Atrial fibrillation
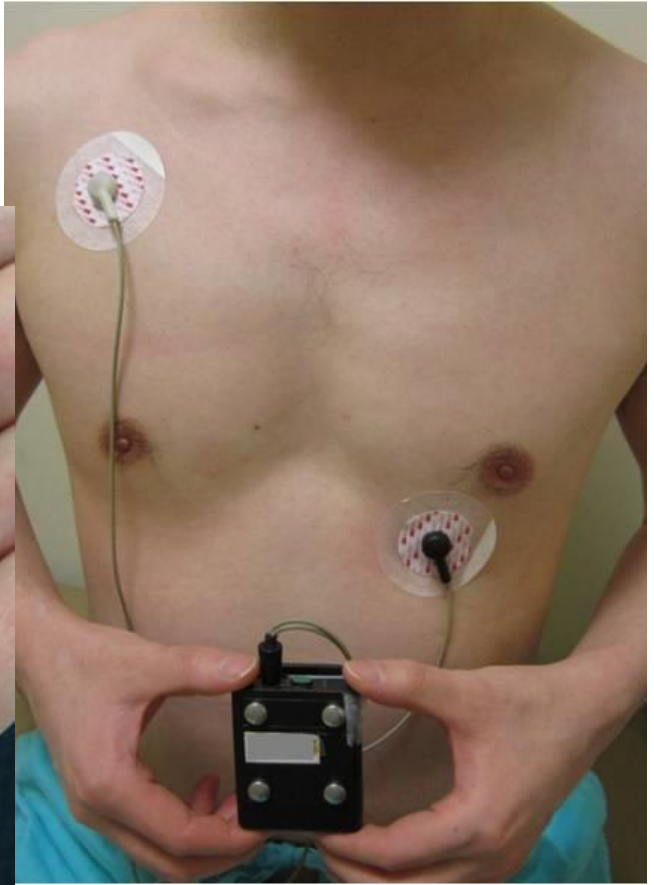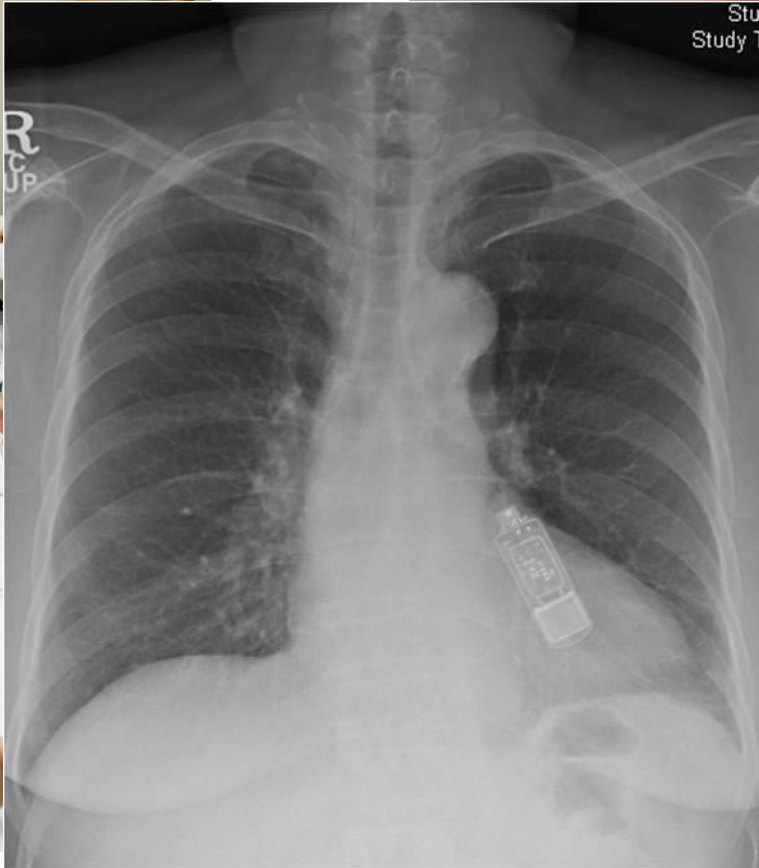
기존 심전도 측정 방식

기존 심전도 측정의 방식

☞ 심전도, HOLTER, implantable Loop recorder

Screening for atrial fibrillation

2020 ESC 심방세동 가이드라인[1]

- Definition and diagnosis of atrialfibrillation

Recommendations	Class[a]	Level[b]
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.[6]	I	B

©ESC 2020

Recommendation	Class[a]	Level[b]
Opportunistic screening for AF by pulse taking or ECG rhythm strip is recommended in patients ≥65 years of age. [188,211,223,225]	I	B
When screening for AF it is recommended that[217,218] • The individuals undergoing screening are informed about the significance and treatment implications of detecting AF. • A structured referral platform is organized for screen-positive cases for further physician-led		

Table 5 Sensitivity and specificity of various AF screening tools considering the 12-lead ECG as the gold standard[173]

	Sensitivity	Specificity
Pulse taking[203]	87 - 97%	70 - 81%
Automated BP monitors[204−207]	93 - 100%	86 - 92%
Single lead ECG[208−211]	94 - 98%	76 - 95%
Smartphone apps[188,189,191,195,212,213]	91.5 - 98.5%	91.4 - 100%
Watches[196,198,213,214]	97 - 99%	83 - 94%

AF = atrial fibrillation; BP = blood pressure; ECG = electrocardiogram.

©ESC 2020

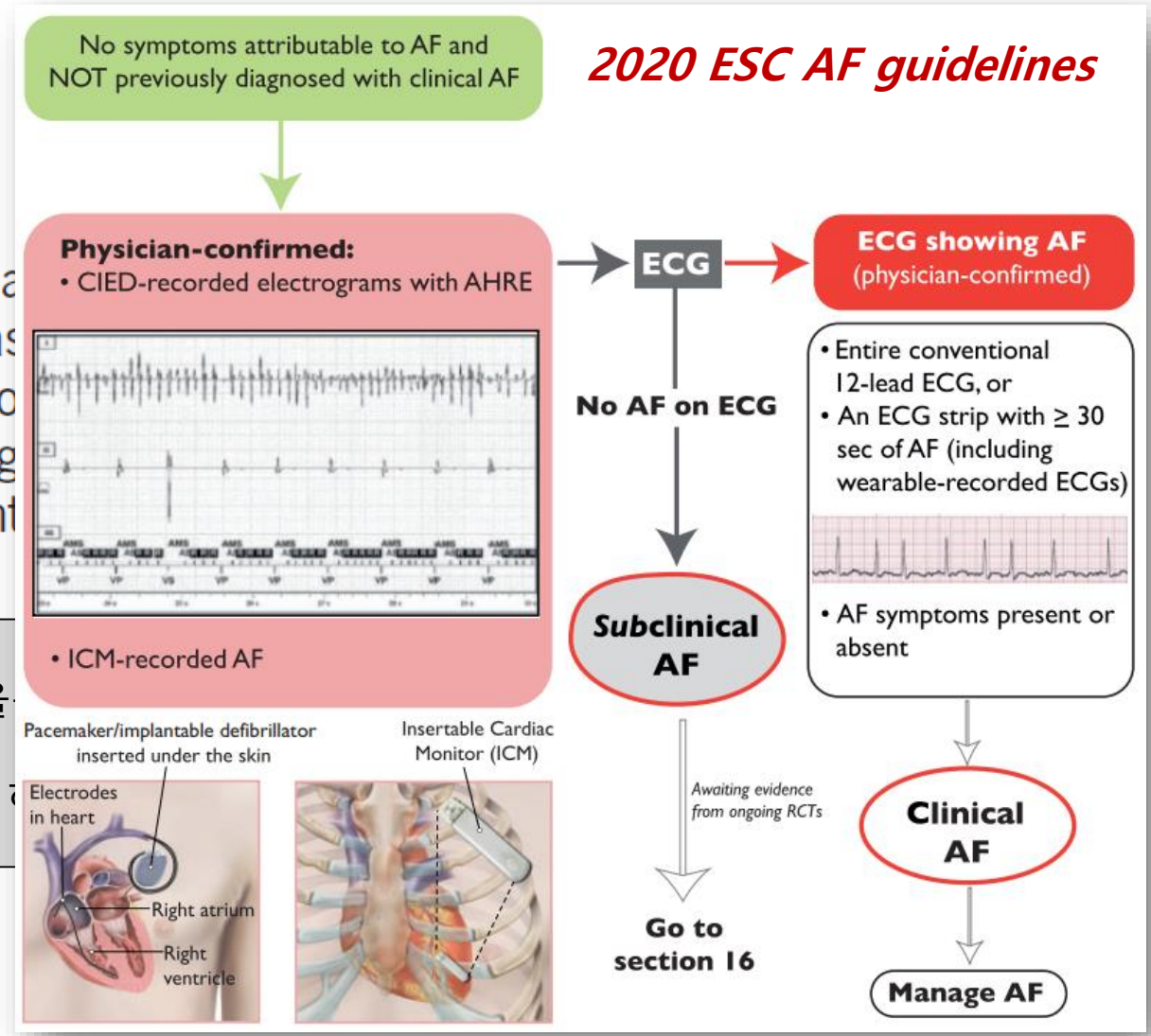|	Class	Level
Systematic ECG screening should be considered to detect AF in individuals aged ≥75 years, or those at high risk of stroke.[212,224,227]	IIa	B

Ref.> 1. Hindricks G, et al. *Eur Heart J.* 2020;ehaa612.
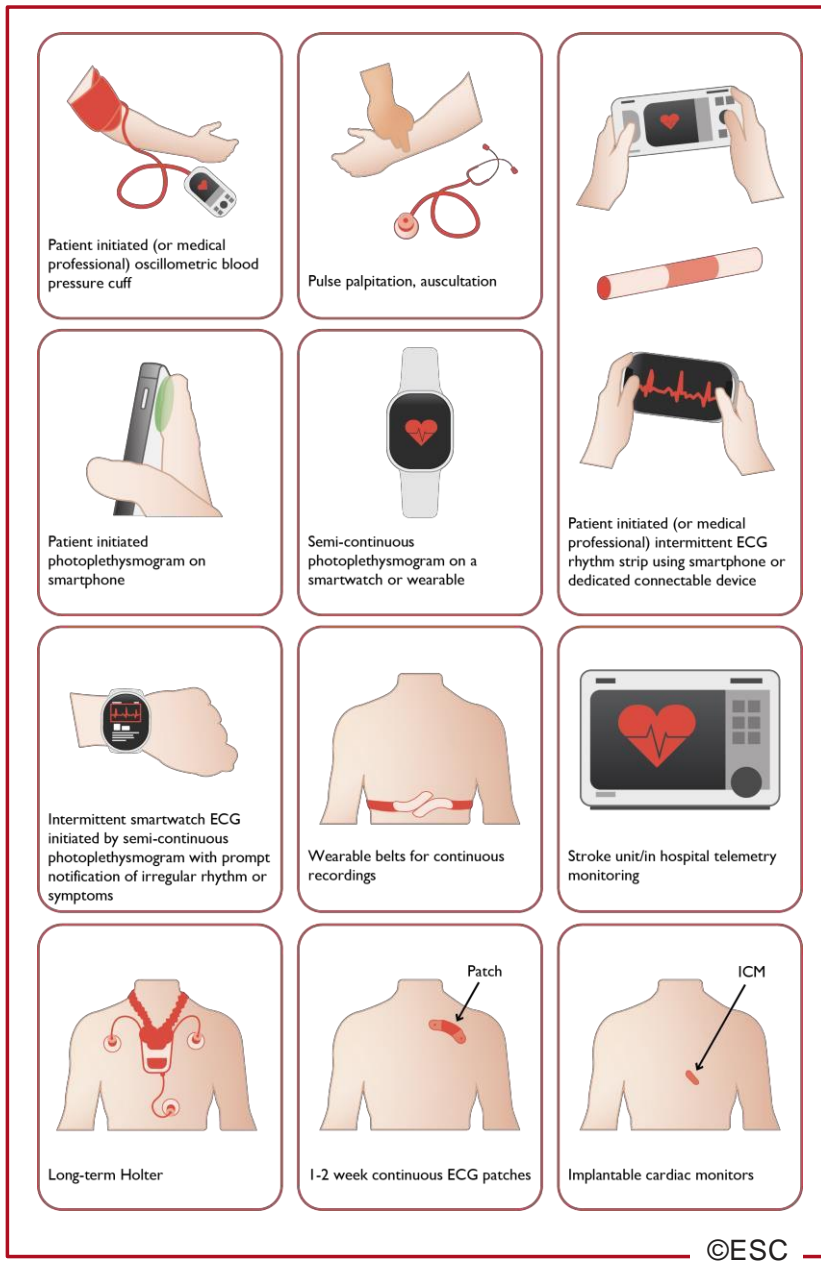
Screening Guideline for AF

심방세동 스크리닝 국제 협력 보고서[3]
(A Report of the AF-SCREEN International Collaboration)

Key Point 2

Single-timepoint screening of people ≥65 yea
the clinic or community appears justified bas
of screening and likely cost-effectiveness. Fo
years of age or in younger age groups at hig
or stroke, 2 weeks of twice-daily intermitten
ing may be warranted.

