Pacemaker remote monitoring challenges in pediatric population: Single center long term experience

Dagmar Kowal[1,2,*], Artur Baszko[3,4], Krzysztof Czyz[3], Waldemar Bobkowski[3], Przemysław Mitkowski[5], Błażej Rubis[1]

[1]Department of Clinical Chemistry and Molecular Diagnostics, Poznan University of Medical Sciences, Poznań, Poland
[2]Doctoral School, Poznan University of Medical Sciences, Poznań, Poland
[3]Department of Pediatric Cardiology, Karol Jonscher Clinical Hospital, Poznań, Poland
[4]2nd Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland
[5]1st Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland

Correspondence to:
Dagmar Kowal, MSc,
Department of Clinical Chemistry and Molecular Diagnostics,
Poznan University of Medical Sciences,
Collegium Pharmaceuticum,
Rokietnicka 3,
60–806 Poznań, Poland,
phone: +48 61 641 83 04,
e-mail:
85126@student.ump.edu.pl

DOI: 10.33963/v.phj.99761

Received:
January 30, 2024

Accepted:
March 13, 2024

Early publication date:
March 14, 2024

ABSTRACT

Background: Remote monitoring (RM) of cardiac implantable electronic devices for adults offers improved treatment efficacy and, consequently, better patient clinical outcomes. There is scant data on the value and prognosis of RM in the pediatric population.

Aims: The goal of this study was to determine the efficacy of RM by analyzing the connectivity of bedside transmitters, adherence to planned automatic follow-ups, and occurrence of alert-based events.

Methods: We evaluated the pediatric population with implanted pacemakers for congenital AV block or after surgically corrected congenital heart diseases.

Results: A total of 69 patients were included in our study. The median (Q1–Q3) patient age was 6.0 (2.0–11.0) years. All patients received bedside transmitters and were enrolled in the RM system. Among them, 95.7% of patients had their first scheduled follow-up successfully sent. Patients were followed up remotely over a median time of 33.0 (13–45) months. Only 42% of patients were continuously monitored, and all scheduled transmissions were delivered on time. Further analysis revealed that 34.8% of patients missed transmissions between June and September (holiday season). Alert-based events were observed in 40.6% patients, mainly related to epicardial lead malfunction and arrhythmic events. Overall compliance was also compromised by socioeconomic factors.

Conclusions: Our findings are in concordance with recently published results by PACES regarding a high level of compliance in patient enrollment to RM and time to initial transmission. However, a lower level of adherence was observed during the holiday season due to interrupted connectivity of bedside transmitters. Importantly, a relatively low occurrence of alert transmissions was observed, mainly related to epicardial lead malfunction and arrhythmic events.

Key words: adherence, bed-side transmitters, pacemakers, pediatric, remote monitoring

INTRODUCTION

Since 2015, remote monitoring (RM) of cardiac implantable electronic devices (CIED) has been recommended for adults as a class I indication, complementary to in-hospital-only device follow-up by the Heart Rhythm Society expert consensus statement [1]. Similarly, in 2021, the Pediatric and Congenital Electrophysiology Society (PACES) recognized RM as an integral part of pediatric patients' follow-up after CIED implantation [2]. The breakthrough that led to establishing RM as the standard of care in the daily practice of patients with CIED was possible due to an extensive body of evidence presenting reduced time from the onset of ventricular and supraventricular arrhythmias (including silent arrhythmias) to their evaluation, early identification of lead or device malfunction and monitoring battery status [3–6]. In contrast to the RM of high-energy devices in adults with heart failure (HF), there is no clear evidence of improved prognosis in the pediatric population, yet. Different problems

WHAT'S NEW?

Although in 2021, the Pediatric and Congenital Electrophysiology Society recognized remote monitoring (RM) as an integral part of pediatric patients' follow-up after cardiac implantable electronic device implantation, there is scant data on the value and prognosis of RM in that population. This research presented high level of the compliance in initial phase of RM (enrollment and time to first transmission) for pediatric patients with implanted pacemaker for congenital AV block or after surgically corrected congenital heart diseases. However, the connectivity of bed-side transmitters was interrupted during the holiday season, resulting in lower adherence — 42%. If the seasonal transmission gap is eliminated the overall compliance and success rate could be improved 2-fold. The occurrence of alert transmissions in the studied group was relatively low and mainly related to epicardial lead malfunction and arrhythmic events, but it should be emphasized that temporarily compromised connectivity can obstruct early detection of alert events and delay medical intervention.

are encountered in children and patients with surgically corrected congenital heart diseases (CHD) with implanted pacemakers. In this cohort, the importance of RM in the early detection of arrhythmias and the device or lead malfunction is emphasized [7, 8].

