

**THE USE OF REMOTE MONITORING OF CARDIAC IMPLANTABLE DEVICES
DURING THE COVID-19 PANDEMIC - AN EHRA PHYSICIAN SURVEY**

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ABSTRACT

It is unclear to what extent the COVID-19 pandemic has influenced the use of remote monitoring (RM) of cardiac implantable electronic devices (CIEDs). The present physician-based EHRA survey aimed to assess the influence of the COVID-19 pandemic on RM of CIEDs among EHRA members and how it changed the current practice. The survey comprised 27 questions focusing on RM use before and during the pandemic. Questions focused on the impact of COVID-19 on the frequency of in-office visits, data filtering, reasons for initiating in-person visits, underutilization of RM during COVID-19 and RM reimbursement. A total of 160 participants from 28 countries completed the survey. Compared to the pre-pandemic period, there was a significant increase in the use of RM in patients with PM and ILRs during the COVID-19 pandemic (PM 24.2 vs 39.9%, $p = 0.002$; ILRs 61.5 vs 73.5%, $p = 0.028$), while there was a trend towards higher utilization of RM for CRT-P devices during the pandemic (44.5 vs 55%, $p = 0.063$). The use of RM with ICDs and CRT-D did not significantly change during the pandemic (ICD 65.2 vs 69.6%, $p=0.408$; CRT-D 65.2 vs 68.8% vs, $p = 0.513$). The frequency of in-office visits was significantly lower during the pandemic ($p < 0.001$). Nearly two thirds of participants (57 out of 87 respondents), established new RM connections for CIEDs implanted before the pandemic with 33.3% ($n=29$) delivering RM transmitters to the patient's home address, and the remaining 32.1% ($n=28$) activating RM connections during an in-office visit. The results of this survey suggest that the crisis caused by COVID-19 has led to a significant increase in the use of RM of CIEDs.

INTRODUCTION

Remote monitoring (RM) of cardiac implantable devices (CIEDs) was initially introduced for complementary evaluation of device function but now represents the standard of care and is recommended by major cardiology societies worldwide (1,2). RM of CIEDs reduces the number of scheduled in-office visits and leads to early detection of events, such as atrial fibrillation and ventricular arrhythmias, inappropriate shocks, lead failure, premature battery depletion, loss of biventricular capture, and mortality (3,4). However, despite the international guidelines' recommendations based on these numerous benefits, its use in the routine clinical setting remains modest (1,2,5).

Although the COVID-19 pandemic caught us unprepared, it facilitated and accelerated the use of telemedicine and digital solutions (6). RM and teleconsultations, new digital tools, mobile health apps were available to replace traditional clinician-patient, face-to-face interaction and enabled the follow-up and treatment of patients during the lockdown. Although it is clear that the COVID-19 pandemic has expedited the utilization of digital tools, it remains unclear to what extent the pandemic has influenced the use of RM of CIEDs.

The aim of this physician-based survey, disseminated by the Scientific Initiatives Committee of the European Heart Rhythm Association (EHRA), was to evaluate and describe the impact of the COVID-19 pandemic on the use of RM of CIEDs among EHRA members.

METHODS

An online survey was prepared and disseminated by the EHRA Scientific Initiatives Committee to the EHRA Scientific Research Network members, national electrophysiology (EP) working groups, and social media platforms (Twitter, LinkedIn and Facebook), with the help of the EHRA e-Communication Committee. The survey was conducted between March 17th, 2021, and April 30th, 2021. It was designed after reviewing the literature and using expert opinion to examine the changes in RM practice induced by COVID-19 pandemic, and comprised a total of 27 questions distributed in four blocks focusing on the impact of COVID-19 on the frequency of in-office visits, data filtering, reasons for initiating in-person visits, underutilization of the RM during the pandemic and RM reimbursement (see Supplemental Material).

Participants who disagreed with GDPR compliance were excluded from the analysis.

Statistical analysis

Mean and standard deviation (SD) were used to present continuous variables, while categorical variables are expressed as numbers and percentages. Student's t-tests, Mann–Whitney U tests and One-way ANOVA, as appropriate, and Chi-square test (χ^2) for categorical variables were used to compare groups. Statistical analysis was performed using SPSS 25.0 for Macintosh (SPSS Inc., Chicago, IL, USA). P values less than 0.05 were considered statistically significant.

