

Anticoagulants and the National Patient Safety Goals

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Minnesota Hospital Association

Medication Safety Conference

Disclosures

- Grant Funding
 - NHLBI
 - Pfizer/Bristol-Myers Squibb
- Consulting
 - Pfizer/Bristol-Myers Squibb
 - Janssen
 - Portola
 - AMAG Pharmaceuticals
- Board of Directors
 - Anticoagulation Forum
 - National Certification Board of Anticoagulation Providers

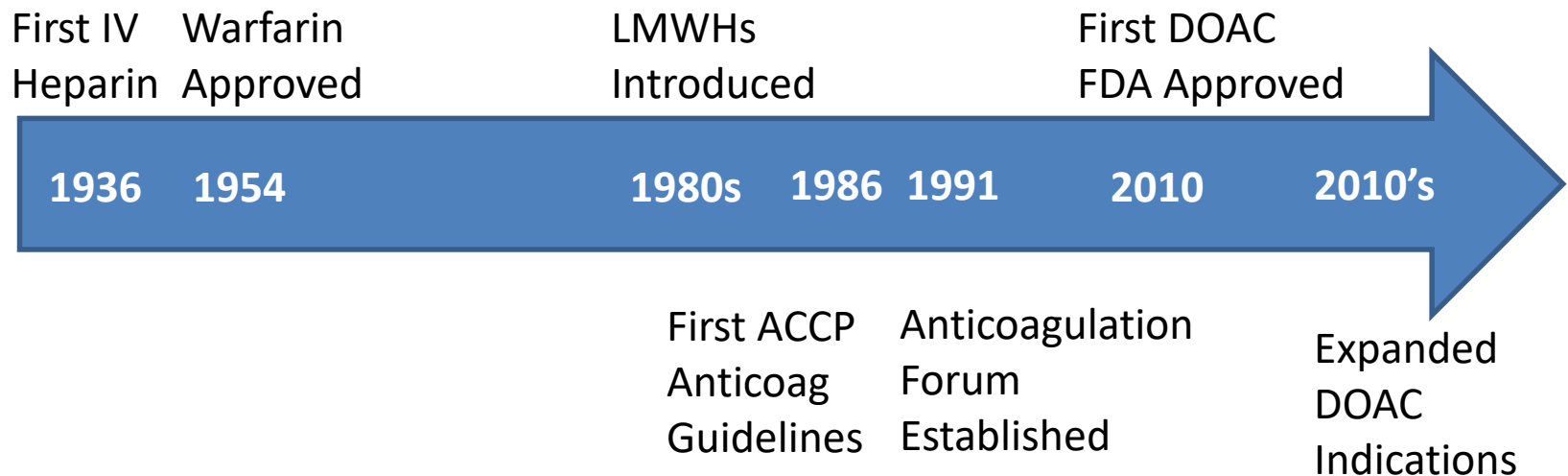
Outline

- Oral Anticoagulants - Review
- Recent Updates in Anticoagulation
- Joint Commission Anticoagulation Safety Goals
- Tips for Implementation

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Anticoagulation Timeline



LMWH – Low-molecular-weight heparin
DOAC – direct oral anticoagulant
ACCP – American College of Chest Physicians

