Evidence-Based Medicine: Implantable Cardiac Monitoring to Detect Atrial Fibrillation Following Ischemic Stroke

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CUSOM

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CAMPBELL UNIVERSITY | Jerry M. Wallace School of Osteopathic Medicine

Our patient . . .

An 81-year-old woman presents to the ER with increased difficulty with her vision since waking up this morning. She describes waking up and being “unable to see things on the right”. She also has a mild posterior headache.

She denies slurred speech, focal weakness, numbness or difficulties with balance. She denies recent fever, chills, changes in weight, chest discomfort, palpitations, shortness of breath, nausea, abdominal pain, changes in bowel movements or urination.

PMH:

- HTN
- Hyperlipidemia
- OA of knees

PSurg hx:

- s/p cholecystectomy, age 45 years
- s/p hysterectomy for for fibroids, age 41 years

Meds:

- ASA 81 mg po daily
- Atorvastatin 20 mg po daily
- Lisinopril 10 mg po daily
- Tylenol 1000 mg po bid prn knee pain

Sochx:

- Widowed, lives with her son and his family.
- Retired nurse.
- Smoked for 15 years but quit 20 years ago.
- No hx alcohol or drugs.
- Walks for exercise with her dog at 20 minutes daily.

Fam hx:

- mother, d 92, natural causes
- father d 89, hx HTN
- 1 brother age 78, hx HTN, COPD
- 1 brother age 80, HTN
- 1 son age 50, HTN
- 1 daughter, age 48 healthy

On exam, the patient is an elderly woman in no acute distress. She is alert and oriented x 3 and cooperative.
Vitals: bp 200/90 p 84 RR 20 afebrile, O2 sat 94% on RA

HEENT:	PERRL; EOMI; Conjunctivae without injection oropharynx: moist mucous membranes; dentition fair
Neck:	Full ROM; supple; no adenopathy; no thyromegaly; trachea midline
Car:	r/r/r without r/m/g
Lungs:	CTA
Abd:	non-distended, soft, nontender, no organomegaly
Extr:	no edema; dp pulses 1+ B/L

Neuro:

CNs: II, III: vision: R visual field cut noted but L visual fields are 20/30 in each eye with corrective lenses
III, IV, VI: PERRL; EOMI
V: facial sensation intact
VII: face symmetric
VIII: hearing adequate
IX, X: elevates soft palate symmetrically; gag intact
XI: shoulder shrug 5/5, symmetric
XII: tongue midline

Motor: 5/5 wrist ext, forearm flex, forearm ext, hip flex, leg ext, leg flex, first toe dorsiflexion

Sens: light touch, vibratory sense intact throughout

CBL: slight difficulty with R finger to nose testing; otherwise normal

Refl: 1+ throughout, toes downgoing B/L

Gait: normal

Her work up includes:

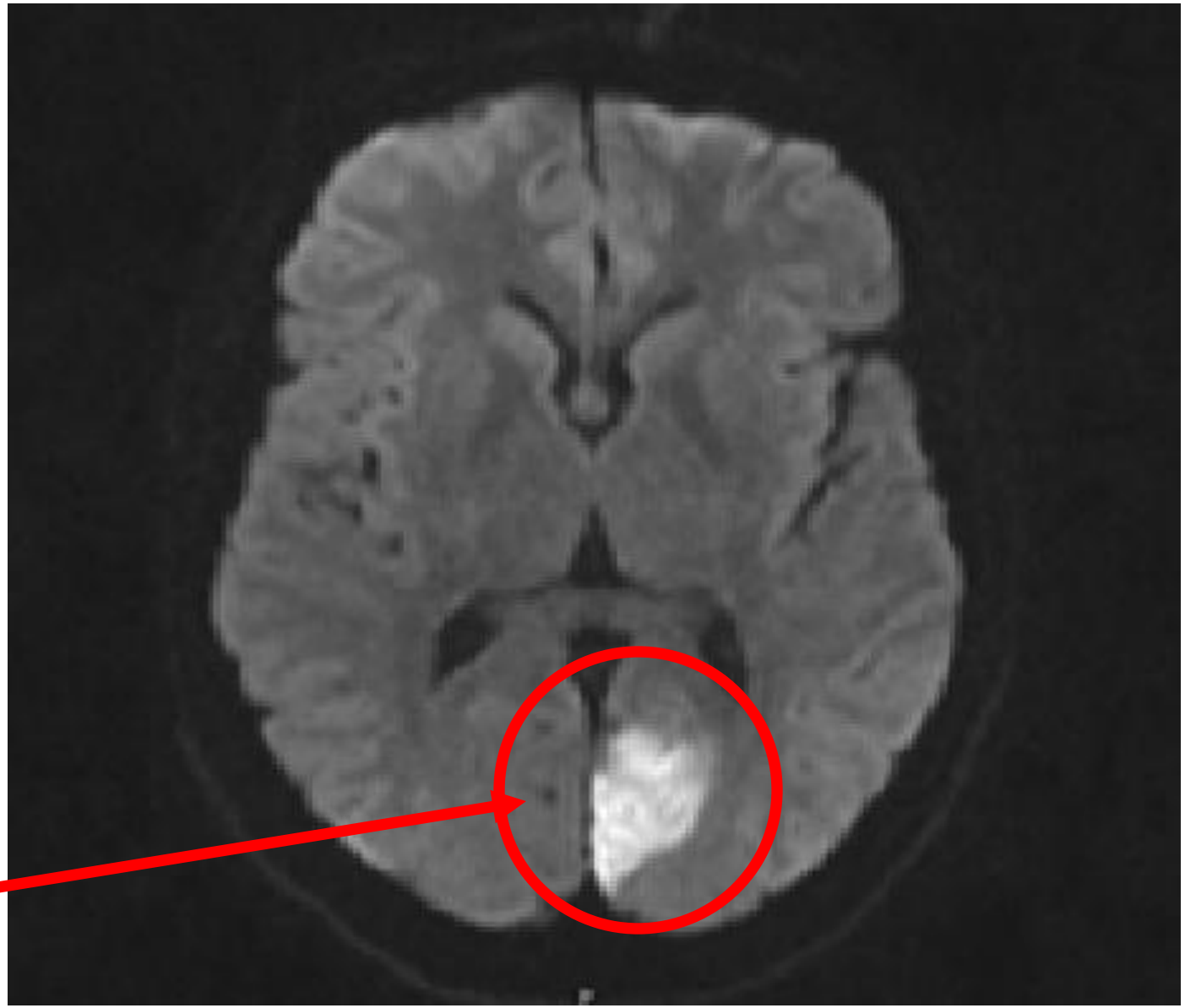
- Head CT without contrast: cerebral atrophy; otherwise normal
- CBC, chem-8: normal
- Lipids: Total chol 150 HDL: 50 LDL: 95 Trig 101
- TSH: 3.5 (normal)
- HgbA1C: 6.1% (normal)

