

## ORIGINAL ARTICLE

# Effects of COVID-19 lockdown on arrhythmias in patients with implantable cardioverter-defibrillators in southern Italy

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Email: [valentino.ducceschi10@gmail.com](mailto:valentino.ducceschi10@gmail.com)**Abstract**

**Background:** The effects of lockdown on non-COVID patients are varied and unexpected. The aim is to evaluate the burden of cardiac arrhythmias during a lockdown period because of COVID-19 pandemics in a population implanted with cardiac defibrillators and followed by remote monitoring.

**Methods:** In this retrospective, multicentre cohort study, we included 574 remotely monitored implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy-defibrillator (CRT-D) recipients implanted before January 1, 2019, at seven hospitals in the Campania region, comparing the burden of arrhythmias occurred during the lockdown period because of COVID-19 epidemics (from March 9 to May 1, 2020) with the arrhythmias burden of the corresponding period in 2019 (reference period). Data collection was performed through remote monitoring.

**Results:** During the lockdown period, we observed ventricular tachyarrhythmias (ventricular tachycardia or fibrillation) in 25 (4.8%) patients while in seasonal reference period we documented ventricular tachyarrhythmias in 12 (2.3%) patients; the comparison between the periods is statistically significant ( $P < .04$ ). Atrial arrhythmias were detected in 38 (8.2%) subjects during the lockdown period and in 24 (5.2%) during the reference period ( $P < .004$ ).

**Conclusion:** In seven hospitals in the Campania region, during the pandemic lockdown period, we observed a higher burden of arrhythmic events in ICD/CRT-D patients through device remote monitoring.

**KEYWORDS**

arrhythmias, COVID-19, ICD/CRT-D, lockdown, remote monitoring

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## 1 | INTRODUCTION

The ongoing 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, 2020. At the end of June 2020, 240000 cases were registered in Italy with more than 34000 deaths.<sup>2</sup>

As restrictions included the reduction or the interruption of several routine public health and hospital services, such as outpatient 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.

The effects of the pandemic and lockdown on non-COVID patients are varied and unexpected. Recently, during a national lockdown in Denmark,<sup>3</sup> a significant reduction of 47% in the diagnosis of new-onset cases of atrial fibrillation was observed. On the other hand, an increase in admissions to the emergency department caused by severe or life-threatening rhythm disturbances has been recently observed in our region during the lockdown period, despite a reduction in arrhythmias related to urgent unplanned hospitalization.<sup>4</sup>

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

## 2 | METHODS

### 2.1 | Italy's context

Since February 20, 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, 2020, the Italian government extended a tight lockdown to the rest of Italy, including the Campania region, regardless of the very few covid cases. This included also restrictions in economic activities with consequent widespread workers' layoffs causing widespread social discomfort. 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

remote monitoring (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>

### 2.2 | Study period

We focused on the Campania region in order to examine the influence of lockdown in terms of atrial and ventricular arrhythmias recorded among patients with ICD/CRT-D from March 9 to May 4, 2020. We compared these data with data from a seasonal reference period (from March 9 to May 4, 2019). The global observation window was set from January 1, 2019, to May 4, 2020, and two evaluation periods were defined during the 16 months of observation: a reference period (from March 9 to May 4, 2019) and the lockdown period (March 9 to May 4, 2020).

### 2.3 | Study population and data available

This is a multicentre cohort study that included 574 patients retrospectively selected from seven hospitals in the Campania region. The study included all patients with ICD and CRT-D implanted before January 1, 2019, and who have received remote monitoring devices after signing a specific written informed consent. All patients enrolled had been implanted according to the European Society of Cardiology/European Heart Rhythm Association guidelines criteria for ICD/CRT-D implant. Among all subjects under ICD and CRT-D remote monitoring at our hospitals, we selected 574 patients who had undergone ICD or CRT-D implantation before 2019. In order to make the population homogeneous, we considered only those patients regularly presenting at the outpatient clinic during the global observation period.

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

This study was conducted according to the Declaration of Helsinki and approved by the institutional ethics committees (ID-210520).

