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Telemonitoring in patients with heart failure: Is there a long-term effect?

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Abstract

Introduction: Evidence suggests that telemonitoring decreases mortality and heart failure (HF)-related hospital admission in patients with HF. However, most studies follow their patients for only several months. Little is known about the long-term effects of telemonitoring after a period of application.

Methods: In 2007, the TEHAF study was initiated to compare tailored telemonitoring with usual care with respect to time until first HF-related hospital admission. In total, 301 patients completed the study after a follow-up period of one year. No differences could be found in time to first HF-related admission between intervention and control groups. Here, we performed a retrospective analysis in order to investigate potential long-term effects of telemonitoring. The primary endpoint was time to first HF-related hospital admission. Secondary endpoints were, amongst others, all-cause mortality, hospital admission due to HF and days alive and out of hospital (DAOOH). Electronic files of all included patients were reviewed between October 2007 and September 2015.

Result: Mean follow-up duration was 1652 days (standard deviation: 1055 days). No significant difference in time to first HF-related hospital admission (log-rank test, $p = 0.15$), all-cause mortality (log-rank test, $p = 0.43$), or DAOOH (two-sample t-test, $p = 0.87$) could be found. However, patients that underwent telemonitoring had significantly fewer HF-related hospital admissions (incident rate ratio 0.54, 95% confidence interval 0.31–0.88).

Discussion: Telemonitoring did not significantly influence the long-term outcome in our study. Therefore, extending the follow-up period of telemonitoring studies in HF patients is probably not beneficial.

Keywords

Heart failure, telemonitoring, long-term effects, hospital admission, mortality

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Introduction

Heart failure (HF) is a disabling disorder with increasing prevalence and poor prognosis.[1–3] HF care is highly expensive, mainly because of frequent hospital (re)-admissions[4] with a median hospital-readmission rate within 30 days after discharge of nearly 25%.[5] The risk for readmission is associated with increasing age and comorbidity burden.[6] Nonetheless, more than 50% of readmissions may be preventable, with non-compliance with HF therapy as the most important reason.[7] At the same time, patients demonstrate a significant delay of nearly three days between awareness of first symptoms and seeking medical help.[8] Both this delay and the non-compliance may be caused by lack of knowledge.[9] It has been shown that knowledge about HF symptoms, HF treatment and self-care behaviour is low in HF patients,[10] which could be due to the

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cognitive impairment occurring in up to 25–50% of HF patients or due to a low educational level.[11,12]

Telemedicine has been applied to adapt patients' knowledge and support patients' behaviour,[13] but results about its effectiveness on decreasing mortality and hospitalization in HF patients have been mixed.[14–19] In 2010 and 2015, two Cochrane reviews showed that the application of structured telephone support (STS) or telemonitoring may decrease mortality[20] and hospitalization in HF patients.[21] However, the mean follow-up time of the 41 studies included in the Cochrane review of 2015 was only 10 months, with a range from three to 27 months. Thus, the long-term effects of telemonitoring in HF patients remain largely unknown.

In 2012, results of the TEHAF study were published.[22] TEHAF was a multicenter, randomized controlled trial comparing tailored telemonitoring with usual care in HF patients. It was shown that disease-specific knowledge and self-care were increased in patients with telemonitoring.[23] Nevertheless, time to first HF-related hospital admission or mortality was not different between both groups after one year of follow-up. One could argue that the initial follow-up period in the TEHAF study might have been too short to reveal long-term effects of telemonitoring. Learning effects of the tailored education system may not become clear during a one-year follow-up period. Therefore, we conducted a retrospective analysis eight years after patients participated in the TEHAF study. We hypothesized that initial trends observed after one-year follow-up, particularly in time to first hospital admission due to HF, may have become stronger over time.

Methods

TEHAF study

As previously described,[24] the TEHAF study (NCT00502255) was a randomized controlled trial comparing tailored telemonitoring with usual care in 382 HF patients between October 2007 and December 2009, of which 301 completed the trial phase. The study was conducted in three hospitals in the Netherlands (Maastricht, Heerlen, Sittard) with an initial follow-up duration of 12 months. The intervention group received an electronic device, the Health Buddy®, which offered education, self-care support and monitoring by asking patients about their symptoms, knowledge and behaviour on a daily basis. Incorrect answers about knowledge or behaviour were revised automatically and the right answers were shown to the patient. If symptoms were reported, patients were contacted with advice or for further investigation. Twice during the study period, patients had personal contact with a HF specialist (i.e. a heart failure nurse (HFN) or cardiologist). Control patients had four personal contact moments with a HF specialist. Patients in both groups were treated according to the guidelines of the European Society of Cardiology.[25] The primary endpoint of the original TEHAF study was time to first HF-related hospital admission. Secondary endpoints were mortality, hospitalizations, costs, disease-specific knowledge, self-care, self-efficacy and depression.

