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Variations in cardiac implantable electronic device surveillance and ancillary testing in the paediatric and congenital heart disease population: an international multi-centre survey from the Paediatric and Congenital Electrophysiology Society

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Abstract

Background: Expert guidance from scientific societies and regulatory agencies recommend a framework of principles for frequency of in-person evaluations and remote monitoring for patients with cardiac implantable electronic devices. However, there are limited data regarding adherence to recommendations among paediatric electrophysiologists, and there are no data regarding cardiac implantable electronic device-related ancillary testing. *Methods:* To assess current clinical practices for cardiac implantable electronic device in-person evaluation, remote monitoring, and cardiac implantable electronic device-related ancillary testing, the Paediatric and Congenital Electrophysiology Society members were surveyed. The main outcome measures were variations in frequency of in person evaluation, frequency of remote monitoring, and cardiac implantable electronic device-related ancillary testing. *Results:* All respondents performed in-person evaluation at least once a year, but <50% of respondents performed an in-person evaluation within 2 weeks of cardiac implantable electronic device implantation. Remote monitoring was performed every 3 months for pacemakers and implantable cardioverter defibrillators by 71 and 75% respondents, respectively. Follow-up echocardiography was performed every 2–3 years by 53% respondents for patients with >50% ventricular pacing. Majority of respondents (75%) did not perform either an exercise stress test or ambulatory Holter monitoring or chest X-ray (65%) after cardiac implantable electronic device implantation. *Conclusion:* This survey identified significant practice variations in cardiac implantable electronic device in- person evaluation, remote monitoring, and ancillary testing practices among paediatric electrophysiologists. Cardiac implantable electronic device management may be optimised by development of a paediatric-specific guidelines for follow-up and ancillary testing.

Cardiovascular implantable electronic devices have increased in number and complexity and with technological advancements, all cardiovascular implantable electronic devices now have the ability to monitor their own function, record arrhythmias and other physiological parameters, and send wireless communication to health care providers.[1,2] In addition to monitoring the cardiovascular implantable electronic device itself, it is equally important to evaluate the patient and the impact of any cardiovascular implantable electronic device- related consequences with appropriate ancillary testing.[3–5] In an effort to characterise current follow-up practice patterns regarding cardiovascular implantable electronic device follow-up and ancillary testing, we surveyed paediatric electrophysiologists and allied health professionals at institutions involved in the care of children with cardiovascular implantable electronic devices.

Methods

An 11 question survey (Table 1) was electronically distributed to all members of the Paediatric and Congenital Electrophysiology Society to evaluate follow-up for pacemakers, implantable cardioverter defibrillators, and implantable loop recorders. Cardiac resynchronization therapy devices were excluded from the questionnaire due to small number of patients. The main

Table 1. CIED follow-up survey questions and variables

Post CIED implant in-person follow-up:

1. Do you recommend that implanting centre should provide CIED follow-up?
2. What is the timing of first post implant in person CIED evaluation?
3. What is the frequency of follow-up after first post implant visit for the each of the following devices until signs of battery depletion:
   - Single-Chamber PPM
   - Dual-Chamber PPM
   - ICD
   - ILR

Post CIED implant remote monitoring:

4. What is the percentage of CIEDs in your practice that are evaluated by remote monitoring?
5. What is the method of RM for pacemakers (transtelephonic versus automated)?
6. What is the frequency of RM after first post implant visit for each of the following devices until signs of battery depletion?
   - Single-Chamber PPM
   - Dual-Chamber PPM
   - ICD
   - ILR
7. In patients with CIED nearing ERI, when do you request changing RM transmissions to monthly?
8. Which personnel perform initial review of RM transmission?
   - Physician
   - Nurse Practitioner
   - Physician Assistant
   - Nurse
   - Technician

Adherence to CMS published Medicare frequency guidelines for pacemakers:

9. Do you follow the above guidelines for pacemaker follow-up?

CIED-related ancillary testing:

10. How often do you perform the following tests on patients with structurally normal hearts who are > 50% VP?
    - Echocardiogram
    - Exercise stress test
    - Holter monitoring
    - Chest X-ray
11. How often do you perform an echocardiogram on patients who are <50% VP?
    - Echocardiogram
    - Exercise stress test
    - Holter monitoring
    - Chest X-ray

CIED = cardiovascular implantable electronic device; ERI = elective replacement indicator; RM = remote monitoring.

