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Virtual clinics for follow-up of pacemakers and implantable cardioverter defibrillators in children

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Original Article

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Abstract

There is growing interest in the use of digital medicine to reduce the need for traditional outpatient follow-up. Remote interrogation of pacemakers and implantable cardioverter defibrillators is now possible with most devices. The aim of our study was to evaluate the safety and efficacy of virtual pacing clinics in following up children with pacemakers and implantable cardioverter defibrillators, including epicardial systems.

Methods: The study was retrospective over 8 years (2010–2017), with review of patient records and analysis of downloads from the implantable cardiac devices to the virtual clinics. *Results:* A total of 75 patients were set up for virtual clinic follow-up during the study period, 94.5% with a pacemaker and 5.5% an implantable cardioverter defibrillator. The majority (76.8%) had an epicardial system. Data on lead impedance, battery longevity, programmed parameters, detected arrhythmias, percentage pacing and delivered defibrillator therapies were obtainable by download. Lead threshold measurements were obtainable via download in 83.7% of the devices, including epicardial systems. No concerning device issue was missed. In 15% of patients a major issue was detected remotely, including three patients with lead fractures. The virtual clinics resulted in fewer hospital attendances while enhancing monitoring and enabling more frequent device checks. The vast majority (91.4%) of families who responded to a questionnaire were satisfied with the virtual clinic follow-up. *Conclusions:* Virtual clinics allow safe and effective follow-up of children with pacemakers and implantable cardioverter defibrillators, including those with epicardial systems and are associated with high levels of parent satisfaction.

There is need for change in the traditional approach to outpatient follow-up and interest in the use of technology to effect this change.[1,2]

Remote interrogation of pacemakers and implantable cardiac defibrillators is now possible with most devices.[3,4] Follow-up of pacemakers and implantable cardioverter defibrillators in children in Scotland is coordinated by the national paediatric cardiac service at the Royal Hospital for Children in Glasgow. However, many children live remotely from the national centre. Since 2010, we set up virtual pacing clinics for follow up of children with pacemakers and implantable cardioverter defibrillators. The setting up of virtual clinics was done gradually, with patients allocated to the clinics once they had implantation of a device that was compatible with remote follow-up. To start virtual clinic follow-up and allow remote monitoring of their child's device, parents had to sign a consent form for their home address and contact telephone number to be shared with the device company. Cardiac pacing technicians demonstrated the use of remote monitoring equipment to the patient and parents and asked for a test download to be sent once the family arrived home. Following receipt of a satisfactory download, patients were given an appointment for a virtual clinic with instructions to download from the child's device the day before. On the day of virtual clinic, two cardiac pacing technicians reviewed the download, filing the results in the patient's handheld record and uploading them to the patient's electronic case notes. A consultant paediatric cardiologist with expertise in implantable electronic cardiac devices subsequently reviewed the download. A letter to the parents and the patient's general practitioner was generated, advising of the results and date of follow-up appointment and download. In addition, devices were set up to automatically send an alert in response to concerning events, including abnormal changes in impedance, battery or threshold. Patients or parents could perform additional downloads (patient-triggered downloads) if they had concerns about their child's device. For any programming alterations or more detailed pacemaker interrogation, arrangements were made for the child to attend a hospital-based pacemaker clinic.

The aim of our study was to evaluate the safety, efficacy and patient experience of the virtual pacemaker/implantable cardioverter defibrillator clinics.

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Methods

The study was a retrospective review over 8 years, from the establishment of the first virtual paediatric pacemaker/implantable cardioverter defibrillator clinic coordinated by the Royal Hospital for Children Glasgow in 2010 to the end of 2017. All patients under 18 years of age in Scotland who had follow-up of their pacemaker or implantable cardioverter defibrillator by the virtual pacemaker/implantable cardioverter defibrillator clinics during the study period were included. Digital and handheld records were reviewed for all patients and all downloads received via remote monitoring were analysed.

For the 34 patients who had hospital-based clinic follow-up prior to virtual clinic follow-up, a comparison was made of the frequency of hospital pacemaker clinic attendances and number of device interrogation checks prior to virtual clinic follow-up and after. Statistical analysis was performed using the paired Student's t-test.

Parent satisfaction with virtual clinics

A patient satisfaction questionnaire was sent to the parents of all patients followed up by the virtual clinics.

"Did not attend" rates

The "did not attend" rate was taken as the percentage of patients scheduled for the virtual clinic who did not perform a download, despite being asked to do so by an appointment letter. This information was obtained from the hospital outpatient audit department, over a sample year, 2017–2018, and compared with the "did not attend" rates for the hospital-based paediatric pacemaker clinics and general paediatric cardiology outpatient clinics during the same period.