Long-term follow-up

In this analysis, we included all patients who completed the TEHAF study ($n = 301$), on the basis of the original TEHAF randomization.[22] More specifically, patient data obtained from the start of the TEHAF study in October 2007 until October 2015 was employed. This approach was not part of the original TEHAF study protocol, but represents a new retrospective study. The current analysis was approved by the local ethics committees of Maastricht (METC 15-4-195.1/ivb) and Heerlen/Sittard (METC 15-N-188(15-4-195)). The investigation conforms to the principles outlined in the Declaration of Helsinki.[26]

Electronic patient files of all three participating hospitals were screened for several parameters: time to first HF-related hospital admission, number, duration and cause of all hospital admissions, day of death, emergency cardiac care visits, telephonic consultations (TCs) and outpatient department visits. Hospital admissions were classified as HF-related, cardiac origin or other (non-cardiac and non-HF). TCs and outpatient department consultations were performed by a specialized HFN, HF cardiologist or non-HF cardiologist, and were subdivided into HF or cardiac-related consultations. Emergency cardiac care visits were counted and classified as visits due to exacerbation of HF or due to other causes.

We also determined whether patients from the intervention group continued using the Health Buddy® and whether patients from the control group started with telemonitoring after completing one-year follow-up of the TEHAF study to evaluate the use of telemedicine devices after the study period. The Health Buddy® was the only telemonitoring device for HF patients prescribed by the participating hospitals.

Endpoints

The primary endpoint was the time to first HF-related hospital admission. Secondary endpoints were all-cause mortality, days alive and out of hospital (DAOOH), number and duration of (HF-related, cardiac-related or other) hospital admissions, as well as HF-related or cardiac-related outpatient department visits, TCs or emergency cardiac care visits.

Statistical analysis

Descriptive statistics were used to describe the baseline characteristics of the population, stratified by treatment group. To analyse differences in baseline variables, the Student's t-test (if data were normally distributed) or Mann–Whitney test (if data were not normally distributed) were used. Cox regression and the associated Kaplan–Meier survival estimates were used to analyse time to first

HF-related hospital admission and overall survival. All significant variables from the univariate analysis were included in the Cox regression. In addition, log-rank tests were used to test for differences between the treatment groups. Explorative Kaplan–Meier survival curves were estimated for patients receiving telemonitoring after the initial trial period (stratified by original treatment group).

The number of events for the number and duration of hospital admissions, outpatient department visits, TCs and emergency cardiac care visits were analysed using Poisson tests. Zero-inflated Poisson regression was used for hospital admissions and emergency cardiac care visits (to handle excess zeros), while 'standard' Poisson regression was used for outpatient department visits and TCs (as no excess zeros were present, i.e. almost all patients had one or more outpatient department visits and TCs). For the 'standard' Poisson regression, the 'sandwich' package was used to obtain robust standard errors to handle potential over-dispersion. DAOOH was analysed using the Student's *t*-test (assuming a normal distribution), since the Poisson distribution can be approximated by a normal distribution for high event rates. In both the Cox and Poisson regression analyses, forward selection was used to select covariates (using the stepAIC) function in R: (k = qchisq(0.05, 1, lower.tail = F)). A *p*-value of < 0.05 was considered statistically significant. Single stochastic regression imputation was used to impute missing values for (total number of missing values in brackets): ejection fraction (4), duration of HF (19), pacemaker (13), New York Heart Association (NYHA) Functional Classification (12), marital status (2), rhythm at baseline (0), educational level (16), left bundle branch block (6) and cause of HF (3).[27] This imputation was performed using the following R code: mice(data, method = 'pmm', m = 1, maxit = 1, seed = 1).

All analyses were performed in R version 3.1.3.

Results

The baseline characteristics as described in Table 1 were derived from the original TEHAF study.[22] We included an elderly HF population consisting of slightly more males than females, with mild to moderate symptoms. There were no significant differences in baseline characteristics between control and intervention groups apart from the underlying heart rhythm. Mean follow-up was 1652 days (standard deviation (SD): 1055 days).

