Evaluation of an Integrated Telemonitoring Surveillance System in Patients with Coronary Heart Disease

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Summary
Objectives: Cardiovascular diseases are the most frequent cause of death in industrialized countries. Non-adherence with prescribed medication and recommended lifestyle changes significantly increases the risk of major cardiovascular events. The telemonitoring programme MyCor (Myocardinfarkt und Koronarstent Programm in Tirol) is a multi-modal intervention programme to improve lifestyle and medication management of patients with coronary heart disease (CHD). It includes patient education, self-monitoring with goal-setting and feedback, and regular clinical visits. We evaluated the MyCor telemonitoring programme regarding technical feasibility, user acceptance, patient adherence, change in health status, and change in quality of life.

Methods: A 4½-month study was conducted with two telemonitoring phases and one interim phase. The study comprised patient surveys, standardized assessment of quality of life using the MacNew questionnaire at study entry and after 4 and 18 weeks, analysis of adherence to medication and physical activity during the two telemonitoring phases, and analysis of reached goals regarding health conditions during the telemonitoring phases.

Results: Twenty-five patients (mean age: 63 years) participated in the study. Patients showed a high acceptance of the MyCor telemonitoring programme. Patients reported feelings of self-control, motivation for lifestyle changes, and improved quality of life. Adherence to daily measurements was high with 86% and 77% in the two telemonitoring phases. Adherence to medication was also high with up to 87% and 80%. Pre-defined goals for physical activity were reached in up to 86% and 73% of days, respectively.

Quality of life improved from 5.5 at study entry to 6.3 at the end (p<0.01; MacNew questionnaire). Reductions in blood pressure and heart rate or an improvement in reaching defined goals could not be observed.

Conclusions: The MyCor telemonitoring programme Tirol for CHD patients has a high rate of acceptance among included patients. Critical evaluation revealed subjective benefits regarding quality of life and health status as well as high adherence rates to medication and lifestyle changes. Achieving long-term adherence and verifying clinical outcomes, however, remains an open issue. Our findings will promote further studies, addressing different strategies for an optimal mix of patient education, telemonitoring, feedback, and clinical follow-ups.

1. Background
Cardiovascular diseases are the most frequent cause of death in industrialized countries. In Austria, about sixteen percent of patients with cardiovascular disease die from acute myocardial infarction [1]. To prevent myocardial (re-)infarction, lifestyle modifications, life-long medical therapy, and regular follow-up are necessary.

Medical therapy is often needed for several years, or even life-long, to reduce the risk of recurrent cardiovascular events [2]. Non-adherence with prescribed medication significantly increases the risk of major cardiovascular events [3, 4]. However, up to half of patients with coronary heart disease (CHD) do not comply with prescribed medication regimens [5–7]. Even among patients suffering an acute myocardial infarction, 34% do not completely adhere to prescribed medication [8]. Non-adherence is not only associated with a higher risk of cardiovascular hospi-
talization but also with higher healthcare costs [7, 9]. Conversely, higher adherence is associated with better clinical outcome, fewer cardiovascular events [7], and net economic return [9]. Interventions to improve medication adherence comprise, among other things, specially packed pill boxes, patient education, (telemedical) monitoring with (automatic or phone-based) feedback, regular follow-ups, and the use of motivational strategies [7]. Multimodal interventions that combine several of these interventions have been found to be more successful regarding adherence and clinical outcome than single interventions [7].

Besides medication, lifestyle modifications are equally important to reduce the risk of recurrent events in CHD patients. Lifestyle changes comprise the reduction of stress and weight, a healthy diet, and increased physical activity as part of the daily routine. Comparable to medication adherence, motivation for lifestyle changes in CHD patients is often low [10]. Lifestyle management is – like medication management – part of the patient self-management and has an impact on clinical outcome [10]. Home-monitoring of physiological parameters and individual goal-setting have been successfully used to support patient self-management [10]. For example, electronic activity monitors in pedometers use goal-setting and display the discrepancy between defined goals and actual behaviour [11]. A combination of regular clinical follow-ups, complemented by self-monitoring with goal-setting, may substantially support self-management in CHD patients [10, 12].

The telemonitoring programme MyCor (Myokardinfarkt und Koronarstent Programm in Tirol) was piloted in 2014 and aims at improving the care of patients following acute myocardial infarction and/or percutaneous coronary intervention. MyCor is a multi-modal intervention programme to improve lifestyle and medication management. It includes patient education, self-monitoring with goal-setting and feedback, and regular clinical visits. The aim of MyCor is to improve adherence with medication regimens and lifestyle changes and so improve clinical outcome.

