ORIGINAL ARTICLE

Usefulness of Remote Monitoring of Pediatric Patients with Cardiac Implantable Electronic Devices

Utilidad de los dispositivos cardíaco-eléctricos con monitoreo a distancia en pacientes pediátricos

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ABSTRACT

Background: The aim of this study is to evaluate the usefulness of cardiac implantable electronic devices with remote monitoring system in a pediatric population and the limitations of its implementation in Argentina.
Methods: Twenty-seven patients receiving a cardiac implantable electronic device with remote monitoring system at Hospital Nacional Garrahan and Hospital Italiano de Buenos Aires were included in the study. The rate of events, complications and device-related therapies were evaluated. The anticipated actions taken in response to alert notifications were described. Mean follow-up was 46.6 ± 32.1 months.
Results: Median age was 12.2 years (IQR: 8.75-13.3). An implantable cardioverter defibrillator device was placed in 7 patients (25.9%) and 20 (74%) underwent pacemaker implant. Five patients (18.5%) presented seven red alerts: 3 due to ventricular arrhythmia in monitoring zone of ventricular fibrillation and 4 due to lead dysfunction. Twelve patients (44%) presented a yellow alert: 6 due to lead dysfunction, 4 due to deactivation of the monitoring system because of lack of signal reception, one due to ventricular tachycardia and another with sinus tachycardia in monitoring zone of ventricular tachycardia. Active actions were taken in 9 patients (33.3%) to manage the alert notification: the atrial lead was replaced in one patient and the ventricular in lead in another; in 2 patients non-compliance with pharmacological treatment and exercise limitation were detected and in the rest of the patients, the device was reprogrammed according to the abnormalities observed in the recording or capture.
Conclusions: Remote monitoring of cardiac implantable electronic devices is very useful in the pediatric population, allowing for the rapid detection and management of device failure or significant arrhythmias.

Key words: Pacemaker, Artificial - Defibrillators, Implantable - Remote Sensing Technology/methods - Monitoring - Physiologic/methods

RESUMEN

Objetivo: Evaluar la utilidad de los dispositivos cardíacos eléctricos con sistema de monitoreo a distancia en una población pediátrica y las limitaciones de su implementación en la República Argentina.
Material y métodos: Se incluyeron 27 pacientes a quienes se le implantó un dispositivo cardíaco-eléctrico implantable con sistema de monitoreo a distancia en el Hospital Nacional Garrahan y en el Hospital Italiano de Bs. As. Se evaluó la tasa de eventos, complicaciones y terapias por parte de los dispositivos. Se describieron las conductas anticipadas según la alerta recibida. Se realizó un seguimiento medio de 46,6 meses ± 32,1.
Resultados: La edad fue 12,2 años (RIC: 8,75-13,3), a 7 pacientes (28%) se les implantó un cardiodesfibrilador implantable y 20 pacientes (78%) un marcapaso endocavitario. Cinco pacientes (18,5%) presentaron 7 alertas rojas: 3 por arritmia ventricular en rango de fibrilación ventricular y 4 por alteraciones en alguno de los cables. Doce pacientes (44%) presentaron una alerta amarilla: 6, por alteraciones en los cables; 4, por desactivación del sistema por falta de recepción de señal; 1, por taquicardia ventricular; y 1, por taquicardia sinusal en rango de taquicardia ventricular. En 9 pacientes (33,3%) se tomó una conducta activa para resolver el aviso de alerta: en 2 pacientes se realizó recambio de cable auricular en uno y ventricular en otro, en 2 pacientes se detectó incumplimiento del tratamiento farmacológico y en la limitación del ejercicio, en el resto se reprogramó el dispositivo, según el tipo de alteración en el registro o la captura.
Conclusiones: El sistema de monitoreo remoto de los dispositivos cardíaco-eléctricos implantables es muy útil en la población pediátrica, lo que permite una rápida detección y acción cuando se produce un fallo en el dispositivo o un evento arrítmico de relevancia clínica.

Palabras claves: Marcapasos artificial - Desfibriladores implantables - Tecnología de sensores remotos/métodos - Monitoreo fisiológico/métodos

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Abbreviations

ICD	Implantable cardioverter defibrillator	**IQR**	Interquartile range
CIED	Cardiac implantable electronic device	**VT**	Ventricular tachycardia