- A carotid Doppler shows <20% stenosis in the R ICA and 21 to 50% stenosis in the L ICA

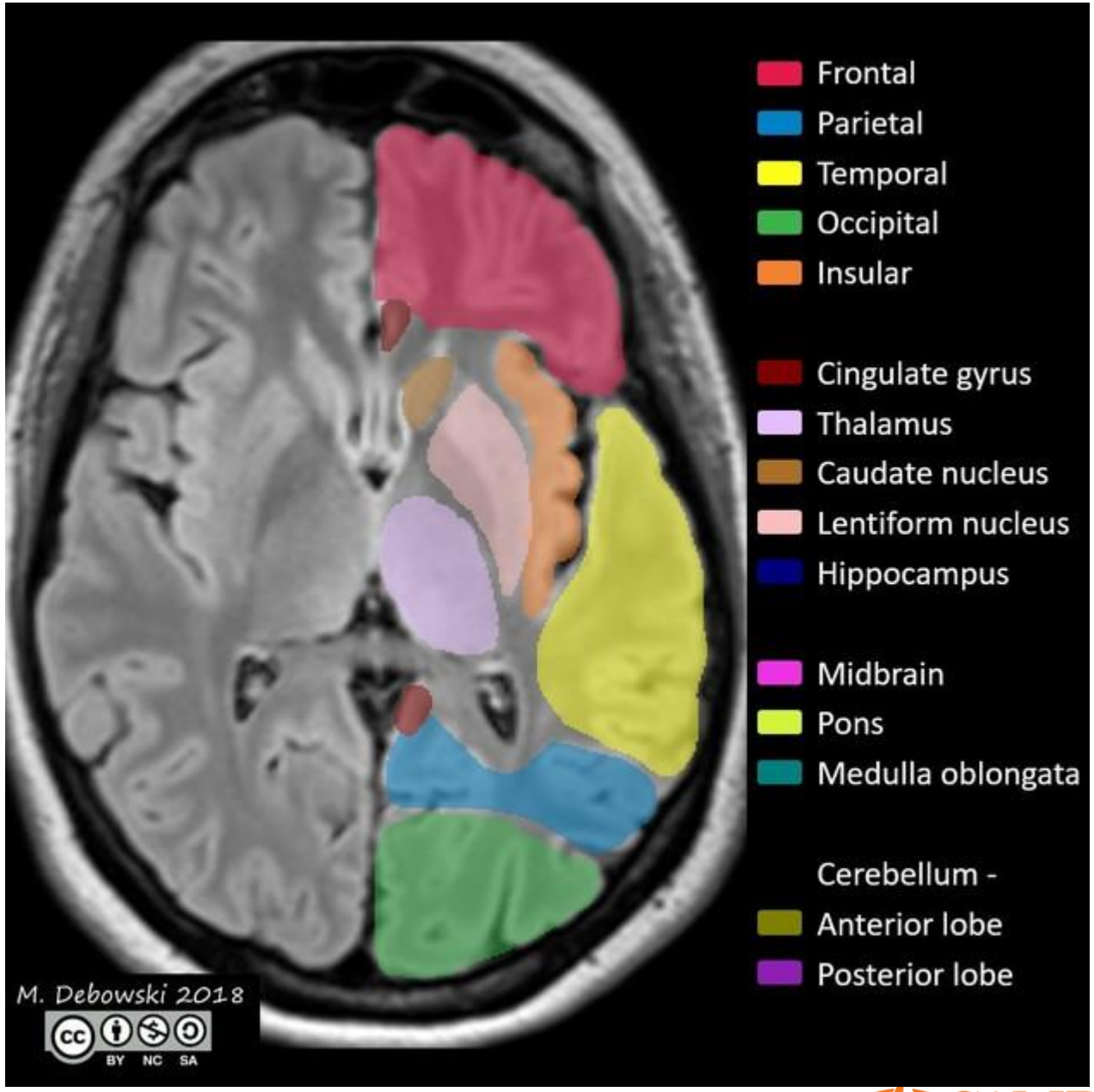
- A 2-D echo shows a LVEF 50%; stage 2 diastolic dysfunction; no significant valvular heart disease

A brain MRI is performed . . .