### 2.4 | Diagnosis of arrhythmias and device programming

We focused on relevant cardiac arrhythmias including atrial arrhythmias (AA) and ventricular arrhythmias (VA). The diagnosis was initially made by the device via automatic detection and discrimination of episodes, in the second instance diagnosis was confirmed by an experienced physician via remote analysis of the endocavitary strip received automatically according to remote monitoring rules of each hospital involved in the research. Generally monitored patient data were automatically received every 1 or 2 weeks; according to the

clinical practice of each center, a dedicated physician checks the transmission at least once a week.

Among all arrhythmias recorded by the device, we exclusively considered VAs that required device interventions: anti-tachycardia pacing (ATP) and/or shock therapy. As regards atrial arrhythmias (AT and AF), we considered episodes with a duration of at least six hours and atrial rate above 220 beats to reduce the rate of false positive during the validation analysis.

Subjects with permanent AF were excluded from the AT/AF analysis.

Patients were excluded from the analysis if during follow-up they experienced hospital admission for VT or AF ablation procedure, transcatheter aortic valve implantation, and 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> All patients implanted for primary prevention have two detection zones programmed: VT zone (from 170–180 to 200–220bpm) with ATP and shock therapies and VF zone (>200–220bpm) with shock therapies with a sequence of ATP during capacitor charging if available. Among patients implanted for secondary prevention, 65% of cases have received a specific “MADIT-RIT” programming: therapies only for high heart rates (>200bpm, VF zone),<sup>8,9</sup> for the others a “tailored” programming approach was adopted. No Monitor zone were found in all the devices examined. No change in devices programming was performed during the study period (from January 12, 2019 to May 4, 2020).

## 2.5 | Medical therapy

All participants were following optimal medical therapy as prescribed during in-office visits (pre-lockdown); telephone support was carried out with the patients during the lockdown, in order to allow appropriate management and implementation of drug therapy.

## 2.6 | 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 one 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). Univariate binary logistic regression analysis was performed to evaluate the correlation between atrial and ventricular events and baseline characteristics. A two-sided *P*-value of less than .05 was considered significant. Statistical analyses were undertaken using SPSS version 22 (IBM SPSS Statistics).

## 3 | 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, 2019, have been retrospectively included in the study.

During follow-up, 20 patients were excluded because of VT or AF ablation therapy, eight 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. Finally, in addition, 11 patients were excluded because they died before the lockdown period.

Therefore, as illustrated in Figure 1, the data regarding 519 patients have been finally analyzed 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

TABLE 1 Baseline characteristics of the population

| Characteristics                          | Overall (519)   |
|--|-----------------|
| Age (years)                              | 66.9 $\pm$ 13.2 |
| Genere, 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 $\pm$ 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%)     |
| Amiodarone                               | 113 (21.8%)     |
| Beta-blockers                            | 454 (87.4%)     |
| ACEIs                                    | 225 (43.4%)     |
| Angiotensin receptor blockers, sartanics | 126 (24.3%)     |
| Valsartan/sacubitril                     | 97 (18.7%)      |
| Diuretics                                | 410 (79.0%)     |
| NOACs                                    | 223 (42.9%)     |

Note: Values are presented as mean  $\pm$  SD or as *N* (%).

Abbreviations: ACEIs, angiotensin converting enzyme inhibitors; AF, atrial fibrillation; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CRT-D, cardiac resynchronization therapy-defibrillator; IHD, ischemic heart disease; LVEF, left ventricular ejection fraction; NOACs, new oral anticoagulants; PTCA, percutaneous transluminal coronary angioplasty; SCD, sudden cardiac death.

more than half of the patients, with hypertension being the most common comorbidity, followed by ischemic heart disease (IHD), chronic obstructive pulmonary disease (COPD), and a history of AF (Table 1).

We classified as VT all recorded arrhythmias in the VT zone (from 180 to 200–220bpm based on the manufacture's device) and as VF all recorded arrhythmias in the VF zone (> 200–220bpm).