Primary endpoint

No statistically significant difference in time to first HF-related hospital admission between the intervention group and the control group was found ($p = 0.15$; Figure 1).

Secondary endpoints

In the intervention group, 97 patients died during follow-up compared to 82 patients in the control group. The time to all-cause mortality was not significantly different ($p = 0.43$; Figure 2).

In total, 95 HF-related hospital admissions were reported in the intervention group compared to 142 in the control group. Patients in the intervention group had significantly fewer HF-related hospital admissions than patients in the control group (incident rate ratio 0.54, 95% confidence interval (CI) 0.31–0.88) (Table 2). However, the duration of HF-related hospital admissions was not significantly shorter in the intervention group (incident rate ratio 0.60, 95% CI 0.33–1.07).

Patients that underwent telemonitoring had significantly fewer total outpatient clinic visits and HF-related outpatient clinic visits than control patients (Table 2). Total hospital admissions (incident rate ratio 0.87, 95% CI 0.40–1.66), duration of hospital admissions (incident rate ratio 0.93, 95% CI 0.71–1.18) and number of emergency cardiac care visits (incident rate ratio 0.85, 95% CI 0.25–2.45) were not significantly different between both groups. Similarly, TCs did not differ between both groups (incident rate ratio 1.14, 95% CI 0.90–1.43).

We did not find significant differences in DAOOH between both groups. Mean DAOOH for the intervention group was 1618 days (SD: 1052 days) compared to 1635 days (SD: 1061 days) in the control group ($p = 0.87$).

Patients in the NYHA class 3 or 4 had an increased risk for all-cause mortality (hazard ratio (HR) 1.74, 95% CI 1.29–2.34; Table 3). Advanced age and ischemic HF increased the risk for mortality, whereas sinus rhythm at baseline reduced risk for all-cause mortality.

Cross-over characterization

In total, 84 patients (43%) of the intervention group continued using the Health Buddy® after completing the TEHAF study; mean time of usage was 1.74 years (SD: 1.21 years). Eighteen patients (10%) of the control group started with telemonitoring after the TEHAF study was completed. The rest of the control group did not use telemonitoring during follow-up period, ranging from date of inclusion in the TEHAF study to October 2015. Mean time of telemonitoring in the control group was 2.67 years (SD: 1.30 years). Mortality was comparable between both groups (Figure 3).

Furthermore, we compared patients who used telemonitoring to patients who never used telemonitoring. There were no significant differences in mortality ($p = 0.51$, calculated with log-rank test) or time to first hospital admission due to HF ($p = 0.39$, calculated with log-rank test) between both groups.

Discussion

In our retrospective analysis, telemonitoring did not reduce the time to first HF-related hospital admission and did not decrease all-cause mortality in the long term. These results are consistent with the findings of the original TEHAF study.

Table 1. Comparison of baseline characteristics of intervention and control groups.