Remember, with CT or MRI, **imagine you are looking up from the patient's feet to the image,** so **right-sided structures** are on the **left side of the screen** and **left sided structures** are on the **right side of the screen**

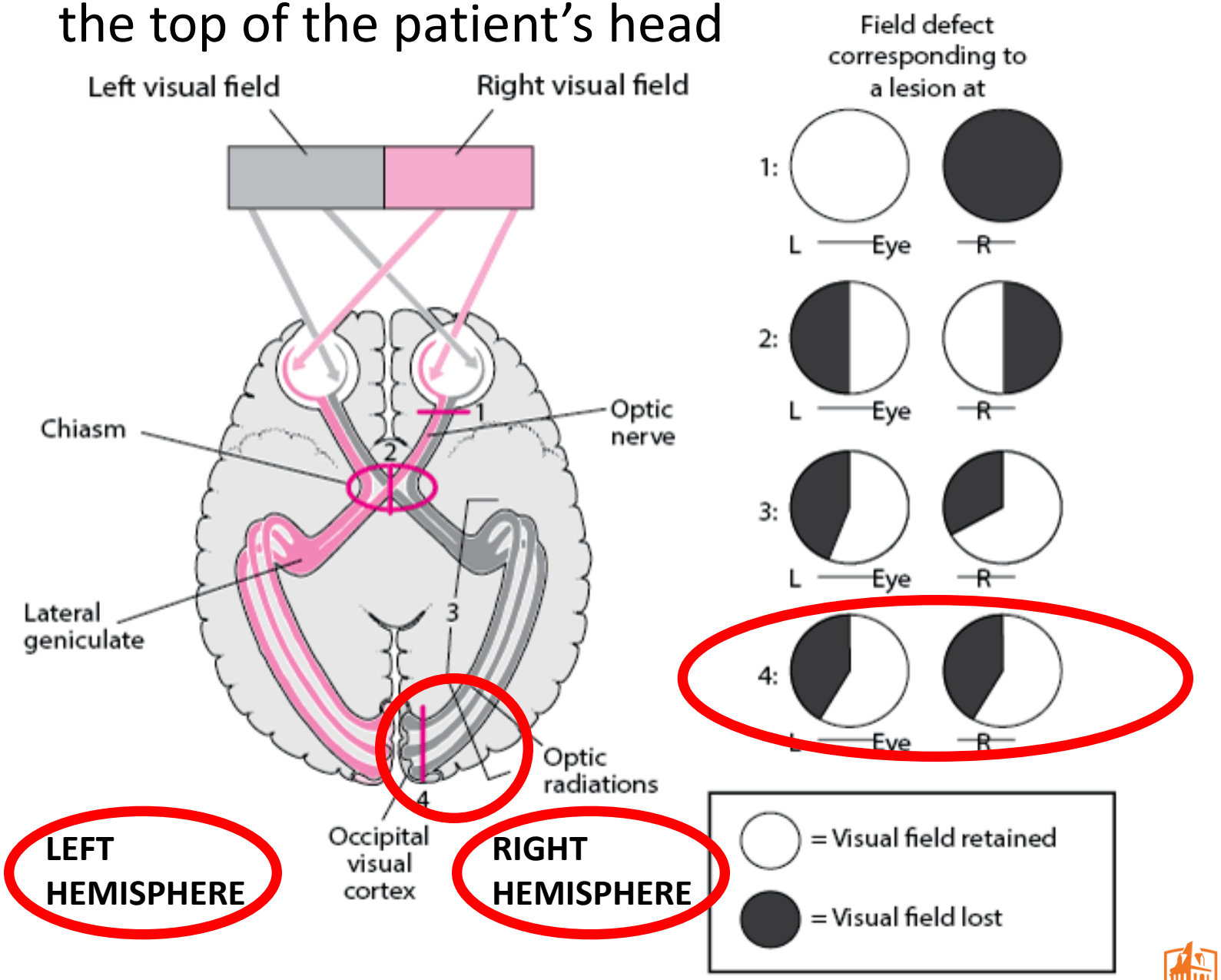


Left occipital lobe ischemic infarct



radiopaedia.org

Figure looking DOWN on to the top of the patient's head



A stroke of the LEFT occipital cortex, (which is on the RIGHT side of the head CT or MRI image but the opposite in **this** figure), will lead to a RIGHT HOMONOMOUS HEMIANOPIA

Merckmanuals.com

- During her hospital admission, cardiac telemetry demonstrates normal sinus rhythm with no evidence of arrhythmia. You are still suspicious that her stroke was embolic. A transesophageal echo shows no additional findings.

- Her ASA is stopped and changed to clopidogrel 75 mg po daily.

- Her atorvastatin is increased to 80 mg po daily.

- She is discharged with outpatient occupational therapy and is instructed not to drive until she follows up with her primary physician.

Given your patient's age, and your continued suspicion that her stroke resulted from an embolism to the posterior circulation, what is the best way to evaluate her for occult atrial fibrillation as an outpatient? You have three choices:

- A 24-hour Holter monitor
- A 30-day external loop recorder
- An implantable loop recorder/cardiac monitor for 12 months or more

Clinical question:

Among patients with recent ischemic stroke, what is the diagnostic yield of an implantable cardiac monitor (ICM) (ie. implantable loop recorder) compared to an external loop recorder in the detection of atrial fibrillation?

Source:
Buck BH, et al, Effect of Implantable vs Prolonged External Electrocardiographic Monitoring on Atrial Fibrillation Detection in Patients with Ischemic Stroke. *JAMA* 2021; 325(21): 2160-2168.

Critical Appraisal of a Study of a Diagnostic Test: Is the study valid?

1. Was there an independent, blind comparison with a reference ("gold") standard of diagnosis?
2. Was the diagnostic test evaluated in an appropriate spectrum of patients (ie. like those in whom it would be used in practice)?
3. Was the reference standard applied regardless of the diagnostic test result?

In Sackett DL, Richardson WS, Rosenberg W and Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. New York: Churchill Livingston, 1997.

Critical Appraisal of a Study of a Diagnostic Test:

Are the valid results of this diagnostic study important?

In Sackett DL, Richardson WS, Rosenberg W and Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. New York: Churchill Livingston, 1997.

