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ORIGINAL ARTICLE

# The benefits of remote monitoring in long-term care for patients with implantable cardioverter-defibrillators

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**Abstract**

**OBJECTIVE:** The increasing number of patients with implantable cardiac devices raises the need for more efficient outpatient follow-up care. Due to technological progress in communication and transmission systems and in the implantable devices themselves, telemonitoring can be widely used as an important part of care for patients and devices. Our objective was to evaluate the benefits of continuous remote monitoring using the BIOTRONIK Home Monitoring® (HM) system compared to standard outpatient follow-ups.

**METHODS:** 198 patients with single- or dual-chamber implantable cardioverter-defibrillator (ICD) implanted for primary or secondary prevention of sudden cardiac death were randomized into a group of patients followed through standard outpatient visits ( HM–) and a group telemonitored by the HM system (HM+). Planned and emergency visits, ICD-related hospitalizations, and delivered shocks and their appropriateness were evaluated in the respective groups.

**RESULTS:** A significant reduction was achieved in the number of planned (by 48%, $p<0.001$) and total visits (by 45%, $p<0.001$) during a three-year evaluation. A comparable number of patients experienced one or more shocks. Mortality rates were equivalent, as was the number of patients hospitalized in relation to their ICD. However, there was a significant reduction in the number and proportion of inappropriate shocks delivered in the HM+ patient group: by 80% ($p=0.002$) in outpatient follow-up care and by 90% ($p<0.001$) when multiple shocks requiring hospitalization were included.

**CONCLUSIONS:** The HM system was an effective and safe method of follow-up in patients with an implanted ICD. Remote monitoring reduces the number of outpatient visits and inappropriate shocks.

**Abbreviations:**

| | |
|---|---|
| ATP | - antitachycardia pacing |
| CRT | - cardiac resynchronization therapy |
| CRT-P | - cardiac resynchronization therapy – pacing function only |
| CRT-D | - cardiac resynchronization therapy with cardioverter-defibrillator |
| EMI | - electromagnetic interference |
| EOS | - end of service life of the implantable device |
| ERI | - elective replacement interval (device replaced due to near-end of battery life) |
| ESC | - European Society of Cardiology |
| HM | - Home Monitoring |
| HRS/EHRA | - Heart Rhythm Society/European Heart Rhythm Association |
| ICD | - implantable cardioverter-defibrillator |
| IHD | - ischemic heart disease |
| MI | - myocardial infarction |
| PCI | - percutaneous coronary intervention |
| PM | - pacemaker |
| SVT | - supraventricular tachycardia |
| VT | - ventricular tachycardia |

## INTRODUCTION

In recent years, European countries have witnessed a substantial increase in the number of patients with implanted devices. It is estimated that approximately 950 implanted pacemakers (PM), 150 implantable cardioverter-defibrillators (ICD), 25 cardiac resynchronization therapy pacemaker systems (CRT-P), and 85 CRT and ICD combinations (CRT-D) are required annually per million inhabitants of the economically developed European countries (Eucomed 2010). This represents approximately 470,000 PMs and 74,000 ICDs every year for a population of about 500 million.

An expert consensus recommends regular outpatient monitoring visits with a comprehensive inspection of the device every 3 to 6 months and even more frequently immediately following implantation and again towards the end of the device service life (Ricci *et al.* 2008; Wilkoff *et al.* 2008). These inspections should include an assessment of technical functionality and system integrity and a specific device programming with respect to the patient's clinical status. Implantable devices generally have four functions (based on the type): cardiac pacing, data storage (Holter functions, episode recordings including intracardiac electrograms), arrhythmia detection, and arrhythmia treatment (antitachycardia pacing-stimulation /ATP/ and shock therapy). All these functions are valuable for monitoring and treating patients. However, clinically relevant information needs to be obtained in a timely manner and correctly assessed in order to enable early intervention when needed. Periodic outpatient visits do not allow this due to a lack of continuity.

The aim of our study was to assess the benefits of remote continuous monitoring of a group of patients with an implanted ICD using the BIOTRONIK Home Monitoring® system (BIOTRONIK SE & Co. KG, Berlin, Germany) with respect to the number of scheduled and urgent outpatient clinic visits, the number of ICD-associated hospitalizations, the number of shock therapies delivered by the device and their appropriateness, and the overall effectiveness of the process.

## MATERIAL AND METHODS

*Patient sample and methods*

A prospective evaluation was made of patients indicated for a single-chamber or dual-chamber ICD implantation, relative to primary or secondary prevention, according to the guidelines of the European Society of Cardiology (Zipes *et al.* 2006). The patients were recruited from a single center in 2008 and 2009, and were randomized such that one group received active telemonitoring, i.e. the Home Monitoring® (HM) service run by BIOTRONIK (HM+) while the second group did not receive the service (i.e. the service was disabled or inaccessible) ( HM–).