Variable	*n*	Overall	Intervention (197)	Control (185)	*p*-value
Age	382	71 ± 11	71.0 ± 11.9	71.9 ± 10.5	0.621
⩾75		173 (45)	88 (45)	85 (46)	0.199
Gender	382				0.747
Male		226 (59)	115 (58)	111 (60)	
Married/partner ($n = 379$)	379	245 (64)	122 (62)	123 (66)	0.265
Education	363				0.589
Primary school		122 (34)	63 (33)	59 (34)	
Secondary school/low vocational training		162 (45)	91 (48)	71 (41)	
Middle vocational training		42 (12)	19 (10)	23 (13)	
High vocational/university		37 (10)	17 (9)	20 (11)	
History of HF (months)[a]	382	18 (6–40)	19 (6–41)	17 (6–40)	0.413
HF history <18 months		196 (51)	98 (25)	98 (26)	
Range			1–18–240	1–15–293	
NYHA classification/no (%)	382				0.404
NYHA II		219 (57)	110 (56)	109 (59)	
NYHA III		153 (40)	79 (40)	74 (40)	
NYHA IV		10 (3)	8 (4)	2 (1)	
Blood pressure[a]	382				
Systolic		123 (110–140)	120 (110–140)	125 (110–140)	0.156
Diastolic		70 (65–80)	70 (64–80)	73 (65–80)	0.193
Heart rate[a]	382	74 (65–85)	75 (68–85)	72 (68–85)	0.252
LBBB	382	42 (11)	20 (10.2)	22 (11.9)	0.587
Heart rhythm at baseline	382				
Sinus rhythm		209 (55)	96 (48.7)	113 (61.1)	0.015
Atrial fibrillation		97 (25)	62 (31.5)	35 (18.9)	0.007
Pacemaker rhythm		71 (18)	36 (18.3)	35 (18.9)	0.817
Other		5 (1)	3 (1.5)	2 (1.1)	na
Echocardiography					
Ejection fraction[a]	374	36 (28–48)	36 (28–50)	35 (26–42)	0.751
Ischemia	382	190 (50)	99 (50.3)	91 (49.2)	0.835
Pacemaker		112 (29)	59 (29.9)	53 (28.6)	0.147
DDD		34 (30)	15 (25)	19 (36)	
Biventricular		9 (8)	2 (3)	7 (13)	
ICD		25 (22)	14 (24)	11 (21)	
Biventricular ICD		38 (34)	24 (41)	14 (26)	
Other		6 (6)	4 (7)	2 (4)	
Medication					
Diuretics	380	333 (87)	170 (86)	163 (88)	0.783
ACE inhibitors	378	217 (57)	113 (58)	104 (57)	0.826
ATII-antagonists	373	123 (33)	67 (35)	56 (31)	0.459
Beta-blockers	379	310 (82)	161 (82)	149 (81)	0.689
Digoxin	372	91 (24)	46 (24)	45 (25)	0.770
Nitrates	376	136 (36)	64 (33)	72 (39)	0.212
Statins	377	218 (57)	111 (57)	107 (58)	0.900
Coumarins	377	214 (57)	119 (61)	95 (52)	0.084
ASA	373	131 (35)	60 (31)	71 (39)	0.091

Values are presented as number (%) or mean ± standard deviation.

[a]Median (interquartile range 25–75).

ACE: angiotensin-converting enzyme; ATII: angiotensin II; ASA: acetylsalicylic acid; DDD; dual-chamber pacing; ICD: implantable cardioverter-defibrillator; LBBB: left bundle branch block; NYHA: New York Heart Association Functional Classification.

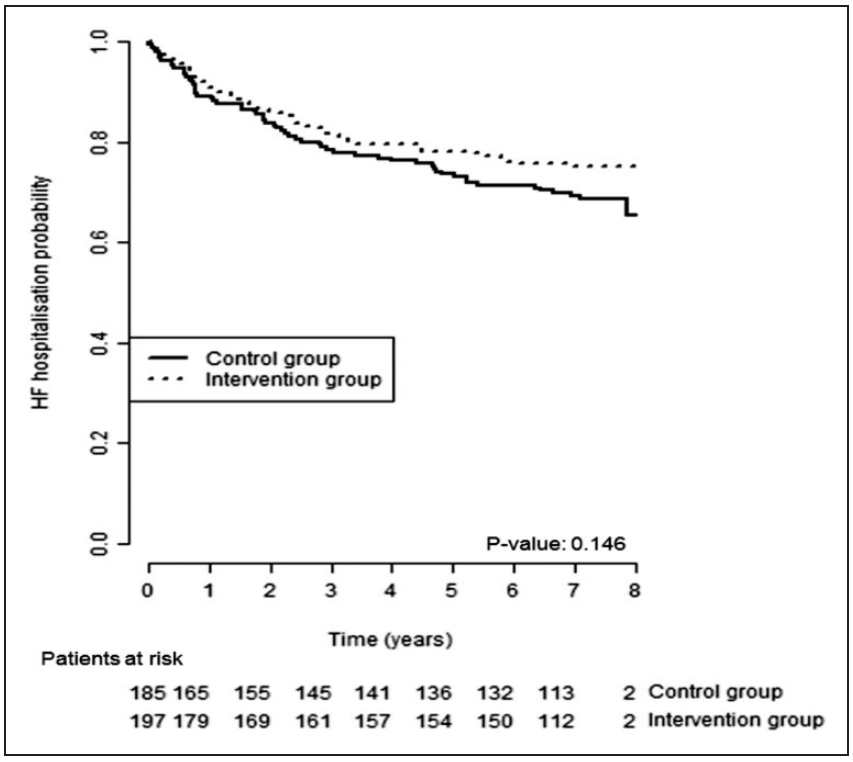

Figure 1. Time to first HF-related hospital admission.

