



EDITORIAL COMMENT

Can the good be the enemy of the best? Monitoring of patients with implanted cardiac devices[☆]



Pode o bom ser inimigo do ótimo? Como fazer o seguimento em doentes com sistemas cardíacos implantados?

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Remote monitoring (RM) of pacemakers was introduced in 2001¹ and was subsequently extended to implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy defibrillators (CRT-Ds) and, most recently, implantable loop recorders.

The introduction of RM was a response to the need to monitor the equipment for failures of implanted devices that could impact patient survival.²

RM provides daily data on the functioning of such devices and access to electrograms and clinical parameters. However, it cannot be used for remote reprogramming to resolve malfunctions.

The value of the information RM provides has been demonstrated in various observational studies involving hundreds of thousands of patients, and the ability to assess clinical parameters, particularly in patients with heart

failure, has led an increasing number of centers to take advantage of the technology.³

However, the costs of RM can be high, with significantly increased demands on technical and human resources that may not be readily available. It is thus important to perform cost-benefit analyses.⁴

The value of RM lies in the immediate transmission of data and hence the ability to perform more timely therapeutic interventions. The less efficiently these data are used, the less benefit is derived from the technique. The efficiency of centers using RM is difficult to assess based on published reports, but it could have a considerable effect on their clinical results. It is therefore no surprise that while some results of RM programs are highly favorable, others reveal major disadvantages and limitations.

Among the more positive studies is the ALTITUDE registry, which included 69 556 patients with ICDs and CRT-Ds, and showed a 50% reduction in mortality.⁵ The large study population means that this registry gives a close approximation to real-life clinical practice.

Randomized prospective trials on RM have been small and are therefore of less clinical significance. A study by

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Hindricks et al. of 664 patients with ICDs and CRT-Ds confirmed the benefits of RM, with a significant reduction in the composite endpoint of mortality and hospitalization and in one-year mortality (10 vs. 27 patients).⁶

By contrast, a meta-analysis of nine randomized trials involving over 6000 patients showed no significant difference in mortality or hospitalization or reduction in appropriate therapies. There were, however, fewer inappropriate shocks.⁷

The article by Portugal et al. in this issue of the *Journal*⁸ is a retrospective study of patients with ICDs for primary prevention of sudden death (SD). It excluded patients with pacemakers, ICDs for secondary prevention and ventricular resynchronization systems. This exclusion is of no little importance, since the clinical benefits expected from RM include detection of supraventricular arrhythmias, particularly atrial fibrillation (an indication for anticoagulant therapy) and assessment of signs of heart failure decompensation, especially useful in patients with ventricular resynchronization systems. The decision to include only patients with ICDs for primary prevention of SD limits their evaluation of the benefits of RM.

Even so, the study confirms the beneficial effects of RM, since it showed a reduction in the composite outcome of first hospital admission for heart failure or cardiovascular death, as well as a non-significant trend towards lower overall mortality.

Since this was a single-center study, the size and characteristics of the study population (propensity score-matched paired sample of 168 patients selected from 312 with ICDs for primary prevention) should be borne in mind.

The proportion of patients hospitalized for heart failure would probably have been greater if patients without left ventricular dysfunction had been excluded.

The rate of appropriate therapies in this cohort was similar in the RM and conventional follow-up groups, and RM did not reduce the number of inappropriate shocks.

There was no mention of device dysfunction being detected, particularly oversensing due to lead fracture.

Our experience at Hospital de Santa Cruz is in many ways similar. We have over a thousand patients followed remotely with only one routine in-office visit a year, and so RM has enabled the number of consultations to be safely reduced. RM has been effective at detecting events and has led to faster responses to alerts that require rapid intervention. It also detects more events, thus confirming that it provides more complete and reliable data. Most of our patients consider that RM helps improve their quality of life.⁹

Since RM is known to increase, improve and speed up transmission of the information recorded by implanted devices (pacemakers, ICDs and CRT-Ds) and that it reduces the number of routine in-office visits, why is it not more generally implemented?

Could it be that the good is the enemy of the best?

One of the most important laws of human nature is the principle of least effort. This means that RM would have

to confer proven, clear and significant advantages to be consistently recommended.

The European guidelines on pacemakers, ICDs and CRT-Ds¹⁰ recommend the use of RM for early detection of clinical problems, such as ventricular tachyarrhythmias or atrial fibrillation, and technical issues like lead fracture or insulation defect.

The study by Portugal et al. highlights the benefits of RM and points out that follow-up by RM was associated with a significant reduction in morbidity and mortality (the composite endpoint) in patients with an ICD for primary prevention of SD.

The study's impact would be enhanced if its results could be confirmed in prospective, randomized and multicenter trials with a wider range of patients. Such a study, adapted to the situation in Portugal, could determine to what extent RM is implemented in this country, and would be particularly valuable if it included patients with severe ventricular dysfunction, particularly those with ventricular resynchronization devices to treat heart failure refractory to optimal medical therapy.

Conflicts of interest

The author has no conflicts of interest to declare.

References

1. Wallbrück K, Stellbrink C, Santini M, et al. The value of permanent follow-up of implantable pacemakers: first results of an European trial. *Biomed Tech (Berl)*. 2002;47 Suppl 1 Pt. 2: 950–3.
2. Kallinen LM, Hauser RG, Lee KW, et al. Failure of impedance monitoring to prevent adverse clinical events caused by fracture of a recalled high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. 2008; 5:775–9.
3. Bui AL, Fonarow GC. Home monitoring for heart failure management. *J Am Coll Cardiol*. 2012;59:97–104.
4. Heidbuchel H, Hindricks G, Broadhurst P, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring. *Eur Heart J*. 2015;36: 158–69.
5. Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. 2010;122:2359–67.
6. Hindricks G, Taborsky M, Glikson M, et al. IN-TIME Study Group. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet*. 2014;384:583–90.
7. Parthiban N, Esterman A, Mahajan R, et al. Remote monitoring of implantable cardioverter-defibrillators: a systematic review and meta-analysis of clinical outcomes. *J Am Coll Cardiol*. 2015;65:2591–600.
8. Portugal G, Cunha P, Valente B, et al. A link to better care: the effect of remote monitoring in long-term adverse cardiac events in a propensity-score matched cohort. *Rev Port Cardiol*. 2017;36:189–95.

9. Nabais I, Adragão P, Durazzo A, et al. Seguimento remoto por sistema latitude: segurança e qualidade de vida. *Rev Port Cardiol*. 2013;32(Espec Congr):101.
10. Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the task force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC), Developed in collaboration with the European Heart Rhythm Association (EHRA). *Europace*. 2013;15:1070–118.