

# **Anticoagulation in the Fall Risk Patient To Do or Not to Do?**

**Annette Carron, DO, FACOI, FAAHPM, CMD  
Geriatrics and Palliative Care  
Henry Ford Macomb Hospital**

# Objectives

- **Learn how to appropriately assess and prevent falls in the older adult**
- **Acknowledge guidelines for anticoagulation in atrial fibrillation in the older adult**
- **Recognize interventions to prevent accidents and injuries in the older adult**

# Disclosures

- I have nothing to disclose

# THE PROPORTION OF OLDER AMERICANS IS GROWING

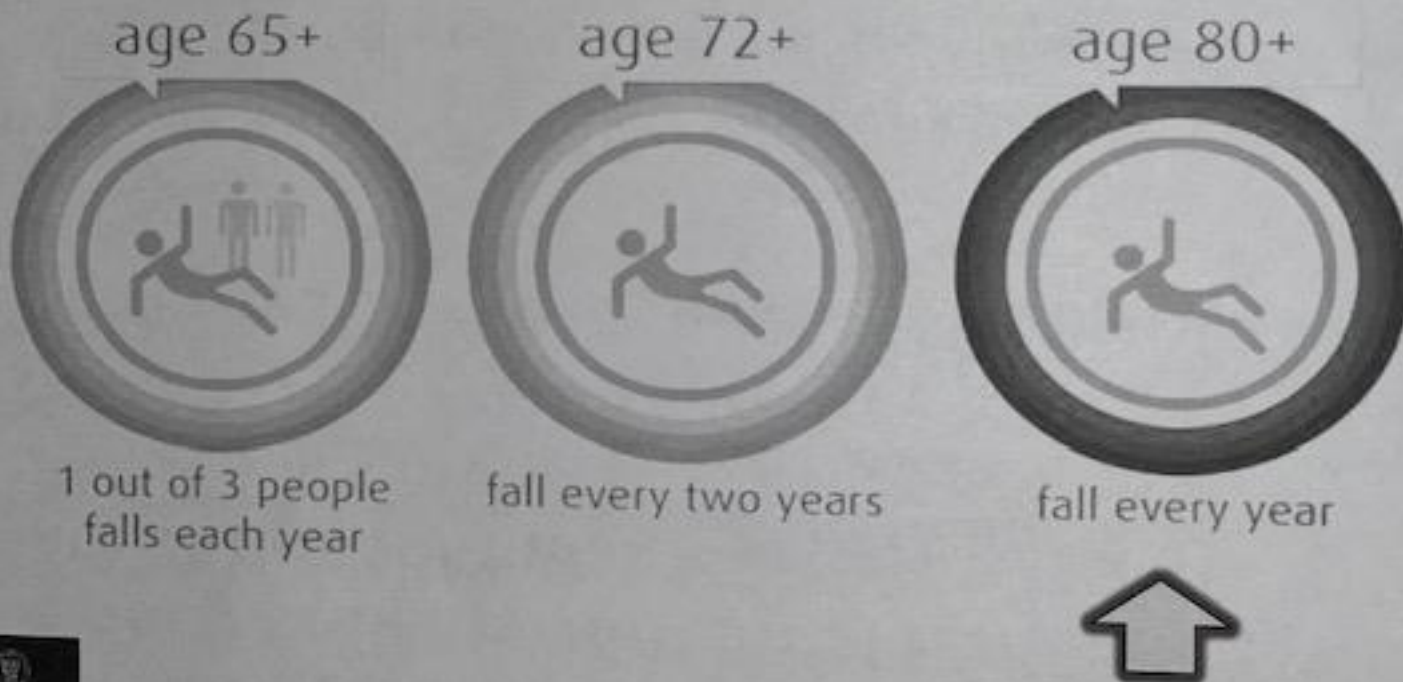
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Year	% of People 65 & Older
1950	8.3
2000	12.4
2004	12.7
2050	20.6

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**Source:** Health, United States, 2005. Figure 2.  
<http://www.cdc.gov/nchs/data/hus/hus05.pdf>.

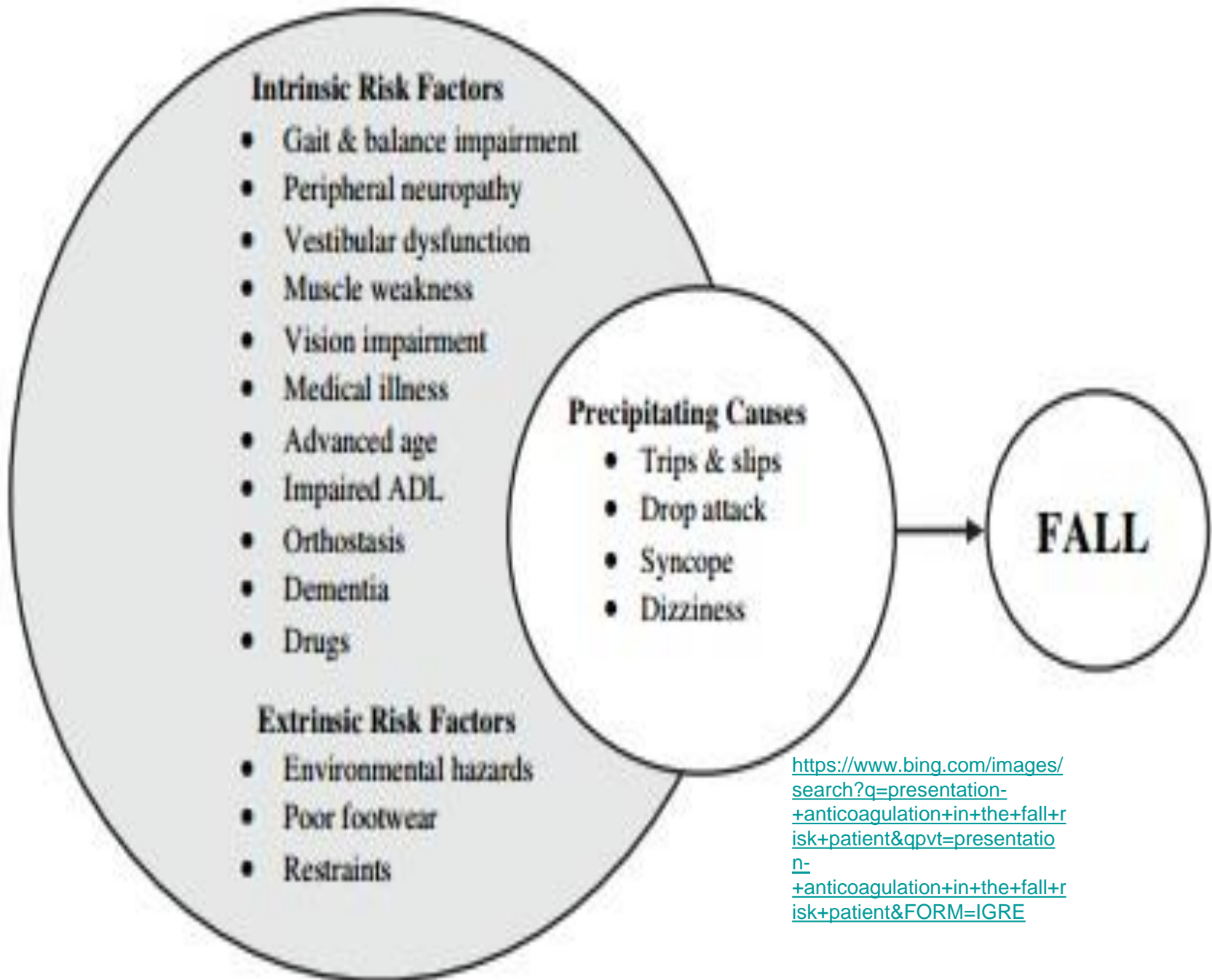
# Prevalence of Falls increases with Age



