after a negative PCR test result and normalization of inflammatory markers in the blood. Also, the perioperative management of such patients is not regulated, for example, safe dosages and duration of immunosuppressive and anticoagulant therapy before and after surgery are not approved. The urgency of the problem remains high, because, despite the gradual decrease of COVID-19 cases worldwide and the mitigation of anti-epidemic measures by several countries, there is still a need for specialized medical care for patients with bradyarrhythmias.

Aim. To analyze the experience of a multidisciplinary hospital in the implantation of pacemakers in patients with COVID-19, to evaluate the features of the procedure, predictors and the incidence of complications and adverse outcomes.

METHODS

A single-center retrospective study included 125 patients who underwent PM implantations from 04/01/2020 to 11/30/2021 in the cardiovascular surgery department of a multidisciplinary hospital repurposed to provide medical care to patients with COVID-19. The study was approved by the local ethics committee.

The inclusion criteria for the study was the presence of active COVID-19 infection (confirmed by a positive PCR test for the SARS-CoV-2 virus the day before or on the day of surgery). Patients with a negative PCR test result or no test result on the day of surgery despite the symptoms of an active viral infection were excluded from the study.

Procedural timing depended on the clinical picture of the viral infection and the severity of the patient's condition. The operation was performed if there was no fever within 48 hours before the intervention and no need for non-invasive / invasive ventilation of the lungs, since these indicators, along with laboratory data (CRP level), were regarded as predictors of the development of a "cytokine storm".

The severity of the disease was classified according to temporary guidelines for the treatment of coronavirus infection. With mild severity, there was no viral pneumonia according to multislice computed tomography of the chest, and the patient did not need respiratory support. Moderate severity was characterized by the presence of pneumonia and/or respiratory failure with a saturation of at least 93%; hypoxia was corrected using low-flow oxygen through nasal prongs or a face mask. In severe cases of infection, respiratory support was performed using non-invasive ventilation of the lungs - high-flow ventilation through nasal cannulas or ventilation in the positive pressure mode at the end of expiration through a sealed mask. The extremely severe course of the infection required invasive ventilation at one of the stages of treatment.

Statistical analysis was carried out using the StatTech v. 2.5.8 (developer - Stattech LLC, Russia). Quantitative indicators were assessed for compliance with the normal distribution using the Shapiro-Wilk test (with the number of subjects less than 50) or the Kolmogorov-Smirnov test (with the number of subjects more than 50). In the absence of a normal distribution, the quantitative data were described using the median (Me) and the lower and upper quartiles (Q1 – Q3), when the normal distribution was confirmed, using the mean value (M) and standard deviation (SD). Categorical data were described with absolute values and percentages. Comparisons were made based on the division of the study group according to the criteria for the presence or absence of complications, as well as the presence or absence of a lethal outcome. Comparison of two groups by a quantitative indicator, the distribution of which differed from the normal one, was performed using the Mann-Whitney U-test, and with a normal distribution, using the Student's t-test. Comparison of percentages in the analysis of four-field cross tables was performed using Pearson's chi-square test (with a minimum expected frequency of 10 or more) or using Fisher's exact test (with a minimum expected frequency of less than 10), and in the analysis of multi-field cross tables - using the test Pearson's chi-square.

RESULTS

Procedural rate

During the observation period, out of 26,814 hospitalized patients, PM implantations/replacement were per-

formed in 168 patients (some patients appeared without confirmation of coronavirus infection by a PCR test). The procedural rate was 6.3 per 1000 patients.

Clinical characteristics

The study included 125 patients with active coronavirus infection (38.4% men, median age of patients 81 [73-86] years) in whom pacemaker implantation (n=101), pacemaker replacement (n=20), lead replacement (n=2) or lead reposition (n=2) were performed. Replacement/reposition of leads was carried out in patients with pacemakers, initially implanted in other institutions. Clinical characteristics of patients, as well as procedure parameters are presented in table 1.

Indications for procedure

The main indications for surgery were II-III degree AV block (n=71, [56.8%]) and sick sinus syndrome (n=30, [24.0%]), hemodynamically significant (Morgagni-Adams-Stokes syndrome or its equivalents). PM was replaced in 20 (16.0%) patients with signs of battery depletion of the PM (recommended replacement time according to programming data). Surgery was performed for lead fracture in 1 (0.8%) patient, and for exit-block - in 3 (2.4%) patients. In 55 patients (44%), syncope was present. Procedural timing was 8th [4-14th] day after the diagnosis of COVID-19.