▶ "65세 이상에서 심방세동 스크리닝은 비용-효율

  75세 이상 또는 고위험군 환자에서는 2주 동안

2020 ESC AF guidelines

No symptoms attributable to AF and NOT previously diagnosed with clinical AF

Physician-confirmed:
• CIED-recorded electrograms with AHRE

• ICM-recorded AF

Pacemaker/implantable defibrillator inserted under the skin

Insertable Cardiac Monitor (ICM)

Electrodes in heart
Right atrium
Right ventricle

ECG

No AF on ECG

Subclinical AF

Awaiting evidence from ongoing RCTs

Go to section 16

ECG showing AF (physician-confirmed)

• Entire conventional 12-lead ECG, or
• An ECG strip with ≥ 30 sec of AF (including wearable-recorded ECGs)

• AF symptoms present or absent

Clinical AF

Manage AF

2021 Korea HRS AF guidelines.

표 5.	12유도 표준 심전도와 비교한 다양한 심방세동 선별검사 방법들의 민감도와 특이도		
	민감도 (Sensitivity)	특이도 (Specificity)	참고문헌
맥박 촉지	87-97 %	70-81 %	9
자동 혈압계	93-100 %	86-92 %	
단일유도 심전도	94-98 %	76-95 %	
스마트폰 어플리케이션	91.5-98.5 %	91.4-100 %	
시계 (스마트워치)	197-99 %	83-94 %	
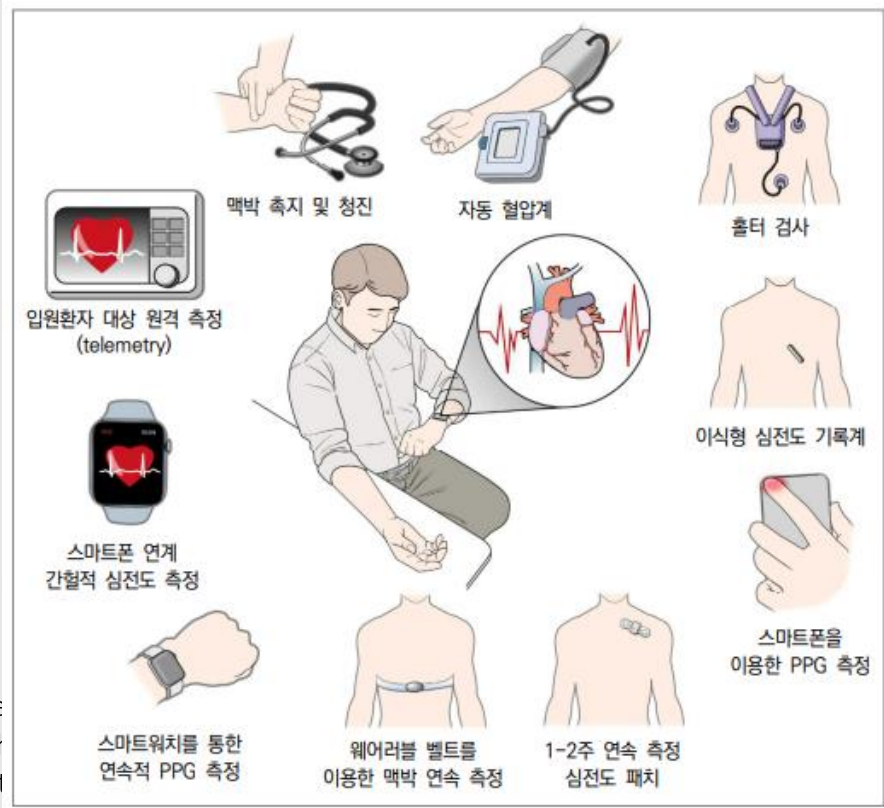
그림 5. 심방세동의 선별검사에 사용될 수 있는 다양한 방법

Wearable Device 와 single lead EKG data (1)

ORIGINAL ARTICLE

Large-Scale Assessment of a Smartwatch

Subgroup	No. of Patients with AF/Total No. (%)
Overall	153/450 (34)
Age	
≥65 yr	63/181 (35)
55–64 yr	47/114 (41)
40–54 yr	34/106 (32)
22–39 yr	9/49 (18)
Sex	
Female	26/102 (25)
Male	124/335 (37)

AF Yield (%)

<Yield of Atrial Fibrillation on ECG Patch Monitoring>
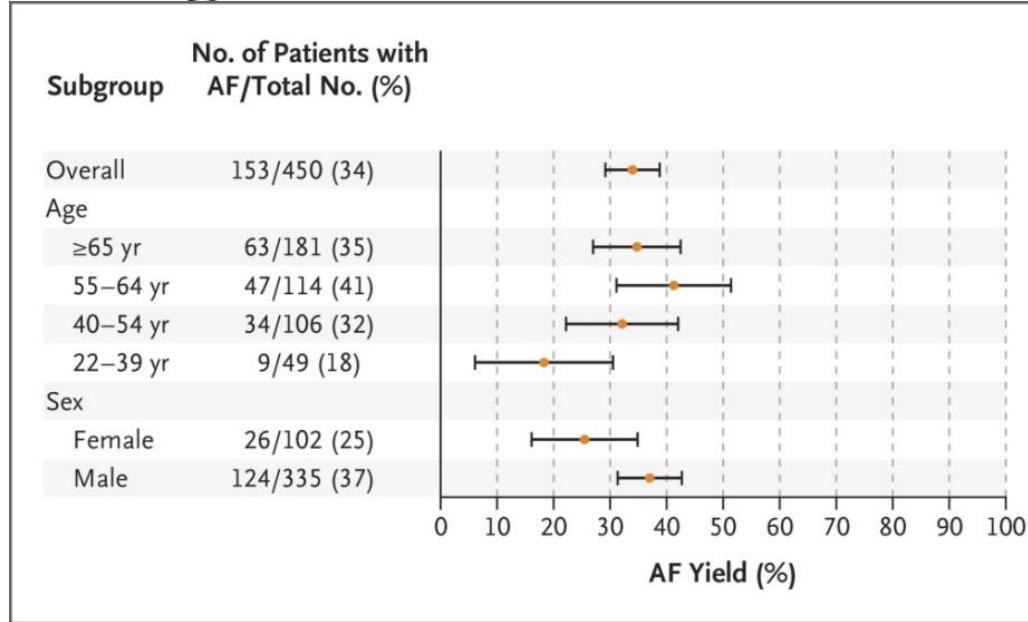
Table 2. End-of-Study Survey.

Variable	Notification Subgroup (N=929)	Non-notification Subgroup (N=293,015)
New diagnosis — no. (%)		
Atrial fibrillation	404 (43)	3070 (1.0)
Stroke	7 (0.8)	321 (0.1)
TIA	12 (1.3)	498 (0.2)
Heart failure	30 (3.2)	648 (0.2)
Myocardial infarction	10 (1.1)	574 (0.2)
Major bleeding	7 (0.8)	842 (0.3)
Medication use — no. (%)*		
Warfarin	20 (2.2)	265 (0.1)
Direct oral anticoagulant	202 (22)	996 (0.3)
Aspirin	338 (36)	40,774 (14)

* This category refers to medication use since enrollment in the study, as reported by the participants.

"스마트 워치와 ECG 패치 판독은 84% 일치하였으며,
스마트 워치로부터 알림을 받은 군은 받지 않은 군 대비 심방세동/뇌졸중 진단, 항응고제요법 시작 등의 비율이 높았음

Wearable Device 와 single lead EKG data (2)

**The REHEARSE-AF Study**
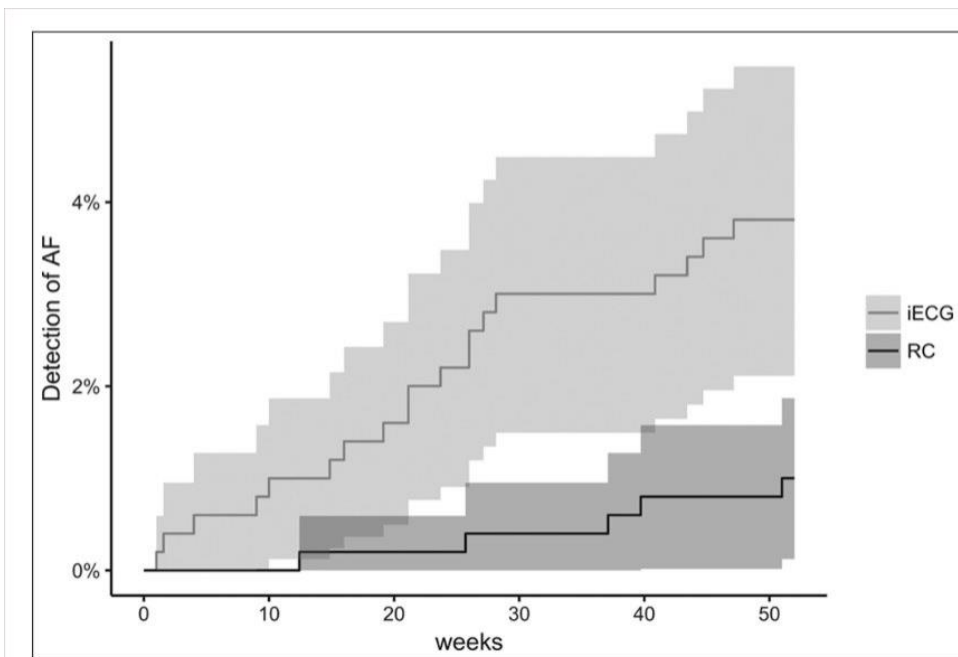
AliveCor (R), KARDIA

Kaplan-Meier plot showing the estimated detection probabilities for atrial fibrillation (AF) in each study arm over the 52 weeks of the trial.