In the global observation period of 16 months, we recorded a total of 285 ventricular arrhythmic events, needing device therapies, in 62 patients: 228 episodes in the VT zone and 57 episodes in the VF zone. In the VT zone, 61% of events were resolved by ATP, the

remaining 39% needed DC shock; in the VF zone, 35% of events were successfully treated only by ATP, the remaining 65% needed one or more shocks.

In the global observation period, we also counted 480 episodes of AAs in 72 patients.

During the lockdown period, 71 VA occurred in 25 patients instead, in the reference period, we recorded 27 VA in 12 patients. The number of VA in the lockdown period is significantly higher with respect to the reference period ( $P = .043$ ); the same when we considered the percentage of patients with at least one VT or VF event (4.8% in lockdown period vs 2.3% in reference period,  $P = .014$ ). When we considered the number of VT and VF events separately, the differences between lockdown and reference period were statistically significant ( $P = .023$  for VT and  $P = .021$  for VF), not the same when we considered the percentage of patients with at least one event. All details are presented in Tables 2 and 3.

Among 461 patients in sinus rhythm at implantation and at the beginning of the global observational period, 38 (8.2%) patients have shown at least one AA during the lockdown period and 24 (5.2%) during the reference period, the difference was statistically significant ( $P = .03$ ). Likewise, when we considered the number of AA: in the lockdown period, we recorded 135 events with respect to 62 events in the reference period ( $P < .001$ ).

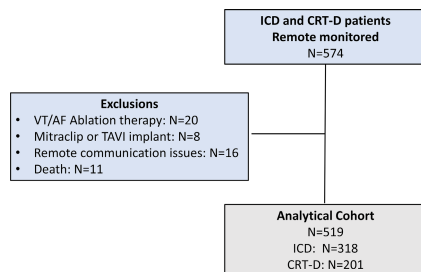


FIGURE 1 Study flowchart

| Type of arrhythmia | Number of arrhythmias     |                  |                 | P-value <sup>a</sup> |
|--------------------|---------------------------|------------------|-----------------|----------------------|
|                    | Global period (16 months) | Reference period | Lockdown period |                      |
| VT/VF              | 285                       | 27               | 71              | .043                 |
| VT                 | 228                       | 18               | 58              | .023                 |
| VF                 | 57                        | 9                | 13              | .021                 |
| AT/AF <sup>b</sup> | 480                       | 62               | 135             | <.001                |

Abbreviations: AF, atrial fibrillation; AT, atrial tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

<sup>a</sup>Comparison between Reference and Lockdown period.

<sup>b</sup>AT/AF has been evaluated only in patients at sinus rhythm at implant/enrolment (461 patients).

TABLE 2 Comparison of the number of arrhythmias at reference period and at lockdown period

| Type of arrhythmia | All patients (519)  |                  |                 |                      |
|--------------------|---|------------------|-----------------|----------------------|
|                    | Percentage of patients with at least one VA and AA (number of patients) |                  |                 |                      |
|                    | Global period (16 months)   | Reference period | Lockdown period | P-value <sup>a</sup> |
| VT/VF              | 12% (62)  | 2.3% (12)        | 4.8% (25)       | .014                 |
| VT                 | 7.9% (41)   | 1.3% (7)         | 2.9% (15)       | .057                 |
| VF                 | 5.2% (27)   | 1.2% (6)         | 2.1% (11)       | .267                 |
| AT/AF <sup>b</sup> | 15.6% (72)  | 5.2% (24)        | 8.2% (38)       | .030                 |

Abbreviations: AA, atrial arrhythmias; AF, atrial fibrillation; AT, atrial tachycardia; VA, ventricular arrhythmias; VF, ventricular fibrillation; VT, ventricular tachycardia.

<sup>a</sup>Comparison between Reference and Lockdown period.

<sup>b</sup>AT/AF has been evaluated only in patients at sinus rhythm at implant/enrolment (461 patients).

TABLE 3 Comparison of number and percentage of patients with at least VA and AA at reference period and at lockdown period

At univariate analysis, there was no statistically significant association between the burden of any arrhythmic events and baseline characteristics.

