

Cardiac implantable electronic devices replacements in patients followed by remote monitoring during COVID-19 lockdown

Vincenzo Russo^{1*}, Antonio Rapacciuolo², Pia Clara Pafundi³,
Marcello de Divitiis⁴, Mario Volpicelli⁵, Antonio Ruocco⁶, Anna Rago⁷, Carlo Uran⁸,
Felice Nappi⁹, Emilio Attena¹⁰, Raffaele Chianese¹¹, Francesca Esposito¹²,
Giuseppe Del Giorno¹³, Antonello D'Andrea¹⁴, Valentino Ducceschi⁴,
Giovanni Russo¹¹, Ernesto Ammendola⁷, Angelo Carbone¹³, Gregorio Covino⁵,
Gianluca Manzo¹⁴, Gianna Maria Montella¹⁵, Antonio D'Onofrio¹⁵, and
Gerardo Nigro¹

¹Division of Cardiology, Department of Medical Translational Sciences, University of Campania "Luigi Vanvitelli", Via L. Bianchi, 80131, Naples, Italy; ²Division of Cardiology, Department of Advanced Biomedical Sciences, University of Naples Federico II, Via S. Pansini, 80131, Naples, Italy; ³Department of Advanced Medical and Surgical Sciences, University of Campania "Luigi Vanvitelli", Piazza L. Miraglia, 80138, Naples, Italy; ⁴Division of Cardiology, Pellegrini Hospital, Health Authority Naples 1, Via Portamedina, 80134, Naples, Italy; ⁵Division of Cardiology, San Giovanni Bosco Hospital, Health Authority Naples 1, Via F.M. Briganti, 80144, Naples, Italy; ⁶Interventional Cardiology and Cardiological Care Unit, Cardarelli Hospital, Via A. Cardarelli, 80131, Naples, Italy; ⁷Cardiology Unit, AORN dei Colli, Via L. Bianchi, 80131, Naples, Italy; ⁸Cardiology Unit, San Giuseppe and Melorio Hospital, Santa Maria Capua Vetere, Via Melorio, 81055, Caserta, Italy; ⁹Division of Cardiology, Moscati Hospital, Contrada Amoretta, 83100, Avellino, Italy; ¹⁰Division of Cardiology, San Giuliano Hospital, Giugliano in Campania, Health Authority Naples 2 North, Via. G. Basile, 80014, Naples, Italy; ¹¹Division of Cardiology, San Leonardo Hospital, Castellammare di Stabia, Health Authority Naples 3 South, Viale Europa, 80053, Naples, Italy; ¹²Division of Cardiology, San Giovanni di Dio e Ruggi d'Aragona, Via San Leonardo, 84131 13, Salerno, Italy; ¹³Cardiology Unit, Maria SS Addolorata, Via M. Pagano, 84025, Eboli, Italy; ¹⁴Cardiology Unit, Umberto I Hospital, Via A. de Nicola, 84014, Nocera Inferiore, Italy; and ¹⁵Division of Cardiology, Monaldi Hospital, Via L. Bianchi, 80131, Naples, Italy

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Aims

Following coronavirus disease (COVID-19) outbreak, the Italian government adopted strict rules of lockdown and social distancing. The aim of our study was to assess the admission rate for cardiac implantable electronic devices (CIEDs) replacement procedures in Campania, the 3rd-most-populous region of Italy, during COVID-19 lockdown.

Methods and results

Data were sourced from 16 referral hospitals in Campania from 10 March to 4 May 2020 (lockdown period) and during the same period in 2019. We retrospectively evaluated consecutive patients hospitalized for CIEDs replacement procedures during the two observational periods. The number and type of CIEDs replacement procedures among patients followed by remote monitoring (RM), the admission rate, and the type of hospital admission between the two observational periods were compared. In total, 270 consecutive patients were hospitalized for CIEDs replacement procedures over the two observation periods. Overall CIEDs replacement procedures showed a reduction rate of 41.2% during COVID-19 lockdown. Patients were equally distributed for sex ($P = 0.581$), and both age [median 76 years (IQR: 68–83) vs. 79 years (IQR: 68–83); $P = 0.497$]. Cardiac implantable electronic devices replacement procedures in patients followed by RM significantly increased (IR: +211%; $P < 0.001$), mainly driven by the remarkable increase rate trend of both PM (IR: +475%; $P < 0.001$) and implantable cardiac defibrillator replacement procedures (IR: +67%, $P = 0.01$), during COVID-19 lockdown compared with 2019 timeframe.