Patients were randomized using the sealed envelope system. All HM+ patients received a Biotronik ICD with the active Home Monitoring function (HM). HM– patients received either BIOTRONIK ICD with the HM function inactivated (16%) or were implanted with an ICD from a different manufacturer (84%), in which case telemonitoring was not available; however, audible alarms were set to be active, if this option was available for the device (35%). Patients were subsequently monitored for at least 36 months so that all relevant events could be recorded.

ICD programming was done in accordance with the recommendations of the system manufacturer in patients with primary prevention indications. In patients with secondary prevention and in case of programmed ventricular stimulation, the programming was adjusted according to the documented ventricular arrhythmia. Implant functions, including Holter monitor function analysis, were verified in all patients shortly after implantation (24–72 hours) and then again 1 month later. During the follow-up visits, system functionality, the need for re-programming of brady- or tachycardic settings, identification of ventricular arrhythmic episodes requiring ICD intervention (anti-tachycardic pacing or shock), and appropriately or inappropriately administered shocks and their frequency were all assessed.

HM– patients were monitored through outpatient visits every 3 and then 6 months according to the current recommendations. In the HM+ group, other than yearly visits were supplemented with continuous telemetric monitoring by the HM system initiated immediately after implantation. HM system reports were analysed daily by a physician during working days and office hours. The potential need for a therapeutic intervention was assessed and the patient contacted by phone if needed. If the patient was inaccessible, his or her physician was contacted and requested to clinically assess the patient, to modify medications, or to refer the

patient to a cardiac centre for ICD re-programming, change or modification of pharmacotherapy, catheter ablation planning or system revision.

Additional visits were made in both groups upon request from referring outpatient specialists, regional healthcare institutions or the patients themselves, and in cases where a significant clinical event was identified by the HM system (e.g. multiple appropriate or inappropriate ICD therapies, unsatisfactory technical parameters measured by the system and requiring an intervention or, alternatively, suspected system malfunction, etc.).

Longitudinal monitoring included the number of planned and additional visits, frequency of shocks and their appropriateness in both groups, and the number and duration of hospitalizations related to the implanted ICD (repeated appropriate or inappropriate shock therapies, other arrhythmias requiring treatment during hospitalization, system malfunction, and local complications in the chamber (i.e. lead dislodgement, sudden pacing threshold increase or signal amplitude decrease) or, alternatively, death. The number of patients hospitalized for new onset or exacerbated heart failure or hospitalization for non-cardiac reasons were not assessed because mainly single-chamber ICDs do not offer enough indirect parameters for heart failure management unlike CRT-Ds.

*Statistical analysis*

Continuous variables are presented as a mean±standard deviation; events are presented as absolute numbers with percentages. Continuous variables were evaluated with an F-test for analysis of variance and Student's t-test. Categorical variables were evaluated using the $\chi^2$ test or Fisher's exact test, where appropriate. The *p*-values <0.05 were considered statistically significant.

## RESULTS

The study involved 198 patients (160 men and 38 women) with a mean age of 67±12 years. A total of 152 patients (77%) had ischemic heart disease (IHD), of which 124 (82%) had had a previous myocardial infarction (MI), 95 (63%) had undergone at least one percutaneous coronary intervention (PCI), 51 (34%) had undergone surgical revascularization of the myocardium, and 16 (11%) also had dilated cardiomyopathy. 29 patients (15%) had no evidence of organic heart

**Tab. 1.** Main clinical characteristics of the patient group.

| | HM+ | HM– | Total | *p*-value |
|---|---|---|---|---|
| **Number of patients** | 97 | 101 | 198 | |
| **Men** | 81 (83.5%) | 79 (78.2%) | 160 (80.8%) | NS |
| **Women** | 16 (16.5%) | 22 (21.8%) | 38 (19.2%) | NS |
| **Age** | 66±11 | 68±12 | 67±12 | NS |
| **The presence of ischemic heart disease** | 75 (77.3%) | 77 (76.2%) | 152 (76.8%) | NS |
| **Previous myocardial infarction** | 62 (82.7%) | 62 (80.5%) | 124 (81.6%) | NS |
| **Percutaneous coronary intervention** | 49 (65.3%) | 46 (59.7%) | 95 (62.5%) | NS |
| **Coronary bypass** | 26 (34.7%) | 25 (32.5%) | 51 (33.6%) | NS |
| **Ischemic cardiomyopathy** | 7 (9.3%) | 9 (11.7%) | 15 (7.6%) | NS |
| **No evidence of organic heart disease** | 17 (17.5%) | 12 (11.9%) | 29 (14.6%) | NS |
| **Dilated cardiomyopathy** | 5 (5.2%) | 10 (9.9%) | 15 (7.6%) | NS |
| **History of heart failure** | 26 (26.8%) | 33 (32.7%) | 59 (29.8%) | NS |
| **Arterial hypertension** | 70 (72.2%) | 68 (67.3%) | 138 (69.7%) | NS |
| **Diabetes mellitus** | 48 (49.5%) | 37 (36.6%) | 85 (42.9%) | NS |
| **History of cerebrovascular event** | 14 (14.4%) | 14 (13.9%) | 28 (14.1%) | NS |
| **Chronic obstructive pulmonary disease** | 19 (19.6%) | 17 (16.8%) | 36 (18.2%) | NS |
| **Renal insufficiency** | 14 (14.4%) | 11 (10.9%) | 25 (12.6%) | NS |
| **Sinus rhythm** | 66 (68.0%) | 64 (63.4%) | 130 (65.7%) | NS |
| **Paroxysmal/persistent atrial fibrillation** | 26 (26.8%) | 32 (31.7%) | 58 (29.3%) | NS |
| **Permanent atrial fibrillation** | 5 (5.2%) | 5 (5.0%) | 10 (5.1%) | NS |
| **QRS width before implantation (ms)** | 108±17 | 114±20 | 111±19 | NS |
| **NYHA functional class** | 1.8±0.9 | 1.9±0.9 | 1.8±0.9 | NS |
| **Left ventricular ejection fraction (%)** | 41±15 | 39±14 | 40±15 | NS |

