Telemedical Interventional Management in Heart Failure (TIM-HF II)

Telemedical Interventional Management in Heart Failure II (TIM-HF2)

Chronic heart failure is a widespread disease that currently affects about 1.2 million patients in Germany. With approximately 450,000 hospitalizations in 2016, it represents the most frequent reason for hospitalization. The outcome of this is the enormous charging of costs for care on these patients from the health and care insurance providers which makes more than three billion euros p.a. (Statistisches Bundesamt 2017).

In a controlled, prospective, multicentre, randomized, controlled clinical trial TIM-HF II (NCT01878630, DRKS00010239) the non-inferiority of a new ambulatory care model for underdeveloped rural area without resident cardiologists in patients with chronic heart failure (CHF) compared to regions with practicing cardiologists regarding medical health and economic effectiveness will be tested.

Primary endpoint is “Percentage of days lost due to unplanned cardiovascular (CV) hospitalization or due to death for any reason during the individual follow-up time”.

1,538 patients were recruited from metropolitan areas with more than 200,000 inhabitants and/or with a medical University and in rural areas in Germany.

inclusion criteria

- chronic heart failure New York Heart Association (NYHA) class II or III
- echocardiographically determined left ventricular ejection fraction (LVEF) ≤45% or >45% + minimum 1 diuretic in permanent medicinal therapy
- hospitalization due to decompensated HF within the last 12months before randomization
- informed consent

exclusion criteria

- Hospitalization within the last 7 days before randomization
- Implantated cardiac assist system
- Acute coronary syndrome within the last 7 days before randomization
- High urgent listed for heart transplantation (HTx)
- Planned revascularization, Transcatheter Aortic Valve Implantation (TAVI), MitraClip and/or Cardiac Resynchronization Therapy (CRT)-implantation within the last 3 months before randomization
- Revascularization and/or CRT-implantation within 28 days before randomization
- Known alcohol or drug abuse
- Terminal renal insufficiency with hemodialysis
- Impairment or unwillingness to use the telemonitoring equipment (e.g. dementia, impaired self-determination, lacking ability to communicate)
- Existence of any disease reducing life expectancy to less than 1 year
First clinical results

Primary Outcome: Patients of the RPM Group lost less days due to unplanned cardiovascular hospitalisation or all-cause death in contrast to the Usual Care Group (RPM: 17.8 days; Usual Care: 24.2 days; p=0.046).

Secondary outcomes: Also the all-cause mortality was significant reduced (RPM: 8 days, Usual Care: 11 days, p:0.028). For unplanned hospitalisation due to heart failure patients of the RPM Group lost 3.8 days per year while patients of the Usual Care Group lost 5.6 days per year (p=0.007).

Relevance for Clinical Practice

The TIM-HF2 trial results indicate that, in a well-defined HF population followed for 12 months, a holistic RPM approach reduces:

1. Days lost due to unplanned CV hospitalisations and all-cause death
2. Total mortality and
3. Days lost due to unplanned HF hospitalisations.

A well structured Telemedical Centre, providing 24/7 service, is a key element within the RPM intervention.

The subgroup analysis suggests that RPM is an effective approach to overcome regional differences in HF Management.

Publications:


Age < 18 years
Pregnancy
Participation in other treatment studies or remote patient management programmes (register studies possible)