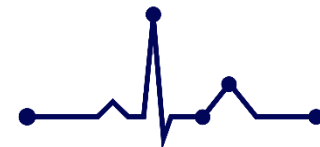


Clinical Significance of Wearable ECG Monitoring Devices



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COI Disclosure

The authors have no financial conflicts of interest
to disclose concerning the presentation



Wearable ECG monitoring devices

- Indication

- Screening in patients with high risk of stroke (for early detection of AF) (including cryptogenic stroke)
- Evaluation in patients with suspected arrhythmia (recurrent syncope or recurrent palpitation)

- Available Devices

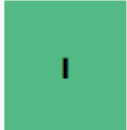
- Single-lead ECG devices (including patch-type), Smart watch, Ring-type
- ~~PPG-based monitoring devices~~
 - cannot diagnose arrhythmia because it does not detect electrical signal

Diagnosis of AF

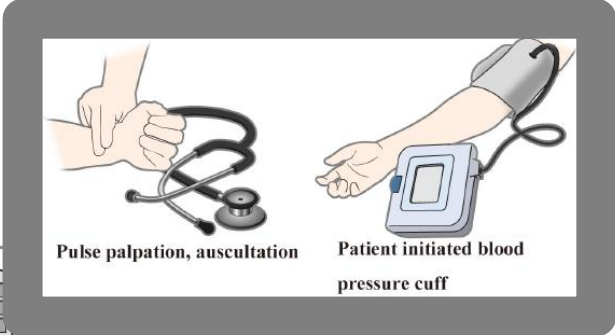
Recommendations for diagnosis of AF

ECG documentation is required to establish the diagnosis of AF.

A standard 12-lead ECG recording or a single-lead ECG tracing of ≥ 30 s showing heart rhythm with no discernible repeating P waves and irregular RR intervals (when atrioventricular conduction is not impaired) is diagnostic of clinical AF. **NOT PPG-based!**



2020 ESC Guidelines



Telemetry



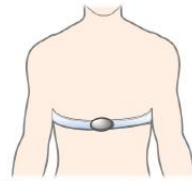
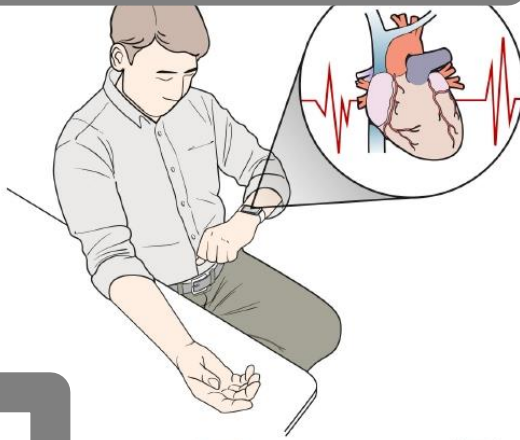
Long-term Holter



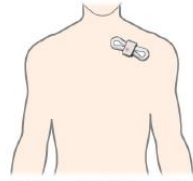
Implantable loop recorder



Intermittent smartwatch ECG



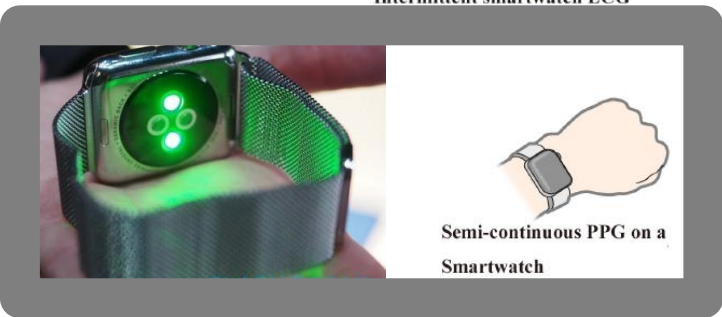
Wearable belt for continuous monitoring



1-2 week ECG patches



Patient initiated PPG on smartphone



Patch type ECG monitor devices

JAMA | Original Investigation

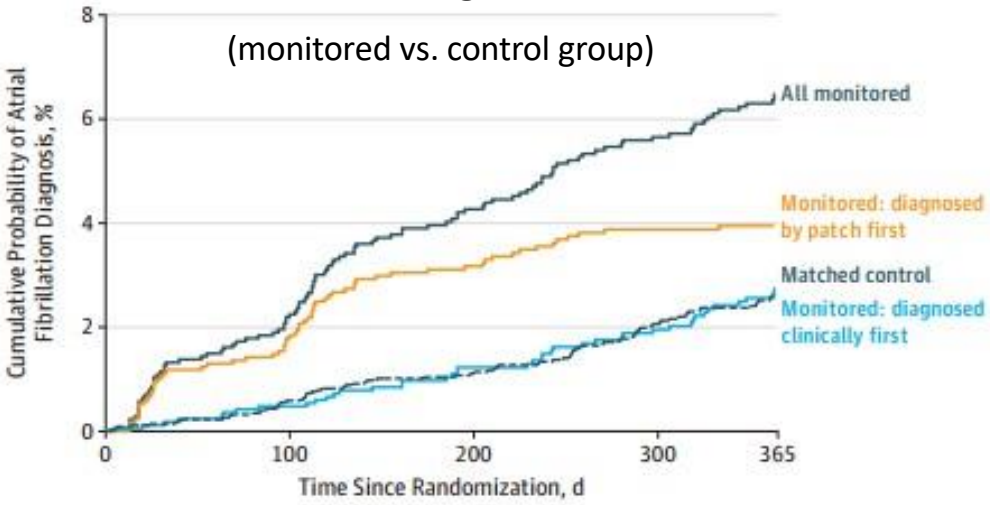
Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation The mSToPS Randomized Clinical Trial



- Patients with increased risk for AF (median CHA₂DS₂-VASc 3)
 - **Home-Monitored group** vs. Matched control group
 - 2659 patients in monitored group
 - Immediate group vs. 4-month delayed group

Rate of 1st diagnosis of AF

(monitored vs. control group)

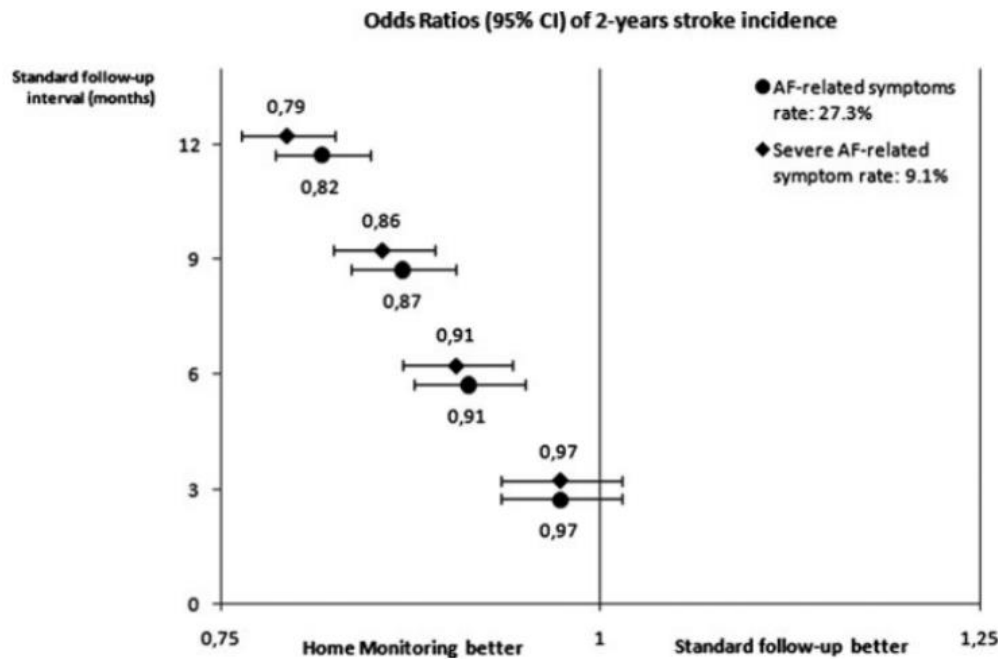


- **Monitoring vs. unmonitored group**
 - higher rate of AF diagnosis
 - increased initiation of anticoagulants
 - more outpatient cardiology visits
- **Immediate vs. delayed group**
 - 3.9% vs.0.9% (difference 3.0%)

JAMA 2018;320:146-55.



