

# Effects of Covid-19 Lockdown on Patients with Implantable Cardioverter-Defibrillators in South of Italy: possible causes?

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## Abstract

Aims to evaluate the incidence of cardiac arrhythmias during a lockdown period due to COVID-19 pandemics in a population followed by remote monitoring through implanted cardiac defibrillators. Methods and results In this retrospective, multicentre cohort study, we included 574 remotely monitored automatic (AICD) and cardiac resynchronization devices (CRT-D) recipients implanted before January 1st 2019 at seven Hospitals of Campania Region, comparing the incidence of arrhythmias occurred during the lockdown period due to COVID-19 epidemics (from March 9th to May 1st 2020) with the arrhythmias rate of the corresponding period in 2019. An effective retrospective data collection was performed through remote monitoring, as this tool allows the direct transfer of the the information stored by the implantable devices to medical personnel. During the lockdown period, we observed ventricular tachyarrhythmias (ventricular tachycardia or fibrillation) in 25 (4.8%) patients as compared to 12 (2.3%) during the corresponding 2019 period ( $p < 0.04$ ); new-onset atrial fibrillation was detected in 38 (8.2%) subjects during lockdown period and in 24 (5.2%) during the reference period ( $p < 0.004$ ). Conclusion During pandemics lockdown period we observed an higher incidence of arrhythmic events in ICD/CRT-D patients followed up through device remote monitoring by seven hospitals of Campania region.

Effects of Covid-19 Lockdown on Patients with Implantable Cardioverter-Defibrillators in South of Italy: possible causes?

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### *Statements*

All authors listed takes responsibility for all aspects of the reliability and freedom of bias of the data presented and their discussed interpretation.

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### **Aims**

to evaluate the incidence of cardiac arrhythmias during a lockdown period due to COVID-19 pandemics in a population followed by remote monitoring through implanted cardiac defibrillators.

### **Methods and results**

In this retrospective, multicentre cohort study, we included 574 remotely monitored automatic (AICD) and cardiac resynchronization devices (CRT-D) recipients implanted before January 1<sup>st</sup> 2019 at seven Hospitals of Campania Region, comparing the incidence of arrhythmias occurred during the lockdown period due to COVID-19 epidemics (from March 9<sup>th</sup> to May 1<sup>st</sup> 2020) with the arrhythmias rate of the corresponding period in 2019. An effective retrospective data collection was performed through remote monitoring, as this tool allows the direct transfer of the the information stored by the implantable devices to medical personnel.

During the lockdown period, we observed ventricular tachyarrhythmias (ventricular tachycardia or fibrillation) in 25 (4.8%) patients as compared to 12 (2.3%) during the corresponding 2019 period ( $p < 0.04$ ); new-onset atrial fibrillation was detected in 38 (8.2%) subjects during lockdown period and in 24 (5.2%) during the reference period ( $p < 0.004$ ).

### **Conclusion**

During pandemics lockdown period we observed an higher incidence of arrhythmic events in ICD/CRT-D patients followed up through device remote monitoring by seven hospitals of Campania region.

**Keywords** SARS-COV-2, COVID-19, Arrhythmias, remote monitoring, ICD/CRT-D, lockdown

### **INTRODUCTION**

The on-going pandemic of coronavirus disease 2019 (COVID-19) has created a worldwide emergency:<sup>1</sup> on March 8th, Italy became the second most affected country in the world after China, and specific rules for restricting social contacts in the whole country were applied by the Italian Government in order to contain the epidemic spread. These emergency measures were in force until May 4<sup>th</sup>, 2020. At the end of June 2020, 240.000 cases were registered in Italy with more than 34.000 deaths.<sup>2</sup>

As restrictions included the reduction or the interruption of several routine public health and hospital services, as out-patient clinics and office visits and routine hospital admissions for chronic disease, there was widespread major concern regarding also the management of non-COVID patients, such as patients with advanced cardiac disease, and its prognostic implications during the lockdown period.

Recently a significant reduction of 47% in diagnosis of new-onset cases of atrial fibrillation (AF) was observed in the danish adult population during national lockdown in Denmark, suggesting that the risk of complications of non-diagnosed AF could rise significantly and influence the outcome unfavourably<sup>3</sup>. Furthermore

an increase of admissions to emergency department caused by rhythm disturbances has been recently observed in our region during lockdown period, despite a reduction in dysrhythmia-related urgent unplanned hospitalization<sup>4</sup>.