Initiating RM within 2–4 weeks of a new CIED implant and performing remote follow-up every 3–12 months for both adults and children is recommended [9]. Daily remote checks followed by transmission of predefined alert events allowing early diagnosis of arrhythmic episodes or device-based events are integral components of the system. Consequently, the correct and structured reaction of the dedicated medical team to incoming alerts translates into an improved prognosis, which was emphasized in the latest consensus [9]. It was also noticed that maintaining connectivity between CIED, transmitter and internet-accessible manufacturer websites poses a challenge, thus influencing overall compliance and the final success rate of RM.

Remote monitoring compliance in adult patients is defined as overall enrollment of CIED patients in RM, transmission within 2–4 weeks of new CIED implant and adherence to recommended follow-up interval guidelines. In several studies, RM compliance ranged from 53%–79% [10, 11]. The possible reasons for low adherence to the scheduled follow-up scheme were transmitter type, geographic localization, socioeconomic status, clinic facilities, patient age and gender [12, 13]. The above challenges described in adult patients can also apply to the pediatric population. Thus, PACES has recently published a Quality Improvement (QI) initiative to ameliorate RM in pediatric and CHD patients with CIEDs [14]. As there is still limited data on RM in the pediatric population, we decided to analyze our database of patients with implanted pacemaker (PM).

The goal of this study was to determine the efficacy of remote monitoring in the pediatric population with implanted PMs by analyzing the connectivity of bedside transmitters, evaluating the adherence to planned automatic follow-ups, and evaluating the number and time to alert-based events reported by remote monitoring. The second goal was to determine the reasons for low adherence to follow-up transmissions.

METHODS

A retrospective analysis was conducted on patients who had pacemakers implanted with RM capability (Abbott, formerly St. Jude Medical, Plymouth, MN, US; Biotronik, Berlin, Germany) between September 2014 and August 2023 at the Department of Pediatric Cardiology, Karol Jonscher Clinical Hospital, Poznan. The indications for permanent cardiac pacing were according to guidelines at the time of implantation [15]. The remote monitoring program was implemented in the hospital in March 2018. Patients who received implants before 2018 were consecutively included in the program. Newly implanted patients were enrolled in the program either at discharge or during their first scheduled visit to the pacemaker outpatient clinic. All patients were provided with bedside transmitters and a wireless gateway. A combined follow-up protocol was proposed for all patients: automatic, every 91-days remote follow-up with daily alert checks and standard in-clinic visit every 6–12 months. During our observation in Poland, no dedicated medical facility or team with an established workflow was organized due to the lack of reimbursement of RM. Two cardiologists, trained in the pacemaker implantation technique and follow-up regularly evaluated the device transmissions (daily on weekdays) using the manufacturer' internet-accessible website (merlin.net, Abbott; biotronik-homemonitoring.com, Biotronik). If the device alerted the cardiologist of a loss of transmitter connection (Abbott) or missed transmission (Biotronik), they attempted to establish telephone contact with the patient's family.

During the discharge or enrollment visit, families received training on how to operate the transmitter, including instructions on its proper location, and how to perform manual transmissions (in the Abbott transmitter). The importance of the quality of daily connections performed at night time was stressed to ensure the best adherence and compliance with the transmission schedule or sudden alert events. The following parameters were included in the analysis: patient demographics; clinical data regarding cardiac diagnosis and indications for PM implantation; RM adherence defined as time to enrollment and the first transmission; the number and regularity of scheduled transmissions; total duration of RM; and detection of alert-

based clinical events. The types of alert-based events were classified into groups with respect to device functioning (lead dysfunction, high pacing output, battery) and arrhythmic events. The patient was called for an additional visit if the justified alert-based transmission was triggered. Information regarding the patient's death was collected from hospital records or parents.

Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by Institutional Ethics Committee of Poznan University of Medical Sciences (protocol code 805/20 on November 4, 2020). Patient consent was waived due to the observational character of the study.

Statistical analysis

Descriptive statistics including mean, standard deviation or median with interquartile range (Q1–Q3), range, number of events, frequency of occurrence and percentages were used to express data. The Shapiro–Wilk test was conducted to verify normal distribution. All statistical analyses were performed in Tibco Statistica software version 13 (StatSoft, Tulsa, OK, US).