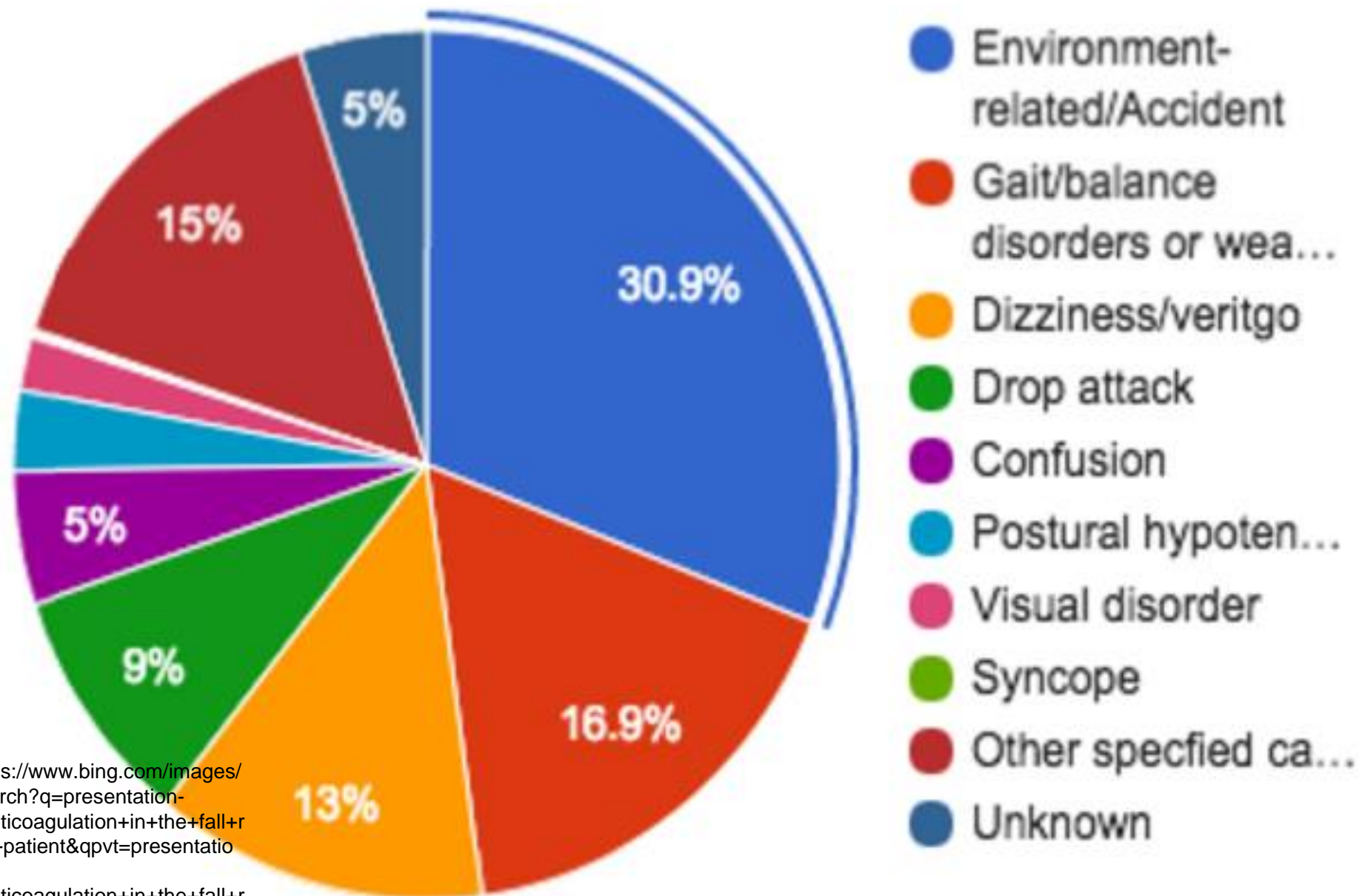
# Fall History Taking

- **Have you had a fall in the past year? Did you tell your primary care provider?**
- **Were you hurt?**
- **Do you worry about falling?**
- **Do you feel unsteady when standing or walking?**
- **A previous fall increases your future fall risk.**

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# Causes of Falls in Elderly Adults





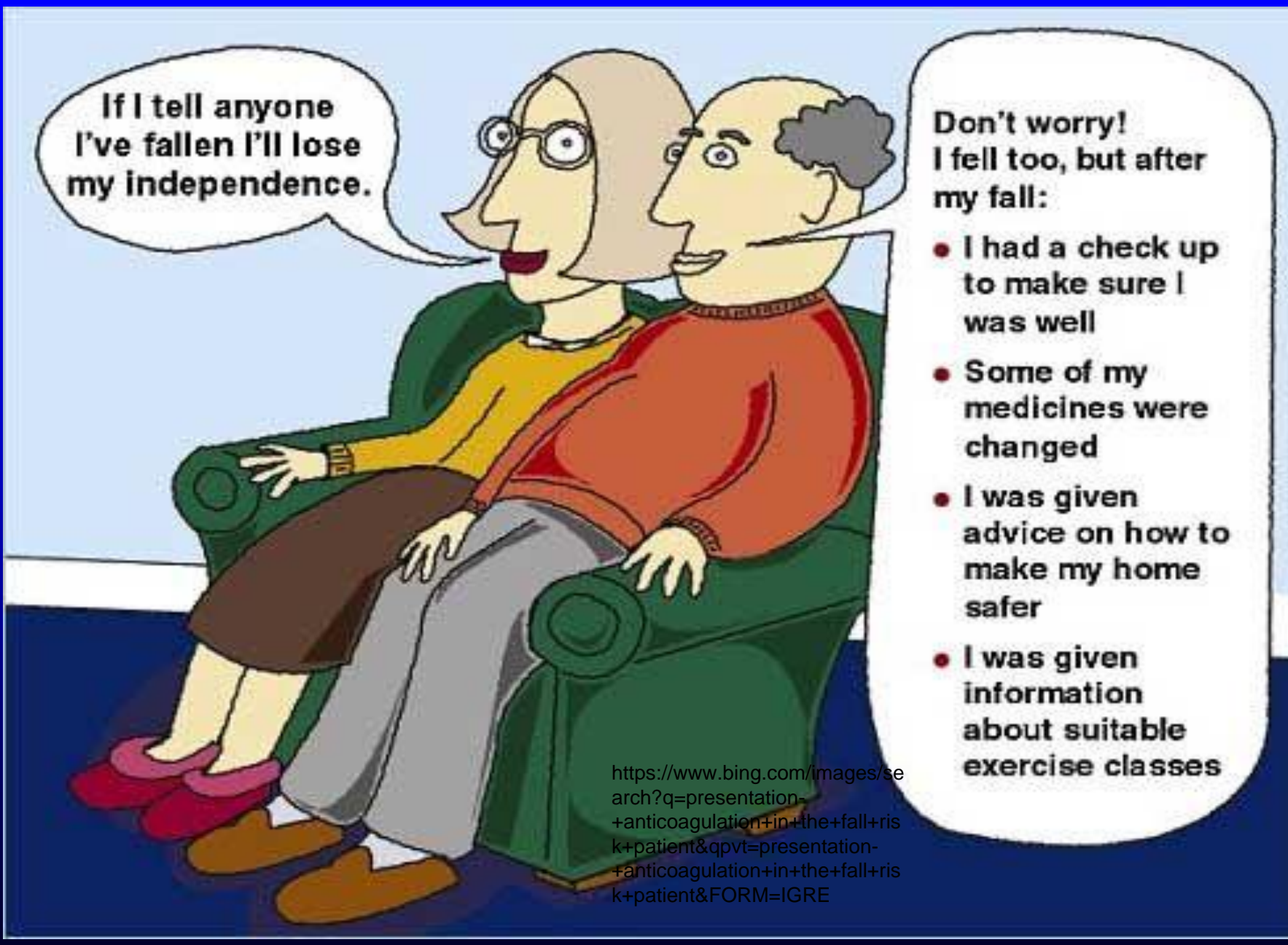
# Do you limit activities?

