

# Update on stroke and TIA

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# Disclosures

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- UR Medicine Stroke Program receives research funding from:
  - NIH/NINDS
  - AGA Medical
  - Boehringer-Ingelheim
- I have unpaid volunteer positions with:
  - American Heart Association/American Stroke Association
  - American Academy of Neurology

## **AHA/ASA Guideline**

### **Guidelines for the Early Management of Patients With Acute Ischemic Stroke**

**A Guideline for Healthcare Professionals From the American Heart  
Association/American Stroke Association**

Stroke. 2013; 44:87-947

## **AHA/ASA Guideline**

### **2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment**

**A Guideline for Healthcare Professionals From the American Heart  
Association/American Stroke Association**

Stroke. 2015; 46:3020-3025

# AHA/ASA Guideline

## **Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack**

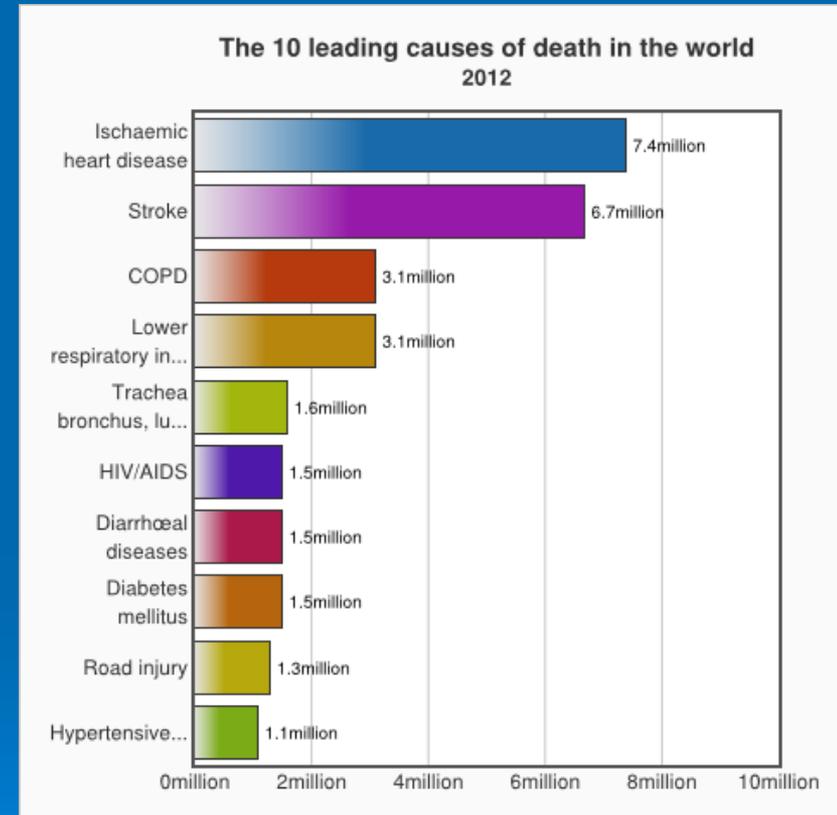
### **A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association**

*The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists.  
Endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons*

Walter N. Kernan, MD, Chair; Bruce Ovbiagele, MD, MSc, MAS, Vice Chair; Henry R. Black, MD; Dawn M. Bravata, MD; Marc I. Chimowitz, MBChB, FAHA; Michael D. Ezekowitz, MBChB, PhD; Margaret C. Fang, MD, MPH; Marc Fisher, MD, FAHA; Karen L. Furie, MD, MPH, FAHA; Donald V. Heck, MD; S. Claiborne (Clay) Johnston, MD, PhD; Scott E. Kasner, MD, FAHA; Steven J. Kittner, MD, MPH, FAHA; Pamela H. Mitchell, PhD, RN, FAHA; Michael W. Rich, MD; DeJuran Richardson, PhD; Lee H. Schwamm, MD, FAHA; John A. Wilson, MD; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Peripheral Vascular Disease

# Scope of the problem

- Stroke is common
  - Roughly 800,000 strokes annually in U.S.
- Stroke is a high morbidity, high mortality, costly disease
  - Fifth leading cause of death in U.S.
  - Second leading cause of death worldwide
  - Leading cause of long-term disability
  - \$33 billion in direct and indirect costs



World Health Organization  
[www.who.int](http://www.who.int)

# Scope of the problem

- We can do better at stroke prevention
  - Roughly 25-30% of strokes are recurrent strokes
- There is a huge public education gap regarding stroke
  - Almost 40% of patients cannot name a *single* stroke symptom
  - Less than 10% can name most of the common symptoms
- Not enough patients are getting acute stroke treatments
  - Nationally, 3-5% of patients get treated with IV tPA
  - In our region, 12-15% receive tPA or endovascular stroke therapy

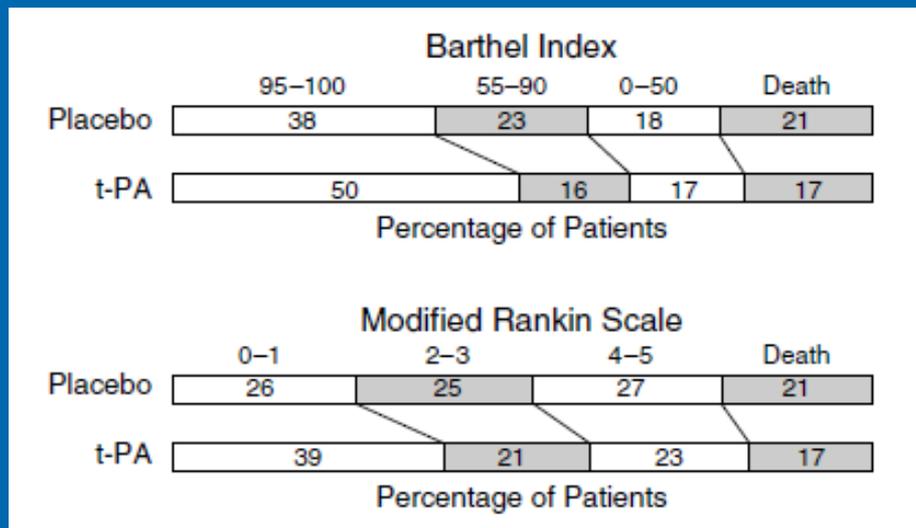
# Outline

- Acute stroke treatment
    - IV thrombolytics
    - Endovascular stroke therapy
  - Secondary stroke prevention
    - Antithrombotic choice
    - Risk factor management
  - My strategies
  - Questions
- 

# IV thrombolysis (Alteplase)

- Tissue plasminogen activator (tPA) remains the only FDA-approved treatment of acute ischemic stroke
  - Approved for use up to 3 hours from symptom onset
  - Supported for use up to 4.5 hours in certain patients (age < 80, without severe stroke, not on any anticoagulant, etc.)
- Based largely on NINDS rtPA trial and ECASS-3 trials:
  - Patients treated with tPA had better chance of achieving functional independence at 90 days
  - Also showed more symptomatic hemorrhages and more deaths from hemorrhage in tPA group
  - Still a strong net clinical benefit favoring tPA treatment

# IV thrombolysis



N Engl J Med 1995;333:1581-7

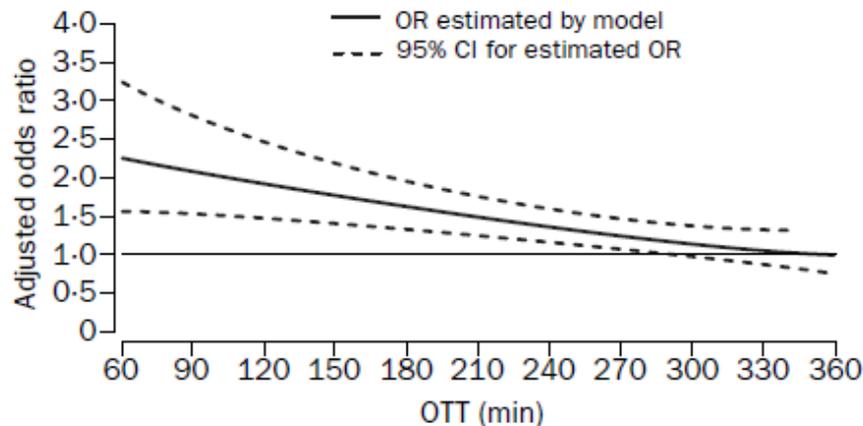


Figure 3: Model estimating odds ratio for favourable outcome at 3 months in rt-PA-treated patients compared with controls by OTT

