First real-world experience with mobile health telemonitoring in adult patients with congenital heart disease

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Abstract

Background Arrhythmias and heart failure are common and invalidating sequelae in adult patients with congenital heart disease (CHD). Mobile health (m-Health) enables daily monitoring and a timely response that might prevent deterioration. We present an observational prospective registry to evaluate feasibility of an m-Health telemonitoring program for managing arrhythmia, heart failure and blood pressure in symptomatic adults with CHD.

Methods Symptomatic adult patients with CHD are enrolled in an m-Health telemonitoring program, which evaluates single-lead ECG, blood pressure and weight measurements. In case of symptoms extra measurements could be performed. Data are collected by mobile apps, matched with individualised thresholds. Patients are contacted if thresholds were exceeded or if arrhythmias were found, for treatment adjustments or reassurance. Data on emergency care utilisation, hospitalisation and patient-reported outcome measures are used to assess quality of life and self-management.

Results 129 symptomatic CHD patients were invited to participate, 55 participated. Reasons for refusing consent included too time consuming to participate in research (30) and to monitor vital signs (14). At baseline 22 patients were in New York Heart Association class ≥ II heart failure, 43 patients had palpitations or documented arrhythmias, and 8 had hypertension. Mean follow-up was 3.0 months, one patient dropped out, and adherence was 97%.

What's new?

- m-Health seems a very promising new tool for telemonitoring of adult patients with CHD.
- m-Health is well used by adult patients with CHD.
- m-Health is a valuable instrument to give patients immediate feedback and personalised coaching.
- m-Health results shown directly in the electronic medical records overcomes limitations mentioned in first-generation telemonitoring.
Conclusion  The first results indicate that this program is feasible with high adherence.

Keywords  adult congenital heart disease · m-Health · e-Health · heart failure · arrhythmia

Introduction

Telemonitoring is now available and could be a powerful tool for diagnosing and treating arrhythmia and heart failure. It can also be useful for adjusting antihypertensive medication in order to reach optimal blood pressure in real-life circumstances. This may be especially true for adult patients with congenital heart disease (CHD). They are a growing patient population [1, 2]. Most of these patients need lifelong follow-up because of residual sequelae predominantly causing heart failure and arrhythmias. Contemporary care is organised by several outpatient visits per year. These visits are needed to optimise dosing of medication and detect complications or disease progression [3–7]. The current organisation of care is hampered by frequent emergency hospitalisations, possibly due to a slow response to clinical signs of deterioration.

Telemonitoring may facilitate a faster response to the first warning signs of deterioration [8]. If directly followed by properly adjusting therapy or surveillance this may result in a reduction in emergency care utilisation. Also patients may be reassured in case of benign but terrifying symptoms resulting in better patient reported outcome measurements (PROMs), quality of life and self-management [9].

Results of studies on telemonitoring in patients with heart failure are conflicting [10–13]. Several meta-analyses suggest clinical and economic benefits, but numerous prospectively initiated clinical trials have not confirmed these findings [12, 14]. Moreover, professionals are often hesitant to start using telemonitoring because they fear an overload of data with a subsequent increase in workload [15–17].

However, adult patients with CHD seem particularly suitable for telemonitoring. These patients commonly experience health-related fears and insecurities [18]. They are of a young age, they have affinity with mobile devices and a chronic condition necessitating lifelong surveillance [15, 19, 20]. In our recent study, only a small minority (14%) of adult patients with CHD were already using telemonitoring, whereas a large majority responded that they would be willing to start using it (75%) [15, 16].

An observational prospective registry was initiated to evaluate feasibility of a new mobile health (m-Health) program for telemonitoring in symptomatic adults with CHD.

Methods

This prospective study is being conducted in a tertiary referral centre in the Netherlands. The institutional ethics committee approved the study. Informed consent is obtained in all patients. Consecutive symptomatic adult patients with CHD patients are included. Symptomatic is defined as palpitations or documented arrhythmias in the last 3 years or New York Heart Association (NYHA) heart failure class ≥ II. Patients are screened at the outpatient clinic or clinical ward and if eligible they are invited for a detailed explanation of the study. Inclusion and exclusion criteria are listed in Tab. 1. We distinguish three subgroups: patients with arrhythmias, heart failure, and hypotension or hypertension.