- **Fear of Falling is a lasting concern about falling that may cause a person to stop doing activities s/he remains able to do.**
- **Fear of falling increases future fall risk.**
- *Tinetti and Powell, 1993*



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If I tell anyone  
I've fallen I'll lose  
my independence.

Don't worry!  
I fell too, but after  
my fall:

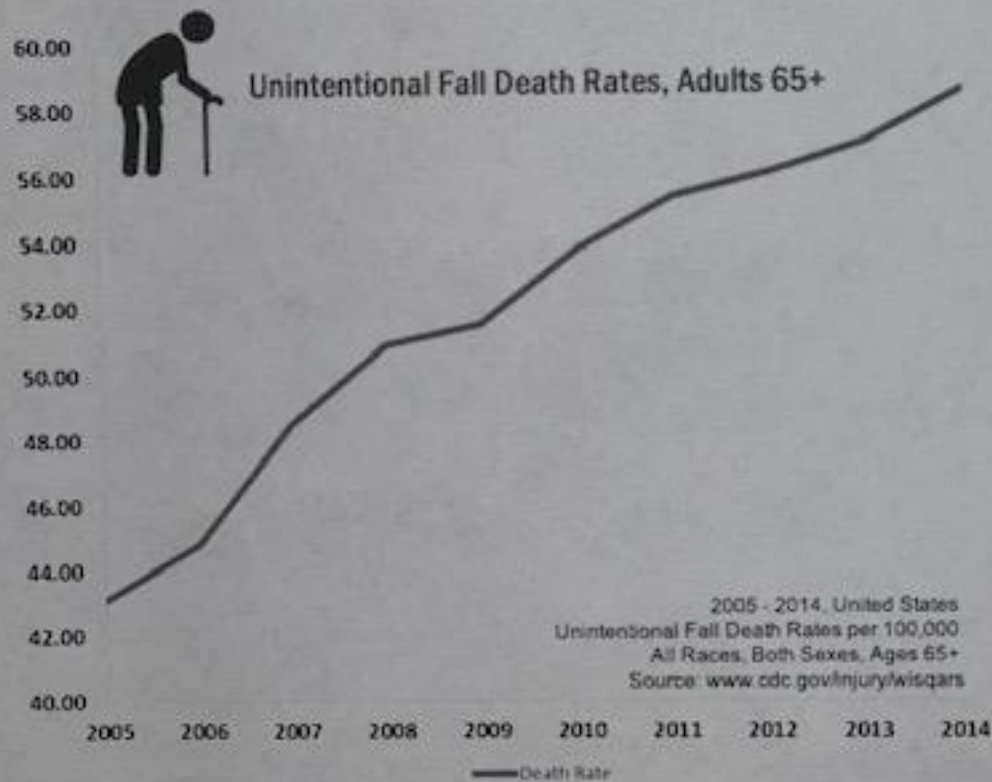
- I had a check up to make sure I was well
- Some of my medicines were changed
- I was given advice on how to make my home safer
- I was given information about suitable exercise classes

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# History of Falls!

## Does it change your decision to anticoagulate?

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American Geriatrics Society May 2018

# Falls in Community-Dwelling Elderly

- Increases with age.
- Approximately  $\frac{1}{2}$  of these fallers have multiple episodes.
- Women are twice as likely to suffer injuries during a fall.
- Fear of falling common post fall anxiety syndrome

# Falls Assessment in the Older Adult

- **Get up and Go- (Timed Up and Go Test –TUG) Assesses Gait, Balance and Transfers**
  - Begin timing
  - Patient rises from standard arm chair
  - Walk 10 feet away and back to chair
  - Sit in chair
  - Stop timing

# Falls Assessment in the Older Adult

- **Get up and Go- (Timed Up and Go Test –TUG) Assesses Gait, Balance and Transfers**
  - Normal time to complete – 7-10 sec.
  - More than 10 sec and especially if >20 sec, mobility problems
  - Done for baseline then annually

# Example: Morse Fall Scale

## Falls: Morse Fall Scale

The Morse Fall Scale (MFS) is a rapid and simple method of assessing a resident's likelihood of falling. The MFS is used widely in acute care settings.

Resident name: \_\_\_\_\_ Room #: \_\_\_\_\_  
 Medical record #: \_\_\_\_\_ Date of assessment: \_\_\_\_\_ Assessment #: \_\_\_\_\_

Variables		Score
History of falling	<input type="checkbox"/> No (score as 0) .....	_____
	<input type="checkbox"/> Yes (score as 25).....	_____
Secondary diagnosis	<input type="checkbox"/> No (score as 0) .....	_____
	<input type="checkbox"/> Yes (score as 15).....	_____
Ambulatory aid	<input type="checkbox"/> Bed rest/nurse assist (score as 0) .....	_____
	<input type="checkbox"/> Crutches/cane/walker (score as 15) .....	_____
	<input type="checkbox"/> Furniture (score as 30).....	_____
IV or IV access	<input type="checkbox"/> No (score as 0) .....	_____
	<input type="checkbox"/> Yes (score as 20).....	_____
Gait	<input type="checkbox"/> Normal/bed rest/immobile (score as 0) .....	_____
	<input type="checkbox"/> Weak (score as 10) .....	_____
	<input type="checkbox"/> Impaired (score as 20).....	_____
Mental status	<input type="checkbox"/> Knows own limits (score as 0).....	_____
	<input type="checkbox"/> Overestimates or forgets limits (score as 15).....	_____
<b>Total Score</b>		_____

Risk Level	MFS Score	Action
No risk	0 - 24	Good basic nursing care
Low to moderate risk	25 - 45	Implement standard fall prevention interventions using the Falling Leaf Program
High risk	46 +	Implement high-risk fall prevention interventions using the Falling Leaf Program

# Treating Falls

- **Pharmacist & Doctor — review medications for side effects that may cause falls**
  - Vision check, gait assessment, H&P, neuropathy, underlying medical illnesses, orthostasis, cognition, goals of care, family/caregiving situation, labs
- **Occupational Therapist — home assessment and recommendations to make home safer**
- **Physical Therapist — help with physical activity, balance, strength, and moving safely, assistive devices**





# 10 FALL PREVENTION TIPS for Seniors

**June is National Safety Awareness Month** — The National Safety Council has designated the third week of the month — the week of June 20th — to raise awareness around falls and fall prevention.

