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Implantation of cardiac electronic devices in active COVID-19 patients: Results from an international survey

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BACKGROUND Cardiac implantable electronic device (CIED) implantation rates as well as the clinical and procedural characteristics and outcomes in patients with known active coronavirus disease 2019 (COVID-19) are unknown.

OBJECTIVE The purpose of this study was to gather information regarding CIED procedures during active COVID-19, performed with personal protective equipment, based on an international survey.

METHODS Fifty-three centers from 13 countries across 4 continents provided information on 166 patients with known active COVID-19 who underwent a CIED procedure.

RESULTS The CIED procedure rate in 133,655 hospitalized COVID-19 patients ranged from 0 to 16.2 per 1000 patients ($P < .001$). Most devices were implanted due to high-degree/complete atrioventricular block (112 [67.5%]) or sick sinus syndrome (31 [18.7%]). Of the 166 patients in the study survey, the 30-day complication rate was 13.9% and the 180-day mortality rate was 9.6%. One patient had a fatal outcome as a direct result of the procedure. Differences in patient and procedural characteristics and outcomes were found between Europe and North America. An older population (76.6 vs 66 years; $P < .001$) with a nonsignificant higher complication rate (16.5% vs 7.7%; $P = .2$) was observed in Europe vs North America, whereas higher rates of critically ill patients (33.3% vs 3.3%; $P < .001$) and mortality (26.9% vs 5%; $P = .002$) were observed in North America vs Europe.

CONCLUSION CIED procedure rates during known active COVID-19 disease varied greatly, from 0 to 16.2 per 1000 hospitalized COVID-19 patients worldwide. Patients with active COVID-19 infection who underwent CIED implantation had high complication and mortality rates. Operators should take these risks into consideration before proceeding with CIED implantation in active COVID-19 patients.

KEYWORDS Active COVID-19; Cardiac implantable electronic device procedure; Complications; Mortality; Personal protective equipment

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Introduction

Coronavirus disease 2019 (COVID-19) is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since late December 2019, the world has faced a pandemic caused by COVID-19, which has affected more than 160 million people and led to more than 3 million deaths.[1] The main clinical manifestation of COVID-19 is respiratory disease, but cardiac manifestations, including

cardiac arrhythmias, have been reported in a substantial number of hospitalized patients.[2] In a recent worldwide case series, 18.3% of admitted COVID-19 patients suffered a cardiac arrhythmia.[3] About 70% of patients who developed an arrhythmia presented with atrial tachyarrhythmia, with bradyarrhythmia seen in approximately 20% of patients. Atrioventricular block (AVB) was noted in 1.57% of COVID-19 admitted patients and sinus pauses >3 seconds in only 0.22%.[3] Among COVID-19 patients with telemetric monitoring, 3.5% had AVB.[4] Several studies have reported a substantial decrease in overall cardiac implantable electronic device (CIED) implantation rates during the pandemic, but none of the studies reported the procedure rate in patients with active COVID-19 disease.[5–10] There are only a few case reports and small case series in the literature of patients with COVID-19 who were implanted with a CIED while they had active disease, and none of the studies reported procedural complications.[11–21] Active COVID-19 has implications for treating physicians and staff, and impacts CIED planning. The implanting physician and supporting staff need to wear personal protective equipment (PPE) during the procedure, with possible impairment in their ability to perform the procedure. Optimal indications, timing, and periprocedural management are unclear. The Heart Rhythm Society, American College of Cardiology, and American Heart Association released a joint statement with recommendations regarding the management of electrophysiological procedures.[22] These recommendations are primarily based mainly on expert opinion and acknowledge that published data on arrhythmia management in COVID-19 patients currently are limited.[22] Whether early implantation during active COVID-19 disease is beneficial or is associated with higher complication or mortality rates and whether different device types carry different risks of complications is unknown. Given that many centers implanted only a few devices, we conducted an international survey in order to gather clinically relevant information. We received responses from 53 centers in 13 countries across 4 continents. We sought to assess the rate of device implantation, patient and procedural characteristics, and outcomes of all types of CIED implantations and replacements in patients with active COVID-19.

Methods

The Shaare Zedek Medical Center Institutional Review Board committee approved the study. All centers complied with local international review board registry protocols. Share Zedek Medical Center served as the coordinating center.

Data source and center selection

A Medline search using the terms "COVID-19 or SARS-CoV-2 and device implantation or atrioventricular block or bradyarrhythmias" was performed to select worldwide centers with experience in the diagnosis and management of active COVID-19 and device implantations. In addition, multiple world-known electrophysiologists were contacted and offered to participate in an international multicenter survey on device implantations in active COVID-19 patients.

Study inclusion and exclusion criteria

Patients were eligible if they fulfilled 2 conditions: (1) they were diagnosed with active COVID-19 illness (confirmed by nasopharyngeal polymerase chain reaction testing) immediately before the procedure; and (2) they were treated by an operator and supporting staff who were required to use PPE in compliance with hospital recommendations. Patients were excluded from the study if they (1) underwent implantation of a temporary transvenous pacing (TVP) or implantable loop recorder; (2) had recovered from COVID-19 and underwent CIED implantation by an operator and supporting staff without the use of PPE; or (3) had active but unrecognized COVID-19 and underwent CIED implantation by an operator and supporting staff without the use of PPE.

COVID-19 disease severity

Disease severity was classified according to the following degrees: (1) mild: no need for O_2 support; (2) moderate: need for O_2 support via nasal cannula or mask; (3) severe: need for noninvasive ventilation (high-flow, continuous positive airway pressure, etc); and (4) critical: mechanical ventilation or multiorgan failure, or need for inotropic support.