Early detection of AF: Stroke risk reduction



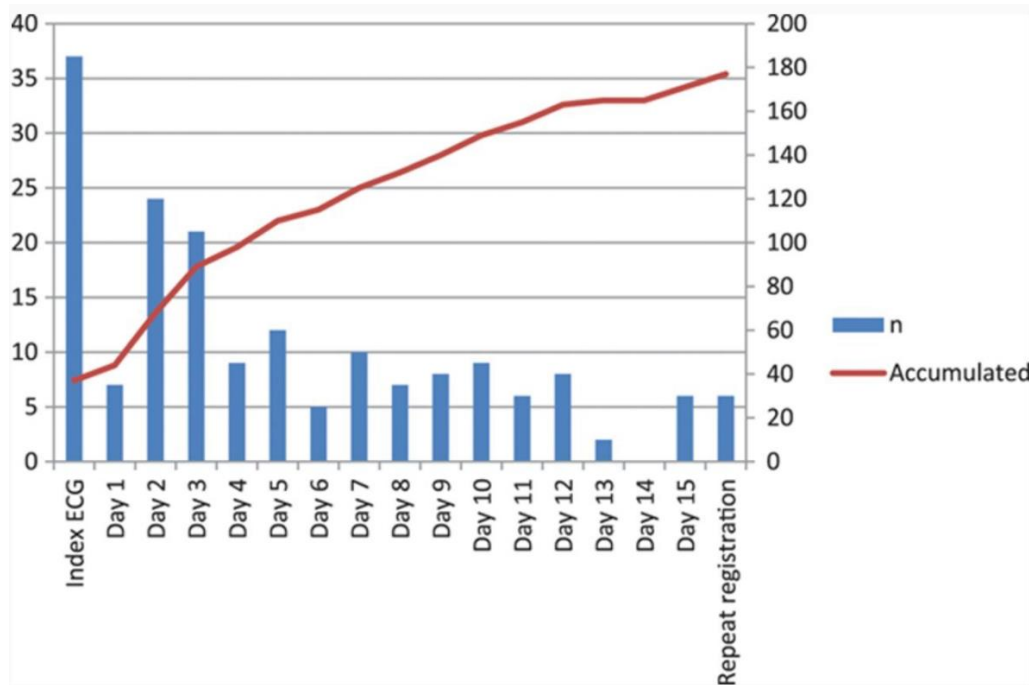
- Comparison remote monitor and routine f/u in patients with CIED
- Two-year data were entered in a computer Monte Carlo model



6-month: 9% stroke risk reduction
12-month: 18% stroke risk reduction
- via early AF detection

2009 J Cardiovasc Electrophysiol 20(11):1244-1251

Screening for AF: increased New AF detection



- Only 37 cases were diagnosed from the ECG at the index visit
- Intermittent ECG monitoring diagnosed 4 times as many individuals with New AF.

E Svennberg et al., STROKESTOP Study, 2015 Circulation

F/57, PAF with intermittent palpitation

- Initial AF → No AF detect during regular 12-lead ECG and Holter f/u, but patient complains intermittent palpitation Sx
 - AF detect (+) at Smart watch device (NOT PPG-based)
 - Recommend AF ablation

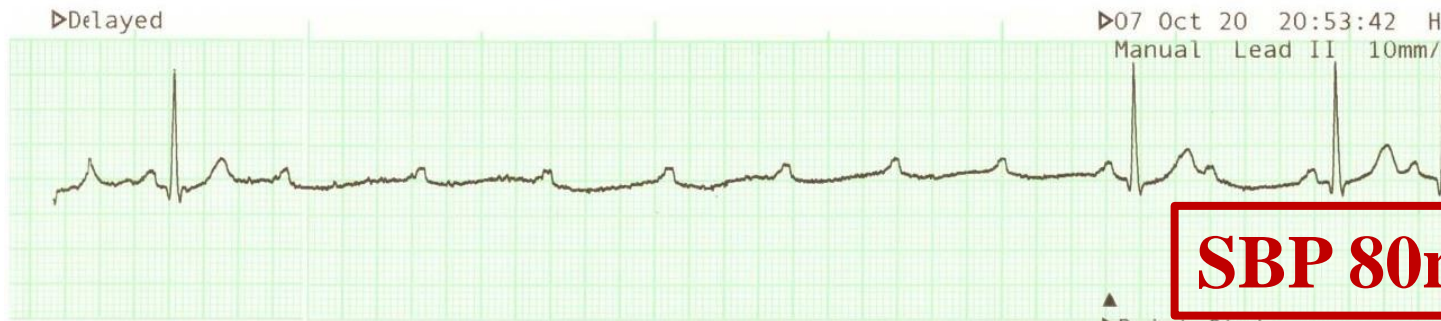
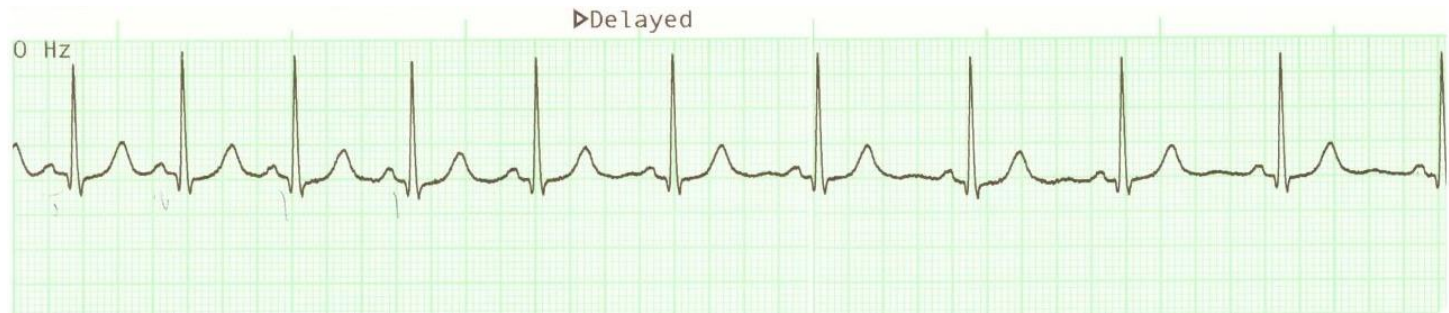


F/51, Recurrent syncope, dizziness

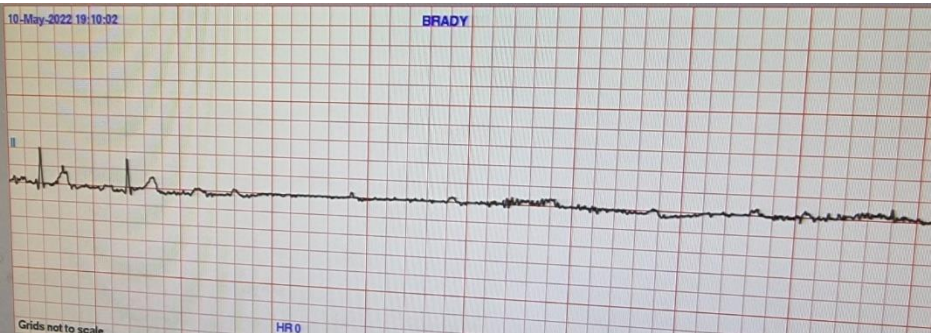
- No related ECG detect during regular 12-lead ECG and Holter f/u, but patient complains recurrent syncope, faintness, dizziness
 - Paroxysmal AVB (+) at Smart watch device (NOT PPG-based)
 - Recommend admission and telemetry monitoring



