

Supplementary Online Content

Steinhubl SR, Waalen J, Edwards AM, et al. Effect of a home-based wearable continuous electrocardiographic monitoring patch on detection of undiagnosed atrial fibrillation in individuals at increased risk: the mSToPS randomized clinical trial. *JAMA*. doi:10.1001/jama.2018.8102

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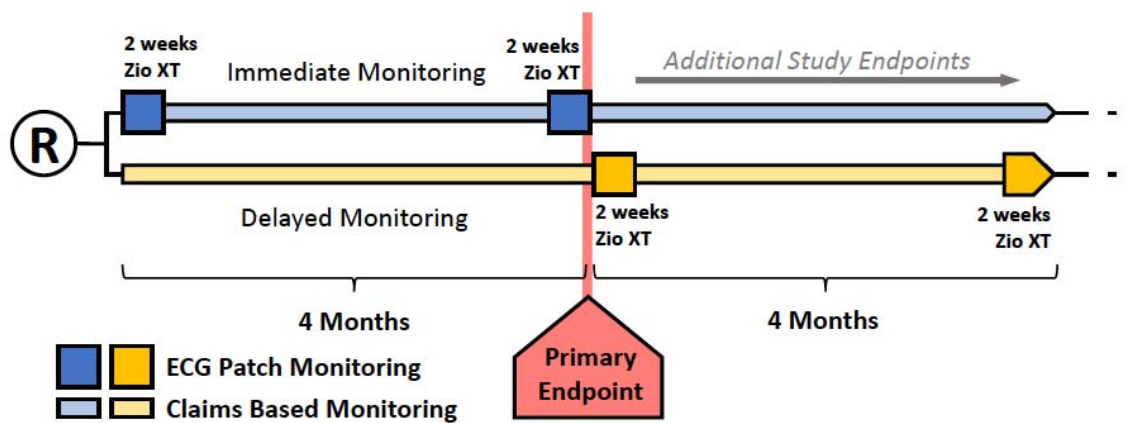
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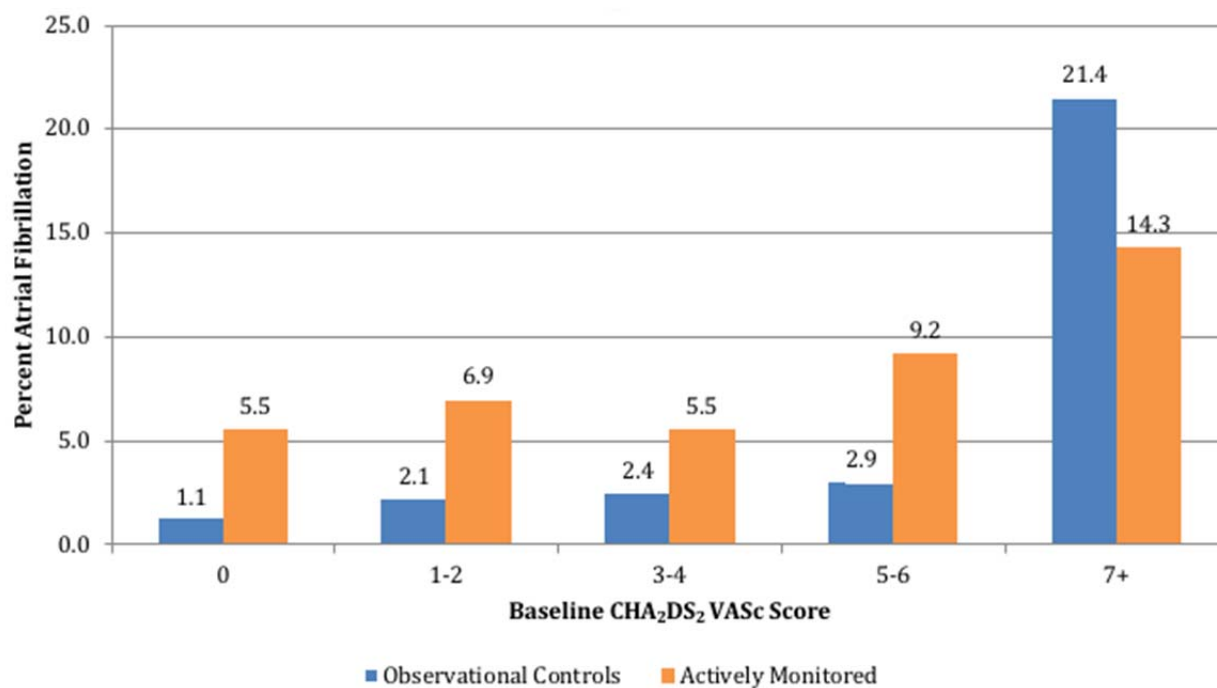
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This supplementary material has been provided by the authors to give readers additional information about their work.