Complications

Complications were noted in 16 (12.8%) patients, of which 15 (12.0%) had complications during the first 30 days after surgery. In 1 patient, a complication developed after 2 months (suppuration of the PM pocket). Another patient had two complications - dislocation of the atrial lead, for which reposition was performed, and then suppuration of the PM pocket. The patient was reassessed for arrhythmias, and it was decided to refrain from re-implantation. The pacemaker system has been removed.

The most common intraoperative complication was pneumothorax (7 patients, 43.7% of all complications). Pocket hematoma was diagnosed in 4 patients. In one case, the hematoma was tense, and evacuation of the hematoma was then performed. Another 4 patients had atrial lead dislocation. In all cases, the lead was repositioned.

Suppuration of the PM pocket in 60 days after surgery was noted in one patient. For unknown reasons, he did not seek medical attention. 5 months after the operation, he was transferred from another hospital with a severe pocket inflammation, for which removal of the pacemaker system was performed. Complications and patients characteristics are given in table 2.

A univariate analysis of factors influencing complications revealed that patients with complications had a statistically significantly higher preoperative D-dimer level (825.5 [488.5-1673.0] ng/mL versus 533.0 [317, 2-1023.2] g/ml, p=0.033) and no direct oral anticoagulants were used (0 vs 27 (100%) patients, p=0.022).

Mortality

21 (16.8%) patients from the study group died, of which 20 (16%) within the first 30 days after the operation, and 1 patient died within 180 days (the patient with suppuration of the PM pocket, which was described above, died 5 months after the primary implantation of the pacemaker from sepsis, after removing the pacemaker system).

Mortality increased in proportion to the severity of the course of COVID-19 and amounted to 0%, 2.5%, 28.6% and 100% in patients with mild, moderate, severe, and extremely severe infection, respectively.

When comparing the probability of death depending on the presence of complications, significant differences were found (p=0.018) (method used: Pearson's Chi-square). The risks of death in the group with complications were 3.760 times higher than in the group without complications, the difference in odds was statistically significant (95% CI: 1.191-11.869).

In the analysis of mortality, depending on the type of complications, significant differences were also found (p=0.024). The presence of pneumothorax had a statistically significant effect on the risk of death (p=0.026), compared with the absence of postoperative complications (Fig. 2). Since the risk of developing pneumothorax increases with central venous puncture, a statistically significant effect of the method of venous access on the risk of death was observed. This risk increased with subclavian vein puncture (10 (35.7%) patients with venous access through the subclavian vein versus 7 (10.0%) patients with access through the cephalic vein, p = 0.014).

Mortality was statistically significantly higher in older patients (87.0 84.0-89.0] years vs 81.0 [72.0-85.0] years, p<0.001). Patients with high preoperative CRP levels (23.0 [11.0-67.0] mg/L vs. 11.5 [6.2-27.0] mg/L, p = 0.032), D-dimer (1174, 5 [609.0-2952.2] ng/mL vs. 483.5 [313.8-818.5] ng/mL, p=0.002), lactate dehydrogenase (364.5[287.8-390.5] U/l vs. 270.0[228.0-350.0] U/l, p=0.013), creatinine (193.0 [127.00-285.00] μmol/l vs. 101.5 [88.0- 130.5] μmol/L, p<0.001) also had a high risk of death. The use of a temporary pacemaker had no statistically significant effect on mortality and complications (Table 1).

DISCUSSION

The study reports the experience of PM implantation/replacement in hospitalized patients with active COVID-19, performed in the Department of Cardiovascular Surgery of a city multidisciplinary hospital, repurposed to provide care for patients with coronavirus infection.

The procedural rate during the pandemic in our department decreased by almost 4 times (for example, in 2019 it was 25.2 per 1000 patients). There was also a high rate of 30-day complications (12.0%) and 180-day mortality (16.8%) in infected patients, while in 2019 these were 3.1% and 0.5%, respectively.

We reviewed studies over the past 10 years on complications after implantation of CIED prior to the COVID-19 pandemic.