The m-Health program (HartWacht) consisted of hardware for single-lead ECG measurements, equipment to measure blood pressure, and a scale for body weight measurement, in combination with mobile applications to receive and transfer data. Patients were instructed on how to use the devices and mobile applications. Palpitations and arrhythmias were evaluated with single-lead ECG measurements (not only QRS complexes, but also P waves could be detected and visualised), which were recorded using a wireless ECG device and transferred to a remote telemonitoring centre using a smartphone application (Kardia [21]). ECGs were assessed daily by trained nurses, under supervision of a cardiologist. If an ECG was uninterpretable (artefacts) patients were asked to send a new recording. Blood pressure and weight parameters were evaluated with a blood pressure monitor (Omron) and a weight scale (i-Health) wireless connected to the patient’s smartphone. These data were transferred to the telemonitoring centre through a different smartphone application (cVitals). Data were processed using personalised thresholds and trend deviation settings, and were assessed daily. Routine measurements were done twice a week at predefined times. Patients could perform extra measurements in case of symptoms. If necessary, patients were contacted by their treating cardiologist in order to adjust therapy, for surveillance or in order to provide reassurance. Patients received an app reminder when a measurement was not performed at the required moments. Study measures (i.e. extensive history-taking and PROM questionnaires) were obtained in all

Table 1  Inclusion and exclusion criteria

| Inclusion criteria                                                                 |
|-----------------------------------------------------------------------------------|
| symptomatic ACHD patients                                                          |
| – documented arrhythmias                                                          |
| – palpitations within last 3 years                                                 |
| – heart failure NYHA class ≥ II                                                   |
| age ≥ 18 years                                                                    |
| possession of mobile device (e.g. smartphone, tablet)                             |
| impaired cognition, assessed by treating physician                               |
| tremors                                                                           |

| Exclusion criteria                                                                 |
|-----------------------------------------------------------------------------------|
| asymptomatic adult CHD patients                                                   |

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participants at baseline. PROM questionnaires were repeated every 3 months. Results were automatically added to the electronic medical record (EMR) of the patient.

The following data are collected during follow-up: 1) emergency care utilisation and 2) PROMs; 3) number of visits to the outpatient clinic; 4) number of telephone contact moments; and (5) medication changes induced by results of the telemonitoring program. Additionally, we were interested in the percentage of consenting patients. Emergency care utilisation was defined as any unplanned visit to the hospital due to cardiac-related symptoms. Outpatient clinic visits were defined as a visit to a cardiologist, cardiologist in training, heart failure nurse or dedicated adult CHD nurse. An outpatient clinical visit was defined as unplanned if the electronic medical record (EMR) explicitly stated that the patient was seen pre-emptively in case of symptoms. Contact moments were defined as a contact initiated by a cardiologist, cardiologist in training or specialised nurse by telephone or email. Interventions were defined as alteration of medication, catheterisations, pacemaker or ICD implantation, electrical cardioversions, catheter-based interventions and any type of open-heart surgery. All the data were extracted from the EMR, so only events registered in the EMR were used. Historical data of care utilisation from the last year before inclusion were obtained to have an indication of disease burden of these patients.

Careful evaluation of the patient experienced health status, quality of life and self-management was performed using the PROM questionnaires. Three PROM questionnaires were used (EQ-5D-5L, PAM-13 and CaReQoL CHF) [22–24].

For statistical analyses, SPSS 25.0 (SPSS Inc., Chicago, Illinois) for Windows was used. A two-tailed probability value of <0.05 was considered statistically significant. Descriptive data are presented as numbers with percentage, as mean with standard deviation or as median with range.

**Results**

Patient enrolment started in June 2017 (Fig. 1). Up to March 2018, 129 symptomatic adult CHD patients were eligible, of whom 55 (43%) consented to participate (median age of 45 years (range 19–70), 34.5% male and CHD severity of mild (n=6), moderate (n=29) and severe (n=20)). Reasons for refusing consent are shown in Tab. 2. At baseline 22 patients were in NYHA class ≥ II heart failure, 43 patients had palpitations or documented arrhythmias and eight patients were known with hypertension. Baseline characteristics of the study population are summarised in Tab. 3.

One patient dropped out before the first measurement because of difficulties experienced during installation of the smartphone applications and devices. Mean follow-up was 3.0 months, adherence was 97%.

