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Telemedical care: feasibility and perception of the patients and physicians: a survey-based acceptance analysis of the Telemedical Interventional Monitoring in Heart Failure (TIM-HF) trial

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Abstract

Background: The randomized Telemedical Interventional Monitoring in Heart Failure (TIM-HF) trial (NCT00543881) was performed during 2008 and 2010 to determine whether physician-led remote patient management (RPM) compared with usual care would result in reduced mortality and morbidity in stable out-patient heart failure (HF) patients. However, besides results of clinical benefit, the acceptance by patients and primary physicians is necessary for the implementation of RPM as part of the upcoming out-patient HF-care programs.

Methods: Two months after finishing of the trial, a survey based analysis of the perception of telemedical care with patients ($n = 288$) and primary physicians ($n = 102$) was carried out. The survey included questions regarding self-management, usability and physician-patient communication.

Results: The concept of RPM was perceived positively by patients and physicians. The devices were assessed as easy to use (98.6%, $n = 224$) and robust (88.8%, $n = 202$). Through trial participation and daily measurements most of the patients (85.5%, $n = 195$) felt more confident in dealing with their disease than before. The perception of the nurses and physicians of the telemedical centers was professional (92.1%, $n = 210$ and 89.9%, $n = 205$) and committed (94.3%, $n = 215$ and 91.7%, $n = 209$). Also more than half of the patients noticed an improvement in the contact with their primary physician (52.6%, $n = 120$); and for 46.1% ($n = 105$) the contact has not been changed.

Conclusions: RPM will be a medical care concept for recently hospitalized HF- patients in the near future but the optimal telemedical setting of RPM and the duration of this intervention have to be defined in further clinical trials.

Keywords

Chronic heart failure, remote patient management, TIM-HF trial, hospitalisation, perception, telemedicine

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Introduction

Despite improvements in medical and interventional therapy during the last years, cardiovascular diseases, including heart failure (HF), are one of the major causes of death and hospitalizations. HF patients suffer from multiple comorbidities like diabetes mellitus, depression or chronic obstructive pulmonary disease (COPD) and need a treatment concept elaborated in close co-operation with interdisciplinary healthcare providers. For this reason new technological strategies to improve outpatient care for heart failure patients were developed and several randomized

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controlled trials have evaluated different remote patient management (RPM) interventions as an additional part of outpatient care concept over the last 10 years.[1] However, as described by Clark and Thompson, the clinical results are due to the different interventions of these trials inconsistent and difficult to compare.[2]

The rationale of RPM is the detection of clinical deterioration and early intervention to prevent (re-)hospitalization or mortality. As a second aspect, RPM should support interactions between healthcare providers to generate a balanced and structured treatment concept. Furthermore, due to the interactive communication technologies it will be possible to provide training models for patients to enhance their self-management capabilities.[3]

To achieve these aims of RPM and their implementation as part of medical care, one important aspect is the acceptance of RPM by the patients and their primary physicians (general practitioners and specialists). Complementary measurement methods for acceptance are the evaluation of compliance within the process of telemedical care and the survey as a reflexive perception of telemedical care after completion.

For this reason a survey about the perception of telemedical care of patients and physicians two months after finalization of the trial Telemedical Interventional Monitoring in Heart Failure (TIM-HF, NCT00543881) was carried out.

The TIM-HF trial

TIM-HF was performed as a part of the 'Partnership for the heart' project, sponsored by the German Federal Ministry of Economics and Technology (grant number 01MG531). Within the project, a RPM system was developed and evaluated in the TIM-HF trial. This system consists of a three-lead-electrocardiogram, blood pressure device, weighing scale, mobile phone for data transmission and self-assessment of the health-status, in-house emergency call with direct connection to the telemedical centers (24 h/7 d) and an electronic health record in the telemedical centers. This third generation system as classified by Anker et al.[4] is shown in Figure 1 and described previously.[5,6]

The system as a part of RPM was assessed during 2008 and 2010 in a randomized controlled trial with 710 stable patients with chronic heart failure (CHF). Inclusion criteria were: New York Heart Association (NYHA) functional class II or III with a left ventricular ejection fraction (LVEF) $\leq$35% and a history of CHF decompensation within the previous two years or with a LVEF $\leq$25%. The patients were randomly assigned (1:1) to RPM or usual care (UC). The mean age at baseline was 66.9 ± 10.8 years for the RPM group and 66.9 ± 10.5 years for the UC group. The duration of heart failure was 6.7 ± 6.6 years for RPM and 6.8 ± 6.4 for the UC group. Baseline clinical and laboratory characteristics were similar between the two groups and described previously.[7]

The objective of the TIM-HF trial was to prove the superiority of RPM compared to guideline-based UC in terms of total mortality (primary endpoint). Secondary endpoints included HF-hospitalization, cardiovascular death, quality of life and others.