Critical Appraisal of a Study of a Diagnostic Test: Can you apply this valid, important evidence about a diagnostic test in caring for your patient?

1. Is this diagnostic test available, affordable, accurate and precise in your setting?
2. Can you estimate a clinically sensible estimate of your patient's pretest probability?
3. Will the resulting post-test probability affect your management and help your patient?
4. Would the consequences of the test help your patient?

In Sackett DL, Richardson WS, Rosenberg W and Haynes RB. *Evidence-Based Medicine: How to Practice and Teach EBM*. New York: Churchill Livingston, 1997.

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib)

Design: Open-label, randomized clinical trial

Setting: Two university hospitals and one community hospital
In Alberta, Canada

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Patients included

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Patients included

- Adults 18 years or older
- Arterial ischemic stroke confirmed by neuroimaging
- Randomization occurred within six months of the ischemic stroke if patients had no evidence of atrial fibrillation.

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Patients excluded

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Patients Excluded

- Previously documented atrial fibrillation
- Pacemaker or AICD that would allow detection of atrial fibrillation
- Stroke work up that already included external loop recorder > 7 days

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Interventions

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Interventions

- Intention-to-test analysis: every subject included in data analysis once randomization has occurred.

Were all patients who entered the trial accounted for at its conclusion? And were they analyzed in the groups to which they were randomized?

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Interventions

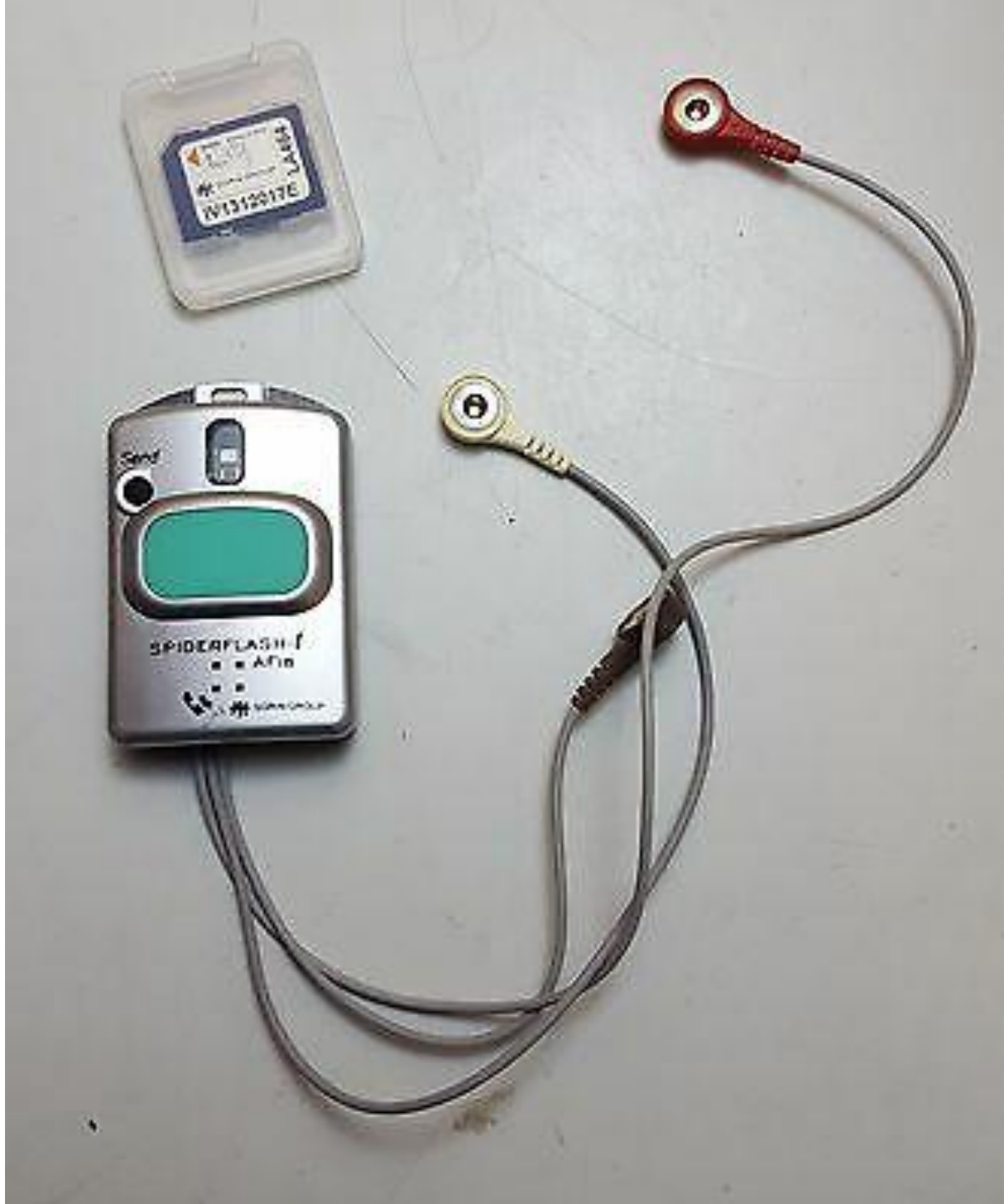
- Patients enrolled six to eight weeks after stroke

- Assigned to:
  - External loop recorder and told to wear it as much as possible for four weeks. Patients tracked hours worn with a diary