**Falls remain a leading cause for injury in the United States:** in fact, one in three older adults falls each year. In 2013 alone, over 2.5 million non-fatal falls were treated in the emergency room. Although falls may be more common in older adults, they can happen to anyone of any age, and there are many things you can do both in and out of the home to decrease the risk of falling.

## Below are 10 Simple Tips for Fall Prevention from the National Safety Council and Other Resources

- |   |  |  |  |
|---|--|--|--|
| <p><b>1</b> Remove tripping hazards such as books and papers, shoes, and boxes from stairs and hallways, and secure rugs.<sup>1</sup></p> |  | <p><b>6</b> Wear sensible shoes with nonskid soles and a proper fit.<sup>2</sup></p>   |  |
| <p><b>2</b> Install grab-bars in the bathroom, both around the toilet and in the shower.<sup>3</sup></p>                                  |  | <p><b>7</b> Poor vision is a major factor in falls. Get an eye exam at least once a year to keep prescriptions current and eyes functioning their best.<sup>3</sup></p>  |  |
| <p><b>3</b> Keep frequently used items within easy reach, so you don't have to climb or strain for them.<sup>1</sup></p>                  |  | <p><b>8</b> Consider adding extra personal security by using a mobile alert systems with GPS to access emergency help at any time.</p>   |  |
| <p><b>4</b> Make sure that both inside and outside the home has adequate lighting so you can see your path while walking.<sup>1</sup></p> |  | <p><b>9</b> Medication errors are one of the main catalysts for falls. Keep an updated medication list, as well as all current labels attached to the bottle. Make sure to take the instructed dose, and talk to the pharmacist about any questions.<sup>4</sup></p> |  |
| <p><b>5</b> Check and repair any damages to walkways or steps regularly.<sup>1</sup></p>  |  | <p><b>10</b> Stay active! Even gentle exercise can increase strength and balance, helping to reduce the risk of falls.<sup>5,6</sup></p>   |  |

<sup>1</sup> [http://www.nsc.org/NSCDocuments\\_Advocacy/Fact%20Sheets/Slips-Trips-and-Falls.pdf](http://www.nsc.org/NSCDocuments_Advocacy/Fact%20Sheets/Slips-Trips-and-Falls.pdf)

<sup>2</sup> <http://www.mayoclinic.org/healthy-lifestyle/healthy-aging/in-depth/fall-prevention/art-20047358>

<sup>3</sup> <http://www.healio.com/optometry/primary-care-optometry/news/print/primary-care-optometry-news/%7B789705b83b-ca71-4c57-b838-59e9e764e190%7D/optometrists-can-play-significant-role-in-fall-prevention-for-older-adults>

<sup>4</sup> <http://www.aplaceformom.com/blog/1-27-2014-medication-management-tips>

<sup>5</sup> <http://www.nsc.org/learn/safety-knowledge/Pages/safety-at-home-falls.aspx>

<sup>6</sup> <http://www.mayoclinic.org/healthy-lifestyle/healthy-aging/in-depth/fall-prevention/art-20047358>

# **Use of Direct Oral Anticoagulants Safely in Older Adults**

- **Accurate assessment of stroke risk and bleeding risk is the key**
- **Do not overemphasize bleeding and fall risks in decision-making**
- **Appropriate judgement**
- **Follow renal function with CrCl**
- **Meticulous dosing, meticulous follow up**
- **Monitor for unexplained anemia**

# Anticoagulant use in Older Adults

- **Risk VS Benefit**
  - **Assess and decide by:**
    - Clinical trials
    - Bleeding risk calculations
    - Clinical judgment
    - Personal bias
    - Patient preference.

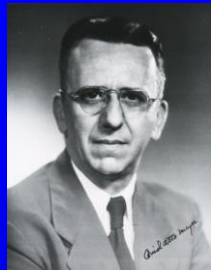
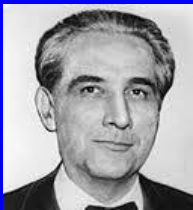
# Consider Comorbidities in Older Adults

- **Renal Impairment**
- **Dementia**
  - Any cognitive impairment
  - Med compliance
- **Hepatic Disease**
  - DOACs can increase hepatotoxicity
- **Mobility disorders**
- **Failure to thrive**

# **Aging is a Hypercoagulable State**

- **Fibrinogen level increases**
- **D-dimer increases**
- **Factor VIII level increases**
- **von Willebrand factor increases**
- **Factor VIIa increases**
- **Thrombomodulin decreases**
- **Homocysteine increases**
- **Endothelial dysfunction increases**

# History of anticoagulant therapy



1910    1920    1930    1940    1950    1960    1970    1980    1990    2000    2010

Anticoagulant in spoiled sweet clover (K.P. Link)

First clinical use of 4-hydroxycoumarin (O. Meyer et al)

Warfarin mechanism elucidated (J. Suttie)

Warfarin dosing/INR

Warfarin clinical trials

**Oral thrombin and Xa inhibitors**

Heparin discovered by medical student (McLean)

Clinical use of heparin

Requirement for plasma cofactor discovered (K. Brinkhous)

Cont infusion of heparin; aPTT monitoring

LMWH (J. Hirsch)

LMWH trials

Fondaparinux trials



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# Bleeding Risk

Letter	Clinical Characteristic	Points
H	Hypertension	1
A	Abnormal liver or renal function	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INR	1
E	Elderly (age>65)	1
D	Drugs or Alcohol	1 or 2

- Most common tool used to assess bleeding risk: HAS-BLED score.
- Should be used to identify risk factors or define patients at elevated bleeding risk, not to determine who should or should not receive anticoagulation.

Points	0	1	2	3	4	5
Annual bleed rate	0.9%	3.4%	4.1%	5.8%	8.9%	9.1%



BAPTIST HEALTH

# Assessing Bleeding Risk

- Apps available for phone
  - HAS-BLED
  - Aspirin Guide
  - DAPT risk calculator
  - CRUSADE bleeding score
  - BLEEMACS risk score

**A Novel User-Friendly Score (HAS-BLED) to assess 1-year risk of major bleeding inpatients with atrial fibrillation: Chest. 2010; 138(5): 1093-1100**

Prediction of the Risk of Bleeding During Anticoagulant Treatment *Arch Intern Med* 1999; 159; 457-460



# Balancing the Risks

- All patients require an individualized assessment of their bleeding risk before the initiation of anticoagulation

	NCCN 2015	ASCO 2014
<b>Absolute</b> Contraindication to Therapeutic Anticoagulation for VTE	<ul style="list-style-type: none"> <li>Recent intracranial or spinal lesion at high risk for bleeding</li> <li>Active bleeding (&gt; 2 units transfused in 24 hours)</li> </ul>	<ul style="list-style-type: none"> <li>Active bleeding</li> <li>Severe, uncontrolled hypertension</li> <li>Severe platelet dysfunction or inherited bleeding disorder</li> <li><b>Platelets &lt; 20,000/mcL</b></li> <li>Surgery or invasive procedure including lumbar puncture, spinal anesthesia, &amp; epidural catheter placement</li> </ul>
<b>Relative</b> Contraindication to Therapeutic Anticoagulation for VTE	<ul style="list-style-type: none"> <li>Chronic, measureable bleeding &gt; 48 hours</li> <li><b>Platelets &lt; 50,000/mcL</b></li> <li>Recent major operation</li> <li>Underlying hemorrhagic coagulopathy</li> <li>High risk for falls (head trauma)</li> <li>Neuraxial anesthesia/lumbar puncture</li> </ul>	<ul style="list-style-type: none"> <li>Intracranial or spinal lesions</li> <li>Active peptic or other gastrointestinal ulceration</li> <li>Active, but non-life threatening bleeding</li> <li>Intracranial bleeding within 4 weeks</li> <li>Major surgery or serious bleeding within 2 weeks</li> <li><b>Platelets &lt; 50,000/mcL</b></li> </ul>