Table 2. Contrast between expert consensus statement recommendations and current PACES CIED monitoring practices

HRS expert consensus statement recommendations[1,2]	PACES survey response	Comments
It may be beneficial to initiate RM within 2 weeks of CIED implantation	Discordant	All PACES respondents did not initiate RM within 2 weeks of CIED implantation
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks post implantation	Concordant	100% PACES respondents indicated that CIEDs were checked through direct patient contact within 12 weeks post implantation
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy	Discordant	94% of PACES respondents initiated RM out of which 23% utilised trans-telephonic transmissions for pacemakers
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up for equivalent experience	Discordant	PACES respondents indicated that RM interpretations were performed by allied health care professionals with varying qualifications and experience
Intensified (monthly) in-person or remote monitoring should be considered when the CIED nears its elective replacement indicator	Discordant	A change in schedule to monthly transmissions was made by 18, 50, 27% respondents when the estimated battery longevity was <3 months, <6 months, and <12 months, respectively

CIED = cardiovascular implantable electronic device; PACES = Paediatric and Congenital Electrophysiology Society; RM = remote monitoring.

outcome measures were variations in frequency of in person evaluation, frequency of remote monitoring, and cardiovascular implantable electronic device-related ancillary testing (echocardiogram, ambulatory monitoring, chest X-ray, and exercise stress testing. All responses were received in a de-identified format. After responses were obtained, direct comparisons of results were made with published expert consensus recommendations.[1,2]

Results

The survey was sent to 102 institutions. A total of 88 institutions completed the survey (86%). Overall, 92% of respondents believed that the implanting centre should provide cardiovascular implantable electronic device follow-up and management in order to ensure consistency and programming optimisation. Amongst cardiovascular implantable electronic device monitoring personnel, the preliminary review of the transmitted data was predominantly performed by a nurse (53%), technician (26%), nurse practitioner (13%), and physician (6.5%). Concordance or discordance between Expert Consensus Statement Recommendations[1,2] and current Paediatric and Congenital Electrophysiology Society cardiovascular implantable electronic device monitoring practice variations are shown in Table 2.

Frequency of cardiovascular implantable electronic device in person evaluation

Only 3% of respondents performed an in-person evaluation within 1 week of the cardiovascular implantable electronic device implantation. For the remainder, in person evaluation occurred at 1–2, 2–4, and 4–8 weeks by 47, 6.4, and 34% of respondents, respectively for the first time post implant in-person evaluation. Patients with pacemakers and implantable cardioverter defibrillators were

