Scientific letters

Early remote monitoring of pacemaker devices and benefits of this paradigm shift. The FAST REMOTE study

Monitorización a distancia y precoz del marcapasos y los beneficios de un cambio de paradigma. Estudio FAST REMOTE

To the Editor,

The recommendations of scientific societies during the COVID-19 pandemic[1] have strongly encouraged remote monitoring (RM). There is increasingly widespread use of RM for implantable cardioverter defibrillators (ICDs) as there is evidence that its activation reduces the time to detection of adverse events.[2] Nevertheless, its use remains uncommon for pacemaker monitoring, at a rate of 18.5% in Spain in 2020,[3] despite having a similar benefit[4] and a class IIa indication, or class I for devices on advisory (I C) or patients with limited mobility (I A).[5]

Large multicenter studies[2] support the immediate activation of RM after ICD implantation. However, to our knowledge, this practice is supported by only 1 single-center study after pacemaker implantation.[6]

We created a multicenter registry (exempt from informed consent, due to its design) with 2 aims: to study the impact of the pandemic on RM of pacemakers and assess the benefit of early (in the first 2 weeks after implantation) activation of pacemaker RM on reducing time to detection of adverse events, using the platform Home Monitoring (HM) from Biotronik (Germany).

The study included 8510 pacemakers from the 5 main manufacturers (table 1), implanted in the year prior to the COVID-19 pandemic lockdown (from 1 March 2019 to 1 March 2020) and the year following the start of lockdown (1 March 2020 to 1 March 2021), in 16 hospitals (10 tertiary and 6 secondary) that were selected, prioritizing high rates of RM and early activation (first 2 weeks). As most of these early activations were performed using the HM platform, the final analysis included only this platform.

We recorded a significant increase (9%) in activation of pacemaker RM (58% in the year prior to the COVID-19 lockdown, vs 67% in the year following lockdown; $P < .001$), but not in early RM (table 1).

Early RM comprised 56% of all RM, equivalent to 2979 pacemakers, of which 1947 (65%) were analyzed using HM. The time from implantation until HM activation was 1.63 $\pm$ 2 days. In the first 2 weeks of follow-up, 903 alerts were detected in 389 pacemakers (20% of all the pacemakers with HM) (table 1), which were significant in 23 (6% of the pacemakers with alerts) and led to a diagnosis of 10 lead dysfunctions (D) and 13 episodes of atrial fibrillation (AF). The rate of

Table 1
Description of the pacemakers and alerts in the FAST REMOTE study

Pacemakers		Pre-COVID-19	Post-COVID-19
Total	8510 (100)	4495 (53)	4015 (47)
RM	5322 (67)	2635 (58)	2687 (67)
Early RM	2979 (35)	1421 (32)	1558 (39)
Early RM with HM	1947 (23)	885 (20)	1062 (26)
Alerts recorded with HM in the first 2 weeks		NS	S
		880 (97)	23 (3)
Atrial impedance out of range		2	
Atrial sensing below limit		40	1 D
Atrial autocapture deactivated		2	2 D
Ventricular impedance out of range		14	
Ventricular sensing below limit		13	4 D
Ventricular autocapture deactivated		23	2 D, 1 AFa
Atrial load over limit		82	4 AFa
Long atrial episode		36	1 AFa, 3 AFb
Number of atrial episodes over daily limit		56	4 AFa
Mode switch counter over limit		52	
Mode switch duration over limit		34	
High ventricular rate during mode switches			6
Feature of arrhythmia episode		238	
Percentage ventricular pacing over limit		74	
Ventricular extrasystole over limit		47	1 D
Episodes of high ventricular rate		52	
Episodes of high ventricular rate over limit		8	
High mean ventricular rate over limit			101

AFa, unknown atrial fibrillation, alert leading to initiation of OAC (10); AFb, known atrial fibrillation, alert leading to a change in treatment (3); D, lead dysfunction; HM, home monitoring; NS, alert not significant; Pre-COVID-19, period between 1 March 2019 and 1 March 2020 (the year prior to COVID-19 lockdown); Post-COVID-19, period between 1 March 2020 and 1 March 2021 (year since the start of COVID-19 lockdown); RM, remote monitoring; S, alert significant.
Unless otherwise indicated, values are expressed as No. (%).

significant alerts (leading to an intervention of some kind) was 1.2% of the pacemakers with HM (0.5% due to dysfunction and 0.6% due to AF).