Center recruitment

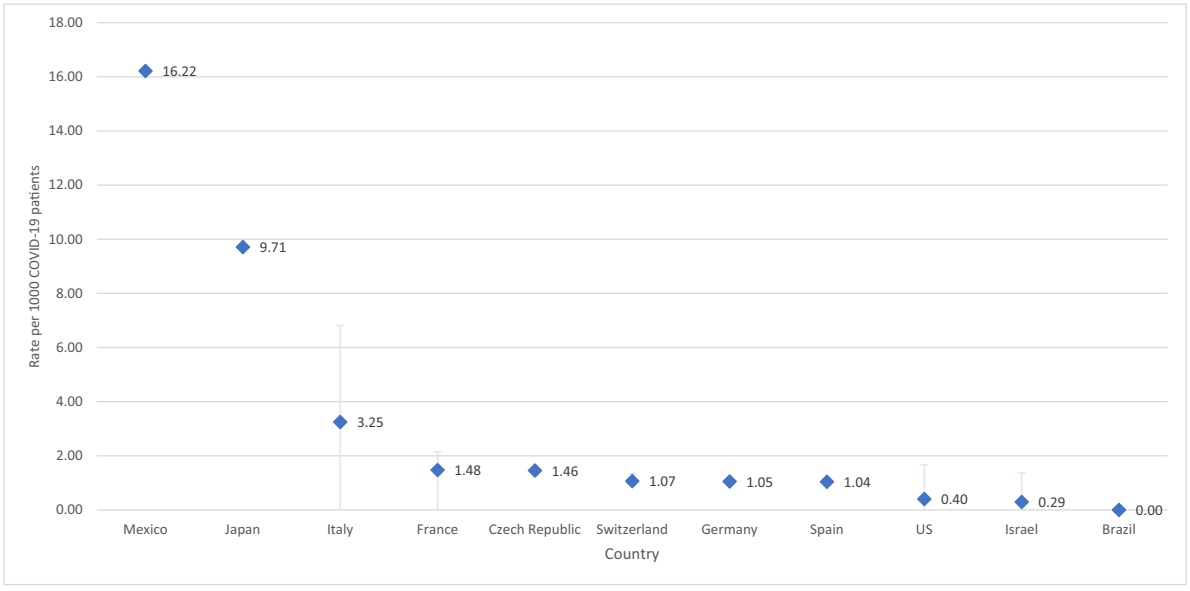
Of the 126 centers that were initially contacted, 53 (42%) from 13 countries across 4 continents agreed to participate in the survey.

Data acquisition

Participating centers were requested to provide data on the number of device procedures in active COVID-19 patients and the number of hospitalized COVID-19 patients from the beginning of the pandemic until the data collection date in March to April 2021. In addition, de-identified clinical data including demographics; comorbidities; baseline electrocardiographic (ECG) parameters; COVID-19 disease severity; cardiac magnetic resonance data; procedural indications and details including device type, implantation technique, PPE, and subjective operator feeling of impairment in the ability to perform the procedure; procedural complications; mortality cause and timing; and 1- and 3-month follow-up (FU), were collected in a microsoft excel spreadsheet provided to all participating centers.

Statistical analysis

Continuous variables are given as mean ± SD or median [interquartile range] and for categorical variables as number (percentage). Comparisons were performed by dividing the study group into (1) procedure complications (Yes/No); (2) continent (North America/Latin America/Europe); and (3) mortality (Yes/No). Relationships between categorical variables were evaluated by χ^2 and Fisher exact tests. The effect of categorical variables on continuous measurements was



	Mexico	Japan	Italy	France	Czech Republic	Switzerland	Germany	Spain	US	Israel	Brazil
Number of patients	1110	103	23399	14915	2743	3751	1900	2885	52150	23736	8127
Rate (R/1000)	16.22	9.71	3.25	1.48	1.46	1.07	1.05	1.04	0.40	0.29	0.00
Rate (R/1000) range	16.22 - 16.22	9.71 - 9.71	0.00 - 6.81	0.00 - 2.15	1.46 - 1.46	0.99 - 1.34	1.05 - 1.05	1.04 - 1.04	0.00 - 1.66	0.00 - 1.37	0.00 - 0.00
Number of centers	1	1	11	4	1	2	1	1	7	14	1
Number of procedures	18	1	76	22	4	4	2	3	21	7	0
Number of procedures range	18-18	1 - 1	0 - 22	1 - 11	4 - 4	1 - 3	2 - 2	3 - 3	0 - 7	0 - 4	0 - 0

Figure 1 Rate of cardiac implantable electronic device (CIED) procedures per 1000 hospitalized coronavirus disease 2019 (COVID-19) patients per country. The number of centers that contributed data from each country and the number of procedures performed used for rate calculation are presented beneath the graph. The procedural rate varied significantly between 0 and 16.2 per 1000 hospitalized patients ($P < .001$). Of note, 6 centers that did not perform CIED implantations (see text for discussion) and 3 centers that provided data on CIED implantations (2 from Israel and 1 from the United States with 2, 1, and 5 implanted patients, respectively) could not provide data on the total number of hospitalized COVID-19 patients.

tested by the Student *t* test and Mann-Whitney test or by 1-way analysis of variance and Kruskal-Wallis test. The choice of a parametric or nonparametric test was dependent on the distribution of a continuous variable. Multivariable logistic regression model with stepwise backward elimination was applied in order to identify independent predictors for procedure complications. Criteria for entrance into the model was univariate $P < .2$. All tests were 2-sided, and $P < .05$ was considered significant. Analyses were performed using SPSS Statistics for Windows Version 25.0. (IBM Corp., Armonk, NY).