Lancet 2004; 363: 768-74

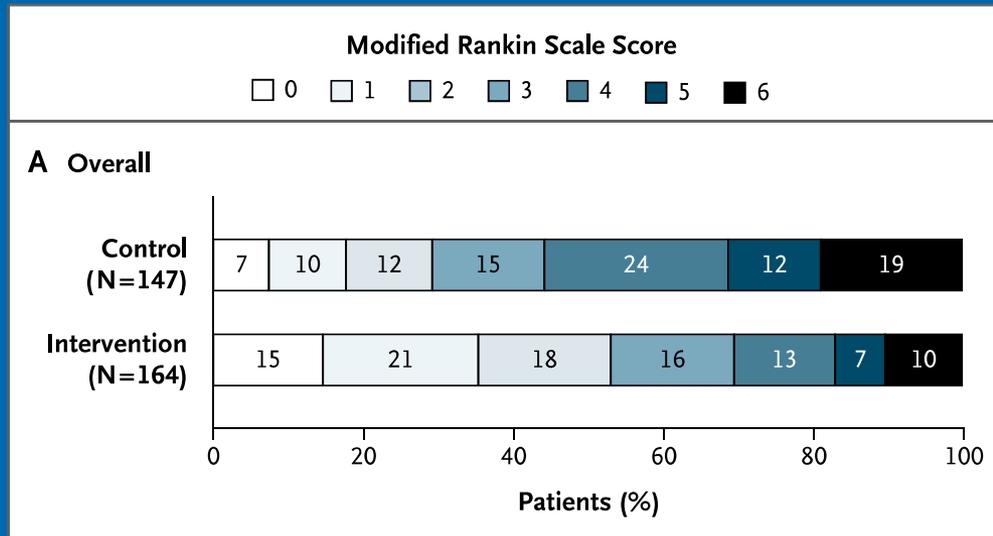
# Endovascular stroke treatment

- Generally reserved for patients with severe deficits and symptoms/imaging suggestive of large vessel occlusion
  - Often guided by multimodal CT imaging
- Clot extraction/mechanical thrombectomy
  - Multiple early generation devices (MERCI, Penumbra) received FDA approval as clot removal devices
  - IMS-3, MR RESCUE, SYNTHESIS trials (2013): all negative trials, showing no benefit to endovascular therapy
    - Older devices with lower recanalization rates
    - Slower door-to-puncture times
    - Failure to identify patients at highest likelihood of success

# Endovascular stroke treatment

- More recent data has definitively established a role for endovascular therapy in stroke:
  - 5 recently published trials (MR CLEAN, ESCAPE, EXTEND-IA, SWIFT PRIME, REVASCAT), all showing benefits to endovascular therapy over IV tPA alone
    - Large effect sizes – NNT in the 3-7 range
  - Differences with prior endovascular studies:
    - Newer generation devices
    - Much faster door-to-puncture times (90 minutes in SWIFT PRIME)
    - Proven ICA and/or MCA occlusion prior to treatment
    - High rates of IV tPA utilization (~70%)

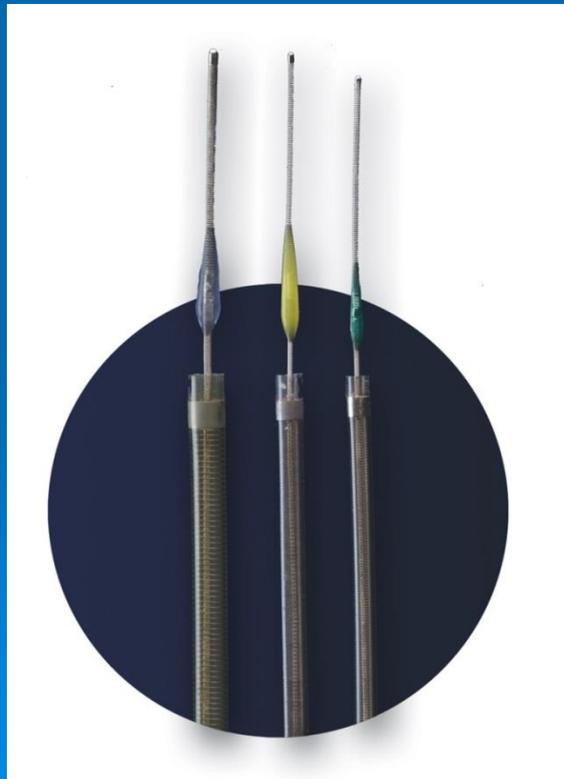
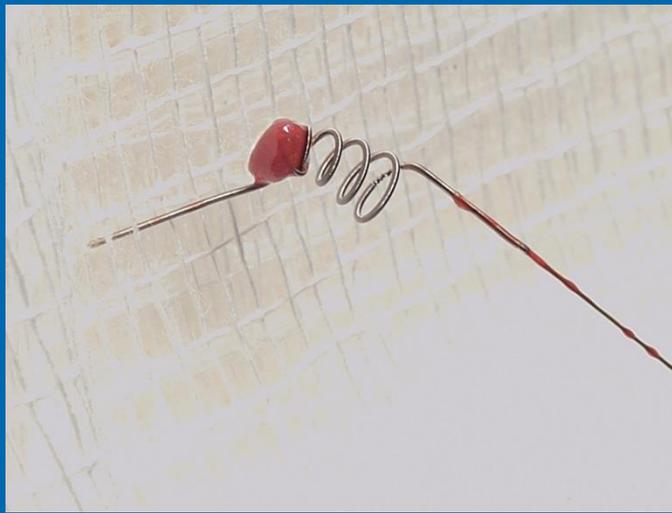
# Endovascular stroke treatment



NEJM. 2015;372:1019-1030

**Table 2. Primary and Secondary Efficacy Outcomes.**

Outcome	Intervention (N=165)	Control (N=150)	Difference (95% CI)*	Effect Variable	Unadjusted Value (95% CI)	Adjusted Value (95% CI)†
Primary outcome: modified Rankin score at 90 days‡				Common odds ratio	2.6 (1.7–3.8)	3.1 (2.0–4.7)
Modified Rankin score of 0–2 at 90 days — no./total no. (%)§	87/164 (53.0)	43/147 (29.3)	23.8 (13.2–34.4)	Rate ratio	1.8 (1.4–2.4)	1.7 (1.3–2.2)
NIHSS score of 0–2 at 90 days — no./total no. (%)	79/153 (51.6)	31/134 (23.1)	28.4 (17.8–39.2)	Rate ratio	2.2 (1.6–3.2)	2.1 (1.5–3.0)
Barthel Index score of 95–100 at 90 days — no./total no. (%)¶	94/163 (57.7)	49/146 (33.6)	24.1 (13.3–34.9)	Rate ratio	1.7 (1.3–2.2)	1.7 (1.3–2.2)
TICI score of 2b or 3 at final angiogram — no./total no. (%)	113/156 (72.4)					



# Conclusions

- tPA and endovascular therapy are both associated with improved outcomes in patients with acute stroke
- Effects of both treatments are highly influenced by earlier treatment – time is brain!!
  - 1.9 million neurons, 14 billion synapses, and 7.5 miles of nerve fibers are lost with every minute of brain ischemia
  - Patients with possible stroke symptoms should activate 911 and be transported to the nearest stroke center

# Secondary stroke prevention

- Relevant diagnostic testing
  - Antiplatelet/anticoagulant medication
  - Risk factor modification through pharmacotherapy and lifestyle changes
  - Patient education
- 

# Diagnostic testing – Imaging

## ➤ Brain imaging:

- CT highly sensitive for detection of intracranial hemorrhage
- MRI with diffusion weighted imaging (DWI) is effective for detecting acute injury due to ischemia
- CT does not reliably show ischemic changes for the first 6-12 hours – normal head CT at presentation does not rule out stroke

## ➤ Evaluation of extracranial circulation:

- Carotid Doppler, MR angiography, CT angiography

## ➤ Evaluation of intracranial circulation:

- Transcranial Doppler, MR angiography, CT angiography

# Diagnostic testing - Cardiac

- Evaluation of cardiac function and potential sources of cardiac emboli:
  - Echocardiography
- Screening for atrial fibrillation:
  - Electrocardiogram (also important to look for concomitant coronary artery disease)
  - Holter monitor
  - Extended cardiac monitoring/implantable loop recorders

