



Long-Term ECG Monitoring with Smartwear Enhances Atrial Fibrillation Detection Rate

Tokyo, Japan, March 31, 2023 – Toray Industries, Inc., and University of Tsukuba announced today that their collaborative research team, led by Takeshi Machino, MD, an assistant professor at the University of Tsukuba Faculty of Medicine, has verified clinical utility of two-week electrocardiogram (ECG) monitoring using medical smartwear, which comprises a garment incorporating dry ECG electrodes (see note 1) that employ fiber technology, in detecting recurrent atrial fibrillation following catheter ablation treatment (see note 2).

The number of patients with atrial fibrillation, which is a prime risk factor for all-cause mortality, cardiovascular death, and cerebral infarction, is now more than one million in Japan, and still increasing, due to its aging population. Although catheter ablation is a standard therapy for atrial fibrillation, it can recur in a few months after treatment, where around half are without symptoms. To detect the recurrence, it has been known that a continuous ECG monitoring for about 14 days is necessary (see note 3), so as to formulate suitable treatment plans that encompass reablation therapy, anticoagulants, and antiplatelet agents.

In conventional continuous ECG monitoring, electrodes are attached on the skin with conductive creams or gels. Average continuous monitoring duration with this conventional method is reported to be limited around seven days (see notes 3 and 4), due to skin rashes and other skin ailments, to which some people could be susceptible.

To solve this problem, the joint research group conducted a clinical research to verify the clinical utility of smartwear with skin-friendly dry fiber electrodes, which is expected to help extend continuous ECG monitoring duration up to two weeks, because neither creams or gels are in contact with the skin.

To this end, detection of atrial fibrillation recurrence by the smartwear ECG monitoring was compared to Holter monitoring in 67 patients that received initial ablation therapy. Standard ECG recording with a Holter monitor over 24 hours revealed four recurrences of atrial fibrillation, whereas smartwear ECG monitoring identified 12 recurrences with a mean continuous monitoring duration of 14 days. This showed that capability to detect atrial fibrillation by the smartwear ECG monitoring was three times more than Holter monitors, with a statistically significant difference of $p=0.008$. Thus, this research demonstrated the clinical utility of smartwear ECG monitoring with dry fiber electrodes lasting an average of 14 days to detect recurrent atrial fibrillation.

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The smartwear is easy to put on and remove, so that patients can bathe as needed during the monitoring period. Around 80% of subjects said that the smartwear ECG monitor was more comfortable than Holter monitors. Another potential benefit of this smartwear is that it could provide often overlooked detection of paroxysmal atrial fibrillation, as well as helping to diagnose embolic stroke of undetermined sources (see note 5).

This study was published in the online journal PLOS ONE on February 24, 2023 (see note 6).

Notes

1. For the joint research between Toray and the University of Tsukuba, the company provided the smartwear, comprising the hitoe™ wearable electrocardiogram monitoring system manufactured by Toray Medical Co., Ltd.
2. Catheter ablation is a standard treatment for atrial fibrillation where a catheter is threaded into the heart through a vein in the groin, and high-frequency current from the catheter tip cauterizes specific areas of the heart tissue.
3. Turakhia MP, Hoang DD, Zimetbaum P, Miller JD, Froelicher VF, Kumar UN, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. *J Cardiol.* 2013; 112: 520-524. <https://doi.org/10.1016/j.amjcard.2013.04.017> PMID: 23672988
4. Eisenberg EE, Carlson SK, Doshi RN, Shinbane JS, Chang PM, Saxon LA. Chronic ambulatory monitoring: results of a large single-center experience. *Innov Card Rhythm Manag.* 2014; 5: 1818-1823.
5. A cerebral infarction is called cardiogenic or non-cardiogenic according to the location of the thrombus causing the infarction. An infarction with an unknown cause is called an embolic stroke of undetermined source. Such strokes account for an 15% to 20% of all cerebral infarctions.
6. <https://doi.org/10.1371/journal.pone.0281818>