2. Objectives

The objective of this paper is to present the results of the formative evaluation of the MyCor telemonitoring programme regarding technical feasibility, user acceptance, patient adherence, change in health status, and change in quality of life.

3. The MyCor Programme

The telemonitoring programme MyCor addresses patients that have recently suffered acute myocardial infarction and/or have undergone percutaneous coronary intervention.

Upon hospital discharge, patients were provided disease-specific education and were equipped with a telemedical monitoring system. All devices of this system were able to communicate via Near Field Communication (NFC) [13, 14] and were included in a carrying case. In particular, the system comprised a smartphone (NFC Android smartphone), a blood pressure meter (type UA 767 NFC, A&D), a pedometer (type UW-101 NFC, A&D), and an NFC personal identification card (Figure 1). In addition, diabetes patients received a glucometer (type OneTouch Ultra II, LifeScan) and obese patients received a weighing scale (type UC-324 NFC, A&D). Figure 1 shows the MyCor devices.

Patients were asked to measure blood pressure and weight at least once daily and to use the pedometer for continuous footstep counting. Also, patients were requested to document drug intake and subjective well-being on the smartphone once daily. Data were locally stored in the MyCor Health Diary App on the smartphone and synchronised automatically via secure protocol with the central MyCor server. Figure 2 shows a screenshot of the smartphone showing the possible user interactions.

Based on transmitted data, patients were provided an individual, automatic
feedback report that was sent to their smartphone once weekly. This weekly report included information on reaching individual goals regarding blood pressure, footsteps, weight, and blood glucose. Further details on these feedback reports can be found in [13].

Access to the data was strictly limited to the individual patients and to the responsible physicians. Patients could use their MyCor App on their smartphone to view all data. The MyCor clinician could access the documented data via a web interface for discussion during the follow-ups (►Figure 3).

4. Methods
4.1 Design of the MyCor Evaluation Study
The MyCor evaluation included two telemonitoring phases and one interim phase. Overall study duration was 4 ½ months.

- Study entry: Upon hospital discharge, patients were provided disease-specific education and were trained in the use of the telemonitoring system by a specially trained nurse. Together with a MyCor physician, individual goals for blood pressure, footsteps, and weight were defined. Patients were provided the MyCor telemedical monitoring system.
- Telemonitoring phase 1 (4 weeks): Patients were asked to use the telemedical equipment for four weeks. A hotline was available for technical problems. Automatic feedback reports were sent electronically to the patient each week. These reports summarized the measured parameters and showed alerts in case of exceedance of the predefined goals.
- First follow-up visit: After four weeks, patients were invited for the first follow-up visit in which documented health diary data was re-discussed with the MyCor physician and medication was adjusted where needed.
- Interim phase (12 weeks): Over the next three months, patients were asked to follow the recommendations regarding medication management and lifestyle in their daily life without support of the telemedical system.
- Telemonitoring phase 2 (2 weeks): Patients were handed out the MyCor equipment again and were asked to use it for another two weeks.
- Second follow-up visit: At the end of telemonitoring phase 2, patients were invited for a second follow-up visit in which the documented health diary data was re-discussed with the MyCor physician and medication was adjusted where needed.

►Figure 4 summarizes the phases of the study and the instruments used.

No direct communication between the patient and the MyCor clinicians was planned in between the scheduled follow-ups. In case of any medical need, patients were referred to their family physician.

4.2 Patient Recruiting and Ethical Approval
Patients hospitalized for acute myocardial infarction and/or percutaneous coronary intervention at Innsbruck Medical University between February and October 2014 were recruited for participation in the MyCor programme. Participation was voluntarily and not dependent on comorbidities, type of medical or surgical interventions, age or residence. Most contacted patients agreed to participate. Only three patients declined due to different personal reasons.

Recruited patients had to be insured by an Austrian private insurance that focused on self-employed persons, as this insurer provided part of the funding for MyCor. It was planned to recruit 25 patients, as this number was found sufficient for a formative evaluation.

Ethical approval was obtained through the ethical committee of the Innsbruck Medical University.