Results

Fifty-three centers from 44 cities in 13 countries across 4 continents participated in the study. Of the participating centers, 33 had implanted CIEDs in active COVID-19 patients. Twenty replied that no device implantation that met the inclusion criteria occurred in their center. Of these 20 centers, 14 provided the number of hospitalized COVID-19 patients since the beginning of the pandemic until data collection, and 6 did not have these data available (3 from Israel, 2 from Canada, and 1 from Hong Kong).

CIED procedure rate

Forty-four centers provided the number of hospitalized COVID-19 patients at their center since the beginning of the pandemic until data collection. In 3 centers that provided data on CIED implantations, the total number of hospitalized COVID-19 patients was unavailable (2 from Israel and 1 from United States, with 1, 2, and 5 procedures, respectively). The CIED procedure rate in 133,655 hospitalized known COVID-19 patients ranged from 0 to 16.2, with a crude rate of 1.17 per 1000 hospitalized COVID-19 patients. The rates of CIED procedures per 1000 hospitalized COVID-19 patients per country and continent are shown in Figure 1. The procedural rate varied significantly among the different countries and continents. The average implantation rate was higher in European compared to US centers (1.61 and 0.4, respectively; $P < .001$).

Clinical characteristics

The study population included 166 patients (61.4% male; mean age 74.6 ± 12 years) who underwent CIED implantation (n = 159) or replacement (n = 7) during active COVID-19 illness, during which the operating physician and staff

Table 1 Comparison of patients with and without complication or mortality

	All (N = 166)	No complication (n = 143 [86.1%])	Complication (n = 23 [13.9%])	*P* value	Alive (n = 150 [90.4%])	Died (n = 16 [9.6%])	*P* value
Age (y)	74.6 ± 12	74.3 ± 12	76.7 ± 13	.353	74.2 ± 11	78.1 ± 11	.212
Female gender	64 (38.6)	54 (37.8)	10 (43.5)	.601	56 (37.3)	8 (50.0)	.322
BMI (kg/m^2)	26 [24.5–30.5]	26 [24.4–30.0]	26.7 [25.0–31.1]	.539	26.1 [24.5–30.75]	25.95 [24.14–29.9]	.699
DM	54 (32.5)	45 (31.5)	9 (39.1)	.467	45 (30.0)	9 (56.3)	.033
AF	45 (27.1)	37 (25.9)	8 (34.8)	.372	42 (28.0)	3 (18.8)	.429
IHD*	36 (25.5)	29 (24.2)	7 (33.3)	.374	35 (28)	1 (6.3)	.06
LVEF (%)	57 [50–60]	58 [50–60]	56 [50–60]	.38	56 [50–60]	60 [51.8–61.8]	.072
Days from COVID-19 diagnosis to procedure	8 [2–15]	8 [2–15]	6 [1–14]	.461	7 [2–15]	14 [4.5–27.25]	.072
Continent							
Asia	1 (0.6)	1 (0.7)	0 (0.0)	.432	1 (0.7)	0 (0.0)	.004
Central America	18 (10.8)	17 (11.9)	1 (4.3)		15 (10.0)	3 (18.8)	
Europe	121 (72.9)	101 (70.6)	20 (87.0)		115 (76.7)	6 (37.5)	
North America	26 (15.7)	24 (16.8)	2 (8.7)		19 (12.7)	7 (43.8)	
Procedural indication							
Urgent	123 (74.1)	107 (74.8)	16 (69.6)	.753	112 (74.7)	11 (68.8)	.622
Emergent	39 (23.5)	33 (23.1)	6 (26.1)		34 (22.7)	5 (31.3)	
Elective	4 (2.4)	3 (2.1)	1 (4.3)		4 (2.7)	0 (0.0)	
Syncope	73 (44.2)	64 (44.8)	9 (40.9)	.735	63 (42.3)	10 (62.5)	.122
High-degree/complete AVB	112 (67.5)	96 (67.1)	16 (69.6)	.293	102 (68)	10 (62.5)	.457
SSS	31 (18.7)	28 (19.6)	3 (13.0)		26 (17.3)	5 (31.3)	
Secondary prevention of ventricular arrhythmias	7 (4.2)	6 (4.2)	1 (4.3)		7 (4.7)	0 (0.0)	
CRT for heart failure	5 (3.0)	4 (2.8)	1 (4.3)		5 (3.3)	0 (0.0)	
Other	4 (2.4)	2 (1.4)	2 (8.7)		3 (2.0)	1 (6.3)	
Replacement	7 (4.2)	7 (4.9)	0 (0.0)		7 (4.7)	0 (0.0)	
Laboratory test values							
Platelet count (1000/μL)	192 [150–254.8]	195 [153.5–254.5]	180 [116–270]	.184	192.5 [153–254]	187 [127.3–227.5]	.601
INR	1.13 [1.03–1.29]	1.13 [1.05–1.27]	1.09 [1.01–1.3]	.551	1.13 [1.03–1.29]	1.11 [1.07–1.30]	.905
Creatinine (mg/dL)	1.07 [0.83–1.36]	1.07 [0.86–1.34]	1.07 [0.72–1.42]	.708	1.06 [0.83–1.51]	1.36 [0.97–3.03]	.022
CRP (mg/dL)	8.24 [3.1–31.1]	8 [3–24.9]	32.4 [5.4–79.5]	.037	7.7 [3–24.9]	38.9 [22.59–183]	.002
Troponin I (ng/L)	28 [10–85.25]	31.5 [10–85.75]	24.24 [12.18–74.5]	.876	28 [10–85.25]	26.5 [15–112.5]	.935
Elevated troponin†	57 (51.8)	50 (54.3)	7 (38.9)	.23	53 (52.5%)	4 (44.4)	.644
Anticoagulation							
NOAC	32 (19.3)	25 (17.5)	7 (30.4)	.499	32 (21.3)	0 (0.0)	.206
Warfarin	7 (4.2)	6 (4.2)	1 (4.3)		6 (4.0)	1 (6.3)	
Heparin	1 (0.6)	1 (0.7)	0 (0.0)		1 (0.7)	0 (0.0)	
Enoxaparin	21 (12.7)	17 (11.9)	4 (17.4)		17 (11.3)	4 (25.0)	
Any anticoagulation	61 (36.7)	49 (34.3)	12 (52.2)	.098	56 (37.3)	5 (31.3)	.631
Antiplatelets							
Aspirin	45 (27.1)	38 (26.6)	7 (30.4)	.735	37 (24.7)	8 (50.0)	.143
Clopidogrel	6 (3.6)	5 (3.5)	1 (4.3)		6 (4.0)	0 (0.0)	
DAPT	7 (4.2)	7 (4.9)	0 (0.0)		7 (4.7)	0 (0.0)	
Steroid therapy	33 (19.9)	27 (18.9)	6 (26.1)	.387	29 (19.3)	4 (25.0)	.628