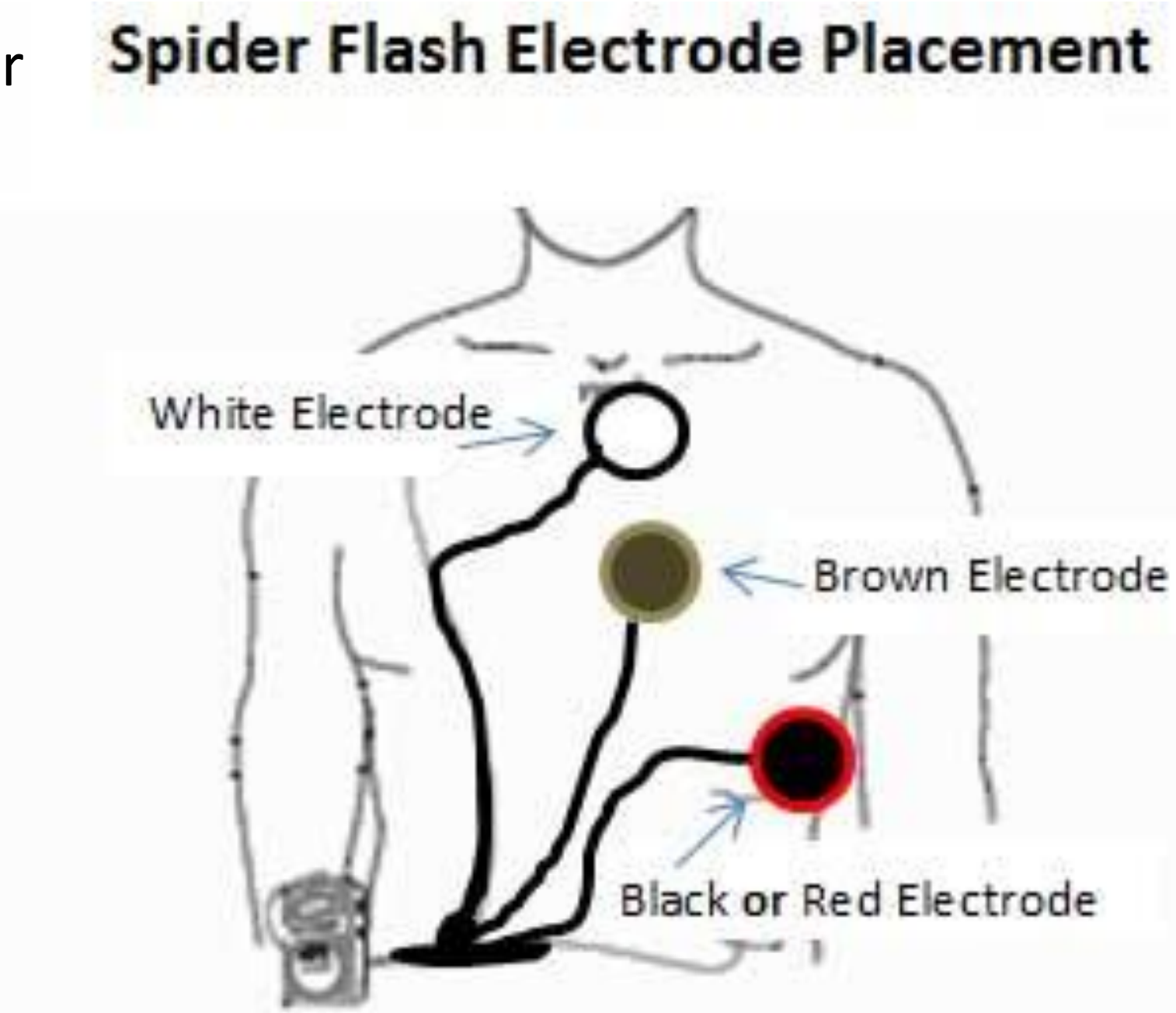
  OR

  - Implantable cardiac monitor (ICM)/implantable loop recorder which remained in place for 12 months

External Loop Recorder



External Loop Recorder Placement



Implantable Loop Recorder/Cardiac Monitor

mpo-mag.com

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Implantable Loop Recorder/Cardiac Monitor Placement

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Interventions

- Each external or internal device was programmed to detect a minimum of **two continuous minutes of atrial fibrillation.** Diagnosis of atrial fibrillation confirmed independently by two cardiac electrophysiologists

- All patients were given a diary to track clinical symptoms

- Follow up visits were scheduled at 30 days, 6 months, and 12 months tracked
  - New diagnoses of atrial fibrillation, stroke or TIA
  - Intracerebral hemorrhage
  - Other bleeding events

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Outcomes

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Primary Outcome

- Development of definite or highly probable atrial fibrillation lasting two minutes or more with 12 months after randomization