disease. Simple dilated cardiomyopathy was identified in 15 patients (8%). At least one episode of acute decompensated chronic heart failure was present in 59 (30%) patients. A total of 130 patients (66%) had sinus rhythm, 58 patients (29%) had paroxysmal or persistent atrial fibrillation or atrial flutter, and 10 (5%) had permanent atrial fibrillation. The mean ejection fraction in both groups was 40±15%, the mean NYHA functional class was 1.8±0.9. No significant differences between the groups (HM+ vs. HM–) were identified for any of the above-stated characteristics, including comorbidities (Table 1).

An ICD was implanted for primary prevention of sudden cardiac death in 75 patients (38%) and as secondary prevention in 123 patients (62%). Patients in secondary prevention presented with ventricular fibrillation (37%), persistent ventricular tachycardia (49%), and syncope with suspected cardiogenic etiology and inducible malignant ventricular arrhythmia during electrophysiological assessment (14%).

The only significant difference was observed between single and dual-chamber ICDs, with a higher proportion of dual-chamber devices in the HM– group (25% vs. 10% for HM+, $p$=0.01) as a result of a decision of cardiac pacing specialist prior to surgery. The basic indications for implantation are presented in Table 2.

The mean duration of patient monitoring was 1116±434 days without a significant difference between groups. A total of 1,113 outpatient ICD inspections were performed over study period. There were 716 (63%) outpatients visits in the HM– group and 397 (36%) in the HM+ group. Of the overall number of visits, 1053 (95%) were planned: 692 (66%) in the HM– group and 361 (34%) in the HM+ group. This is approximately 7.1±3.0 visits per patient in the HM– group vs. 4.3±1.8 visits in the HM+ group, representing a 45% reduction in the total number of visits in the HM+ ($p$<0.001). Similarly, for planned visits there was a 48% reduction in the HM+ group ($p$<0.001), i.e. 3.7±1.4 planned visits per patient over the follow-up period in the HM+ group vs. 6.8±3.0 visits in the HM– group.

Of the total of 60 additional outpatient visits (i.e. 5% of the total number of visits), 24 (40%) were in the HM– group and 36 (60%) in the HM+ group ($p$=0.12), 22 (61%) of which were initiated by the cardiac centre based on received and analysed reports from the HM system. The data are presented in Figure 1. Table 3 shows reasons for additional visits and their frequency in the HM– and HM+ groups and reasons for additional visits in the HM+ group due to physician-scheduled visits based on events reported by the HM system.

The HM– patients received a total of 62 interventions to correct their clinical status or the technical status of their ICD with respect to ICD reprogramming, changes of pharmacotherapy, or system revision. There were 38 such interventions in the HM+ group, which was significantly lower ($p$=0.049).

In the HM+ group, 29 patients (30%) died over the period of follow up, and 1 patient was lost to follow-up. In the HM– group, 28 (28%) patients died, 3 patients