F/51, Recurrent syncope, dizziness

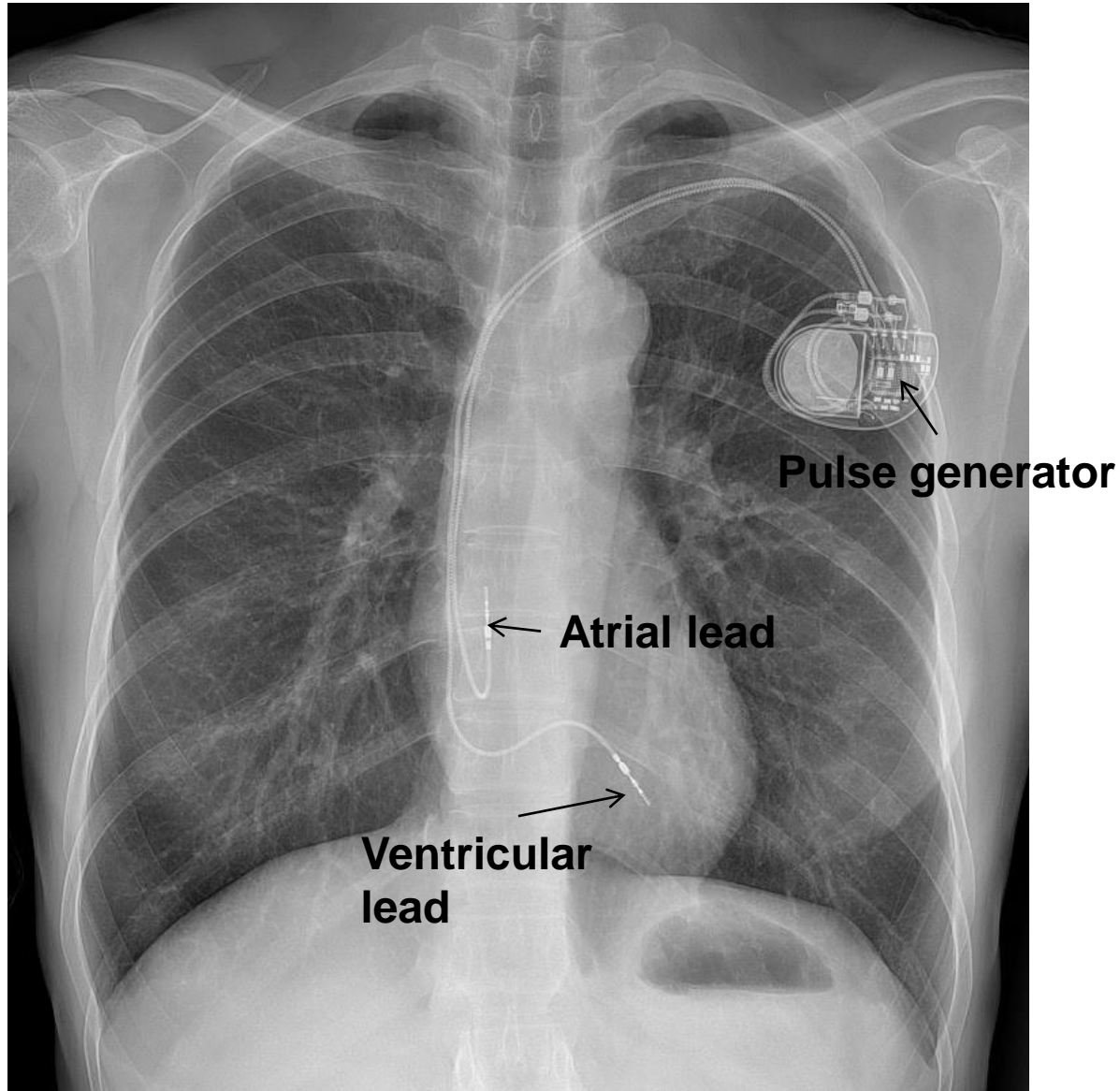


SBP 80mmHg

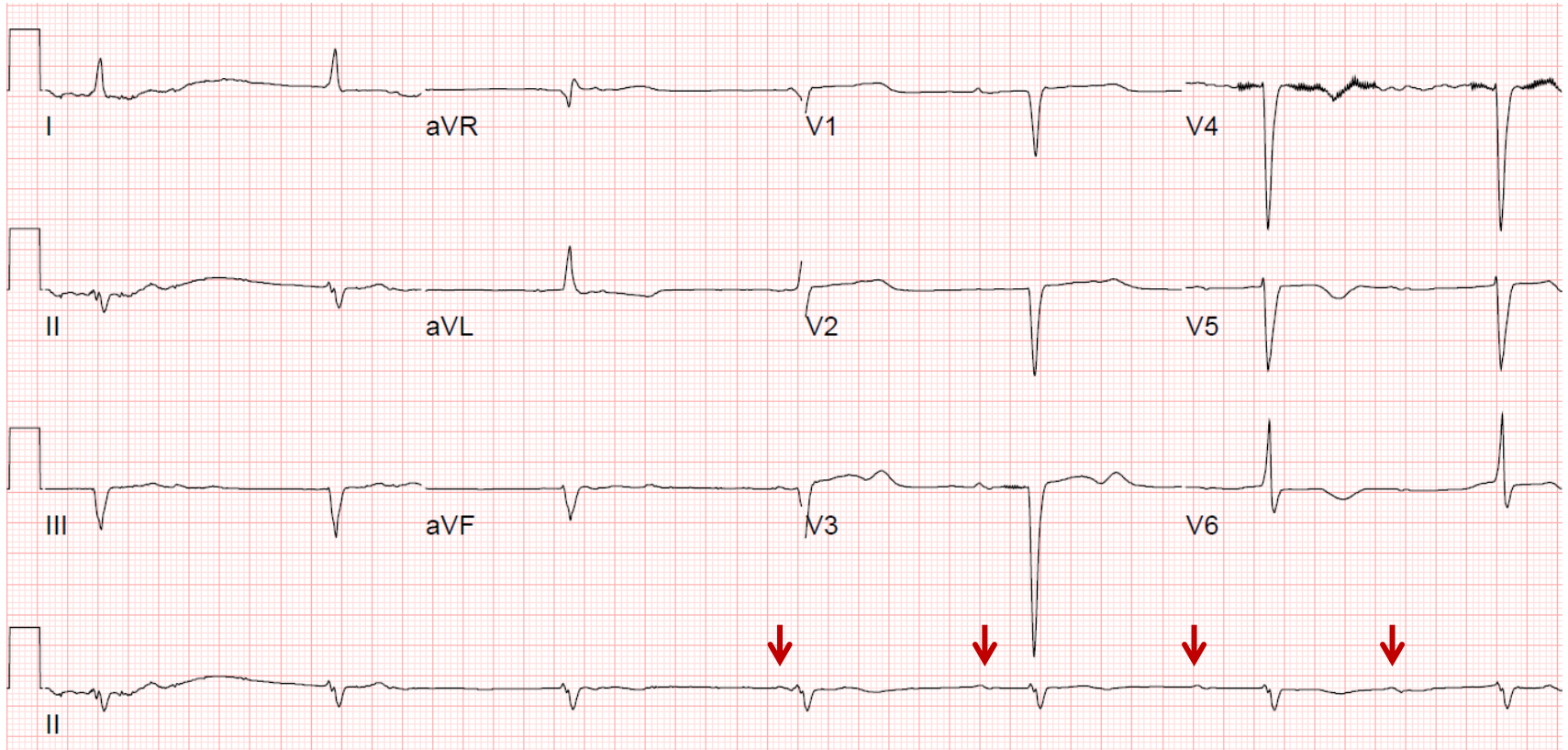


: Cardiogenic shock d/t Paroxysmal AVB → PM implantation

F/51, Recurrent syncope, dizziness

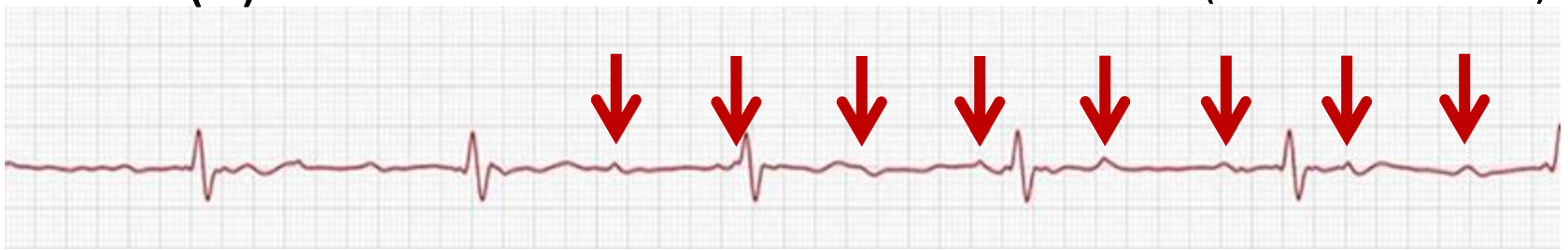


M/69, Dizziness, DOE



• ER adm d/t Dizziness, DOE

→ CAVB (+) at 12-lead ECG and Smart watch (NOT PPG-based)



M/54, Recurrent palpitation – Accuracy problem

Atrial Fibrillation — ❤️ 118 BPM Average

This ECG shows signs of AFib.


If this is an unexpected result, you should talk to your doctor.



- Sometimes Smart watch detected arrhythmia is not accurate.
→ Confirmation by physician should be needed.

Benefits and risks of screening for AF

< 뒤로 **고심박수 알림**



알림이 켜져 있으며, 기준 수치는 120BPM입니다.
활동이 없는 상태에서 10분 동안 심박수가 높으면
알림을 받습니다.


'IL-YOUNG의 Apple Watch'에서 활성화됨

알림 기준 수치

- 끔
- 100BPM
- 110BPM
- 120BPM ✓
- 130BPM
- 140BPM
- 150BPM

10분 동안 활동이 없는 것으로 보이는 상태에서 심박수가 120BPM보다 더 오른 것을 Apple Watch가 감지하는 경우 알림을 받습니다.

< 뒤로 **저심박수 알림**



알림이 켜져 있으며, 기준 수치는 40BPM입니다.
최소 10분 동안 심박수가 낮으면 알림을 받습니다.


'IL-YOUNG의 Apple Watch'에서 활성화됨

알림 기준 수치

- 끔
- 40BPM ✓
- 45BPM
- 50BPM

10분 동안 심박수가 40BPM 미만으로 내려간 것을 Apple Watch가 감지하는 경우 알림을 받습니다.

< 뒤로 **불규칙한 박동 알림**



알림이 켜져 있습니다.
Apple Watch가 심방세동일 수 있는 심장 박동을 여러 차례 감지하는 경우 알림을 받습니다.