Two telemedical centers, located in two German regions, provided physician-led medical support for 24 h a day, seven days per week according defined standard operating procedures. The patients were enrolled from 165 medical practices in cardiology, internal medicine or general medicine and followed for at least 12 months with outpatient visits after 3, 6, 9 and 12 months during the first year and after 18 and 24 months in the second year. The follow-up (mean 26 months) was achieved by 99.9% of the patients.

Within seven days after randomization the telemedical system was installed in the home of the RPM patient group by a service provider and the patients were trained in using the devices by nurses of the telemedical center or service providers. During this training the patients were instructed to measure daily body weight, blood pressure, electrocardiogram (ECG) and the self-assessed health status. The measurements were transmitted automatically by mobile communications to telemedical centers. The average of the individual training time for the patient to use this equipment was 60 min.

At least once a month the telemedical centers called the patients for a structured telephone contact to discuss the status of their disease and also to instruct the patients in dealing with emergency situations.[8] Besides this monthly contact the staff of the telemedical center contacted the patient when requested by patient, to initiate or change concomitant treatments or for verification of measurements.

The results of the trial showed no significant effect on all-cause mortality for the RPM group compared to the UC group (hazard ratio (HR) 0.97; 95% confidence interval (CI) 0.67–1.41; $p = 0.87$) or on cardiovascular death or HF-hospitalization (HR 0.89; 95% CI 0.67–1.19; $p = 0.44$).[7] However, in an exploratory analysis (patient profiling) a subgroup with significant treatment effects for cardiovascular mortality and reduction in the number of days lost due to cardiovascular mortality and HF-hospitalization has been identified. The patient responding to telemedicine was likely to have had a previous episode of HF decompensation did not show depressive symptoms (PHQ-9$<$10) and had LVEF$\geq$25%. For this patient

subgroup RPM can be a 'bridge to stability' after hospitalization. Furthermore, for the predefined PHQ-9 <10 subgroup treatment effects were significant for total mortality (p for interaction <0.027). For the subgroup of patients with a prior HF decompensation or an implantable cardioverter defibrillator (ICD) or a PHQ-9 score of <10 and patient-profiling subgroup the treatment effects for the outcome 'number of days lost due to hospitalization for HF or death' were significant (p for interaction <0.05).[9]

Methods

In June 2010, two months after the TIM-HF trial had been completed, questionnaires regarding the perception of the clinical trial itself and the provided RPM were designed by the medical staff of the telemedical center in Berlin, Germany. One questionnaire was developed for the patients and one for the primary physicians. Design requirements for practicability reasons for these one page questionnaires were simplicity and a maximum completion time of five minutes.

The perception of the RPM during the trial was operationalized by three aspects: (a) information and handling of the disease (self-management); (b) the usability of the telemedical devices; and (c) the evaluation of the communication between patient and telemedical centers/ patient and primary physicians.

The perception part of the questionnaire included seven closed questions for the patients and three closed questions for the physicians. At the end of the questionnaire the respondents had the opportunity for supplementary notes. Further questions regarding the organizational aspects of the clinical trial, e.g. study documentation, will not be presented here.

Questionnaires were sent by post, and a stamped envelope enclosed, to all patients of the RPM group known to be alive and who had not declined RPM after randomization in the telemedical study arm ($n=279$) as well as all physicians ($n=165$). Patient selection for the survey is shown in Figure 2. To receive honest answers, the collection of the questionnaires was blinded.

Results

The number of the questionnaires answered was 81.7% ($n=228$) for patients and 61.8% ($n=102$) for physicians.

Self-management

Through the participation in this trial and the daily measurements, 85.5% ($n=195$) of the patients felt more confident in dealing with their disease than before. The additional information about their disease was considered as reasonable by the patients (86.8%, $n=198$).

In the supplementary notes the patients emphasized that the RPM had given them safety and support in handling their chronic disease ($n=17$), especially by the monitoring and the contemporary feedback by the telemedical centers of their transmitted vital parameters. The daily 24 h/7 d accessibility of the telemedical center was reported as important by the patient (84.6%, $n=193$). Only 5.7% ($n=13$) rated this opportunity as unimportant and 9.7% ($n=22$) rated this as neutral or did not answer this question.