In the FOLLOWPACE study, which followed 1517 patients with CIED for the treatment of bradycardia, the 60-day complication rate was 12.4% [12]. Of 5918 patients (data from the Danish National Registry 2010-2011) who underwent implantation of traditional single-chamber and dual-chamber devices as well as cardiac resynchronization therapy and implantable cardioverter-defibrillators, 9.5% had at least one complication [13]. In a 2019 analysis of a database of hospitalized patients in Australia and New Zealand, of 65,711 patients who were implanted with CIED,

Table 1.

Comparison of patients and procedural characteristics with and without complications or mortality (continued)

	All, n=125	No complication, n=109	Complication, n=16	p-value	Alive, n=104)	Died, n=21	p-value
Age (median [IQR]), y	81 [73-86]	81.0 [72.0-85.0]	84.0 [79.5-87.0]	0.104	81.0 [72.0-85.0]	87.0 [84.0-89.0]	<0.001
Male gender, n (%)	48 (38.4)	41 (85.4)	7 (14.6)	0.784	38 (79.2)	10 (20.8)	0.341
Female gender, n (%)	77 (61.6)	68 (88.3)	9 (11.7)		66 (85.7)	11 (14.3)	
BMI (M±SD), kg/m^2	28.33±5.23	28.55±5.12	26.73±5.95	0.226	28.39±5.48	27.98±3.84	0.757
DM, n (%)	42 (33.6)	36 (85.7)	6 (14.3)	0.724	34 (81.0)	8 (19.0)	0.633
AFib, n (%)	64 (51.2)	48 (87.3)	7 (12.7)	1.000	44 (80.0)	11 (20.0)	0.396
IHD, n (%)	47 (37.6)	39 (83.0)	8 (17.0)	0.283	37 (78.7)	10 (21.3)	0.299
Hypertension, n (%)	118 (94.4)	102 (86.4)	16 (13.6)	0.594	98 (83.1)	20 (16.9)	1.000
Ao stenosis, n (%)		5 (83.3)	1 (16.7)	0.568	5 (83.3)	1 (16.7)	1.000
Days (median [IQR])*	8.0 [4.0-14.0]	8.0 [4.0-15.0]	8.0 [5.8-13.2]	0.739	8.0 [4.0-15.2]	7.0 [4.0-13.0]	0.506
Procedural indication							
SSS, n(%)	30 (24.0)	24 (80.0)	6 (20.0)	0.686	27 (90.0)	3 (10.0)	0.688
High-degree/complete AV block, n (%)	71 (56.8)	63 (88.7)	8 (11.3)		57 (80.3)	14 (19.7)	
Battery depletion, n (%)	20 (16.0)	18 (90.0)	2 (10.0)		17 (85.0)	3 (15.0)	
Lead fracture, n (%)	1 (0.8)	1 (100.0)	0		1 (100.0)	0 (0.0)	
Exit block, n (%)	3 (2.4)	3 (100.0)	0		2 (66.7)	1 (33.3)	
Laboratory test values							
CRP preprocedural (median [IQR]), mg/l	13.0 [6.6 - 36.0]	13.0 [6.7-27.0]	18.5 [3.8-62.5]	0.462	11.5 [6.2-27.0]	23.0 [11.0-67.0]	0.032
CRP max (median [IQR]), mg/l	55.0 [22.0-96.0]	48.0 [22.0-88.0]	78.5 [44.25-102.25]	0.133	44.0 [16.0-86.25]	80.0 [67.0-118.00]	0.002
D-dimer (median [IQR]), ng/ml	561.5 [351.2-1126.5]	533.0 [317.2-1023.2]	825.5 [488.5-1673.0]	0.033	483.5 [313.8-818.5]	1174.5 [609.0-2952.2]	0.002
LDH (median [IQR]), U/l	290.0 [235.0-367.0]	275.0 [232.0-364.5]	345.5 [278.5-368.5]	0.243	270.0 [228.0-350.0]	364.5 [287.8-390.5]	0.013
INR (median [IQR])	1.15 [1.07-1.23]	1.15 [1.07-1.23]	1.17 [1.06-1.23]	0.901	1.14 [1.06-1.22]	1.21 [1.10-1.26]	0.277
Platelet count (x10^9/l) (median [IQR])	199.0 [156.0-250.0]	202.0 [156.0-263.0]	189.0 [155.8-223.8]	0.340	200.0 [164.2-251.2]	192.0 [152.0-249.0]	0.822
Creatinine (median [IQR]), µmol/l	110 [91.0 - 146.0]	109.0 [92.00-134.0]	134.5 [87.5-200.5]	0.462	101.5 [88.0-130.5]	193.0 [127.00-285.00]	<0.001
Anticoagulation							
NOAC, n (%)	27 (22.1)	27 (100.0)	0 (0.0)	0.022	25 (92.6)	2 (7.4)	0.185
Warfarin, n (%)	1 (0.8)	0 (0.0)	1 (100.0)	0.131	1 (100.0)	0 (0.0)	1.000
Enoxaparin, n (%)	103 (92.6)	88 (85.4)	15 (14.6)	0.270	86 (83.5)	17 (16.5)	0.509
Antiplatelets, n (%)	12 (9.8)	11 (91.7)	1 (8.3)	0.605	9 (75.0)	3 (25.0)	0.343