RESULTS

Patients

A total of 69 patients were included in our study (34 males and 35 females). The median (Q1–Q3) patient age at pacemaker implantation was 6.0 (2-11) years and at the final analysis, it was 9.0 (5–15) years. The 45 patients (65.2%) were diagnosed with surgically corrected congenital heart disease. The indication for PM implantation was sick sinus syndrome in 12 patients (17.4%) and atrioventricular block in 57 (82.6%). The group of 28 (40.6%) patients received a single chamber pacemaker, and 41 (59.4%) received a dual chamber pacemaker. In 51 patients (73.9%), epicardial leads were implanted (Table 1). Four patients (5.8%) received pacemakers before the RM program was implemented in the hospital and were covered by the program late after implantation.

Patients were followed up remotely over a median period of 33.0 (13–45) months. Six hundred eighty-five scheduled transmissions were collected, reviewed, and analyzed by medical personnel. Of 69 patients, 47 (68.1%) are still under remote surveillance.

During the follow-up, 3 patients died. The mechanism was sudden in one patient, and pneumonia with multiorgan failure in the remaining two. No deaths were related to device dysfunction. Two patients died in the hospital. Nine patients (13%) reached the age of 18 and were transferred to the adult outpatient clinic, mostly without RM capabilities. During observation, 10 patients (14.5%) lost RM. The most common cause was geographic localization, socioeconomic status (family income, education, awareness), and technical issues.

Table 1. Baseline characteristics of patients

Number of patients	69
Age, median (Q1–Q3), (min–max), years	9.0 (5–15), (2–22)
Age at initial device implantation, median (Q1-Q3), (min-max), years	6.0 (2–11), (0–17)
Male gender	34 (49.3%)
Reason for PM implantation	
SSS	12 (17.4%)
AV block	57 (82.6%)
Type of PM implanted	
Single-chamber PM	28 (40.6%)
Dual-chamber PM	41 (59.4%)
Abbott/St. Jude Medical	56 (81.2%)
Biotronik	13 (18.8%)
Patients with epicardial lead	51 (73.9%)
Congenital heart disease	
AVSD	12 (17.4%)
TGA+VSD	7 (10.1%)
VSD	6 (8.7%)
ASD	5 (7.3%)
ToF	4 (5.8%)
PA	3 (4.4%)
DORV	2 (2.9%)
APVD	2 (2.9%)
Other	4 (5.8%)

Abbreviations: APVD, anomalous pulmonary venous return; ASD, atrial septal defect; AV, atrioventricular; AVSD, atrioventricular septal defect; DORV, double outlet right ventricle; PA, pulmonary atresia; PM, pacemaker; SSS, sick sinus syndrome; TGA, d-transposition of the great arteries; ToF, tetralogy of Fallot; VSD, ventricular septal defect

The median (Q1–Q3) time from PM implant to remote monitoring enrollment was 3 (1–7) days for patients with PM implanted after the surveillance program's activation in our hospital. The delay of RM initiation in group of 4 patients (range 172–417) was related to the lack of initial parental consent (2 patients) and a place of residence covered by another clinic (2 patients). Ultimately, parental consent was granted during the COVID lockdown, and two patients were subjected to RM due to Abbott pacemaker corrective action. The median enrollment time for patients with PM implanted before March 2018 was 1745 days (range 1460–2407).

There were 56 patients (81.2%) with successfully paired bedside transmitters and activated monitoring before discharge. The remaining group of 13 patients (18.8%) were enrolled in RM during a visit to the outpatient clinic, including 5 patients who experienced technical issues with mobile signal range while pairing bedside transmitters.

All patients were subjected to a detailed assessment of RM efficacy described below.

Compliance with pacemaker RM

The compliance was defined as the overall enrollment of PM patients in RM, initial RM transmission within 2–4 weeks of enrollment, and adherence to the recommended scheduled follow-up interval (91 days). All patients received paired bedside transmitters and were enrolled in the RM system. Among them, 66 patients (95.7%) had their first