'IL-YOUNG의 Apple Watch'에서 활성화됨

불규칙한 박동

Apple Watch가 심방세동일 수 있는 심장 박동을 여러 차례 감지하는 경우 알림을 받습니다. 불규칙한 박동 알림은 일부 지역에서만 사용할 수 있습니다.
[더 알아보기...](#)

Benefits and risks of screening for AF

AF SCREENING

RISKS

- Abnormal results may cause anxiety
- ECG misinterpretation results may lead to overdiagnosis and overtreatment
- ECG may detect other abnormalities (true or false positives) that may lead to invasive tests and treatments that have the potential for serious harm (e.g., angiography / revascularisation with bleeding, contrast-induced nephropathy and allergic reactions to the contrast)

BENEFITS

Prevention of:

- Stroke/SE using OAC in patients at risk
- Subsequent onset of symptoms

Prevention/reversal of:

- Electrical/mechanical atrial remodelling
- AF-related haemodynamic derangements
- Atrial and ventricular tachycardia-induced cardiomyopathy

Prevention/reduction of:

- AF-related morbidity; hospitalization; mortality

Reduction of:

- The outcomes associated with conditions / diseases associated with AF that are discovered and treated as a consequence of the examinations prompted by AF detection

Current recommendation for AF Rhythm control

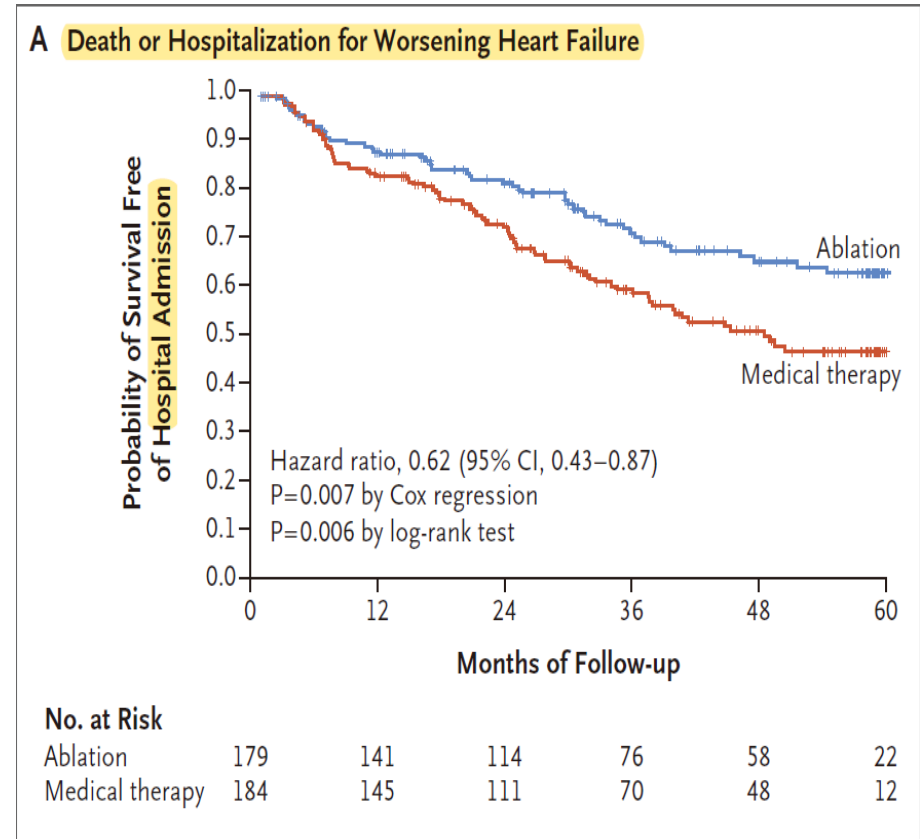
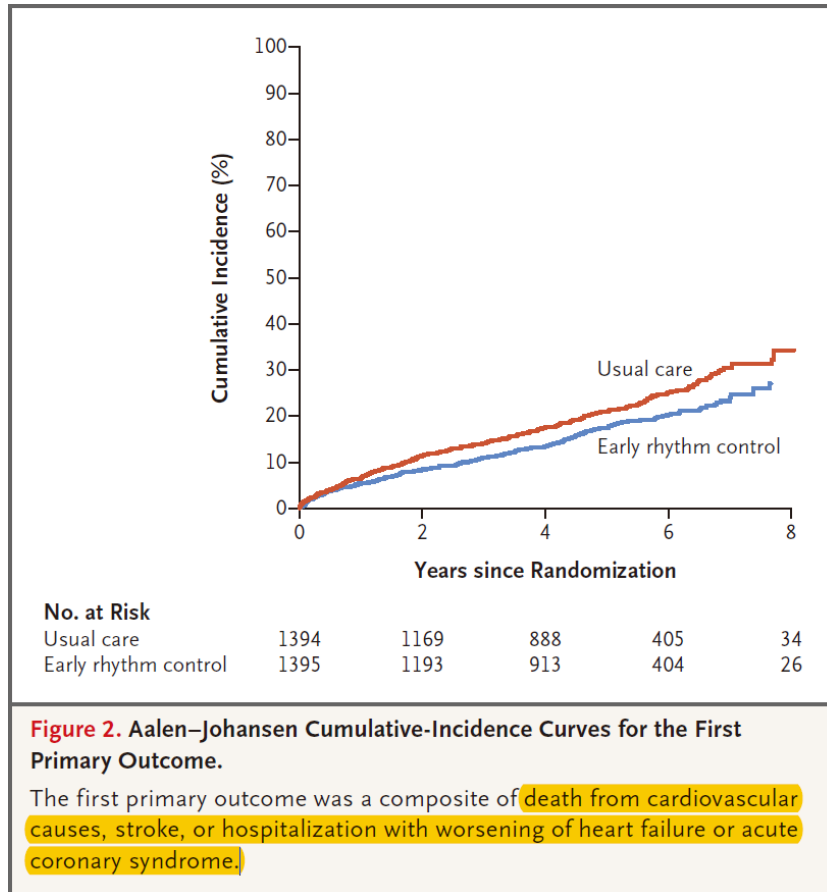
Recommendations	Class	Level
Rhythm Control therapy is recommended for symptom and QoL improvement in symptomatic patients with AF	I	A

Eur HJ 2021;42:373-498



AF Management : Rhythm control

■ Rhythm control :



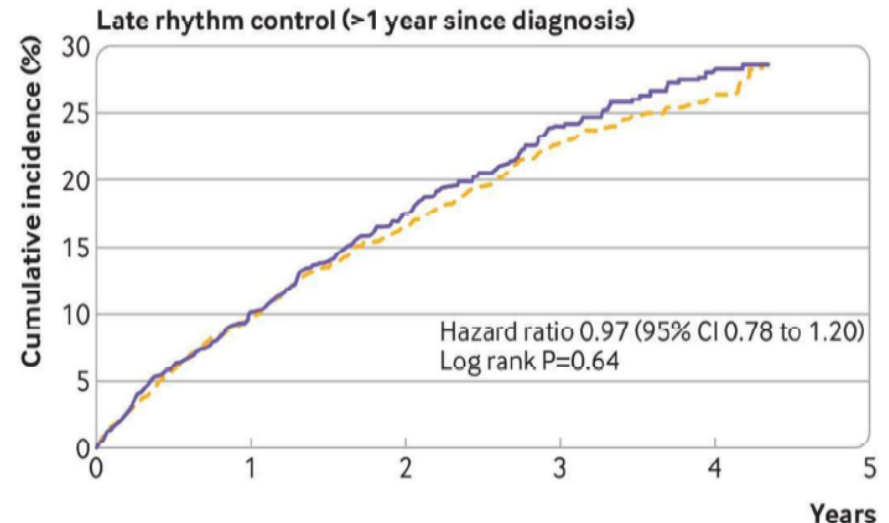
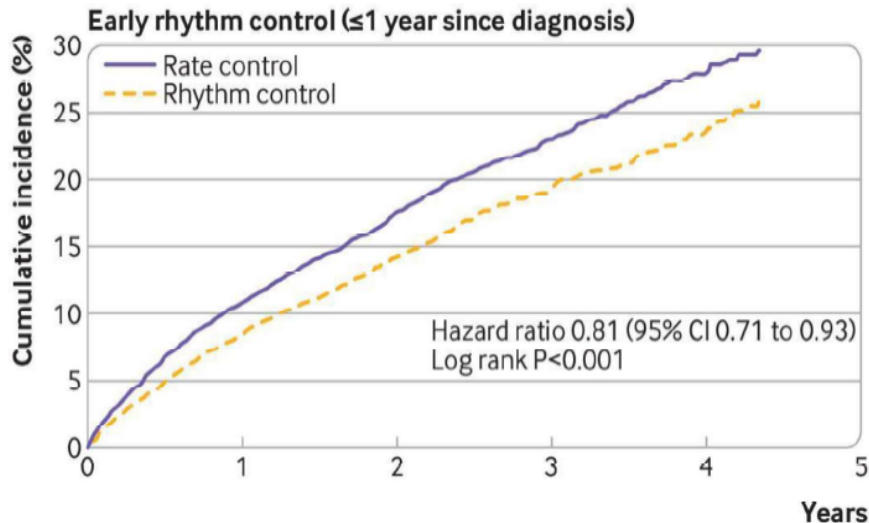
→ AF Rhythm control improved MACE (including CV mortality) (2020 EAST-AFNET4 trial)

→ AF RFCA improved mortality and HF admission in AF with HF patients (2018 CASTLE-AF trial)

2020 NEJM 383:1305-1316
2018 NEJM 378:417-427

AF Management : Rhythm control

- National administrative claims database of Korea.
- 22,635 AF pts, treated with Rhythm control (AADs or Ablation) vs. Rate control strategies.
- 12,200 (53.9%) male, the median age 70, and median follow-up duration 2.1 years.