Results

During the study period, 75 patients were set up for follow-up by the virtual pacing clinics, comprising 80% of all children in Scotland with a pacemaker or implantable cardioverter defibrillator. Forty-eight per cent of patients were set up for virtual clinic follow-up at their first implantation of pacemaker or implantable cardioverter defibrillator and the rest after upgrade of their implantable cardiac device to a device compatible with remote follow-up. Two patients subsequently opted out of the virtual pacing clinic follow-up and were excluded from further analysis. Both patients were at the beginning of our setting up of the virtual clinics, and their parents were not confident with the new technology, preferring the familiar setup of hospital-based clinics. One of the patients has since transitioned to adult services. The other is now followed up by the virtual clinic system, but after the end of the study period.

Median length of patient follow-up by the virtual clinics was 27 months (range 5–95). The median age at which patients were first set up for virtual clinic follow-up was 8 years (range 15 days–18 years), and the median weight was 22 kg (range 2.8–76).

Of 73 patients, 69 (94.5%) had a pacemaker and 4 (5.5%) an implantable cardioverter defibrillator. Of the 69 patients who had a pacemaker, 50 had a single-chamber pacemaker, 16 a dual-chamber pacemaker and 3 a cardiac resynchronisation device. Twelve patients had >1 device during the study period, giving a total of 88 devices (84 pacemakers and 4 implantable cardioverter defibrillators). Of 88 devices, 57 (64.8%) were followed up remotely using the Carelink system (Medtronic), 28 (31.8%) the Merlin system (Abbott) and 3 (3.4%) the Latitude system (Boston Scientific). The majority of pacemakers (65/84; 77.3%) were epicardial systems. For all but one epicardial pacemaker, Medtronic 4968 Capsure epicardial steroid-eluting leads were used. For the remaining epicardial pacemaker, a sutureless bipolar nonsteroid-eluting Myopore epicardial lead (model 511212; Enpath Medical Inc., St. Paul, Minnesota, United States of America; now Greatbatch Medical, Alden, New York, United States of America) was used. Bipolar steroid-eluting active fixation leads were used for all endocardial systems.

Downloads received

Although all patients performed a test download, these were not included in the analysis. Excluding test downloads, a total of 703 device downloads were received during the study period. Data on lead impedance, battery longevity, programmed parameters, detected arrhythmias, percentage pacing and delivered defibrillator therapies were obtainable on all downloads from relevant devices. Automatic lead threshold measurements were consistently obtainable by download in 72/86 (83.7%) devices (excluding the two subcutaneous implantable cardioverter defibrillators), including 20/28 (71.4%) devices with AutoCapture (Abbott) and 52/57 (91.2%) devices with Capture Management (Medtronic) (Fig 1).

Of the eight devices where AutoCapture was not consistently available, AutoCapture measurements were intermittent or erratic (all epicardial systems) in six devices and AutoCapture (both epicardial systems) was not recommended in two devices. Of the five devices where Capture Management was not available (all epicardial systems), this was due to a high heart rate in two patients, T-wave oversensing in one patient, and unclear reasons in one patient with biventricular pacing where the threshold was not available for the left ventricular lead, and for one patient with atrial pacing. The automatic pacing threshold was not consistently available for the single endocardial Boston Scientific implantable cardioverter defibrillator due to a high ventricular threshold.

A comparison of manually measured threshold with automatically measured threshold, where consistently available, showed excellent correlation, but with Capture Management, the automatic threshold was only available for a pulse width of 0.4 ms, and precise measurements were not given for voltages >2.5 V, affecting three patients (seven devices, all epicardial).

Hospital-based appointments and device interrogation before and after virtual clinic follow-up

For the 34 patients who had changed from hospital-based clinic follow-up to virtual clinics, virtual clinic follow-up resulted in fewer hospital attendances (median of 2.09 per year before, compared with median of 1.15 after, $p<0.001$) while enhancing monitoring and enabling more device checks (median of 2.09 per year before, compared with 4.59 per year after, $p<0.001$).