# What is the bleeding risk with anticoagulant therapy?

- Young patient with good anticoagulant control:  $<1\%/yr$
- Elderly patient with multiple risk factors for bleeding:  $>4\%/yr$
- Case fatality rates from bleeding while on anticoagulant therapy  $\approx 20\%$

*Blood* 2014;123:1794

*Thromb Haemost* 2013; 110:834

# Anticoagulation

## Risk of stroke in patients with atrial fibrillation

### CHADS<sub>2</sub> → CHA<sub>2</sub>DS<sub>2</sub>VASc

CHADS2 Risk	Score
CHF	1
Hypertension	1
Age > 75	1
Diabetes	1
Stroke or TIA	2

CHA2DS2-VASc Risk	Score
CHF or LVEF ≤ 40%	1
Hypertension	1
Age ≥ 75	2
Diabetes	1
Stroke/TIA/Thromboembolism	2
Vascular Disease	1
Age 65 - 74	1
Female	1

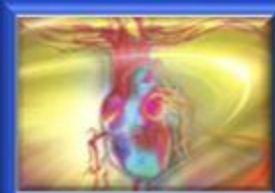
*From ESC AF Guidelines  
<http://escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf>*

Score ≥ 2. Long term anti-coagulation is recommended

# Atrial Fibrillation

Draft NICE guidance January 2014

- Use the HasBled score to highlight / correct and modify the following modifiable risk factors
  - Uncontrolled hypertension
  - Labile INRs
  - Concurrent medication e.g aspirin / NSAID
  - Harmful alcohol intake
- A HAS-BLED score of  $\geq 3$  suggests the patient is at high risk and additional caution should be used, whether the patient is on aspirin or warfarin.
- Do not withhold anticoagulation solely due to the fact that patients may be at risk of a fall
- For most patients benefits of anticoagulation outweighs the risk



## Choosing Antithrombotic Therapy for Elderly Patients with AF Who are at Risk for Falls

- ▶ A Markov decision analytic model

*For patients with average risks of stroke and falling ...*

- ▶ Warfarin therapy associated with 12.90 quality-adjusted life-years per patient;
- ▶ Aspirin therapy, 11.17 quality-adjusted life-years; and
- ▶ No antithrombotic therapy, 10.15 quality-adjusted life-years.

'Elderly persons who fall have a mean of 1.81 falls per year.

*... Given that the risk of SDH must be 535-fold or greater for the risks of warfarin therapy to outweigh the benefits, persons taking warfarin must fall about 295 ( $535/1.81$ ) times in 1 year for warfarin to not be the optimal therapy.'*

# Anticoagulation and Risk of Falls in the Elderly – Putting Matters in Perspective

- The risk of a subdural hematoma from falling is so small.
- A patient with a 5% annual stroke risk from AF would need to fall **300 times** in a year for the calculated risk of subdural hematoma from falling to outweigh the stroke reduction benefit of warfarin.
- [Man-Son-Hing M, Laupacis A. Anticoagulant-related bleeding in older persons with atrial fibrillation: physicians' fears often unfounded. Arch Intern Med 2003; 163:1580.](#)
- [Man-Son-Hing M, Nichol G, Lau A, Laupacis A. Choosing antithrombotic therapy for elderly patients with atrial fibrillation who are at risk for falls. Arch Intern Med 1999; 159:677.](#)
- [Sellers MB, Newby LK. Atrial fibrillation, anticoagulation, fall risk, and outcomes in elderly patients. Am Heart J 2011; 161:241.](#)

# Falls

- Studies evaluating anticoagulation risk in the elderly at high risk of falls indicate only 50% of eligible patients received warfarin
- Falls frequently cited as reason for no warfarin
- 3 studies specifically assessing risk-benefit analyses all found benefit of warfarin outweighs risk in falling patients with AF
- Education shown to reduce risk bleeding in elderly and should be a vital part of the management

(Ann Pharmacother 2008)

# Thromboembolic prevention in frail elderly patients with atrial fibrillation

- **A practical algorithm using**
  - **Clinical Frailty Index**
    - 1-9 scale
    - 1 very fit
    - 9 terminally ill

– Journal of Pharmacy Practice and Research Vol 45, issue 2, pages 217-225. 10 Jun 2015



# Clinical Frailty Index

1- Very Fit- Robust and Active

2- Well persons who have no active symptoms, very active occasionally

3- Managing well persons with medical problems well controlled, not regularly active

4- Vulnerable- symptoms limit activity but not dependent on others

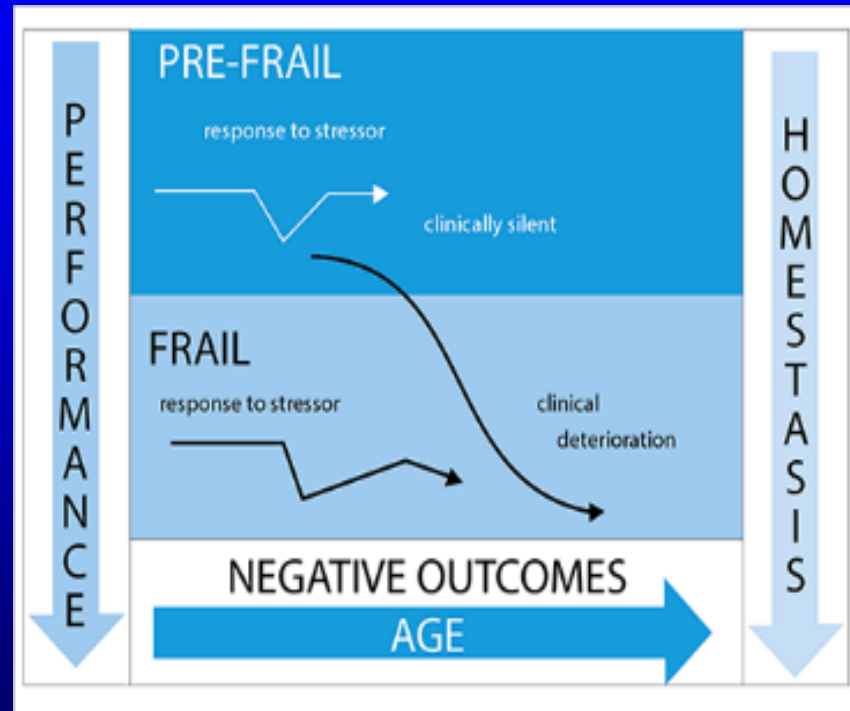
5- mildly frail, need help higher order IADLs