RESULTS

The survey was completed by 160 participants from 28 countries (mean age 45.5 ± 11 years, female 28.3% (n= 37) (see Table 1). The majority of survey participants (76%) stated that their hospitals were partially turned into COVID-19 centres, while 16% declared that the entire hospital was converted into a COVID-19 centre at some point during the pandemic.

RM before, during and after the COVID-19 pandemic

RM was used in 24.2% of pacemaker (PM) patients even before the COVID-19 pandemic. The percentage of PM patients with RM increased significantly during the pandemic to 39.9% ($p = 0.002$). Similarly, usage of RM for implantable loop recorders (ILR) increased from 61.5% to 73.5% ($p = 0.028$) (see Figure 1). Utilization of RM for implantable cardioverter-defibrillators (ICD) did not change significantly during the pandemic (ICDs: 65.2% before vs. 69.6% during the pandemic, $p=0.408$; CRT-Ds: 65.2% before vs. 68.8% during the pandemic, $p=0.513$). There was a trend for a higher utilization of RM for cardiac resynchronization therapy pacemakers (CRT-P), with 44.5% of devices with RM before vs. 55% of devices with RM during the pandemic ($p=0.063$).

The majority of respondents declared willingness to increase the use of RM of all CIEDs after the pandemic: 53.7% for PMs, 80% for ICDs, 71.5% for CRT-P, 80.5% for CRT-Ds and 81.8% for ILRs.

Establishment of new RM connections for pre-COVID implanted CIEDs & adherence to ESC and HRS guidance for COVID-19

Nearly two thirds of participants (57 out of 87 respondents), established new RM connections for CIEDs implanted before the pandemic with 33.3% (n=29) delivering RM

transmitters to the patient's home address, and the remaining 32.1% (n=28) activating RM connections during an in-office visit.

More than half of the respondents (54.1%) stated that recent guidance by the *European Society of Cardiology* (ESC) (7) and *Heart Rhythm Society* (HRS) (8) on management of cardiovascular disease during the COVID19 pandemic did not lead to any significant changes on the management of CIED patients. Up to 42.2% acknowledged some degree of modification in practice, and only 3.7% stated that it "absolutely changed" their practice during the pandemic.

Frequency of in-person visits of RM patients

Of 109 responses, respondents stated that 57.4% of all CIEDs in-clinic follow-ups were delayed due to the pandemic. The mean period between face-to-face appointments for RM patients with an implanted PM changed from 10.3 ± 5.4 months to 16 ± 12.5 months during the pandemic ($p < 0.001$). For patients with an ICD this changed from 8.6 ± 5.8 months to 15.1 ± 13.9 months during the COVID-19 pandemic ($p < 0.001$), and for CRT patients it increased from 8.3 ± 6 months to 14.3 ± 14 months ($p < 0.001$). ILR were checked in person every 11.1 ± 11.9 months before vs 17.6 ± 17.2 months during the pandemic ($p = 0.002$) (see Figure 2).

RM data filtering

The COVID-19 pandemic did not significantly impact on the recruitment and organization of the RM data filtering personnel ($p = 0.818$, see Figure 3.). In most cases, a specialized nurse or physician assistant was in charge of data filtering (56.1% before vs 55.9% during the pandemic), followed by doctors (33.3% vs 31.2%) and allied professionals (6.1% vs 5.5%, respectively).

Clinical impact of RM during the pandemic

The clinical impact of RM findings did not significantly differ before and during the COVID-19 ($p = 0.687$). Of 114 responses, participants replied that the need for phone calls (64%

vs 64.2%) or in-office visits (12.3% vs 15.6%) following significant RM findings was similar between the pre-and post-pandemic period.