eFigure 1. Diagram of Participant Activities, Timing and Flow in the Randomized Study of Immediate vs Delayed Monitoring



eFigure 2. Atrial Fibrillation Diagnosis Rates by CHA₂DS₂-VASc Score by Actively Monitored or Observational Groups



eTable 1. List of All Inclusion and Exclusion CriteriaInclusion Criteria:

- Age \geq 75 years old, or
- Male age > 55 years, or females age > 65 years, and
- Prior stroke or transient ischemic attack, or
- Heart failure, or
- Diagnosis of both diabetes and hypertension, or
- Mitral valve disease, or
- Left ventricular hypertrophy, or
- Chronic Obstructive Pulmonary Disease requiring home oxygen, or
- Sleep apnea, or
- History of pulmonary embolism, or
- History of myocardial infarction, or
- Diagnosis of obesity

Exclusion Criteria:

- Current or prior diagnosis of atrial fibrillation, atrial flutter or atrial tachycardia
- Receiving chronic anticoagulation therapy
- Hospice care
- End stage renal disease
- Diagnosis of moderate or greater dementia
- Implantable pacemaker and/or defibrillator
- History of skin allergies to adhesive patches
- Known metastatic cancer
- Aetna Compassionate Care Program (ACCP) participants – individuals with advanced illness and limited life expectancy

eTable 2. Baseline Characteristics of Consented Participants and Invited but Not Consented

	Enrolled (n=2,659)	Sent an invitation but did not enroll (n=99,877)	Differences and 95% Confidence Intervals
Age (years), mean (SD)	72.4 (7.3)	74.4 (8.4)	-2.0 (-2.3, -1.8)
Female , n (%)	1,026 (38.6%)	48,397 (48.5%)	-9.9 (-11.7, -8.0)
CHA₂DS₂ VASc Score , median (Q1- Q3)	3 (2-4)	3 (3-4)	-0.29 (-0.34, -0.25)
Stroke , n (%)	172 (6.5%)	7,160 (7.2%)	-0.7 (-1.6, 0.3)
Heart Failure , n (%)	101 (3.8%)	5,013 (5.0%)	-1.2 (-2.0, -0.5)
Hypertension , n (%)	1,900 (71.5%)	73,223 (73.3%)	-1.8 (-3.6, -0.1)
Diabetes Mellitus , n (%)	929 (34.9%)	37,569 (37.6%)	-2.7 (-4.5, -0.9)
Sleep Apnea , n (%)	536 (20.2%)	11,179 (11.2%)	9.0 (7.4, 10.5)
Prior Myocardial Infarction , n (%)	178 (6.7%)	6,929 (6.9%)	-0.2 (-1.2, 0.7)
Chronic Obstructive Pulmonary Disease , n (%)	144 (5.4%)	6,354 (6.4%)	-0.9 (-1.8, -0.1)
Obesity , n (%)	289 (10.9%)	9,045 (9.1%)	1.8 (0.6, 3.0)

CHA₂DS₂ VASc – A clinical prediction score for estimating the risk of stroke in individuals with non-rheumatic atrial fibrillation. An individual’s score can range from 0-9 with a high score associated with higher risk. Components include **C**- Congestive Heart Failure (1 point); **H** – Hypertension (1 point); **A₂** – Age \geq 75 years (2 points); **D** – Diabetes Mellitus (1 point); **S₂** – Prior stroke or transient ischemic attack (2 points); **V** – Vascular disease (1 point); **A** – Age 65-74 (1 point); **Sc** – Sex category (female=1 point)

Obesity was defined a documented BMI of 30.0 or greater, and/or an obesity-related diagnosis or procedure (e.g. bariatric surgery)

eTable 3. Baseline Characteristics of Those in the Actively Monitored Group Who Did and Did Not Wear an ECG Sensor Patch