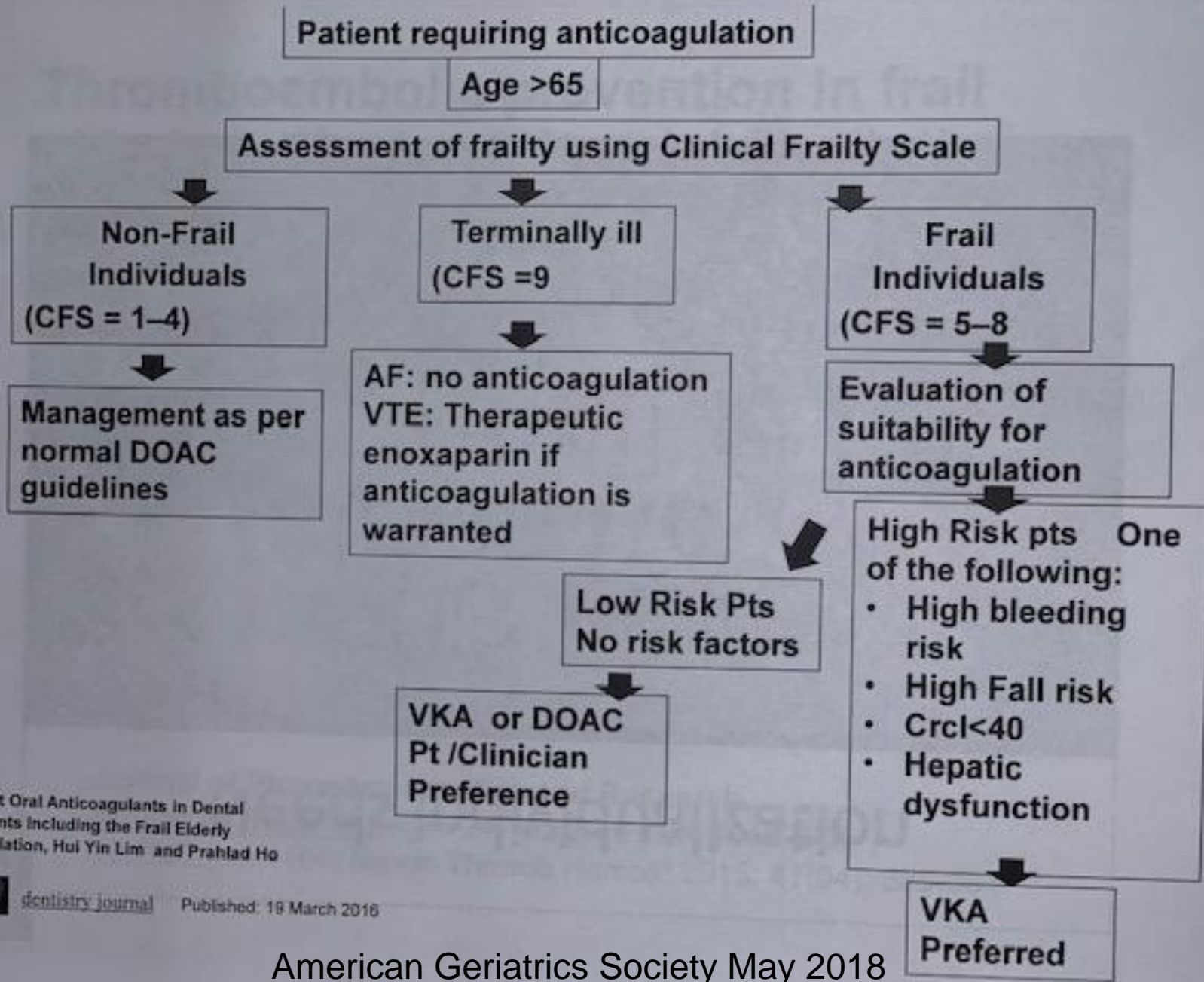
6- mod frail –need help all outside activity and keeping house

7- severely frail, completely dependent for personal care

8- very severely frail –completely dependent approaching EOL

9- terminally ill





Direct Oral Anticoagulants in Dental Patients Including the Frail Elderly Population, Hui Yin Lim and Prahlad Ho



dentistry journal

Published: 18 March 2016

American Geriatrics Society May 2018

# New Oral Anticoagulants in Elderly Adults- Evidence from a META-Analysis of Randomized Trials

ParthaSardar, MD, SauravChatterjee, MD, Shobhana Chaudhari, MD,andGregory Y. H. Lip, MD

- •OBJECTIVES: To evaluate the efficacy and safety of new oral anticoagulants (NOACs) in elderly adults.
- •SETTING: PubMed, Cochrane Library, EMBASE, Web of Science, and CINAHL databases were searched from January 1, 2001, through March 30, 2013.
- •PARTICIPANTS: **Elderly population ( $\geq 75$ )** in RCTs comparing NOACs (rivaroxaban, apixaban, and dabigatran) with conventional therapy.
- (Ten RCTs included 25,031 elderly participants. )
- •**CONCLUSION:**NOACs did not cause excess bleeding.
- •Equal or greater efficacy than conventional therapy.
- JAGS 62:857–864, 2014 © 2014

# Who are the best candidates for new oral anticoagulants?

- Patients who have unstable INR on warfarin not due to poor compliance
- Adequate renal & hepatic function
- No mechanical valve
- Not pregnant (drugs cross placenta)
- Not at extremes of weight (can't adjust dose)
- Not at high risk of lower GI bleeding
- Not at high risk for ACS (dabigatran)

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## **Stroke, Bleeding and Mortality Risks in Elderly Medicare Beneficiaries Treated with Dabigatran or Rivaroxaban for Nonvalvular Atrial Fibrillation**

- **Retrospective new-user cohort study of 118,891 patients with non-valvular afib who were 65 years or older, enrolled in fee-for-service Medicare, and who initiated treatment with dabigatran or rivaroxaban from 11/4/2011 through 6/30/2014**
- **Dabigatran, 150mg bid; Rivaroxaban 20mg daily**
- **In patients 75 years or older or with CHADS-2 score greater than 2, Rivaroxaban use was associated with significantly increased mortality (HR=1.15) compared with Dabigatran use. The excess rate of ICH (HR=1.65) with Rivaroxaban use exceeded its reduced rate of thromboembolic stroke (HR=0.81)**
- **Graham, Reichman et al JAMA IM. 2016;176(11):1662-1671**

# LESSONS FROM AF TRIALS WITH DOACS

- **Main result: New agents at least as effective as warfarin, can be given without routine monitoring**
- **Other/unexpected findings:**
  - Reduction in intracranial bleeding
  - Higher MI rates (dabigatran)
  - Higher rates of GI bleeding (active drug in lower intestine)
  - Extracranial bleeding risk higher in older patients

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# Pharmacology of oral anticoagulant drugs

