Center of Rehabilitation Research

Remote Telemonitoring in Chronic Heart Failure Does Not Reduce Healthcare Cost but Improves Quality of Life: Endpoints of the CardioBBEAT Trial

Heinz Völler[1,2], Dominik Bindl[3], Klaus Nagels[3], Reiner Hofmann[3], Eik Vettorazzi[4], Karl Wegscheider[4], Eckart Fleck[5], Eckhard Nagel[3]
on behalf of the CardioBBEAT Investigators

Background

Evidence that home telemonitoring (HTM) for patients with chronic heart failure (CHF) offers clinical benefit or a health economic advantage over usual care is controversial. Therefore the CardioBBEAT trial was designed to prospectively assess simultaneously the benefit and the health economic impact of a dedicated home monitoring system for patients with CHF based on actual costs directly obtained from patients' health care providers.

Methods

Between January 2010 and June 2013, 621 patients (mean age 63,0 ± 11,5 years, 88% male) with a confirmed diagnosis of CHF (LVEF ≤ 40%) were enrolled and randomly assigned to two study groups (Tab. 1 + 2) comprising usual care with and without an interactive bi-directional HTM (Motiva®). Patients measured their vital signs (blood pressure, heart rate and weight) every day and Motiva® transferred the data to the telemonitoring center. A call was made if patients gained more than 2 kg within 3 days, if their systolic blood pressure ereceeded 140 mmHg or was lower than 90 mmHg, or their resting heart rate exceeded 80 bpm or was lower than 50 bpm.

Table 1: Baseline characteristics of study participants

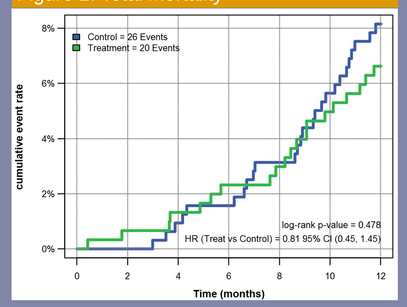
Characteristic	All patients n = 621	Usual care n = 319 (51%)	Monitoring n = 302 (49%)	*p*-value
Demographic profile				
Age (years) mean ± SD	63.0 ± 11.5	63.5 ± 11.4	62.5 ± 11.6	0.303
Male sec, *n* (%)	544 (88)	280 (88)	264 (87)	0.990
Living alone, *n* (%)	159 (26)	77 (24)	82 (27)	0.442
Education (years) mean ± SD	12 ± 3	12 ± 3	12 ± 3	0.803
Causes of heart failure, *n* (%)				0.797
Ischemic CM	363 (59)	185 (58)	178 (59)	
Non-ischemic CM	258 (42)	134 (42)	124 (41)	
NYHA class III-IV, *n* (%)	191 (31)	110 (35)	81 (27)	0.048
Peripheral edema, *n* (%)	131 (21)	83 (26)	48 (16)	0.003
Comorbidities, *n* (%)				
Stroke/TIA	41 (7)	21 (7)	20 (7)	1.000
COPD	87 (14)	48 (15)	39 (13)	0.516
Renal dysfunction (GFR ≤ 60 ml/min)	148 (24)	87 (27)	61 (20)	0.048
Depression	51 (8)	24 (8)	27 (9)	0.619
Diabetes mellitus, *n* (%)	219 (35)	103 (32)	116 (38)	0.131

Table 2: Baseline characteristics of study participants – diagnostic and devices

Characteristic	All patients n = 621	Usual care n = 319 (51%)	Monitoring n = 302 (49%)	*p* value
Diagnostic				
ECG				0.031
Sinus rhythm	379/619 (61)	185/318 (58)	194/301 (65)	
Atrial fibrillation	78/619 (13)	46/318 (15)	32/301 (11)	
Pacemaker ECG	154/619 (25)	86/318 (27)	68/301 (23)	
LBBB number/total number (%)	145/543 (27)	69/272 (25)	76/271(28)	0.543
RBBB number/total number (%)	49/544 (9)	28/273 (10)	21/271 (8)	0.383
2D echocardiography				
LVEDD; mean (mm) ± SD	62 ± 9	62 ± 9	63 ± 9	0.580
LVEF (%); mean ± SD	30 ± 7	31 ± 7	30 ± 8	0.580
Mitral insufficiency – number/total number (%)				0.319
moderate	121/614 (20)	70/315 (22)	51/299 (17)	
severe	21/614 (3)	10/315 (3)	11/299 (4)	
6-minute-walk test				
mean ± SD	375 ± 132	376 ± 132	374 ± 131	0.804
Devices, *n* (%)				
Pacemaker	101 (16)	61 (19)	40 (13)	0.061
ICD				0.280
with monitoring	63 (10)	31 (10)	32 (11)	
without monitoring	242 (39)	134 (42)	108 (36)	
CRT-D	89 (14)	40 (13)	49 (16)	0.232