Shaded areas represent 95% confidence regions. Log-rank *P*=0.004 (Mantel-Cox). RC indicates routine care

TOGETHER.
TOMORROW.
EWHA

Wearable Device 와 single lead EKG data (3)
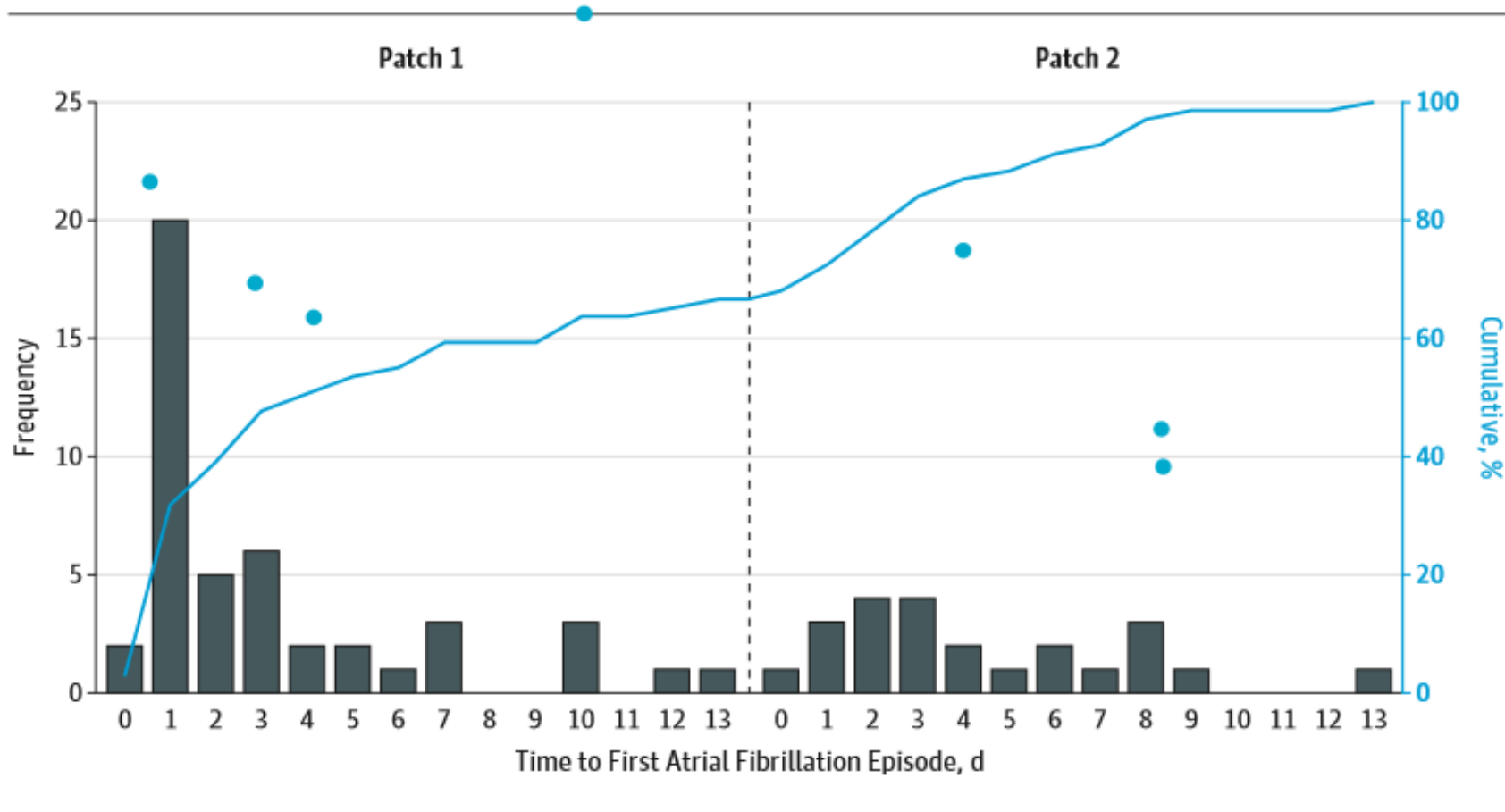
ThemSToPS Randomized Clinical Trial

✓ Age of 75 years or older,
✓ male older than age 55 years
  or female older than age 65 years
  with 1 or more comorbidities
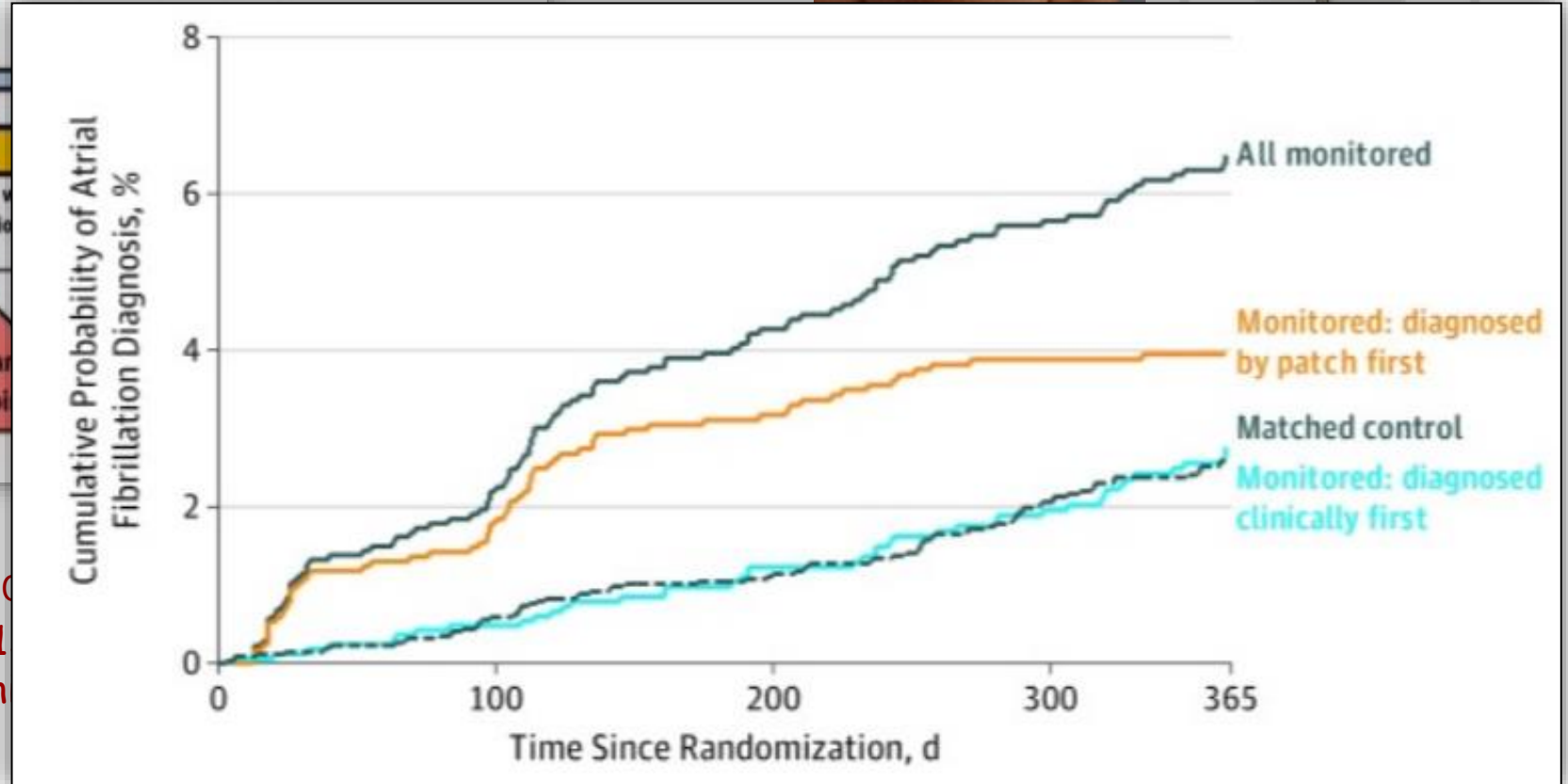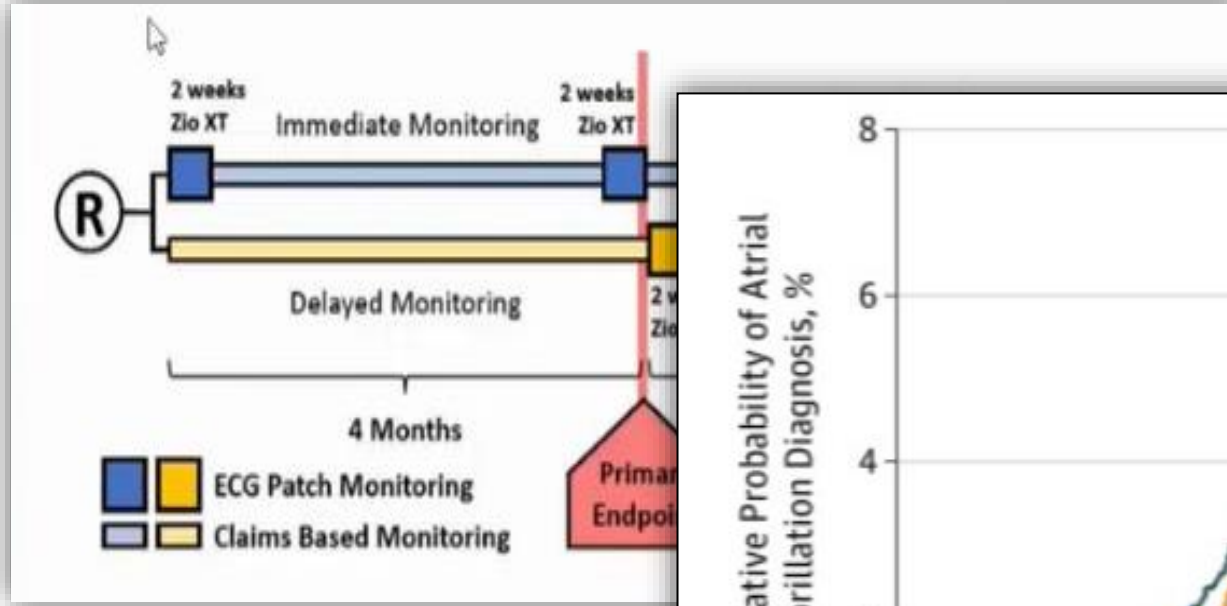
"심방세동 고위험군 환자에서,
웨어러블 ECG 패치를 통한 즉각적(
• Immediate group : 3.9% (53/1
• 항응고제 처방률 [Actively mon
  100persons-years]

Steinhubl SR, et al. *JAMA*. 2018;320(2):146-155.

ThemSToPS Randomized Clinical Trial

Steinhubl SR, et al. *JAMA*. 2018;320(2):146-155.

Screening for AF in the Older Population (≥75yrs old)