By comparing the burden of VA and AA between the quarters occurring from March 1, 2019, and February 29, 2020, there was no significant differences in the arrhythmic episodes recorded.

## 4 | DISCUSSION

Patients with advanced cardiac disease are at high risk of arrhythmic events that may impact prognosis, such as AT, AF, VT, and VF. In this study, we have shown that during the 56 days long lockdown because of COVID-19 epidemics, the burden of both atrial and VAs was significantly increased in subjects with ICD and CRT-D.

The effects of the lockdown period were explored in different contexts and terms: eating habits and lifestyle changes,<sup>10</sup> approaches implemented to support teleconsultations<sup>11</sup> and management of AF and heart failure patients<sup>12,13</sup> impact on interventional electrophysiology units routine and emergency work.<sup>14</sup>

In our study, we investigated the effects of the lockdown period in a cohort of stable patients followed up through ICD and CRT-D remote monitoring in terms of burden of cardiac arrhythmias, by comparing these data with data from the same period in 2019. Study population has shown an increase in the number of arrhythmias: during lockdown period VA occurred in 4.8% and AA 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: both atrial and ventricular episodes were recorded during the lockdown time interval much more frequently than during 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<sup>3,15</sup> and to the reduction of hospitals' accessibility. The effects of the pandemic and lockdown on non-COVID patients are varied and unexpected. Recently, during a national lockdown in Denmark, a significant reduction of 47% in the diagnosis of new-onset cases of atrial fibrillation was observed.<sup>3</sup>

Recently, a remarkable study by O'Shea et al.<sup>16</sup> has investigated the issue of VA burden during COVID-19 in the USA, comparing, similarly to our study, the COVID-19 period with the seasonal control period. This study has demonstrated a 32% reduction in VAs needing device therapies, although the percentage of patients that experienced VA were similar in COVID-19 and seasonal control period. In particular, the VA reduction coinciding with measures of social isolation and was higher in states with higher COVID-19 incidence. On the other hand, by analyzing the data in a more detailed fashion, the authors found no difference in VA episodes, between lockdown

and seasonal control period, in the US states with a lower incidence of COVID-19 infection and, in some cases, they observed even an increment in VA events. The results of our study should not be considered in contrast with the ones by O'Shea et al. In fact, the Campania region showed one of the lowest incidence rates of COVID-19 infection during the lockdown period of 2020, as compared with the rest of Italy.

Another recent study by O'Shea et al.,<sup>17</sup> has investigated AF occurrence during the COVID-19 period with the same methods as the aforementioned study. The major finding of this study is a significant increase of AF episodes during the COVID-19 period compared with the identical period a year early; in particular, for episodes >6h duration, the increase was 54% ( $P < .001$ ). These results are very similar to ours, and, as stated by O'Shea et al., the increase in AF episodes seen during the COVID-19 lockdown is not solely attributable to the natural history of AF over time.

Other relevant publications have dealt with similar aspects with different results compared to our study.

Sassone et al.,<sup>18</sup> conducted a similar study during the same period of Italy lockdown. He reported no difference in ICD therapies and AA in the lockdown period with respect to the control period (10 weeks prior to lockdown) and, moreover, he reported a decrease in non-sustained ventricular tachycardia during the lockdown period. Compared to our work, however, there are many differences that could justify the different results. First, there are some important differences in terms of patients enrolled: in our study, we excluded patients who had invasive procedures, perhaps in the Sassone et al. study such patients were included and influenced the results. Even more important it might be the proportion of patients implanted for secondary prevention, in our study, the proportion is almost 21%, while Sassone et al. do not report the exact number of ICD implanted for primary and secondary prevention. We could then speculate that the two populations enrolled exhibited different substrates if in Sassone et al. paper there was a significantly lower percentage of subjects included for secondary prevention; indeed, mental stress might result more harmful in more susceptible arrhythmic substrates.<sup>19,20</sup> Another substantial difference lies in the programming of the devices; in our study, the absence of a monitor zone and the rigorous and almost homogeneous programming windows could influence the classification of the events. On the other hand, Sassone et al. do not mention any physician review of the recorded events; this, with such low incidences of events, could have substantially affected the results.