Major problems identified

During the 8 years, there were no deaths in patients followed up by the virtual clinics, and no concerning device issue was missed by the virtual pacing clinics. Major issues were identified in 11 patients (15%). Three patients had ventricular lead fracture,

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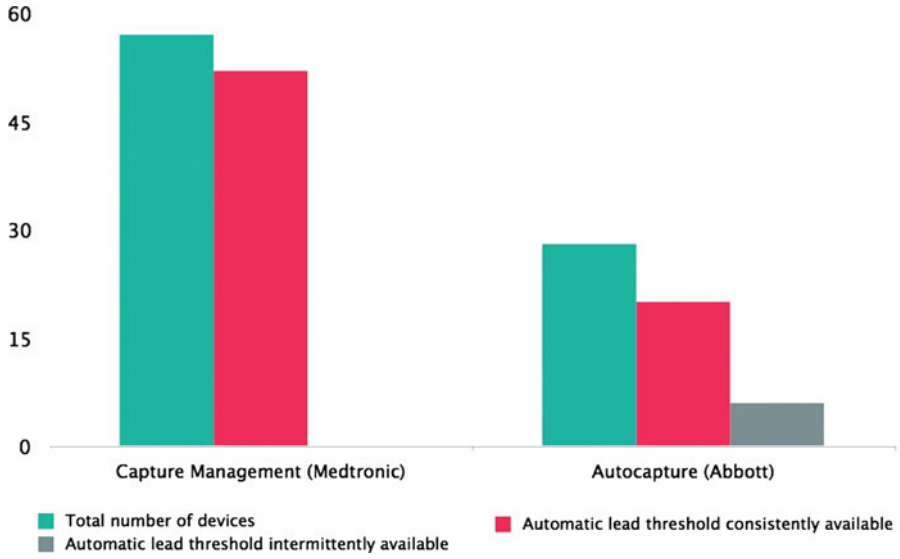

Figure 1. Availability of Automatic Threshold measurements dependent upon pacemaker manufacturer.

recognised remotely by excessively high lead impedance. All three patients had loss of capture, which resulted in syncope for one patient, whereas the other two patients were asymptomatic. Pacing systems were replaced for all three patients. Another patient had loss of capture due to a rise in ventricular lead threshold, but lead impedance remained stable. The ventricular lead output was increased and successful pacing resumed. One patient's implantable cardioverter defibrillator automatically alerted to the delivery of two shocks, one appropriate and one unnecessary, as well as multiple episodes of self-terminating ventricular tachycardia. A decision was made for the patient to have a sympathectomy, after which there were no further detected tachyarrhythmias or required defibrillator therapies. In four patients with pacemakers for heart block following cardiac surgery, episodes of ventricular tachycardia were detected, two of whom were treated medically and the others observed. One patient's implantable cardioverter defibrillator alerted to the presence of atrial flutter as well as the delivery of anti-tachycardia pacing, due to the ventricular rate during atrial flutter falling within the ventricular tachycardia detection zone. Lastly, in one patient, ventricular lead impedance on bipolar pace/sense demonstrated significant variability, along with a variable R-wave measurement and rise in ventricular lead threshold, which was resolved by changing the pace/sense configuration to unipolar.

Patient-triggered downloads

There were 82 patient-triggered downloads from 25 patients (11.6% of all downloads received within the study period), of which only two (2.4%) indicated a problem. One patient with syncope performed a download that revealed a high lead impedance and loss of capture. On manual check of the pacemaker, the lead was fractured and the pacemaker system replaced on an urgent basis. One patient performed a download because of palpitations and was found to have episodes of non-sustained atrial and ventricular tachycardia. All other patient-triggered downloads showed satisfactory device function with no detected concerning events. Six families performed downloads for reassurance that the pacemaker was functioning normally, four of them during and on return from holiday, one after the installation of a new phone line, and one because their child was next to a large speaker. Seventeen patient-triggered downloads were performed without the parents advising of the reason for the download. The remaining downloads were performed because parents either felt that their child looked generally unwell or had symptoms such as dizziness, chest pain or palpitations.

"Did not attend" rates for the virtual pacing clinic

The "did not attend" rate for the virtual pacing clinics was 28%. This compared with a "did not attend" rate of 11.4% for hospital-based paediatric pacing clinics (where patients attend the appointment) and 14.8% for general paediatric cardiology clinics.

Patient satisfaction survey

Forty-five per cent of families responded to the satisfaction questionnaire. 91.4% of respondents strongly agreed that downloads from the devices were easy to perform, 91.3% that the virtual clinics had made follow-up easier, 74.3% that the virtual clinics had made their child safer, and 91.4% that they were satisfied with the setup of the virtual clinics (Fig 2).

