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Feasibility of Using a Leadless Patch Monitor in Community Cohort Studies: The Multiethnic Study of Atherosclerosis

Michael J. Zhang, MD, PhD[a], **Nicholas S. Roetker, PhD, MS**[b], **Aaron R. Folsom, MD, MPH**[b], **Alvaro Alonso, MD, PhD**[c], **Susan R. Heckbert, MD, PhD**[d], and **Lin Y. Chen, MD, MS**[a]

[a]Cardiovascular Division, Department of Medicine, University of Minnesota, Minneapolis, MN

[b]Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, Minneapolis, Minnesota

[c]Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA.

[d]Cardiovascular Health Research Unit and Department of Epidemiology, University of Washington, Seattle, WA

Asymptomatic and undetected “silent” atrial fibrillation (AF) is an important public health problem because it is often detected only after a stroke and its prevalence in the general population is not precisely known. The Zio Patch (Zio) is a simple device that can continuously record heart rhythm for 14 days. Although it is most commonly applied in clinic, data are sparse on the reliability of patient self-application. We therefore conducted a randomized controlled trial to evaluate whether a community-based cohort can self-apply the Zio, thus reducing the burden of an in-person visit.

The Multi-Ethnic Study of Atherosclerosis (MESA) is a cohort study of 6,814 men and women from six US communities evaluating progression of subclinical cardiovascular disease. We enrolled 45 participants older than 65 (Table 1) from the University of Minnesota field center.

We randomized 30 participants to self-application (Group 1) using written instructions and as-needed telephone assistance and 15 participants to in-office application by MESA staff (Group 2). We compared the Zio data using wear time (from device activation to the last recorded analyzable signal) and analyzable time fraction (proportion of total wear time that the ECG signal was sufficiently free of noise to be interpretable).

Table 2 displays the wear time and analyzable time fraction for the two study groups.

Address for correspondence: Lin Yee Chen, MD, MS, University of Minnesota Department of Medicine – Cardiovascular Division, 420 Delaware Street SE, MMC 508 Mayo, 8508A (Campus Delivery Code), Minneapolis, MN 55455, Fax number: 612-626-4411, Telephone number: 612-625-4401, chenx484@umn.edu.

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There was no statistical difference in mean wear time or analyzable time fraction between the Group 1 and 2. Although we excluded patients with previously documented AF, we nevertheless diagnosed two participants (4%) with AF. The most common adverse reaction was skin irritation; three participants removed their Zio as a result, and one participant self-administered diphenhydramine and left the Zio in place.

Our results suggest that self-application of the Zio is equivalent to in-office application. It also suggests it is feasible to conduct community-based cohort studies involving ambulatory event monitoring with self-applied Zio to detect silent AF in the general population. Because the Zio is a small, leadless, self-contained device with straightforward installation, the likelihood of a patient successfully self-applying the Zio is inherently high.

The primary limitation of this study was its small sample size. We only enrolled participants from a single MESA study site; it also did not encompass all the ethnicities represented in the entire cohort. Finally, our study did not have the power to correlate success of self-application with specific functional capacity of the participant. Thus, future studies with larger sample sizes can help identify specific patient factors that predict successful Zio self-application.

The overall implication of this study is that participants in community-based cohort studies can apply the Zio by themselves at home. If ever new clinical data emerge or widespread consensus forms to support screening for AF , self-application of the Zio is a potential screening method.

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Table 1.

Baseline Characteristics.

	All N=45	Group 1 (self-application) N=30	Group 2 (clinic-application) N=15
Age, (years) (SD)	71.6 (6.2)	72.2 (5.9)	70.3 (6.8)
Female sex	19 (42)	11 (37)	8 (53)
Hispanic ethnicity *	14 (31)	9 (30)	5 (33)
Hypertension	23 (51)	15 (50)	8 (53)
Diabetes	8 (18)	6 (20)	2 (13)
Coronary heart disease	2 (4)	2 (7)	0 (0%)

Data are presented as number (%) of participants unless otherwise stated.

SD, standard deviation

* Only Hispanic and non-Hispanic white participants were enrolled at the MN field center

Table 2.

Performance Metrics of Zio Patch in MESA. Participants were randomized to self-application vs. clinic-application. Group 1 participants self-applied the Zio Patch. Group 2 participants received Zio Patches in-office.

	Group 1 N=30	Group 2 N=15	p-value
Wear time (days)			
Mean (SD)	13.29 (2.27)	13.44 (1.06)	0.76†
Median (25th, 75th percentile)	13.86 (13.70, 13.99)	13.89 (13.09, 13.99)	0.80‡
≥48 hours	97%	100%	
≥6 days	97%	100%	
≥13 days	93%	80%	0.31§
Analyzable time fraction			
Mean (SD)	94% (12%)	97% (4%)	0.11†
Median (25th, 75th percentile)	98% (94%, 99%)	99% (98%, 100%)	0.07‡

† Differences tested using two-sample t-tests

‡ Wilcoxon rank sum tests

§ Fisher's exact test