Mascioli et al.,<sup>21</sup> also conducted a similar interesting study in another Italian region. Using RM, he reported in the lockdown period a significant reduction in physical activity and heart rate but no significant change in arrhythmias incidence. Compared to our study, there are no major differences in the enrolled population, in particular, the proportion of patients implanted for secondary prevention are 20.5%, very close to our proportion. The results show similar trends to those found in our work, in particular, there are three patients that experienced appropriate shocks in the lockdown period versus only one in the pre-lockdown period. Another similar result is the

AF burden that is significantly higher in the lockdown period in the subgroup of patients aged <70 years. In light of this, the Mascioli et al. results could differ because of the smaller number of patients enrolled and the shorter observation period.

Another important study that needs to be considered is published by Galand et al.<sup>22</sup> on a very large cohort of patients with ICD and CRTD in France. In this study, an increase in VA was observed after the first Covid case and especially during the 2 weeks before lockdown at the time of major government measures; then, after the lockdown order, the incidence of VA dropped significantly. So, the lockdown decision was hailed as a rescue measure, therefore it is not surprising that VAs appeared more frequent in the 2 weeks just preceding the lockdown.

The results of our study, which may seem completely different, are actually not very dissimilar if we consider that the lockdown periods do not coincide and occur at different pandemic moments. In particular, in the Campania region the lockdown took place a week earlier in a much less alarming pandemic condition and it could probably have been initially seen only as a constraint on personal freedom.

As also reported by Galand et al. the incidence curve of arrhythmias does not follow that of the incidence of the covid, but rather the emotional state of the patients. This might explain why the apparently different results of our study and Galand et al. are, on the contrary, very similar. In both, in fact, VAs and psychological stress seem to be closely related.

The increased incidence of arrhythmias during lockdown may be related to "high-stress conditions" that have characterized the 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>23</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 because of "the heart-brain interaction".<sup>19,20,24</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. Mental stress and anger predispose to AAs, particularly in younger patients with "lone" AF; furthermore, stress increases both the frequency of cardiac rhythm disturbances and the lethality of VAs.<sup>20,24</sup> Specific regions in the brain may be responsible for mediating the pro-arrhythmic effects of emotions.<sup>24</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>24</sup> may be even more pronounced in a population with advanced cardiac disease and might play a causative role in 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.

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>25</sup>

## 5 | LIMITATIONS OF THE STUDY

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

Since the association between asymptomatic viral infection and arrhythmia risk has not been clearly established, as suggested by few published studies,<sup>15,22</sup> and although none of the studied patients was hospitalized for COVID-19 infection or respiratory illness, we are not able to exclude that asymptomatic COVID infections may have influenced our results.

## 6 | CONCLUSIONS

During lockdown period because of COVID-19 pandemics, an higher incidence of atrial and VAs was observed in ICD and 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

No conflict of interest to declare.

### AUTHOR CONTRIBUTIONS

Valentino Ducceschi: concept and Approval of article; Marcello de Divitiis: drafting and critical revision; Valter Bianchi: data collection and results interpretation; Raimondo Calvanese: data collection and analyses; Gregorio Covino: data collection and critical revision; Antonio Rapacciuolo: Data collection and critical revision; Vincenzo Russo: data collection and critical revision; Michelangelo Cancelli: Data analysis and critical revision; Mario Volpicelli—Critical revision; Giuseppe Ammirati—Data collection; Raffaele Sanguolo—data collection; Giovanni Papaccioli—data collection.; Carmine Ciardiello—Results Interpretation and Statistics; Sara Innocenti—drafting and Statistics; Antonio D'Onofrio—approval of article. All authors listed take responsibility for all aspects of the reliability and freedom of bias of the data presented and their discussed interpretation.

## DATA AVAILABILITY STATEMENT

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

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