* Corresponding author. Tel: +39 0817062815, Email: v.p.russo@libero.it

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Conclusions

We showed a significant increase trend rate of replacement procedures among CIEDs patients followed by RM, suggesting the hypothesis of its increased use to closely monitoring and to optimize the hospital admission time during COVID-19 lockdown.

Keywords

Remote monitoring • Arrhythmias • Cardiac implanted device • COVID-19 • Defibrillator • Pacemaker • Replacement

Introduction

Coronavirus disease (COVID-19) outbreak commenced in China with the rapid worldwide spread of devastating pandemic proportions¹ and alarming mortality.² Italy is among the most severely affected countries by COVID-19, with more than 233 836 laboratory-confirmed cases by 3 June 2020 and more than 33 600 deaths.³ Following COVID-19 outbreak, the Italian government adopted strict rules characterized by lockdown and social distancing to contain virus diffusion from 10 March to 4 May 2020.⁴ During COVID-19 outbreak and the consequent lockdown period, some changes in the pattern of hospital admissions for cardiovascular conditions have been observed.⁵ The use of daily remote monitoring (RM) for the follow-up of patients with cardiac implantable electronic devices (CIEDs) has shown significant benefits on cardiovascular outcomes,⁶ however, little is known about the changes in its use during COVID-19 pandemic. The aim of our study was to evaluate the rate of CIEDs replacement procedures among patients followed by RM during the COVID-19 lockdown in Campania Region, the region of Southern Italy majorly hit by COVID-19.

Materials and methods

Data were sourced from 16 referral hospitals in Campania from 10 March to 4 May 2020 (lockdown period) and during the same period in 2019. Among consecutive patients hospitalized for cardiac rhythm management (CRM) procedures during the two observational periods, we retrospectively evaluated subjects admitted for CIEDs replacement procedures. For each patient, we collected the age, the type of CIED, the type of hospital admission, and the follow-up modality (RM or in-person visits). All data were validated by two investigators (V.R. and P.C.P.) before the analysis. The study was approved by the local ethics committee and was in accordance with the 1976 Declaration of Helsinki and its later amendments.

Endpoints

The primary outcome was the overall rate of CIEDs replacement procedures, including pacemaker (PM), implantable cardiac defibrillator (ICD), and cardiac resynchronization therapy (CRT) replacements, with regard to patients followed by RM. The secondary outcome was the rate of different types of admission to CRM centres sub-divided into: emergency department (symptomatic patients self-referred either to ED or delivered by out-of-hospital emergency system); urgent unplanned hospitalization (as soon as possible following outpatient follow-up visit), planned hospitalization (organized by

physicians according to patients' and hospital needs), inpatient stays (in-hospital symptomatic patients).

Statistical analysis

All data were presented as either numbers and percentages, in the case of categorical variables, or median and interquartile ranges for the concerns associated continuous variables, after appropriately testing their distribution using the Shapiro Wilk and Kolmogorov-Smirnov tests. All continuous data were non-normally distributed. Differences between variables were assessed either by the chi-square test for categorical variables or the non-parametric Mann Whitney U test for continuous variables. The incidence rates for the primary outcome were computed considering the number of cumulative admissions by the number of days for each time period. A p -value <0.05 was considered statistically significant. All analyses were performed using SPSS software, Version 24 (IBM, Armonk, New York) and STATA 14.0 software (StataCorp. 2015. College Station, TX, StataCorp LP).

Results

Among 951 consecutive patients hospitalized for CRM procedures over the two observations periods, 270 (28.4%) consecutive patients were hospitalized for CIEDs replacement procedures, of which 100 during the COVID-19 lockdown and 170 during the same time period in 2019. The overall CIEDs replacement procedures showed a reduction rate of 41.2% during COVID-19 lockdown. Patients were equally distributed for sex ($P = 0.581$), and both age (median 76 years [IQR: 68–83] vs. 79 years [IQR: 68–83]; $P = 0.497$). There was a statistically significant difference in both PM (IR: +4.5%) and ICD (IR: +40%) replacement procedures in 2020 compared to the same timeframe in 2019; whilst a remarkable reduction in CRT replacement procedures (RR: -88.8%) procedures between the two observation periods. Population-specific data are shown in [Table 1](#).