According to the respondents, the most frequent reasons for face-to-face visits before and during the pandemic were inappropriate ICD therapies (69.3% vs 64.2% responses, respectively, $p = 0.321$), followed by appropriate ICD therapies (64% before vs 56.9% during the COVID-19; $p = 0.242$). Even though no significant differences in reasons for initiating in-office visits for RM patients when comparing before and during pandemic were reported (all p NS, Figure 4), there was a trend towards less face-to-face appointments for all indications during COVID-19, except for ventricular arrhythmias (61.4% vs 62.4%, $p = 0.424$).

Reimbursement for RM of CIEDs

Of 114 respondents, 57% ($n=65$) did not receive any reimbursement for RM of CIEDs, before the pandemic. Reimbursement of RM before the pandemic was declared by 25.4% of respondents for PM, 41.2% for ICDs, 29% for CRT-P, 37.7% for CRT-D, and only 8.8% of centers received reimbursement for RM of ILRs. Additional reimbursement for RM of CIEDs was declared by 7.3% respondents for PM and ICDs during the COVID-19 pandemic of 109 respondents. A 5.5% increase in respondents receiving reimbursement for RM of CRT-P and CRT-D was observed during the pandemic. Only 1.8% of participants received additional reimbursement for RM of ILRs during the COVID-19 (see Figure 5.).

Reasons for underutilization of RM

Out of 114 respondents, only a third of participants (24.6%) considered RM sufficiently utilized prior to the pandemic. During the pandemic this percentage significantly increased to 35.8% ($p = 0.048$). The main reasons for underutilization of RM before the pandemic were lack of

personnel (46.5%) and lack of reimbursement (50.9%). Interestingly, during the pandemic these percentages dropped to 34.7% ($p=0.053$) and 40.4% ($p=0.085$) (see Figure 6.).

DISCUSSION

The main findings of this survey were: (a) use of RM increased during COVID-19, and a further increase may be expected after the pandemic; (b) the pandemic significantly reduced the frequency of face-to-face appointments of RM patients with CIEDs; (c) the reasons for in-office visits of RM patients during the pandemic were similar to those prior to it; and (d) COVID-19 did not change the RM data filtering personnel profile.

Use of RM of CIEDs pre-, during, and the plan for the post-COVID period

Even though RM had been available for two decades before the pandemic and the international guidelines' recommended its use since 2015, the full capacities of RM had not been fully exploited, with a low adoption rate across European centres (2,4,9). The measures of physical distancing implemented in many countries during the COVID-19 created a broader and urgent need for wider adoption of digital solutions, among them, RM. Indeed, the wEHRables survey-II showed increased use of teleconsultations during the pandemic, while the HRS survey showed almost 10-fold higher adoption of routine use of video-telehealth (6,10). The results of our survey confirm the greater use of RM in patients with CIEDs, particularly PM and ILRs (and CRT-P to a lower extent). RM of high-energy devices was adopted in a larger number of centers during the pandemic but differences were not significant. These findings are in concordance with the results of the 2015 EHRA survey on the RM implementation across Europe, which showed very high rate of RM use in ICD and CRT devices, comparable to the rate in our survey (4). Additionally, in Italy there was no significantly increase use of RM for ICD and CRT devices from 2012 to 2017, although there was significantly higher use of RM for ILRs, as we have seen in our study (11).

Unlike the wEHRables survey-II results, which showed that the same level of telemedicine use is expected after the COVID-19 pandemic, our survey shows that further increase of the RM use after the pandemic is likely and planned by the majority of physicians (10).

Frequency of in-office visits of RM patients, changes introduced by ESC and HRS guidance and establishment of new RM connections for pre-COVID implanted CIEDs

To reduce transmission of the SARS-CoV-2 virus, “lock-down” measures were put into practice worldwide. In addition, the ESC and HRS guidance for cardiac electrophysiologists during the COVID-19 pandemic recommended the postponement of elective or in-person visits for CIEDs routine follow-up (7,8). Our findings revealed a significantly lower frequency of in-office visits of RM patients with CIEDs during the pandemic, showing an adjustment of the clinical practice to the emerging epidemiological situation. Despite the application of measures presented in the ESC and HRS guidance, more than half of the respondents stated that such guidance did not lead to any significant changes in their clinical practice. Reasons for this lack of change in behavior remain to be clarified, and we consider these results as a call to action for further official guidance promotion.