Discussion

Studies in adult patients have demonstrated that the use of remote interrogation of implantable cardioverter defibrillators and pacemakers is safe, enables earlier detection and intervention of concerning issues, and helps reduce patient and hospital costs.[5–8] In addition, early introduction of remote monitoring in patients with implanted cardiac devices has been shown to reduce mortality.[9] Despite these demonstrated benefits, the introduction of remote follow-up has been modest.[10]

Implanted electronic cardiac devices are associated with a higher incidence of complications in children.[11] Two published studies on the remote follow-up of cardiac devices in children suggest remote monitoring can help to detect complications earlier, potentially improving clinical outcomes.[12–14] In these studies, downloads were arranged at fixed three-monthly intervals or were patient-triggered and the majority reviewed by a pacing technician alone. However, not all patients need to have downloads as

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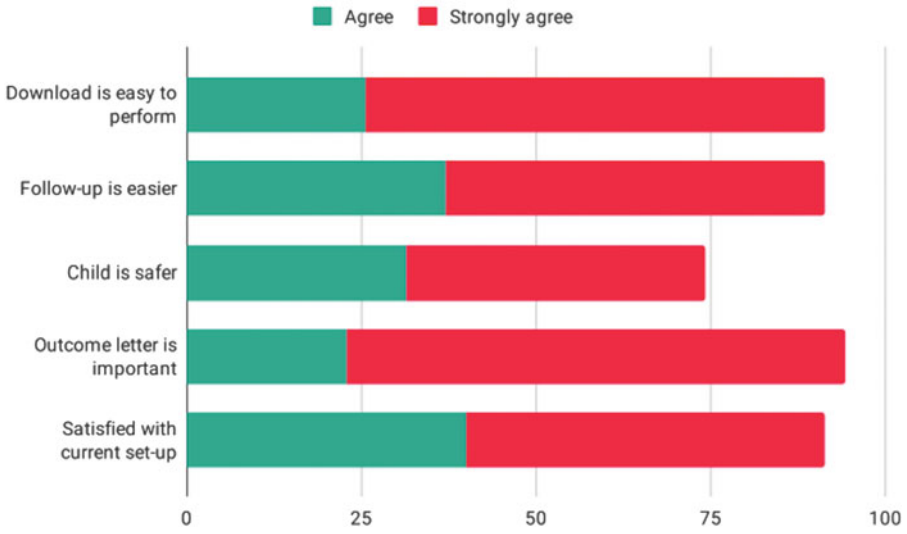

Figure 2. Results of virtual clinic satisfaction questionnaire.

frequently as three-monthly, especially if set up for device-triggered automatic alerts. Conversely, some patients may require more regular downloads depending on their clinical status and whether there are any concerning trends regarding their device. Malloy et al identified the need for physicians to take responsibility for responding to the patient data, creating appropriate documentation and scheduling future device downloads.[14] They also noted that with increased use of remote monitoring and the rising volume of remote data, methods are needed to manage the flow of information, with appropriate infrastructure and protocol. We addressed these issues by organising patients into virtual pacemaker/implantable cardioverter defibrillator clinics supervised by a cardiologist with expertise in devices, where the results of device interrogation were considered alongside the patient's clinical history and particular device needs, so that appropriate clinical action and further follow-up could be given.

By the end of the study period, 80% of children in Scotland who had a pacemaker or implantable cardioverter defibrillator were followed up by the virtual clinic system. This has since increased to >90% as older devices have been replaced with those compatible with remote interrogation. It is anticipated that all children in Scotland with an implantable cardiac device will be followed up by the virtual clinic system within the next 5 years.

The system of virtual clinics helps to detect problems earlier than might happen with traditional outpatient follow-up; minimises disruption to family, school and work life; reduces need to travel to clinics; and allows a more flexible way of working for pacemaker technicians and the cardiologist. A detailed analysis of costs saved by the virtual clinics is beyond the scope of this study. However, virtual clinics took approximately half the time of an in-hospital pacing clinic for two cardiac technicians and a cardiologist to complete for the equivalent number of patients with similar administrative time. In addition, the reduced need for patients to attend hospital-based appointments meant a reduction in travel costs, especially relevant to a country like Scotland with a wide geographical area.