COVID-19 severity							
Mild	73 (44.5)	66 (46.5)	7 (31.8)	.268	70 (47.3)	3 (18.8)	<.001
Moderate	59 (36.0)	50 (35.2)	9 (40.9)		55 (37.2)	4 (25.0)	
Severe	14 (8.5)	10 (7.0)	4 (18.2)		12 (8.1)	2 (12.5)	
Critical	18 (11.0)	16 (11.3)	2 (9.1)		11 (7.4)	7 (43.8)	
Died/complications	16 (9.6)/23 (13.9)	13 (9.1)	3 (13.0)	.551	20 (13.3)	3 (18.8)	.468
Antibiotic prophylaxis							
None	3 (1.8)	3 (2.1)	0 (0.0)	.118	2 (1.3)	1 (6.3)	.527
Cefamezine	135 (81.8)	119 (83.8)	16 (69.6)		123 (82.6)	12 (75.0)	
Clindamycin	1 (0.6)	1 (0.7)	0 (0.0)		1 (0.7)	0 (0.0)	
Other	26 (15.8)	19 (13.4)	7 (30.4)		23 (15.4)	3 (18.8)	
Vancomycin[‡]	13 (6.0)	10 (2.1)	3 (56.5)	.316	11 (1.3)	2 (81.3)	.465
Tyrx	11 (6.6)	11 (7.7)	0 (0.0)	.169	10 (6.7)	1 (6.3)	.949
Fever >38°C	14 (8.4)	13 (9.1)	1 (4.3)	.433	12 (8.2)	2 (11.1)	.557
Anesthesia							
Local only	111 (66.9)	99 (69.2)	12 (52.2)	.298	103 (68.7)	8 (50.0)	.007
Sedation without anesthesiologist	21 (12.7)	18 (12.6)	3 (13.0)		20 (13.3)	1 (6.3)	
Sedation with anesthesiologist	24 (14.5)	18 (12.6)	6 (26.1)		21 (14.0)	3 (18.8)	
General anesthesia	10 (6.0)	8 (5.6)	2 (8.7)		6 (4.0)	4 (25.0)	
Anesthesiologist present	34 (20.5)	26 (18.2)	8 (34.8)	.067	27 (18.0)	7 (43.8)	.015
Protective equipment during implantation							
Full bodysuit	103 (62.0)	86 (60.1)	17 (73.9)	.334	98 (65.3)	5 (31.3)	.007
Only face shield and N95 mask	56 (33.7)	50 (35.0)	6 (26.1)		45 (30.0)	11 (68.8)	
Only N95 mask	7 (4.2)	7 (4.9)	0 (0.0)		7 (4.7)	0 (0.0)	
Eyeglasses (implanting physician)	157 (94.6)	134 (93.7)	23 (100.0)	.216	141 (94.0)	16 (100.0)	.314
Antifog technology used during implant	6 (3.6)	0 (0.0)	6 (26.1)	.317	5 (3.3)	1 (6.3)	.552
Protective equipment routine use during pandemic							
All procedures	49 (29.5)	46 (32.2)	3 (13)	.172	39 (26)	10 (62.5)	.007
Only in positive COVID-19 cases	19 (11.4)	16 (11.2)	3 (13)		19 (12.7)	0 (0.0)	
In positive or suspected COVID-19 cases	98 (59)	81 (56.6)	17 (73.9)		92 (61.3)	6 (37.5)	
Venous access							
Axillary vein	32 (20.4)	28 (20.6)	4 (19.0)	.87	29 (20.9)	3 (18.8)	<.001
Subclavian vein	86 (54.7)	73 (53.7)	13 (61.9)		79 (56.8)	7 (43.8)	
Cephalic vein cutdown	24 (15.3)	22 (16.2)	2 (9.5)		24 (17.3)	0 (0.0)	
Femoral vein	15 (9.6)	13 (9.6)	2 (9.5)		7 (5)	6 (37.5)	
Device type							
Dual-chamber PM	74 (44.6)	61 (42.7)	13 (56.5)	.849	71 (47.3)	3 (18.8)	<.001
Single-chamber PM	49 (29.5)	44 (30.8)	5 (21.7)		43 (28.7)	6 (37.5)	
Dual-chamber ICD	5 (3.0)	4 (2.8)	1 (4.3)		5 (3.3)	0 (0.0)	
Single-chamber ICD	5 (3.0)	4 (2.8)	1 (4.3)		5 (3.3)	0 (0.0)	
CRT-D/CRT-P[§]	8 (4.2)	7 (4.9)	1 (4.3)		8 (5.3)	0 (0.0)	
His pacing	1 (0.6)	1 (0.7)	0 (0.0)		0 (0.0)	1 (6.3)	
Micra VVI	6 (3.6)	6 (4.2)	0 (0.0)		3 (2.0)	3 (18.8)	
Micra AV	9 (5.4)	7 (4.9)	2 (8.7)		6 (4.0)	3 (18.8)	
Replacements	7 (4.2)	7 (4.9)	0 (0.0)		7 (4.7)	0 (0.0)	
S-ICD	2 (1.2)	2 (1.4)	0 (0.0)		2 (1.3)	0 (0.0)	