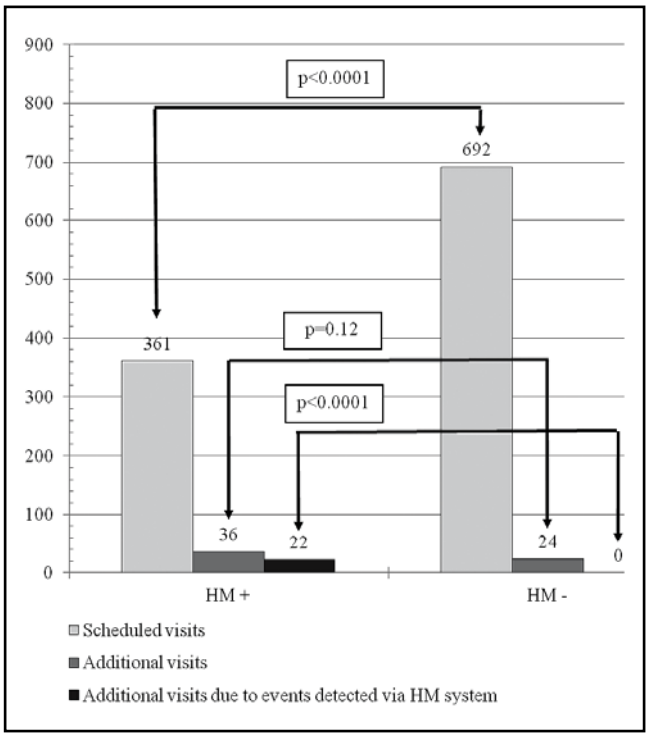


**Fig. 1.** Comparison of outpatient visits in the patient cohort followed by standard outpatient visits (HM–) and the group telemonitored by the Home Monitoring system (HM+).

**Tab. 2.** Indications for ICD implantation.

| | HM+ | HM– | Total | *p*-value |
|---|---|---|---|---|
| **Primary prevention** | 38 (39.2%) | 37 (36.6%) | 75 (37.9%) | NS |
| **Secondary prevention** | 59 (60.8%) | 64 (63.4%) | 123 (62.1%) | NS |
| **Ventricular fibrillation** | 23 (39.0%) | 23 (35.9%) | 46 (37.4%) | NS |
| **Persistent ventricular tachycardia** | 30 (50.8%) | 30 (46.9%) | 60 (48.8%) | NS |
| **Cardiogenic syncope with inducible ventricular arrhythmia** | 6 (10.2%) | 11 (17.2%) | 17 (13.8%) | NS |
| **Single-chamber ICD implanted** | 87 (89.7%) | 76 (75.2%) | 163 (82.3%) | 0.01 |
| **Dual-chamber ICD implanted** | 10 (10.3%) | 25 (24.8%) | 35 (17.7%) | 0.01 |

**Tab. 3.** Reasons for additional visits in the HM–/HM+ groups and physician-scheduled early visits in the HM+ group based on events reported by the HM system.

| | Indication/reason for the visit | Number | Proportion |
|---|---|---|---|
| **HM– additional visits** | Shock therapy | 9 | 37.5% |
| | Dyspnoea/Heart failure | 5 | 20.8% |
| | Syncope | 3 | 12.5% |
| | Injury/Other reason | 3 | 12.5% |
| | Suspected stimulation disorder | 2 | 8.3% |
| | Bradycardia/Tachycardia | 1 | 4.2% |
| | Audio alarm from the device | 1 | 4.2% |
| **Total** | | 24 | 100.0% |
| **HM+ additional visits** | Shock therapy | 6 | 42.9% |
| | Syncope | 3 | 21.4% |
| | Dyspnoea/Heart failure | 2 | 14.3% |
| | Bradycardia/SVT | 2 | 14.3% |
| | Pain following implantation | 1 | 7.1% |
| **Total** | | 14 | 100.0% |
| **HM + initiated visits** | Inappropriate detection of SVT/VT | 6 | 27.3% |
| | Detected high stimulation threshold | 5 | 22.7% |
| | VT accumulation with shock | 3 | 13.6% |
| | Newly detected atrial fibrillation | 3 | 13.6% |
| | Detected low sensing | 2 | 9.1% |
| | Detection of ERI/device reset | 2 | 9.1% |
| | Detection of EMI | 1 | 4.6% |
| **Total** | | 22 | 100.0% |

Abbreviations: EMI, electromagnetic interference; ERI, elective replacement interval (device replaced due to near-end of battery life); SVT, supraventricular tachycardia; VT, ventricular tachycardia

were lost to follow-up, and 1 patient underwent heart transplantation ($p$=NS). Twenty patients in the HM+ and 21 patients in the HM– group (21%, $p$=NS) were hospitalized for reasons related to their implanted ICD. Of these, 4 patients in the HM+ and 5 in the HM– group were hospitalized for an arrhythmic storm. One patient in the HM– group was hospitalized for defibrillation lead malfunction with an accumulation of inappropriate shocks and subsequent depletion of the ICD power source. The ICD power source was depleted prematurely, i.e. before expected average lifetime, in 4 patients (1 HM+ and 3 HM–) and the ICD had to be reimplanted; a device reset or malfunction (ICD software error reported during interrogation) was identified in 3 patients (1 HM+ and 2 HM–). Table 4 provides an overview of these data.