During follow-up two emergency presentations and one hospitalisation was recorded (Fig. 2). This figure also contains historical data to give further insight,
Table 2  Reasons for refusing consent

| reasons                                      | number (%) |
|----------------------------------------------|------------|
| too time consuming to participate in research | 30 (40.5)  |
| too time consuming to monitor vital signs     | 14 (18.9)  |
| cost of health insurance deductibles          | 5 (6.8)    |
| expected decrease in quality of life          | 17 (23.0)  |
| no mobile device                              | 0 (0)      |
| emigration                                    | 1 (1.4)    |
| other                                         | 7 (9.5)    |
| total                                         | 74         |

demonstrating ten emergency presentations and nine hospitalisations.

Serial PROM questionnaires were available for 12 patients at baseline, nine patients after 3 months and six patients after 6 months and showed a non-significant change in quality of life during m-Health telemonitoring (Fig. 3) Compared with baseline mean scores of PROM questionnaires, quality of life (CaRe-QoL CHF (social, physical and safety) and EQ-5D-5L) improved by 51.7% \(p=0.502\), 14.3% \(p=0.28\), 3.3% \(p=0.87\) and 0.2% \(p=0.89\) respectively. Interestingly, patient-reported self-management decreased by 7.3% \(p=0.153\). Also after a first increase in PROMs, this positive effect seems to fade, yet a small positive effect remains.

During follow-up 13 patients visited the outpatient clinic 19 times, medication changes were made in six patients based on telemonitoring measurements.

Table 3  Baseline characteristics

| characteristics                  | total patients \(n= 55\) | heart failure \(n= 22\) | palpitations or arrhythmia \(n= 43\) | hypertension \(n= 8\) |
|----------------------------------|--------------------------|-------------------------|--------------------------------------|----------------------|
| median age (years)               | 45 (19 to 70)            | 45.5 (19 to 66)         | 45 (21 to 70)                       | 60 (32 to 70)        |
| male (%)                         | 19 (34.5)                | 9 (40.9)                | 14 (32.6)                           | 4 (50.0)             |
| severity of CHD                  |                          |                         |                                      |                      |
| – mild (%)                       | 6 (10.9)                 | 0 (0)                   | 6 (14.0)                            | 2 (25.0)             |
| – moderate (%)                   | 29 (52.7)                | 12 (54.5)               | 21 (48.8)                           | 4 (50.0)             |
| – severe (%)                     | 20 (36.4)                | 10 (45.5)               | 16 (37.2)                           | 2 (25.0)             |
| history of cardiac surgery (%)   | 52 (94.5)                | 22 (100)                | 40 (93.0)                           | 8 (100)              |
| pacemaker (%)                    | 11 (20.0)                | 6 (27.3)                | 10 (23.3)                           | 1 (12.5)             |
| arrhythmia at baseline (%)       | 43 (78.2)                | 10 (45.5)               | 43 (100)                            | 6 (75.0)             |
| NYHA class                       |                          |                         |                                      |                      |
| – II (%)                         | 17 (30.9)                | 17 (77.3)               | 6 (14.0)                            | 2 (25.0)             |
| – III (%)                        | 5 (9.1)                  | 5 (22.7)                | 4 (9.3)                             | 1 (12.5)             |
| – IV (%)                         | 0 (0)                    | 0 (0)                   | 0 (0)                                | 0 (0)                |
| symptoms                         |                          |                         |                                      |                      |
| – palpitations (%)               | 31 (56.4)                | 5 (22.7)                | 31 (72.1)                           | 5 (62.5)             |
| – dyspnoea (%)                   | 8 (14.5)                 | 7 (31.8)                | 4 (9.3)                             | 0 (0)                |
| – chest pain (%)                 | 4 (7.3)                  | 1 (4.5)                 | 4 (9.3)                             | 0 (0)                |
| – near collapse (%)              | 2 (3.6)                  | 2 (9.1)                 | 2 (4.7)                             | 0 (0)                |
| – dizziness (%)                  | 7 (12.7)                 | 4 (18.2)                | 7 (16.3)                            | 1 (12.5)             |
| – no symptoms (%)                | 15 (27.3)                | 8 (36.4)                | 7 (16.3)                            | 3 (37.5)             |
| RV function                      |                          |                         |                                      |                      |
| – poor (%)                       | 3 (5.5)                  | 1 (4.5)                 | 3 (7.0)                             | 0 (0)                |
| – moderate (%)                   | 16 (29.1)                | 8 (36.4)                | 13 (30.2)                           | 6 (75.0)             |
| – good (%)                       | 36 (65.5)                | 13 (59.1)               | 27 (62.8)                           | 2 (25.0)             |
| medication                       |                          |                         |                                      |                      |
| – antiarrhythmics (%)            | 35 (63.6)                | 14 (63.6)               | 31 (72.1)                           | 8 (100)              |
| – diuretics (%)                  | 12 (21.8)                | 10 (45.5)               | 9 (20.9)                            | 2 (25.0)             |
| – anticoagulation (%)            | 28 (50.9)                | 8 (36.4)                | 27 (62.8)                           | 5 (62.5)             |