Table 1.

Comparison of patients and procedural characteristics with and without complications or mortality (continuation)

	All, n=125	No complication, n=109	Complication, n=16	p-value	Alive, n=104)	Died, n=21	p-value
Steroid therapy (Dexamethazone)							
No therapy, n (%)	41 (32.8)	37 (90.2)	4 (9.8)	0.722	35 (85.4)	6 (14.6)	0.691
<=8 mg/day, n (%)	56 (44.8)	47 (83.9)	9 (16.1)		45 (80.4)	11 (19.6)	
9-16 mg/day, n (%)	25 (20.0)	22 (88.0)	3 (12.0)		22 (88.0)	3 (12.0)	
17-24 mg/day, n (%)	3 (2.4)	3 (100.0)	0 (0.0)		2 (66.7)	1 (33.3)	
Monoclonal antibodies, n (%)	20 (16.0)	16 (80.0)	4 (20.0)	0.293	12 (60.0)	8 (40.0)	0.002
COVID-19 severity							
Mild, n (%)	1 (0.8)	1 (100.0)	0	0.090	1 (100.0)	0(0.0)	<0.001
Moderate, n (%)	81 (64.8)	75 (92.6)	6 (7.4)		79 (97.5)	2 (2.5)	
Severe, n (%)	35 (28.0)	27 (77.1)	8 (22.9)		24 (68.6)	11 (31.4)	
Critical, n (%)	8 (6.4)	6 (75.0)	2 (25.0)		0 (0.0)	8 (100.0)	
Venous acces							
Cephalic vein, n (%)	70 (66.0)	64 (91.4)	6 (8.6)	0.207	63 (90.0)	7 (10.0)	0.022
Subclavian vein, n (%)	28 (26.4)	22 (78.6)	6 (21.4)		18 (64.3)	10 (35.7)	
Axillary vein, n (%)	7 (6.6)	5 (71.4)	2 (28.6)		6 (85.7)	1 (14.3)	
External jugular vein, n (%)	1 (0.9)	1 (100)	0		1 (100.0)	0 (0.0)	
Single-chamber, n (%)	12 (11.9)	11 (91.7)	1 (8.3)	0.555	10 (83.3)	2 (16.7)	1.000
Dual-chamber, n (%)	89 (88.1)	76 (85.4)	13 (14.6)		74 (83.1)	15 (16.9)	
Procedure							
PM implantation, n (%)	101 (80.8)	87 (86.1)	14 (13.9)	0.842	84 (83.2)	17 (16.8)	0.567
PM replacement, n (%)	20 (16.0)	18 (90.0)	2 (10.0)		17 (85.0)	3 (15.0)	
Lead replacement, n (%)	2 (1.6)	2 (100.0)	0		2 (100.0)	0 (0.0)	
Lead reposition, n (%)	2 (1.6)	2 (100.0)	0		1 (50.0)	1 (50.0)	
Procedure time (median [IQR]), min	30.0 [25.0-40.0]	30.0 [25.0-35.0]	35.0 [28.8-45.0]	0.092	30.0 [25.0-35.0]	30.0 [30.0-40.0]	0.295
X-Ray time (median [IQR]), min	0.41 [0.24-1.06]	0.40 [0.24-1.06]	0.54 [0.24-1.18	0.395	0.39 [0.24-1.06]	0.52 [0.20-1.03]	0.611
Radiation dose (median [IQR]), mGy/m^2	798.0 [396.0-1450.0]	837 [385.0-1352.0]	687.0 [522.0-1683.75]	0.620	817.5 [382.0-1456.5]	726.0 [468.0-1420.0]	0.802
Temporary PM, n (%)	28 (22.4)	23 (82.1)	5 (17.9)	0.363	21 (75.0)	7 (25.0)	0.188

