Long-term patient acceptance of and satisfaction with implanted device remote monitoring

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Aims
To evaluate patients’ acceptance and satisfaction of the Home Monitoring (HM) remote control system after 1 year of follow-up by a self-made questionnaire (HM Acceptance and Satisfaction Questionnaire, HoMASQ) specifically designed for this purpose.

Methods and results
The HoMASQ contains 12 items designed to investigate five different aspects strictly connected to patient’s acceptence and satisfaction of remote monitoring: (i) relationship with their healthcare provider, (ii) easy of use of HM technology, (iii) related psychological aspects, (iv) implications on general health, and (v) overall satisfaction. Each item was rated on a five-point scale: from 0 to 4 with favourable responses score $\geq 2$. The theoretical maximum total score (the highest detected acceptance and satisfaction level) was 48. The HoMASQ was given to 119 patients followed by HM during the 1-year follow-up visit. Ninety-nine percent of all the administered questionnaire items were answered. The mean total score was $40.8 \pm 5.4$ with a mean percentage of favourable answers of $96.3 \pm 18.8\%$ (CI 95.2 – 97.2%). The mean scores for each of the five areas of the HoMASQ were: $3.0 \pm 0.9$ for relationship, $3.4 \pm 0.6$ for easy of use, $3.4 \pm 0.9$ for psychological aspects, and $3.4 \pm 0.8$ for clinical implication and overall satisfaction. Cronbach’s alpha for reliability of the HoMASQ was 0.73.

Conclusion
A high level of acceptance and satisfaction after 1-year remote control by HM was detected by the five-point scale HoMASQ, which showed a good internal reliability.

Keywords
Remote monitoring • Pacemaker • Implantable cardioverter defibrillator • Patient’s acceptance • Quality of life • Questionnaire

Introduction
Since 2000, when the first remote control system of implantable devices was introduced in clinical practice, the diffusion of this new technology has rapidly increased and it is now becoming the gold-standard for the follow-up of patients with pacemaker and implantable cardioverter defibrillator (ICD).1 During the last decade, several studies have been carried out to evaluate technical performance and clinical applications of implantable device remote control. Although safety, efficacy, and impact on standard care of remote control have been already demonstrated,2–7 few data on long-term patient acceptance and satisfaction are available.8–10 The patient point of view is of high interest and strongly condition- ing new technology implementation in clinical practice. As a matter of fact, remote monitoring is deeply changing the consistency and quality of relationship between caregivers and patients. In fact, when the remote control is applied, the patient is no more waiting for the next scheduled follow-up or symptoms to know if everything is fine or if something is going wrong in his clinical status or in technical device performance. He is aware that the clinical staff are continuously following him and that they will contact him in case of trouble. For these reasons, it is essential for the optimal use of this new technology to collect data on patient perception and perspective of the innovative symbiosis between remote control technology and new healthcare organization.

The aim of this study was to evaluate patient acceptance and satisfaction through a self-made questionnaire after 1 year of...
follow-up by using the Biotronik Home Monitoring® (HM) remote control technology (Biotronik GmbH & Co. KG, Berlin, Germany).

Methods

Home Monitoring feature and healthcare resource organizational protocol

Since 2006, all patients implanted in our institution with Biotronik devices have been followed as standard practice by HM technology. Technical features of HM technology as well as the organizational protocol used in our clinical practice have been previously described in detail. In brief, HM allows completely automatic and patient-independent diagnostic data transmissions on daily basis providing the patient with a mobile transmission unit (called CardioMessenger) connected to the GSM network. Although the CardioMessenger is portable, transmissions preferably occurred during night-time (as standard program setting). Therefore, patients were told to keep the transmitter close to the bed where they normally slept (so to let the HM transmissions take place while sleeping). Anyway, bringing the CardioMessenger with them during daily outdoor activities was allowed and left to his/her own preference. Dedicated nurses, expert in cardiac pacing and computer technology, play a key role in the organization for management of HM patients and data reviewing. Nurse duties include patient training and education on data transmitter functioning and on remote monitoring organization, website data entering, HM data and alert reviewing, critical case submission to the physician for clinical judgement, contacts with the patients, monitoring of patient compliance, and therapy benefits. Physician duties include informed consent submission, clinical judgement of critical cases, general supervision. Relationship with the patients are mainly kept by the nurses either in-person at enrolment or during in-hospital follow-up or by phone, in case of no transmission or in case of minor alert events.

