

The latest research in telecardiology presented at ESC Congress 2018

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Abstract

In this article, we presented the late-breaking trials in the Telemedicine session during the European Society Cardiology Congress 2018. TIM-HF2, REMOTE-CIED, RM-ALONE and

DIGITAL-AF trials are briefly summarized. Based on these studies, remote monitoring seems to play a more and more important role in cardiology.

During the 2018 European Society Congress, approximately 4500 scientific abstracts were featured. The most significant trials were presented in the special "Late-Breaking Science" sessions. In this article, we present the latest research in telemedicine featured at the Late-Breaking Science in Telemedicine session on August 25 during the ESC Congress 2018.

The TIM-HF2 study was designed to assess whether the remote patient management program has an impact on mortality, morbidity and quality of life in patients with heart failure (HF). These study results were published simultaneously in The Lancet on August 25, 2018^[1,2]. More than 1500 patients with heart failure New York Heart Association (NYHA) class II and III, who had been admitted to hospital for heart failure within 12 months before randomization, without major depression, were included. Patients were randomized to remote patient

management plus usual care or usual care only. Patients were followed for approximately one year. The primary endpoint was the percentage of days lost due to unplanned cardiovascular hospital admissions or all-cause death. The remote patient management intervention consisted of daily transfer of body weight, blood pressure, heart rate, heart rhythm, saturation, and self-rated health status to the telemedical centre. Nurses and physicians assessed the data sent on a daily basis and contacted the patient or primary physician if necessary.

The mean age of all participants was 70 years. Approximately 70% were men. The mean left ventricular ejection fraction was 41%. More than 90% of patients received beta-adrenolytics, more than 80% received angiotensin-converting enzyme inhibitors, and more than 50% received aldosterone antagonists. Loop diuretics were prescribed in more than 90% of participants.

One third had an implantable cardioverter-defibrillator (ICD), and 15% of patients had a cardiac resynchronization therapy (CRT) device implanted. The primary endpoint occurred in 4.88% of patients in the remote patient management group and 6.64% of patients in the usual care group (95% CI 0.65–1.00; $p=0.046$). Patients in the remote patient management group lost a mean of 17.8 days per year and in the usual care group 24.2 days. Total mortality was 7.86 per 100 person-years in the remote patient management group compared with 11.34 per 100 person-years in the usual care group (HR 0.70, 95% CI 0.5–0.96, $p=0.028$). The authors commented: “this is the first randomized controlled trial to use a structured remote patient management intervention that was designed to be a true holistic approach for the management of patients with heart failure, involving cardiologists, general practitioners, nurses, other health-care providers, and the patient”. A key factor in the success is to organize a telemedical centre with personnel available 24/7 able to act promptly if necessary.

The REMOTE-CIED trial was aimed to assess the patient-reported outcome of patients referred to remote monitoring in a group of ICD recipients with heart failure [2]. This prospective, multicenter trial was supported by a research grant from Boston Scientific and sponsored by University Medical Center Utrecht in the Netherlands. A total of 600 patients aged 18–85, with heart failure NYHA II–III class and scheduled first ICD or CRT-D implantations, were included in the study. After implantation patients were randomized in a 1:1 scheme to an in-clinic group or a remote patient monitoring and in-clinic group. The remote patient monitoring was performed via the Latitude system. After implantation patients were asked to complete questionnaires referring to health status and patients’ acceptance of ICD. Outcome measures included the Kansas City Cardiomyopathy Questionnaire (KCCQ) and Florida Patient Acceptance Survey (FPAS). Patients were followed for 2 years. Moreover, the cost-effectiveness of remote patient monitoring was also assessed. The in-clinic group was followed up every 3–6 months in the hospital. The remote patient monitoring group was seen in the hospital once a year and the follow-up was performed by remote monitoring.