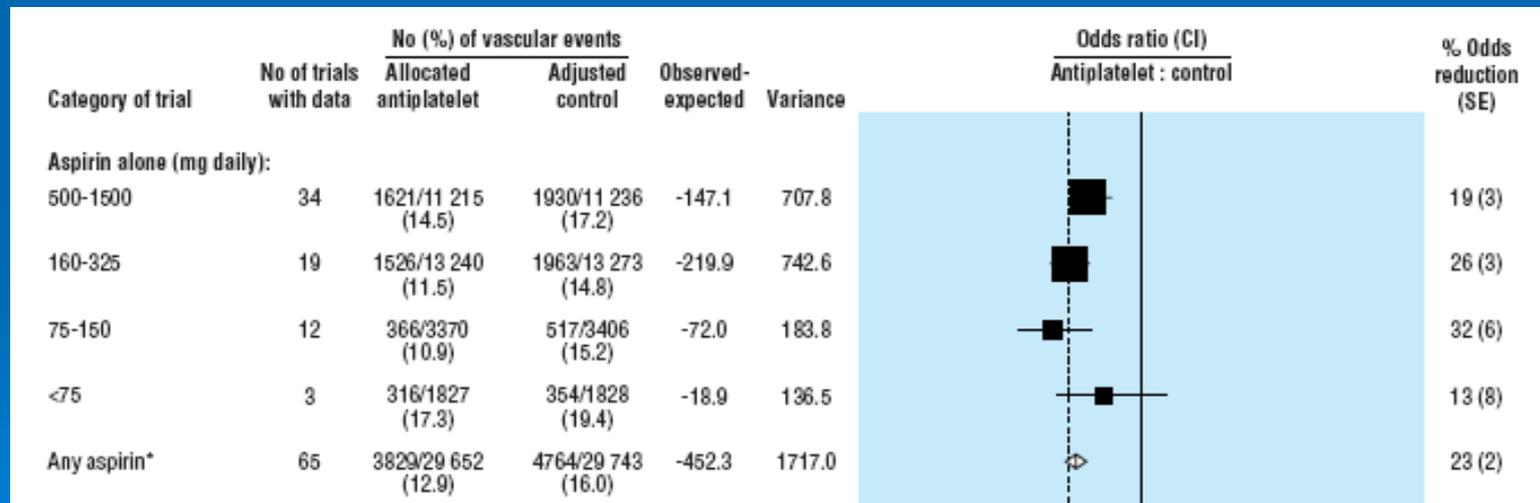
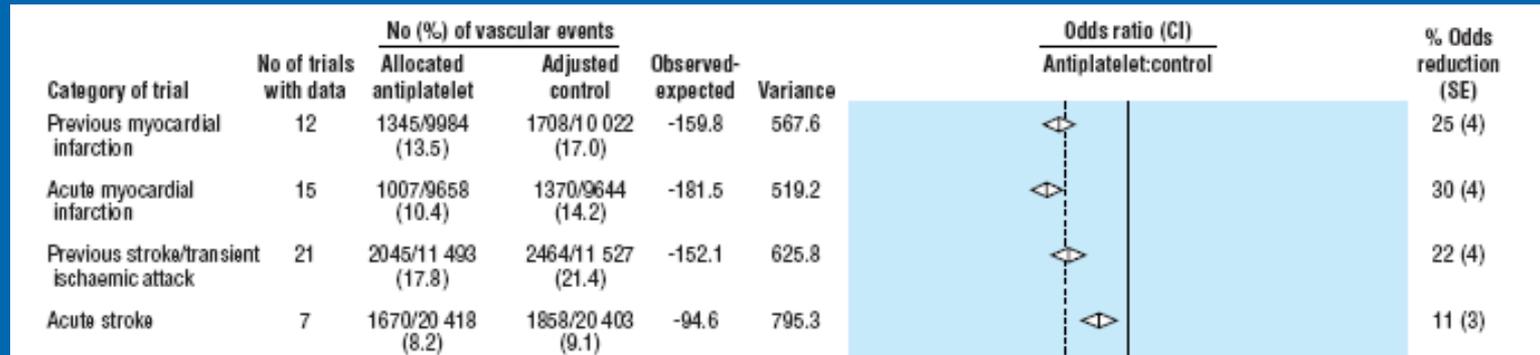
# Diagnostic testing - Laboratory

- Bloodwork to evaluate for other risk factors:
  - Glucose and glycosylated hemoglobin measurement
  - Serum lipid evaluation
  - In some cases, testing for hypercoagulable states, autoimmune conditions, etc.
  
- All diagnostic testing should be taken in the context of:
  - Patient's overall prognosis
  - Patient's other co-morbid conditions
  - Test's potential to change management

# Antiplatelet therapy

- Use of aspirin has been shown to decrease risk of second stroke by ~22%
  - No evidence that one dose of aspirin is superior to another for stroke prevention
  - Shown to decrease risk of early recurrent stroke in patients with acute stroke when given within 48 hours.
- Clopidogrel and ASA/dipyridamole are other options for antiplatelet therapy
  - High NNT (eg, 196 patients need to be treated with clopidogrel instead of ASA to prevent one vascular event at two years)

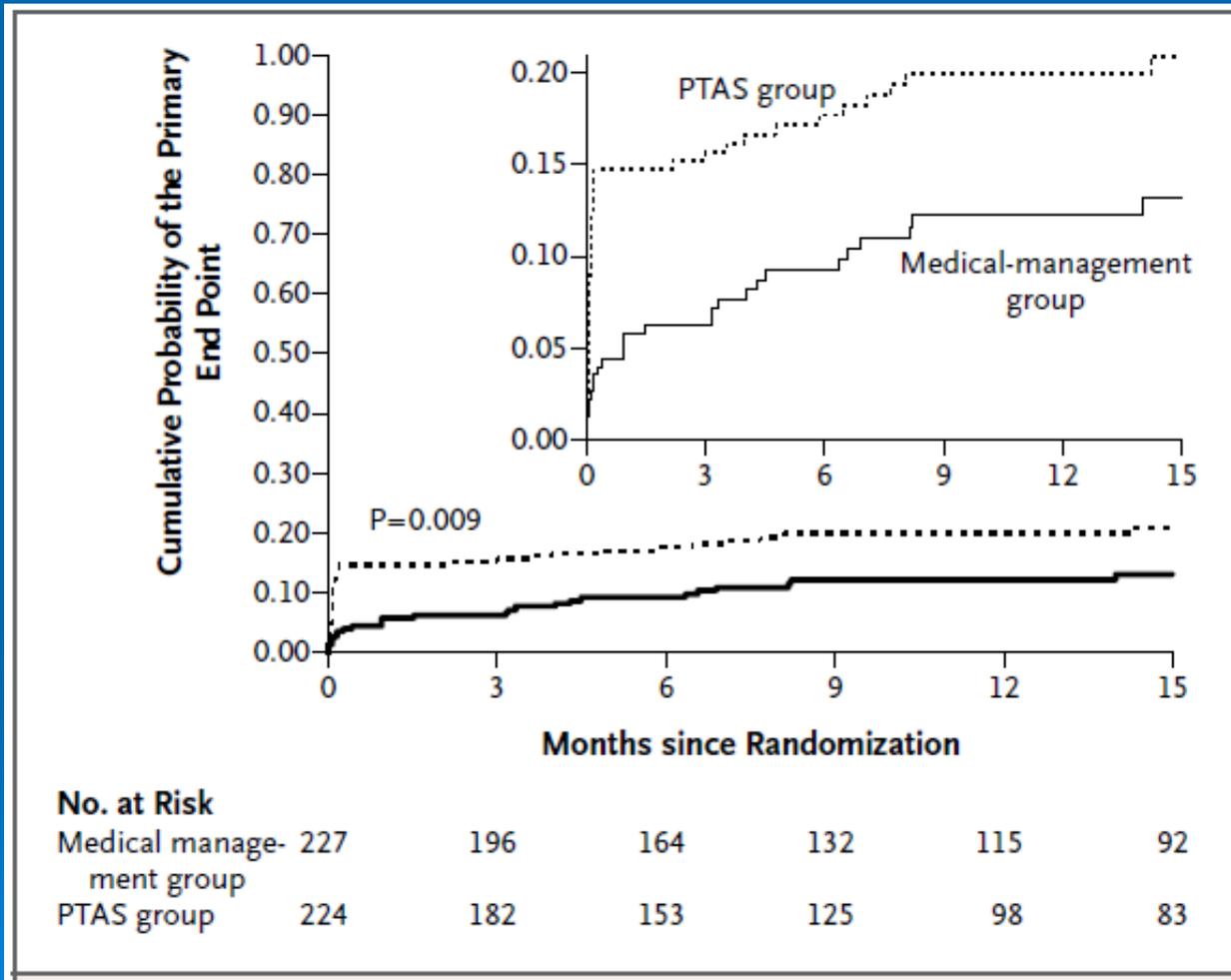
# Aspirin meta-analysis



# Clopidogrel + ASA

- Results of multiple clinical trials have led to guidelines against the *routine* use in patients with cerebrovascular disease alone
  - AHA/ASA Class III recommendation
- Based on SAMMPRIS study, combination often used (plus aggressive medical management) for 3 months following stroke due to symptomatic intracranial atherosclerotic disease
  - More effective and safer than intracranial angioplasty and stenting

# SAMMPRIS results



# Warfarin/novel anticoagulants

- No clear indication for recurrent stroke patients
  - Studies show trend (though not significant) towards lower stroke risk in ASA treated group, with significantly increased risk of hemorrhage in warfarin group
- Except in clear cases of cardioembolic stroke (AF, valvular disease, etc.), the routine use of anticoagulation is not recommended for secondary stroke prevention

# Conclusions

- ASA, clopidogrel, and combination ASA/dipyridamole are all considered reasonable options for patients with non-cardioembolic stroke
- Decisions regarding antiplatelet choice should weigh efficacy and risks of each agent, stroke etiology, cost considerations, and other medical issues
  - Still unknown - what is the optimal strategy in patients who have a stroke while taking an antiplatelet agent?