(*Continued*)

Table 1 (*Continued*)

	All (N = 166)	No complication (n = 143 [86.1%])	Complication (n = 23 [13.9%])	*P* value	Alive (n = 150 [90.4%])	Died (n = 16 [9.6%])	*P* value
Skin closure							
Absorbable suture	127 (77.7)	110 (85.3)	17 (73.9)	.17	119 (84.4)	8 (80.0)	.393
Dermabond	10 (6.0)	9 (7.0)	1 (4.3)		10 (13.5)	0 (0.0)	
Clips/staples	11 (6.6)	7 (5.4)	4 (17.4)		9 (6.4)	2 (20.0)	
Interrupted nonabsorbable suture	3 (1.8)	3 (2.3)	0 (0.0)		3 (2.1)	0 (0.0)	

Values are given as mean ± SD, no. (%), or median [interquartile range] unless otherwise indicated.

AF = atrial fibrillation; AVB = atrioventricular block; BMI = body mass index; COVID-19 = coronavirus disease 2019; CRP = C-reactive protein; CRT = cardiac resynchronization therapy; CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker; DAPT = dual antiplatelet therapy; DM = diabetes mellitus; ICD = implantable cardioverter-defibrillator; IHD = ischemic heart disease; INR = international normalized ratio; LVEF = left ventricular ejection fraction; NOAC = new oral anticoagulants; PM = pacemaker; S-ICD = subcutaneous implantable cardioverter-defibrillator; SSS = sick sinus syndrome.

‡Most patients received vancomycin in addition to another antibiotic drug.

§One patient underwent upgrade from PM to CRT-P.

*Data not available for all patients.

†Elevated troponin was defined as >14 ng/L for troponin T and >26 ng/L for troponin I.

used PPE. Clinical and procedural characteristics, complications, and mortality for all patients are given in Table 1. Six patients underwent cardiac magnetic resonance imaging, of whom 1 was diagnosed with myocarditis, 1 with sarcoidosis, and 1 with possible myocarditis. Details are given in the Supplemental Data. Baseline ECG parameters are given in Supplemental Table 1. The number of CIED procedures, complications, and mortality by month and continent are shown in Figure 2.

Indication for CIED

The majority of devices (n = 112 [67.5%]) were implanted because of high-degree or complete AVB, followed by sick sinus syndrome (SSS) (n = 31 [18.7%]). Smaller proportions were implanted for secondary prevention of ventricular arrhythmias (n = 7 [4.2%]) and cardiac resynchronization therapy (CRT) (n = 5 [3%]). Device replacements were performed in 7 patients (4.2%). Other indications were 1 primary prevention implantable cardioverter-defibrillator, 1 syncope with left bundle branch block, 1 right ventricular lead revision due to lead malfunction (noise) with inappropriate shock, and 1 pacemaker-dependent patient who underwent CRT–defibrillator extraction due to infective endocarditis and was later reimplanted with a single-chamber pacemaker. Persistent and transient AVB were seen in 91 (54.8%) and 23 (13.9%) patients, respectively; persistent and transient SSS were seen in 17 (10.2%) and 14 (8.4%) patients, respectively; and ventricular arrhythmia was seen in 7 (4.2%) patients. Pause duration was 6 [4.15–10] seconds and 5 [4–6.5]seconds in patients with SSS and AVB, respectively. The procedure was defined as urgent, emergent, or elective in 122 (73.5%), 39 (23.5%), and 5 (3%) patients, respectively. Elective procedures details are given in the Supplemental Data. Seventy-three patients (44.2%) presented with syncope. A single-chamber pacemaker or Micra VVI pacemaker (Medtronic, Minneapolis, MN) was implanted in 55 patients, of whom 35 (63.6%) had no history of atrial fibrillation. Nine pacemakers were implanted at 5 different centers without knowledge of the patient's left ventricular ejection fraction. Procedural time was 8 [2–15] days after the diagnosis of COVID-19.

PPE

Three combinations of PPE were used during the procedures and varied among countries. (1) A full bodysuit, including an N95 mask, face shield, full body protective suit, sterile gloves, and sterile coat, was used in 103 cases (62%). (2) N95 mask and face shield only in addition to sterile gloves and coat was used in 56 cases (33.7%). (3) N95 mask only in addition to sterile gloves and coat was used in 7 cases (4.2%). The use of PPE was routine for all procedures performed during the pandemic in 7 centers (21.9%), only for positive COVID-19 cases in 7 centers (21.9%), only for positive or suspected COVID-19 cases in 17 centers (53.1%), and the policy changed from routine use for all procedures to use only for positive COVID-19 cases in 1 center