Standard in hospital follow-up intervals have been doubled compared with the standard clinical practice: all patients had in person follow-up 1 month after implant and then every 6 months for ICD patients and once a year for pacemaker patients.

Questionnaire development and administration

We report the first experience with the administration of a self-made questionnaire designed to evaluate patients’ acceptance and satisfaction of implantable device remote control: the HM Acceptance and Satisfaction Questionnaire (HoMASQ). This is a self-made questionnaire developed by taking into account staff experience and patient interview or pilot testing was performed. Ninety-nine percent of HoMASQ items were answered by the patient during questionnaire filling.

Patients were asked to fill out the questionnaire focusing on five different aspects strictly connected to patient’s acceptance and satisfaction: (i) relationship with their healthcare provider at enrolment and during all the monitored period (two items), (ii) easy of use of HM at first utilization and during all the monitored period (two items), (iii) related psychological aspects (four items), (iv) implications on general health (two items), (v) overall satisfaction (two items). All items of HoMASQ (but one), allowed only one answer choosing among five options. For the question on the overall satisfaction, the patient was asked to confirm his/her intention to continue with HM remote control: possible answers were ‘Yes’, ‘No’, ‘I do not know’. Each item was rated on a five-point scale: from 0, strongly unfavourable, to 4, strongly favourable. An answer was considered favourable with a score ≥2. The total score for each patient was obtained by summing the rate of all items. To reduce a potential influence toward more favourable scores, some reversal items were included for which the response score was reversed before summing for the total score. As the HM transmitter is small and portable, an additional item was added to investigate if patients usually took their CardioMessenger with them during daytime outdoor activities. The HoMASQ was submitted to all patients implanted with HM devices during the 1-year follow-up visit. The nurse provided the patients with the HoMASQ asking them to return it filled in before leaving the hospital. There was no support or interaction between the nurse and the patient during questionnaire filling.

Statistical analysis

Normally distributed continuous variables were expressed as mean ± standard deviation. The reliability of the administered questionnaire was estimated by Cronbach’s alpha. A multiple linear regression model was studied by means of the ordinary least squared method, correlating each patient questionnaire total score with a number of clinical and demographic explanatory variables (age, gender, device, instruction level, job activity, and number of phone contacts or visits requested by HM). Rates and percentages were reported with 95% confidence interval (CI). Statistical significance was set at a level of P = 0.05.

Results

Patient characteristics

One hundred and nineteen patients (mean age 73 ± 11 years, 78 males) implanted with HM devices (95 Cylos DR-T pacemakers, 16 Lumos DR-T ICDs, and 8 Kronos LV-T or Lumax HF-T ICDs with cardiac resynchronization therapy) were asked to fill out the HoMASQ during the 1-year visit. Clinical characteristics and implant indications of patients are summarized in Table 1.

Educational level was elementary school in 44%, junior high school in 28%, high school in 20%, and university degree in 8%. With regard to the employment, 76% of patients were retired, 9% housewives, 8% employees, 5% self-employed workers, and 2% unemployed. Sixty-six percent of the patients declared to always leave the CardioMessenger at home, 13% to bring it with them seldomly, 3% sometimes, 6% often, and 11% always. During the first year of remote follow-up, 79 patients (66%) were contacted at least once by the nurse due to HM data review, whereas 40 patients (34%) did not require any contact because of normal device functioning and good clinical status.

Item scores and analysis

Ninety-nine percent of HoMASQ items were answered by the patients. In Figure 1, the average and standard deviation of the five-point scale mean scores are reported as grouped in the five areas of patient acceptance and satisfaction. Furthermore, the percentages of favourable answers (score ≥2) are given. The mean total score was 40.8 ± 5.4 (theoretical scale from 0 to 48) with a mean percentage of favourable answers of 96.3 ± 18.8% (CI 95.2 – 97.2%).
In Figure 2, the distribution of the collected answers within the five areas is shown.

Ninety-seven percent of patients defined their relationship with the referring nurse and physician as positive, both at the enrolment and during all the monitored period. Regarding the easy of use of transmitter, near all patients were able to activate the transmitter and to manage it during the follow-up.