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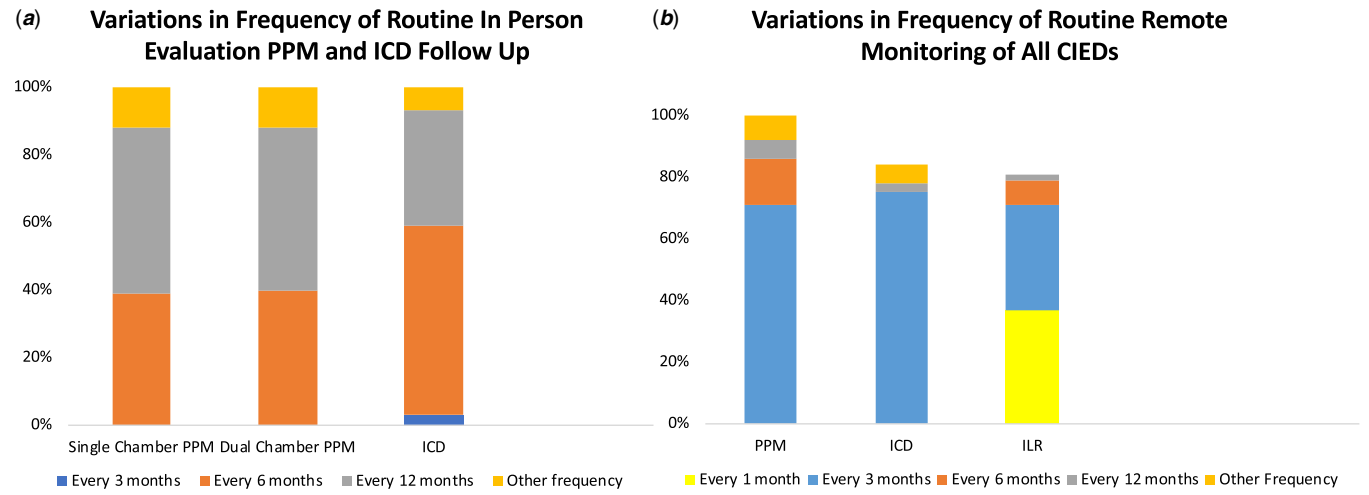

Figure 1. (*a*) Results of in-person evaluation (IPE) frequency from time of first CIED implantation follow-up to time nearing end of replacement indicator. (*b*) Results of remote monitoring (RM) frequency from time of first CIED implantation follow-up to time nearing end of replacement indicator. CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter defibrillator; PPM = permanent pacemaker.

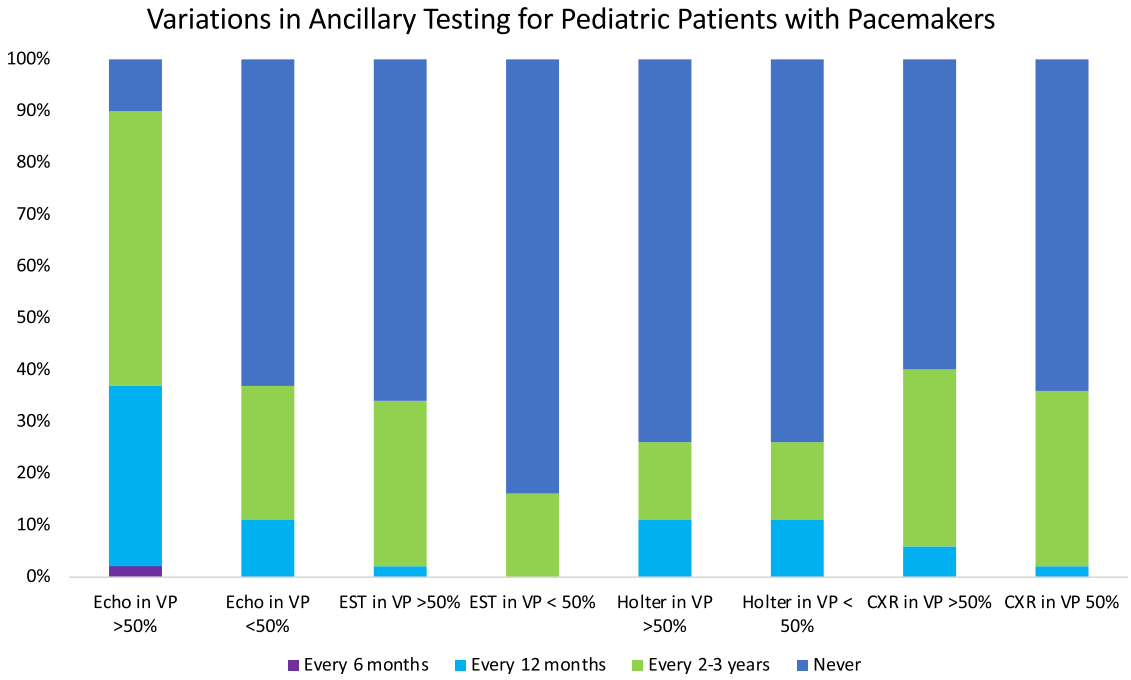

Figure 2. Results of variations in CIED-related ancillary testing in patients with pacemakers. CIED = cardiovascular implantable electronic device; CXR = chest roentgenogram; Echo=echocardiogram; VP = ventricular paced.