Time from implantation to lead dysfunction alert detection was 10 (range, 2-14) days and from implantation to AF alert detection, 3 (1-13) days.

As an indirect measure of the benefit of early RM for the detection of adverse events, we calculated the difference between the median time to detection with HM and the median time to the first scheduled in-office review for the 15 patients with a scheduled appointment (theoretically when the adverse event would have been detected without HM). This difference was statistically significant (figure 1) for lead dysfunction (10 vs 30 days; $P = .016$), AF episodes (3 vs 15 days; $P = .036$) and the combination of the 2 (4 vs 29 days; $P = .001$).

The FAST REMOTE registry confirms an increase in RM in Spain and, to our knowledge, is the first multicenter study to analyze early RM of pacemakers.

The results confirm the usefulness of early RM after pacemaker implantation, compared with conventional follow-up, for earlier diagnosis of clinically relevant episodes of AF and lead dysfunction, comparable to that seen in studies of ICDs.

The benefit of early RM in terms of reduced time to diagnosis of adverse events may be lesser in asymptomatic patients, but large studies of RM have shown that most detected events are silent; indeed, in our registry, only 1 patient presented with symptoms before being called in as a result of the alert generated.

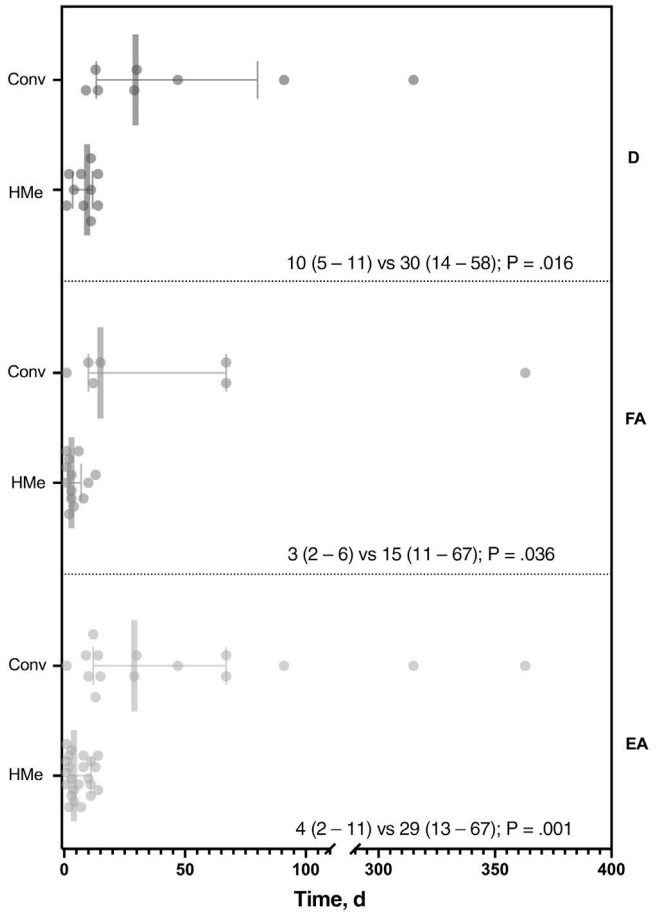

Figure 1. Comparison of time to detection using early home monitoring of lead dysfunction (n = 10), episodes of atrial fibrillation (n = 13), and the 2 combined (n = 23), and time to first in-office scheduled follow-up (n = 15). AE, all adverse events; AF, atrial fibrillation; Conv, conventional follow-up; D, lead dysfunction; HMe, early home monitoring.