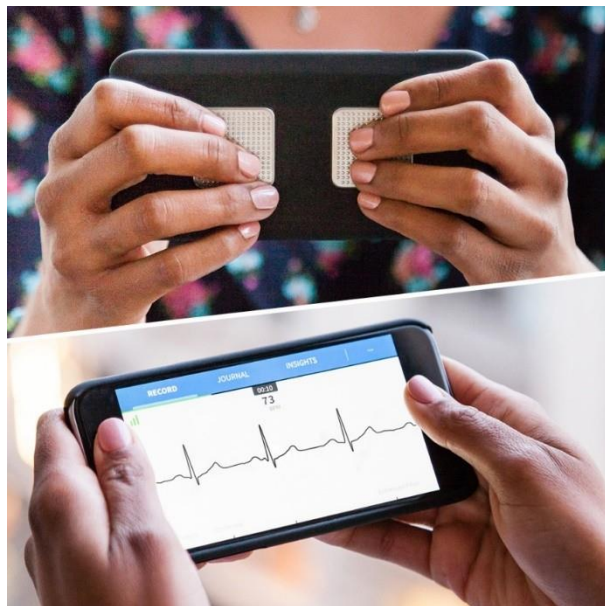
→ **Early rhythm control was associated with a lower risk of adverse cardiovascular events than rate control in patients with recently diagnosed AF, but not in patients who had AF for more than one year.**

D Kim, PS Yang, B Joung, et al., 2021 BMJ

Portable ECG monitoring device



- **AliveCor – KardiaMobile™**
- FDA approved (2012), OTC sales
- iOS / Android available
- **Remote monitoring (AliveInsight™)**
- **Fused with EMR in America**
- Pioneer of mobile healthcare, most representative device



	<p>해외 AliveCor KardiaMobile EKG</p> <p>117,120원</p> <p>석마존 </p> <p>리뷰 1</p>		<p>해외 AliveCor KardiaMobile</p> <p>136,300원</p> <p>두루모어 </p>
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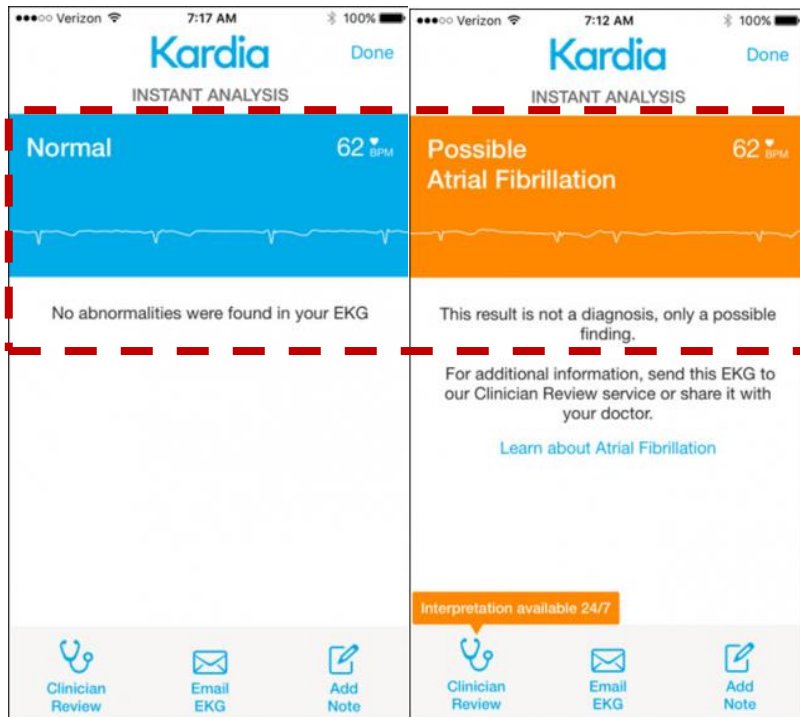
www.alivetec.com/alivecor-heart-monitor

: 처방없이 구매가능

AliveCor – KardiaMobile™



- Single channel
- 10mV peak-to-peak input dynamic range
- Frequency response : 0.5~40Hz

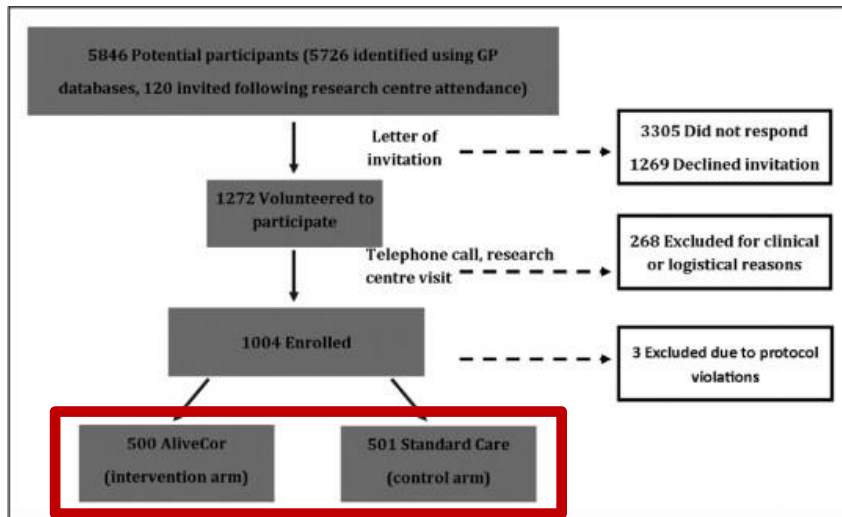


- **Automated AF detection algorithm**
 - Criteria – p wave absence and R-R interval irregularity
 - Sensitivity 71.4%, specificity 99.4%, negative predictive value 100%

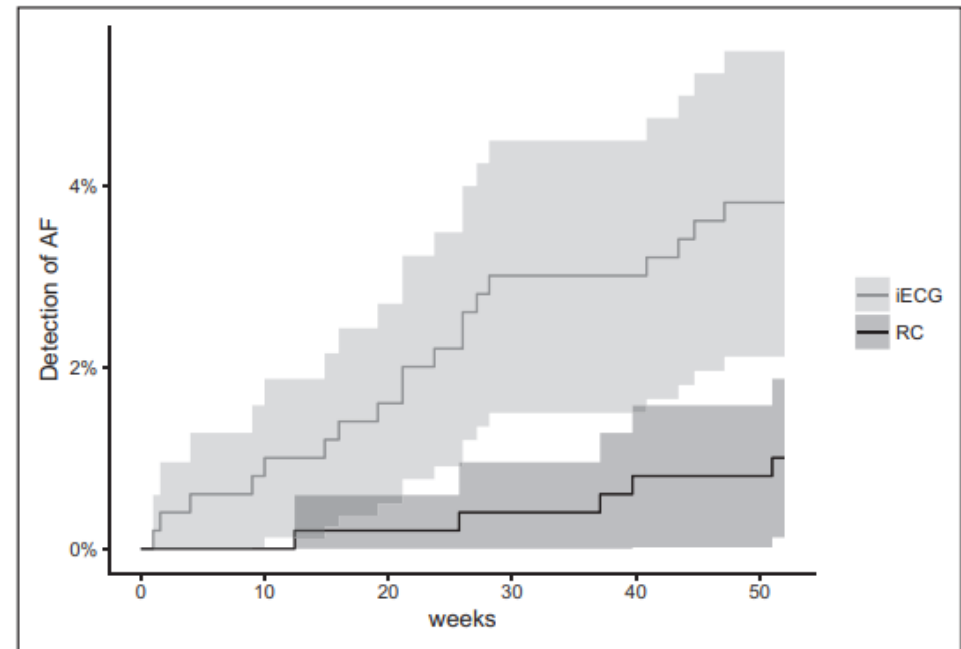
AliveCor – KardiaMobile™

Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation: The REHEARSE-AF Study.

- Participants > 65yrs with $CHA_2DS_2-VASc \geq 2$, no prior AF
- twice/wk check for 12 weeks vs. Routine Care



- AF detection rate
19 vs. 5 patients (**HR 3.9**, $p=0.007$)



Circulation 2017;136(19):1784-1794.

Benefits and risks of screening for AF

7.3 Benefits from and risks of screening for atrial fibrillation

Potential advantages and disadvantages of detecting a previously undiagnosed AF through screening are shown in *Figure 7*.¹⁷³

Screening can also highlight cases of known suboptimally managed AF.²¹⁷ Intermittent ECG recording increased new AF detection four-fold.²¹⁷ In the REHEARSE-AF (REmote HEArt Rhythm Sampling using the AliveCor heart monitor to scrEen for Atrial Fibrillation) controlled study using a smartphone/tablet-based single-lead ECG system twice weekly over 12 months vs. routine care resulted in a 3.9-fold increase in AF detection in patients aged ≥ 65 years.²¹⁸

Appropriate patient information and screening programme organization with rapid ECG clarification may reduce anxiety induced by suspicion of abnormality.

Other portable devices : ER-2000



- Product in Korea (Boryung)
- Single channel
- 30sec / 24hr mode
- 99g, 24hr battery
- Approved as “의료기기”
- 시중가 27만원~

ER-2000 특징점

01

소형, 경량 간편측정 30초

제품에 부착된 건조 전극을 이용하여, 언제 어디서나 간편하게 측정하고자 할 때 사용합니다.