Controversially, the approach for establishing new RM connections for pre-COVID implanted CIEDs was equally split between delivering an RM transmitter to the patient’s home address and in-office RM connection activation. Noteworthy, one-third of centers did not offer RM connections to CIED patients implanted prior to the pandemic. This discrepancy in the respondents’ answers to this survey, and non-compliance with the advice of the practice document proposed by the ESC and HRS should be indicative, and eventually helpful for further recommendations or consensus documents. Recent studies on patients that received RM devices at home addresses show that the majority of patients were able to successfully activate the

transmitter, and experienced higher degree of satisfaction, as well as a reduced anxiety levels when compared to the face-to-face activation of RM connection (12,13). This increase in RM utilization, even for CIEDs implanted before the pandemic, was in accordance with the ESC and HRS guidance for COVID-19 (7,8).

RM data filtering and initiation of in-office visits of RM patients

RM is an efficient and safe method of monitoring patients with CIEDs, while simultaneously reducing the number of in-office visits and mortality of these patients, mainly by earlier recognition and management of arrhythmias, device malfunction and heart failure (3,4). Our survey shows that despite COVID-19, there were no changes in the clinical value of the data received via RM before and during the pandemic. However, the volume of transmissions is increasing alongside the alerts. In a recent study, 40% of all RM transmissions were alerts, with 50% of all alerts being produced by implantable loop recorders (ILR), even though these only accounted for 18.8% of all followed devices (14). This represents a considerable burden, and therefore, efficient data filtering is a crucial part of RM by reducing data overload. In our survey, no changes were observed in the RM data filtering personnel. Surprisingly, in 2.6% of responding centers in pre- and 1.8% during COVID-19, no one filtered the data. Despite the tiny percentage of respondents for whom no one filters the data, concerns and encouragement for organizing teams for RM data filtering, according to the guidelines, must be expressed (2). In addition to data filtering, RM teams' crucial tasks are timely recognition and initiation of in-person visits. In this survey, reasons for initiating an face-to-face visits did not differ before and during the COVID-19. Despite the lock-down measures, recent research investigating data from RM transmissions during COVID-19 showed a significant increase in thoracic impedance and decreased physical activity

(15). On the other hand, a 33% increase in atrial fibrillation episodes was observed in CIED patients during the COVID-19 pandemic (16).

Reimbursement of RM during the pandemic

The results of the 2015 EHRA survey showed that 80% of respondents did not receive reimbursement for RM of CIEDs and that the lack of reimbursement was the most significant barrier for implementation of RM of CIEDs (4). However, results from our survey show that the number of centers not receiving reimbursement for RM of CIEDs before the COVID-19 was now more than 50%, demonstrating a significant increase in the rate of reimbursement. Additionally, our results show an increase in the rate of participant centers being reimbursed during the COVID-19 pandemic across all devices. These results are promising, but it must be borne in mind that a large number of participants still do not receive reimbursement for RM preventing its wider use.

Reasons for underutilization of RM during COVID-19

Besides increased use of RM of CIEDs during COVID-19, a significant number of respondents expresses additional reasons for the relative underutilization of RM. Despite not achieving statistical significance, it is essential to note a declining trend of reasons, such as lack of reimbursement, personnel and hospital organizational issues during the COVID-19. Moreover, as a reason for the underutilization of RM in our survey, privacy concerns and legal obstacles represented an insignificant proportion. It can be interpreted either as: (1) the pandemic having reduced the legal and privacy concerns or (2) as an improvement and a greater adherence to the GDPR during the crisis.

Limitations

Considering that 50% of the answers to the survey came from France and Spain, the results of this survey may apply only to a minority of European tertiary centres, and assumptions cannot

be made that our results are generalizable to the whole of Europe. Additionally, the voluntaristic nature of surveys like this one adds uncertainty to the estimates and raise questions whether these results represent a realistic reflection of the actual situation. The lack of space for additional questions in the survey prevented a more detailed investigation of the observed changes, and further research is needed.

CONCLUSIONS

The results of this survey highlight the impact of COVID-19 on the increased use of RM of CIEDs, leading to a reduction of unnecessary in-office visits. Further implementation of RM use after the pandemic is warranted and planned by the majority of physicians.