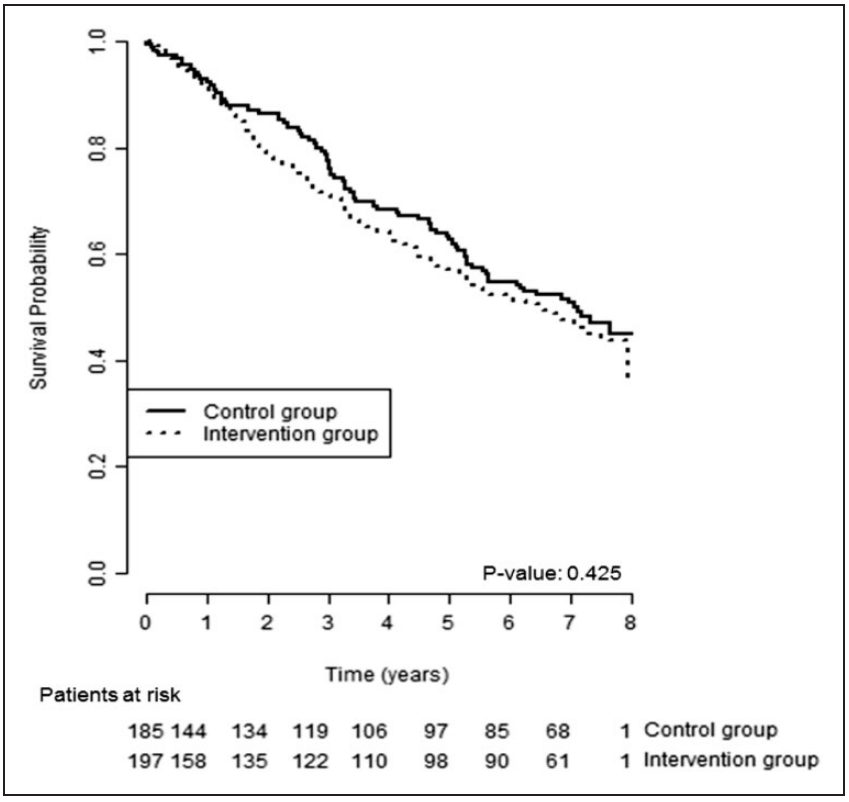

Figure 2. Survival analysis of all-cause mortality.

Table 2. Hospital admission, hospital stays, outpatient clinic visits, emergency cardiac care visits and telephonic consultation compared between intervention and control groups.

HF	Events control group ($n = 144$)	Events intervention group ($n = 157$)	Incident rate ratio (I vs. C)	95% CI
Total hospital admission (*n*)	142	95	0.54	**(0.31; 0.88)**
Hospital admission (days)	1379	1038	0.60	(0.33; 1.07)
Outpatient clinic visits (*n*)	1319	1233	0.81	**(0.67; 0.98)**
Telephonic consultation (*n*)	3395	4436	1.13	(0.89; 1.43)
Emergency cardiac care (*n*)	80	65	0.86	(0.63; 1.24)
Cardiac, non-HF				
Total hospital admission (*n*)	132	132	1.10	(0.33; 3.26)
Hospital admission (days)	673	692	0.88	(0.75; 2.50)
Outpatient clinic visits (*n*)	1007	965	0.91	(0.76; 1.09)
Telephonic consultation (*n*)	84	122	1.62	(0.75; 3.50)
Other				
Total hospital admission (*n*)	333	345	0.89	(0.71; 1.10)
Hospital admission (days)	3099	3244	1.03	(0.75; 1.43)
Total				
Total hospital admission	607	572	0.87	(0.40; 1.66)
Hospital admission (days)	5151	4974	0.93	(0.71; 1.18)
Outpatient clinic visits (*n*)	2326	2198	0.85	**(0.76; 0.95)**
Telephonic consultation (*n*)	3479	4558	1.14	(0.90; 1.43)
Emergency cardiac care (*n*)	198	178	0.85	(0.25; 2.45)

C: control group; HF: heart failure; I: intervention group; Incident rate ratio: incident rate of intervention group divided by incident rate of control group; Other: non-cardiac, non-HF; total: HF plus cardiac plus other; 95% CI: 95% confidence interval.

Table 3. Cox regression analysis of all-cause mortality.