Usability

The handling of the telemedical devices was easy (98.6%, $n=224$) and robust (88.8%, $n=202$) for nearly all responding patients. Only two patients indicated problems with the telemedical devices in the supplementary notes; four patients asked explicitly for the opportunity to buy the devices for further use after the trial.

The monitoring of the vital parameters was evaluated by the physicians as an important addition of the usual medical care because of the extension of the medical diagnostics which provides further information about the patient ($n=6$) and the opportunity for professional exchange ($n=10$). They indicated also in the notes that, due to the telemedical care, acute events like cardial decompensation or other relevant problems (like weight gain) could be detected earlier ($n=9$). This additional information and the possibility of a faster intervention in case of deterioration were the main reasons why physicians emphasized the telemedical care as helpful. In their view the patients felt better and firmly supported which furthermore increased their therapy compliance and satisfaction ($n=13$).

Communication between patients and healthcare providers

The patients assessed the nurses and physicians of the telemedical centers as professional (92.1%, $n=210$ and 89.9%, $n=205$, respectively), committed (94.3%, $n=215$ and 91.7%, $n=209$, respectively), and pleasant (95.6%, $n=218$ and 93.0%, $n=212$, respectively). There was no significant difference between the evaluation of the nurses and the physicians by the patients. The treating physicians also rated the telemedical