The aim of our study was to evaluate the risk of clinically relevant cardiac arrhythmias during lockdown period in a study population with advanced cardiac disease and high risk of cardiac arrhythmias and mortality. In particular, we studied the impact of lockdown restrictions on the incidence of new onset of AF and ventricular tachycardia (VT) and fibrillation (VF) in patients with Implantable cardioverter-defibrillators (AICD) and Cardiac Resynchronization Therapy-defibrillators (ICD/CRT-Ds) for primary and secondary prevention of sudden cardiac death.

## METHODS

### Italy's context

Since February 20<sup>th</sup> 2020, the SARS-COV2 infection has spread in Lombardy and North Italy, and successively to the remaining Italian regions, forcing the Italian government to impose emergency measures to counteract the COVID-19 outbreak. On March 9<sup>th</sup> 2020, the Italian government extended a tight lockdown to the rest of Italy, including Campania region, prohibiting any kind of mobility and social activities except certain health or professional needs. This included also restrictions in economic activities with consequent widespread workers' layoffs causing widespread social discomfort.

### Study period

We focused on the Campania region in order to examine the influence of lockdown in terms of new-onset of cardiac arrhythmias among patients with ICD/CRT-D from on March 9 to on May 4, 2020. We compared these data with data from the same period in 2019. The observation window was set from January 1 2019 to May 4 2020 and 3 evaluation periods were defined during the 16 months of observation: a global period (from January 1<sup>st</sup> 2019 to May 4<sup>th</sup> 2020), a reference period (from March 9<sup>th</sup> to May 4<sup>th</sup> 2019) and lockdown period (March 9<sup>th</sup> to May 4<sup>th</sup>, 2020).

### Study population and Data Available

During the COVID-19 pandemic, Italian hospitals have been forced to adapt and to restructure their organization to cope with this urgent new critical situation.

As patients' office visits were discouraged and many outpatient clinics were temporarily closed, alternative solutions, such as remote telematic health visits and telemonitoring (RM) have been adopted or implemented in order to focus on selected "high risk" patients in need of closer surveillance, as recommended by HRS Expert Consensus Statement and, more specifically, by Italian Arrhythmology and Cardiac Stimulation Society (AIAC).<sup>5,6</sup>

RM provides the automated transmission of data based on prespecified alerts related to device function and clinical events. This allows rapid detection of abnormal device function and/or arrhythmia events. RM of these devices allows the transfer of the information stored in the implantable device so that it can be accessed by the clinic personnel via a secured website.

By this tool, we analysed a large cohort of remotely monitored ICD and CRT-D recipients, who had undergone device implantation before January 1<sup>st</sup>, 2019 at 7 Hospitals of Campania Region, comparing the arrhythmias incidence of the lockdown to the arrhythmias rate of the corresponding period in 2019. In total, 574 patients were initially selected in a retrospective fashion for this multicentre and observational study. All patients enrolled had been implanted according to European Society of Cardiology/European Heart Rhythm Association guidelines criteria for ICD/CRT-D implant, had received remote monitoring devices after signing a specific written informed consent for the utilization of their device data. Among all subjects under AICD and CRT-D remote monitoring at our hospitals, we selected 574 patients who had undergone AICD or CRT-D implant before 2019 and at least one office visit in the last 2 years and during the global

observation period. None of the included patients was hospitalized due to COVID-19 infection or to acute respiratory distress.

## Diagnosis of Arrhythmias and Device Programming

The devices of all patients selected for this study are equipped with reliable diagnostic algorithms that provide a series of alerts related to technical issues and to the occurrence of arrhythmic events. We focused on relevant cardiac arrhythmias including AF, ventricular tachycardia (VT) and ventricular fibrillation (VF). The diagnosis was initially made by the device via automatic detection and discrimination of episodes (AF/VT/VF); at second instance diagnosis was confirmed by an experienced physician via remote analysis of endocavitary strip received for each patient once or twice a week from January 2019 to May 2020, according to remote monitoring rules of each hospital involved in the research. Specifically, for all patients, we reviewed telemetry logs and confirmed the diagnosis of arrhythmias detected by device. Among all arrhythmias recorded by device, the ones analysed included incident VT, VF and new-onset AF. Out of these, we examined exclusively the ones that required device intervention: switch mode in the case of AF, life-saving therapy as anti-tachycardia pacing (ATP) and/or shock therapy in other cases. For AF count, in addition to device intervention, episodes with a duration of at least six hours and a cardiac rate above 220 beats per minute threshold were considered.