Systematic ECG screening should be considered to detect AF in individuals aged ≥75 years, or those at high risk of stroke.[212,224,227]
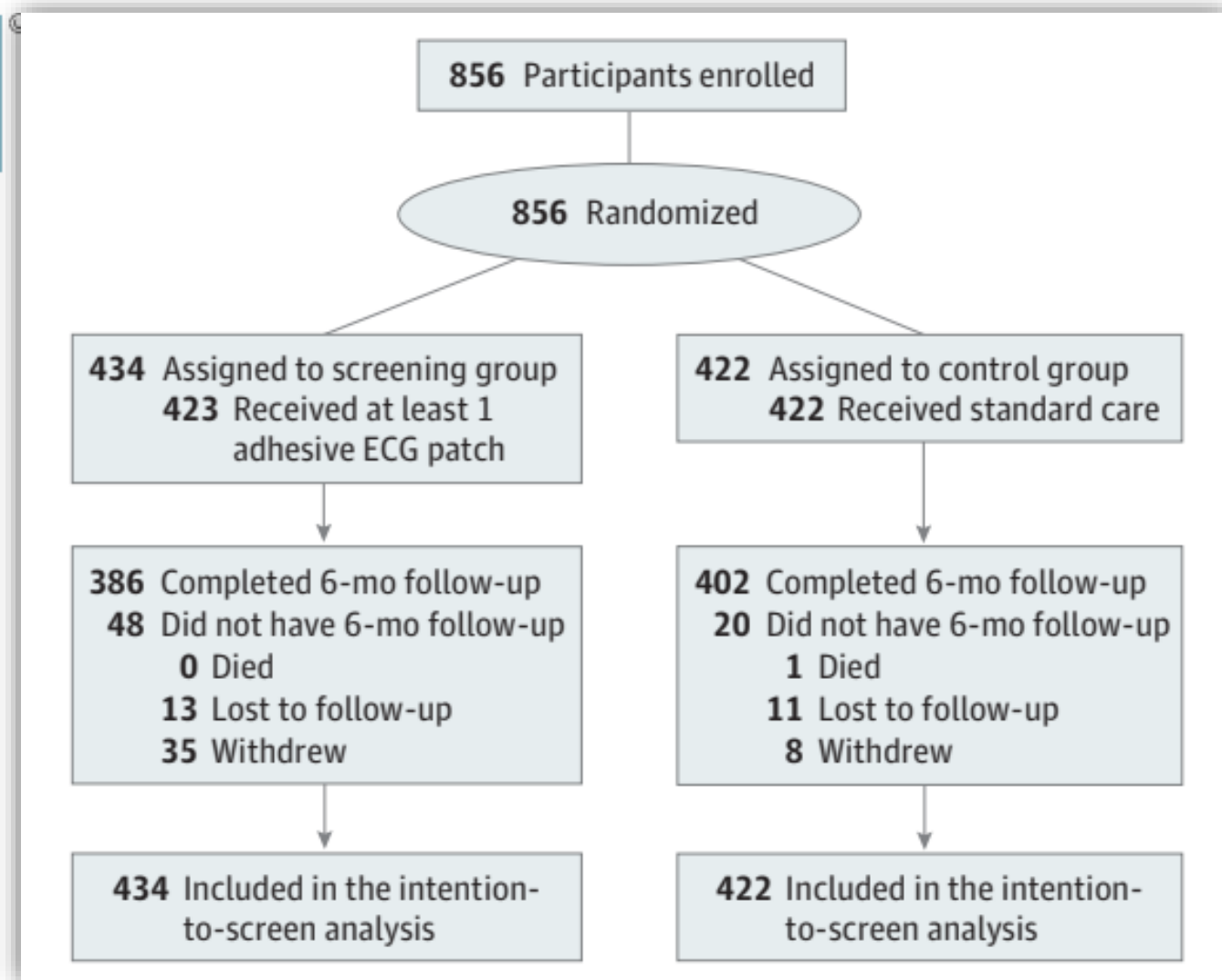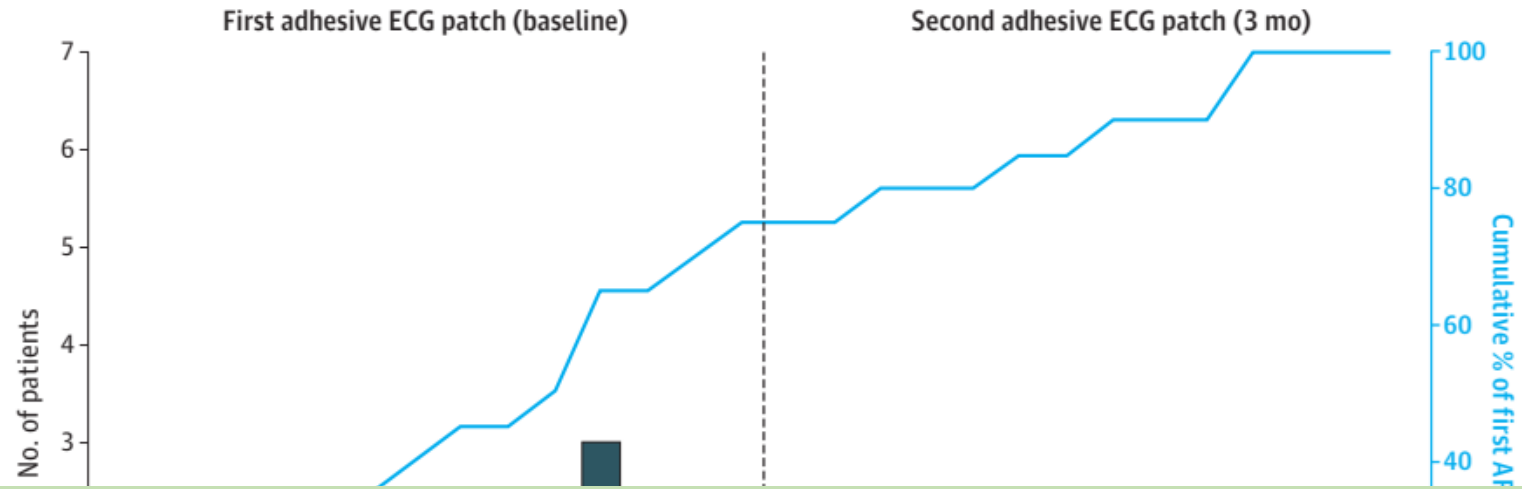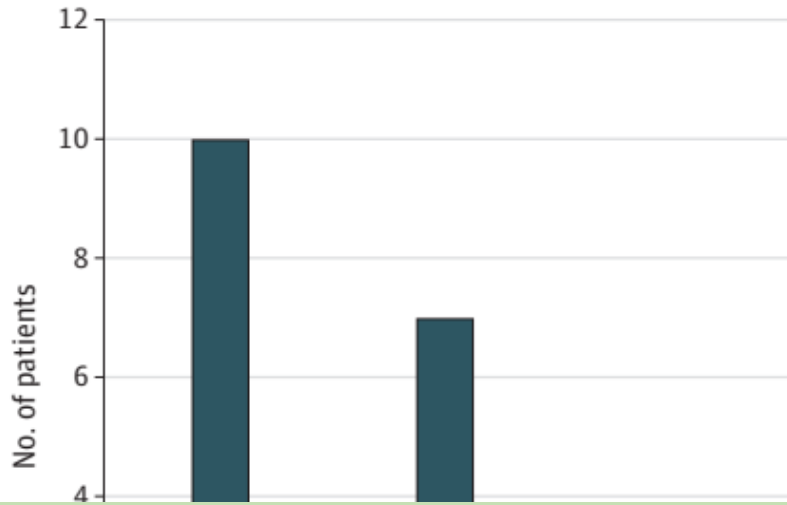
| IIa | B |

Screening Group
: patch cECG (Zio XT; iRhythm Technologies)
: up to 2week (baseline and 3months)

The home BP monitor (Watch BP-Home A; Microlife Corp)
✓ Twice daily (morning and evening)
✓ If 2 or more of the 3 consecutive measurements were positive for AF.
✓ Participants and clinicians were advised not to act upon the home BP monitor AF screening results.

856 Participants enrolled

856 Randomized

434 Assigned to screening group
423 Received at least 1 adhesive ECG patch

422 Assigned to control group
422 Received standard care

386 Completed 6-mo follow-up
48 Did not have 6-mo follow-up
  0 Died
 13 Lost to follow-up
 35 Withdrew

402 Completed 6-mo follow-up
20 Did not have 6-mo follow-up
  1 Died
 11 Lost to follow-up
  8 Withdrew

434 Included in the intention-to-screen analysis

422 Included in the intention-to-screen analysis

TOGETHER.
TOMORROW.
EWHA

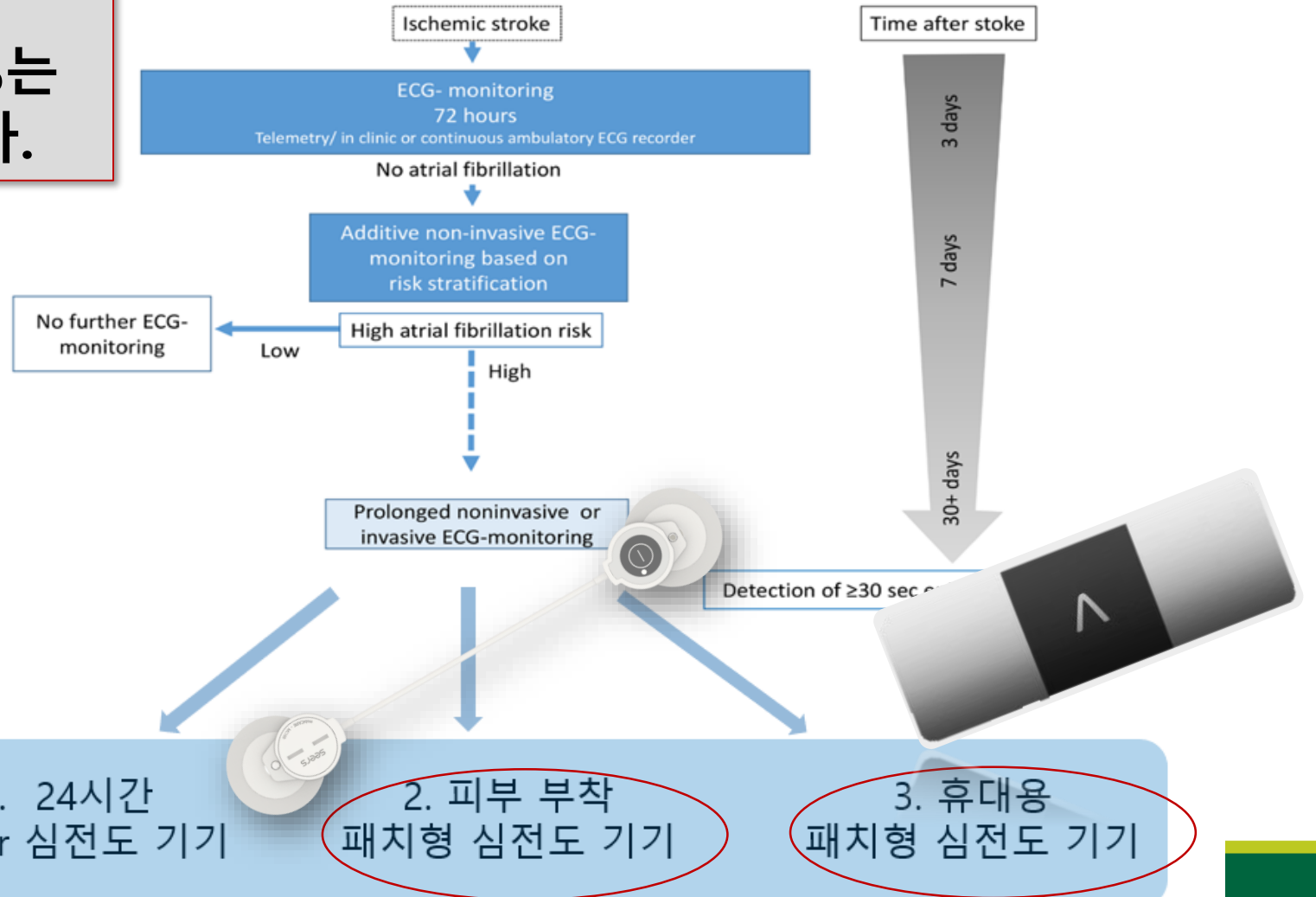# Screening for AF in the Older Population (≥75yrs old)

- AF was detected in 23 of 434 participants (**5.3%**) in the screening group vs 2 of 422 (**0.5%**) in the control group (relative risk, 11.2; 95% CI, 2.7-47.1; P = .001)

- Anticoagulant therapy had been prescribed for 18 of 434 participants (**4.1%**) in the screening group vs 4 of 422 (**0.9%**) in the control group (relative risk, 4.4; 95% CI, 1.5-12.8; P = .007)

- **Twice-daily AF screening using the home BP** monitor :
  - ✓ sensitivity of 35.0% (95% CI 15.4%-59.2%), specificity of 81.0% (95% CI, 76.7%-84.8%)
  - ✓ positive predictive value of 8.9%(95% CI, 4.9%-15.5%),negative predictive value of 95.9% (95% CI, 94.5%-97.0%).

심방세동의 진단을 위해서 어떤 Wearble 심전도를 사용할 것인가?

- Wearable devices 를 이용한 대규모 전향적 연구 성과가 필요하다.
- Wearable devices 를 활용할 수 있는 새로운 치료 적응증을 발견하는 것이 필요하다.