During the follow-up period, at least 1 shock was administered to 50 of the 198 patients, i.e. 25% of the sample (21, i.e. 22% of the HM+ group and 29, i.e. 29% of the HM– group, $p$=0.25). Shocks were appropriate in 14 (14%) HM+ patients and 14 (14%) HM– patients ($p$=0.91) and inappropriate in 6 HM+ patients (6%) and 12 (12%) HM– patients ($p$=0.16). A total of 4 patients (1 HM+ and 3 HM–, $p$ = 0.33) received appropriate as well as inappropriate ICD intervention (Figure 2).

Outpatient monitoring of the 50 patients with at least one shock therapy identified 35 appropriate shocks in the HM+ group and 54 appropriate shocks in the HM– group, and 11 inappropriate shocks in the HM+ group and 55 inappropriate shocks in the HM– group. Considering outpatient monitoring only, the frequency of inappropriately administered shocks in the HM+ group was by 80% lower and there was a mean of 2.3±1.2 administered shocks per one patient, representing 76% appropriateness of therapy compared to 3.8±6.5 shock per HM– patient and only 50% appropriateness ($p$=0.002) (Figure 3).

Considering repeated shocks requiring hospitalization (including hospitalization for arrhythmic storms and lead malfunction), there was a total of 61 appropriate and 13 inappropriate shock therapies in the HM+ group and 189 appropriate and 133 inappropriate

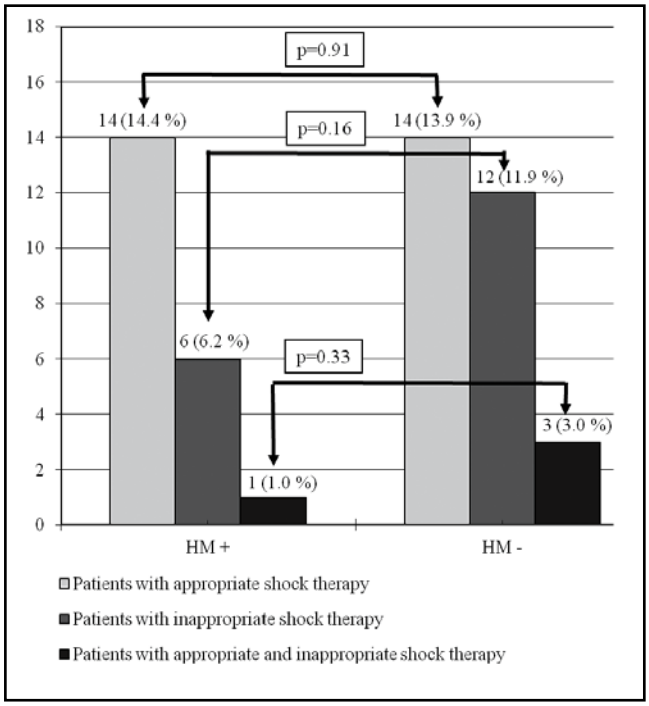


**Fig. 2.** Number of patients with shock therapy during the monitoring period in the patient cohort followed by standard outpatient visits (HM–) and the group telemonitored by the Home Monitoring system (HM+).

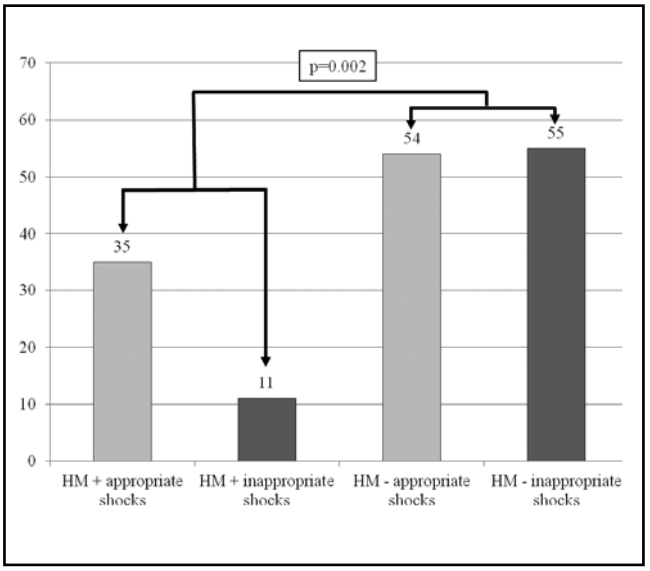


**Fig. 3.** Number of shocks identified during outpatient monitoring. HM+ group telemonitored by the Home Monitoring system, HM– group monitored with standard out-patient visits.