	Wore Patch (n=1,738)	Did Not Wear Patch (n=917)	Differences and 95% Confidence Intervals
Age (years), mean (SD)	73.7 (7.0)	72.6 (7.7)	1.1 (0.5, 1.7)
Female , n (%)	704 (40.5)	321 (35.0)	5.5 (1.6, 9.4)
CHA₂DS₂ VASc Score , median (Q1-Q3)	3 (2-4)	3 (2-4)	0.04 (-0.07, 0.15) (Difference in means)
Stroke , n (%)	220 (12.7)	148 (16.2)	-3.5 (-6.3, -0.6)
Heart Failure , n (%)	87 (5.0)	41 (4.5)	0.5 (-1.2, 2.2)
Hypertension , n (%)	1,307 (75.2)	737 (80.5)	-5.2 (-8.5, -1.9)
Diabetes Mellitus , n (%)	606 (34.9)	393 (42.9)	-8.0 (-11.9, -4.1)
Sleep Apnea , n (%)	462 (26.6)	252 (27.5)	-0.9 (-4.5, 2.7)
Prior Myocardial Infarction , n (%)	91 (5.2)	56 (6.1)	-0.9 (-2.7, 1.0)
Chronic Obstructive Pulmonary Disease , n (%)	138 (7.9)	103 (11.2)	-3.3 (-5.7, -0.9)
Obesity , n (%)	289 (16.6)	185 (20.2)	-3.6 (-6.7, -0.4)
Chronic Renal Failure , n (%)	186 (10.7)	86 (9.4)	1.3 (-1.1, 3.7)

CHA₂DS₂ VASc – A clinical prediction score for estimating the risk of stroke in individuals with non-rheumatic atrial fibrillation. An individual’s score can range from 0-9 with a high score associated with higher risk. Components include **C**- Congestive Heart Failure (1 point); **H** – Hypertension (1 point); **A₂** – Age \geq 75 years (2 points); **D** – Diabetes Mellitus (1 point); **S₂** – Prior stroke or transient ischemic attack (2 points); **V** – Vascular disease (1 point); **A** – Age 65-74 (1 point); **Sc** – Sex category (female=1 point)

Obesity was defined a documented BMI of 30.0 or greater, and/or an obesity-related diagnosis or procedure (e.g. bariatric surgery)

eTable 4. Randomized Clinical Trial 4-Month AF Diagnosis Rate in the Primary Analysis and Per Protocol Populations Based on Different Definitions of AF in Claims Data

	Per Protocol		Unadjusted absolute difference (95% CI)	p-value	Primary Analysis		Unadjusted absolute difference (95% CI)	p-value
	Immediate Monitored (n=908)	Delayed Monitored (n=834)			Immediate Monitored (n=1,366)	Delayed Monitored (n=1,293)		
AF first diagnosed by ECG patch, – n (%)	37 (4.1%)	X			37 (2.7%)	X		
AF diagnosed clinically using first mention of ICD9 or ICD10 code, – n (%)	9 (1.0%)	5 (0.6%)			16 (1.2%)	12 (0.9%)		
Combined AF Diagnosis – n (%)	46 (5.1%)	5 (0.6%)	4.5% (3.0%, 6.0%)	<0.0001	53 (3.9%)	12 (0.9%)	3.0% (1.8%, 4.1%)	<0.0001
AF first diagnosed by ECG patch– n (%)	37 (4.1%)	X			37 (2.7%)	X		
AF diagnosed clinically requiring two mentions of ICD9 or ICD10 code– n (%)	1 (0.1%)	4 (0.5%)			6 (0.4%)	7 (0.5%)		
Combined AF Diagnosis – n (%)	38 (4.2%)	4 (0.5%)	3.7% (2.3%, 5.1%)	<0.0001	43 (3.1%)	7 (0.5%)	2.6% (1.6%, 3.6%)	<0.0001
AF first diagnosed by ECG patch – n (%)	37 (4.1%)	X			37 (2.7%)	X		
AF diagnosed clinically using Aetna Informatics Health Profile Database (HPD) algorithm – n (%)	3 (0.3%)	3 (0.4%)			6 (0.4%)	8 (0.6%)		
Combined AF Diagnosis – n (%)	40 (4.4%)	3 (0.4%)	4.0% (2.6%, 5.4%)	<0.0001	43 (3.1%)	8 (0.6%)	2.5% (1.5%, 3.6%)	<0.0001

eTable 5. Observational 1-Year AF Diagnosis Rate in the Per Protocol and Intention to Treat Populations Based on Different Definitions of AF in Claims Data