**뇌졸중 / 심방세동
- 뇌졸중의 30-40 %는 심방세동에 기인하다.**

기존 가이드 라인

Ischemic stroke

ECG- monitoring
72 hours
Telemetry/ in clinic or continuous ambulatory ECG recorder

No atrial fibrillation

Additive non-invasive ECG-
monitoring based on
risk stratification

No further ECG-
monitoring ← Low ← High atrial fibrillation risk

High

Prolonged noninvasive or
invasive ECG-monitoring

Detection of ≥30 sec

Time after stoke

3 days

7 days

30+ days

연구 구조
심방세동 진단 비교

1. 24시간
Holter 심전도 기기

2. 피부 부착
패치형 심전도 기기

3. 휴대용
패치형 심전도 기기

CANDLE - AF Trial (Clinicaltrials.gov / NCT04624646)

대상 환자

- 다기관, 전향적, 무작위, 우월성 입증 연구 (이화여대 목동 병원/ 서울 병원)
- 대상자 등록 및 적응증: 급성 뇌졸중 (Stroke) 이 발생한 환자 중 심방세동이 발견되지 않는 환자 (Unknown origin Stroke)
  - 18세 ~ 90세 성인
  - 3개월 이내의 급성 뇌졸중
  - 뇌졸중 진단 1년 이내의 심방세동(Atrial fibrillation, ICD10 : I48)을 진단 받지 않음.
  - 뇌졸중의 원인을 위한 Lab, Image W/u에서 명확한 원인을 찾지 못함.
  - 뇌졸중 진단 이후 7일간의 Continous EKG monitoring에서 AF이 진단되지 않은 경우

Clinical implication of **A**trial fibrillatio**N** **D**etection using wearab**LE** device in patients with cryptogenic stroke
- The comparison between short-term continuous patch and long-term continuous monitoring **(CANDLE –AF**

환자 등록 (이화여대 목동 / 서울 병원) : 다기관, 전향적, 무작위 (1:1:1) 배정

이화여대 목동, 서울, 고려대학교 구로, 한양대, 경희대, 세브란

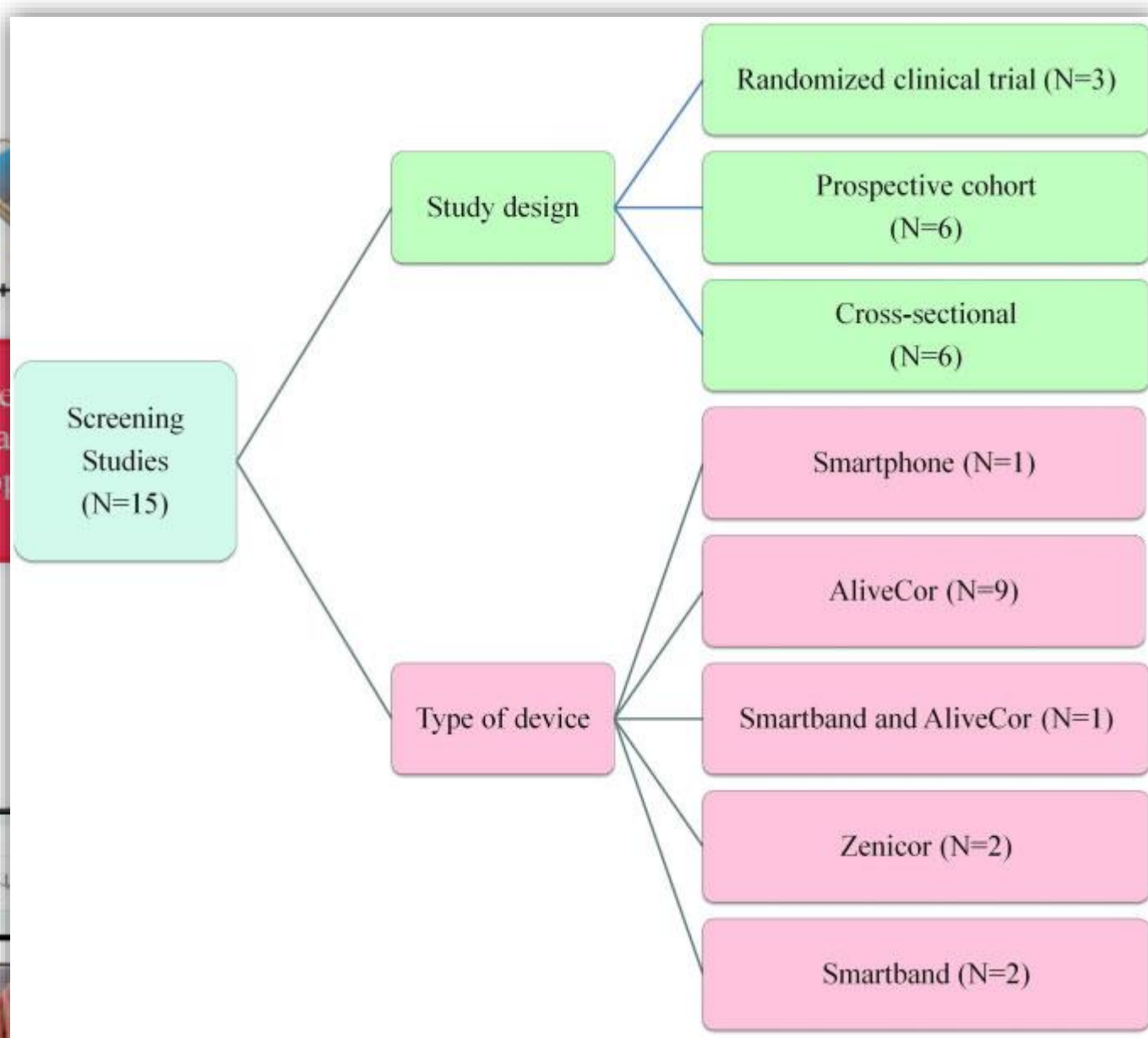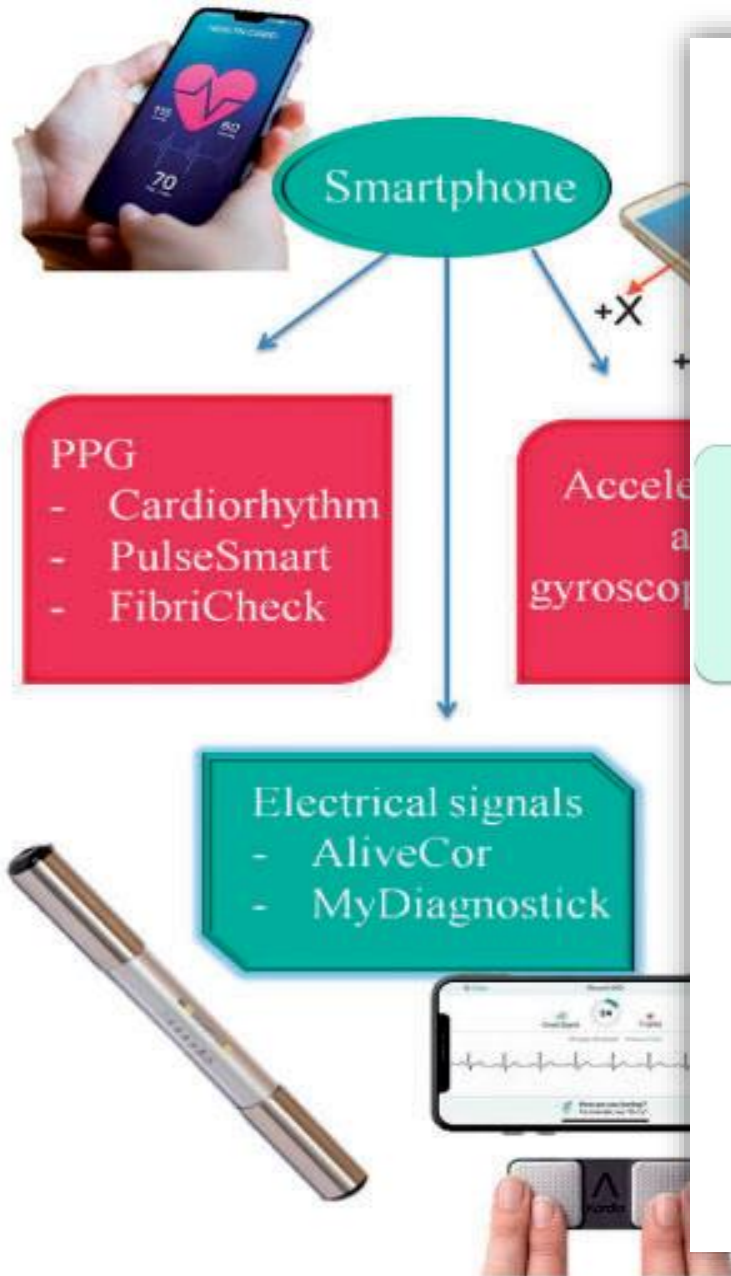| Guideline Group (Control:N=200)	Wearable Device Group 1 (대상 의료기기) (N=200): (Continous Short-term monitoring)	Wearable Device Group 2 (현재 시판중 타 의료기기) (N=200): (Discontinous Long-term monitoring)
■ 뇌졸중 진단 7일 ~ 30일 사이의 퇴원전 원내 EKG monitoring ■ 퇴원 이후 정기적인 외래 방문과 심전도 (필요시 Holter), 증상 발현시 심전도	■ 뇌졸중 진단 7일 ~ 30일 사이의 퇴원전 원내 EKG monitoring ■ 퇴원 이후 정기적인 외래 방문과 심전도 (필요시 Holter), 증상 발현지 심전도 + ■ 외래 방문시 마다 (최소 3개월마다) Patch type wearable device 추가 처방 (72 시간 연속 측정)	■ 뇌졸중 진단 7일 ~ 30일 사이의 퇴원전 원내 EKG monitoring ■ 퇴원 이후 정기적인 외래 방문과 심전도 (필요시 Holter), 증상 발현지 심전도 + ■ 퇴원시 KARDIA, AliveCor ® 처방 : 매일 하루 2-3 번 30 초씩의 심전도를 측정하도록 함

국내 웨어러블 심전도기 현황
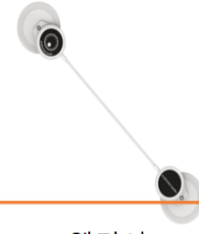
	SEERS	휴이노	스카이랩스	메쥬	웰리시스	에이티센스	드림텍
의료기기 제조업허가	○	○	○	○	○	○	○
GMP인증	○	○	○	○	○	○	○
ISO13485	○	X	X	X	○	X	X
국내 보유 인증 항목	심전계 홀터심전계 1등급 유헬스케어 게이트웨이	유헬스케어심전계	홀터심전계	홀터심전계 1등급 유헬스케어 게이트웨이	홀터심전계	홀터심전계	홀터심전계
FDA 510(K)	X	X	X	X	X	X	X
CE MDD	○	X	X	X	○	○	X
비고	대웅제약과 판매계약	유한양행 투자	종근당 투자		삼진제약 투자	아이마켓코리아와 판권계약	*

