UPDATE ON ARRHYTHMIAS: HIGHLIGHTS FROM THE 2018 ESC MEETING IN MUNICH

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REMOTE MONITORING

Use of telemonitoring in patients with a cardiac implantable device failed to improve patient-reported outcome and device acceptance

The REMOTE-CIED trial is the first trial to investigate the role of telemonitoring in patients with cardiac implantable devices and heart failure, with respect to patient-reported outcomes and device acceptance. This prospective, multicenter, randomized controlled trial enrolled 600 patients from 5 countries. The patients were equally randomized to either remote patient monitoring or routine care by in-clinic follow-up. The primary outcome was the impact on patient-reported health status and implantable cardioverter defibrillator acceptance determined by the Kansas City Cardiomyopathy Questionnaire and the Florida Patients Acceptance Survey. Follow-up was 24 months and included in-office visits as well as telemonitoring in the remote patient monitoring group. The analysis of the primary outcome revealed identical values for all assessed patient-reported outcomes by the Kansas City Cardiomyopathy Questionnaire and device acceptance outcomes by the Florida Patients Acceptance Survey. Analyses of secondary outcomes, including mortality and implantable cardioverter defibrillator therapy, also did not show any between-group differences, only a trend toward a potential benefit with respect to less implantable cardioverter defibrillator therapies (P=0.1) could be observed in the remote patient monitoring group. Estimated cost calculations in both groups revealed lower costs in the remote patient monitoring group (-22%; P=0.02 vs routine care). In summary, the REMOTE-CIED trial failed to provide any evidence for a potential benefit by remote patient monitoring regarding patient-reported outcomes in patients with heart failure and cardiovascular implantable electronic devices. The results showing lower cost estimation in remote patient monitoring vs routine care are promising, but only hypothesis-generating that needs direct validation in future trials.

Benefit on mortality by use of telemonitoring-guided care in patients with heart failure

The TIM-HF 2, a prospective randomized open-label national trial, was conducted in Germany at 113 sites. The aim of the study was to evaluate the effect of the utilization of a telemonitoring system including pre-specified diagnostic and therapeutic algorithms in patients with heart failure. The primary end point was a composite of all-cause mortality and percentage of lost days due to hospitalization based on cardiovascular reasons. Inclusion criteria comprised symptomatic heart failure with a recent heart failure–associated hospitalization within the last 12 months. The main difference from previous telemonitoring trials was based on the prespecified algorithms including 24/7 surveillance by a telemedical center and immediate initiation of actions based on the telemonitoring findings (eg, occurrence of arrhythmias). In total, 1538 patients were enrolled and randomized in a 1:1 fashion to the groups of remote patient monitoring or routine care. The follow-up was 12 months. The primary end point was a significant reduction in the remote patient monitoring group compared with the standard care group (HR, 0.8; *P*=0.046). In addition, the single secondary end point of all-cause mortality was also reduced in the remote patient monitoring group (HR, 0.7; *P*=0.028). Analysis of quality of life (QOL) was unaffected by the use of remote patient monitoring. Further prespecified subgroup analysis also failed to show an interaction for subgroups benefitting more from remote patient monitoring than others. In contrast to previous trials, the TIM-HF2 trial provides evidence for a potential benefit of remote patient monitoring use with respect to clinical outcomes in a setting with an around-the-clock telemonitoring center and predefined workflows for initiation of diagnostic and therapeutic work-ups based on the telemonitoring findings.[1]

ATRIAL FIBRILLATION

First trial on smartphone-based arrhythmia detection using a pulse plethysmogram application

The DIGITAL-AF trial presented by Pieter M. Vandervoort (BE) was one highlight of the ESC meeting from an electrophysiological point of view, since it is the first trial showing that the world's first medically approved smartphone application using pulse plethysmography can detect AF in a broad real-life population. The objective of this trial was to compare the detection of AF based on the pulse plethysmography smartphone algorithm to an established 1-lead ECG device and to determine the prevalence of AF in a voluntary real-life population.