* Data are number of patients (percentage), median (range) or mean (±standard deviation) 
CHD congenital heart disease, NYHA New York Heart Association, RV right ventricle
Twelve patients had 21 telephone contacts with their cardiologist (19 were for reassurance, two were referrals to the outpatient clinic for further follow-up). One patient improved in functional class after increasing the dose of diuretics after two consecutive threshold-exceeding weight measurements. In two patients antiarrhythmic treatment was adjusted and in three patients antihypertensive treatment was adjusted.

Single-lead ECG measurements were performed frequently, and turned out to predominately be sinus rhythm. In Fig. 4 the rhythms of 176 ECGs during symptoms are shown. The majority (74.4%) of the patients could be reassured since sinus rhythm was found while the patient experienced palpitations. In one patient with palpitations, previously undiagnosed atrial fibrillation was found and another ECG also showed asymptomatic sinus node dysfunction. Larger scaled studies are warranted to distinguish which subgroup has most benefits from which type of telemonitoring.

**Discussion**

The study is the first prospective study that evaluates telemonitoring through a comprehensive m-Health program in adult patients with CHD. The program is well used by symptomatic adults with CHD. The program is feasible with a high adherence.

Data on telemonitoring in patients with heart failure are still conflicting [10–13]. Several meta-analyses suggest clinical and economic benefits, but numerous prospectively initiated clinical trials have not confirmed these findings [12, 14]. Reasons for the lack of success could be classified into six dimensions: clinical, economic, user perspective, organisational, and technical [20, 25–27]. A meta-analysis of 16 high-quality randomised controlled trials showed that telemonitoring overall yields hardly any significant improvement for the average patient. However, interventions based on personalised coaching and feedback have been associated with successful results [27]. The purpose of the unique infrastructure of our m-Health telemonitoring program (HartWacht) is to overcome limitations mentioned in these earlier studies in order to improve the benefits. This program consists of apps on patients’ mobile devices, wireless-linked to devices for measuring heart rhythm, body weight and blood pressure, controlled by a dedicated team of cardiac care nurses and cardiologists. Results are directly shown in the patient’s EMR. The treating physician could easily find an overview of measurements and therapy in the EMR and this is also true for the PROMs. This makes performing measurements relatively uncomplicated and accessible for every patient with a mobile device. It enables instant feedback to the patient. If measurements are normal they are reassured by the app and if not, as judged by a ded-
Fig. 3 Patient-reported outcome measures (light blue baseline, blue 3 months, dark blue 6 months). Baseline is set as median. (Self-management PAM-13, quality of life, general EQ-5D-5L, Safety CaReQoL safety, Physical CaReQoL physical restrictions, Social and emotional CaReQoL social and emotional)

Fig. 4 176 rhythms in 17 patients during palpitations in the first 3 months, N = number, %

- Sinus Rhythm (N = 131, 74.4%)
- Artifacts (N = 23, 13.1%)
- PACs (N = 20, 11.4%)
- Atrial Fibrillation (N = 1, 0.6%)
- SVT (N = 1, 0.6%)

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Conclusion
A new m-Health telemonitoring program evaluating arrhythmia, heart failure and blood pressure is well used by symptomatic adults with CHD. The relatively young population of adults with CHD demonstrated a high adherence. m-Health telemonitoring might be a powerful tool for diagnosing and managing arrhythmias and heart failure. It can also be useful for adjusting antihypertensive medication in order to reach optimal blood pressure in real-life circumstances. This could result in better quality of healthcare in this patient group. However randomised control trials are needed to prove this hypothesis.

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Conflict of interest
D.A.J. Dohmen, A.G. Somsen and I.I. Tulevski are shareholders in ventures supplying hardware and software implemented in the methods of this study. M.A.C. Koole, D. Kauw, M.M. Winter, R. de Haan, M.P. Schijven, D. Robbers-Visser, B.J.M. Mulder, B.J. Bouma and M.J. Schuuring declare that they have no competing interests.

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