* 드림텍은 Cardiac Insight의 Cardea Solo와 Life Signals이 Biosensor 1A의 제조사임

심방세동

8월 18일 오후 3:06

66 bpm

심방세동

8월 18일 오후 3:01

66 bpm
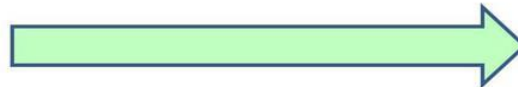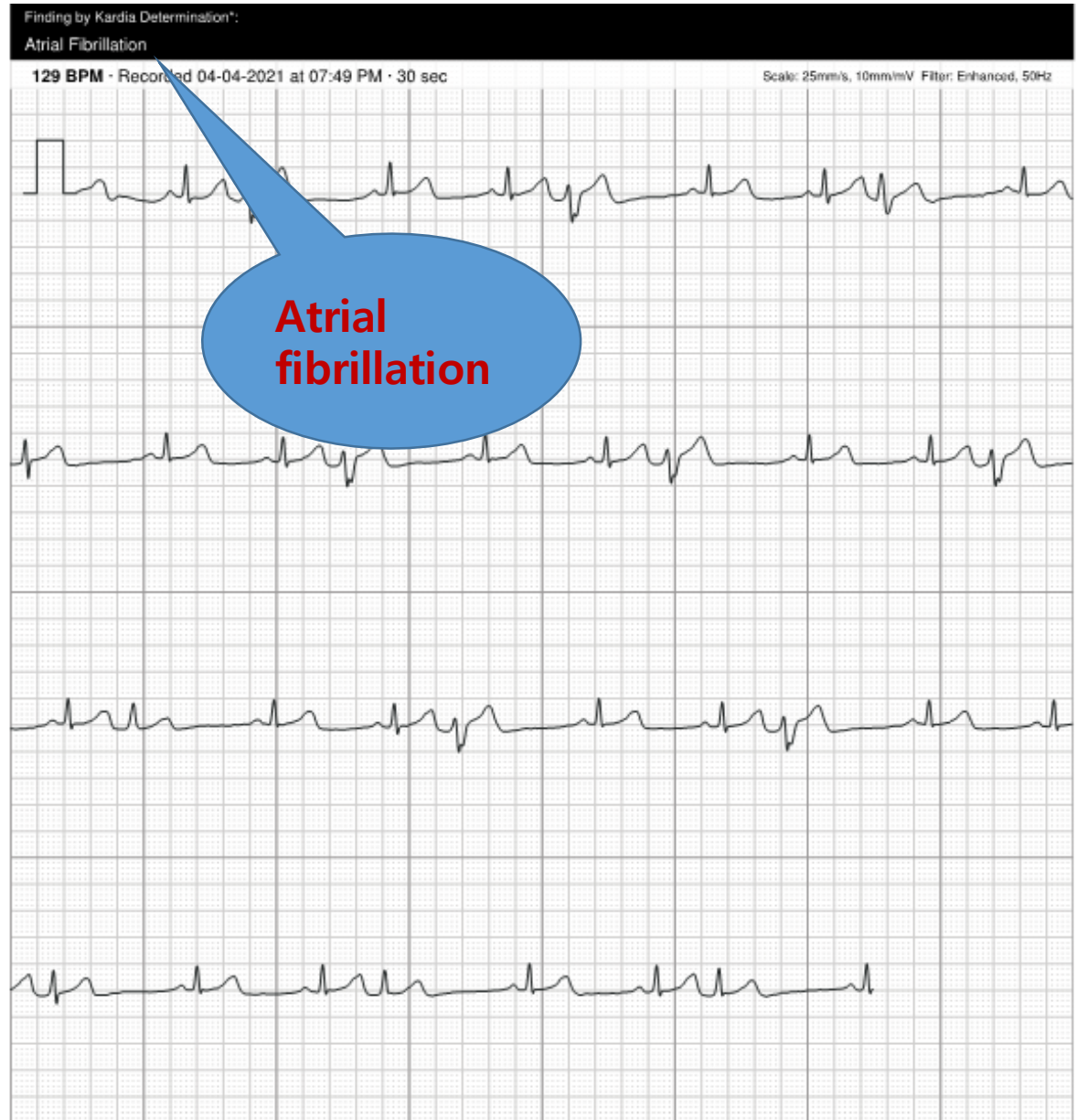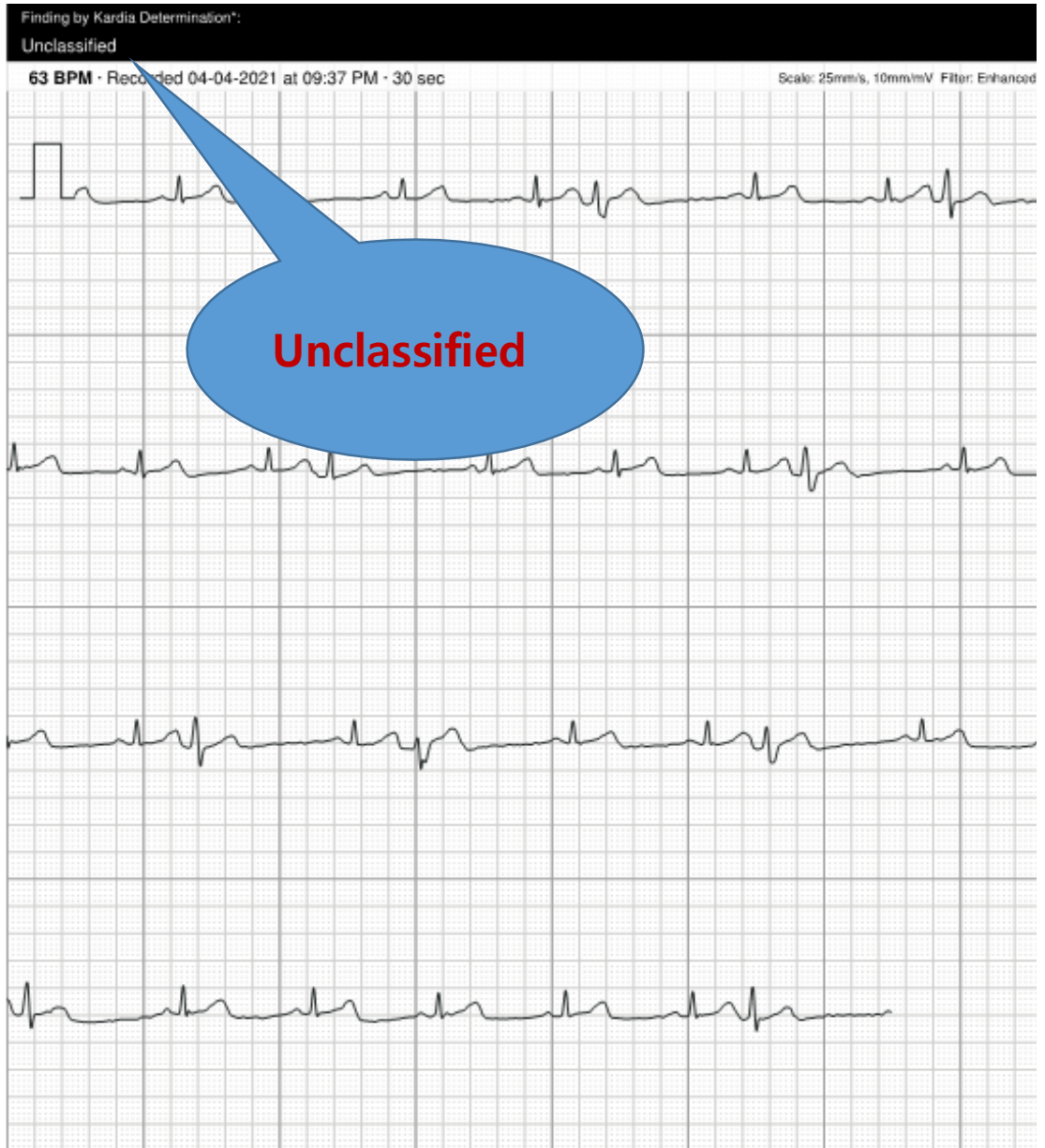
장 통증을 호소
치에 탑재된 심
를 잡아냈다는
원에서도 통증
스마트워치 심
전문 병원을 찾
을 받았다는 것

뮤니티에는 '포
이프 백신 아스트
아냈다'는 글이

HOLTER REPORT

Location: Unknown

Room ID: MC

심방세동 ; 평균 109BPM
이 심전도는 심방세동의 징후를 보입니다.
예상치 못한 결과라면 의사와 상의하십시오.

Overreading Physician ,
Referring Physician ,
Ordering Physician: **Park Joon Beom, M.D**
Hook-Up Technician: ,
Indication/Diagnosis: **Palpitation**
Medications

General

98462	QRS complexes
1	Ventricular beats (< 1%)
45	Supraventricular beats (< 1%)
< 1	% of total time classified as noise

Heart Ra...

46	Min...
70	Ave...
125	Ma...
2126	Bea...
17351	Bea...
1.4	Se...

Suprave...

32	Iso...
2	Co...
0	Big...
3	Ru...
3	Bea...
3	Bea...

Ventriculars (V, F, E, I)

1	Isolated
0	Couplets
0	Bigeminal cycles
0	Runs totaling 0 beats

25mm/s, 10mm/mV, 리드 I, 512Hz, iOS 14.5, watchOS 7.4.1, Watch5,4, 앱규제품 버전 1 — 이 세부한 리드 I 심전도와 비슷합니다. 자세한 사항은 새로 기침을 참조하십시오.

Mobile Health Technology for Improved AF Screening and Transfer Into a Holistic and Integrated Care (Huawei Heart Study)
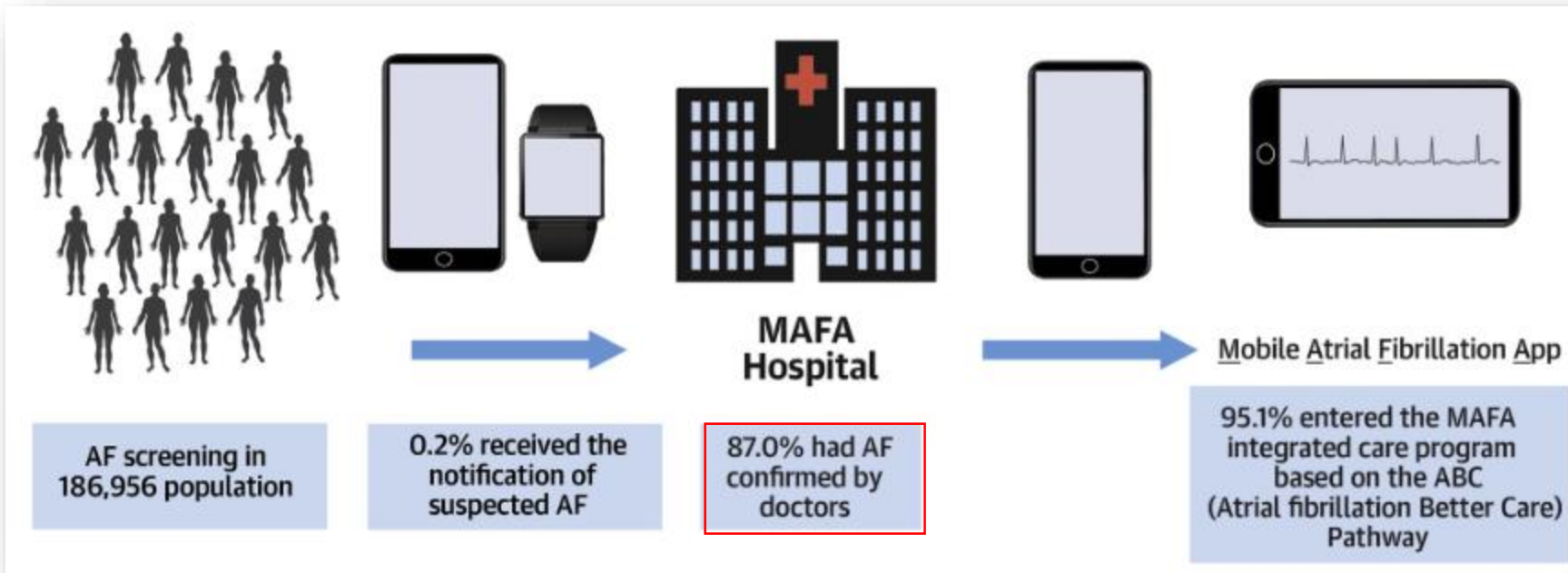
1. **Trial design:** wristand 또는 wristwatch 를 14일간 모니터한다.
2. PPG algorithm에서 possible AF로 분석 하면 통지한다.
3. 187,912명이 참여하였고 424명이 suspected AF를 통지 받았다.

AF screening in 186,956 population

0.2% received the notification of suspected AF

87.0% had AF confirmed by doctors

MAFA Hospital

Mobile Atrial Fibrillation App

95.1% entered the MAFA integrated care program based on the ABC (Atrial fibrillation Better Care) Pathway

✓ Continuous home monitoring with smart device–based PPG technology could be a feasible approach for AF screening.