CIEDs replacement procedures in patients followed by RM significantly increased during COVID-19 lockdown (IR: +248%; $P < 0.001$), mainly driven by the remarkable increase rate trend of both PM (IR: +475%; $P < 0.001$) and ICD replacement procedures (IR: +67%, $P = 0.01$) during compared to 2019 timeframe.

Regarding the type of admission to hospitals for patients in need of CIEDs replacement, no statistically significant difference in the attendance to ED during lockdown for COVID-19 has been shown; conversely, a significantly increased rate of urgent unplanned hospitalizations was observed (IR: +5.4%; $P < 0.001$). As well, a remarkable significant decreased was found for what concerns both planned hospitalizations (RR: -69.3%; $P < 0.001$) and inpatient stays

Table 1 Anthropometric characteristics and assessment of replacement procedures and access to hospitals in 2019 and 2020

Parameter	Year 2019 (n = 170)	Year 2020 (n = 100)	RR/IR (%)	p
Age (years), median [IQR]	76 [68–83]	79 [68–83]		0.497
Sex, n (%)				0.581
M/F	110 (64.7)/60 (35.3)	68 (68)/32 (30)		
PM replacement, n (%)	66 (38.8)	69 (69)	+4.5	<0.001
ICD replacement, n (%)	15 (8.8)	21 (21)	+40	0.0045
CRT replacement, n (%)	89 (52.4)	10 (10)	-88.8	<0.001
Elective procedures, n (%)	114 (67.1)	56 (56)	-50.9	0.069
Emergency department, n (%)	20 (11.8)	19 (19)	-5	0.102
Urgent unplanned hospitalization, n (%)	55 (32.4)	58 (58)	+5.4	<0.001
Inpatients stays, n (%)	16 (9.4)	2 (2)	-87.5	0.018
Planned hospitalization, n (%)	79 (22.9)	21 (21)	-69.3	<0.001
Remote monitoring				
Overall procedures in RM patients, n (%)	27 (4.6)	94 (94)	+248	<0.001
PM replacement in RM patients, n (%)	4 (14.8)	63 (63)	+475	<0.001
ICD replacement in RM patients, n (%)	12 (44.4)	20 (20)	+66.7	0.001
CRT replacement in RM patients, n (%)	8 (4.7)	10 (10)	+25	0.09

Number and percentages are referred to enrolled patients.

CRT, cardiac resynchronization therapy; F, female; ICD, implantable cardioverter defibrillator; IQR, interquartile range; IR, increased rate; M, male; PM, pacemaker; RM, remote monitoring; RR, reduction rate.