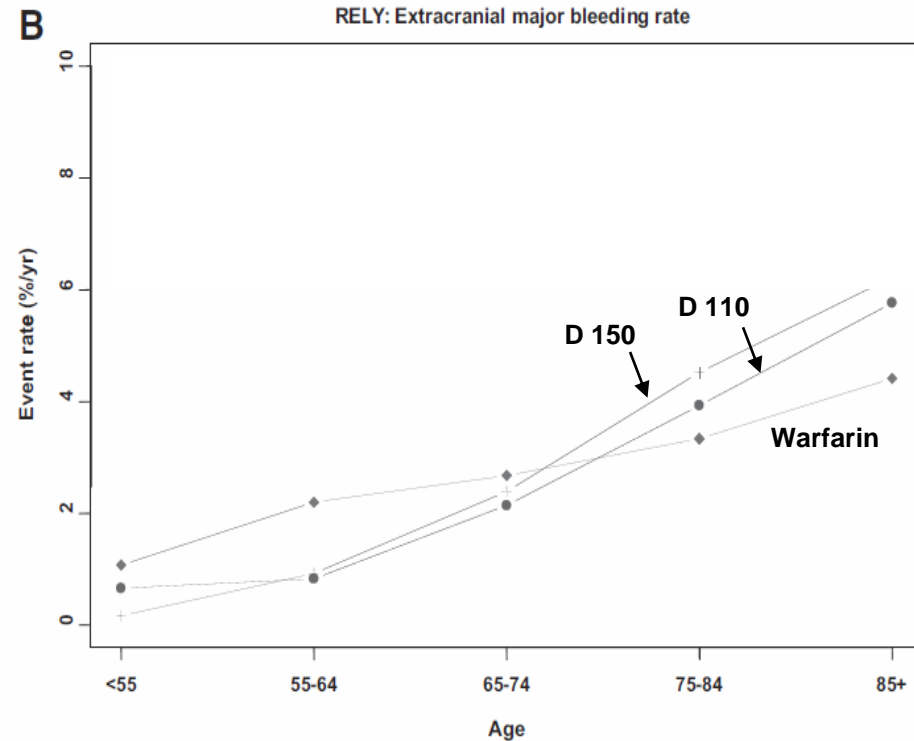
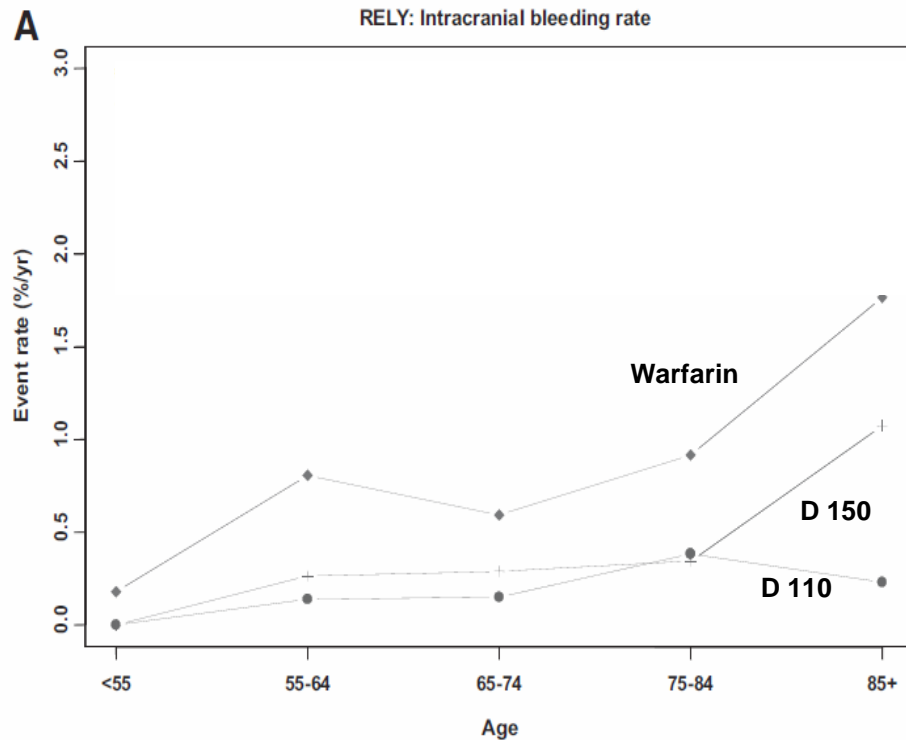
	<b>Warfarin</b>	<b>DOACs</b>
Bioavailability	99%	6-80% (some active drug in large bowel)
Tmax	72-96 hours	2-4 hours
Half-life	40 hours	5-17 hours
Metabolism	Cytochrome P450	Biliary/Renal
Drug Interactions	Many	Not so many
Food Interactions	Yes	No
Genetic Variation	Major effects	Minor effects (?)
Monitoring	PT/INR	None
Reversal	Vit K/PCC/FFP	PCC? Dialysis?

# Cost per month of oral anticoagulants

- Rivaroxaban (20 mg/day) : \$290
- Dabigatran (150 mg bid): \$290
- Apixaban (5 mg bid): \$147
- Warfarin (7.5 mg/day): \$31

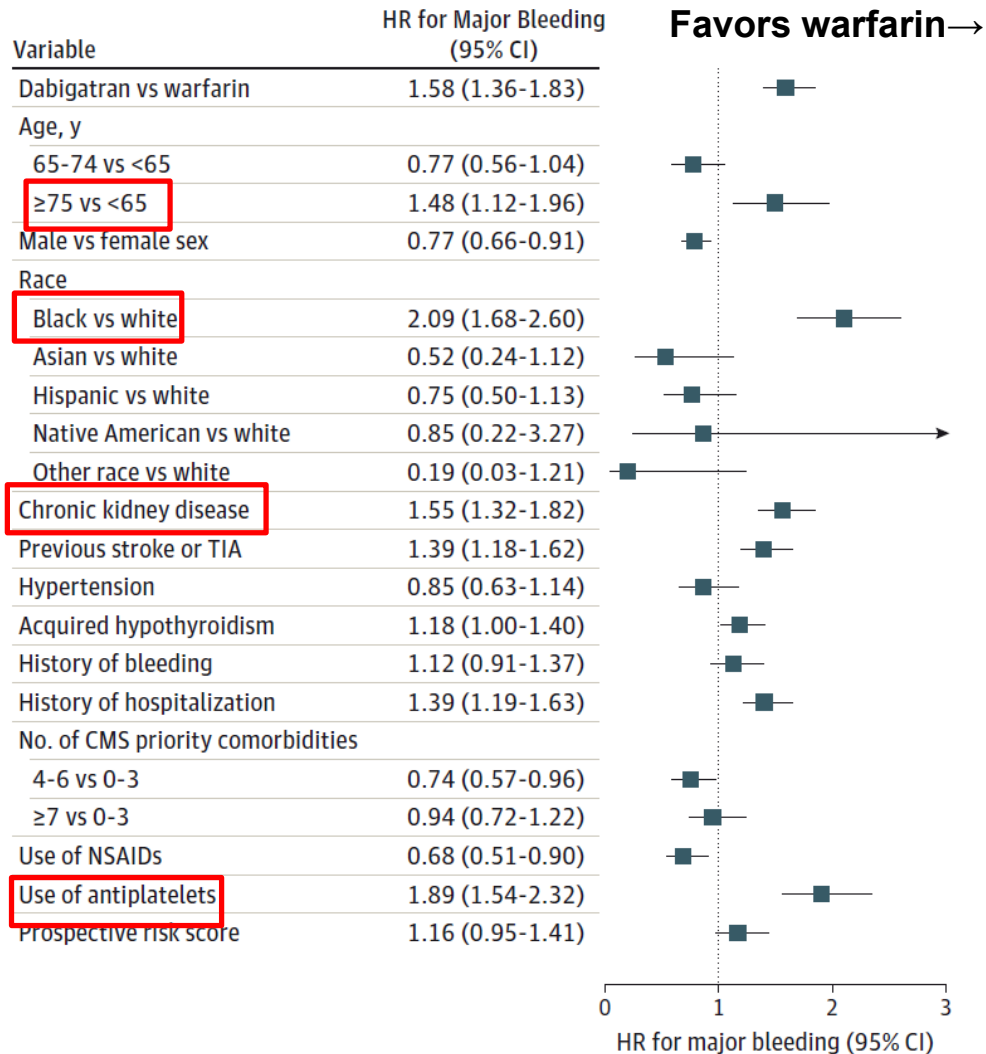


# Bleeding rates with dabigatran vs warfarin as a function of age



- Intracranial bleeding lower with dabigatran at all ages
- Extracranial bleeding rates higher with dabigatran above age 75