02

외부 심전도 케이블 이용 연속측정 24시간

외부 심전도 케이블과 부착 전극(전극 발매)을 이용하여 다양한 측정방법과 장시간 연속측정이 가능합니다. 의식이 없거나 수면 중에도 측정할 수 있어 진단의 효율을 높입니다.



03

Color LCD 장착, 심전도 측정 상태 표시

컬러 액정을 통해 측정상태 확인 및 저장된 파형을 볼 수 있습니다.



04

전용 프로그램으로 데이터 저장 및 관리

유선USB 또는 무선 블루투스 통신을 이용하여 저장된 데이터를 컴퓨터로 전송할 수 있습니다.

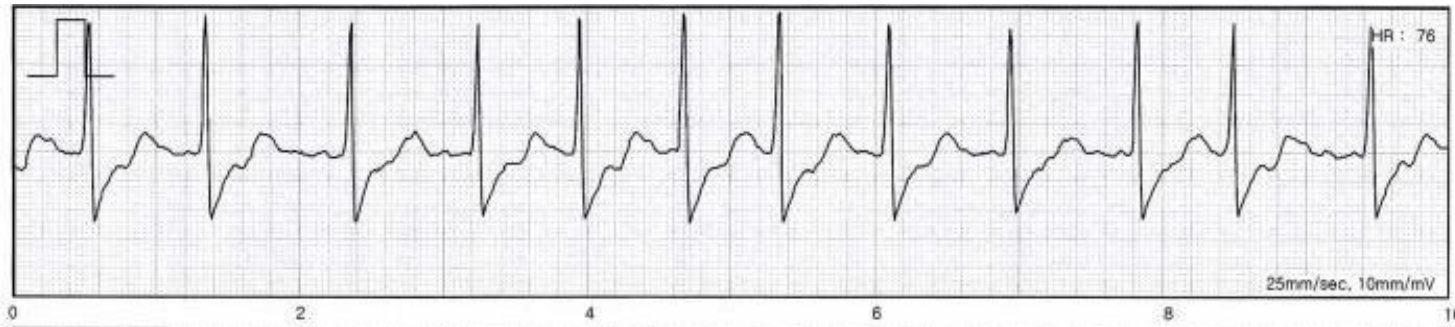


www.boryungconsumer.co.kr

J Arrhythmia 2015;31(4):201-209



AF detection by ER-2000

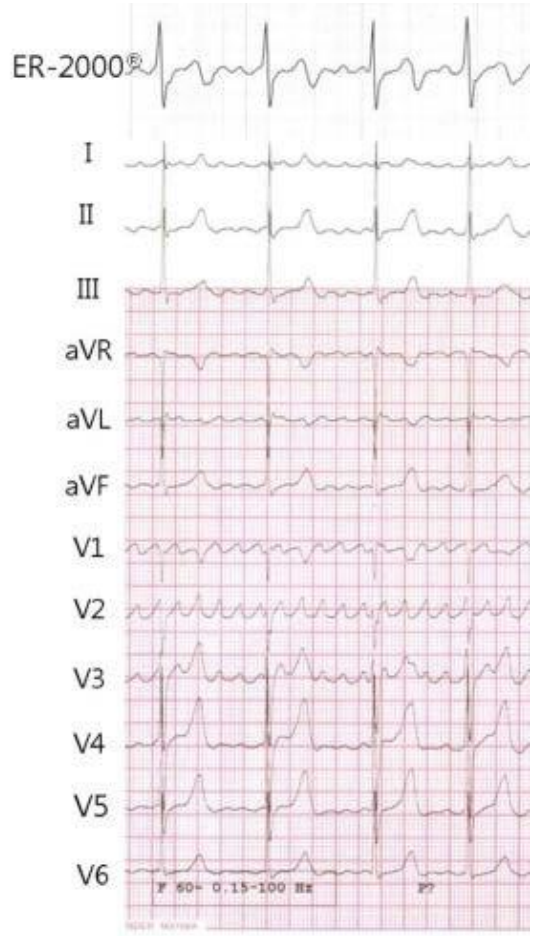


Print Date: 2017-04-25

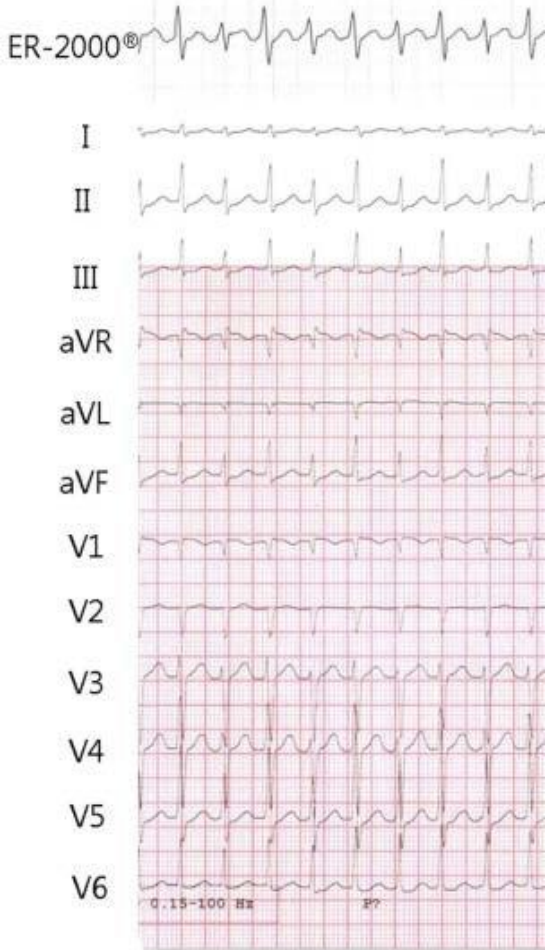
Page 2 / 6

Feasibility of ER-2000 – Arrhythmia detection

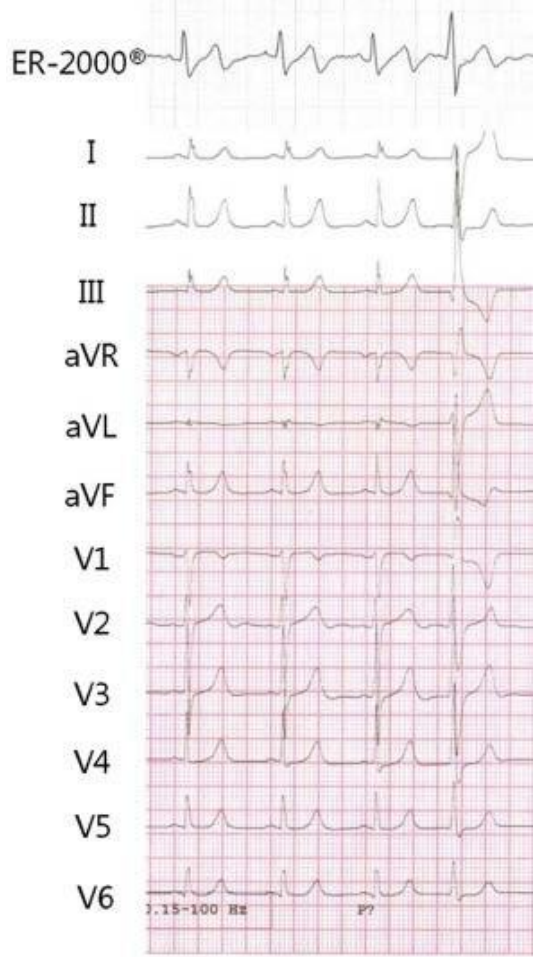
Atrial fibrillation



Narrow QRS tachycardia



PVC during SR



J Arrhythm 2015;31:201-9.



Wearable ECG monitor devices (국내 available)



대웅 (Seers tech.) - 모비케어



삼진 (삼성SDS software) - S-Patch



드림텍 - 카데아솔로



스카이랩스 - CART (반지형) ATP-C100 에이티센스



유한 (휴이노) - MEMO Patch



동아에스티 (MEZOO) - 하이카디

Other portable devices



MyDiagnostick



OMRON HeartScan



Dimetek Dicare micro Ambulatory ECG recorder

ReadMyHeart

InstantCheck

PC-80

MD100E

(Printing) EKG/ECG-80A



EPI Mini



Report: Detect AF and other arrhythmias

제하 21-317호 | 02-3443-3160 | www.huinno.com

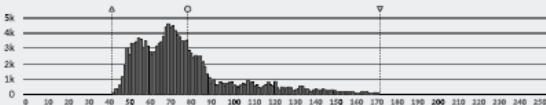
Findings

1. Predominant rhythm: Junctional rhythm
2. A. fib : (nn)% burden. Longest duration: (nn)h (nn)m (nn)s
- Atrial flutter
3. Pause: (nn)episodes, Longest R-R: (n.nnn)secs
4. Ectopic events
- APC (nn %), SVT (nn runs)
- VPC (nn %), VT (nn runs)
5. AV Block
- 2nd AV Block (Mobitz type 1 or 2), 3rd AV Block, High degree AV Block
6. Patient triggered events: AF, Pause, VT, VPC, SVT, APC, Others ...
7. Additional strip: Junctional escape beats, Idioventricular rhythm ...