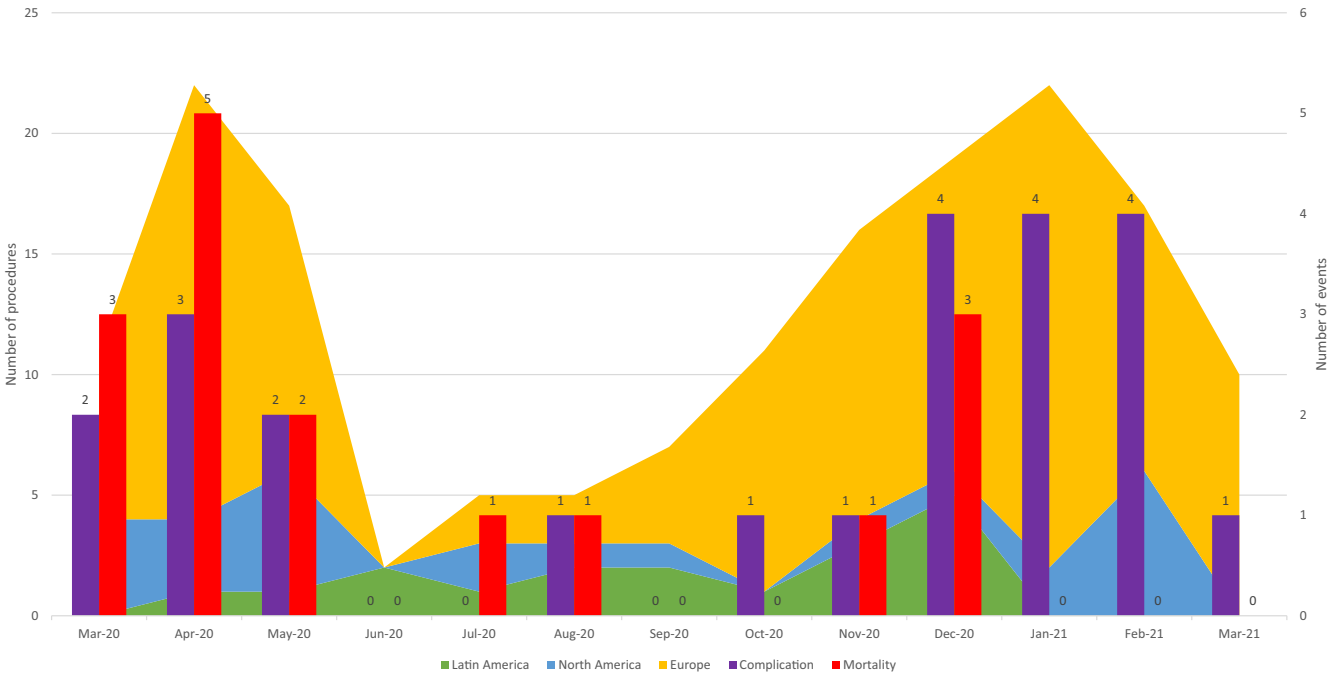


Figure 2 Number of cardiac implantable electronic device procedures, complications, and mortality by month and continent. The number of procedures is presented per continent, with complications in *purple* and mortality in *red*.

(3.1%). Use of a full bodysuit was associated with operators feeling impairment in their ability to effectively perform the procedure. In centers with 80%–100% use of a full bodysuit, 12 of 19 operators (63.2%) reported feeling impairment in their ability due to protective equipment compared to 4 of 14 operators (28.6%) with <50% (0%–40%) use of a full bodysuit (P <.001). Operators reported the subjective feeling of being hot, sweaty, and stressed and having impaired eyesight due to fog accumulation on the face shield and eyeglasses. Antifog technology was used in only 6 cases (3.6%) and included antifog spray and 1 case of a ventilator connected to the bodysuit providing airflow inside the bodysuit for prevention of heat, sweat, and fog formation.

Complications

Complications occurred in 23 patients (13.9%), all early within 30 days of the procedure. Supplemental Table 2 details all patient complications and clinical and procedural characteristics. One patient who underwent Micra AV implantation (vascular ultrasound was not used for vascular access, and a Perclose [Abbott Vascular, Santa Clara, CA] was used for femoral vein closure) was transferred to another hospital to continue COVID-19 care, where she suffered a hemorrhagic shock due to vascular bleeding and retroperitoneal hematoma (possibly due to Perclose dislodgment) and died. Two patients experienced more than 1 complication. One patient suffered from early right ventricular lead dislodgment requiring repositioning, cardiac tamponade after repositioning requiring urgent percutaneous drainage, and, at 1 month, atrial lead dislodgment requiring repositioning. Another patient suffered from a significant pocket hematoma and mild pocket infection that was treated conservatively with antibiotic therapy.

On univariate analysis, C-reactive protein (CRP) levels were significantly higher in patients with a complication (32.4 [5.4–79.5] mg/dL vs 8 [3–24.9] mg/dL; P = .037). No other patient characteristics, baseline ECG parameters, COVID severity, or PPE type was associated with complications. Multivariable analysis model revealed that independent predictors for complications were procedure performed in Europe (odds ratio [OR] 6.18; 95% confidence interval [CI] 1.23–31.10; P = .027) and procedure performed with an anesthesiologist present (OR 3.47; 95% CI 1.12–10.69; P = .031).

One operator reported contracting COVID-19 as a result of performing a pacemaker implantation procedure in an active COVID-19 patient. The PPE that was used during the procedure was an N95 mask and a face shield, without a full body protective suit, per protocol at that center. The operator consequently developed severe COVID-19 requiring intensive care but later fully recovered.