Subjects with permanent AF were excluded from the AF analysis.

Patients were excluded from the analysis if during follow-up they experienced hospital admission for: VT or AF ablation procedure, trans-catheter aortic valve implantation, mitral clip implantation.

At implant and at in-office evaluations (pre-lockdown) specific recommendations for device programming according to patient profile had been adopted, thus minimizing troubleshooting during follow up<sup>7</sup>. In particular, both standardized and conventional and tailored device programming was adopted to guarantee efficacy and safety of the therapy. All patients implanted for primary prevention have shown as first therapy three attempts of ATP for VT zone (from 180 to 200-220 bpm) and a sequence of ATP during capacitor charging for VF zone (>200-220 bpm); long detection time (intervals or cycles) in any window (setting depends on manufacturer's device); shocks always delivered at the maximum energy (at least 30 J) in VT and VF zone; and the use of discrimination criteria for VT zone up to 200-220 bpm. Among patients implanted for secondary intervention, the 65% of cases has received a specific "MADIT-RIT" programming: therapies only for high heart rates (> 200 bpm, VF zone).<sup>8,9</sup> In these patients a "tailored" programming approach was adopted through the knowledge of arrhythmic history, ECG morphology, cycle length and patients' tolerance, in order to cover all clinical arrhythmias efficiently. No Monitor zone were found in all the devices examined.

## Medical Therapy

All participants was following optimal medical therapy (OMT) at office evaluations (pre-lockdown) and underwent appropriate up titration of medications to the maximal tolerable dosage if needed.

Telephone support was effective in keeping connections with the patients during the lockdown, allowing appropriate management and implementation of drug therapy.

## Statistical analyses

Continuous variables are expressed as mean  $\pm$  standard deviation for normal distribution and as median and interquartile range in case of skewed distribution. Categorical data are expressed as number and percentages. To compare proportions of patients with at least 1 episode in the two periods of comparison (reference and lockdown periods) we used a test for categorical dependent samples (McNemar). To assess differences in numbers of events over the two periods of interest (reference and lockdown periods) we used a non-parametric paired samples test (Wilcoxon). A two-sided p-value of less than 0.05 was considered significant. Statistical analyses were undertaken using SPSS version 22 (IBM SPSS Statistics).

Observation time was divided in 3 periods: lockdown period (March 9 through May 4, 2020) with the corresponding reference period in 2019 (March 9 through May 4, 2019) with a global observation period of

16 months (January 1, 2019 to May 4, 2020). We compared cardiac arrhythmias rate during lockdown period (March 9 through May 4, 2020) to the corresponding reference period in 2019.

## RESULTS

Patients' demographics and clinical characteristics are described in Table 1.

Five-hundred-seventy-four adult patients followed-up by remote monitoring of ICD or CRT-Ds implanted before January 1<sup>st</sup> 2019 have been retrospectively included in the study.

During follow-up, 20 patients were excluded because of VT or AF ablation therapy, 8 patients for percutaneous mitral repair with the MitraClip and/or transcatheter aortic valve implantation (TAVI). Furthermore 16 subjects were excluded because of issues related to remote communication; 11 patients died during the observation period. Therefore the data regarding 519 patients have been finally analysed and are presented in this paper.

The mean age of the 519 patients was 67-years ( $\pm 13.2$ ) and most patients were male (74.7%). Comorbidities were present in more half of patients, with hypertension being the most common comorbidity, followed by Ischemic heart disease (IHD), Chronic obstructive pulmonary disease (COPD) and history of AF (Table 1).

In the global observation period we recorded a total of 285 arrhythmic events in VT and VF zones that required appropriate ICD therapies; 228 episodes in VT zone and 57 episodes in VF zone; out of these 46% of cases were treated by a DC shock, while 61% of episodes in VT zone and 35% in VF zone were successfully treated by ATP. In the global observation period, we also counted 480 episodes of atrial arrhythmias.