Cost data were obtained from patients health insurance companies subdivided into cost of inpatient and outpatient care, rehabilitation, nursing, medication and life-saving appliances. The primary endpoint was the Incremental Cost-Effectiveness Ratio (ICER) established by the groups' difference in total cost and in the combined clinical endpoint "days alive and not in hospital nor inpatient care per potential days in study" within the follow up of 12 months (difference intervention minus control). Secondary outcome measures were total mortality and health related quality of life (SF-36, WHO-5 and KCCQ).

Figure 1: Total mortality

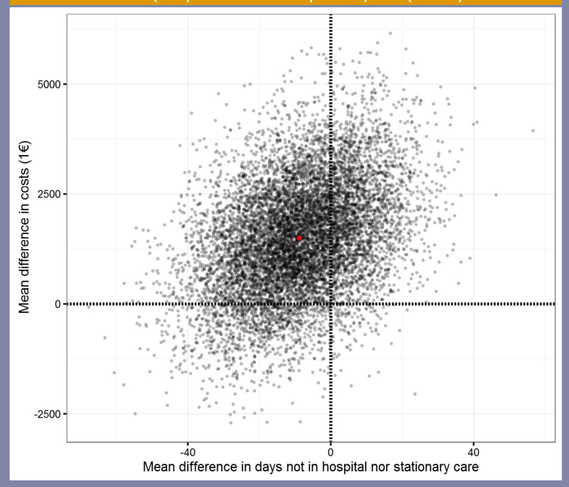


Results

Total mortality (HR 0.81; 95% CI [0.45, 1.45]) and days alive and not in hospital (HTM mean days 340.8, SD 58.6 vs usual care 345.5, SD 45.9; p = 0.784) were not significantly different between HTM and usual care (Fig. 1).

It was possible to gather cost data from 38 out of 55 health insurances for 492 patients. The resulting primary endpoint ICER was neutral (−171.3, 95% CI [−1680.6, 1626.0 €/day]) (Fig. 2).

Figure 2: Cost effectiveness of telemonitoring: observed ICER (red) and bootstrap samples (black)

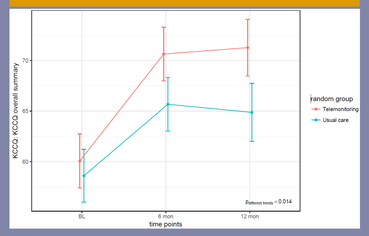


Quality of life assessed by SF-36, WHO-5 and KCCQ as a secondary endpoint was significantly higher in the HTM group at 6 and 12 months of follow-up (Tab. 3, Fig. 3).

Table 3: Estimated difference in change (12-month value baseline) of quality of life

	N	Est. Diff	Confidence interval 2.5 %	Confidence interval 97.5 %	*p* value
KCCQ Overall Summery Score	416	5.48	2.295	8.66	< 0.001
KCCQ Clinical Summary Score	416	4.00	0.272	7.27	0.017
WHO-5 raw	409	1.26	0.301	2.22	0.010
WHO-5 percent	409	5.04	1.206	8.88	0.010
SF-36 PCS	412	1.99	0.492	3.49	0.009
SF-36 MCS	412	2.74	0.862	4.61	0.004

Figure 3: KCCQ overall summery score



Conclusions

Simultaneous assessment of clinical and economic outcome of HTM in patients with CHF showed no incremental cost effectiveness, but an improved quality of life compared to usual care without HTM. The place of the tested HTM solution in the recent health care setting remains to be defined.

1 Center of Rehabilitation Research, University of Potsdam, Germany
2 Klinik am See, Rüdersdorf, Germany
3 Institute for Healthcare Management and Health Sciences, University of Bayreuth, Germany
4 University Medical Center Hamburg-Eppendorf (UKE), Germany
5 German Heart Institute Berlin, Germany

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Contact: heinz.voeller@klinikamsee.com