Mortality

Sixteen patients (9.6%) in the entire cohort died (Table 1). Death within 30 days and between 31 and 180 days from the procedure occurred in 10 (6%) and 6 (3.6%) patients, respectively. One patient died as a direct result of a procedural complication (hemorrhagic shock as discussed in the Complications section). All other early deaths were attributed to COVID-19 complications unrelated to the procedure. Mortality increased gradually with COVID-19 severity and was 4.1%, 6.8%, 14.3%, and 38.9% in patients with mild, moderate, severe, and critical disease severity, respectively (P <.001). CRP levels were significantly higher in patients who died vs those who did not (38.9 [22.59–183] mg/dL

vs 7.7 [3–24.9] mg/dL; $P = .002$). Documented pause duration was significantly longer in patients who died vs patients who were alive (17 [10–36] seconds vs 5.1 [3.9–6.5] seconds; $P = .005$). Mortality increased with the use of anesthesia delivered by an anesthesiologist: 7.2%, 4.8%, 12.5%, and 40% in patients receiving local anesthesia only, those sedated without anesthesiologist, those sedated by an anesthesiologist, and those receiving general anesthesia, respectively ($P = .007$). Mortality was lower during procedures performed without vs with the presence of an anesthesiologist (6.8% vs 20.6%; $P = .015$). Increased mortality was observed in patients who were implanted with a single-chamber pacemaker or Micra pacemaker (either VVI or AV Micra) ($P < .001$). Patients who died had significantly more pre-existing diabetes mellitus (56.3% vs 30%; $P = .03$).

FU

At 1-month FU, abnormal lead parameters (high thresholds) were found in 4 patients (2.4%), and a pocket infection and pocket hematoma was found in 1 patient each. Six patients (3.6%) were lost to FU, and in 10 patients (6%) less then 30 days had passed from the procedure to data collection. At 3-month FU, 3 patients (1.8%) still had abnormal parameters, 22 (13.3%) were lost to FU, and in 44 patients (26.7%) less than 3 months had passed from the procedure to data collection.

Differences among continents

Multiple differences were found in baseline patient and procedural characteristics among the different continents. Clinical and procedural characteristics of all patients according to continent are given in Supplemental Table 3.

Clinical differences

Mean age was 65.9 ± 14 years, 73.8 ± 11 years, and 76.6 ± 11 years in North America, Latin America, and Europe, respectively ($P < .001$). Patients from North America had a higher body mass index compared with those in Latin America and Europe (31.7 [25.44–36.05], 26 [26–27.5], and 26 [24.04–26], respectively; $P < .001$). The number of days from COVID-19 diagnosis to the procedure was significantly longer in Latin America vs North America and Europe (15 [14–15], 5 [2–26], and 5 [2–14] days, respectively; $P < .001$). The procedural indication differed among continents. Implantations in Latin America were due to high-degree or complete AVB in 94.4% of cases, whereas in North America and Europe other indications for device implantation were reported ($P = .168$). All procedures in Latin America were urgent and patients presented with syncope, whereas in North America more elective procedures were performed (3 [11.5%]; $P = .001$). Supplemental Table 4 lists the arrhythmia details and baseline ECG parameters according to continent. Patients in North America who were implanted due to SSS presented with longer pause durations than did patients in Europe (10 [7–36] vs 4.5 [3.25–6], respectively; $P = .008$). Patients from Europe more frequently had a wide QRS ≥120 ms compared with patients in Latin America and North America (29 [50.9%], 6 [37.5%], and 7 [33.3%], respectively; $P < .001$). The use of systemic anticoagulation was significantly more frequent in Europe (55 [45.5%]) than in North America (6 [23%]) and Latin America (0). Steroid therapy was used more frequently in Europe (25.2%) than in North America (12.5%) or Latin America (0%). COVID-19 severity distribution differed, with higher rates of critically ill patients in North America (33.3%) and Latin America (33.3%) than in Europe (3.3%) ($P < .001$).

Procedural differences

The type of CIED differed markedly according to continent. In Latin America, only conventional pacemakers were implanted, whereas in North America, 30.7% of the implantations included leadless pacemakers and a high rate of defibrillators ($P < .001$). The type of anesthesia also differed significantly, with the presence of an anesthesiologist for 73.1%, 0%, and 12.4% of patients in North America, Latin America, and Europe, respectively ($P < .001$). In addition, the type of PPE differed significantly. Full bodysuit was used in 7.7%, 0%, and 83.5% of patients in North America, Latin America, and Europe, respectively ($P < .001$). Finally, the routine use of PPE during all procedures differed significantly (83.3%, 100%, and 6.25% of centers in North America, Latin America, and Europe, respectively; $P < .001$).

Outcome differences

Complication rates were 7.7%%, 5.6%, and 16.5% in North America, Latin America, and Europe respectively ($P = .27$). Mortality rates were 26.9%, 16.7%, and 5% in North America, Latin America, and Europe, respectively ($P = .002$).

Differences between transvenous and leadless pacing systems are given in the Supplemental Data and Supplemental Table 5.

Discussion

This study reports the global rates of CIED implantation or replacement in hospitalized patients with known active COVID-19 disease. We present the largest international cohort of patients during active COVID-19 disease who underwent CIED implantation or replacement for which the operator and staff had to use PPE. In accordance with published joint statement recommendations,[22] the vast majority of implantations were due to urgent or emergent indications.

The primary findings from the present survey are as follows. (1) The complication rate within 30 days for CIED implant during active COVID-19 (13.9%) was higher than for traditional devices, with more complications noted in Europe and in patients perceived to be sicker for whom an anesthesiologist was used for the procedure. (2) Mortality rate also was substantially higher than that typically found during CIED implant (9.6% at 6 months), with higher mortality noted in North America than Europe. (3) Use of PPE varied across regions, although use of an N95 mask was present across regions. At least 1 case of patient-to-provider transmission of COVID-19 was noted.