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Safety Outcomes

- All serious adverse events were tracked through 12 months after study began

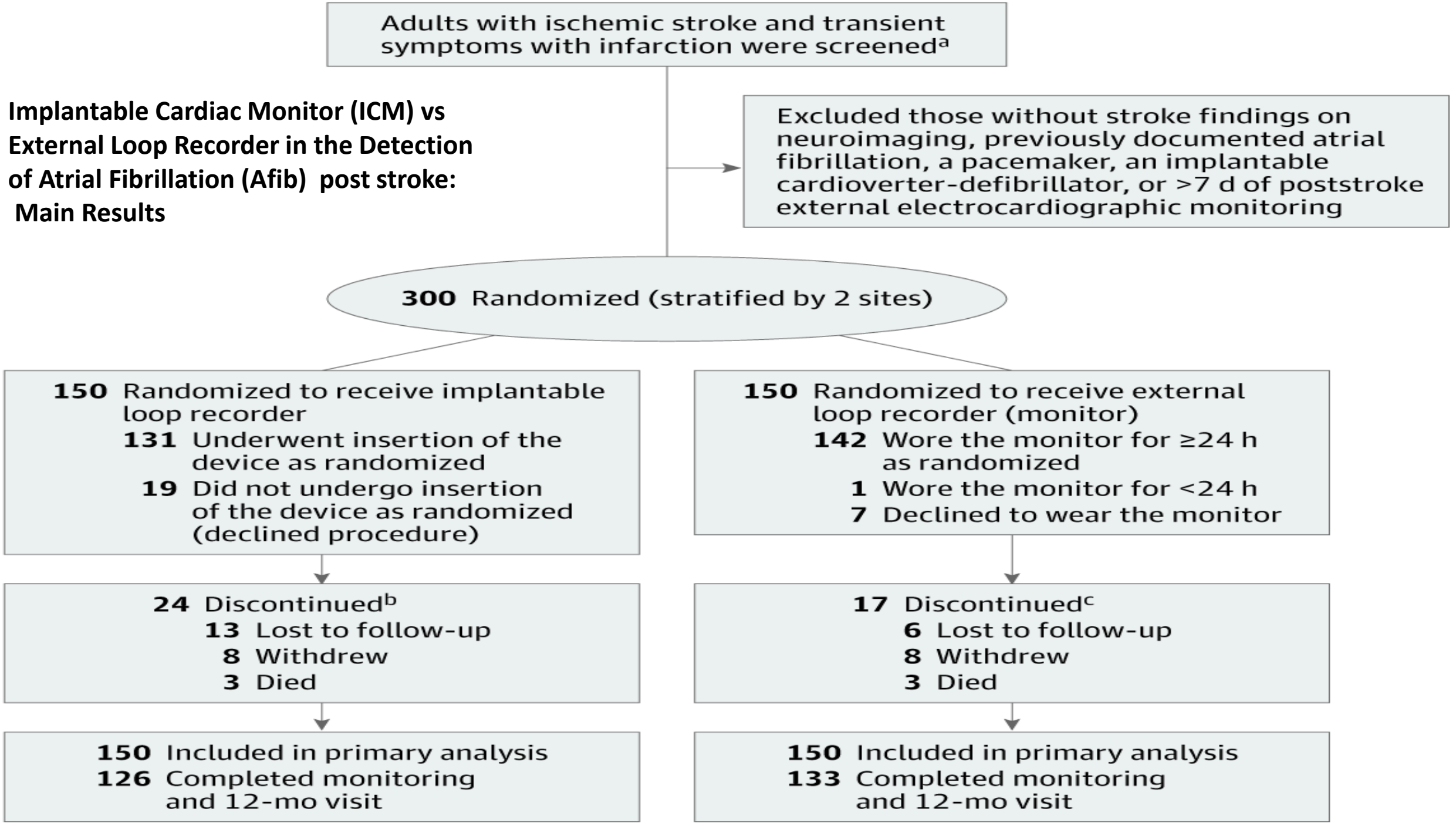
Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib):Study Power

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib):Study Power

- Assumptions:
  - 20% rate of detection of afib among patients with the implantable cardiac monitor
  - 10% rate of detection of afib among patients with the external loop recorder
  - 8% inflation rate
    - 2% for cross over between groups
    - 5% loss to follow up rate in each group
- With the above assumptions, **a total sample size of 300 patients** would allow 85% power to detect a significant difference in afib detection between groups
- Risk of type 1 error (ie. finding a difference which occurred just by chance alone) of 5% (ie. $p < 0.05$)

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Main Results

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib) post stroke: Main Results



Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

Characteristic	**Implantable loop recorder (cardiac monitor) (n= 150)**	**External loop recorder (n =150)**
Median age (years)	65.5	63.4
Female (%)	40.7	40
Male (%)	59.3	60

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

Medical History (%)	Implantable loop recorder (cardiac monitor) (n= 150)	External loop recorder (n =150)
HTN	62	62.7
Previous Stroke	24	22.7
Diabetes	20	20

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

Medical History (%)	Implantable loop recorder (cardiac monitor) (n= 150)	External loop recorder (n =150)
CAD	13.3	15.3
CHF	1.3	2.7
Oral anticoagulant therapy	4.7	1.3
CHA2D2-VASC score, median	4	4