INTRODUCTION

Over the past 30 years, the technological development of cardiac implantable electronic devices (CIED) has increased, allowing better programming to reduce complications and increase benefits. In 1971, the first remote CIED monitoring via telephone connections was launched and, since then, with the advent of the Internet, remote interrogation of the devices has improved as well as the access to the data stored regarding device performance or the presence of arrhythmias during follow-up. (1) Remote CIED monitoring is a safe strategy that lowers the number of ambulatory visits and reduces costs for the health care system and patients, especially in those countries with centralized systems with extensive territorial surface areas such as Argentina. (2) On the other hand, it provides the possibility of taking actions before the follow-up visit, reducing complications and unnecessary visits to the emergency room, and permits the indication of preventive treatments despite the distance. (3) In the pediatric population, CIED implant presents distinctive features that makes it different from adults, such as growth, increased inflammatory reaction and fibrosis, greater need of battery replacement and, in the case of congenital heart defects, unfavorable anatomy for device insertion. All these factors explain the higher incidence of complications associated with CIED implantation in children. (4) Many publications have reported the benefits of remote monitoring systems, particularly in the adult population. (3, 4) In pediatric patients, the evidence is lower but the incidence of complications is higher. Therefore, the use of this system would allow physicians to detect these complications earlier, reducing risks, particularly in those patients living in areas distant from health care centers with capabilities for evaluating CIED recipients. The aim of our study was to evaluate the usefulness and feasibility of this monitoring system in a pediatric population belonging to two tertiary care hospitals with national coverages.

METHODS

This retrospective and observational cohort study included consecutive patients undergoing implantation of pacemakers or implantable cardioverter defibrillator (ICD) devices with remote monitoring system. The study was conducted in two medical centers: Hospital Nacional J. P Garrahan and Hospital Italiano de Buenos Aires. The clinical characteristics of the population, the rate of events, complications and therapies delivered by the devices were evaluated in the long-term. Actions taken in response to alert notifications were described, as well as the difficulties of the system to transmit the information. The follow-up period was 46.6± 32.1 months.

Patients who lived within 100 km from the center were invited to be examined every 6-8 months, depending on their preferences, while those who lived further away could be examined every 8 to 12 months in the absence of alert notifications. In case of a red alert, the clinical staff immediately called the patient's relatives and indicated the actions to be taken according to the findings. In case of a yellow alert, the clinical implication of the notification was evaluated and the patient was contacted if it was necessary.

Statistical analysis

Data were stored using Microsoft Office Excel 2010. All the calculations were performed using Stata 12.0 software statistical package.

Frequency and/or percentage distribution was established for all the variables in relation with the total number of cases and the values were expressed as proportions, mean and standard deviation (SD) or median and interquartile range (IQR), as applicable.

Ethical considerations

The study was conducted following the recommendations of the 1975 Declaration of Helsinki, corrected in 1983 and revised in1989, and was approved by the Hospital Garrahan ethics committee.

RESULTS

Population characteristics

The cohort consisted of 27 patients. Median age was 12.2 years (IQR: 8.75-13.3) and 11 patients (40.5%) were boys. Figure 1 shows the geographical distribution of the patients, with 85.1% (23 patients) living in regions more than 100 km away from the health care center. Nine patients (33.3%) presented congenital heart defects. Seven patients (25.9%) received an ICD device and 20 (74%) underwent pacemaker implantation. The pacemakers were implanted due to complete AV block in 17 (62.9%) patients and to sick sinus syndrome in 3 (11.1%). Implantable cardioverter defibrillators were implanted for secondary prevention in all the patients, except in one. Its indication was due to channelopathies in 5 (18.5%) patients and to ventricular tachycardia (VT) in 2 (7.4%) patients with congenital heart defects. Twenty-five Biotronik devices (Home Monitoring System) and two Abbot-St Jude Medical devices (Merlin Home) were implanted.

Analysis of remote CIED monitoring

Five patients (18.5%) presented seven red alerts. Three alerts were due to tachycardia in the monitoring zone of ventricular fibrillation; in two of these alerts, patients received appropriate shocks and the episode reverted spontaneously in one case; one patient presented a sudden change first in the atrial lead impedance and then in the ventricular lead; in