# Risk factor modification

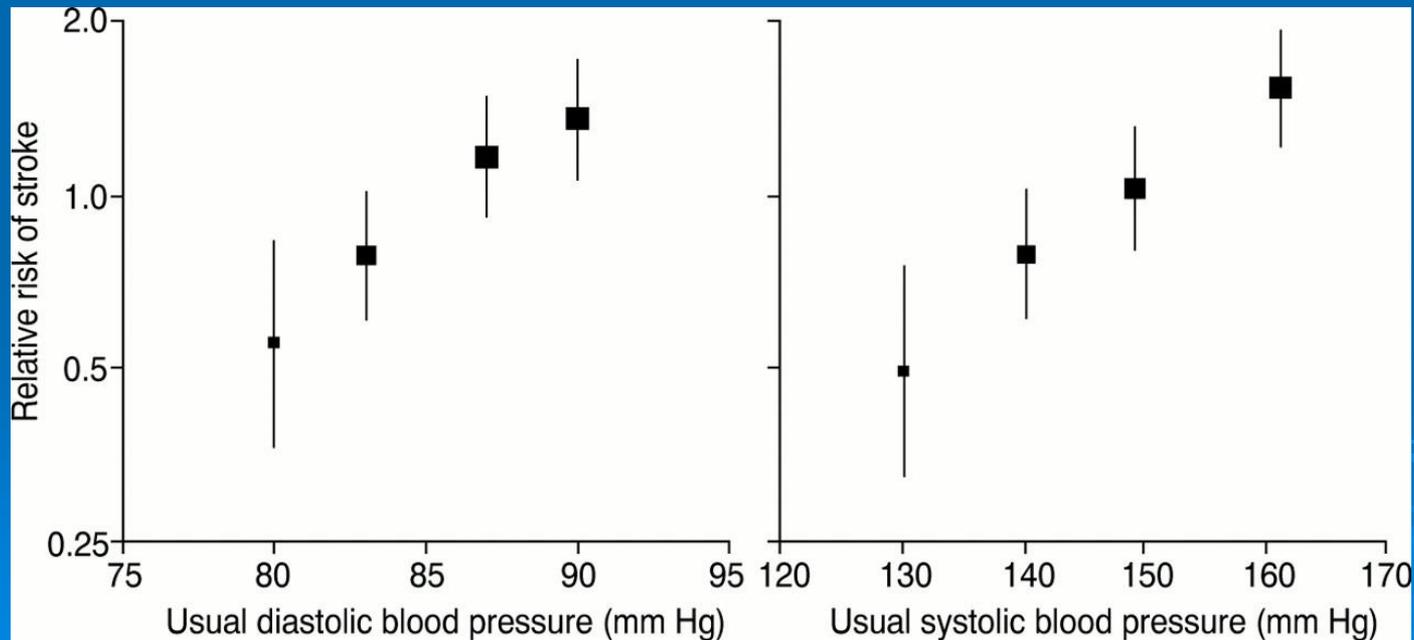
- Hypertension
  - Hyperlipidemia
  - Atrial fibrillation
  - Patent foramen ovale
  - Other risk factors
- 

# Hypertension

- Hypertension is the leading modifiable risk factor for cerebrovascular disease
  - Both ischemic and hemorrhagic stroke
- The degree of blood pressure reduction appears more important than the class of antihypertensive used
  - HOPE: ACE inhibitor
  - PROGRESS: ACE inhibitor/diuretic
  - ALLHAT: Calcium channel blockers or diuretics

# How low can you go?

- Epidemiological studies have shown a linear association between blood pressure and stroke risk
  - ~30% risk reduction for each 10 mm Hg drop in SBP and 5 mm Hg drop in DBP



# How low should you go?

- Treatment-related complications are more likely with intensive BP control
  - Syncope, falls, cognitive dysfunction, etc.
  - Possible higher risk of stroke in patients with BP 110 or lower
- Recent BP guidelines advocate not initiating treatment until BP > 150/90 and treat to goal < 140/90
  - Written from primary prevention standpoint; no mention of cerebrovascular disease-specific goals

# Conclusions

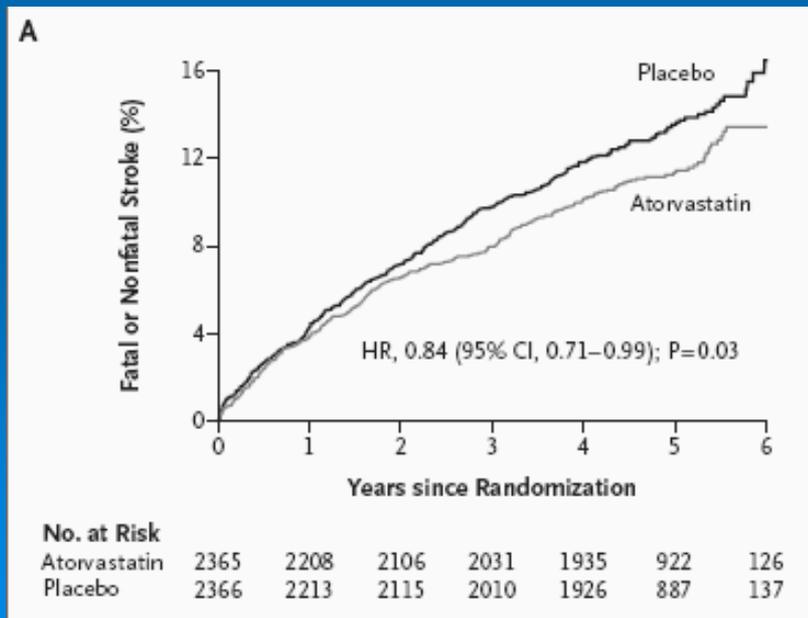
- Outside of the immediate post-stroke period, antihypertensive treatment should be *considered* for all stroke patients, even those without a known history
  - May simply be lifestyle modifications
- Blood pressure goal and antihypertensive regimen should be tailored to the individual patient
  - Minimum goal < 140/90
  - More aggressive target of < 130/80 considered for patients with lacunar stroke or patients with diabetes
  - Choice of agent based on other comorbidities, patient/provider preferences

# Hyperlipidemia

- There is a weak epidemiological relationship between elevated cholesterol and stroke risk.
  - Not as clear a relationship as seen with coronary disease
  - Stroke has a variety of different mechanisms, some more closely linked with high cholesterol
- Several studies have investigated the role of lipid-lowering therapy in preventing recurrent stroke.
  - SPARCL (2006)

# SPARCL results

Outcome <sup>a</sup>	Atorvastatin (N=2365)	Placebo (N=2366)	Unadjusted P Value <sup>†</sup>	Prespecified Adjusted Model <sup>‡</sup>	
				HR (95% CI)	P Value
	<i>no. (%)</i>				
<b>Primary outcome</b>					
Nonfatal or fatal stroke <sup>§</sup>	265 (11.2)	311 (13.1)	0.05	0.84 (0.71–0.99)	0.03
Nonfatal stroke	247 (10.4)	280 (11.8)	0.14	0.87 (0.73–1.03)	0.11
Fatal stroke	24 (1.0)	41 (1.7)	0.04	0.57 (0.35–0.95)	0.03