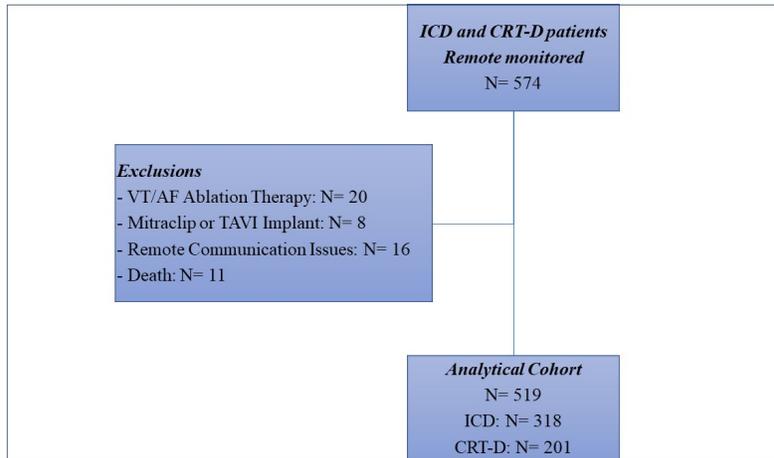
During lockdown 206 arrhythmic events were recorded: 58 VTs, 13 VFs and 135 AFs; in the reference period 18, 9 and 62 VTs, VFs and AFs respectively were observed ( $p=0.0232$ ,  $p=0.0215$  and  $0.0004$  respectively) (Table 2). The number of events in the case of both VTs and VFs or any arrhythmias is significantly higher in lockdown period.

Furthermore, during lockdown period, 25 (4.8%) patients have showed at least one VT or VF compared with 12 (2.3%) during reference period ( $p=0.015$ ). More specifically, at lockdown VT and VF were found in 15 (2.9%) and in 11 (2.1%) patients respectively, while at reference period in 7 (1.3%) and 6 (1.2%) patients ( $p=0.06$ ,  $p=0.267$  respectively).

Among 461 patients in sinus rhythm at ICD implant, 38 (8.2%) and 24 (5.2%) patients have shown AF during lockdown and reference period respectively ( $p=0.03$ ). AF was the most encountered cardiac arrhythmia detected in patients at all observation periods: 8.2% at lockdown, 5.2% at reference and 15.6% at global period (table 3). There were no significant statistical associations of our outcome with both age and gender.

By comparing VT/VF and AF between the quarters occurring from March 1<sup>st</sup> 2019 and February 29<sup>th</sup> 2020, there was no significant differences in the arrhythmic episodes recorded.

### Figure 1, Study Flowchart



**Table 1, Baseline characteristics of the population**

<i>Characteristic</i>	<i>Overall (519)</i>
Age (Years)	66.9±13.2
Genre, Male	387 (74.7%)
IHD	173 (33.3%)
PTCA	99 (19.1%)
CABG	35 (6.7%)
Valvular Disease	46 (8.9%)
AF at Implant	58 (11.2%)
AF History	126 (24.3%)
LVEF	29.6±11.7
CRT-D device	201 (38.8%)
SCD for Secondary Prevention	108 (20.8%)
COPD	148 (28.5%)
CKD	55 (10.6%)
Hypertension	275 (53.0%)
Diabetes	110 (21.2%)
Beta-blockers	454 (87.4%)
ACEI's	225 (43.4%)
Angiotensin Receptor Blockers, Sartanics	126 (24.3%)
Valsartan/sacubitril, <i>Entresto</i>	97 (18.7%)
Diuretics	410 (79.0%)
NOACs	223 (42.9%)

*Values are presented as mean ± SD or as N (%).*

IHD= Ischemic Heart Disease; PTCA= Percutaneous Transluminal Coronary Angioplasty; CABG= Coronary Artery Bypass Grafting; AF=Atrial Fibrillation; LVEF=Left Ventricular Ejection Fraction; CRT-D= Cardiac Resynchronization therapy-defibrillator; SCD= Sudden Cardiac Death; COPD= Chronic Obstructive Pulmonary Disease; CKD= Chronic Kidney Disease; ACEI's= Angiotensin Converting Enzyme Inhibitors; NOACs= New Oral Anticoagulants.