4.3 Data Capture and Analysis
The evaluation comprised four studies:

4.3.1 Patient Survey
All patients were surveyed using a questionnaire that was based on the Information System Success Model [14]. This questionnaire was pre-tested and included 37 closed questions (four-point Likert scale) and four open questions. The closed questions addressed system quality (10 questions), information quality (2 questions), service quality (4 questions), user satisfaction (3 questions), intention to use (7 questions), and net benefit (11 questions). The questionnaire was applied twice (see also Figure 4): during the first follow-up visit and (in a reduced version, only addressing intention to use and net benefit) during the second follow-up visit. Quantitative data was analysed using descriptive statistics, and mean scores were calculated for each of the six dimensions of the Information System Success Model. Free text comments were analysed using qualitative and quantitative content analysis [15].

4.3.2 Quality of Life
The validated MacNew instrument [16] was applied to all patients three times (see also ►Figure 4): at study entry, at first follow-up visit, and at second follow-up visit. The MacNew instrument is an internation-
ally validated instrument for the standardized assessment of quality of life of patients after myocardial infarction. The instrument comprises 27 closed questions on emotional, social, and physical quality of life. Scores were calculated for each of the three MacNew sub-scales. Comparison between the three measurement times was done using Friedman and Wilcoxon-Signed-Rank test with alpha set to 0.05.

4.3.3 Patient Adherence

The log files of all documented and transmitted health diary data were analysed regarding number and completeness both during telemonitoring phase 1 and telemonitoring phase 2. For this, data was aggregated to calculate the number of daily measurements that were documented per patient and per week.

4.3.4 Health Condition

All health diary data (weight, blood pressure, footsteps) were analysed. Mean values per patient and per week were calculated. The percentage of patients reaching the goals was calculated for telemonitoring phase 1 and telemonitoring phase 2. To allow comparison of data, goals were uniformly set to: steps > 3,000 per day, blood pressure < 140/90 mmHg, and heart rate < 70 beats/minute. Data was aggregated to obtain the number of times the goals were reached per patient and per week.

5. Results

5.1 Participating Patients

Twenty-five patients (24 male, 1 female) were recruited and equipped with the MyCor telemedical system. Mean age was 63 years (range: 47–89 years). Table 1 shows the baseline characteristics of participants.

All patients participated in both telemonitoring phases, attended all MyCor follow-up visits, and filled in all questionnaires. There were no drop-outs.

Before entry into the study, 15 patients (60%) had regularly used a computer, and 13 patients (52%) had used a smartphone. Eighteen patients (72%) felt “very confident” or “partly confident”...
when working with computers and smartphones.

Eighteen patients (72%) had used a blood pressure device at home before study entry, and one patient had used a pedometer. Eight patients (32%) had measured their blood pressure at least four times a week before the study. Eleven patients (44%) had measured their weight at least four times a week.

5.2 Patient Survey

Results of the patient survey at the end of telemonitoring phase 1 showed mostly positive answers. Figure 5 shows the answers to selected survey questions.

Figure 6 shows the survey results after telemonitoring phase 1, aggregated for each of the six dimensions of the Information System Success Model (namely, information quality, service quality, system quality, intention to use, user satisfaction, and net benefit). For this aggregation, the mean values are displayed for all questions in that dimension.

The results of the patient survey after telemonitoring phase 2 showed comparable positive responses, with a mean value of 3.6 for information quality and a mean value of 3.5 for intention to use.

In the free text comments issued by the 25 patients to the open questions, the following major benefits were mentioned:

- Improved self-control of individual health (6 comments)
- Improved health consciousness (3 comments)
- Motivation for physical activity (3 comments)
- Better overview on individual data (2 comments)
- Reaching goals, visible results (2 comments)
- Motivation to come to follow-up visits (1 comment)

5.3 Quality of Life

The MacNew questionnaire showed an improvement of the quality of life over the three measurement times (entry visit, first follow-up visit, second follow-up visit) (Figure 7). Detailed analysis confirmed these results for the three sub-dimensions of physical, emotional, and social quality of life (details not shown).

The change between the entry visit and the second follow-up visit as well as the change between the first follow-up visit and the second follow-up visit were significant for all MacNew scores (p < 0.01 in each case).

5.4 Adherence of Patients

In telemonitoring phase 1, 86% of all daily measurements were completely conducted, meaning that weight, blood pressure, footsteps, and medication intake were documented and successfully transmitted. In telemonitoring phase 2, 77% of all daily

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Table 1
Clinical parameters of the 25 MyCor patients. # = "number of"
Measurements were completely conducted. 78% of all weekly feedback reports sent electronically to the patient were read by the patients.

