The use of remote monitoring of patients with cardiac implantable electronic devices in Poland

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The use of remote monitoring of patients with cardiac implantable electronic devices in Poland

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INTRODUCTION
Remote monitoring (RM) of patients with cardiac implantable electronic devices (CIED) allows to regularly gather detailed information concerning the functioning of the devices, without the necessity to present for an in-person examination (IPE) [1]. With the use of RM, vital parameters such as arrhythmia burden, the pacing percentage, or thoracic congestion indicators, already proven to predict heart failure decompensation and worsen the patient’s prognosis can be routinely measured, and an appropriately timed response initiated. The recent guidelines of the European
Society of Cardiology on cardiac pacing and resynchronization have stated three recommendations regarding the use of RM in patients with CIEDs, for the first time introducing the possibility of increasing the periods between the IPEs up to 24 months if the patient is monitored remotely [2]. Despite such recommendations, RM of patients with CIEDs in Poland is used in the minority of facilities, although exact data regarding this issue are not available. The purpose of this analysis was to investigate the implementation of RM in patients with CIEDs in Poland at the beginning of the third decade of the 21st century.

**METHODS**
The survey consisting of six brief either single- or multiple-choice questions has been dispatched with support of the Biotronik Polska (Poznań, Poland), among all electrotherapy centers which were on the correspondence list of the company in Poland between July and August 2021. The questions have been designed to assess the utilization of RM, the causes of lack of its implementation, and the perspectives of its initiation. The detailed survey can be found in the Supplementary material. Responses have been received from 50 centers. The approval of an ethics committee was not required for this analysis.

**Statistical analysis**
The data have been summarized and presented as absolute and relative frequencies.

**RESULTS AND DISCUSSION**
Of 50 centers that answered the questionnaire, 48% performed more than 300, while 36% between 100 and 300 procedures per year as presented in Table 1. Among the 50 centers, 14 (28%) used RM, of which 57.1% for more than 5 years, while 28.6% introduced RM in the last 1–5 years. The primary form of RM utilization was an addition to the conventional approach, as 50% of centers maintained the routine schedule of IPEs, and 42.9% of centers prolonged the periods between the consecutive IPEs if the patient was monitored remotely. Only in one center, RM was used as an equivalent of the conventional approach and patients did not present for routine IPEs. In 72% of centers, RM was not used. The primary reasons for not implementing RM were the feasible generation of additional work burden (94.4%) and lack of RM reimbursement (88.9%), while the other reasons including uncertainties from the legal perspective or no scientific evidence evidently
supporting RM were chosen much less frequently. Finally, 58.1% of respondents declared that their centers would introduce RM when its reimbursement was introduced, while 25.8% stated lack of such will.

Although the IN-TIME randomized trial, as well as the TRUECOIN meta-analysis, which included IN-TIME and two other large randomized trials, demonstrated the survival benefit of daily RM transmissions over conventional IPEs, the data regarding the improvement of outcomes with RM are conflicting [3, 4]. In Poland, the randomized trials demonstrated a reduction in the combined endpoint of all-cause mortality and hospitalization due to cardiovascular reasons in patients with implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy-defibrillator (CRT-D) monitored remotely [5], while in another single-center trial, the number of hospitalizations due to progression of HF and all-cause death in patients with CRT has been reduced with the use of multiparameter RM [6]. Therefore, it can be assumed that with the introduction of more advanced algorithms and technologies, including the possibility of connecting the device parameters with patients’ smartphones instead of the presently used transmitters, the number of patients monitored remotely might increase.

Nonetheless, the results of the European Heart Rhythm Association (EHRA) survey conducted in 2015 demonstrated that in 43 centers that responded to the questionnaire, RM was available in 74% of patients with ICD, 69% of patients with CRT, and only 22% of patients with a pacemaker [7]. In our survey, which has not assessed the type of devices, RM was not used in 72% of centers, with its most frequent causes being the generation of additional work burden and lack of RM reimbursement. It has been demonstrated that the mean (standard deviation [SD]) annual time burden for every patient monitored remotely is approximately 1.1 (0.15) hours, and in the recent analysis of the large cohort, more than 50% of patients transmitted at least 1 alert transmission during one year period [8, 9]. Therefore, with no doubt, in the case of RM introduction, there is a great need to create dedicated facilities with established workflows to effectively monitor the patients and properly identify those in the greatest need for a rapid clinical reaction.