✓ This would help efforts at screening and detection of AF, as well as early interventions to reduce stroke and other AF-related complications among **MAFA (mobile AF app) Telecare center** in China.
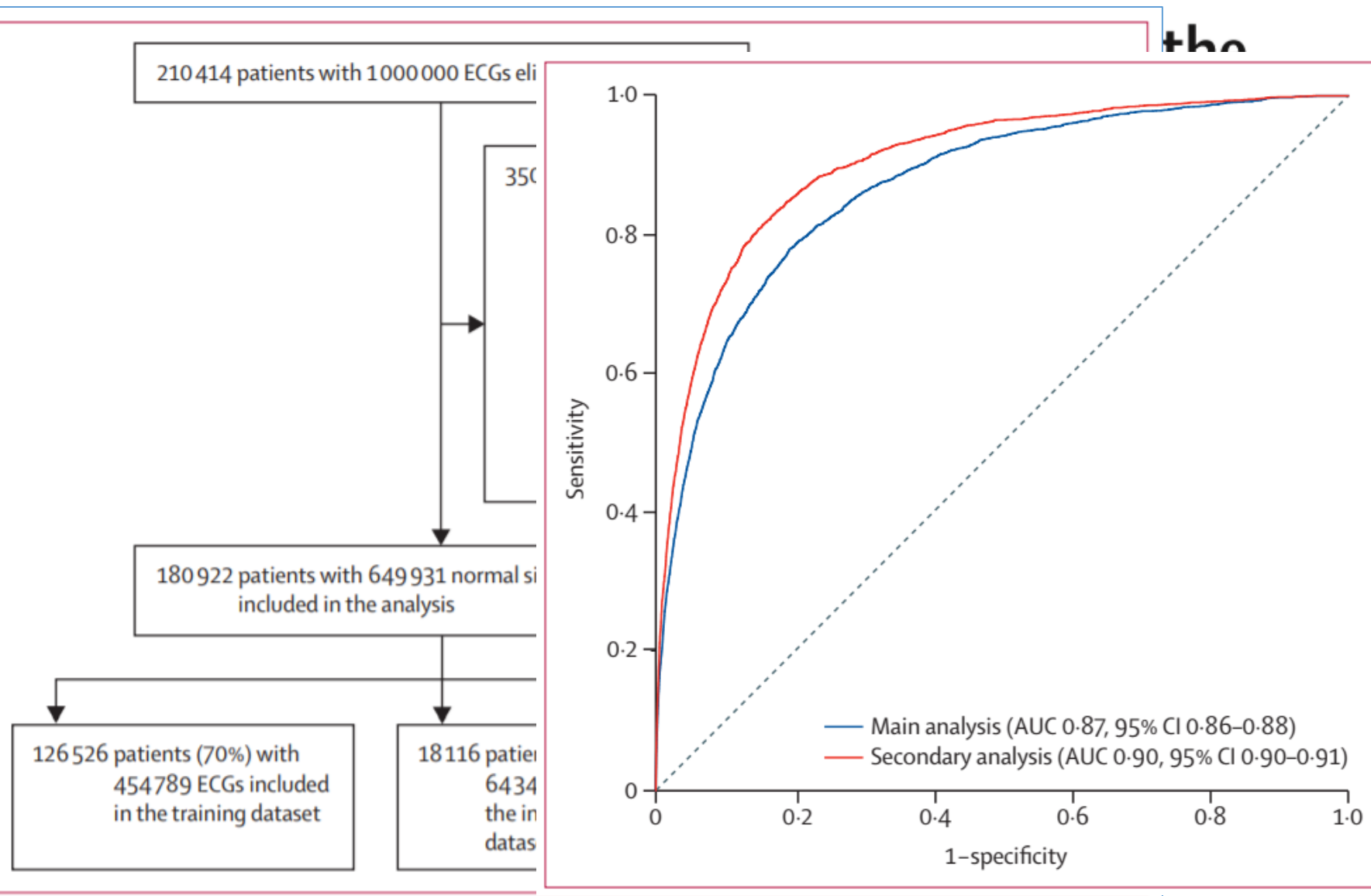
# Automatic diagnosis of the 12-lead ECG using a deep neural network

Atrial fibrillation (AF)

Table 1 (Dataset summary) Patient characteristics and abnormalities prevalence, n (%).

	Train + Val (n = 2,322,513)	Test (n = 827)
Abnormality		
1dAVb		
RBBB		
LBBB		
SB		
AF		
ST		
Age group		
16−25		
26−40		
41−60		
61−80		
≥81		
Sex		
Male	922,780 (39.7%)	321 (38.8%)
Female	1,399,733 (60.3%)	506 (61.2%)

**Table 2 (Performance indexes) Scores of our DNN are compared on cardiology resident (cardio.); (ii) 3rd year emergency resident (eme**

	Precision (PPV)				Recall (Sensitivity)			
	DNN	cardio.	emerg.	stud.	DNN	cardio.	emerg.	stud.
1dAVb	0.867	0.905	0.639	0.605	0.929	0.679	0.821	0.929
RBBB	0.895	0.868	0.963	0.914	1.000	0.971	0.765	0.941
LBBB	1.000	1.000	0.963	0.931	1.000	0.900	0.867	0.900
SB	0.833	0.833	0.824	0.750	0.938	0.938	0.875	0.750
AF	1.000	0.769	0.800	0.571	0.769	0.769	0.615	0.923
ST	0.947	0.968	0.946	0.912	0.973	0.811	0.946	0.838

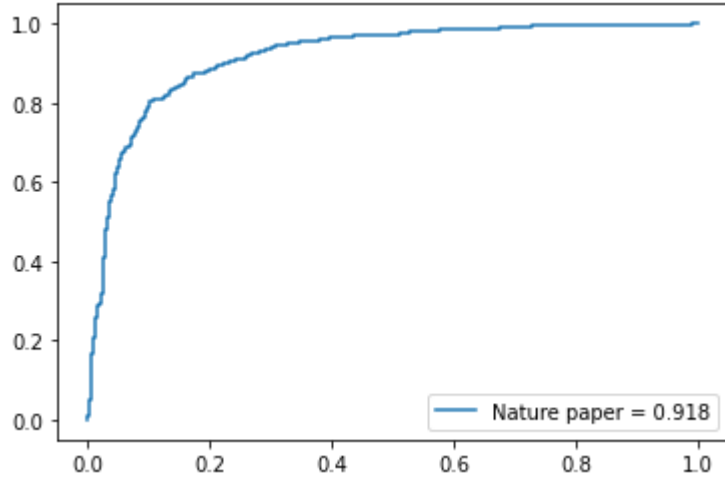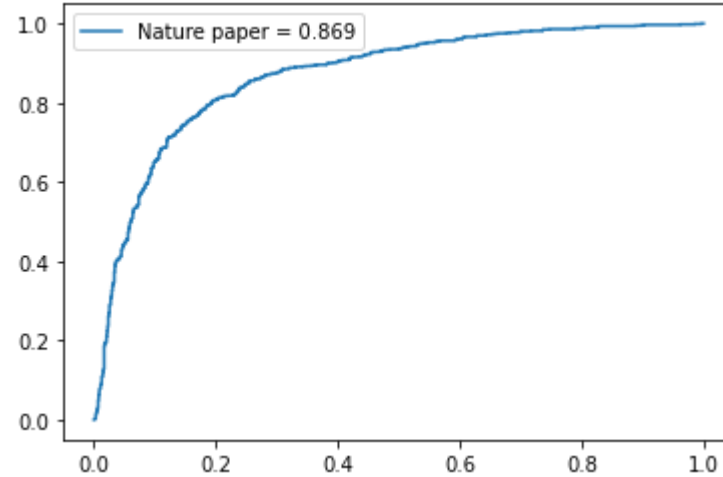*PPV positive predictive value. The bold values represent the best scores.*

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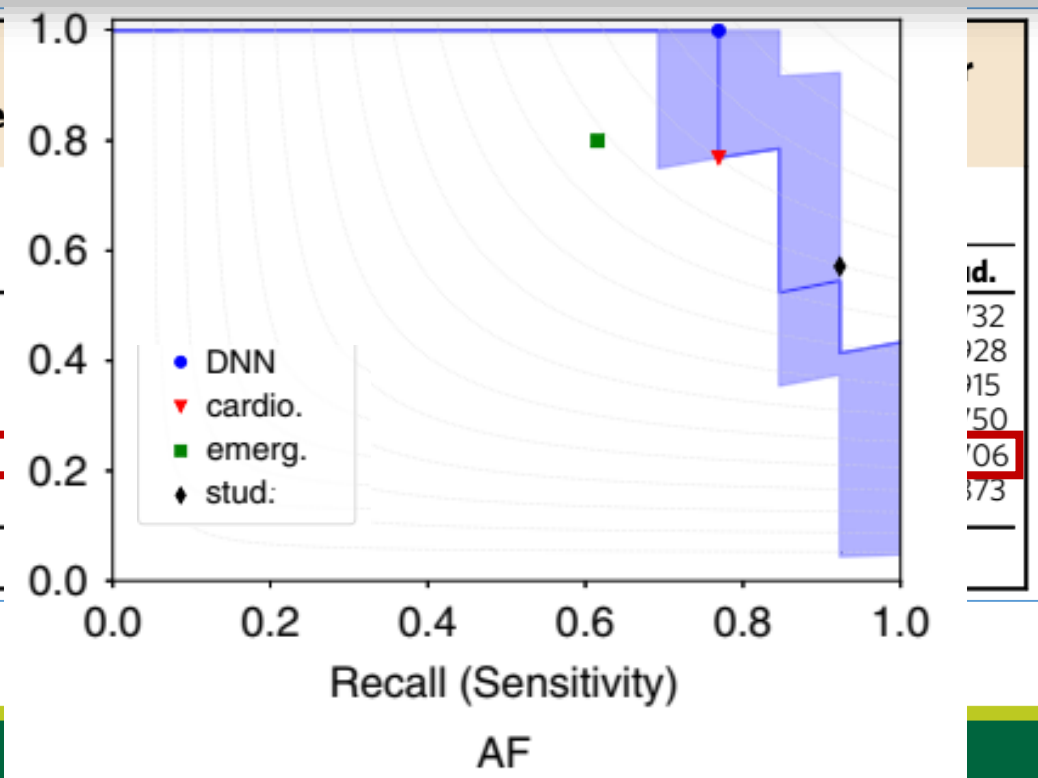
AF data preprocessing
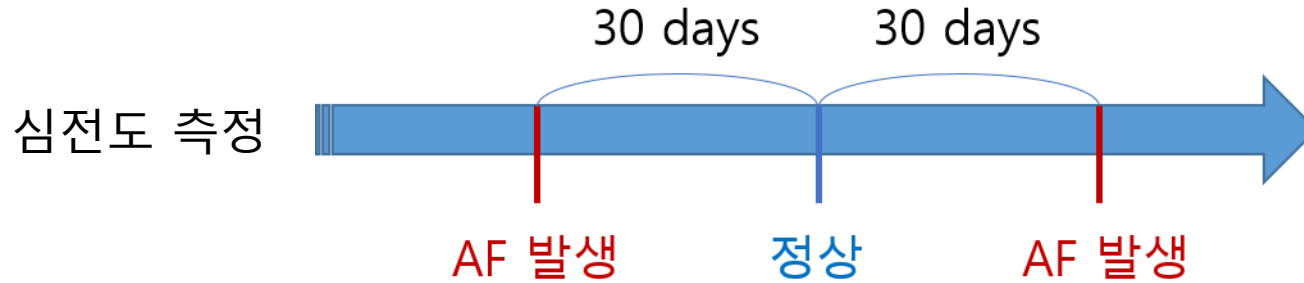
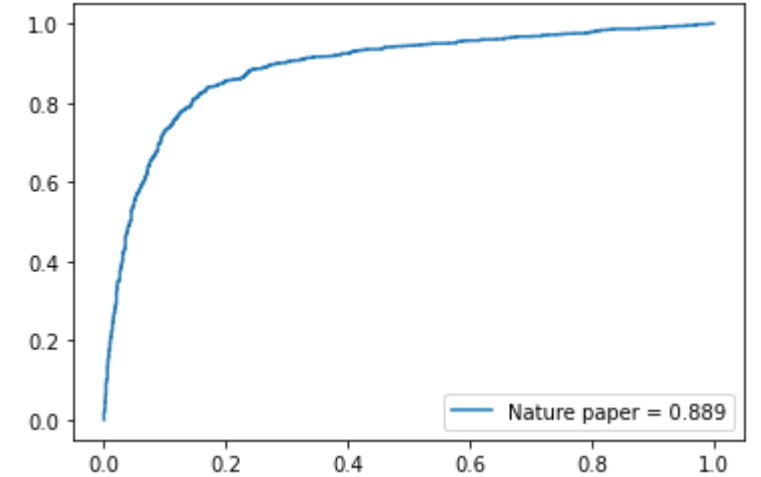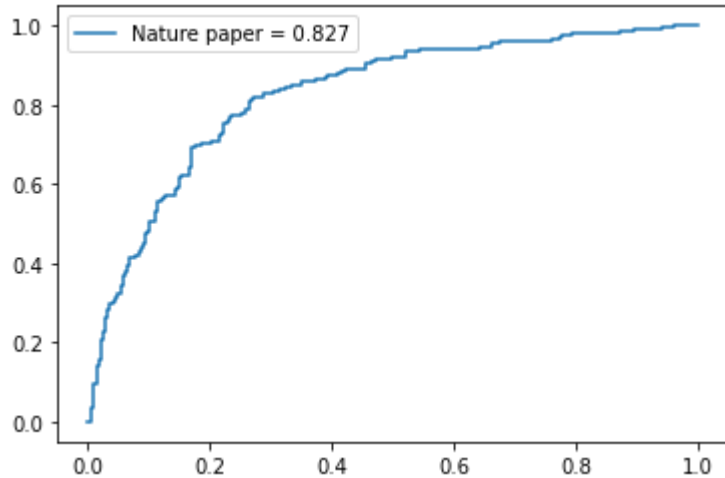| 환자 정보 범위	AF	NSR
Window size = 1개월 (30일)	2903	2903
Window size = 3개월 (90일)	3889	3889
Window size = 6개월 (180일)	4456	4456