**Table 2, Comparison of Number Arrhythmias at reference period and at lockdown period**

Type of arrhythmia	Number of arrhythmias	Number of arrhythmias	Number of arrhythmias	Number of arrhythmias
	Global period	Reference Period	Lockdown Period	P-value
VT/VF	285	27	71	0.0435
VT	228	18	58	0.0232
VF	57	9	13	0.0215
AF**	480	62	135	0.0004

\* Comparison between Reference and Lockdown period

\*\*AF has been evaluated only in patients at sinus rhythm at implant/enrolment (461 patients).

VT=Ventricular Tachycardia; VF= Ventricular Fibrillation; AF=Atrial Fibrillation.

**Table 3, Comparison of Incidence Arrhythmias at reference period and at lockdown period in ICD/CRT-D patients**

Type of arrhythmia	All patients (519)	All patients (519)	All patients (519)	All patients (519)
	Incidence of arrhythmias (number of patients) Global period	Incidence of arrhythmias (number of patients) Reference Period	Incidence of arrhythmias (number of patients) Lockdown Period	Incidence of arrhythmias (number of patients) P-value*
VT/VF	12% (62)	2.3% (12)	4.8% (25)	0.0146
VT	7.9% (41)	1.3% (7)	2.9% (15)	0.0574
VF	5.2% (27)	1.2% (6)	2.1% (11)	0.267
AF**	15.6% (872)	5.2% (24)	8.2% (38)	0.0303

\*Comparison between Reference and Lockdown period

\*\*AF has been evaluated only in patients at sinus rhythm at implant/enrolment (461 patients).

VT=Ventricular Tachycardia; VF= Ventricular Fibrillation; AF=Atrial Fibrillation.

## DISCUSSION

Patients with advanced cardiac disease are at high risk of arrhythmic events that may impact prognosis, such as AF, VT and VF. In this study we have shown that during the 56 days long lockdown due to COVID-19 epidemics, the incidence of both atrial and ventricular arrhythmias was significantly increased in subjects with AICD and ICD/CRT. These data were available through remote device monitoring and raise some interesting issues regarding both cardiac pathophysiology and patients' clinical management.

In order to contrast the spread of the new COVID-19 epidemic, at the beginning of March 2020 the Italian Government decided for more restrictive containment measures: a sudden and radical change has occurred in the habits and lifestyles of the population, with a drastic reduction of any form of personal contacts and socialisation with relevant social and economic consequences. These preventive measures did limit the spread of this contagious disease in southern Italy. The effects of lockdown period were explored in different contexts and terms: eating habits and lifestyle changes,<sup>10</sup> approaches implemented to support teleconsultations and management of AF and heart failure patients.<sup>11,12</sup> new-onset of arrhythmic events such as atrial fibrillation,<sup>3</sup> impact on interventional electrophysiology units routine and emergency work,<sup>13</sup> .

It is well established that patients affected by COVID-19 infection may develop cardiac complications, also in

terms of both atrial and ventricular arrhythmias. Such complications are more frequent in severely ill subjects and may represent a negative prognostic factor in terms of morbidity and mortality<sup>14</sup>. This created major concern for the patients with chronic heart disease. However even in cardiopathic subjects who were not affected by COVID-19 related pneumonia, restrictive measures created distress and cardiac complications.

In our study we investigated the effects of lockdown period in a cohort of stable patients followed up through AICD and CRT-D remote monitoring in terms of incidence rate of cardiac arrhythmias, by comparing these data with data from the same period in 2019. Study population has shown an increase in the incidence of arrhythmias: during lockdown period VT/VF occurred in 4.8% and new-onset AF in 8.2% of study patients, while the same arrhythmias were respectively observed in 2.3% and 5.2% of subjects during the corresponding 2019 period. These results were strengthened in terms of number of arrhythmic events: VT, VF and AF episodes were recorded during the lockdown time interval much more frequently than the correspondent reference period.