evaluated at least once a year subsequently with substantial variability in frequency (Fig 1a). Majority of implantable loop recorders patients (80%) had in-person evaluation at least once a year (3% every 3 months, 16% every 6 months, and 61% every 12 months). Majority of respondents (68%) reported that they did not follow CMS published Medicare frequency guidelines for pacemakers.

Frequency and type of cardiovascular implantable electronic device remote monitoring

Ninety four percent of respondents performed remote monitoring for all cardiovascular implantable electronic device patients. Apart from the 23% of respondents who still utilised transtelephonic transmissions for pacemaker patients, the remainder of respondents utilised automated manufacturer-specific wireless remote telemetry systems for all cardiovascular implantable electronic devices. Majority of respondents scheduled remote monitoring every 3 months for implantable cardioverter defibrillators and permanent pacemaker and every 6 months for implantable loop recorders until signs of battery depletion (Fig 2). A change in schedule to monthly transmissions was made by 18, 50, 27% respondents when the estimated battery longevity was <3 months, <6 months, and <12 months, respectively.

Ancillary testing

Follow-up echocardiography was the most commonly performed investigation in patients with a structurally normal heart

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(frequency of every 2–3 years by 53% respondents for >50% ventricular pacing and by 26% of respondents for <50% ventricular pacing). Majority of respondents did not perform an exercise stress test, chest X-ray, or ambulatory Holter monitoring during follow-up.

Discussion

This survey shows that there continues to be a wide variation in cardiovascular implantable electronic device in person evaluation, remote monitoring, and cardiovascular implantable electronic device-related ancillary testing practices in the paediatric population. A variety of factors might be influential including patient age, patient/family preferences, patient symptoms, reimbursement schedules, cardiovascular implantable electronic device management resources, geographic location, cost of Wi-Fi and internet services, underlying CHD, and complex clinic scheduling. Since 2015, a major difference in paediatric cardiovascular implantable electronic device monitoring practice is the reduction in utilisation of TTM for monitoring pacemakers (down to 23% from 67%) and increase in wireless remote monitoring (up to 94% from 87%).[6]

While it may be impossible to counter some heterogeneity in clinical practice, a paediatric-specific cardiovascular implantable electronic device follow-up paradigm that provides recommendations for minimal frequency of in-person evaluation, remote monitoring, and ancillary testing in uncomplicated patients is necessary. Standardized guidelines may maximise the opportunity for early detection and intervention of cardiovascular implantable electronic device system problems, prolong cardiovascular implantable electronic device battery longevity, enable early detection of haemodynamic and adverse events, initiate appropriate follow-up with corrective action/safety alerts, and minimises unnecessary device in-person evaluation and excessive testing.[1,2,7–9] In particular, there are two phases after device implantation that are crucial and should be addressed in an expert consensus statement as immediate post implant "acute" phase and nearing elective replacement indicator phase. Many complications, such as lead dislocation and perforation, wound infection, and loose set-screws, can be seen within the first 7–10 days after implantation, if not recognised prior to discharge from the hospital. In this survey, <50% of respondents performed an in-person evaluation within 2 weeks of cardiovascular implantable electronic device implantation. When a cardiovascular implantable electronic device approaches elective replacement indicator, intensified surveillance frequency may be helpful.[1,2] Conversely, during the "maintenance" phase of the device, less frequent follow-up may be sufficient, thereby reducing patient travel, time, and economic burdens as well as surplus workload on the clinical providers. A 2015 Paediatric and Congenital Electrophysiology Society survey of cardiovascular implantable electronic device monitoring showed that remote monitoring utilisation did not reduce the frequency of in-person evaluation.[6] The recent remote monitoring experience during the ongoing COVID19 pandemic has highlighted its utility in reducing in-person evaluation.[10] However, despite the ease with which patients are able to send remote interrogations, the amount of data produced from these reports is extensive and time for staff to prepare, interpret reports, and follow-up with patients is substantial. While assessment of variability in programming various cardiovascular implantable electronic device alert settings triggering automatic remote transmissions was beyond the scope of this survey, this was also an area where a streamlined and standardised approach may benefit the patient and providers.[1,2,6,7]