The main limitations of our study are the selection bias, using centers with a high rate of RM, which may mean a faster response to alerts than in less experienced centers, the inclusion in the analysis of only 1 RM platform, and the retrospective, nonrandomized design. All of these should be borne in mind when interpreting the results, and further studies are warranted.

In conclusion, the FAST REMOTE study shows that RM of conventional pacemakers increased by 9% in the year following the COVID-19 lockdown and that early RM in the first 2 weeks after implantation enabled earlier diagnosis of potentially serious adverse events; therefore, in our opinion it should be implemented as standard, as is done with ICD.

FUNDING

This study was funded by Biotronik (grant number FF070).

AUTHORS' CONTRIBUTIONS

M. González Vasserot, B. González Chana, C. González Matos, and L. Villagraz Tecedor carried out data collection and analysis. F.J. García Fernández drafted the manuscript. All the authors have reviewed the manuscript and approved the final version.

CONFLICTS OF INTEREST

None.

Acknowledgements

We thank all the investigators from the FAST REMOTE study (see Appendix A of the supplementary data) for their collaboration in the collection and sending of data to the respective centers, as well as Marina Rujas, Alicia Moreno, and Ángel Madrid, from Biotronik, for their technical advice.

APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version, at https://doi.org/10.1016/j.rec.2022.09.015

Irene Valverde André,[a,*] Mar González Vasserot,[a]
Beatriz Gonzalez Chana,[b] Carlos González Matos,[c]
Lola Villagraz Tecedor,[d] and F. Javier García Fernández[a,b,c,d]
en representación de los investigadores del estudio FAST REMOTE

[a]*Servicio de Cardiología, Hospital Universitario de Cabueñes, Gijón, Asturias, Spain*
[b]*Servicio de Cardiología, Complejo Hospitalario Universitario de Orense, Orense, Spain*
[c]*Servicio de Cardiología, Hospital del Mar, Barcelona, Spain*
[d]*Servicio de Cardiología, Complejo Hospitalario Universitario de Burgos, Burgos, Spain*

[*] Corresponding author.
E-mail address: irene.valverde.andre@gmail.com (I. Valverde André).

Available online 22 November 2022

REFERENCES

1. Bertomeu-González V, Pombo M, Chimeno J, Lillo IM, Cano O. Estimulación cardiaca tras la pandemia de la COVID-19 Propuesta de desescalada de la Sección de Estimulación Cardiaca de la Sociedad Española de Cardiología. *REC Cardioclinics.* 2020;55:170–176.
2. Varma N, Epstein AE, Schweikert R, Michalski J, Love CJ. TRUST Investigators. Role of Automatic Wireless Remote Monitoring Immediately Following ICD Implant: The Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) Trial. *J Cardiovasc Electrophysiol.* 2016;27:321–326.
3. Pombo Jiménez M, Chimeno García J, Bertomeu-González V, Cano Pérez O. Registro Español de Marcapasos XVIII Informe Oficial de la Sección de Estimulación Cardiaca de la Sociedad Española de Cardiología (2020). *Rev Esp Cardiol.* 2021;74:1085–1095.
4. Ploux S, Strik M, Varma N, Eschalier R, Bordachar P. Remote monitoring of pacemakers. *Arch Cardiovasc Dis.* 2021;114:588–597.
5. Glikson M, Nielsen JC, Kronborg MB, et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *Eur Heart J.* 2021;42:3427–3520.
6. Parahuleva MS, Soydan N, Divchev D, Lüsebrink U, Schieffer B, Erdogan A. Home monitoring after ambulatory implanted primary cardiac implantable electronic devices: The home ambulance pilot study. *ClinCardiol.* 2017;40:1068–1075.

https://doi.org/10.1016/j.rec.2022.09.015
1885-5857/

Initial experience with the coronary sinus reducer for the treatment of refractory angina in Spain

Resultados iniciales del dispositivo reductor de seno coronario para el tratamiento de la angina refractaria en España

To the Editor,

The term refractory angina (RA) refers to a clinical picture of chronic angina-like chest pain, lasting for ≥ 3 months and is associated with reversible ischemia that persists despite optimal medical treatment and current percutaneous and surgical revascularization.[1] Coronary sinus reducers (CSR) have proven to be effective in reducing symptoms in patients with RA,[2] although experience with these devices and available evidence remain scarce.[3,4] The aim of the present study was to describe the safety and efficacy of CRSs during an initial experience in Spain.