Table 2. Remote monitoring characteristics

Number of patients	69
RM follow-up time, median (Q1–Q3), (min–max), months	30.0 (13–45), (1–68)
All scheduled remote transmissions	684
Patients enrolled to RM	69 (100.0%)
Patients with PM implanted since March 2018 when RM was implemented	65 (94.2%)
Patients with PM implanted before March 2018	4 (5.8%)
Time to RM enrollment after March 2018, median (Q1–Q3), (min–max), days	3 (1–7), (1–417)
Patients with at least 1 FU after RM enrollment	66 (95.7%)
Patients with more than 1 FU after RM enrollment	62 (89.9%)
Continuous adherence to RM FU scheme	29 (42.0%)
1 FU missed, up to 182 days gap	29 (42.0%)
2 or more consecutive FU missed, more than 182 days	6 (8.7%)
FU missed on summer season (Jun–Sep)	27 (39.1%)
Actively monitored patients at final analysis	47 (68.1%)
Patients turned age 18 years	9 (13.0%)
Mortality	3 (4.4%)
Patient lost RM during observation	10 (14.5%)

Abbreviations: FU, follow up; PM, pacemaker; RM, remote monitoring

scheduled follow-up successfully sent, and respectively, 62 patients (89.9%) had more than one (2 patients died, 4 patients turned age 18 and 1 patient experienced technical issues following the first completed follow-up).

Only 29 patients (42.0%) were continuously monitored during the study, and all scheduled transmissions were delivered on time. Further analysis demonstrated connectivity breaks resulting in one missed planned remote follow-up (gap of 182 days) in 29 patients (42.0%) and two or more consecutive follow-ups missed (gap above 182 days) in 6 patients (8.7%). Interestingly, further analysis of patients who did not adhere to the follow-up scheme revealed that 24 (34.8%) missed transmission between June and September (Table 2), which is the summer holiday season in Poland (Figure 1).

Alert-based transmissions

Since the fast diagnosis of arrhythmic events and device functioning may be critical for patients' outcomes, the goal was to evaluate the first detection of alert-based events. It was observed in 28 patients (40.6%). A group of 20 patients (29.0%) were diagnosed with appropriate, justified alert transmission and 8 (11.6%) with false positive notification. The median (Q1–Q3) time to the first transmission was 514.5 (97.5–587.5) days. Appropriate alert-based events were classified into two groups: related to arrhythmic events and device functioning. In 9 patients (13.0%), alerts were related to arrhythmic events: 6 (8.7%) non-sustained ventricular tachyarrhythmias (nsVT); 2 (2.9%) supraventricular tachyarrhythmias (SVT) or atrial tachyarrhythmias (AT); and 1 (1.5%) was associated with consecutive premature ventricular complexes (PVCs). Four out of 6 patients with diagnosed nsVT and one patient with PVCs had congenital heart block. The other two patients with nsVT and two patients with SVT/AT had congenital heart disease (Table 3).

In 10 patients (14.5%) with alert transmissions classified as device functioning, there were 5 patients (7.3%) with elevated right ventricle capture threshold and intermittent loss of capture (Supplementary material, *Figure S1*) due to lead malfunction (AutoCapture output at 5.0 V), and 3 patients (4.3%) with lead dysfunction manifested by impedance trend change or lead noise. The remaining 2 patients (2.9%) were diagnosed with oversensing in the