Regarding items on psychological aspects, ~10% of the patients reported that this new technology influenced their daily activity, but only 5% of them considered the use of transmitter as a bother. Ninety-two percent of patients received a sense of security by the transmitter, whereas 8% did not.

Over 95% of patients considered HM to have a positive implication on their general health and 98% of patients were completely satisfied by remote monitoring and by how remote control healthcare service was organized. Finally, 110 patients (93.2%) claimed their intention to proceed with remote monitoring, 5 patients (4.3%) were doubtful about that, and only 3 patients (2.5%) did not appreciate remote monitoring as standard care and refused to go on with it.

**Regression analysis**

A multiple linear regression model was also studied including the total score for each patient as the dependent variable and age, gender, device, instruction level, job activity and contacts (phone

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**Table 1** Patient population clinical characteristics

<table>
<thead>
<tr>
<th>Pacemaker (n = 95)</th>
<th>ICD (n = 24)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>74.8 ± 8.4</td>
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<tr>
<td>Male (%)</td>
<td>62</td>
</tr>
<tr>
<td>Implant indication</td>
<td></td>
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<tr>
<td>Sick sinus syndrome</td>
<td>56 (59%)</td>
</tr>
<tr>
<td>Atrioventricular block</td>
<td>22 (23%)</td>
</tr>
<tr>
<td>Neurally mediated syncope</td>
<td>17 (18%)</td>
</tr>
</tbody>
</table>

**Figure 1** Score average, standard deviation, and percentages of favourable answers (score ≥ 2) for each item of the HoMASQ. The mean of the total scores and the favourable answers percentage are also reported.
calls or follow-ups) requested by HM as covariates. The results of such analysis are reported in Table 2. All the considered variables resulted largely uncorrelated \((F=0.73, P=0.65)\) with the final response score.

### Questionnaire reliability

To evaluate the HoMASQ internal consistency reliability the Cronbach’s alpha was calculated. The HoMASQ reliability was associated to a Cronbach’s alpha of 0.73. Excluding items 5 and 6 (psychological area) resulted in an increase of this value up to 0.82.

### Discussion

The main finding of our study is that patients with implanted devices chronically followed by using a remote monitoring system as standard clinical practice show a high level of acceptance and satisfaction of this new technology.

We evaluated five areas that are recognized\(^{13}\) as associated with remote control patient acceptance and satisfaction.

As regard to the first area, the relationship of patients with their healthcare providers is a crucial issue. Usually, patients implanted with pacemaker or ICD are followed up at scheduled in-hospital visits during which technical device performance and patient clinical status are checked. During the visit, the patient is informed about device functioning and clinical status and reassured by his/her nurse and physician when no abnormalities are detected. Such a personal contact is psychologically important for the patient. Whenever HM is started, the number or the frequency of personal contact with healthcare providers may be reduced, due to remote control. Therefore, the patient needs to receive clear, detailed, and convincing explanations on how HM works, in order to trust the system and to have a good compliance to remote monitoring. Our study showed that 97% of patients claimed to be satisfied with both initial training and successive contact with healthcare providers. Contact mostly occurred by phone with the dedicated nurses who definitely proved to play a critical role in keeping the human relationship with the patients.\(^{5,13}\)

A very important point contributing to remote monitoring patient acceptance is its easy of use: technology must be simple and require only a minimal interaction between the patient and

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**Table 2** Multiple regression analysis

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Regression coefficient (standard error)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>(-0.01 \pm 0.05)</td>
<td>0.83</td>
</tr>
<tr>
<td>Gender</td>
<td>(-0.22 \pm 1.15)</td>
<td>0.84</td>
</tr>
<tr>
<td>Device</td>
<td>(-0.48 \pm 1.06)</td>
<td>0.64</td>
</tr>
<tr>
<td>Instruction level</td>
<td>0.92 (\pm 0.56)</td>
<td>0.10</td>
</tr>
<tr>
<td>Job activity</td>
<td>0.63 (\pm 0.82)</td>
<td>0.45</td>
</tr>
<tr>
<td>Number of phone calls requested by HM</td>
<td>(-0.15 \pm 0.49)</td>
<td>0.76</td>
</tr>
<tr>
<td>Number of follow-up requested by HM</td>
<td>0.48 (\pm 0.59)</td>
<td>0.41</td>
</tr>
</tbody>
</table>

Dependent variable, total score for each patient.