Note: BMI - body mass index; DM - diabetes mellitus; AFib - atrial fibrillation; IHD - ischemic heart disease; Ao - aortic; SSS - sick sinus syndrome; AV - atrioventricular; CRP - C-reactive protein; LDH - lactatdehydrogenase; INR - international normalized ratio; NOAC- non-vitamine K oral anticoagulants; PM - pacemaker.

Table 2.

Patients with complications

Age	Gen	COVID-19 severity	Procedure date	Venous access	Type of complication	Procedural indication	Procedure	Anticoagulation	Antiplatelets	CRP	Dex	Platelet count	Cr	Death
78	f	severe	01.09.2020	v.cephalica	Dislocation	SSS	DDDR PM	Warfarin	no	53	no	261	175	no
81	f	critical	21.09.2020	v.subclavia	Pneumothorax	SSS	DDDR PM	Enoxaparin	no	80	no	243	540	yes
80	f	moderate	24.09.2020	v.axillaris	Pneumothorax	SSS	DDDR PM	Enoxaparin	no	12	no	223	69	no
83	m	moderate	20.10.2020	v.subclavia	Dislocation	HD/complete AV block	DDDR PM	Enoxaparin	no	87	yes	146	72	no
74	f	severe	06.11.2020	v.cephalica	Dislocation	SSS	DDDR PM	Enoxaparin	no	138	yes	170	91	no
87	m	severe	30.11.2020	v.cephalica	Hematoma	HD/complete AV block	VVIR PM	Enoxaparin	no	123	yes	142	103	yes
86	f	moderate	21.12.2020	v.subclavia	Pneumothorax	HD/complete AV block	DDDR PM	Enoxaparin	Aspirine	75	yes	302	163	yes
87	m	severe	23.12.2020	v.cephalica	Pocket infection	HD/complete AV block	DDDR PM	Enoxaparin	no	118	yes	95	220	yes
84	f	moderate	02.02.2021	v.cephalica	Dislocation	HD/complete AV block	DDDR PM	Enoxaparin	no	89	yes	187	123	no
75	m	moderate	16.02.2021	v.subclavia	Pneumothorax	HD/complete AV block	DDDR PM	Enoxaparin	no	9	no	191	42	no
64	f	severe	25.03.2021	v.axillaris	Pneumothorax	SSS	DDDR PM	Enoxaparin	no	18	yes	207	88	no
90	m	severe	31.03.2021	v.subclavia	Pneumothorax	SSS	DDDR PM	Enoxaparin	no	76	yes	163	194	yes
89	f	severe	14.04.2021	нет	Hematoma	Battery depletion	PM replacement	Enoxaparin	no	77	yes	226	146	no
84	m	critical	06.05.2021	v.subclavia	Pneumothorax	HD/complete AV block	DDDR PM	Enoxaparin	no	215	yes	192	658	yes
86	m	moderate	31.08.2021	v.cephalica	Hematoma	HD/complete AV block	DDDR PM	Enoxaparin	no	16	yes	141	228	no
91	f	severe	01.10.2021	нет	Hematoma	Battery depletion	PM replacement	Enoxaparin	no	97	yes	159	86	no

Note: Gen - gender; Dex - dexamethasone; Cr - creatinine; HD - high-degree

complications, including death, were noted in 7.8%, and a significant scatter of data by centers was found (a total of 98 clinics) - from 5.4% to 12.9% [14]. In another Australian study, which included a group of elderly patients (10883 patients, mean age 86 years), after implantation of traditional CIED, the rate of complications and readmission after 90 days was 1-2%. The 90-day mortality rate was 5% and 3% in patients with single- and dual-chamber pacemakers, respectively [15].

Thus, there is a large scatter of data associated with the heterogeneity of the studied groups. The complication rate reached 12.9%, and the mortality rate did not exceed 5%.