The mean adherence to medication, as self-documented by the patients on a daily basis, was 87% in phase 1 and 80% in phase 2.

5.5 Health Condition

In all weeks of both telemonitoring phases, the median number of steps of all patients was clearly higher than the 3,000 steps per day that had been defined as the minimum number of steps (range: 5,833–7,148 median steps per day). On up to 86% of all days, 3,000 steps could be reached, this rate being higher in phase 1 compared to phase 2 (Figure 8).

Figure 5  Results of patient survey (distribution of answers to selected questions, n = 25 patients): Scale A = information quality, B = system quality, C = service quality, D = user satisfaction, E = net benefit, F = intention to use.

Figure 6  Mean responses to the MyCor patient survey, aggregated to the six dimensions of the Information System Success Model (n = 25 patients). 1 = minimum, 4 = maximum.
The median pulse rate of all patients was 62–64 beats/minutes in all weeks. On up to 80% of all measured days, the pulse rate was less than 70 beats/minutes, this rate being higher in phase 1 compared to phase 2 (▶Figure 9).

Both diastolic and systolic blood pressure were quite stable in all weeks. On up to 80% of all days, the blood pressure was lower than 140/90 mmHg, this rate being rather identical in phase 1 compared to phase 2 (▶Figure 10).

5.6 Medication Changes

At study entry, a mean of seven different drugs were prescribed per patient (range: 4–12 prescriptions/patient). At the first follow-up visit, this number was reduced to a mean of six prescriptions (range: 3–12). At the second follow-up visit, this number was further reduced to a mean of five prescriptions (range: 3–12). The overall number of prescribed drugs could be reduced by around 20% between the entry visit (202 prescriptions for all patients) and the second follow-up visit (162 prescriptions).

Both follow-up visits led to changes in the prescriptions: 55 changes were conducted in the first follow-up visit and 57 changes in the second follow-up visit. In between both follow-up visits, only eleven changes were made by the regular treating physicians (e.g. general practitioner) of the patient.

6. Discussion

Following earlier recommendations on improving medication adherence [7], the telemonitoring programme MyCor for patients with coronary heart disease (CHD) comprised a multimodal intervention including patient education, self-monitoring with goal-setting and automatic feedback, and regular clinical visits with a MyCor physician. The aim of MyCor was to improve adherence to medication and lifestyle recommendations and so improve clinical outcome. Low adherence in CHD patients has been found associated with adverse cardiovascular events [17].

Telemonitoring phase 1 represented the intervention and comprised the following activities: disease-specific education, training in the use of the telemonitoring system, establishment of individual goals regarding blood pressures, physical activity and weight, monitoring over four weeks, and automatic feedback reports on measured parameters and exceedance of personal goals. A 12-week interim phase was meant to show whether patients learned to take care of their parameters themselves without the help of the telemonitoring system. Telemonitoring phase 2 (two weeks) was intended to obtain information on whether...
patients indeed had managed to keep control of blood pressure, steps and weight in the interim phase, and whether the telemonitoring intervention of four weeks could be considered sustainable.

This study was not planned as a controlled clinical trial. It was instead intended as a formative evaluation to obtain information on the weak points of telemedical services regarding organization and technology, on patient adherence over time, on sustainability of the intervention, on possible benefits for the health status, and on possible adverse effects of the intervention. No statistical tests were planned in this first evaluation study, as no independent control group was available.

The patient survey revealed high acceptance of the MyCor telemonitoring programme. Participating patients considered the MyCor technology easy to use and user-friendly. The hotline received only very few calls on technical issues (e.g. regarding data transmission problems); these technical problems were mostly solved by exchanging the telemonitoring set. Free text comments did not reveal any suggestions for improvement of the technology. Thus, using a smartphone with NFC for data acquisition of obtained data seems to be appropriate for this mostly male patient group. It must, however, be stated that the majority of included patients were relatively young (mean age: 63 years), quite confident with computers, and mostly self-employed and thus probably well-educated persons. Less educated patients, older patients or female patients may be less technically oriented and may show less interest in using a telemonitoring system [18]. On the other hand, telemedicine may help to overcome the digital divide and may also be appropriate for older and less IT-experienced persons [19, 20]. Nevertheless, future studies are needed to verify whether older, less educated or less IT-experienced patients also accept MyCor telemonitoring.