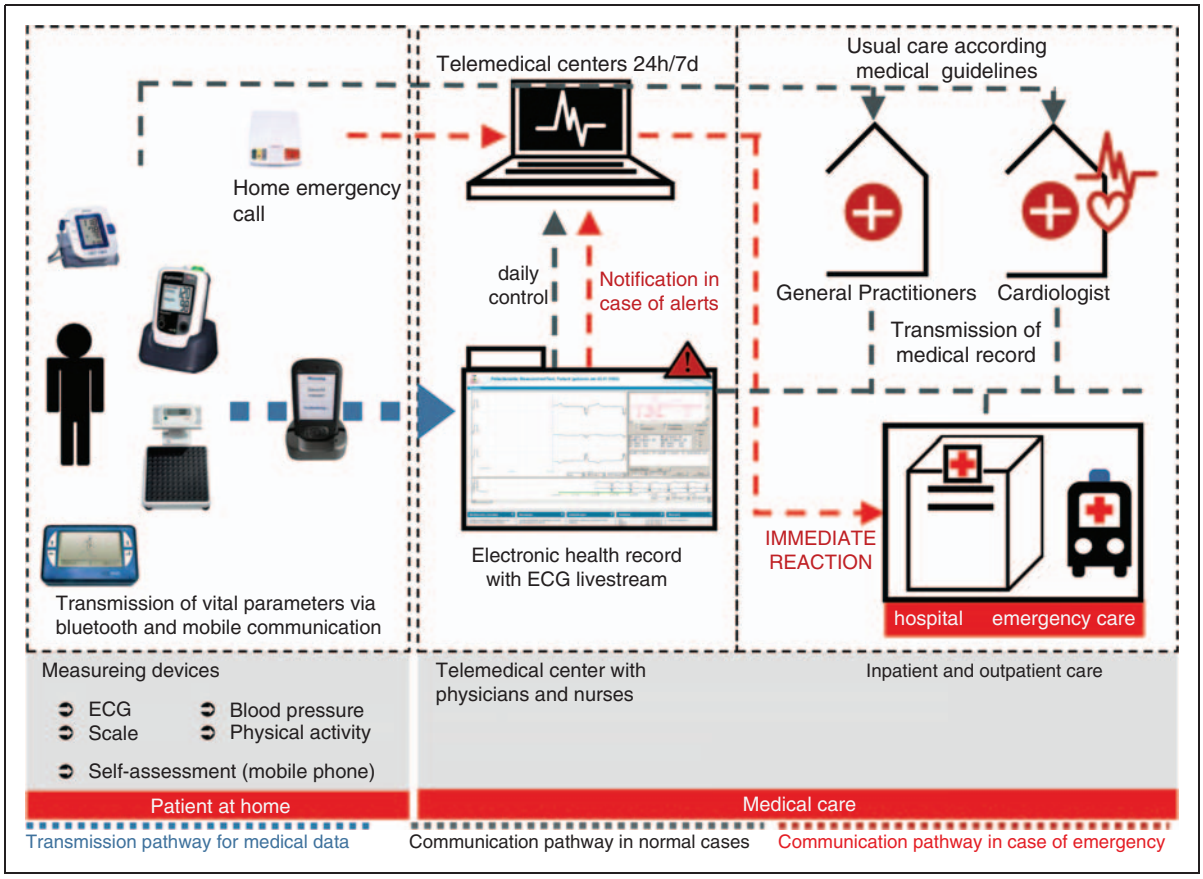

Figure 1. Overview of the remote patient management (RPM) system used in Telemedical Interventional Monitoring in Heart Failure (TIM-HF).
ECG: electrocardiogram.

physicians as professional (90.2%, $n=92$), well informed about the patients (82.4%, $n=84$) and committed (67.6%, $n=69$).

Nearly 60% ($n=61$) of the primary physicians emphasized the support by the telemedical center as helpful (21 physicians did not answer this question). Only 10 physicians found the organizational efforts as part of the clinical trials were disruptive and noticed the engagement of the telemedical center as somewhat excessive.

Also more than half of the patients noticed an improvement in the contact with their primary physician (52.6%, $n=120$), and for 46.1% ($n=105$) the contact had not been changed. A decline of contact was not noticed.

The patients emphasized in the supplemental notes their gratefulness and satisfaction ($n=40$) and regrets about the finalization of the trial, or asked for continuation ($n=13$). Five patients asked for further information about the trial results and a summary of their own medical progress during the trial. Also the primary physicians evaluated their patients as satisfied with the telemedical care (74.5%, $n=76$).

Discussion

There is an increasing evidence that remote patient management is useful in the outpatient care of HF-patients. Nevertheless, there are four remaining issues regarding the implementation of RPM which need to be investigated in running or upcoming clinical trials: which patients (whom) have the greatest benefit (what) with which kind of optimal telemedical setting (how) for what time (when)?

Available medical evidence, including the results of the TIM-HF trial, suggests that only subgroups of HF-patients potentially have benefits from RPM: patients recently hospitalized due to HF, without depressive symptoms and NYHA Class II/III[9]. Intensive telemedical care for 24 h/7 d should be provided at least 12 months after HF-hospitalization. After these 12 event-free months, low threshold care strategies with a focus

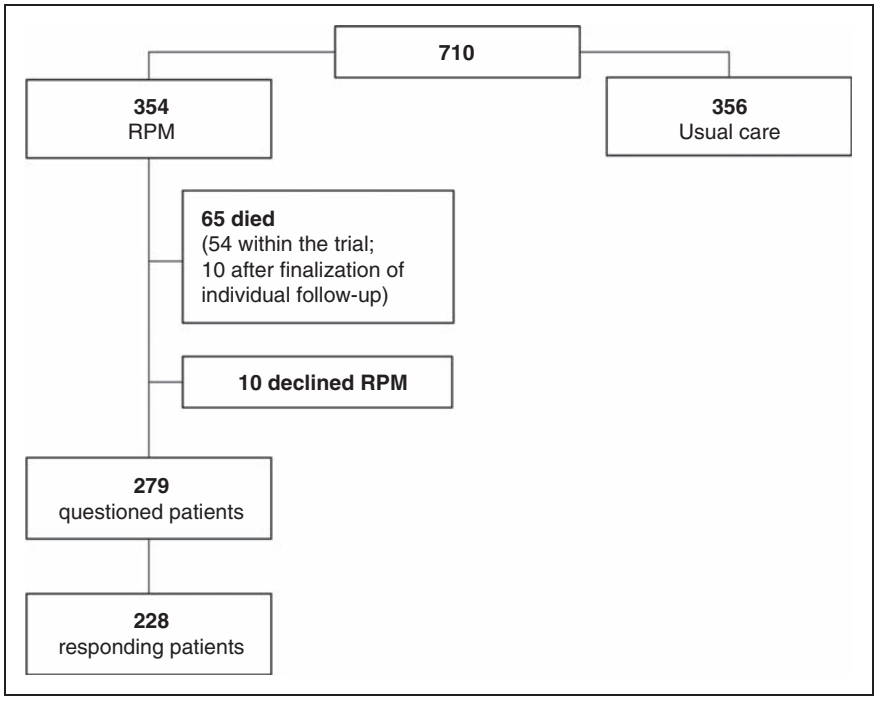

Figure 2. Selection of patients for the survey.
RPM: remote patient management.

on disease-related self-management should be carried out. But the sustainability of the achieved therapy effects in RPM (extended follow up, hospitalizations, self-management, etc.) has to be investigated in adequately powered randomized controlled trials.