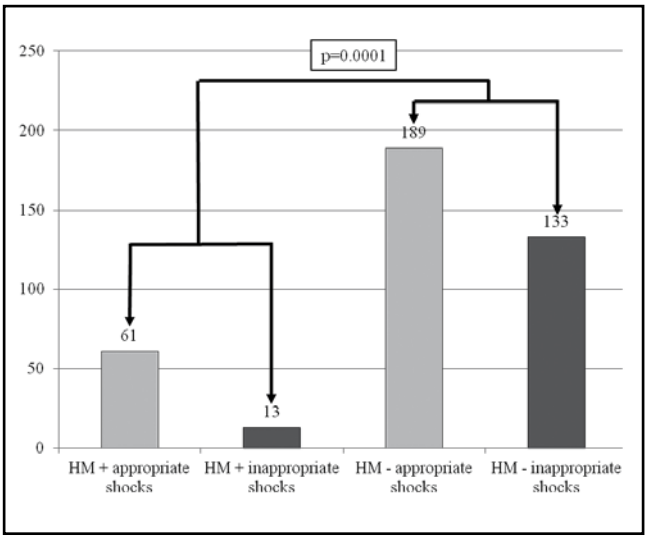


**Fig. 4.** Number of shocks identified during hospitalization, including hospitalizations due to arrhythmic storms and lead malfunction. HM+ group telemonitored by the Home Monitoring system, HM– group monitored with standard out-patient visits.

shocks in the HM– group. This equates to 18% of shocks being inappropriate in the HM+ group compared to 41% in the HM– group ($p<0.001$), corresponding to a 68% reduction of appropriate and 90% reduction of inappropriate shocks in the HM+ group.

Subtracting the shocks administered due to arrhythmic storms (4 HM+ patients and 5 HM– patients) and during defibrillation lead malfunction (1 HM– patient), there were 42 appropriate and 13 inappropriate shocks in the HM+ group and 64 appropriate and 77 inappropriate shocks in the HM– group. This equates to 24% of shocks being inappropriate in the HM+ group and 55% in the HM– group ($p<0.001$) and a 34% reduction of appropriate shocks and an 80% reduction of inappropriate shocks in the HM+ group (Figure 4).

**Tab. 4.** Number of patients hospitalized due to the implanted ICD, mortality, and serious events during follow up.

| | HM+ | HM– | Total | *p*-value |
|---|---|---|---|---|
| **ICD-related hospitalizations** | 20 (20.6%) | 21 (20.8%) | 41 (20.7%) | NS |
| **Mortality** | 29 (29.9%) | 28 (27.7%) | 57 (28.8%) | NS |
| **Arrhythmic storm** | 4 (4.1%) | 5 (5.0%) | 9 (4.5%) | NS |
| **Defibrillation lead malfunction** | 0 (0.0%) | 1 (1.0%) | 1 (0.5%) | NS |
| **Device error; ICD reset** | 1 (1.0%) | 2 (2.0%) | 3 (1.5%) | NS |
| **Premature ICD battery depletion (ERI, EOS)** | 1 (1.0%) | 3 (3.0%) | 4 (2.0%) | NS |

Abbreviations: EOS, end of service life of the device; ERI, elective replacement interval (device replaced due to near-end of battery life)

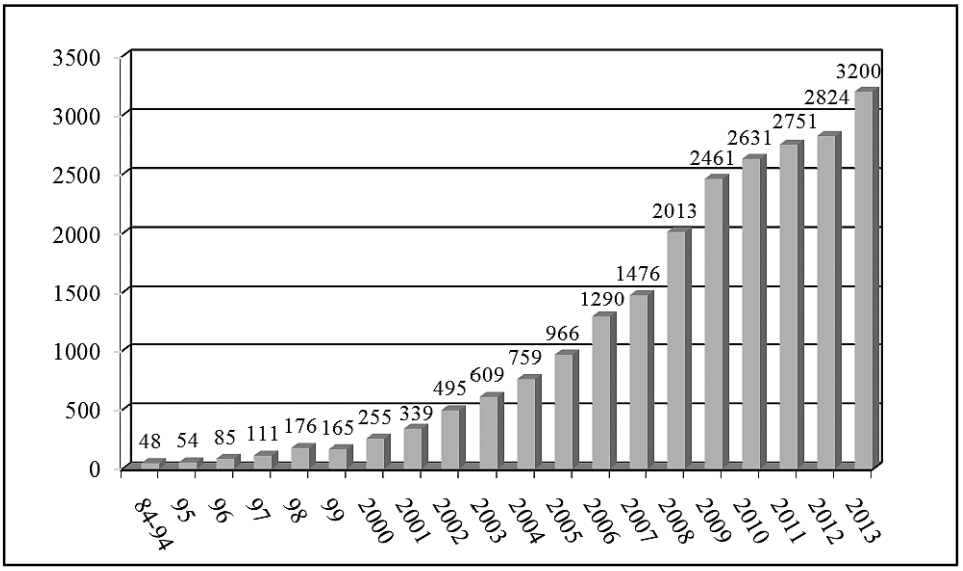


**Fig. 5.** Number of implanted ICDs in the Czech Republic between 1984 and 2013 – adapted from National ICD Register (Czech Republic), 2013.