Within 48 hours, 12328 volunteers were enrolled, resulting in 120447 pulse plethysmography recordings (60 seconds each) over a 1-week recording period. The mean age was 49±14 years, with 58% of all participants being male. The primary automated heart rhythm analysis showed 98586 regular recordings without

rhythm abnormalities, while 12 127 pulse plethysmography recordings suggested a potential arrhythmia; 9733 recordings were insufficient in quality for a further analysis. The final analysis revealed 615 real AF episodes in 136 patients, confirmed by independent and trained technicians. Patients with AF were older (62±11 years), predominantly male (74%), and had a higher BMI. Overall, 76% of all AF episodes were asymptomatic and 72% were paroxysmal in nature. The total prevalence was 1.1% in the studied cohort. While the results of the prevalence are interesting, the main highlight of this trial was the feasibility of using a regular smartphone without an additional ECG device for AF detection in the broad population. In view of this first trial, further upcoming studies using digital devices implicated in the daily routine for arrhythmia screening will clearly follow. The impact of these digital devices on preventive approaches is still unclear and requires delineation in subsequent studies.

Ablation therapy improves QOL in patients with AF

This subanalysis of the CABANA trial, presented by Daniel Mark (US) during the ESC meeting, sought to evaluate the effect of ablation therapy compared with routine drug therapy in patients with AF with respect to QOL outcomes. The main CABANA trial randomized 2204 patients 1:1 to either ablation therapy or drug therapy to evaluate a composite clinical end point of death, disabling stroke, serious bleeding, or cardiac arrest. The primary analysis revealed a neutral result of both treatment strategies regarding the primary end point. This predefined subanalysis aimed to investigate the effect of the two distinct treatment strategies on QOL as a secondary end point. The median follow-up was 48.5 months. QOL was assessed by SF-36, DASI, and EQ5D questionnaires. QOL data were collected for 92% of eligible patients at 12 months and 81% at 60 months. The QOL questionnaire analyses showed a consistent benefit with ablation vs drug therapy regarding a QOL change represented in significantly increased Mayo AF-Specific Symptom Inventory (MAFSI) and Atrial Fibrillation Effect on QualiTy of life (AFEQT) scores over the 60-month follow-up period. In summary, the secondary analysis of this large, prospective, randomized, open-label controlled ablation trial clearly suggests and confirms a substantial improvement in QOL when using an ablation strategy in patients with symptomatic AF, which was sustained for up to 5 years.

UPDATE ON ANTICOAGULATION

Comparative effectiveness of oral anticoagulation in everyday practice

The aim of the GARFIELD Prospective Registry was to (i) compare baseline characteristics and comparative safety and effectiveness of OAC with no OAC and (ii) compare the use of VKA vs non–VKA agents (NOACs) in a real-life AF cohort of the worldwide GARFIELD registry. End points included all-cause mortality,

stroke and/or systemic thromboembolism, and major bleeding episodes during a 2-year follow-up period. Analysis was performed using Cox proportional hazard models with propensity score weighting for treatment. In total, 34 854 patients from 35 countries were screened for eligibility and finally 26 742 patients with a CHA_2DS_2-VASc score ≥2 were included for the analysis. Out of this cohort, 19 134 were on OAC treatment (10 234/53.3% on NOACs and 8 900/46.5% on VKA), while 7 608 received no OAC treatment (60% on antiplatelet agents). Primary analysis revealed a clear benefit of OAC vs no OAC with respect to all-cause mortality (HR, 0.83; 95% CI, 0.75-0.93; *P*<0.001), stroke/systemic thromboembolism (HR, 0.73; 95% CI, 0.59-0.90; *P*=0.003), while major bleeding rates strongly tended to be higher in the OAC group compared with patients not receiving OAC (HR, 1.36; 95% CI, 1.00-1.85; *P*=0.053). The analysis of NOAC vs VKA revealed a clear benefit for NOAC use with respect to all-cause mortality (HR, 0.81; 95% CI, 0.71-0.92; *P*=0.001), while stroke / systemic thromboembolism (HR, 0.85; 95% CI, 0.65-1.11; *P*=0.237) and major bleeding rates (HR, 0.81; 95% CI, 0.59-1.11; *P*=0.192) were unchanged compared with VKA-treated patients. This study provides further evidence for a beneficial use of a preventive OAC treatment in patients with AF. In addition, these results suggest and further highlight a preference for the use of NOACs instead of VKA in patients with AF and an indication for OAC in line with the current guideline recommendation. ■

REFERENCES

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