We conducted an observational retrospective multicenter registry of consecutive patients with RA and CSR implants in Spain. The protocol was approved by a central reference ethics committee, which waived informed consent because the data were guaranteed to be anonymous. The primary efficacy endpoint was change in functional class according to the Canadian Cardiac Society classification (FC-CCS) and the safety endpoint was procedure-related complications.

The CSRs were implanted in 48 patients with RA who could not undergo surgical or percutaneous revascularization. Implantation was considered suboptimal in 1 patient because, during follow-up, we observed device shift toward the pulmonary artery, which was asymptomatic (angiographic finding). Table 1 shows the baseline characteristics of the patients, all of whom had documented ischemia in the left coronary territory. One patient died before completing the 6-month follow-up due to causes unrelated to the intervention, and so no follow-up data are available for this patient. At 6 months postimplantation, FC-CCS class improved in 40 patients (85%), and by ≥ 2 classes ($P<.001$) in 22 (47%) patients (figure 1). The baseline data of the patients show that the severity of angina was higher than that described in previous studies: 90% of our patients were in FC-CCS 3 or 4 before implantation and the patients were taking a mean of 3.8 ± 1.3 antianginal drugs at baseline.

The greater severity of angina in our patients could explain the responses observed, which were significantly superior to those found in the COSIRA study[2] and the RESOURCE and REDUCER-I registries.[3,4] Figure 1B shows the change in FC-CCS at 6 months postimplantation.

Regarding complications, there was bruising at the puncture site in 2 patients (4.2%), although they did not require transfusion or specific treatment. In 1 patient (2.1%), there was minor coronary sinus dissection, which was documented on angiography and

Table 1
Baseline characteristics of the 48 patients undergoing coronary sinus reducer implantation

Clinical characteristics	
Age, y	69 ± 10
Women	13 (27.1)
Hypertension	43 (89.6)
Diabetes mellitus	25 (52.1)
Dyslipidemia	45 (93.8)
Smoking	5 (10.4)
Glomerular filtration rate < 60 mL/min/m^2	17 (35.4)
Kidney failure on hemodialysis	2 (4.2)
Previous myocardial infarction	29 (60.4)
Previous PCI	41 (85.4)
Previous coronary intervention	26 (54.2)
Previous stroke or TIA	5 (10.5)
Left ventricular ejection fraction	53.6 ± 9.9
Drug treatment	
Number of drugs	3.8 ± 1.3
Treatment with beta-blockers	42 (87.5)
Treatment with nondihydropyridine calcium channel blockers	9 (18.8)
Treatment with dihydropyridine calcium channel blockers	34 (70.8)
Treatment with nitrates	43 (89.6)
Treatment with ranolazine	23 (47.9)
Treatment with trimetazidine	8 (16.7)
Treatment with ivabradine	13 (27.1)
Treatment with alopurinol	7 (14.6)
Treatment with antidepressants	18 (37.5)
Angiographic characteristics	
Number of vessels with significant stenosis, nonrevascularized	1.6 ± 1.0
Chronic total occlusion, nonrevascularized	35 (72.9)
Significant disease in common arterial trunk, nonrevascularized	0
Significant disease in left anterior descending artery, nonrevascularized	28 (58.3)
Significant disease in circumflex artery, nonrevascularized	29 (60.4)
Significant disease in intermediate branch, nonrevascularized	6 (12.5)
Significant disease in right coronary artery, nonrevascularized	26 (54.2)
Significant disease in venous graft, nonrevascularized	11 (22.9)
Significant disease en arterial graft, nonrevascularized	8 (16.7)
Coronary arteries without significant stenosis (microvascular angina disease), nonrevascularized	5 (10.4)

TIA, transient ischemic attack; PCI, percutaneous coronary intervention.
Data are expressed as No. (%) or mean ± standard deviation.