## DISCUSSION

In general, telemonitoring means remote health status monitoring. Technological developments and the availability of internet connections via analogue lines and mobile systems have facilitated the use of telemetry systems in several areas of health care. These certainly include cardiology and systems for monitoring patients with implantable pacemakers, cardioverter-defibrillators and cardiac resynchronization therapy systems. The majority of modern implants are able to automatically conduct internal checks of system integrity and assess stimulation parameters, which would otherwise be performed manually in specialized outpatient clinics. Telemetry systems and implanted wireless communication devices enable the transfer of diagnostic and system status data and an almost complete record of patient information that would normally be obtained during outpatient visits. These transmissions can be fully automatic and do not require any intervention by the patient, thus ensuring continuity of the clinical and technical data.

The Home Monitoring® (BIOTRONIK SE & Co. KG, Berlin, Germany) telemetric monitoring system is a fully automatic telemonitoring system implanted in some BIOTRONIK cardiac implants. The system transmits data obtained from the implant, similar to the data obtained during standard outpatient visits, via coded transmissions through the GSM mobile network to the Home Monitoring Service Center. These reports are decoded and made available within minutes via a secure web interface to a physician who is also able to set parameters for event reporting via SMS, fax, or e-mail.

Telemetry data are wirelessly transmitted to the implant unit in a form of periodic and planned data transfers, usually at night and without the need for patient participation. Additional transfers can also be conducted that are initiated by pre-defined clinical and technical events, such as arrhythmic episodes, accumulations or failures of antiarrhythmic therapies, possible integrity defects, and the approaching end of the service life of the system (Lazarus 2007, Nielsen *et al.* 2008). For safety reasons, telemetry systems do not yet allow reprogramming of the devices, but they do enable notification transfer and inform the patient to contact a cardiology centre.

We have witnessed a substantial increase in the number of patients with implanted devices in the developed countries of Europe over the last decade. There was a 20–25% annual increase between 2007 and 2009 and a 5–10% annual increase between 2009 and 2013 in the number of ICD procedures in the Czech Republic (National ICD Register 2013). The steadily increasing population of patients with ICDs demands increased patient monitoring in comprehensive cardiovascular centers (Figure 5). The Department of Cardiology, Hospital České Budějovice became such a center in 2008, establishing, among other things, a geographic region for new ICD patients with a substantial need for secondary preventive implantations during the first 2 years of operation. This generated a high proportion, almost two-thirds of patients with secondary preventive indications of sudden cardiac death in our sample.

The expert consensus of the Heart Rhythm Society/ European Heart Rhythm Association (HRS/EHRA) states that the assessment of a patient in a clinic is required at least once a year. If the patient is stable and device programming is not anticipated, or if a benefit is expected from the early detection of a change in the patient's condition or a device malfunction, remote monitoring could replace other clinical visits during this 12-month period; this period normally has an additional 2 to 3 outpatient visits (Wilkoff *et al.* 2008, Dubner *et al.* 2012).

A follow up of nearly 1,300 patients with implanted ICDs as part of the randomized TRUST study showed the effect of the HM telemonitoring system in reducing planned visits. The total number of visits was reduced by 42% in the active telemonitoring arm and the number of planned visits was reduced by 54% without any effect on morbidity (Varma *et al.* 2008, Ricci *et al.* 2009). This is in line with the significant findings in our study which are that the telemetric monitoring system reduced the total number of visits by 45% and the number of planned visits by 48% in the HM+ group compared to the HM– group. The different rate of reduction of the total and planned visits can be explained by a significant 50% increase in the number of additional visits in the HM+ compared to HM– group. However, there was a minimal increase in the absolute number of additional visits (12 additional visits only) in the HM+ group and, therefore, additional visits contributed to only about 5% to the total number of visits. The higher number of additional visits in the HM+ group was due to physician-scheduled visits based on events reported by the HM system, which account for nearly 2/3 of the additional visits conducted in this group.

Randomized clinical and observational studies suggest 62–100% appropriateness of the additional visits that were made based on the HM system reports with respect to clinical and technical interventions (Varma *et al.* 2010). This also applies to our study, where all of the HM–initiated additional visits in the HM+ group led to an intervention to correct the patient's condition, ICD technical status or settings, or both. Most frequently, the device was reprogrammed according to the identified arrhythmic events based on an intracardiac electrocardiogram (IEGM) reading or the patient's pharmacotherapy was changed. Rarely, the condition required hospitalization or, alternatively, a revision of the system with a reposition or reimplantation of the ICD leads. The ability of the system to detect asymptomatic clinical and technical events in the HM+ group through telemonitoring (detection of an increased stimulation threshold, reduced signal, asymptomatic arrhythmia, or system malfunction) is likely to be responsible for the different spectrum of indications for additional visits in the HM+ and HM– groups.