Another area of inconsistency highlighted by this survey and not previously addressed is cardiovascular implantable electronic device-related ancillary testing. Standardised ancillary testing in paediatric patients may be of benefit as many children will require a lifetime of cardiovascular implantable electronic device therapy that may include a range of hardware implanted during periods of physical growth and vigorous activity. Chest X-rays can be helpful in detecting lead-related problems such as coronary compression, myocardial strangulation, dislodgement, and fracture.[4,5] Echocardiography is useful in monitoring ventricular function in patients with high percentage of ventricular pacing and identifying endocardial lead-related complications.[3] Exercise testing can provide data for programming upper rates, arrhythmia detection parameters, as well as detecting QRS morphology and T wave changes. In patients with single chamber that utilise electrogram morphology template matches during sinus rhythm to discriminate between supraventricular and ventricular arrhythmias, exercise testing may be useful to avoid inappropriate implantable cardioverter defibrillator shocks in patients who develop rate related QRS changes such as bundle branch block. Exercise testing may be particularly useful in patients with subcutaneous implantable cardioverter defibrillators to select a more appropriate sensing vector as well as for troubleshooting T wave oversensing at higher heart rates. Furthermore, important physiologic data can be obtained to guide decision making for pacemaker programming and upgrades.[10,11] Periodic ambulatory Holter monitoring may be useful to identify subclinical device malfunction and arrhythmias.[12]

This survey should serve as a catalyst for proposing a framework for paediatric-specific guidelines for cardiovascular implantable electronic device follow-up and ancillary monitoring. The time frames for cardiovascular implantable electronic device monitoring published in expert consensus recommendations do not vary significantly from current paediatric practice, but given the higher incidence of device-related complications in paediatric patients, revisions to recommendation are needed.[13] For example, in-person follow-up after cardiovascular implantable electronic device implantation should occur as early as possible, and at least within 4 weeks (instead of the recommended 12 weeks) as early detection of surgical wound, lead, and device implant complications have better outcomes when addressed in the acute post implant period.[4] The proposed framework should also include guidance for performing ancillary testing such as imaging, ambulatory rhythm monitoring, and exercise stress testing for cardiovascular implantable electronic device optimisation.[3,10,12] This is an area that is currently not addressed in any published cardiovascular implantable electronic device clinical guidelines. Standardisation of cardiovascular implantable electronic device surveillance is likely to become even more important as technology advances into the realm of remote device programming.[14] In addition, standardisation will provide benchmarks for adequate reimbursement and enable payers to recognise the human and technological resources necessary for cardiovascular implantable electronic device surveillance including ancillary testing to optimise care and safety of this vulnerable patient population.

Limitations

This study was based on a voluntary survey and may not reflect practice preferences of all paediatric electrophysiologists. However,

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respondents from 88 institutions is a relatively large number in the paediatric electrophysiologist community.

Conclusion

Our survey identified significant practice variations in cardiovascular implantable electronic device surveillance and ancillary testing practices amongst paediatric electrophysiologists. A consensus statement addressing standardised surveillance of paediatric cardiovascular implantable electronic devices and ancillary testing may be beneficial for early detection of cardiovascular implantable electronic device complications and subsequent alterations in management.

Conflicts of interest. None.

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