Our study method, based on diagnosis obtained through continuous remote monitoring, has allowed to eliminate the “issue” of potential and dangerous underdiagnosis associated with the routine discontinuous in-office clinical assessment; this issue has become more relevant during the recent COVID-19 pandemic outbreak because of the widely reported patients’ tendency to avoid hospitalization during the epidemic peak phase (Russo, Danish e qualcos’altro) and to the reduction of hospitals’ accessibility. In fact the data of the Danish Registry have shown a 47% drop in registered diagnosed new-onset AF cases, revealing a potential and “dangerous” risk of undiagnosed AF with potential detrimental prognostic effects<sup>3</sup>. This tendency, that could possible cause underdiagnosis and underreporting, was bypassed in our investigation by continuous remote monitoring that allowed us to quantify the real arrhythmic burden associated to lockdown in terms of higher incidence of relevant arrhythmias.

To the best of our knowledge, this is the first study to report on the incidence of cardiac arrhythmias related to the COVID-19 outbreak in AICD patients on such a large sample size. Our results are in agreement with the recently published data of a multi-center study performed in our region, that show a significant increase in the number of hospitalizations through the emergency department due to clinically relevant arrhythmias during the lockdown time interval, despite the reduced number of scheduled hospital admissions and rhythm management procedures<sup>4</sup>.

The increased incidence of dysrhythmias during lockdown may be related to “high-stress conditions” that have characterized lockdown period. As the strict lockdown measures were associated to change in daily habits, social discomfort, economic recession and jobs lay-offs, it is not surprising that in the Italian general population high rates of negative mental health outcomes and different COVID-19 related risk factors were reported<sup>15</sup>. Several studies, both in animal models and humans, suggest that emotions and mental stress play a significant role in the onset of arrhythmias and the occurrence of sudden death due to “the heart-brain interaction”.<sup>16-18</sup> Emotions and mental stress can influence heart rhythm in several ways, including impaired sympathetic/parasympathetic balance, alterations in the spatial distribution of autonomic input to the heart, or by causing coronary arterial vasoconstriction and ischemia. Anger has been shown to be the commonest emotion prior to the onset of ventricular arrhythmia also in patients with ICD.<sup>16,18</sup> Mental stress and anger predispose to atrial arrhythmias particularly in younger patients with ‘lone’ AF; furthermore stress increases both the frequency of cardiac rhythm disturbances and the lethality of ventricular arrhythmias<sup>17,18</sup>. Specific regions in the brain may be responsible for mediating the pro-arrhythmic effects of emotions.<sup>18</sup> This functional connection between the brain and the heart may be the cause of the increased incidence of arrhythmias in our study population that have experienced lockdown-related stressful life. It is conceivable that this phenomenon, assessed for the general population,<sup>18</sup> may be even more pronounced in a population with advanced cardiac disease and might play a causative role of new-onset arrhythmias. In this context, a potential role of disorders of metabolic and hormonal homeostasis caused by mental and psychological stress was not investigated and it cannot be ruled out.

As a change in the incidence of neither atrial nor ventricular arrhythmias was recorded in the year preceding lockdown, it is unlikely that our findings are due to cardiac disease progression.

Our experience confirmed how the use of remote monitoring, recognized as “the new standard of care” for patients with cardiac implantable electronic devices by HRS Expert Consensus Statement<sup>5</sup> plays an even more crucial role during the current pandemic as clinical follow-up during a period of social distancing and limited access to health facilities represent a difficult challenge for subjects who require regular and/or continuous surveillance.<sup>19</sup>

### Limitations of the Study

Potential confounder factors such as education level, occupation (employed, unemployed, student, retired) or family status were not analysed because data not or partially available in history of our patients.

Although none of the studied patients was hospitalized due to COVID-19 infection or to respiratory illness, but we were not able to exclude the asymptomatic COVID-19 carriers, introducing a potential bias. However it has been shown that asymptomatic viral infection is not associated with significant arrhythmic risk.<sup>14</sup>

### CONCLUSIONS

During lockdown period due to COVID-19 pandemics, an higher incidence of atrial and ventricular arrhythmias was observed in AICD and ICD/CRT-D patients followed up by remote monitoring. These results, probably related to lockdown social and psychological “high-stress conditions”, warrant further scientific investigation and closer monitoring of subjects with advanced cardiac disease and at risk of sudden cardiac death during periods of such restrictive daily life limitations.

**Conflict of interest:** none declared.

### DATA AVAILABILITY

The data underlying this article will be shared on reasonable request to the corresponding author.

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