Title:

OPTILOGG - pooled analysis from two randomized controlled trials.

Authors:

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Topic(s):

Heart failure, other

Background:

OPTILOGG® is a home based tool for heart failure (HF) patients, which monitors symptoms, titrates diuretics and educates the patient about HF. Patient Centred Management of Heart Failure (PACEMAN-HF) was a prospective, multi-centre, randomized controlled trial (RCT) that showed that OPTILOGG® significantly reduced in-hospital days by 28% and also reported a system compliance of 85% after 6 months. In addition to RCTs and their focus on efficacy, there is a growing need for real-life data, to make results generalizable. Pragmatic trials are designed to evaluate the effectiveness of interventions in real-life routine practice conditions. Such a trial has been conducted within primary care, in Gotland, Sweden.

Methods:

100 patients were enrolled. The mean age was 78+/-9, 65% were male, 43% NYHA class III, 48% NYHA class II and 9% NYHA class I. All patients were listed at a heart failure clinic in primary care, with a confirmed heart failure diagnosis and recently performed echocardiography. Patients were randomized 1:1 to either receive OPTILOGG® (intervention group, IG) or not (control group, CG). The 2 groups were well balanced at randomization. Aside from prescribing OPTILOGG®, routine practise remained unchanged. All hospitalizations for the patients were recorded for 6 months. All heart failure related hospitalizations were adjudicated by a HF specialist.

Results:

After 6 months, there was a 33% reduction of in-hospital days due to HF [RR: 0.67; 95% CI: 0.45-0.99; p<0.05] in the intervention group, and the compliance to OPTILOGG® was 97% [IQR: 91% - 99%]. A multiple regression analysis, adjusted for differences in health status, was

performed on pooled data from both studies, based on 610 in-hospital days and 172 patients. The adjusted risk ratio with a 95% confidence interval was 29.2% [RR: 0,708; 0,607-0,825], and the median system compliance for the pooled cohort was 94% [IQR: 84% - 98%].

Conclusion:

Results from pooled analysis from two RCTs are consistent with the previously published results, showing a reduction of in-hospital days. This indicates that the results are generalizable and reliable.

Declaration of interest:

The authors report no conflict of interest.