Systematic reviews about telemonitoring in HF-patients indicate a consistent reduction of 20% in heart failure re-admissions for almost all RPM settings, while the benefit in terms of mortality differ between these reviews [10,11] and the results of large clinical trials.[7,12–14] Furthermore the TIM-HF trial showed an improvement of the SF-36 physical functioning score as part of quality of life (QOL).[7] But Desai indicated that only 50% of the clinical trials have QOL as a clinical endpoint and that no standard measuring instrument is defined.[1]

While technology developments enable different RPM approaches, the optimal approach, whether non-invasive and/or invasive, is still under investigation. The invasive CardioMEMS heart sensor based HF-management (CHAMPION trial, NCT00531661) has reduced HF-hospitalization in NYHA Class III patients by 30%.[12] Despite these positive results in the primary endpoint, the system actually lacks the US Food and Drug Administration (FDA) approval. In contrast, devices of non-invasive approaches like the TIM-HF trial were easy to use and have no risk of implantation and they allow individualized patient monitoring including comorbidities (e.g. diabetes mellitus, COPD, depression). However, the results of the trials are inconsistent and the systems used are not comparable.

A very important success factor for any telemedical setting is the acceptance of the patients and treating doctors. According to the overall impression of the presented survey, which investigated the noninvasive approach used in the TIM-HF-trial, it can be assumed that the patients and physicians were satisfied with the telemedical care afterwards as well as during the trial follow-up, as expressed in the high therapy compliance of 70%.[9]

The importance of this positive perception of the provided telemedical care will be underlined by the particular nature of the TIM-HF trial – the long follow up of 26 months (mean, at least 12 months) and inclusion of clinically stable previously hospitalized patients. Factors influencing this perception are the RPM of the chronic disease (telemanagement instead of telemonitoring), also including aspects of patient education and self-management, the physician-patient relationship and the easy handling of the devices.

The feasibility study ahead of the trial, as well the responses of the patients in this survey, suggest that technical robustness and usability could be achieved during the technical development phase of the project.[6]

The additional information about the disease and the daily monitoring increased the confidence regarding the disease-related self-management capabilities of the patients.

The patients assessed the work of the telemedical staff very positively. The minor differences between the positive ratings of the nurses and physicians are probably the result of the frequent contact during the monthly calls of the nurses. Also our survey could not confirm the suspicion of a negative influence of RPM regarding the daily work and patient contact of the primary physicians which is causing negative attitudes in the public perception of this care model[15] as the contact with the primary physicians was improving or at least was without change due to telemedical care. Telemedical care in this way is defined as an additional part of the medical care and not as a substitution.

The results of this survey underline the complementary importance of the telemonitoring of vital parameters and the communication with the medical staff (physician/nurse-patient relationship) as part of the telemanagement of chronic diseases. The neutral results of the TELE-HF trial (NCT00303212) were explained in two author replies as a result of the declining compliance from 90.2% at the beginning to 55.1% after six months.[13,16,17] The reasons for this decline were seen in the lack of telemanagement regarding patient education and self-management as part of intervention[16] and lack of physician-patient communication.[17] These assumptions are concurrent with the qualitative study of Fairbrother et al.[18] but underline the importance of further investigation of factors influencing the patients acceptance of remote patient management programs during the first year after HF-hospitalization and in the long term.

Conclusion

RPM will be a medical care concept for recently hospitalized HF patients in the near future. Ongoing trials as well as the upcoming clinical trial TIM-HF II are focusing on the optimal kind of telemedical setting and the duration of this intervention.

Limitations

Besides those patients who died within the trial or after finalization of the personal follow-up, 11 patients did not receive this questionnaire as they declined RPM at the beginning of the trial. For this reason the representativeness of the survey for all patients of the RPM group in TIM-HF could not be ensured. Furthermore, the survey was performed using an unstandardized self-developed questionnaire and did not include control questions. Also the included patients and study centers in this trial could be assessed a priori as more open-minded about telemedical care compared to the defined subgroup population.[9] Despite the high response rate, it cannot be excluded that patients and study centers with negative experience did not answer these questionnaires. The results of this survey have to be considered under these limitations.

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Conflict of interest

The authors have nothing to declare.

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