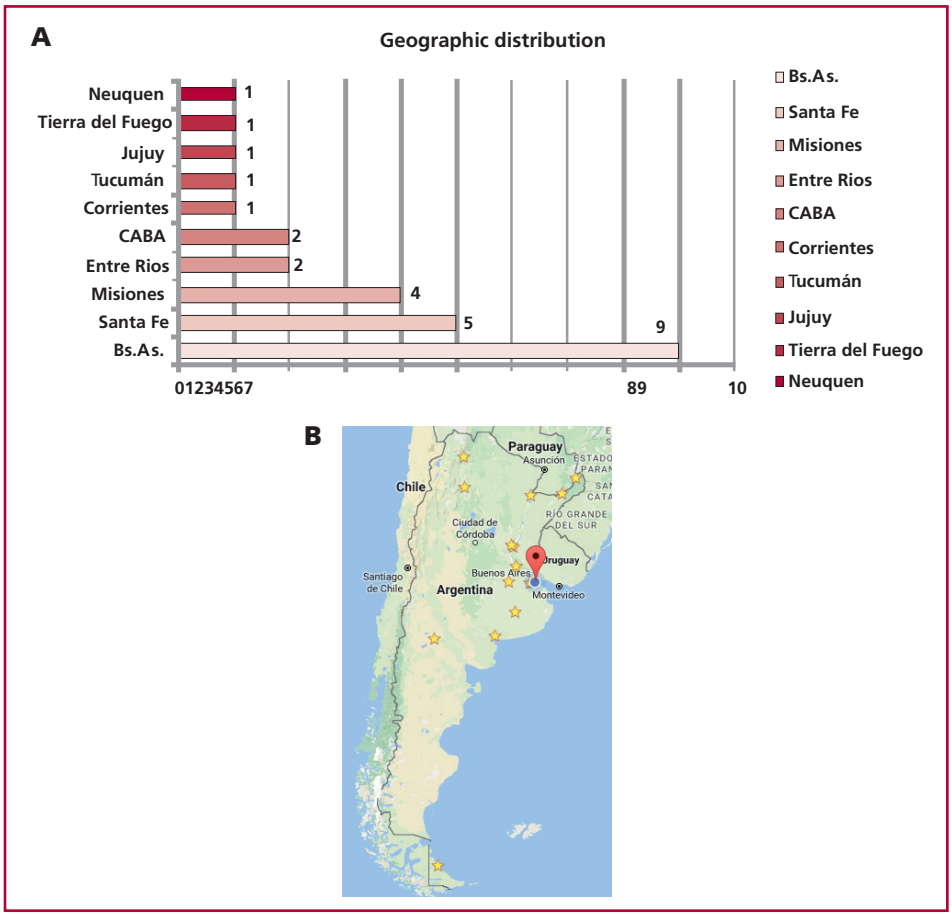

Fig. 1. A. Place of residence of the patients with cardiac implantable electronic devices with remote monitoring system. **B.** Geographic location of the cities in which the patients live.

one patient the alert was due to insulation failure of the atrial lead with loss of capture at maximal output; another patient presented fracture of the atrial lead, and in the last alert the patient received an inappropriate shock to due noise in a fractured ventricular lead. Mean time from the activation of the monitoring system to the event was 23.8 ± 14.9 months.

Twelve patients (44%) presented a yellow alert: 6 due to lead dysfunction (2 with high capture thresholds, 2 with recordings below the cutoff limit established and 2 with atrial lead noise), 4 due to deactivation of the remote monitoring system because of lack of signal reception, and 2 due to arrhythmias (one with VT that reverted with antitachycardia pacing therapy and one patient with an ICD that presented several episodes of sinus tachycardia in monitoring VT-1 zone). Mean time from the activation of the monitoring system to the yellow alert was 17.5 ± 15.7 months. Figure 2 shows some examples of the alert notifications received.

Analysis of the actions taken according to the findings

Active actions were taken in 9 patients (33.3%) to manage the alert notification: the atrial lead was replaced in one patient and the ventricular lead in another; in 2 patients in whom non-compliance with pharmacological treatment and exercise limitation was detected, counseling on therapeutic measures was intensified and antiarrhythmic treatment was adjusted; in the rest of the patients, the device was reprogrammed according to the abnormalities observed in the recording or capture. Temporary deactivation of the system due to lack of signal occurred in 4 patients (14.8%) and was solved by relocating the receiver. The signal could not be reactivated in only one patient living in the jungle of Misiones province, a region where the Wi-Fi signal is very weak. During follow-up, no patient indicated that they would like to discontinue the use of the remote monitoring system.

DISCUSSION

Our registry of pediatric patients with CIED is the first one performed in our country. The study showed a high incidence of clinical events in pediatric patients, including significant arrhythmias as VT, ventricular fibrillation and atrial flutter, lead dysfunction (recording and capture) and lead integrity abnormalities (impedance, change of polarity). While the study by Malloy et al. reported that arrhythmias (atrial fibrillation in 70% of the cases) and lead abnormalities were the most common events during follow-up, the most prevalent findings in our study were lead dysfunction and ventricular tachycardia/fibrillation. (5) This difference can be explained by the age of the pa-