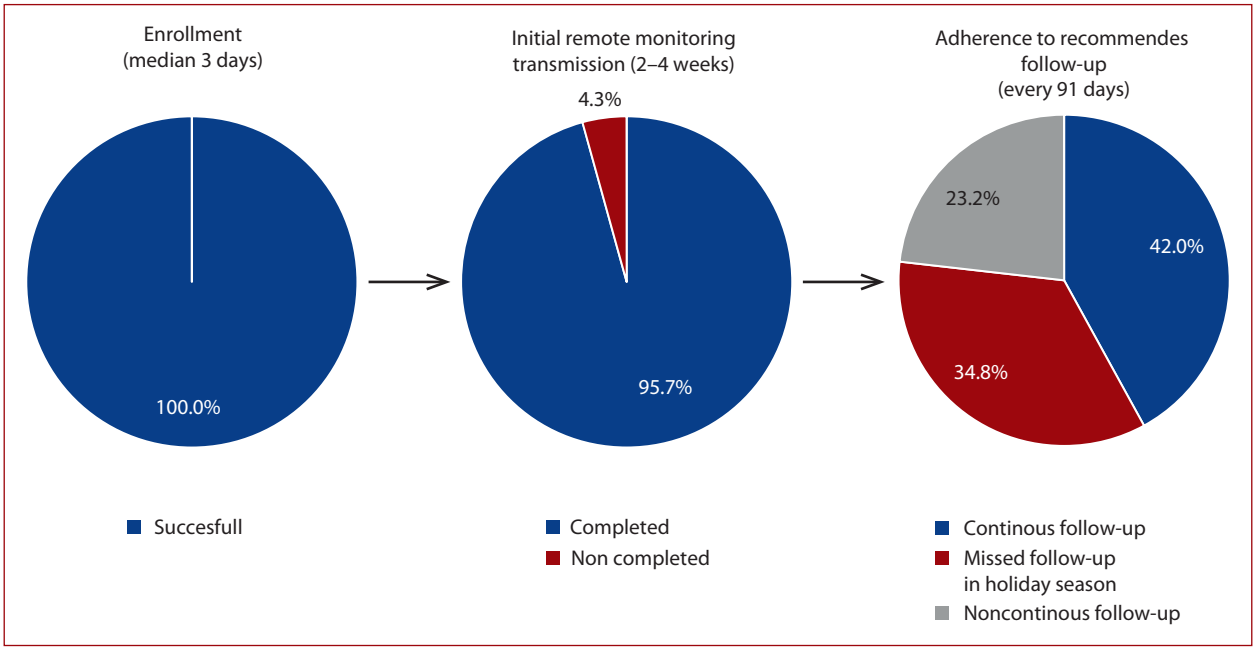

Figure 1. Compliance of remote monitoring of pediatric patients with congenital heart disease and implanted pacemaker (bed-side transmitters)

Table 3. Alert-based transmissions

Patients with first alert transmission			28 (40.6%)		
Time to first alert transmission, median (Q1–Q3), (min–max), days			514.5 (97.5–587.5) (2–1401)		
RM alert type	**n**	**RM details**	**Final diagnosis**	**Corrective actions**	**CHD**
nsVT	6 (8.7%)	HRV histogram + HRV IEGM	nsVT	Medication adjustment or observation	2
High capture output	5 (7.3%)	Real time IEGM + high capture output + AC threshold trend	RV pacing failure	RV lead replacement (2 epi), RV lead reposition (1 His), further observation (2 epi)	4
Lead impedance, noise	3 (4.4%)	RV impedance trend, lead noise	RV lead dysfunction	RV lead replacement (1 epi, 1 endo), observation (1 epi)	2
SVT / AT / HAR	2 (2.9%)	AMS IEGM + atrial rhythm diagnostics	SVT / AT	Medication adjustment	2
HAR due to oversensing	2 (2.9%)	AMS IEGM + oversensing evaluation	Myopotentials and R-wave far-field oversensing	Pacemaker program adjustment	2
Consecutive PVC's	1 (1.5%)	Real time IEGM + ventricular rhythm diagnostics	Consecutive PVC's	No action	0
Atrial noise reversion, EMI	1 (1.5%)	Real time IEGM + atrial rhythm diagnostics	EMI	No action	n/a
False HAR, HVR, nsVT, lead impedance	8 (11.6%)	AMS and real time IEGM + rhythm diagnostics + impedance trend	False positive events	Pacemaker program adjustment	n/a

Legend: AC, autocapture™; AMS, auto mode switch; AT, atrial tachycardia; CHD, congenital heart disease; EMI, electromagnetic interferences; endo, endocardial lead; epi, epicardial lead; HAR, high atrial rate; HVR, high ventricular rate; IEGM, intracardiac electrogram; nsVT, none sustained ventricular tachyarrhythmia; PVCs, premature ventricular complexes; SVT, supraventricular tachyarrhythmia; other — see Table 2

atrial channel caused by myopotentials or far R-wave signal. Five out of 8 (62.5%) patients with whom we observed lead malfunctions were related to epicardial systems. After careful evaluation of lead integrity, including lead provocative testing, the dysfunction was confirmed, and 4 patients were referred to lead replacement procedure and 1 to a lead repositioning (His bundle pacing). Three patients are still under observation to monitor lead parameters (Table 3). In the group of appropriate alert events, 1 patient (1.5%) had atrial noise reversion due to EMI, and no further action was taken.

The analysis also revealed 6 patients (8.7%) with inappropriate alert transmission due to false detection of high atrial or ventricular rhythm, as those parameters were programmed by default to the adult patients' range. Two patients were observed with a well-functioning epicardial lead and good system integrity. However, periodically their impedance fell below the lower limit (range of 200 Ohms), triggering false alerts. Changes to the PM program were made during their next scheduled outpatient clinic visit.