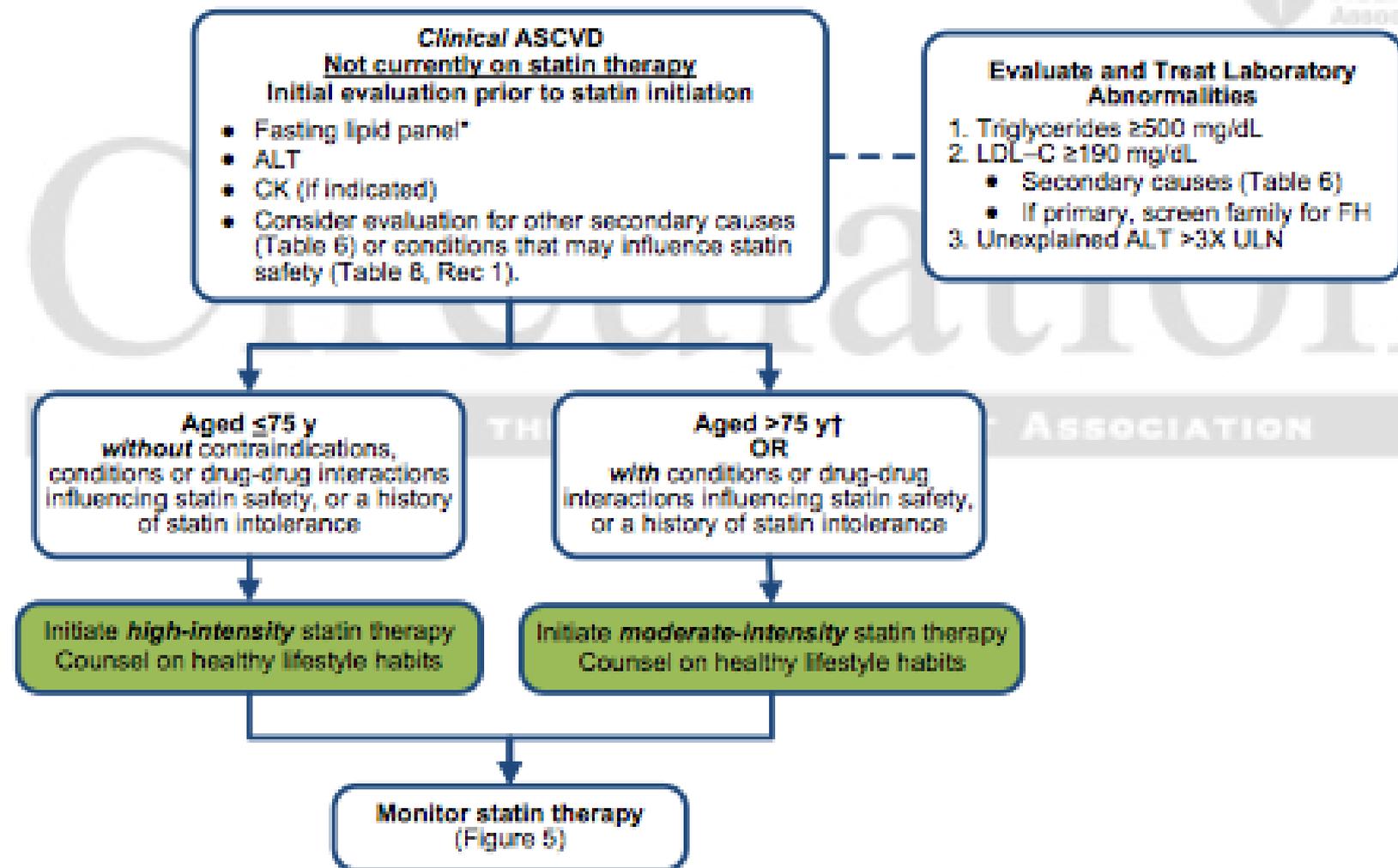
NNT = 53 patients for 5 years  
with atorvastatin 80 mg daily  
to prevent one stroke

NEJM 2006;355:549-59

# How low should you go?

- More intensive lipid management may have more robust effects at reducing vascular endpoints compared to less intensive regimens
  - 14% RRR in stroke risk in patients intensive LDL reduction compared to less-intensive regimen, though event rates low in both groups
  - High intensity regimens include atorvastatin (40 or 80 mg), rosuvastatin (20 or 40 mg), and simvastatin (80 mg)
- Latest lipid-lowering guidelines do not advocate treating to specific levels

Figure 3. Initiating statin therapy in individuals with clinical ASCVD



# What about other lipid components?

- No strong evidence behind lowering of triglyceride levels, increasing of HDL levels.
- Can consider niacin, fibrates, etc., on case-by-case basis.

# Conclusions

- AHA/ASA recommendations include the following:
  - Patients with stroke/TIA and LDL > 100 should be treated with statins with intensive lipid-lowering effects
  - Lower level of evidence: even patients with LDL < 100 may benefit from treatment with statins with intensive lipid-lowering effects
- My approach: think about stroke mechanism
  - Patients with carotid or other large artery atherosclerosis are more likely to benefit from higher potency regimens
  - Patients with lacunar disease – less of a link with hyperlipidemia, maybe spend your efforts on hypertension...

# Atrial fibrillation

- Affects ~5-10% of population > 75 years of age; incidence increases with age
- ~20-25% of strokes in the older adult population are attributable to AF
- Clear benefit to anticoagulation in secondary stroke prevention and in high-risk patients; less robust evidence for primary prevention
  - Must weigh risk of stroke, risks/benefits of treatment

# CHA<sub>2</sub>DS<sub>2</sub>VASc score

- Multiple risk stratification scores can help predict stroke risk (and benefit of anticoagulation) in AF
- CHA<sub>2</sub>DS<sub>2</sub>VASc score is one option:
  - History of CHF (1 point)
  - History of hypertension (1 point)
  - Age (< 65 0 points, 65-74 1 point, > 75 2 points)
  - History of diabetes (1 point)
  - History of stroke or TIA (2 points)
  - History of vascular disease (1 point)
  - Female sex (1 point)

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# CHA<sub>2</sub>DS<sub>2</sub>VASc score

- Higher CHA<sub>2</sub>DS<sub>2</sub>VASc scores are associated with higher risks of stroke
- Treatment recommendations:
  - Score = 0: antiplatelet
  - Score = 1: antiplatelet or anticoagulant
  - Score ≥ 2: anticoagulant

CHA <sub>2</sub> DS <sub>2</sub> -VASc Score	Annual Stroke Risk %
0	0.8
1	2.0
2	3.7
3	5.9
4	9.3
5	15.3
6	19.7
7	21.5
8	22.4
9	23.6

# Weighing risks and benefits

- Bleeding risks are often over-estimated
  - Particularly risk from falls
- Can use HASBLED score to estimate risks of anticoagulation in a specific patient
  - 1 point each for hypertension, abnormal kidney or liver fxn, hx of stroke, history of bleeding events, labile INR values, age > 65, alcohol use, ASA/NSAID use

HAS-BLED Score	Bleeding Risk %
0	0.9
1	3.4
2	4.1
3	5.8
4	8.9
5	9.1
≥6	Insufficient data

# Antithrombotic options (historical)

- Warfarin is very effective at preventing strokes in patients with AF who have had a stroke or TIA
  - Relative risk reduction ~65-70% at recommended goal INR 2-3
- Aspirin can be used when anticoagulation is contraindicated
  - Relative risk reduction ~20-25% (about the same as stroke prevention in general)
  - The routine addition of aspirin or other antiplatelets is not recommended for stroke prevention purposes

# Antithrombotic options (contemporary)

- Four novel oral anticoagulants now approved:
  - Dabigatran (direct thrombin inhibitor)
  - Rivaroxaban, apixaban, edoxaban (factor Xa antagonists)
- Potential benefits over warfarin:
  - No need for routine blood monitoring
  - Limited drug-drug and dietary interactions
  - Comparable/increased stroke prevention benefits with good safety profiles (especially lower risks of ICH)

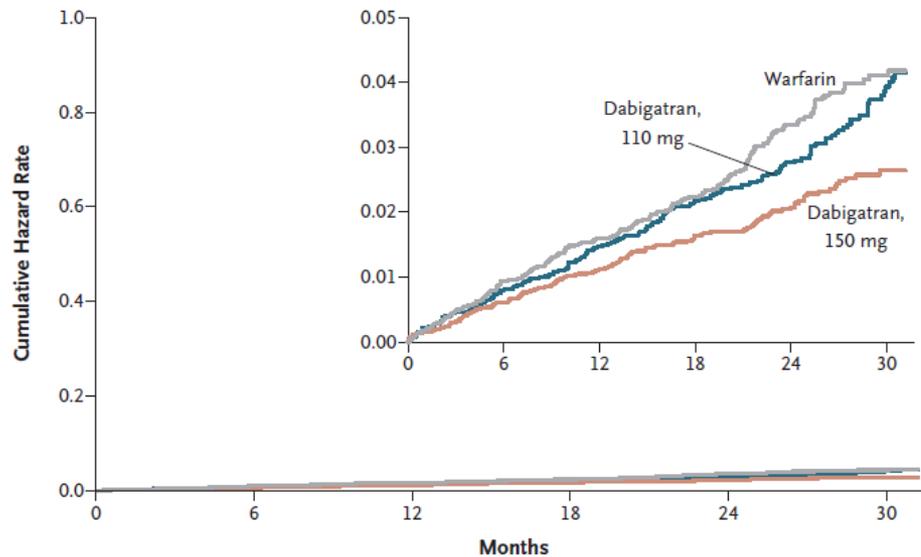
# Novel oral anticoagulants

- Potential concerns compared to warfarin:
  - Costly
  - No widely available method to measure effect
  - Impaired clearance in patients with renal dysfunction and in older adults
  - Disqualifies patients from tPA treatment for stroke
  - No well-established antidote or reversal strategy