In 2018, the Polish Agency for Health Technology Assessment and Tariff System (AOTMiT) has positively recommended the reimbursement of RM in patients with ICD or CRT-D, giving the green light for wider adoption of RM in the Polish electrotherapy facilities [10]. However, since that date, no reimbursement has been introduced, which as indicated in our survey is one of the most important obstacles for RM implementation. The results from the SILCARD registry
demonstrated that during the three-year follow-up, the RM of patients with ICD and CRT-D resulted in a median cost reduction of 33.5%, being more prominent in patients with a CRT-D \( (P < 0.001) \) [11]. In the Health Technology Assessment report of the Health Quality Ontario, the estimated cost reduction with the use of RM could be approximately $14 million during the first five years of RM [12]. Therefore, apart from the probable improvement of the patients’ outcomes, reimbursement and wide adoption of RM could result in large savings for the national healthcare provider.

The primary limitation of our study is that it reflects the experiences of an excerpt of the overall number of electrotherapy facilities in Poland, as only 50 centers responded to the survey. Moreover, lack of division into types of devices prohibits generalizing the data to different device types, which is of importance as the frequency of remote transmissions, and the contents of the alert transmissions could vary depending on the type of the device, therefore generating different burdens of work for the monitoring centers. Finally, the manuscript describes the overall utilization of RM in the Polish electrotherapy facilities, however, the detailed characteristics of the motivation for RM introduction were not evaluated. For instance, in some facilities RM could have been introduced as a result of device recall, therefore the decision of RM introduction could not have been based solely on the willingness of the facility to introduce RM, but the necessity to introduce more active monitoring of the possibly malfunctioning device.

In conclusion, our study demonstrates that only a minority of centers in Poland use RM of patients with CIEDs, and the primary barriers for its wider implementation are the generation of additional work burden and lack of RM reimbursement.

**Supplementary material**

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

**REFERENCES**


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Table 1. The answers to the survey regarding the use of RM in patients with CIEDs

<table>
<thead>
<tr>
<th>Question</th>
<th>Number, n (%) of total n = 50, if not indicated differently</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of RM of CIEDs within the facility:</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14 (28)</td>
</tr>
<tr>
<td>No</td>
<td>36 (72)</td>
</tr>
<tr>
<td>Duration of using RM</td>
<td>More than 5 years</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>1-5 years</td>
</tr>
<tr>
<td></td>
<td>Less than 1 year</td>
</tr>
<tr>
<td>The form in which RM is used</td>
<td>Patients attending IPEs as often as without RM</td>
</tr>
<tr>
<td></td>
<td>Patients attending IPEs visits less frequently than without RM</td>
</tr>
<tr>
<td></td>
<td>Patients not attending FU visits</td>
</tr>
<tr>
<td>Reasons for not using RM (may be more than one)</td>
<td>Lack of reimbursement</td>
</tr>
<tr>
<td></td>
<td>Uncertainties from the legal point of view</td>
</tr>
<tr>
<td></td>
<td>Generation of additional work burden</td>
</tr>
<tr>
<td></td>
<td>Unawareness of RM possibility</td>
</tr>
<tr>
<td></td>
<td>Lack of sufficient evidence supporting RM</td>
</tr>
<tr>
<td>Number of electrotherapy procedures (implantations/replacements/lead extractions) performed per year</td>
<td>More than 300</td>
</tr>
<tr>
<td></td>
<td>From 100 to 300</td>
</tr>
<tr>
<td></td>
<td>Less than 100</td>
</tr>
<tr>
<td>If reimbursement is introduced in Poland will RM be implemented in your center? (for centers not using RM)</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Maybe</td>
</tr>
</tbody>
</table>

Abbreviations: CIED, cardiac implantable electronic device; IPE, in-person examination; RM, remote monitoring