DISCUSSION

The aim of this study was to analyze the efficacy of RM in the pediatric population with implanted PM and with or without CHD. The study examined compliance with enrollment and adherence to recommended RM guidelines for pacemakers, and evaluation of detection and time to first alert transmissions. Collected data included 684 scheduled remote transmissions collected during 33.0 (13–45) months (range 1–68). According to guidelines, the registration and initial RM transmission should be performed within 2–4 weeks from implant or device exchange [2]. Our data presented a high level of compliance achieved in both aims emphasized by PACES QI: overall enrollment of CIED patients in RM and first automatic transmission. Altogether, in our study, all patients were registered in the surveillance system, and the median time from implant to enrollment was 3 days after the RM system was launched in our center. The 95.7% of patients had the first scheduled follow-up successfully sent. Recently published PACES QI data presented that high compliance (defined as high if there was above 80% achievement) of overall enrollment of CIED patients in RM was met in 77% of 22 pediatric centers in the US and Australia. However, only 36 % of centers achieved high compliance in the second aim, which was completing the recommended time for initial RM transmission (2–4 weeks) [14]. Our data in line with PACES analysis shows that the patient registration process, which is directly influenced by the medical team, is more effectively controlled than the first successful remote transmission. Although the date of the initial transmission is determined at the enrollment process, external conditions directly related to the patient and their place of residence afterward can influence its execution.

The third aim related to compliance evaluated in our study was adherence to the automatic follow-up scheme. Our long-term data demonstrated that only 42% of patients followed continuous surveillance without loss of scheduled transmissions, which was planned every 91 days, according to the PACES guidelines [2]. Although it is perceived as a low level of adherence, it is not distant from PACES results presenting adherence at the level of 50% or more for all PM and ICD centers [14]. Importantly, our adherence goal was met when 100% of scheduled transmissions were delivered, whereas PACES defined its threshold at 80% delivery. Our analysis is based on solid, long-term observational data, while the PACES concluded on centers' self-reported data.

Further adherence analysis demonstrated that in the group of 40 patients with noncontinuous RM (58%) another subgroup could be distinguished i.e., 24 patients

(34.8%) who did not adhere to planned follow-ups during the summer holiday season (Table 2). Based on medical history, we observed that lower compliance during that period was correlated with holiday trips without bulky bedside transmitters or insufficient cellular signal coverage. We strongly suggest that if we eliminate the cause of decreased connectivity during that period the adherence could be improved almost 2-fold to 76.8%. As previously presented for adult patients the efficacy of RM based on bedside transmitters can be reduced due to patients traveling or changing their place of residence [12, 13]. Thus, we suggest that a combination of mobile, pocket-sized transmitters (e.g., smartphones) and the recently emphasized in guidelines correct and structured reaction of the dedicated medical team to incoming loss of transmission/connection alerts [9], could considerably eliminate the problem of insufficient compliance. Such studies are already being carried out in numerous units, including hospital units in Poland, leading to preliminary observations that such an approach could significantly improve adherence in adult patients. It should be also emphasized that temporarily compromised connectivity can obstruct alert-based alarm functionality, which is an important safety factor, particularly for pediatric patients.

Challenges we encountered while enrolling patients and maintaining a high level of adherence were related to I) geographic localization and good cellular signal coverage; II) the patient's parents' socioeconomic status, which led to an initial lack or subsequent withdrawal of parental consent, and lack of cooperation, understanding; III) dismantling cellular modem by family members, and iv) parents' failure to update their contact data. Even an established and well-structured workflow of a dedicated medical team, as emphasized in expert consensus [9], could not provide a sufficient solution to the majority of enlisted issues.

As recently described, challenges of decreased connectivity resulting in lower RM compliance can be resolved by the implementation of new technologies based on smartphones. Utilization of low energy Bluetooth (BLE) protocol to communicate between dedicated app and implantable loop recorders (ILRs), PMs, and ICDs led to a higher success rate of completed transmissions (94.6–92.0% for smartphone app transmissions vs. 56.3%–87.1% for manual or wireless console transmissions) [16, 17]. The smartphone app system was also very efficient in swiftly and appropriately diagnosis of arrhythmias, effective data transmission, and improving patient engagement. The successful transmission history available in the patient app and the ability to send immediate manual transmissions have additionally improved RM performance [18]. The prevalence and acceptability of smartphones in modern society, which can simultaneously serve as an RM transmitter, may solve challenges with seasonal and socioeconomic determinants (described above), improving RM adherence and compliance. However, further evaluation of app-based solutions for CIED surveillance to overcome limitations of bedside transmitters, especially for pediatric patients, needs to continue.