	Per Protocol		Unadjusted difference in Incidence Rates per 100 person-years (95% CI)	p-value	Intention to Treat		Unadjusted difference in Incidence Rates per 100 person-years (95% CI)	p-value
	Actively Monitored (n=1,738)	Observational Cohort (n=3,476)			Actively Monitored (n=2,659)	Observational Cohort (n=5,318)		
AF first diagnosed by ECG patch, – n (%)	65 (3.7%)	X			65 (2.4%)	X		
AF diagnosed clinically using first mention of ICD9 or ICD10 code, – n (%)	44 (2.5%)	81 (2.3%)			75 (2.8%)	132 (2.5%)		
Combined AF Diagnosis – n (%)	109 (6.3%)	81 (2.3%)	4.1 (3.9, 4.2)	<0.0001	140 (5.3%)	132 (2.5%)	2.9 (2.8, 3.0)	<0.0001
AF first diagnosed by ECG patch– n (%)	65 (3.7%)	X			65 (2.4%)	X		
AF diagnosed clinically requiring two mentions of ICD9 or ICD10 code– n (%)	30 (1.7%)	64 (1.8%)			51 (1.9%)	100 (1.9%)		
Combined AF Diagnosis – n (%)	95 (5.5%)	64 (1.8%)	3.8 (3.6, 3.9)		116 (4.4%)	100 (1.9%)	2.6 (2.5, 2.7)	<0.0001
AF first diagnosed by ECG patch – n (%)	67 (3.9%)	X			67 (2.5%)	X		
AF diagnosed clinically using Aetna Informatics Health Profile Database (HPD) algorithm – n (%)	26 (1.5%)	64 (1.8%)			49 (1.8%)	93 (1.7%)		
Combined AF Diagnosis – n (%)	93 (5.4%)	64 (1.8%)	3.6 (3.5, 3.8)	<0.0001	116 (4.4%)	93 (1.7%)	2.7 (2.6, 2.8)	<0.0001

eTable 6. Covariates Associated With Incident Atrial Fibrillation in the Full Study Population of 5214 Individuals and 190 New Cases of Atrial Fibrillation

	Unadjusted Incidence Rate Ratio (95% CI)	p-value	Adjusted Incidence Rate Ratio (95% CI)	p-value
Group (Monitored vs. Control)	2.57 (1.93, 3.43)	<0.0001	2.67 (2.00, 3.57)	<0.0001
Age (unit = 10 years)	1.77 (1.43, 2.18)	<0.0001	1.99 (1.53, 2.58)	<0.0001
Female	0.75 (0.55, 1.01)	0.06	0.75 (0.53, 1.07)	0.12
CHA₂DS₂ VASc Score	1.06 (0.95, 1.19)	0.31	0.88 (0.73, 1.04)	0.14
Stroke	1.25 (0.82, 1.92)	0.30	1.37 (0.88, 2.15)	0.16
Heart Failure	2.74 (1.81, 4.14)	<0.0001	2.81 (1.80, 4.36)	<0.0001
Hypertension	1.18 (0.83, 1.67)	0.36	1.41 (0.95, 2.09)	0.09
Diabetes Mellitus	0.57 (0.41, 0.79)	0.0009	0.71 (0.48, 1.03)	0.07
Sleep Apnea	0.96 (0.68, 1.36)	0.83	0.95 (0.65, 1.39)	0.80
Prior Myocardial Infarction	1.50 (0.91, 2.47)	0.11	1.50 (0.88, 2.54)	0.13
Chronic Obstructive Pulmonary Disease	1.74 (1.17, 2.58)	0.006	1.66 (1.11, 2.50)	0.01
Obesity	1.04 (0.72, 1.51)	0.83	1.43 (0.95, 2.13)	0.08
Chronic Renal Failure	0.99 (0.61, 1.61)	0.98	0.79 (0.48, 1.30)	0.35

CHA₂DS₂ VASc – A clinical prediction score for estimating the risk of stroke in individuals with non-rheumatic atrial fibrillation. An individual’s score can range from 0-9 with a high score associated with higher risk. Components include **C**- Congestive Heart Failure (1 point); **H** – Hypertension (1 point); **A₂** – Age \geq 75 years (2 points); **D** – Diabetes Mellitus (1 point); **S₂** – Prior stroke or transient ischemic attack (2 points); **V** – Vascular disease (1 point); **A** – Age 65-74 (1 point); **Sc** – Sex category (female=1 point)

Obesity is defined through the Health Profile Database using a combination of data types including a documented Body Mass Index of 30.0 or greater, and/or an obesity-related diagnosis or procedure (e.g. bariatric surgery)

* p-values and incidence rate ratios (IRRs) are from Poisson regression models that included single covariates (unadjusted) or all listed covariates in a full model (adjusted).