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TABLES

Table 1. Basic characteristics of respondents		
Mean age (years)		45.55 ± 10.62
Female respondents		28.31% (n=37)
Current working position (n=152)	EP specialist	77.34%
	Cardiologist	8.67%
	EP fellow	4%
	Cardiology fellow	3.33%
	Nurse	5.33%
	Allied Professional	1.33%
Main working environment (n=152)	University hospital	58.67%
	Specialized public cardiology centre	7.33%
	Public hospital	16%
	Private hospital	16%
	Private practice	2%
Country (top 5, total 28) (n=152)	France	32.67%
	Spain	18%
	Poland	11.33%
	Serbia	6.67%
	Italy	4.67%
The hospital turned in the COVID-19 centre (n=152)	Yes, the entire hospital	16%
	Yes, part of the hospital	76%
	No	8%

FIGURES

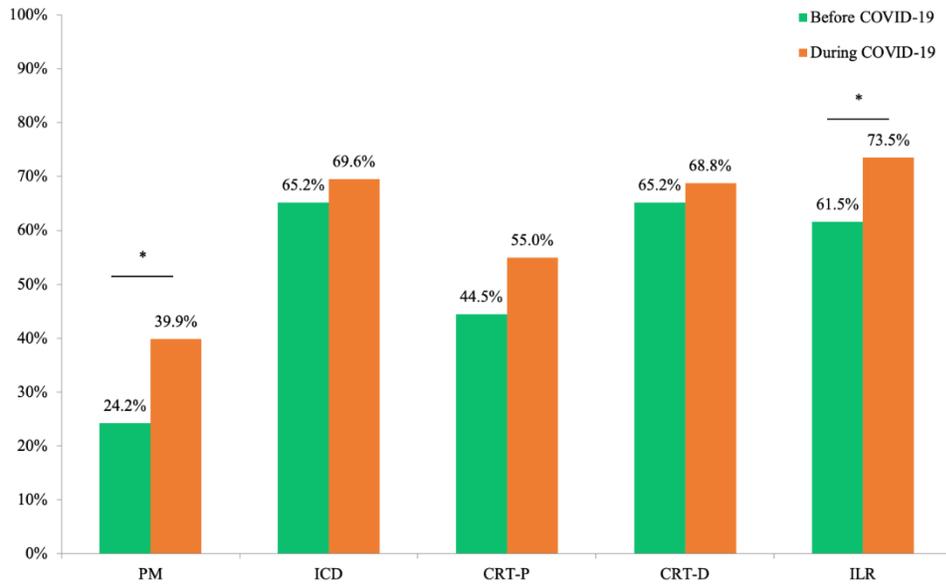


Figure 1. Question: “What percentage of implanted CIEDs before/during COVID-19 had remote monitoring?” Total number of respondents 114. *p<0.05.

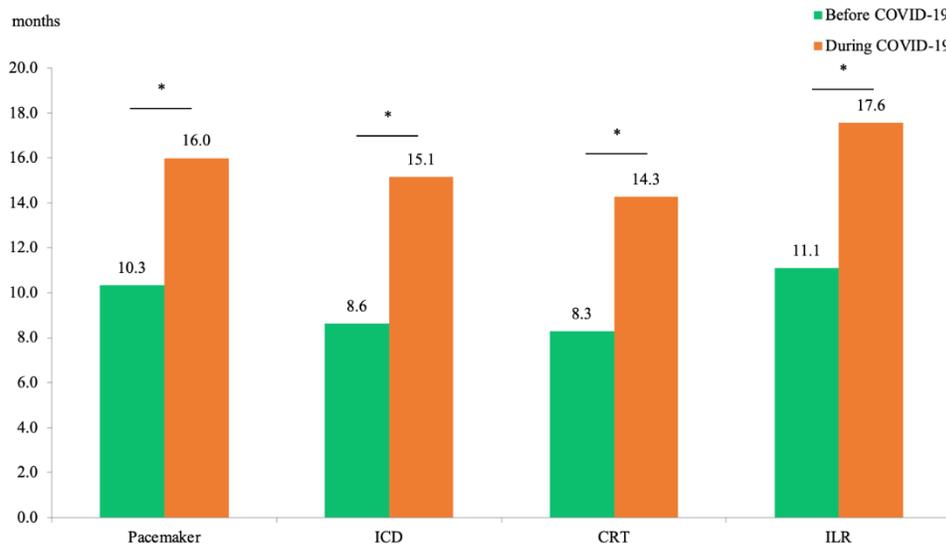


Figure 2. Question: “How frequent were in-person checkups with your remotely monitored patients, before/during COVID-19?”. Total number of respondents 114. *p<0.05.