Baseline characteristics were comparable in both study groups. During the 2-year follow-up there was no significant difference in health status or ICD acceptance between the groups. Patients rated the Latitude system with a median score of 9/10. Approximately 97% of patients would recommend it to other patients and 87% declared better awareness of their health. What is more, remote patient monitoring produced significant cost benefits with regard to ICD follow-up. In-office visit costs were lower in the remote patient monitoring group by about 15% (865 Euro vs. 732 Euro, $p=0.002$) and total costs were lower by about 22% (4268 Euro vs. 3336 Euro, $p=0.02$). The mortality rate in both groups was very low (around 3.3% per year). The authors concluded that we can safely use remote patient monitoring. Remote patient monitoring is cost-effective and patients are highly satisfied with this follow-up strategy.

The RM-ALONE trial was designed to demonstrate non-inferiority of Home Monitoring (HM) only with respect to home monitoring plus in office (IO) visits in patients with pacemakers and ICD [2]. The workload of the staff was also evaluated. The study was funded by Biotronik. After 3 months of implantation, patients were randomized to the HM only group or HM + IO group. The HM group was assessed remotely every 6 months. The HM + IO group was evaluated during routine follow-up every 6 months. After 1 year all patients were contacted via a phone call. Patients were followed for 2 years. After the 2-year period all patients were evaluated in the clinic. After each evaluation the patient received written information about assessed parameters and proper device function. The primary endpoint consisted of death, stroke, hospitalization due to cardiac causes and device-related procedures.

There were 220 patients randomized to the HM only group and 225 randomized to the HM + IO group. The primary endpoint occurred in 20.5% of HM only patients and 19% of HM + IO patients (p value for non-inferiority 0.0152). There were no differences between study groups when individual components of the primary endpoint were evaluated. Scheduled visits were less frequent in the HM only group (0.06 vs. 2.45 rate per patient/24 months follow-up, $p<0.001$). Unscheduled visits were comparable in both groups (0.55 vs. 0.44 rate per patient/24 months follow-up, $p=0.15$). Mean time of physician and nurse work per patient was significantly lower in the HM only group. Authors summarized that remote monitoring is not inferior in terms of safety; it reduces in office evaluations without a significant increase of unscheduled visits and reduces the workload of the staff.

The DIGITAL-AF study evaluated the FibrCheck – the first medically approved smartphone application for heart rhythm disorders (CE certificate, class IIa medical device) [2]. The FibrCheck uses pulse-plethysmography through the smartphone camera to identify atrial fibrillation. First, the authors published the article in a local newspaper and recruited 12 328 participants who downloaded the app in 48 hours. Participants were asked to measure their heart rhythm twice a day and when experiencing symptoms for a 7-day study period. The application made 60-second heart rhythm recordings. Each recording was automatically classified as regular rhythm, possible atrial fibrillation, irregular rhythm or insufficient quality. All recordings were transferred to an external server. After the study patients received feedback with the results and recommendations.

Mean participant age was 49 years; 58% were men. After a week the authors received 120 446 traces. A total of 98 586 were normal rhythm, 9 733 had insufficient quality and 12 127 had possible irregularities. Atrial fibrillation was detected in 615 traces (in 136 participants). In 76% of these patients, atrial fibrillation was asymptomatic. In a group of 136 participants with atrial fibrillation, 38 had permanent/persistent form and 98 had paroxysmal form. The authors contacted patients with atrial fibrillation. Unfortunately, 36 of them did not provide

contact details. In 60 patients atrial fibrillation was diagnosed previously: in 17 patients treatment was changed – in most cases oral anticoagulation was started. In 40 patients atrial fibrillation was newly diagnosed. In 21 of them, atrial fibrillation was confirmed during the primary care physician visit; 19 patients did not make a recommended appointment with a doctor. The DIGITAL-AF study provided the first mass screening for atrial fibrillation using a smartphone only. The authors noted that we can reach a large population and collect clinically meaningful data via the app. Moreover, no clinical infrastructure is needed, and this screening method seems to be cost-effective.

The ESC Congress 2018 featured some of the latest research in the telemedicine area. Telemonitoring plays an important role in cardiovascular patients. Remote monitoring is cost-effective, safe and it decreases the staff workload. Heart failure patients' telemonitoring improves their prognosis. Finally, a smartphone app helps in accurate atrial fibrillation diagnosis in the general population.

References

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