Previous studies

Several large studies conducted throughout the world during the last 2 decades have assessed complication rates following CIED implantations. MOST (MOde Selection Trial), with a patient population having sinus nodal dysfunction who underwent dual-chamber pacemaker implantation, reported a complication rate after pacemaker implantation of 4.8% at 30 days and 5.5% at 90 days.[23] The FOLLOWPACE study, which included patients who for a conventional reason received a first pacemaker for chronic pacing, reported a 12.4% complication rate within 60 days. The use of anticoagulant drugs was an independent predictor for complications within 2 months.[24]

In 2 recent multicenter Australian studies involving 81,000 and 32,000 patients undergoing a new implantation of a mixed device type, in-hospital and 90-day complication rates of 3.3% and 8.2%, and 8% and 9.6% in private and public hospitals were found, respectively.[25,26] In addition, in-hospital and 30-day mortality were low (0.46% and 0.7%, respectively). In patients who required reoperation, 30-day mortality increased to 2.76%.[25]

A study of a large US cohort of 92,000 patients undergoing CRT implantation found a 6.1% in-hospital complication rate and 0.76% mortality rate. Complications increased with older age, more comorbidities, and nonelective procedures.[27] The Micra Investigational Device Exemption (IDE) prospective study found device complications occurred in 3.4% of patients,[28] but real-world data reported an even lower rate of 1.51%.[29]

Results of the present study

We found a high complication rate of 13.9% at 30 days, and mortality rates of 9.6% at 6 months, 6% within 30 days, and 3.6% within 31–180 days of the procedure, much higher than any previously reported large study on CIED implantation or replacement out of the setting of COVID-19 disease.[23–29] The higher complication rate seen in our cohort was likely related to the acute COVID-19 illness, the high comorbidity rates, and the fact that elective procedures on less sick patients may have been deferred. In addition, the use of PPE, reported by many operators to impair their ability to perform the procedure, could have contributed to the high complication rate, even though the difference between PPE types and complication rate did not reach statistical significance. Other unique factors that can explain the high complication rate observed in our cohort are procedures performed in patients during an infectious disease with elevated CRP levels, psychological stress of the operator due to personal exposure, and risk of contracting COVID-19. "Rushing through" the procedure in an attempt to shorten procedural time and minimize self-risk, as well as fog formation on eyeglasses and face shield impairing operator's vision, also might have affected operator performance. Finally, increased patient age, higher rates of anticoagulation and steroid therapy use, and higher rate of full bodysuit use may explain the higher complication rate seen in Europe.

Differences according to continent

Higher mortality was seen in North America compared with Europe. A higher rate of severely and critically ill patients were implanted in the United States. This is in accordance with other US studies.

Chinitz et al[21] reported the outcome of a small series of 7 COVID-19 patients who were treated for severe bradyarrhythmias and required pacing (3 TVP, 4 permanent leadless pacemakers). Among these patients, death from complications of COVID-19 infection occurred in 57% (4/7) during the initial hospitalization and in 71% (5/7) within 3 months of presentation. Another study on leadless pacemaker implantations reported 1 of 3 COVID-19–positive patients experienced in-hospital mortality on the third postoperative day secondary to hypoxic respiratory failure triggered by COVID-19.[16] The use of leadless pacemakers was suggested to reduce operator and staff exposure, and to reduce complications and hospitalization.[16] This approach was used in the US centers in our study, with a higher rate of leadless pacemakers implanted in the United States, and in patients who were severely or critically ill and in those who died. A single-chamber pacemaker or Micra VVI pacemaker was implanted in 55 patients (33.1%); of these patients, 35 (63.6%) did not have a history of AF, and a significantly higher rate was seen among patients who died (56.3% vs 30.7%). This may reflect the implanting physician's attempt to minimize and shorten the procedure in sicker patients. However, the implantations of leadless systems was not associated with a lower complication rate. None of the differences in procedural technique was associated with higher mortality. The significantly higher rate of use of an anesthesiologist for procedures performed in patients who died likely reflected the physicians' perception of sicker patients.

Clinical implications

Due to the high mortality and complication rates observed for procedures performed in active COVID-19 patients, permanent CIED implantations may be postponed whenever possible until patient recovery when PPE will be unnecessary, and the procedure will not pose a risk to the operator and supporting staff. This strategy may result in decreased complication rates and possibly minimize costs. In urgent or emergent procedures, given the known complications associated with TVP[30–32] and the resulting difficulty in handling such patients, a definitive recommendation for preferring TVP and deferring permanent pacemaker implantation cannot be given and should be made on an individual basis. Previous experience with procedures performed in COVID-19 patients when PPE is used can lead to better preparation for future procedures, such as use of antifog technology or powered air-purifying respirator (PPAR) suits. Given the possible occurrence of future pandemics, sharing personal experience between centers would be beneficial.

Study limitations

This was a retrospective cohort study. As only a single center in some countries and continents participated in the study, the

CIED procedure rate might not present an accurate estimation of entire countries and continents. Although data originated from 13 different countries, they might not reflect procedural complication and mortality rates in countries that did not participate in the study. The centers that chose to participate are relatively large academic centers and may not reflect procedural complication and mortality rates in other smaller nonacademic hospitals. In addition, it is possible that centers with very high complication rates may declined participation in the study. Several centers could not provide the total number of hospitalized COVID-19 patients, so results on implantation rates may vary; however, this was not the main goal of the current study.

Conclusion

CIED procedure rates during known active COVID-19 disease ranged from 0 to 16.2 per 1000 hospitalized COVID-19 patients. High complication rate of 13.9% and high mortality rate of 9.6% were found. Operators should take into consideration the increased risk of complications when performing CIED implantation in active COVID-19 patients in order to improve their selection of patients who should undergo the procedure.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2021.10.020.

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