# Novel oral anticoagulants

- Potential concerns compared to warfarin:
  - Costly
  - No widely available method to measure effect
  - Impaired clearance in patients with renal dysfunction and in older adults
  - Disqualifies patients from tPA treatment for stroke
  - ~~No well-established antidote or reversal strategy (?)~~
    - Monoclonal antibody to reverse dabigatran (idarucizumab)
    - Factor Xa decoy protein to competitively inhibit Xa antagonists (andexanet)

# Novel oral anticoagulants



## No. at Risk

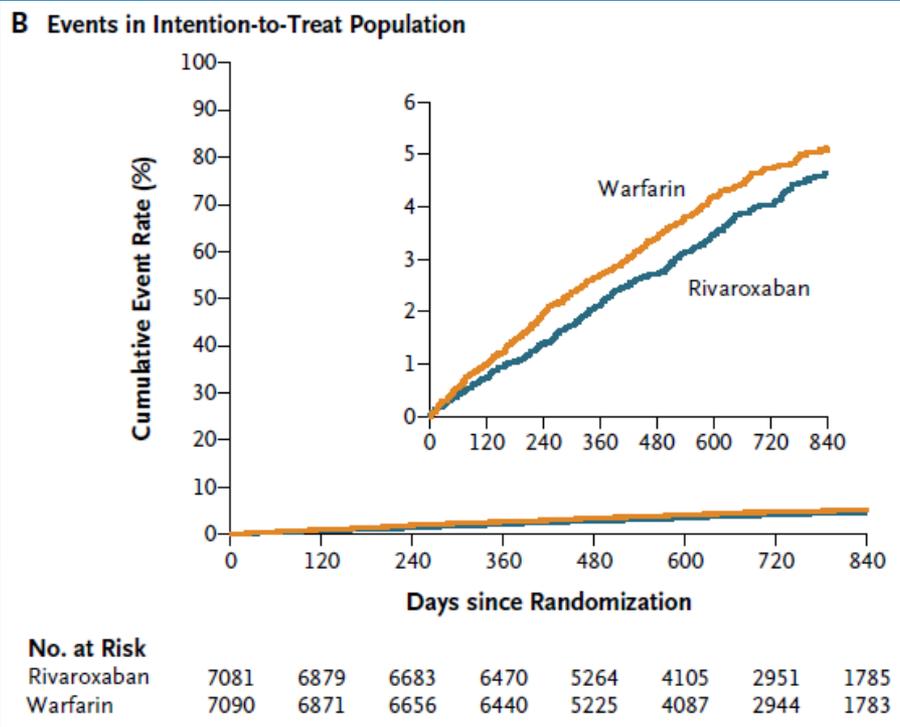
Warfarin	6022	5862	5718	4593	2890	1322
Dabigatran, 110 mg	6015	5862	5710	4593	2945	1385
Dabigatran, 150 mg	6076	5939	5779	4682	3044	1429

Event rates per year:  
 Dabigatran 150 mg 1.11%  
 Warfarin 1.69%

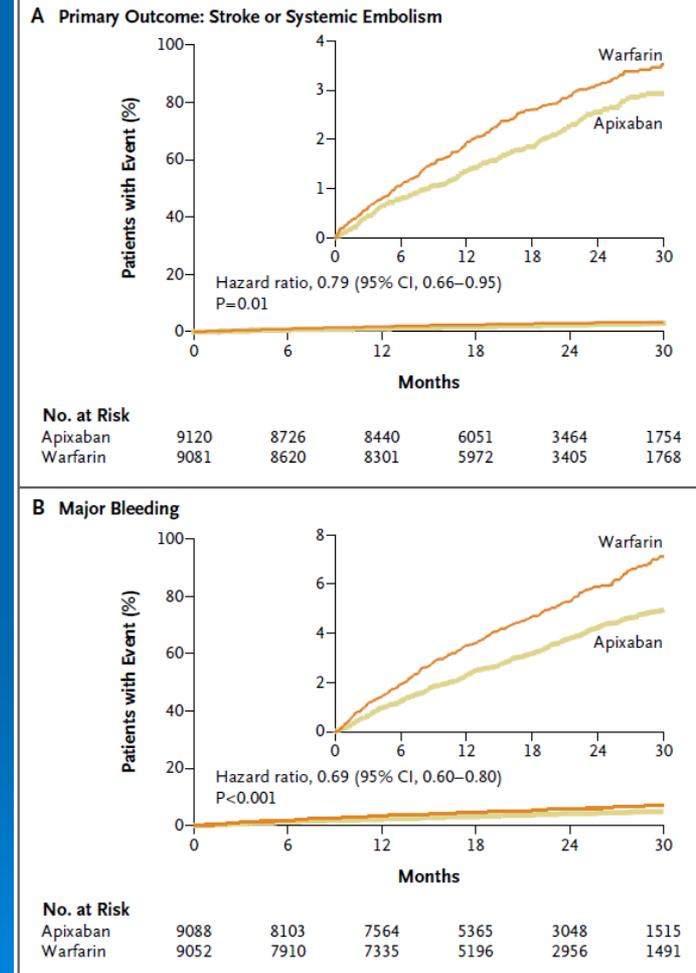
Need to treat ~170 patients with dabigatran instead of warfarin to prevent one stroke or systemic embolism