In our study, the postoperative complication rate was 12.0% at 30 days and 12.8% at 60 days. Complications occurred statistically significantly more often in patients with high preoperative levels of D-dimer, which is a marker of severe COVID-19. It is interesting to note that the use of direct oral anticoagulants, monoclonal antibodies to IL-6, and dexamethasone, regardless of the dose, did not have a statistically significant effect on the incidence of complications.

The surgical complication that influenced the risk of death in our study was pneumothorax (Fig. 2). From our point of view, this can be explained by the fact that even a temporary lung collapse in a patient with viral pneumonia significantly aggravates hypoxia and the risk of infection. Against the background of hypoxia, the risk of developing multiple organ failure and death increases.

Patients with COVID-19 are also at risk of developing spontaneous pneumothorax. This condition is described as an atypical complication of infection that can be diagnosed in patients without chronic lung disease or mechanical ventilation. The incidence of this complication is about 1% among hospitalized patients with COVID-19. However, it can worsen the prognosis [16-18]. We compared the incidence of spontaneous pneumothorax in our hospital during the observation period from 04/01/2020 to 11/30/2021. Out of 26814 hospitalized patients, spontaneous pneumothorax was detected in 61 (0.23%) patients with a positive PCR test result for SARS-CoV-2. Death occurred in 36 (59%) patients.

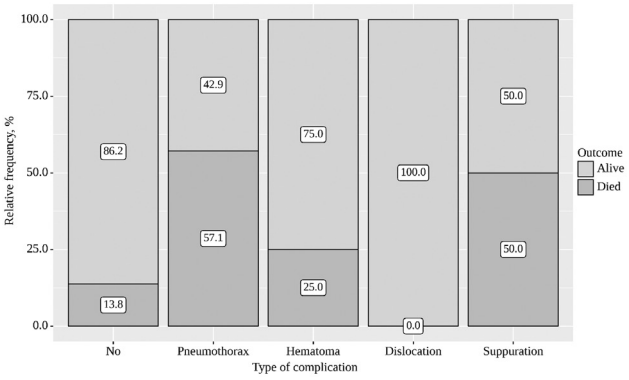

Fig. 2. Analysis of outcome depending on the type of complication.

We conducted an additional analysis of the mortality of patients with various types of pneumothorax. We compared a group of 7 patients with "surgical" pneumothorax (after puncture of the subclavian vein) and a group of 61 patients with spontaneous pneumothorax.

When comparing mortality in these groups, no statistically significant differences were found (p=1.000). However, it is important to emphasize that mortality in both groups exceeded 50%, which confirms the high probability of a poor prognosis in patients with COVID-19 and pneumothorax, regardless of its origin.

The high mortality rate in our study was mainly associated with complications of the COVID-19 infection (15 patients died without surgical complications vs 6 with complications). The risk of death increased with the severity of the infectious process, as well as in patients with high levels of CRP, lactate dehydrogenase, D-dimer and creatinine.

It should be noted that in our study, none of the concomitant chronic diseases had a statistically significant effect on mortality. There was no dependence of complications and outcome on the presence of a temporary pacemaker before surgery, as well as on the technical parameters of the procedure (procedure time, fluoroscopy time, radiation dose) (Table 1).

Practical aspects

There was a single-center retrospective study. However, several practical conclusions can be made. Considering the higher level of postoperative complications and mortality due to COVID-19, as well as the relative safety of using a temporary pacemaker in patients with hemodynamically significant bradyarrhythmias, it is advisable not to perform operations at the height of the infectious process until pro-inflammatory factors are normalized. Of course, it is important to assess and correct kidney function. The choice of venous access should be made in favor of the cephalic or axillary vein, since subclavian vein puncture increases the risk of pneumothorax, which increases the risk of adverse outcome in patients with COVID-19.

Limitations

We conducted a single-centre retrospective study in a department with extensive experience in PM implantations. During the pandemic, we were limited in the range of surgical interventions to traditional single-chamber and dual-chamber pacemakers without defibrillation, so it is not possible to extrapolate the results of our study to the entire range of antiarrhythmic devices. We also understand that our data may differ from other centers with CIED implants compared to our center.

CONCLUSION

Patients with COVID-19 experienced an increased rate of complications and death after pacemaker implantation/replacement compared to pre-pandemic rates. It is necessary to take this fact into account and use an individual approach to the patient, assessing all possible risk factors.

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