데이터 분석
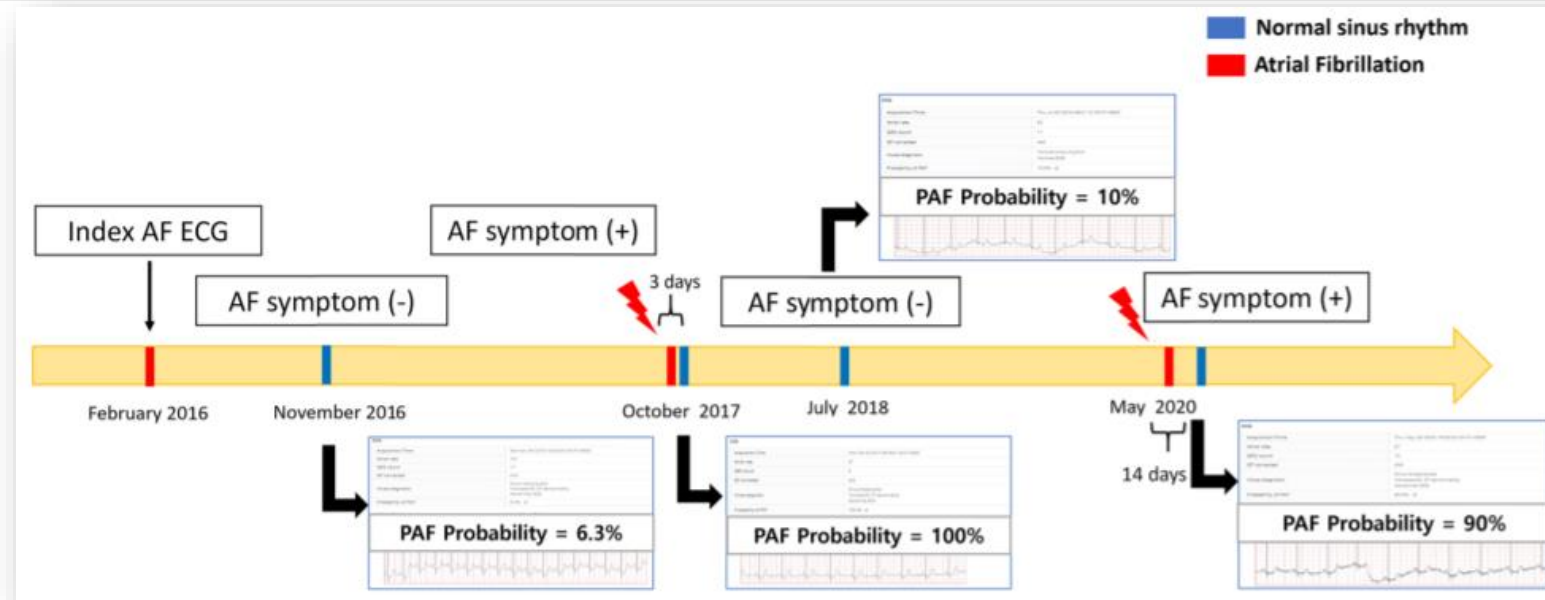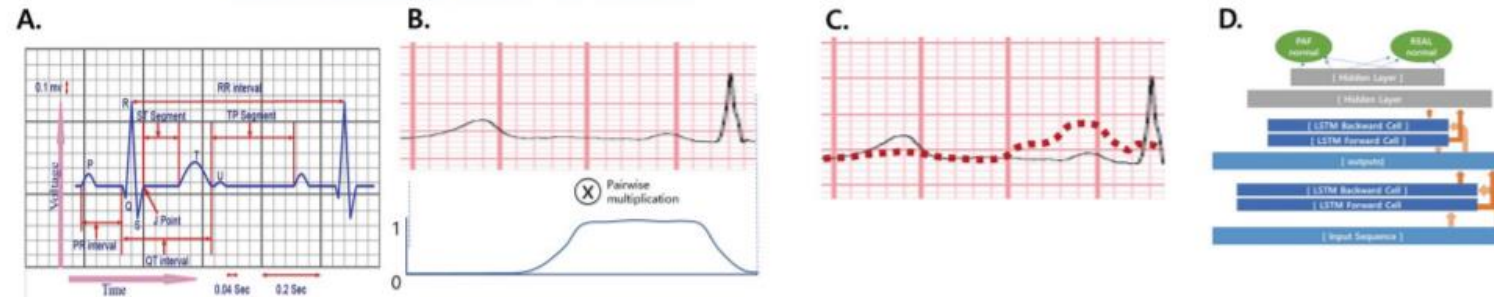

window = 1m

window = 3m

window = 6m

window = 7d
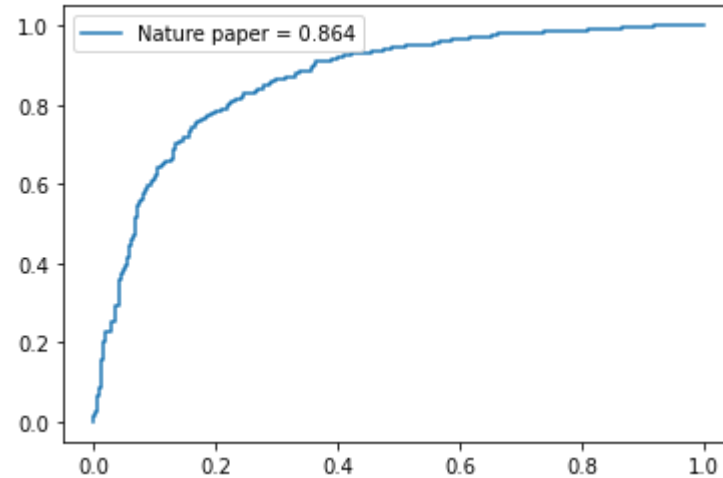
window = 14d

Window size	AUROC
1 M (7000)	0.918
3 M	0.869
6 M	0.889
7 Days (1900)	0.827
14 Days (3300)	0.864

A new deep learning algorithm of 12-lead electrocardiogram for identifying atrial fibrillation during sinus rhythm
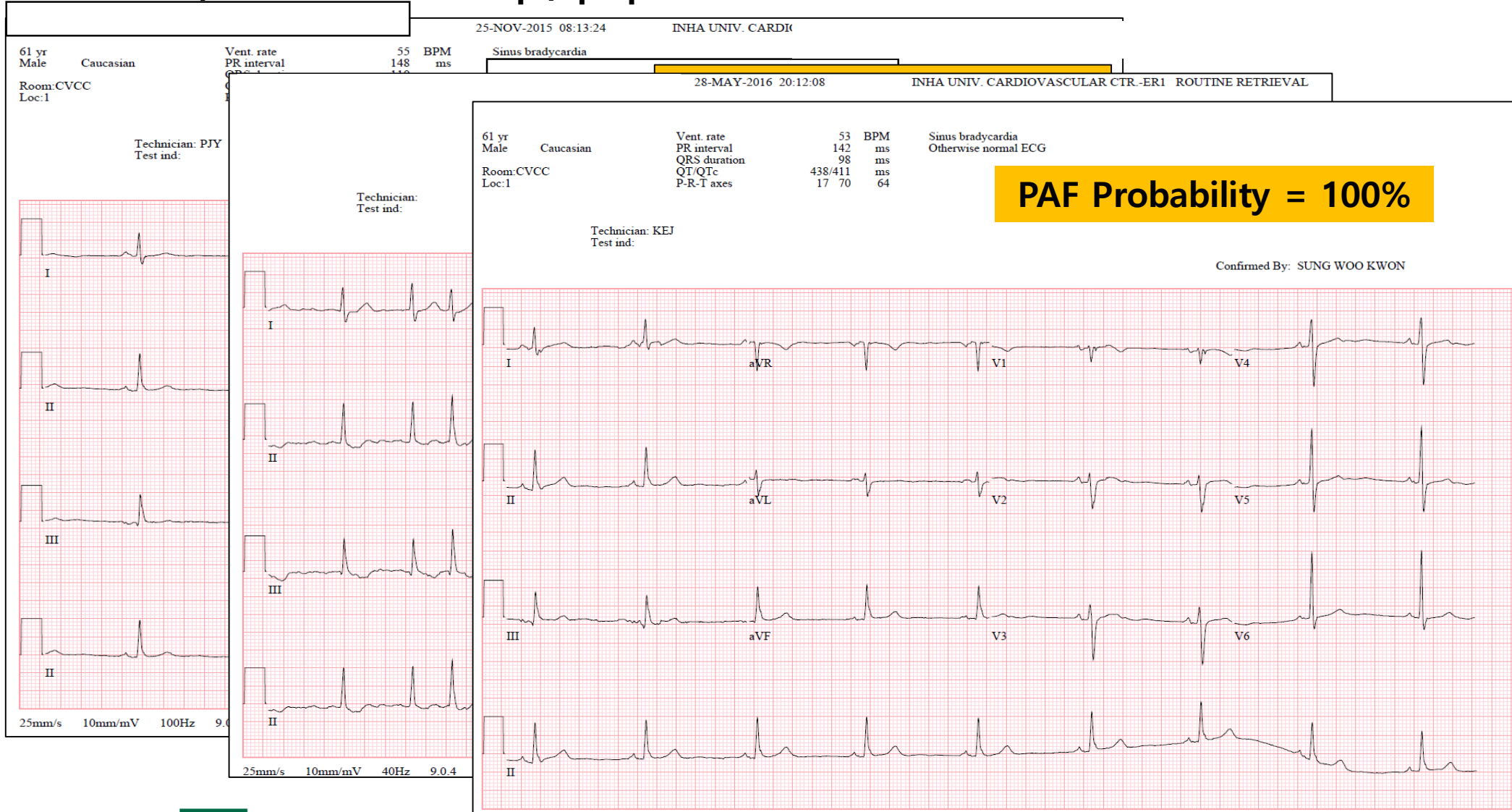
CASE

62/F : Health check up / palpitation in ER

25-NOV-2015 08:13:24   INHA UNIV. CARDI(

61 yr
Male   Caucasian   Vent. rate   55   BPM   Sinus bradycardia
                                 PR interval   148   ms
Room:CVCC
Loc:1

Technician: PJY
Test ind:

28-MAY-2016 20:12:08   INHA UNIV. CARDIOVASCULAR CTR.-ER1   ROUTINE RETRIEVAL

61 yr
Male   Caucasian   Vent. rate   53   BPM   Sinus bradycardia
                                 PR interval   142   ms   Otherwise normal ECG
                                 QRS duration   98   ms
Room:CVCC   QT/QTc   438/411 ms
Loc:1   P-R-T axes   17 70 64

PAF Probability = 100%

Technician: KEJ
Test ind:

Confirmed By: SUNG WOO KWON

25mm/s   10mm/mV   100Hz   9.0

25mm/s   10mm/mV   40Hz   9.0.4

1. AF screenin의 중요성
    : 심방세동의 조기 진단 / 뇌졸중 예방을 위한 항응고요법 시작

2. 웨어러블 진단기기

 (1) Single-lead ECG
- ESC가이드라인에 따르면 Single-lead ECG는 임상 AF 진단이 가능하며, sensitivity와 specificity가 우수하지만, 명확한 한계가 있다.

 (2) 웨어러블 진단기기 관련 대규모 연구
- Apple heart study

경청해 주셔서 감사합니다.

 (3) 심전도를 이용한 부정맥의 진단 뿐 아니라, 질병의 발생을 예측하는 모델에 대한 연구가 필요하다.

 (4) 인공지능의 한계를 극복하기 위한 전향적 임상연구가 뒷받침되어야 한다.

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TOMORROW