Remote monitoring is recommended for the detection of early device and lead dysfunction [3]. The patient population with selected CHD and post-operative heart block, especially with epicardial leads, is vulnerable to a higher risk of sudden cardiac arrest or sudden cardiac death. A recent study presented the performance of epicardial lead in a cohort of pediatric patients (mean age 10 years) [19]. The 3-year freedom from device failure was 80%, with failure causes including lead fracture (59%), lead dysfunction (15%), and lead dislodgement (15%). The other study, which identified 14 actionable events of the total 608 CIED remote interrogations in the pediatric cohort, reported 11 events due to tachyarrhythmia and 3 events due to device/lead malfunction [8].

Our evaluation presented appropriate alert events in 20 of 69 patients (among a total of 684 scheduled remote interrogations) during a median observation time of 33.0 months. Eight patients (11.6%) manifested lead issues and 5 were related to epicardial leads. Amid those 8 events we distinguished 5 patients experiencing elevated right ventricle capture threshold and intermittent loss of capture due to lead malfunction (AutoCapture output at 5.0 V), and 3 patients experiencing lead dysfunction manifested by impedance trend change or lead noise.

Analysis of RM implementation in Polish electrotherapy facilities published in 2022 revealed that only 28% of 50 surveyed centers used RM, and half of them had experience lasting over 5 years. The primary barriers for its wider implementation were concerns about additional workload and lack of RM reimbursement [20]. Considering the published data, our results fall within a narrow group of experienced centers and reveal similar challenges which we had encountered during observation: lack of reimbursement, generation of additional workload with limited resources, legal uncertainties and liability. We believe that recently introduced by the National Health Fund reimbursement for remotely monitored patients with CIED in Poland will provide a breakthrough [21]. Thoughtful and structured implementation, optimized for the presented results in discussion, especially for the pediatric population, will be conducted.

CONCLUSIONS

Our long-term observational study of pediatric patients with implanted PM showed high level of compliance in patient enrollment to RM (100%) and time to initial transmission (95.7%). The connectivity of bedside transmitters was interrupted during the holiday season, resulting in lower adherence — 42%. It could be improved 2-fold if the holiday season transmission gap is eliminated, possibly with the use of a smartphone app-based mobile technology. Similarly, elimination of different socio-economic factors could also contribute to significantly increased

compliance. In the pediatric population with pacemakers, especially with a high proportion of surgically corrected CHD, the occurrence of alert transmissions was relatively low and mainly related to epicardial lead malfunction and arrhythmic events. However, it needs to be emphasized that temporarily compromised connectivity can obstruct early detection of alert events and delay medical intervention.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

Acknowledgments: The research has been conducted as part of PhD thesis at Doctoral School in Poznan University of Medical Science and is portion of large implementing doctoral project supported by grant of Polish Ministry of Science and Higher Education.

Conflict of interest: DK — Abbott employment. Other authors declare no conflict of interest

Funding: This research received funding from Polish Ministry of Science and Higher Education, grant number DWD/4/56/2020.