Adherence to daily measurements was in general high with up to 86% and 77% in telemonitoring phase 1 and 2, respectively. Also, self-reported adherence to medication was high most of the time: Mean adherence to medication was 87% and 80%, respectively, which is clearly higher than adherence rates of 60% for CHD patients as reported in the literature [17]. Transmitted data show that pre-defined goals for physical activity also were reached most of the time (79%–86% in telemonitoring phase 1 and 72%–73% in telemonitoring phase 2).

Altogether, these findings indicate good adherence of patients to lifestyle changes and medication management. However, it must be noted that medication adherence was self-reported and it cannot be verified whether medication was in fact taken as prescribed. Also, comparing telemonitoring phases 1 and 2 showed a decline in adherence rates regarding daily data transfers (drop from 86% to 77% completed daily transmissions) and of physical activity.
(performing at least 3,000 steps a day: drop from a mean of 85% to 72%). These results may reflect a long-term reduction in adherence, which is comparable to what has been found in other adherence studies [7]. Whether a monitoring phase longer than four weeks with continuous weekly automatic feedback reports would help to stabilize adherence and increase sustainability of the telemonitoring intervention is not yet clear and must be evaluated in further studies.

The large majority of patients indicated subjective benefits from their participation in MyCor. The patient surveys, both in the closed and open questions, showed an appreciation of improved self-control and health consciousness. Patients seem to feel motivated for physical activity and for adherence to medical recommendations. More than half of the patients found that participation in the project motivated them to enact lifestyle changes and resulted in improved health and quality of life, and more than one-third agreed to this at least partially.

Along these lines, MyCor may be seen as an intervention affecting patient empowerment. Patient empowerment has been defined a “process of communication and education in which knowledge, values and power are shared between patient and healthcare provider” [21]. MyCor offers patients more information on their health status and provides feedback to support them in their personal choices regarding medication adherence and physical activity. Whether this indeed shows an effect on patient empowerment and related outcomes needs to be verified in future studies.

The patients considered MyCor as positive on all six dimensions of the Information System Success Model. This good success may also explain why no drop-outs were noted during the entire study period. The majority of patients intended to buy the telemonitoring set at the end of the study, and so far 13 patients (52%) in fact did so.

From a medical point of view, nominal reduction in blood pressure and heart rate or an improvement in reaching the pre-defined goals concerning these parameters could not be observed. This, however, was beyond the scope of this study. The MacNew scores showed a significant improvement in quality of life after hospital discharge. Admittedly, this is to be expected in this scenario after hospital discharge. How much of the improvement in physical, social, and emotional quality of life can be assigned to MyCor participation must be determined in a larger and controlled study.

Strong evidence is available on an inverse association between risk of cardiovascular diseases and social class both in women and men [22]. Given the fact that in our study most of the participants were male and self-employed persons, it is not possible to verify the influence of the social status on the participants’ behaviour. In future controlled studies of MyCor, recruiting should include more females as well as patients from other social groups and from various insurers to increase the generalizability of the findings. It must then also be verified whether patients with complex comorbidities are good candidates for a telemonitoring programme.

Summarizing, the evaluation showed that participating patients saw benefits quality of life and health from MyCor participation. Results revealed a generally good adherence to medication and lifestyle recommendations and showed an improved quality of life over time. On the other hand, achieving long-term adherence remains an open issue.

It is now planned to expand the MyCor programme to other healthcare institutions and to test different and individual combinations of multimodal patient education, telemonitoring phases, and follow-up visits, adapted to the individual needs and wishes of the patient. Challenges of sensor-enhanced health information systems such as message and alert logistics, sophisticated user interfaces, and cascading data analysis [23] will need to be tackled. Definite results regarding the effects of the programme on adherence and hard clinical endpoints, however, must be derived from prospective, controlled trials.

7. Conclusion
The telemonitoring programme MyCor includes patient education, self-monitoring with goal-setting and feedback, and regular clinical visits for patients after acute myocardial infarction and/or percutaneous coronary intervention. Formative evaluation revealed high acceptance by the patients, subjective benefits on quality of life and health status, and high adherence rates to medication and lifestyle changes. Long-term adherence and achieving improvements in clinical outcomes remain an open issue. These evaluation results will promote further studies, addressing different strategies for an optimal mix of patient education, telemonitoring, feedback, and clinical follow-ups.

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