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**Figure 2** Mean score, standard deviation, and percentage of answers for each of five HoMASQ areas: (i) relationship with healthcare provider at enrolment and during all the monitored period, (ii) easy of use of HM at first utilization and during all the monitored period, (iii) related psychological aspects, (iv) implications on general health, (v) overall satisfaction.
his/her transmitter unit. The HM system fully matches with this requirement, being completely automatic without any active patient involvement. This is probably the reason why almost all the HoMASQ responders found it easy to manage their remote monitoring system, ensuring a high level of coverage of days of transmissions. We previously reported that >90% of daily transmissions reached the referring centre ensuring a nearly continuous monitoring.2

The third area concerning psychological aspects included items intentionally designed to evaluate how the transmitter may affect patient’s life. A relatively high level of acceptance resulted from these items: 9% of patients stated that the transmitter affected their normal life and only 5% stated that it was a bother. We could speculate that going on with the follow-up, patients may get more familiar with their transmitter and in turn its influence on daily life may even decrease. Ninety-two percent of patients claimed to receive a sense of security by their transmitter. Interestingly, this high rate was obtained despite the nurse and the physician stressing during the initial training that the HM is not an emergency management system but simply a diagnostic tool.

Also patients perception of implication of remote control on general health (fourth area) was positive.

It should be outlined that none of the considered variables (age, gender, device, instruction level, job activity, and contacts requested by HM) appeared able to affect the HoMASQ score, basing on the multiple regression analysis. Identification of predictors of patient acceptance may require larger studies. It is interesting to point out that, quite unexpectedly, no correlation was found even with age, suggesting that elderly patients (who are expected to benefit the most from a remote monitoring system) may also easily manage the HM transmitter.

During the last decade, telemedicine has been introduced in a wide variety of areas involving an increasing number of patients and healthcare providers. This heterogeneous application has made it rather difficult to standardize and to evaluate the relevance of telemedicine benefits. Several studies tried to give an estimation of satisfaction of patients in telemedicine. However, most of them consisted of small populations, were methodologically undefined, and provided uncertain results.11–12 Unlike application in other fields, the remote control of implantable device is having a rapid diffusion, probably because of high patient and physician acceptance.

Currently, there are no validated questionnaires to be applied in remote control in cardiac pacing. Standardized quality of life questionnaires on general health (such as SF36-12) appear not specific for this purpose. This is the reason why we tried to develop a new questionnaire specifically designed to assess patient acceptance and satisfaction with pacemaker and ICD remote control systems.

The HoMASQ, utilized here, showed a good internal consistency: the Cronbach’s alpha was 0.73 (higher than the minimum conventional limit of 0.70). Furthermore, when items 5 and 6 were excluded, reliability reached the value of 0.82, which is comparable with others standardized questionnaires15,16.

Limitations of the study

Our population is relatively small sized: this should be considered as the main limitation of the study. No data on intra-person variability of the questionnaire are available. Further analysis on HoMASQ, specifically repetitive administrations to larger patient population at different times, is needed to validate and possibly to improve the reliability of the questionnaire.

The studied population included only a small number of ICD patients for whom HM is theoretically even more clinically relevant if compared with pacemaker patients. As a consequence, although the patient’s perception of a new control system may be quite similar in pacemaker and ICD patients, especially if the latter did not experience shock therapy, the present findings have to be confirmed in a larger ICD population.

Conclusions

Patients with implanted device chronically followed by using the HM remote control system showed a high level of acceptance and satisfaction for this new technology. All investigated areas of the HoMASQ had >90% of positive responses. After 1-year follow-up only three patients refused to continue to be followed by HM. HoMASQ showed a good internal consistency.

Conflict of interest

No grants, funding, or other forms of financial support were received for this work. R.P.R. and M.S. received minor consultancy fees from Medtronic and St Jude Medical. A.G. and M.T.L. are employees of Biotronik Italia S.p.A., an affiliated of Biotronik GmbH, Berlin, Germany. L.M., L.Q., A.S., and A.P. do not have any conflicts of interest to be disclosed.

References


