

## 心不全において家庭テレモニタリングは役立つ

**IN-TIME：植込み型家庭モニタリングによりICD植え込み後心不全患者の臨床管理が改善する**

**IN-TIME: Implant-based home monitoring improves clinical management of heart failure patients with ICDs**

植込み型除細動器 (ICD) または心臓再同期療法除細動器 (CRT-D) を、異常の可能性を医療専門家に警告するテレモニタリング技術と組み合わせることで、心不全患者は有意な生存上の恩恵を被るとの研究結果が2013年European Society of Cardiology学会で発表された。IN-TIMEトライアルは、3か月以上持続する慢性心不全のNew York Heart Association (NYHA) クラスIIまたはIIIの症状を有し、左室駆出率が35%以下に低下している平均年齢66±9歳の患者664人を解析した。全ての患者がテレモニタリング機能を有する植込み型デバイスを装着され、58%はCRT-Dを、42%は植込み型デュアルチャンバーデバイスを植え込まれた。1か月間の導入期間は心不全治療の最適化に使用され、デバイスのトランスミッションシステムが機能していることが確認された後、テレモニタリング群(333人)または標準治療群(331人)に無作為に割り付けられた。12か月後に悪化した患者はテレモニタリング群よりも標準治療群において多かった(27.5%対18.9%、 $P<0.05$ )。総死亡率および心血管死亡率は、標準治療群よりもテレモニタリング群において低かった(3.4%対8.7%、 $P<0.01$ )。

### Full Text

Heart failure patients have significant survival benefits when their implanted cardioverter-defibrillators (ICD) or cardiac resynchronization therapy defibrillators (CRT-D) are fitted with telemonitoring technology that alerts medical experts to potential problems, results of the IN-TIME trial reveal. New technology that allows transmission of diagnostic data from implanted devices to a monitoring physician or clinic, as opposed to patients being followed via in-office visits, allows early detection of atrial or ventricular arrhythmias or specific trends in certain clinical parameters said lead investigator Gerhard Hindricks, M.D., from the Heart Center Leipzig, Germany.

"The rapid transmission of information compared to traditional methods of monitoring patients gives physicians more time to intervene if necessary, thereby preventing serious or even fatal events."

The IN-TIME trial showed that at one-year, significantly more patients randomized to telemonitoring scored better on a composite endpoint that included all-cause mortality and specific cardiac measures. The prospective, randomized, controlled, multicenter trial analyzed 664 patients, mean age 66±9 years, with chronic heart failure lasting for 3 months or more, class II or III New York Heart Association (NYHA) symptoms, and a reduced left ventricular ejection fraction (LVEF) of ≤35%.

Most patients included had ischemic heart disease (69%), mean LVEF was 26±6%, and heart failure medication diuretics (93%), beta-blockers (91%), and ACE inhibitors or angiotensin receptor blockers (89%). The primary endpoint of IN-TIME was the modified Packer score, a clinical composite score consisting of mortality, overnight hospitalization for worsened heart failure, and NYHA class global self assessment. A secondary endpoint of the trial was all-cause total mortality.

All patients were fitted with implanted devices that had a telemonitoring function, with 58% receiving a cardiac resynchronization device (CRT-D) and 42% an implantable dual chamber. Data transmission was initiated by a time trigger (e.g. 3 AM every day) or by a relevant arrhythmic or technical event, and was transmitted from the patient's implanted device to a central monitoring unit at the Heart Centre Leipzig. A run-in phase of one month was used to optimize patients' heart failure therapy and ensure that the device's transmission system was functioning after which patients were randomized to either telemonitoring (n=333) or standard care (n=331).

This meant that in the standard care group, telemonitoring data was still collected but was not accessible to the central monitoring unit or treating physicians until the end of the study. For these patients all treatment interventions were either patient-initiated or triggered by in-office follow-ups.

In contrast, for telemonitored patients, relevant observations such as frequency of ventricular extrasystoles, or atrial and ventricular tachyarrhythmia episodes were forwarded to the patient's treating physician, which could lead to additional follow-ups, and therapy changes at the physician's discretion.

At 12 months follow-up, significantly more patients in the control group as compared to the home monitoring group worsened according to the modified Packer score (27.5% vs. 18.9%;  $P<0.05$ ). Moreover, there was a significantly lower rate of all-cause mortality as well as cardiovascular mortality in the telemonitoring arm compared to controls (3.4% vs. 8.7%;  $P<0.01$ ;  $P<0.012$ ).

"The next step is to carefully analyze triggers, events, medical actions and of course the time lines to better understand the mechanism(s) by which modified Packer score was improved and all-cause mortality was so strongly reduced in heart failure patients supported by home monitoring," said Dr. Hindricks.

The IN-TIME trial results were presented during a Hotline session at the European Society of Cardiology 2013 Congress.

"That will be the basis for the clinical application of the study results and of course for future research in the field."

Dr. Hindricks declared he has received study grants, educational grants, and honoraria for lectures from Biotronik.

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