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Telemonitoring of patients with chronic heart failure with reduced ejection fraction (HFrEF)

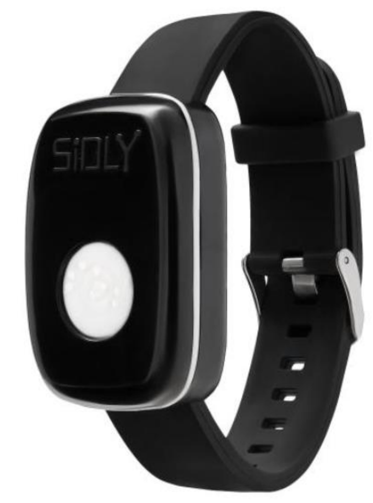
The aim of the study is to explore whether telemonitoring facilitates the early detection of HF aggravation which might enable to counteract HF decompensation and to prevent hospitalisations at the level of an ambulatory intervention.

Introduction

Heart failure (HF) becomes a worldwide health problem due to the fact of its severe and progressive course, the high and constantly growing prevalence reaching 3.2% in the Polish population and a very high annual mortality rate of 17%. Every heart failure decompensation often equivalent to the hospitalisation increases the risk of death or absence of recovery to previous level of functioning.

Methodology

The aim of the study is to assess the quality of life, HF symptoms, the need for treatment modification and the presence of HF decompensation in patients with heart failure with reduced ejection fraction (HFrEF) while using a telemonitoring method of electronic wristband measuring physical activity and physiological parameters. The outcomes in the study group will be compared to the data from the control group of patients having the same medical profile, but not using telemonitoring.



Inclusion criteria:

- provided written informed consent prior to any study specific procedures;
- males and females aged > 18 years of age at the time of consent;
- documented diagnosis of HFrEF (LVEF ≤ 40%) and assessed by echocardiography during 12 months prior to enrolment;
- symptoms of chronic heart failure in the II–IV NYHA (New York Heart Association) class;
- optimal chronic heart failure treatment by means of pharmacological medication and/or implantable devices prior to enrolment

1:1

30 patients — Study group with an electronic wristband

30 patients — Control group without an electronic wristband

1 month | 1 month | 1 month

Visit 1 (enrolment) — Visit 2 — Visit 3 — Visit 4 (wristband use ends)

Assessment of:

- **the quality of life:**
  - the Kansas City Cardiomyopathy Questionnaire (KCCQ),
  - patient's self-assessment of their health status on the visual analogue scale (VAS),
  - frailty syndrome risk questionnaire (6ADL – the 6 activities of daily living);
- **HF signs and symptoms**;
- **the need for treatment modification**;
- **medical events**
- **the presence of HF decompensation or hospitalisation in patients or its equivalents**

Collection of:

- past medical history
- ambulatory or in-hospital examinations
- inclusion in the Heart Failure Observational Study of the Polish Cardiac Society (HEart FailuRe ObsErvational Study – HEROES

Groups	Study	Control	p value
Age: mean (SD)	65.8 (11.92)	68.23 (12.36)	0.329
Gender			
Men: N (%)	18 (60%)	24 (80%)	0.096
Women: N (%)	12 (40%)	6 (20%)	
BMI [kg/m2]: mean (SD)	30.71 (8.83)	27.27 (3.47)	0.156
HFrEF: N (%)	30 (100%)	30 (100%)	0
Enrolment:			
ambulatory: N (%)	12 (40%)	13 (43.33%)	0.802
hospitalised: N (%)	18 (60%)	17 (56.67%)	
LVEF: median % (IQR)	29 (21.25–35.75)	32 (26.0–37.75)	0.213
HF aetiology:			
ischaemic: N (%)	12 (40%)	19 (63.33%)	0.074
non-ischaemic: N (%), including:	18 (60%)	11 (36.67%)	
idiopathic dilated	6 (20%)	3 (10%)	
post-inflammatory	4 (13.33%)	2 (6.67%)	
tachycardia-induced	3 (13.33%)	1 (3.33%)	
chemotherapy-related	2 (6.67%)	2 (6.67%)	
non-compaction	1 (3.33%)	0 (0%)	
alcohol-induced	1 (3.33%)	1 (3.33%)	
related to valvular disease	1 (3.33%)	2 (6.67%)	
NYHA scale:			
I: N (%)	0 (0%)	0 (0%)	0.499
II: N (%)	24 (80%)	26 (86.67%)	
III: N (%)	6 (20%)	4 (13.33%)	
IV: N (%)	0 (0%)	0 (0%)	
Dyslipidaemia: N (%)	30 (100%)	30 (100%)	0
Hypertension: N (%)	28 (93.33%)	30 (100%)	0
Nicotin abuse: N (%)	22 (73.33%)	24 (80%)	0.552
CKD: N (%)	17 (56.67%)	23 (76.67%)	0.105
Diabetes mellitus: N (%)	14 (46.67%)	14 (46.67%)	0.993
Persistent/permanent AF: N (%)	14 (46.67%)	8 (26.67%)	0.585
Implanted ICD/CRT: N (%)	9 (30.00%)	9 (30.00%)	0.993
Stroke/TIA: N (%)	5 (16.67%)	4 (13.33%)	0.347

The hypothesis of the study assumes an improvement of the assessed parameters in the group of patients in which the method of telemonitoring is applied.

AF – atrial fibrillation; BMI – body mass index; CKD – chronic kidney disease defined as GFR< 60 ml/min/1,73m2; CRT – cardiac resynchronization therapy; HF – heart failure; HFrEF – heart failure with reduced ejection fraction; ICD – implantable cardioverter defibrillator; IQR – interquartile range; LVEF – left ventricle ejection fraction; N – number of patients; NYHA – New York Heart Association Functional Classification; SD – standard deviation; TIA – transient ischemic attack; % – percentage of patients