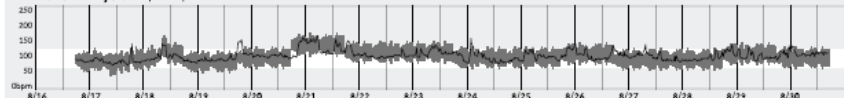
Confirmed & Signed by
2022-08-30, 16:23:00

Heart Rate

Total QRS 81,213 beats
Max HR ▽ 162 bpm 2022-08-16, 07:52:19
Avg HR ○ 78 bpm
Min HR ▲ 44 bpm 2022-08-16, 07:52:19
Max R-R 1,720 ms 2022-08-16, 07:52:19



HR Trend Analysis HR per 1hr period



Patient Events

Total Triggers 16
Not Found 7 events
Found 9 events
Findings AF, Pause, VT, VE(s), SVT, SVE(s), Others

Pauses
Total Episodes 3
Longest R-R 7.259s

AF (30s or longer)

Total AF Burden 37.5% % of Analyzable ECG
Avg HR 97 bpm
HR Range 50 - 154 bpm

AF Duration
Total 100 ep
5mins to <24hrs 80 ep
24hrs or longer 5 ep
Longest Duration 15h 20m 24s
Onset time 2022-08-16, 07:52:19
Termination time 2022-08-16, 07:52:19

Ectopics

Total SVEs 2.4% 14,182
Isolated 2.3% 13,450
Couplets <1.0% 282
SVT(≥3beats) 1.6 ep 450
Longest Run 6 2022-08-16, 07:52:19

Total VEs 2.4% 14,182
Isolated 2.3% 13,450
Couplets <1.0% 282
VT(≥3beats) 1.6 ep 450
Longest Run 6 2022-08-16, 07:52:19

Notable Rhythm Strips



제하 21-317호 | 02-3443-3160 | www.huinno.com

Findings

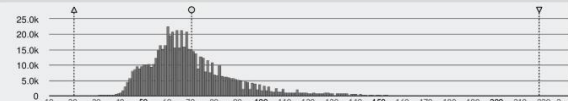
1. Predominant rhythm : Sinus rhythm
2. A. fib : 11.9% burden
- Longest duration : 6h 59m 23s
3. Pause : 199 episodes
- Longest R-R : 2.812 secs
4. Ectopic events
- SVE(1.7%), SVT (277 episodes)
- VE (<1.0%)
5. Patient triggered events : SVE, AF, SVT

6. Additional strip
- Nonconducted APC
- Fusion beat
- Atrial fibrillation (Patient event)

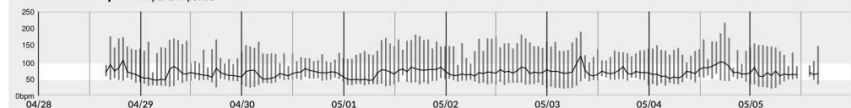
Confirmed & Signed by

Heart Rate

Total QRS 642,376 beats
▽ Max HR 217 bpm 2023-05-04, 17:05:40
○ Avg HR 70 bpm
▲ Min HR 21 bpm 2023-05-03, 03:44:41
Max R-R 2,812 ms 2023-05-05, 04:51:22



HR Trend Analysis HR per 1 hr period



Patient Events

Total Triggers 5
Not Found 2 events
Found 3 events
Findings Others, AF, SVE(s), SVT

Pauses
Total Episodes 199
Longest R-R 2.812s

AF (30s or longer)

Total AF Burden 11.9% % of Analyzable ECG
Avg HR 79 bpm
HR Range 21 - 190 bpm

AF Duration
Total 62 ep
5mins to <24hrs 12 ep
24hrs or longer 0 ep
Longest Duration 6h 59m 23s
Onset time 2023-05-03, 00:02:07
Termination time 2023-05-03, 07:01:33

Ectopics

Total SVEs 1.7% 10,880
Isolated 1.2% 7,635
Couplets <1.0% 441
SVT(≥3 beats) 277 ep 2,363
Longest Run 46 2023-05-01, 19:37:36

Total VEs <1.0% 20
Isolated <1.0% 20
Couplets 0 ep 0
VT(≥3 beats) 0 ep 0
Longest Run 0 -

Notable Rhythm Strips



2022.2/1 장시간 심전도기록 검사 급여개정안

심전도 검사-홀터기록에 대한 건강보험 행위 급여 개정안

시행일: 2022년 2월1일(48시간 이상 심전도 기록 구간 신설)
 카디아슬로: 8일 검사 허가제품으로 8일 이상 구간 행위료 적용

구분	병원 이상(중병,상병포함)			의원		
구간	48시간이하	48시간초과~7일이하	8일이상	48시간이하	48시간초과~7일이하	8일이상
행위료	42,915원	116,491원	156,261원	49,374원	131,588원	179,779원
선별급여	기존동일(50%)	본인부담 80%		기존동일(50%)	본인부담 80%	
본인부담금	21,458원	93,193원	125,009원	24,687원	105,270원	143,823원
보험code	E6545	E6556	E6557	E6545	E6556	E6557
행위점수	547.38	1458.85	1993.12	547.38	1458.85	1993.12
1점당 금액	1점당 78.4원			1점당 90.2원		
재료대	1회용 Electrode, Paper, Battery의 재료대는 삭제/행위수가 내 포함					



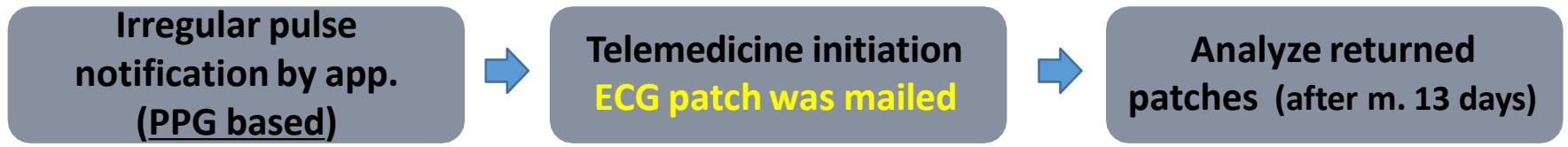
PPG-based app. → Patch type ECG monitor devices



Apple Heart Study

- Predictive value of app. Detecting irregular pulse (possible AF)
- 419,297 without AF & Apple iPhone app users

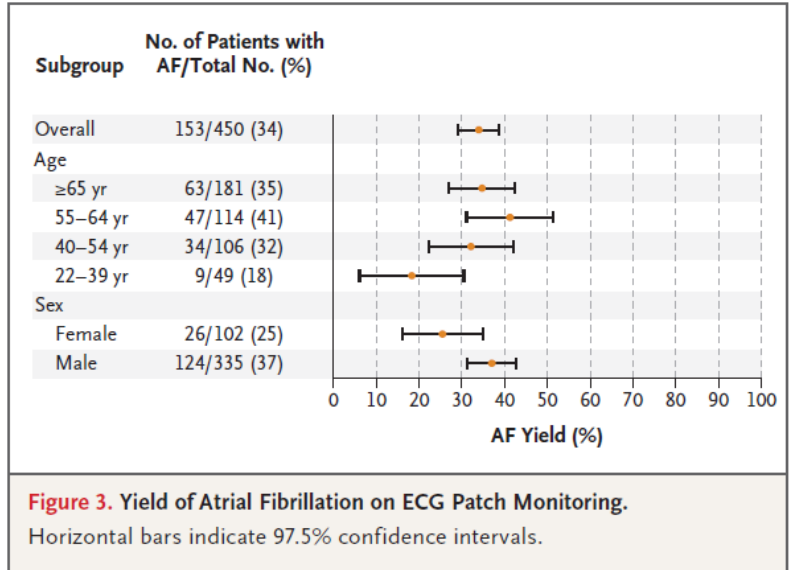
[study design]



2160/419,297 (0.52%)

34% were AF

- Positive predicted value – 0.84 (95% CI, 0.76-0.92)
- Of 1376 notified participants who returned a 90-day survey, 57% contacted health care providers outside the study.