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

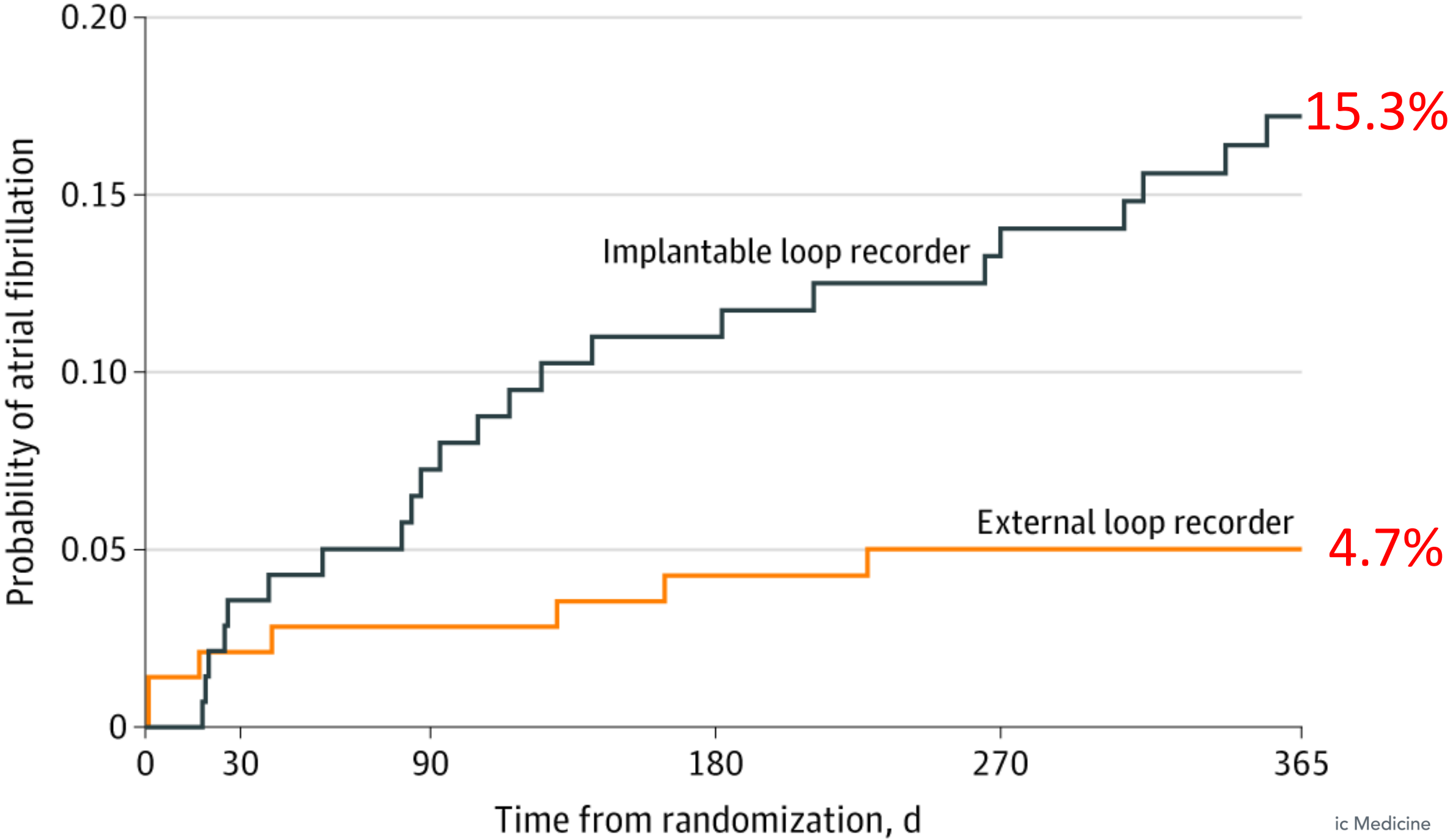
Index Event (%)	**Implantable loop recorder (cardiac monitor) (n= 150)**	**External loop recorder (n =150)**
Transient symptoms with infarction	3.3	2.7
Persistent symptoms with infarction	96.7	97.3

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

Ischemic Stroke Type (%)	**Implantable loop recorder (cardiac monitor) (n= 150)**	**External loop recorder (n =150)**
Partial anterior circulation syndrome	56	54
Posterior circulation syndrome	30	30
Lacunar stroke syndrome	17.3	19.3
Total anterior circulation syndrome	6.7	6.7

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics:

Stroke Etiology (%)	**Implantable loop recorder (cardiac monitor) (n= 150)**	**External loop recorder (n =150)**
No cause for stroke after full investigation	**58**	**60**
Small vessel occlusion	14.7	17.3
Large vessel atherosclerosis	8.7	8.7
Cardioembolism *other* than afib or aflutter	6.7	6.0


0.20
0.15
0.10
0.05
0
Probability of atrial fibrillation
Implantable loop recorder
15.3%
External loop recorder
4.7%
0
30
90
180
270
365
Time from randomization, d

ic Medicine

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Baseline Patient Characteristics: Primary Outcome

	Implantable loop recorder (cardiac monitor) (n= 150)	**External loop recorder (n=150)**	**Adjusted Hazard Ratio (HR) (95% CI)** HR= Risk of detecting afib with an ICM compared to the risk of detecting afib with an external loop recorder at each point in time
Definite or highly probable atrial fibrillation lasting two minutes or more within 12 months from randomization (%)	15.3	4.7	3.36 (1.44 to 7.84)

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Adverse Events

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Adverse Events

- One patient who received an implantable cardiac monitor developed a skin erosion requiring removal of the device a two months

Table 3. Reported Serious Adverse Events[a]

	Implantable loop recorder (n = 150)	External loop recorder (n = 150)
Patients with ≥1 serious adverse event, No. (%)	14 (9.3)	4 (3.3)
Description of serious adverse event, No.		
Bacterial peritonitis	1	0
Bladder neck obstruction	1	0
Cardiac amyloidosis	1	0
COPD exacerbation	0	1
Device-related skin erosion	1	0

Table 3. Reported Serious Adverse Events[a]

	Implantable loop recorder (n = 150)	External loop recorder (n = 150)
Femoral fracture	1	0
Gastrointestinal bleeding	1	0
Hepatocellular carcinoma	1	0
High-grade symptomatic atrioventricular block	1	0
Hip fracture	1	0

Table 3. Reported Serious Adverse Events[a]

	Implantable loop recorder (n = 150)	External loop recorder (n = 150)
Lung cancer	1	0
Myocardial infarction	0	2
Pancolitis	1	0
Pneumonia	1	1
Pneumothorax	1	0

Table 3. Reported Serious Adverse Events[a]

	Implantable loop recorder (n = 150)	External loop recorder (n = 150)
Multiple trauma	1	0
Quadriceps tendon rupture	1	0
Recrudescence of stroke deficits	1	0
Renal colic	1	0
Symptomatic sinus bradycardia	2	0

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Main Conclusions

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Main Conclusions

- Using an implantable cardiac monitor over 12 months in patients following an ischemic stroke led to about a three-fold increase in detection of atrial fibrillation (ie. from about 5% to 15%) compared to a conventional external loop recorder used over 30 days.

- Detecting atrial fibrillation in patients with stroke of unclear etiology despite an otherwise full diagnostic work up has important management implications. Starting these patients on anticoagulant therapy can prevent significant morbidity and mortality from future embolic ischemic strokes.