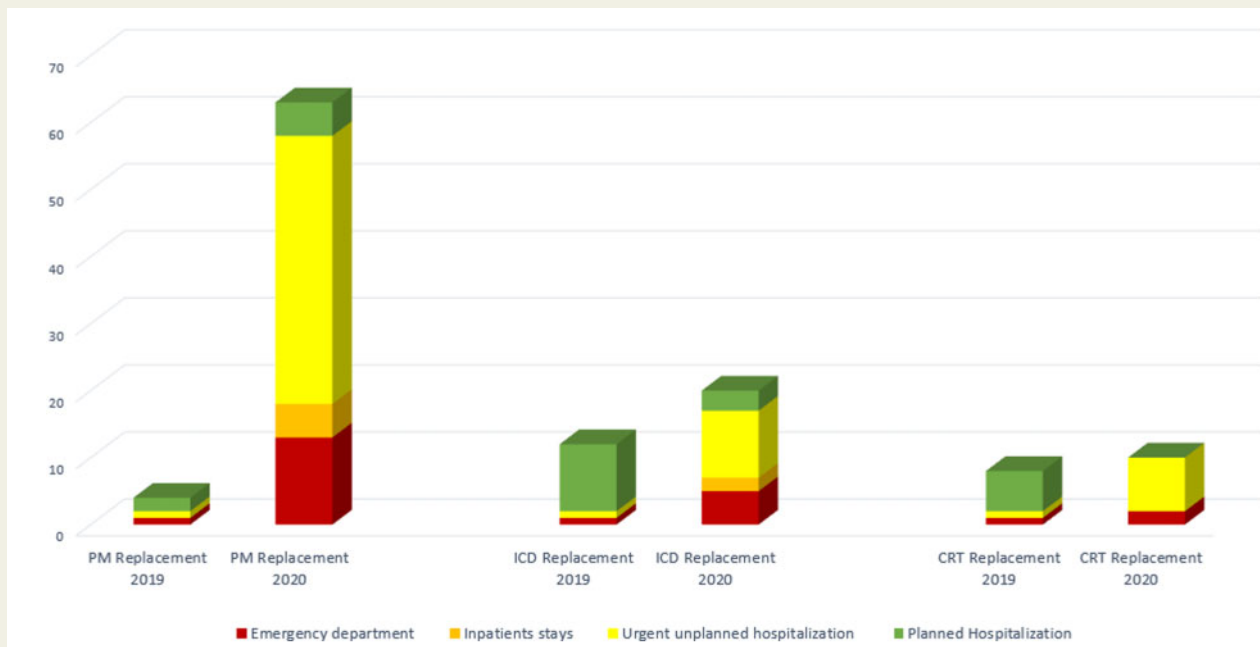


Figure 1 Number of CIEDs replacement procedures in patients followed by remote monitoring for each type of admission during 2019 and 2020 study periods.

(RR: -87.5%; $P = 0.018$) between the two observation periods. The [Figure 1](#) shows the number of CIEDs replacement procedures in patients followed by RM for each type of admission during 2019 and 2020 study periods.

Discussion

Campania was the region of Southern Italy majorly hit by COVID-19, with more than 8.900 laboratory-confirmed cases. Our findings suggest that the COVID-19 lockdown was associated with a significant reduction rate in overall CIEDs replacement procedures (- 41.2%); however, a significant increase in overall procedures in CIEDs patients followed by RM (+248%) has been shown, mainly driven by both PM (+4.5%) and ICD (+40%) replacement procedures. During COVID-19 outbreak, the strict rules adopted by Italian government to contain virus diffusion, the reorganization of the healthcare model, the restructuring of hospital services might be in part responsible for the reduction trend in planned hospitalizations and elective procedures, as observed in our study population. In contrast to previous reports from Northern Italy,^{7,8} which showed a trend of reduction in hospital admission due to cardiovascular diseases leading to cardiac pacing procedures, our data showed no significant difference in Emergency department (ED) admission rate and a remarkably increase in urgent unplanned hospitalizations for patients in need of CIEDs replacement procedures.

Our results might be related to the lower epidemiological pressure of COVID-19 in Campania region compared with other regions in Northern Italy, where the number of positive cases during the observational period was up to 13 times higher. Despite the different prevalence of COVID-19 among Italian regions, Campania was subjected to the same restrictions adopted in the Northern Italy; this allowed us to contain the unnecessary in-person visits and to carefully follow-up CIEDs recipients through RM, eventually planning urgent hospitalizations only in the case of extreme need.⁹ Telemedicine thus helped in preventing patients from excessive risks due to on-site visits and time spent in hospitals waiting rooms. A further advantage is represented by the limited exposure of physicians and allied professionals either to CIED recipients or their caregivers directly involved in the COVID-19 pandemic. In this sense, RM may also represent a tool to be furtherly used also in the future. The lack or inadequate reimbursement and the absence of sharing standards for CIEDs' RM determine its heterogeneous use among different European countries and represent the most important reported barriers to the implementation in the clinical practice.¹⁰

Despite the retrospective nature of our analysis represents a limitation, our data might aid authorities in optimally planning healthcare

resources during COVID-19 outbreak. In particular, given the increased number of CIEDs patients in need of device control or replacement procedures and the low availability of physicians, allied professionals, hospital beds, and operatory rooms, it would be prudent to ensure RM for all CIEDs patients for the optimization of replacement times during outbreak.

Conclusion

Despite the overall reduction rate of 41.2% in CIEDs replacement procedures, we showed a significant increase trend rate of replacement procedures among CIEDs patients followed by RM, suggesting the hypothesis of its increased use to closely monitoring and to optimize the hospital admission time during COVID-19 lockdown.

Conflict of interest: none declared.

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