Independent variable	HR	95% CI	*p*-value
NYHA	1.74	1.29–2.34	<0.01
Age	1.06	1.04–1.08	<0.01
Sinus rhythm	0.57	0.42–0.78	<0.01
Ischemic HF	1.55	1.14–2.11	<0.01

HR: hazard ratio; NYHA: New York Heart Association Functional Classification; 95% CI: 95% confidence interval.

The aim of telemonitoring in HF patients is to reduce hospital admissions and disease-related mortality.[13] This may be achieved by constant supervision to adapt to changes in health status.[28] A variety of telemonitoring systems has been used in HF to date; for example, STS, non-invasive monitoring and even invasive monitoring.[29] The Health Buddy® system includes both STS and non-invasive telemonitoring, whereby patients report symptoms daily and are guided telephonically when necessary. Therefore, the Health Buddy® serves as an alarm system, recognizing early clinical deterioration. Another crucial part of the Health Buddy® is the tailored education system, which helps to increase patients' disease-specific knowledge.[23]

Tailored telemonitoring reduced the number of HF-related hospital admissions in the long term in the present study. These results are novel compared to the original TEHAF study and may be due to the effect of additional disease-specific knowledge obtained during intervention on patients' behaviour, which may continue after completion of the intervention. These findings could potentially represent another indication for telemonitoring. Furthermore, patients in the intervention group had fewer total and HF-related outpatient department visits. At the same time, the number of TCs tended to be higher in the intervention group. It might be that face-to-face contacts could be avoided because both patients and caregivers felt safe to interact by telephone due to prior use of remote telemonitoring. However, no difference in DAOOH could be detected. This is in line with a previous report by Angermann et al.[30] Nevertheless, our study was not designed for this outcome and underpowered to detect differences in hospitalization. Therefore, with a negative primary endpoint, these findings can at most be considered to be hypothesis generating.

In the CHAT study by Krum et al., the use of STS and a computer-based education system led to a significant reduction of total hospital admission and outpatient department visits.[31] However, hospital admissions due to HF did not differ significantly between the telemonitoring and usual care groups. Patients in the CHAT study received education once per month or, if preferred by the patient, several times per month. In contrast, our patients received disease-specific information every day. In the CHAT study, medical follow-up was performed

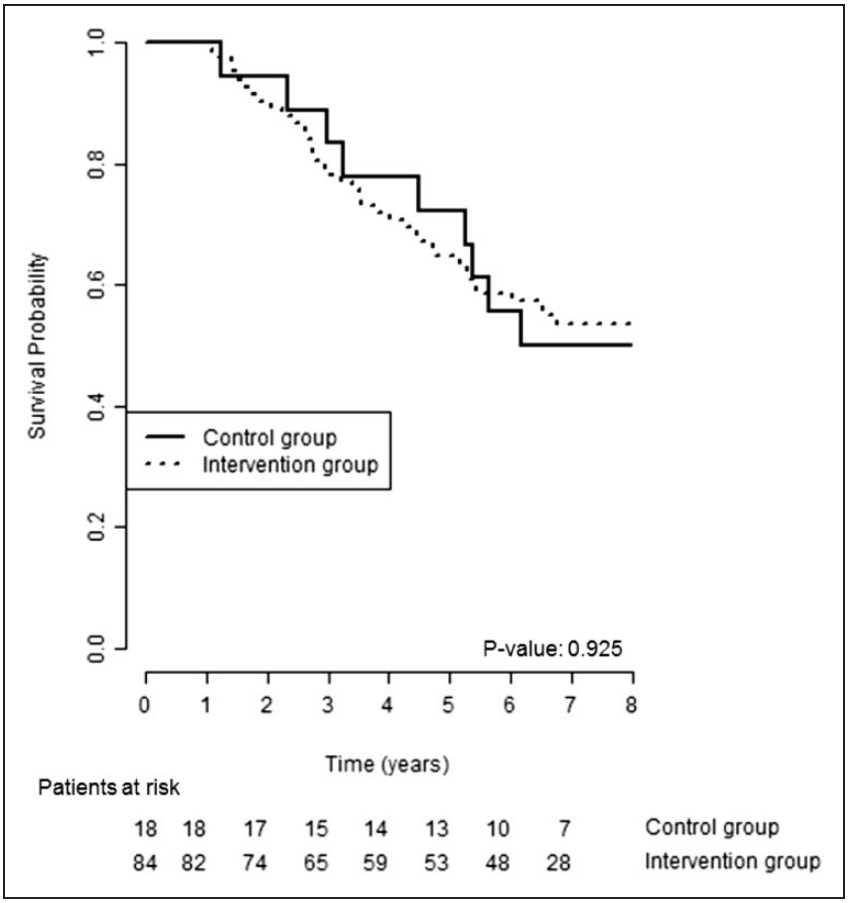

Figure 3. Survival analysis of patients with telemonitoring after completion of TEHAF.

by general practitioners, whereas patients in the intervention group could additionally contact HFN specialists. No fixed specialist consultations were planned. In our study, medical follow-up occurred on a regular basis (four times in the control group, twice in the intervention group) and was performed by a HF specialist (cardiologist or nurse). This might have led to the earlier detection of HF progression in our study population.