Implantable Cardiac Monitor (ICM) vs External Loop Recorder in the Detection of Atrial Fibrillation (Afib): Main Conclusions

- The next step in evaluating the use of ICM in stroke patients is cost-effectiveness.

- The authors of the study point out that the strongest predictor of atrial fibrillation in these patients was age and that patients over age 80 have an estimated rate of atrial fib of over 50%.

- In stroke patients at such high risk for afib, it is more cost-effective to start anticoagulation empirically, rather than use an ICM??

Back to our patient. . .

An 81-year-old woman presents to the ER with increased difficulty with her vision since waking up this morning. She describes waking up and being “unable to see things on the right”. She also has a mild posterior headache.

She denies slurred speech, focal weakness or numbness or difficulties with balance. She denies recent fever, chills, changes in weight, chest discomfort, palpitation, shortness of breath, nausea, abdominal pain, changes in bowel movements or urination.

Neuro:

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Gait: normal

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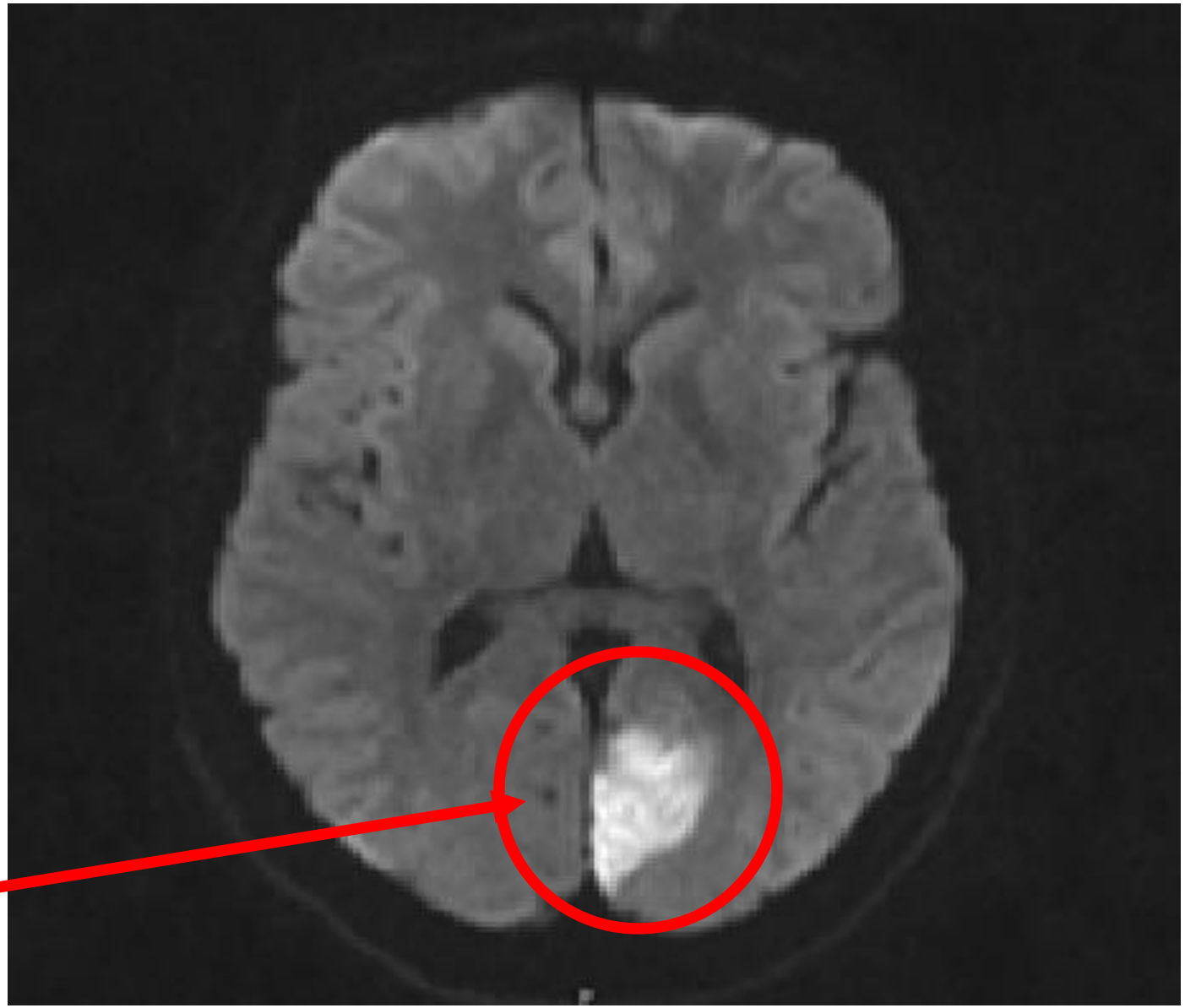

Left occipital lobe ischemic infarct

- During her hospital admission, cardiac telemetry demonstrates normal sinus rhythm with no evidence of arrhythmia. You are still suspicious that her stroke was embolic. A transesophageal echo shows no additional findings.

- Her ASA is stopped and changed to clopidogrel 75 mg po daily

- Her atorvastatin is increased to 80 mg po daily

- She is discharged with outpatient occupational therapy and is instructed not to drive until she follows up with her primary physician.

- You refer your patient to a cardiologist, who places an implantable cardiac monitor two weeks after the patient is discharged.
- At three months of follow-up, the cardiologist finds sporadic, three-minute runs of atrial fibrillation.
- The patient's Plavix is stopped and she is started on Eliquis 5 mg po bid for thromboprophylaxis in the setting of paroxysmal atrial fibrillation.

At six months after her hospitalization, the patient's R visual field cut is nearly resolved and she remains otherwise asymptomatic.

Questions?

Thank you!