Lead impedance, battery data, detection of arrhythmias and device therapies all were available via download, including from devices with epicardial leads. However, there were some important limitations with automatic threshold measurements. These limitations are particularly relevant for children who tend to have higher intrinsic heart rates and are more likely to have epicardial leads, often associated with higher thresholds compared with endocardial systems. Although pacemaker manufacturers may not endorse the use of automatic threshold measurements with epicardial leads, our study confirms that the algorithms can be used safely and effectively with epicardial systems, provided certain limitations are taken into consideration. For automatic threshold measurement by AutoCapture to be enabled, there must be a great enough difference between the polarisation signal on the tip of the lead and the evoked response signal following the pacing impulse.[15] Even when low polarisation leads are used, sometimes the lead/tissue interface does not allow a sufficient difference between lead tip polarisation and evoked response signals to enable AutoCapture. In addition, AutoCapture performs a threshold test at the programmed basic pacing rate in single-chamber ventricular pacemakers, up to a maximum paced rate of 120 bpm, or at the shortest atrioventricular delay of 50 ms in dual-chamber systems (communication from Abbott technical services). If a patient's intrinsic heart rate is higher than the basic pacing rate or there is fusion between paced beats and the patient's intrinsic rhythm, automatic threshold measurements by AutoCapture may not be possible or reliable.[16] AutoCapture is, therefore, less likely to function when patients are mostly in their own intrinsic rhythm as was the case for two of our patients. With Capture Management, precise threshold measurements are not given >2.5 V. AutoCapture may, therefore, be more suitable for those who have higher pacing thresholds, as AutoCapture not only provides threshold measurements up to 3.875 V, it also runs the output at 0.25 V above the threshold, thereby preserving battery life.

AutoCapture measures the threshold at the pulse width programmed on the device. However, both Capture Management and Automatic Capture (Boston Scientific) only provide an automatic threshold at a pulse width of 0.4 ms; so there must be a degree of extrapolation for the likely corresponding threshold if the programmed pulse width is other than 0.4 ms. For this reason, when patients with Medtronic or Boston Scientific devices attend manual threshold measurements, it is prudent to measure the threshold at a pulse width of 0.4 ms in addition to measuring a threshold at the pulse width programmed on the device.

Although we cannot make the claim that follow-up of our patients by the virtual clinics reduced mortality, it did allow for

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an earlier detection of potentially life-threatening clinical situations than would be expected by traditional outpatient follow-up. Three patients with lead failure (fracture or insulation break) had rapid detection and system replacement, and three patients had early treatment for ventricular arrhythmias. This included a patient with catecholaminergic ventricular tachycardia whose ventricular arrhythmias were refractory to medication and finally resolved following left cervical sympathectomy. The virtual clinic system allowed his ventricular arrhythmias to be closely monitored.

An important issue for some patients, particularly those who lived in remote areas with poor internet connectivity, was that performing downloads from the pacemaker or implantable cardioverter defibrillator was not always possible. Sometimes the problem could be overcome by the patient performing the download at a relative's house. Also, sometimes the home equipment for doing device downloads became faulty and had to be replaced.

Although <50% of families responded to our questionnaire, we were pleased by the very high level of patient and parent satisfaction with the virtual clinic system in those who did respond, with the majority of parents finding it easy to do the downloads. However, we were disappointed by the high "did not attend" rates, where no download was sent to the clinics. We would have expected fewer patients to 'fail to attend' the virtual clinics compared with in-hospital clinics as it was quicker and easier to do a download from the device from home than to travel to the hospital to have their device checked. Paradoxically, there was a higher 'fail to attend' rate for the virtual clinics, possibly because it was so much easier and convenient that parents did not feel it essential to do a download for a particular date or time. Where there was no download for the virtual clinics, depending on the clinical situation, parents were either contacted by telephone and asked to send a download, or a letter was sent with a new virtual clinic appointment. It is anticipated that in the future, downloads from the devices will be done through a patient or parent's mobile phone and that it may be possible for the physician to activate a download via the patient's phone, overcoming the problem of "did not attend" rates for the virtual clinics.

We showed that the implementation of virtual clinics for children with pacemakers and implantable cardioverter defibrillators allows a tertiary paediatric cardiac unit to provide safe and effective specialised follow-up of those children whether living locally or remotely from the implanting centre, without overwhelming the clinical team with too much information from excessive downloads. Virtual clinic follow-up is suitable for children with epicardial as well as endocardial systems. To maximise remote follow-up potential, limitations of automatic threshold measurements that are device-dependent should be taken into consideration when choosing an implantable device for a child.

Conclusions

To the best of our knowledge, this is the first study to investigate the efficacy, safety and patient satisfaction of virtual clinic follow-up in a cohort of children with pacemakers and implantable cardioverter defibrillators, including epicardial systems, over several years. Virtual clinics allow safe and effective follow-up of children with pacemakers and implantable cardioverter defibrillators, including those with epicardial systems, whether living locally or remotely and are associated with high levels of parent satisfaction.

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Conflicts of Interest. None.

Ethical Standards. This study was a retrospective review of an aspect of routine medical care and did not involve human or animal experimentation. The study was reviewed by the local Research and Development and Ethical Services, which concluded that a formal ethical approval was not required.

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