Chaudhry et al. used telemonitoring to observe patients more closely (Tele-HF, 2010).[14] The intervention group could respond daily to questions about HF signs and symptoms, and clinicians evaluated the answers. However, at the end of the study only half of the patients responded more than twice a week. They found no differences in death, readmission or days in hospital, or in the combined end-point death or readmission, which may be due to low adherence. Also, the Tele-HF study used telemonitoring and STS as a warning system only and not for educational purposes, as was done in the TEHAF study. Therefore, a combination of education and remote monitoring may be desirable. This is in line with the guideline recommendations, which strongly support education of HF patients.[32] Finally, Ong et al. investigated the combined effect of education, remote monitoring and vital parameters in HF patients.[33] No differences in readmission or mortality between both groups could be seen after 180 days, which could be due to the short, probably inadequate follow-up period. Given the length and variability in HF time course, it seems inconsequent to use telemonitoring for several months only, whereas, for example, HF medication is usually given lifelong.

There was no difference in all-cause mortality between both groups. Similarly, no differences could be found in the survival between patients of the control group starting with telemonitoring after completing the TEHAF trial and patients of the intervention group continuously using telemonitoring.

Besides cross-over, there was a significantly higher prevalence of atrial fibrillation (AF) in the intervention group at baseline compared to the control group.[23] Although the exact relationship between HF and AF is not clear, AF is thought to be an independent predictor of poor prognosis in patients with HF.[34–36]

The characteristics of HF patients suitable for telemonitoring remain unclear. Likewise, there is no consensus on the type of telemonitoring and its optimal scheduling.[37] Therefore, caregivers and patients have to make the decision about whether and how telemonitoring could be applied on an individual basis.

In the original TEHAF study with a follow-up duration of one year, no effect of telemonitoring on time to first HF-related hospital admission or mortality could

be identified. It was hypothesized that the learning effects of a one-year education program may only become apparent after a longer period of time. However, extension of the follow-up period had no impact on our primary outcome. Therefore, the extension of follow-up periods of telemonitoring studies in HF patients is not beneficial. Due to the effects on number of HF admissions and time of hospitalization, a period of telemonitoring may be recommended in daily HF care.

Limitations

The TEHAF study was underpowered to detect differences in time to first HF-related hospital admission and all-cause mortality and was not designed for the endpoint DAOOH. A recently admitted HF population was used for power calculations. In contrast, our study population was enlisted from outpatient clinic visits.[22] Therefore, most patients were already well treated, resulting in a relatively low all-cause mortality rate after one year (7.8%) compared to a more contemporary population; for example, in the PARADIGM-HF trial (9%).[38] Due to the relatively good state of health, the additional use of telemonitoring was probably not essential. Furthermore, due to crossover and a higher prevalence of AF in the intervention group, differences between intervention and control group may be underestimated. Those outpatients, who participated in the intervention or control group of the TEHAF-study, were asked if they wanted to continue or start using the Health Buddy®. Therefore, 10% of the control group and 43% of the intervention group were using telemonitoring after completing the TEHAF trial. Thus, in 53% of patients, treatment over time was different from that assigned by randomization. Also, the reasons for the decision to start or continue application of telemonitoring after cessation of TEHAF cannot be retrieved. Nonetheless, no effect of telemonitoring on mortality or time to first HF-related hospital admission could be observed when patients who used telemonitoring were compared to those that never used telemonitoring. Therefore, the effect of cross-over seems questionable. Still, the most appropriate scenario would have been an extension of the original trial with a longer intervention and control period.

Conclusion

Telemonitoring had no influence on time to first HF-related hospital admission or mortality during long-term follow-up. Telemonitoring reduced hospital admissions due to HF in the long term, and an extension of follow-up period is not recommended.

Declaration of Conflicting Interests

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