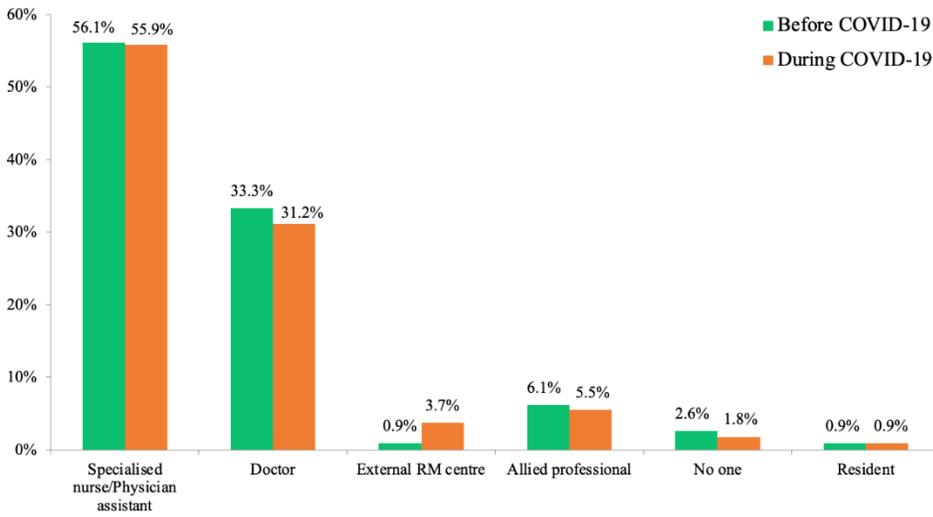


Figure 3. Question: “Who was in charge of filtering remote monitoring data of CIEDs before/during COVID-19?” Total number of respondents 114.

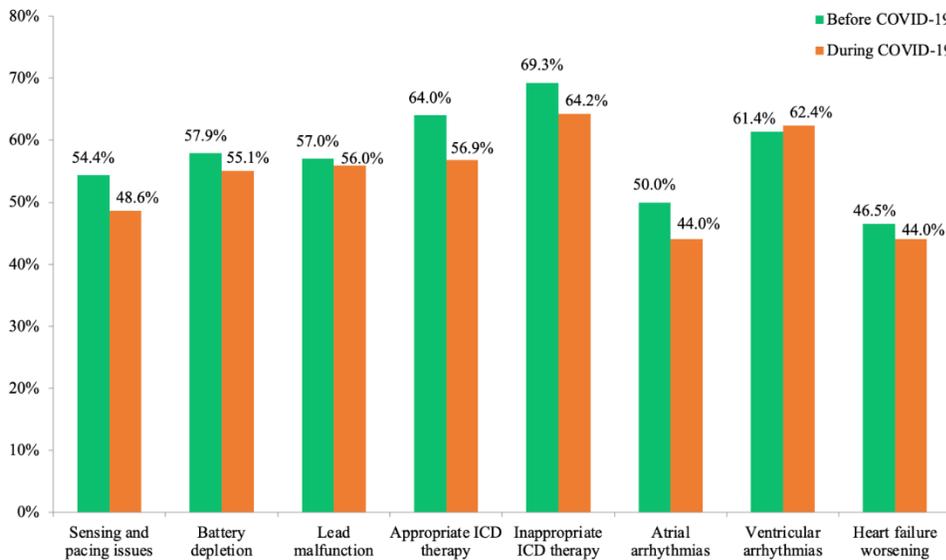


Figure 4. Question: “Please specify the main reasons for initiating in-clinic visits of remotely monitored patients before/during COVID-19 pandemic”. Total number of respondents 114.