REFERENCES

1. Slotwiner D, Varma N, Akar JG, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015; 12(7): e69–100, doi: 10.1016/j.hrthm.2015.05.008, indexed in Pubmed: 25981148.
2. Silka MJ, Shah MJ, Silva JN, et al. 2021 PACES expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients. Cardiol Young. 2021; 31(11): 1738–1769, doi: 10.1017/S1047951121003413, indexed in Pubmed: 34338183.
3. Chiu CSL, Timmermans I, Versteeg H, et al. Effect of remote monitoring on clinical outcomes in European heart failure patients with an implantable cardioverter-defibrillator: secondary results of the REMOTE-CIED randomized trial. Europace. 2022; 24(2): 256–267, doi: 10.1093/europace/euab221, indexed in Pubmed: 34410384.
4. Varma N, Love CJ, Michalski J, et al. TRUST Investigators. Alert-based ICD follow-up: A model of digitally driven remote patient monitoring. JACC Clin Electrophysiol. 2021; 7(8): 976–987, doi: 10.1016/j.jacep.2021.01.008, indexed in Pubmed: 33640345.
5. Crossley GH, Boyle A, Vitense H, et al. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. J Am Coll Cardiol. 2011; 57(10): 1181–1189, doi: 10.1016/j.jacc.2010.12.012, indexed in Pubmed: 21255955.
6. Kempa M, Sławiński G, Zieleniewicz P, et al. Implementation of remote monitoring in patients implanted with T-ICD and S-ICD involved in a recall campaign: An excellent tool with insufficient availability. Kardiol Pol. 2023; 81(6): 612–615, doi: 10.33963/KP.a2023.0059, indexed in Pubmed: 36871303.
7. Leoni L, Padalino M, Biffanti R, et al. Pacemaker remote monitoring in the pediatric population: is it a real solution? Pacing Clin Electrophysiol. 2015; 38(5): 565–571, doi: 10.1111/pace.12600, indexed in Pubmed: 25645302.
8. Dechert BE, Serwer GA, Bradley DJ, et al. Cardiac implantable electronic device remote monitoring surveillance in pediatric and congenital heart disease: Utility relative to frequency. Heart Rhythm. 2015; 12(1): 117–122, doi: 10.1016/j.hrthm.2014.10.009, indexed in Pubmed: 25304681.
9. Ferrick AM, Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Europace. 2023; 25(5): euad123, doi: 10.1093/europace/euad123, indexed in Pubmed: 37208301.
10. Rosenfeld LE, Patel AS, Ajmani VB, et al. Compliance with remote monitoring of ICDS/CRTDS in a real-world population. Pacing Clin Electrophysiol. 2014; 37(7): 820–827, doi: 10.1111/pace.12358, indexed in Pubmed: 24484075.
11. Varma N, Piccini JP, Snell J, et al. The relationship between level of adherence to automatic wireless remote monitoring and survival in pacemaker and defibrillator patients. J Am Coll Cardiol. 2015; 65(24): 2601–2610, doi: 10.1016/j.jacc.2015.04.033, indexed in Pubmed: 25983008.
12. Mantini N, Borne RT, Varosy PD, et al. Use of cell phone adapters is associated with reduction in disparities in remote monitoring of cardiac implantable electronic devices. J Interv Card Electrophysiol. 2021; 60(3): 469–475, doi: 10.1007/s10840-020-00743-9, indexed in Pubmed: 32399863.
13. Theuns DA, Radhoe SP, Brugts JJ. Remote monitoring of heart failure in patients with implantable cardioverter-defibrillators: Current status and future needs. Sensors (Basel). 2021; 21(11): 3763, doi: 10.3390/s21113763, indexed in Pubmed: 34071624.
14. Clark BC, Olen M, Dechert B, et al. Current state of cardiac implantable electronic device remote monitoring in pediatrics and congenital heart disease: A PACES-sponsored quality improvement initiative. Pediatr Cardiol. 2024; 45(1): 114–120, doi: 10.1007/s00246-023-03348-x, indexed in Pubmed: 38036754.
15. 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(8): 1070–1118, doi: 10.1093/europace/eut206.
16. Tarakji KG, Zaidi AM, Zweibel SL, et al. Performance of first pacemaker to use smart device app for remote monitoring. Heart Rhythm O2. 2021; 2(5): 463–471, doi: 10.1016/j.hroo.2021.07.008, indexed in Pubmed: 34667961.
17. Tilz RR, Shaik N, Piorkowski C, et al. Real-world adoption of smartphone-based remote monitoring using the confirm Rx™ insertable cardiac monitor. J Innov Card Rhythm Manag. 2021; 12(8): 4613–4620, doi: 10.19102/icrm.2021.120806, indexed in Pubmed: 34386274.
18. Kowal D, Katarzyńska-Szymańska A, Prech M, et al. Early smartphone app-based remote diagnosis of silent atrial fibrillation and ventricular fibrillation in a patient with cardiac resynchronization therapy defibrillator. J Cardiovasc Dev Dis. 2023; 10(1): 30, doi: 10.3390/jcdd10010030, indexed in Pubmed: 36661925.
19. Griffeth EM, Krishnan P, Dearani JA, et al. Pediatric epicardial devices: early and midterm outcomes. World J Pediatr Congenit Heart Surg. 2023; 14(4): 451–458, doi: 10.1177/21501351231157374, indexed in Pubmed: 36851830.
20. Tajstra M, Dyrbuś M, Grabowski M, et al. The use of remote monitoring of patients with cardiac implantable electronic devices in Poland. Kardiol Pol. 2022; 80(4): 479–481, doi: 10.33963/KP.a2022.0050, indexed in Pubmed: 35176170.
21. Order of the President of the National Health Fund no 68/2023/DSOZ from April 19, 2023 entitled "Amending the ordinance on determining the conditions for concluding and implementing contracts of the following type health services contracted separately". https://baw.nfz.gov.pl/NFZ/document/1778/Zarzadzenie-68_2023_DSOZ (accessed: February 22, 2024).