# Bleeding rates with dabigatran vs warfarin in atrial fibrillation: a “real-world” study



# **Dabigatran Etexilate vs Warfarin (RE-LY)**

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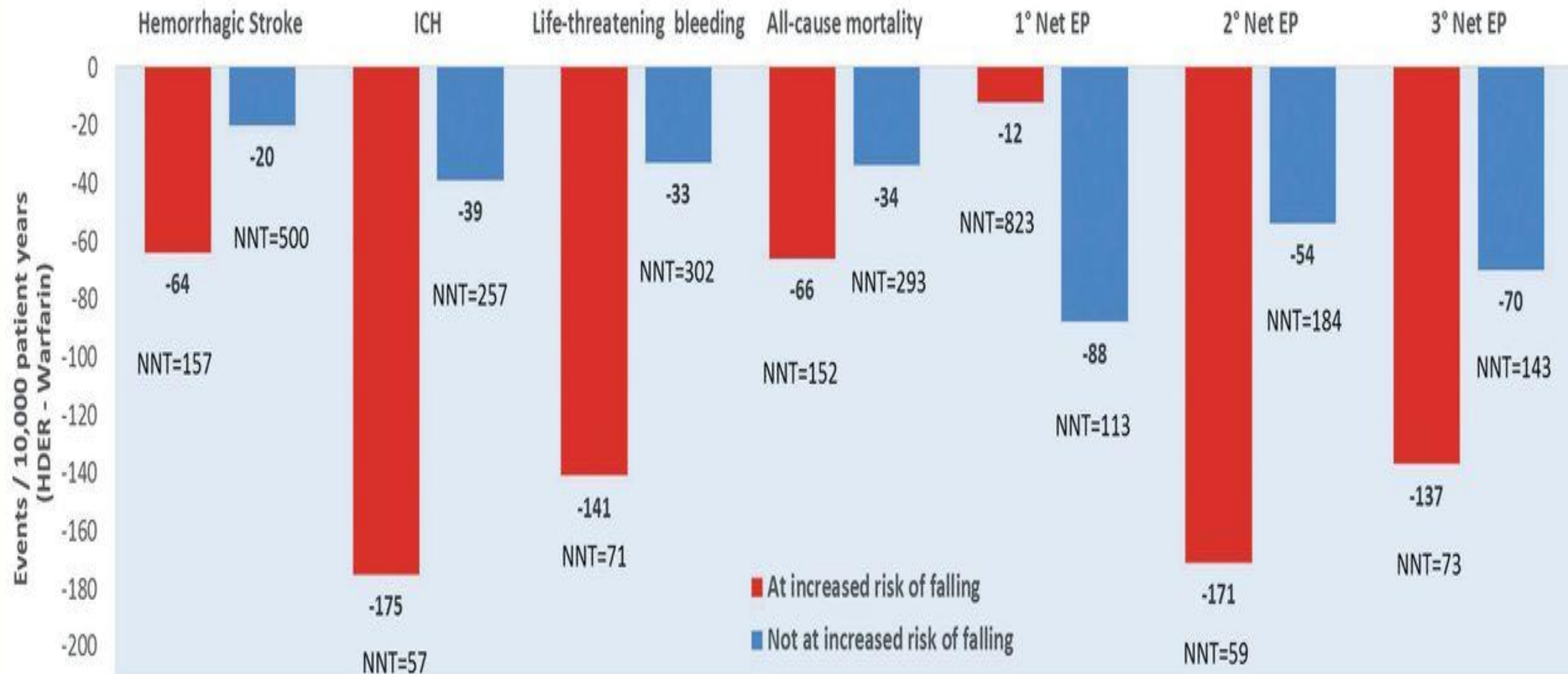
**October 19, 2010**

**FDA Approves Pradaxa to Reduce the Risk of  
Stroke in Patients with Non-Valvular Atrial  
Fibrillation**

***PRADAXA 150 mg BID-higher rate of major (GI)  
bleeds and any GI bleeds compared to warfarin.***

***In patients  $\geq 75$  years of age, the risk of major  
bleeding may be greater with PRADAXA than with  
warfarin.***

# CENTRAL ILLUSTRATION: Absolute Risk Reduction of Higher Dose Edoxaban Regimen Compared With Warfarin in Patients at Increased Fall Risk Versus Not at Increased Fall Risk



Steffel, J. et al. J Am Coll Cardiol. 2016;68(11):1169-78.

# **IDARUCIZUMAB FOR DABIGATRAN REVERSAL**

- **Idarucizumab (Praxbind<sup>®</sup>) is a monoclonal antibody fragment that binds to dabigatran with high affinity (350x that of thrombin)**
- **5 mg of idarucizumab (2 x 2.5 mg vials) completely reverses the anticoagulant effect of dabigatran when the drug is taken at usual recommended doses**
- **This effect occurs within minutes of drug administration and restores normal hemostasis (*NEJM 2015; 373:511*)**
- **Idarucizumab approved by FDA in October 2015**

# 2015 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medications to Be Used with Caution in Older Adults

Drugs	Recommendation, Rationale, Quality of Evidence (QE), Strength of Recommendation (SR)
Dabigatran	<p>Use with Caution in adults <math>\geq 75</math> years old and in patients with CrCl <math>&lt; 30</math> mL/min. Increased risk of gastrointestinal bleeding compared with warfarin and reported rates with other target-specific oral anticoagulants in adults <math>\geq 75</math> years old; lack of evidence of efficacy and safety in individuals with CrCl <math>&lt; 30</math> mL/min</p> <p>QE = Moderate SR = Strong</p>



# THROMBOEMBOLISM IN FRAIL, ELDERLY PATIENTS WITH ATRIAL FIBRILLATION

Granziera S, Cohen AT, Nante G, Manzato E, Sergi G. Thromboembolic prevention in frail elderly patients with atrial fibrillation: a practical algorithm. Journal of the American Medical Directors Association. 2015 May 1;16(5):358-64.

<b>Falls</b>	<ul style="list-style-type: none"><li>• Refer to fall clinic/Fall intervention</li><li>• Physical therapy/Assistive Devices</li></ul>
<b>Dementia</b>	<ul style="list-style-type: none"><li>• Must have Care giver supervision</li><li>• Cognitive evaluation ( Mini-cog)</li></ul>
<b>Dysphagia</b>	<ul style="list-style-type: none"><li>• F Xa inhibitors preferred</li><li>• History of food intake</li></ul>
<b>Multimorbidities</b>	<ul style="list-style-type: none"><li>• Cumulative Illness Rating Scale</li><li>• Multi-dimensional Prognosis Index</li></ul>
<b>Malnutrition</b>	<ul style="list-style-type: none"><li>• Mini Nutritional Assessment</li></ul>
<b>CKD</b>	<ul style="list-style-type: none"><li>• CrCl: Ongoing Renal function monitoring</li><li>• Frequent monitoring for Anemia</li></ul>
<b>Polypharmacy</b>	<ul style="list-style-type: none"><li>• Review Medications</li></ul>

# **Osteopathic Principles and Practice**

## **Falls and Anticoagulation in the Older Adult**

- **Function**
- **Quality of Life**
- **Cost**
- **Living situation**
- **Goals of care**
- **Start low and go slow**
- **Individualize treatment**