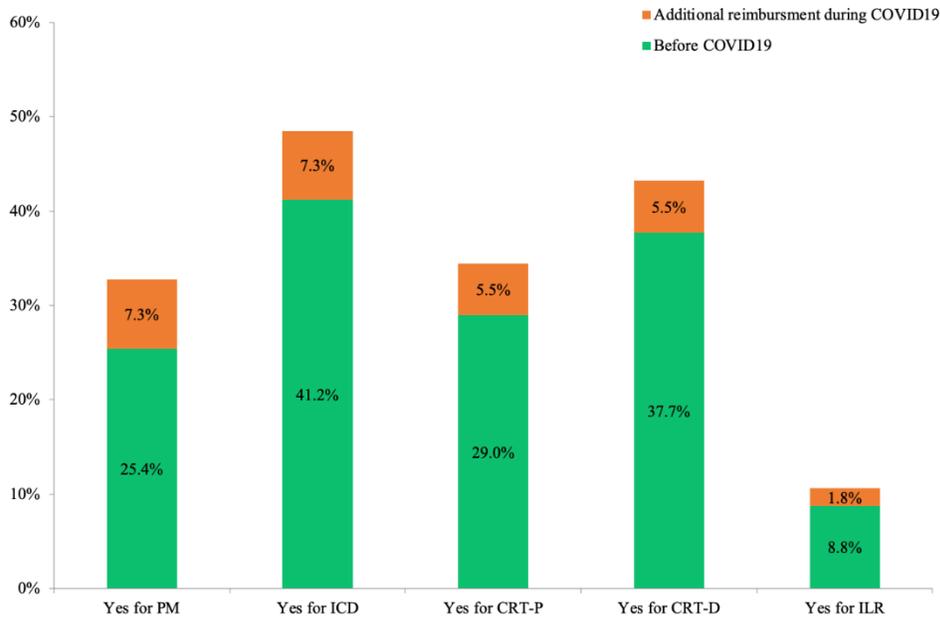


Figure 5. Question: “Did you receive any reimbursement for remote monitoring before/during COVID-19? If yes, please specify for which devices”. Total number of respondents 114.

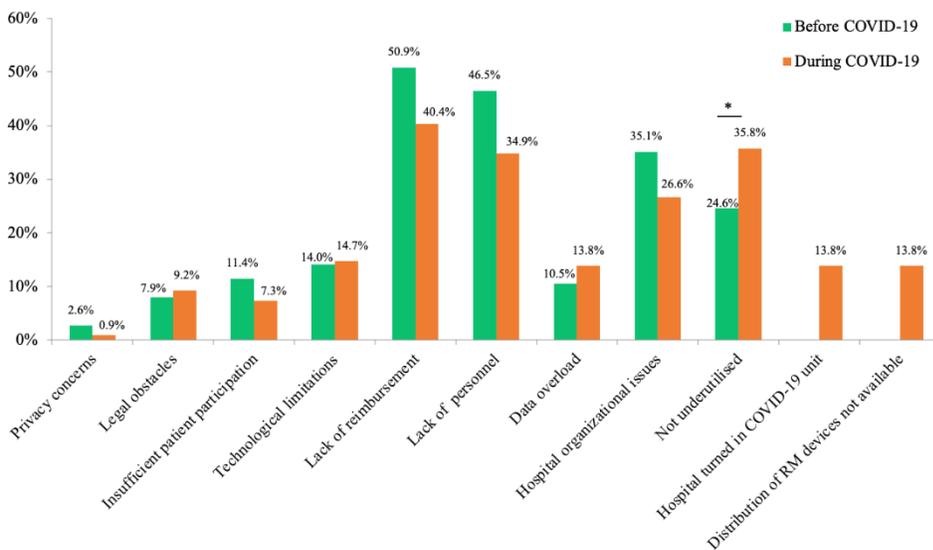


Figure 6. Question: “If you consider that remote monitoring was underutilized before/during COVID-19, please specify the main reasons”. Total number of respondents 114. *p<0.05