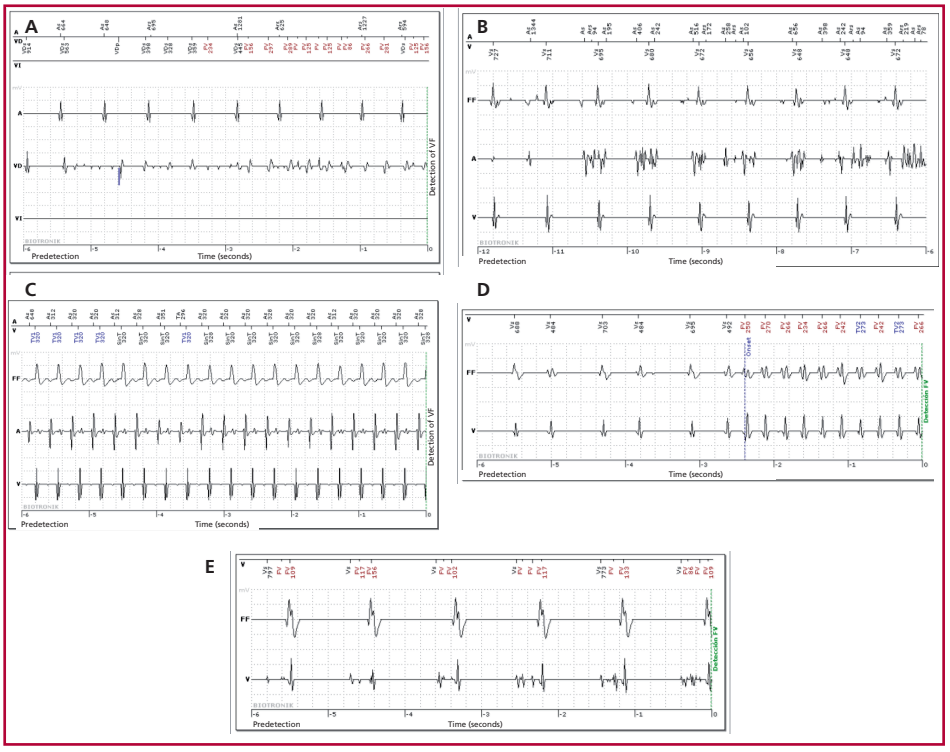

Fig. 2. Examples of the recordings stored and notified as red or yellow alerts. **A.** Recording of an episode of VF in a patient with an ICD and diagnosis of long-QT syndrome. **B.** Recording of atrial lead noise due to lead fracture in an ICD recipient. **C.** Sinus tachycardia in a patient with an ICD who did not follow the recommendations to restrict physical activity. **D.** Onset of a rapid VT reaching the zone of VF in a patient with an ICD. **E.** Recording from a patient with an ICD that presents ventricular lead noise, recorded as VF, with an inappropriate shock.
ICD: Implantable cardioverter defibrillator. VF: Ventricular fibrillation. VT: Ventricular tachycardia.

tients, that was 21 years in the study by Malloy et al. and 12.2 years in ours. Leoni et al. evaluated a population of pediatric patients with an age similar to that of our study (9.4 years) and reported lead dysfunction as the most common clinical event. (6) The incidence of arrhythmias associated with congenital heart defects and some channelopathies increases with age, while lead dysfunction is more common in younger children and is related with growth and heart size. (7, 8) In 75% of the alert notifications an action was taken before the scheduled hospital visit, preventing the development of complications, as shown in the ECOST study in patients with ICD, where inappropriate shocks were reduced by 71% and capacitor charges by 76%, increasing battery longevity. (9) Also, the CONNECT study, conducted in patients implanted with an ICD or a cardiac resynchronization therapy device, showed an 80% reduction from the time an event occurred to clinical decision, while this interval evidenced 25% reduction in patients with pacemaker evaluated in the PREFER study. (10, 11) The use of remote CIED monitoring allows remote management and reduces face-to-face visits without increasing morbidity and mortality as reported in the TRUST study, where remote monitoring reduced the number of in-hospital visits by 45% without presenting major complications. (3) During follow-up, a high rate of deactivation was observed mainly due to lack of the Wi-Fi signal. In most cases the problem was solved by relocating the receiver inside the patient's home. Yet, this finding represents a potential limitation to take into account when indicating this system to a patient, since the quality and distribution of the Wi-Fi signal is very heterogeneous in our country and this may complicate its implementation in some regions. Before indicating this type of system, it would be better to evaluate the environment in which the patient lives and the quality of the Wi-Fi signal to avoid implanting an expensive device which will not be able to be used. Despite these devices are far more expensive than conventional ones, several publications have demonstrated that anticipated actions guided by the remote monitoring system avoid complications and unnecessary in-office visits which are more costly than remote CIED monitoring, particularly if the costs of transportation of patients who live in regions far away from the health care centers are included as a variable. (12, 13) in the cost-benefit relationship.

Study limitations

The results are based on the retrospective analysis of data.

CONCLUSIONS

Remote CIED monitoring is useful in the pediatric population as it allows rapid detection and management of device failure or clinically significant arrhythmias. This benefit is even greater in those patients living far away from the hospital, allowing for longer time intervals between visits.

Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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