NEJM 2009; 361:1139-1151

# Novel oral anticoagulants



NEJM 2011; 365:883-891

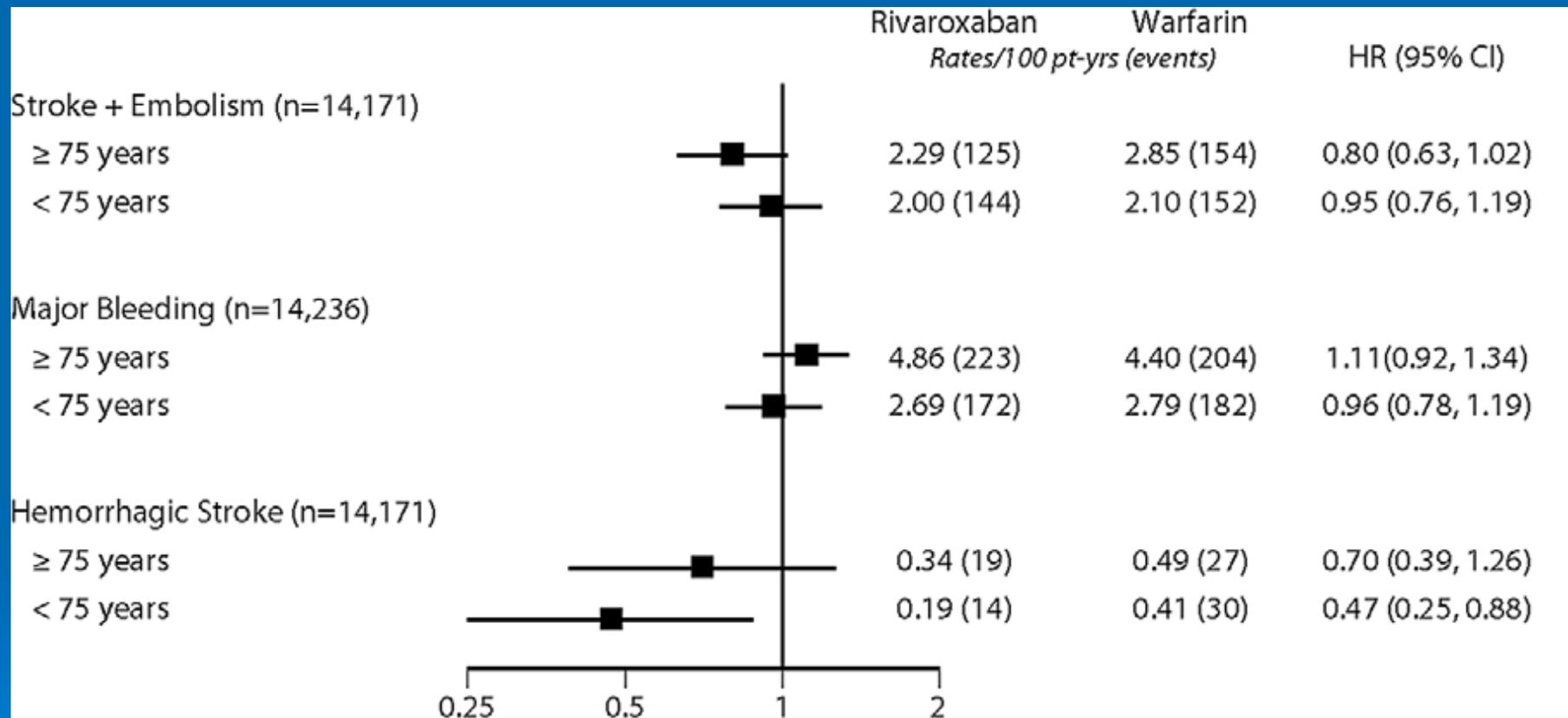


NEJM 2011; 365:981-992

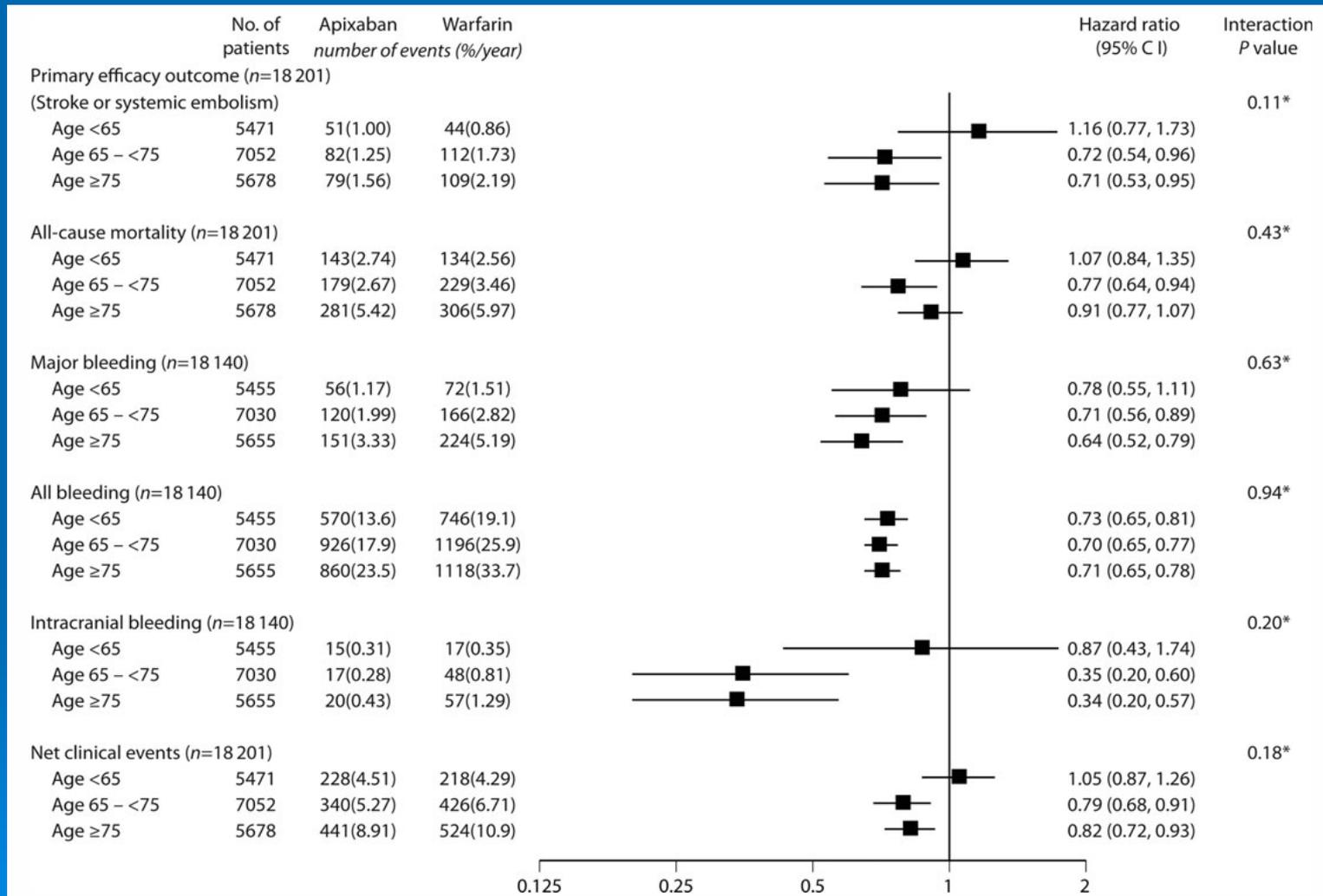
# Novel anticoagulants in older adults

- Limited data on safety of dabigatran in older adults
  - Older adult subgroup not presented in initial trial publication or subsequently
  - Case series NZ: ~2/3 of dabigatran bleeding complications in patients > 80 years old (NEJM. 2012;366:864-866)
- Outcomes for older adults treated with rivaroxaban and apixaban have been reported
  - Stroke risks and bleeding events more common in patients > 75 years old, but efficacy and safety relative to warfarin was comparable in both age groups

# Novel anticoagulants in older adults

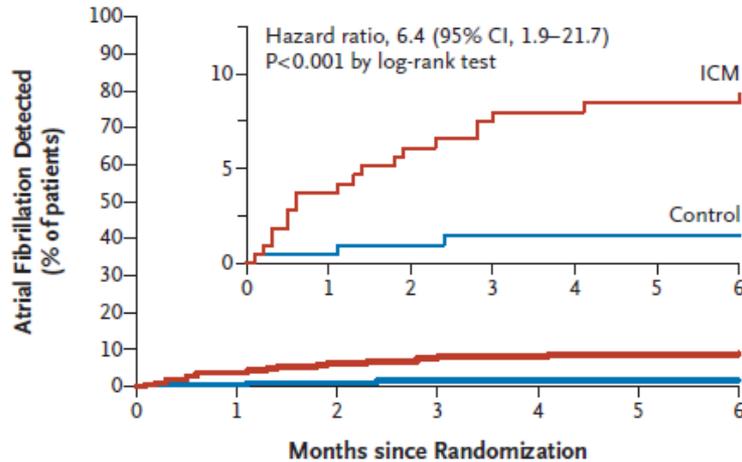


# Novel anticoagulants in older adults



# Prolonged cardiac monitoring

**A** Detection of Atrial Fibrillation by 6 Months



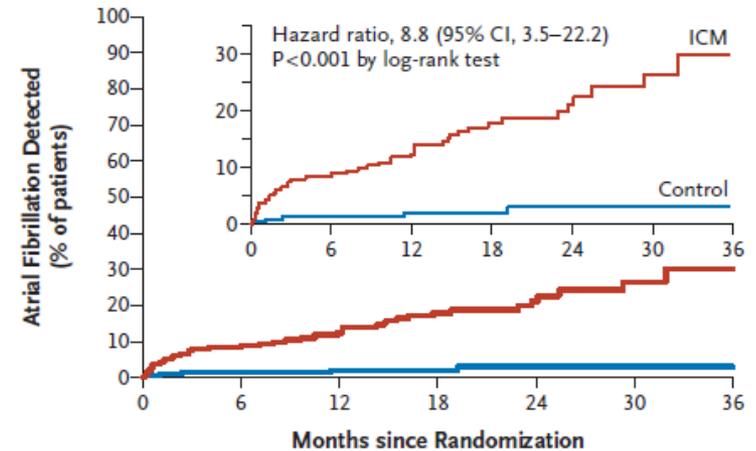
No. at Risk

Control	220	214	200	198	197	197	194
ICM	221	205	198	195	194	193	191

Paroxysmal atrial fibrillation can be difficult to detect

- In patients with cryptogenic stroke and other risk factors (e.g., left atrial enlargement on echo), consider longer term ECG monitoring

**C** Detection of Atrial Fibrillation by 36 Months



No. at Risk

Control	220	194	167	114	72	36	7
ICM	221	191	173	102	57	29	8

# Conclusions

- Anticoagulation is the standard of care in patients with stroke/TIA and atrial fibrillation
  - With prior stroke/TIA, CHADS2 score automatically  $\geq 2$
- Options include warfarin (goal INR 2-3), dabigatran, rivaroxaban, and apixaban
  - Choice should depend on patient/provider preference, other medical issues (dabigatran not recommended for use in valvular disease), costs
  - In patients who are well controlled on warfarin, there does not appear to be a major reason to change agents