A similar reduction in planned visits was observed in the REFORM study, where the once a year monitoring of patients indicated for ICD implantation in primary preventive care (MADIT II patients) was supplemented with a HM system did not increase the frequency of unplanned visits, the number of hospitalizations, or patient mortality. Similarly, our patient sample did not show a significant difference between groups either in terms of mortality over the observed period (29%, with an average mortality of 9.4% per year) or in the number of patients hospitalized for ICD-related reasons (21%). Analysis of subgroup of patients who died during observation revealed higher average age (72±10 years vs. 67±12 years in the whole sample), comparable left ventricular systolic function at the time of implantation (ejection fraction 39%±14% vs. 40%±15%) but its significant drawdown during one year follow up evaluation (ejection fraction 25%±13% vs. 38%±15%) in the subgroup, thus with a substantial progression of heart failure.

We thus can report a comparable safety profile in patients with the HM system, despite the reduced frequency of outpatient visits. On the other hand, the HM system provides the benefit of more timely identification of clinical and technical events, as shown by the TRUST study, where the time from the development of a symptomatic or asymptomatic event to its evaluation by a physician was significantly reduced (<2 days vs. 36 days; $p<0.001$) (Dubner *et al.* 2012).

Different studies report different proportions of inadequate ICD therapies (8–41%) delivered generally due to clinical (most frequently an incorrect discrimination of supraventricular tachycardia in single-chamber ICDs, T-wave oversensing, and QRS double counting) and technical (ICD system integrity issues, lead dislocation, electromagnetic interference events) causes (Theuns *et al.* 2005). The increasing number of primary preventive indications for ICD implantation is associated with the decreasing number of appropriately administered shocks. The HM system seems to be an effective tool for early detection of administered as well as suspended inappropriate therapies and thus contributes to their prevention and elimination (Fauchier *et al.* 2005, Res *et al.* 2006). During the follow up, at least one shock was delivered to a total of 25% of our patient sample. Of these, 56% received appropriate shocks, 36% inappropriate, and 8% received appropriate and inappropriate shocks. There was no significant difference in the number of patients with at least one shock in both monitored groups and only a trend towards fewer, by 50%, patients with inappropriately administered shocks in the HM+ group.

A more detailed assessment of the number and proportion of appropriate and inappropriate shock therapies showed a significantly lower number and proportion of inappropriately delivered shocks in patients monitored and managed by the telemonitoring system. During outpatient follow-up visits, patients in the HM+ group received an average of 2.6 shocks per patient, of which 77% were appropriate, compared to 6.3 shocks per patient in the HM– group, of which 54% were appropriate. This represents an 80% reduction of inappropriate shocks. When repeated shocks requiring hospitalization were also counted, a reduction in the number and proportion of inappropriate shocks in the HM+ group compared to HM– group was even more pronounced and reached 90%. The difference in the number and proportion of shocks in this group was greater due to an accumulation of appropriate shocks in a few patients with an arrhythmic storm and one patient with defibrillation lead malfunction and an accumulation of inappropriate shocks.

Our previous data analysis, with a shorter follow up, showed a statistically significant reduction in the number of planned visits and in the total number of visits as well as a reduction in the proportion of inappropriate shocks in the HM+ group with a comparable number of patients who received shocks (with only a trend, which not reach statistical significance, towards a lower number of patients who received shocks in the HM+ group). We also observed similar mortality and hospitalization rates for ICD-associated events (Ošmera and Bulava 2011).

The ECOST study, presented at the European Society of Cardiology (ESC) Congress in 2011, confirmed, in agreement with the previous TRUST (Varma *et al.* 2008, Varma *et al.* 2010) and COMPAS (Mabo *et al.* 2012) studies, the safety of home monitoring compared to standard outpatient visits and showed that continual telemetric monitoring might reduce the number of patients with inappropriate shocks by 52% and reduce inappropriate shock-associated hospitalizations by 72%. At the same time, the frequency of ICD battery charging before a discharge was reduced by 76% with a significant impact on ICD battery service life and thus a significant economic impact in terms of an extended interval before system reimplantation (Guedon-Moreau *et al.* 2013). This is also in line with our observations that HM–assisted long-term monitoring of patients with ICD might safely reduce inappropriate shock therapies that lead to a reduced quality of life for patients and an increased ICD battery usage and which might also have a negative clinical and, in extreme situations, even life-threatening impacts through their proarrhythmic effects.

The Home Monitoring system complies with the requirements for the clinical application of a telemonitoring system, including high efficacy, clinical utility, continuity of monitoring, reliability, safety, and accessibility. Telemonitoring thus appears to be the most likely future standard of care for patients treated with implanted cardioverter-defibrillators and possibly also pacemakers. Monitoring with the Home Monitoring system is associated with a significant reduction in the number of planned visits with, at least, equivalent safety of care for patients with ICDs. The use of Home Monitoring leads to a reduction in the number of inappropriate shocks with a positive impact on patient quality of life and on the expected service life of the ICD systems.

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