Validation of an algorithm for AF detection: PPG-ECG



W-PPG continuously monitors AF episodes **W-PPG prompted W-ECG Recordings** **Possible AF is Determined**

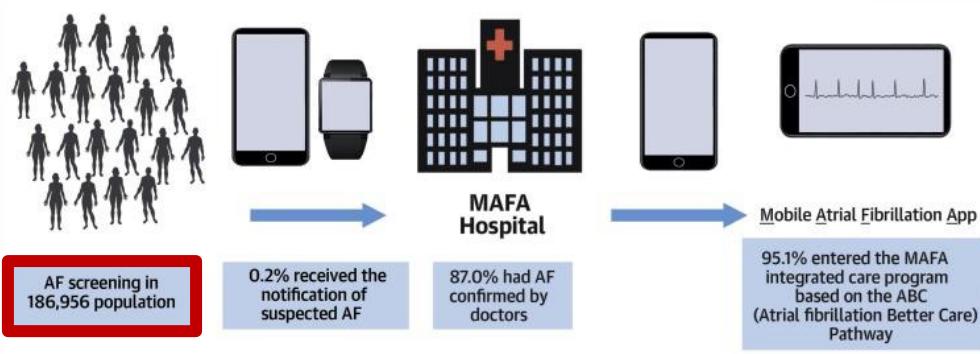
n=204	SENS	SENS _{est} (95% CI)	SPEC	SPEC _{est} (95% CI)	AUC	TP (N)	TN (N)
W-PPG performance							
Algorithm level (every 5-min classification)	89.7	87.8 (83.6–91.0)	97.0	97.4 (97.1–97.7)	93.3	54,754	590,438
Notification level (2-of-3 classifications)	90.8	81.8 (71.2–89.1)	98.8	99.4 (99.3–99.5)	94.8	55,431	601,577
W-ECG performance							
Algorithm level compared to P-ECG	97.4	98.9 (98.1–99.4)	96.5	99.3 (99.1–99.5)	97.1	1,712	10,259
Algorithm level compared to rhythm adjudication by cardiologists	98.8	–	97.0	–	96.0	584	835
W-PPG triggered W-ECG performance							
Diagnosis confirmed by a single W-ECG	96.9	96.9 (93.7–98.5)	99.3	99.7 (99.5–99.7)	97.7	219	51,456
Diagnosis confirmed by 2 W-ECGs ≥1 h apart*	96.0	96.0 (92.9–97.8)	100	100 (100–100)	98.0	265	74,248
Daily participant performance							
W-PPG triggered W-ECG confirmation (2 W-ECGs ≥1 h apart) detection of AF or SR per day*	96.9	96.9 (93.9–98.4)	99.4	99.9 (99.7–100)	98.2	251	3772

→ (smart watch) PPG-algorithm can estimate AF burden.



PPG-based app. : Hwawei Heart Study

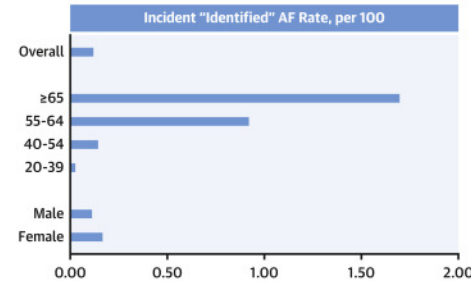
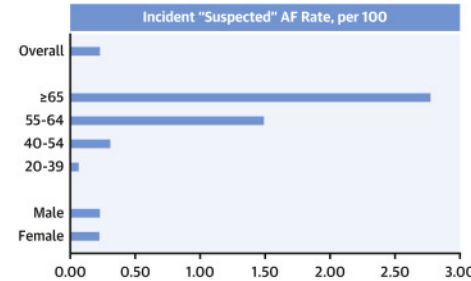
CENTRAL ILLUSTRATION: Mobile Health Technology for Improved Atrial Fibrillation Screening and Transfer Into a Holistic and Integrated Care



Guo, Y. et al. J Am Coll Cardiol. 2019;74(19):2365-75.

	Suspected AF	Total	%	95% CI
Overall	424	187,912	0.23	(0.21-0.25)
≥65	95	3,419	2.78	(2.28-3.38)
55-64	112	7,491	1.50	(1.24-1.80)
40-54	136	44,432	0.31	(0.26-0.36)
18-39	81	132,570	0.06	(0.05-0.08)
Male	369	162,972	0.23	(0.20-0.25)
Female	55	24,938	0.22	(0.17-0.29)

	Identified AF	Total	%	95% CI
Overall	227	187,912	0.12	(0.11-0.14)
≥65	58	3,419	1.70	(1.31-2.19)
55-64	69	7,491	0.92	(0.73-1.16)
40-54	64	44,432	0.14	(0.11-0.18)
18-39	36	132,570	0.03	(0.02-0.04)
Male	185	162,972	0.11	(0.10-0.13)
Female	42	24,938	0.17	(0.12-0.23)



- Positive predictive value of PPG 91.6% (95% CI 91.5%-91.8%)
- Within 14 days, 70.8% of AF episode were found

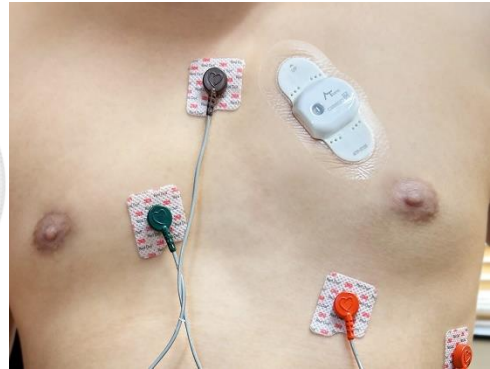
→ Smart device-based PPG monitoring could be a feasible approach for AF screening. (but, PPG-based device only cannot diagnose cardiac arrhythmias)

2019 JACC 74(19):2365-2375



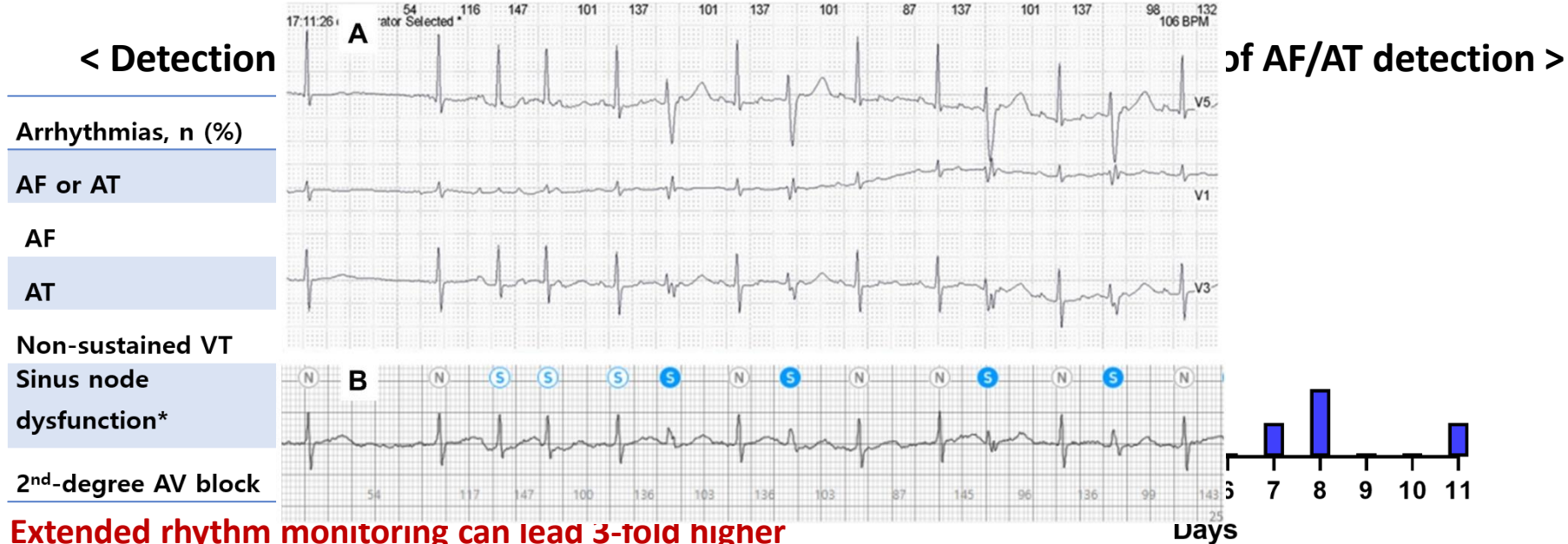
Efficacy of long-term ECG monitor for detection of drug-refractory AF (11day Patch vs. 24hr Holter)

- Study inclusion:
 - Documented diagnosis of paroxysmal AF
 - Currently receiving anti-arrhythmic drug (AAD) therapy (Class Ic or Class III)
 - Sinus rhythm at outpatient clinic visit after AAD therapy



- 59 Patients underwent 11day ECG patch monitor (AT-Patch®, ATsens Co., Ltd) and 24hr Holter simultaneously, while the AAD therapy was continued.

→ Detection rate of drug-refractory AF/AT was compared between the two devices.



→ Extended rhythm monitoring can lead 3-fold higher detection compared to 24hr Holter

Summary

- ECG ITSELF is mandatory to diagnose arrhythmia (NOT PPG-based).
- Home-based, user-owned, self-applied wearable ECG devices improve the diagnosis of arrhythmia (esp. AF in recent papers)
 - select device type: Continuous monitoring type (Patch, Holter),
Event-recording type (Watch-type)
- Feasibility is not bad, but confirmation by physician is needed.
- Various types of devices
 - Portable ECG monitoring devices - KardiaMobile, ER-2000,...
 - Patch type ECG devices – MEMO Patch, MobiCare, S-Patch, AT-patch, CardeaSolo, ...
 - Watch type ECG devices – KardiaBand, Apple watch, MEMO watch,...
 - App based AF detection technology – photoplethysmography, mechanocardiography
- New technology is promising in the field of arrhythmia

경청해 주셔서 감사합니다..