# Patent foramen ovale

- Persistence of fetal communication in the interatrial septum, seen in ~25-30% of adults.
- PFOs are seen more frequently in patients without another obvious stroke mechanism.
  - ~30% in patients with defined stroke mechanism, ~40% in those without stroke mechanism
- Possible mechanisms of PFO leading to stroke include:
  - Paradoxical embolization of deep venous thromboses
  - In-situ thrombus formation at PFO site

# Patent foramen ovale

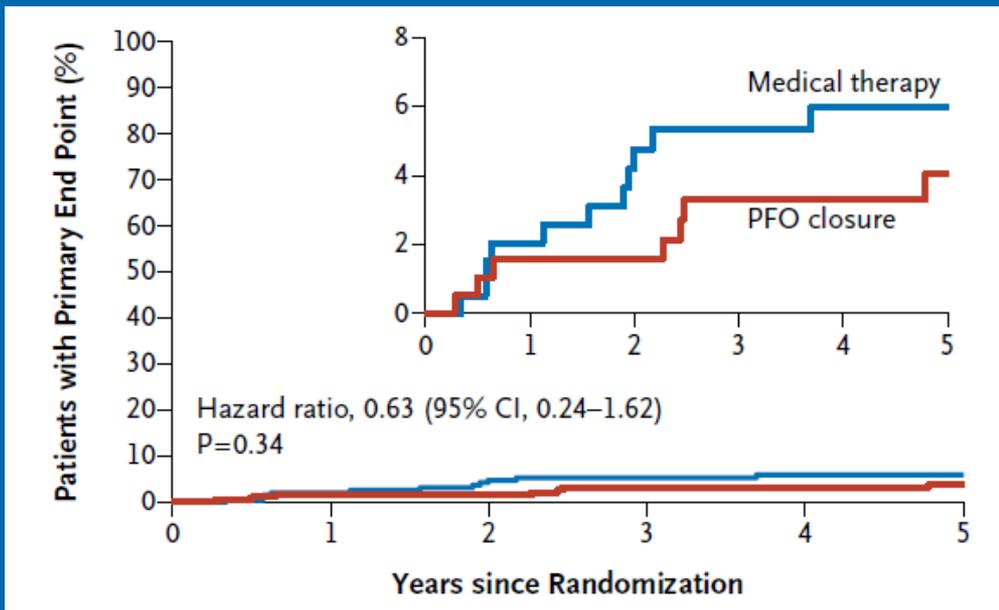
- The presence of PFO does not appear to confer a “high risk” of recurrent stroke.
  - Multiple studies have found no increased risk of stroke compared to cryptogenic stroke patients without PFO
  - Patients were being treated with antiplatelets and/or anticoagulation; no clear evidence that either is preferred
- Patients with PFO should undergo testing for presence of DVT, since this will prompt change to anticoagulation.

# What about PFO closure?

- Results of the first large trial (CLOSURE) were released in 2012:
  - PFO closure was feasible (successful in ~90% of subjects)
  - No significant difference in prevention of recurrent strokes or TIAs compared to best medical management

End Point	Closure (N=447)	Medical Therapy (N=462)	Hazard Ratio (95% CI) <sup>†‡</sup>	P Value <sup>†</sup>
<b>Intention-to-treat population</b>				
Composite end point — no. (%)	23 (5.5)	29 (6.8)	0.78 (0.45–1.35)	0.37
Stroke — no. (%)	12 (2.9)	13 (3.1)	0.90 (0.41–1.98)	0.79
TIA — no. (%)	13 (3.1)	17 (4.1)	0.75 (0.36–1.55)	0.44

*NEJM.* 2012; 366:991-999

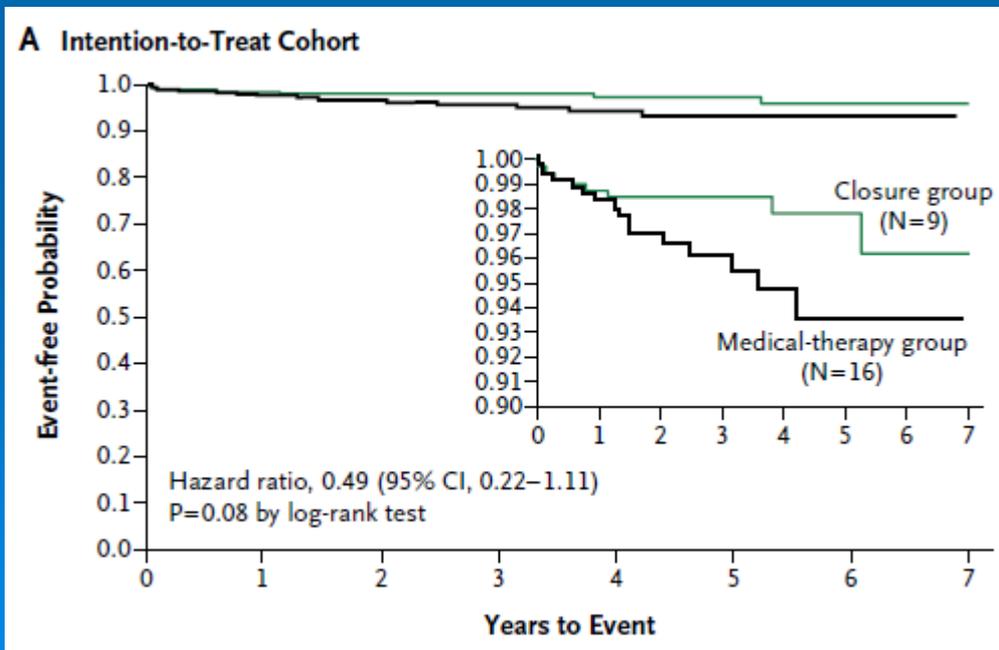


## PC trial

Event rates:

PFO closure 5/204 (3.4%)

Medical therapy 11/210 (5.2%)



## RESPECT trial

Event rates:

PFO closure 9/499 (1.8%)

Medical therapy 16/481 (3.3%)

Subgroup analysis suggestive of possible benefit in high-volume shunts, atrial septal aneurysms

# Summary of PFO closure data

- AHA/ASA Stroke Prevention guidelines (2014):
  - “For patients with cryptogenic ischemic stroke or TIA and a PFO..., available evidence do not support a benefit for PFO closure.” (Class III, Level of Evidence A)
- Will additional analyses identify some subgroups that might benefit from closure?
  - Possible role for closure in patients with high volume shunting or atrial septal aneurysms?

# Other important risk factors

## ➤ Carotid artery disease

- Symptomatic stenosis  $> 50\%$  = revascularization + intensive medical management
- Asymptomatic stenosis = intensive medical management unless stenosis  $> 80\%$  or rapidly progressive
- In general, CEA preferred over CAS

## ➤ Obstructive sleep apnea

- OSA is an independent risk factor for stroke; risk increases with higher severity OSA
- OSA is associated with multiple stroke mechanisms (cardioembolism, lacunar disease, etc.)
- No strong clinical evidence showing that CPAP lowers risk

# Other risk factors

- Diabetes
- Tobacco abuse
- Excessive alcohol consumption
- Obesity/physical inactivity
- Cardiomyopathy
- Valvular heart disease
- Aortic atheromatous disease
- Arterial dissection
- Hypercoagulable states

# My stroke prevention strategies

- Usual starting antithrombotic agent – ASA 325 mg daily.
  - If atrial fibrillation, intracardiac thrombus, or PFO with DVT found, then change to anticoagulation
  - If intracranial stenosis found, add clopidogrel 75 mg daily for three months, then change to single agent
  - If stroke happens while already taking ASA, change to clopidogrel or Aggrenox, ensure there is not coexistent a-fib or carotid stenosis
- Blood pressure control
  - Target goal SBP 120-130 in younger adults, 120-140 in older adults
  - No clear agent of choice, often start with diuretics

# My stroke prevention strategies

## ➤ Lipid-lowering strategies

- High potency, high dose statin for significant intra- or extra-cranial vascular disease (eg, atorvastatin 80 mg daily)
- Otherwise, lower dose statin targeting LDL below 100

## ➤ Prolonged monitoring for atrial fibrillation

- No other identified stroke mechanism
- Acute or chronic bilateral, embolic appearing strokes
- Unilateral embolic appearing stroke with other factors
  - History of palpitations
  - Left atrial enlargement on echo

# My stroke prevention strategies

## ➤ Other recommendations

- Hb A1C below 7%
- Regular brisk activity, 30 minutes most days of the week
- Low fat, heart healthy, Mediterranean type diets
- Evaluate for and comply with OSA treatment if indicated
- Complete abstinence from tobacco
- Minimize alcohol intake to no more than 1 drink per day

Questions?