Wikipedia
Int J Card 212S1 (2016) S1–S4
[Chest](#). 1986 Feb;89(2 Suppl):1S-106S

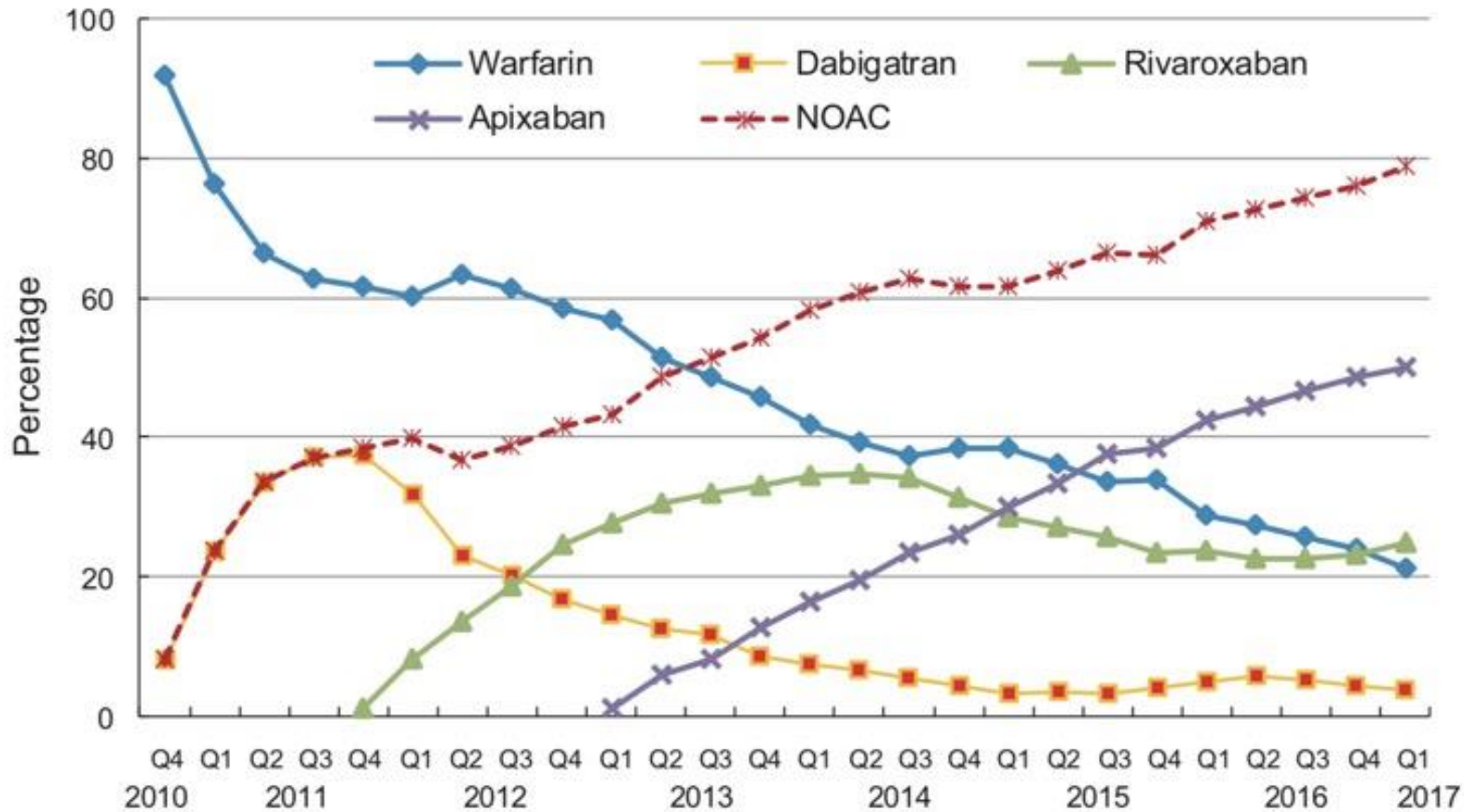
Available Oral Therapies

	Warfarin (Coumadin)	Dabigatran (Pradaxa)	Apixaban (Eliquis)	Edoxaban (Savaysa)	Rivaroxaban (Xarelto)	Betrixaban (BevyXa)
Target	Factors II, VII, IX, X	Factor II (Thrombin)	Factor Xa	Factor Xa	Factor Xa	Factor Xa
Half-Life (effective)	40 hours	8-15 hours	12 hours	10-14 hours	7-11 hours	19 hours
Time to Peak Effect	4-5 days	1-3 hours	1-2 hours	1-2 hours	2-4 hours	3-4 hours
Renal Clearance	None	80%	25%	50%	33%	<10%
FDA Approved Indication	<ul style="list-style-type: none"> • AF • VTE <ul style="list-style-type: none"> • Treatment • 2^o Prevention • Prophylaxis • Valve Replacement 	<ul style="list-style-type: none"> • AF (non-valvular) • VTE <ul style="list-style-type: none"> • Treatment • 2^o Prevention • Hip Surgery Prophylaxis 	<ul style="list-style-type: none"> • AF (non-valvular) • VTE <ul style="list-style-type: none"> • Treatment • 2^o Prevention • Hip or Knee Surgery Prophylaxis 	<ul style="list-style-type: none"> • AF • VTE <ul style="list-style-type: none"> • Treatment 	<ul style="list-style-type: none"> • AF • VTE <ul style="list-style-type: none"> • Treatment • 2^o Prevention • Hip or Knee Surgery Prophylaxis 	<ul style="list-style-type: none"> • VTE <ul style="list-style-type: none"> • Prophylaxis
Reversal Available?	Yes	Yes	Yes	+/-	Yes	+/-

Changing Use of Anticoagulants



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Risk of Anticoagulant Medications

#1 Cause of “Adverse Drug Events”

Table 3. US Emergency Department (ED) Visits for Adverse Drug Events (ADEs) From the Most Commonly Implicated Drug Products by Patient Age, 2013-2014^a

Drug Product	ED Visits for ADEs	
	No. of Cases	National Estimate, % (95% CI) ^b
All Patients (N = 42 585)		
Warfarin	6179	15.1 (12.3-17.9)
Insulin	4859	10.7 (8.6-12.7)
Clopidogrel	1778	4.4 (2.9-5.9)
Amoxicillin	1780	3.8 (3.3-4.3)
Aspirin	1518	3.5 (2.2-4.9)
Sulfamethoxazole-trimethoprim	1152	3.2 (2.7-3.7)
Lisinopril	1096	2.4 (1.8-3.0)
Metformin	766	1.7 (1.4-2.1)
Ibuprofen	722	1.6 (1.3-2.0)
Rivaroxaban	526	1.3 (0.8-1.8)
Acetaminophen-hydrocodone	492	1.3 (1.0-1.6)
Cephalexin	431	1.2 (0.9-1.5)
Acetaminophen-oxycodone	459	1.1 (0.8-1.4)
Acetaminophen	479	1.0 (0.8-1.2)
Amoxicillin-clavulanate	422	1.0 (0.9-1.2)

Anticoagulation Management

Individual
Doctor or Nurse



Dedicated
Anticoagulation Clinic



Dedicated Hospital
Staff



Protocol

Driven by need to manage warfarin:

- Frequent dose changes
- Frequent INR lab draws

Driven by need to manage heparin:

- Frequent dose changes
- Improve quality

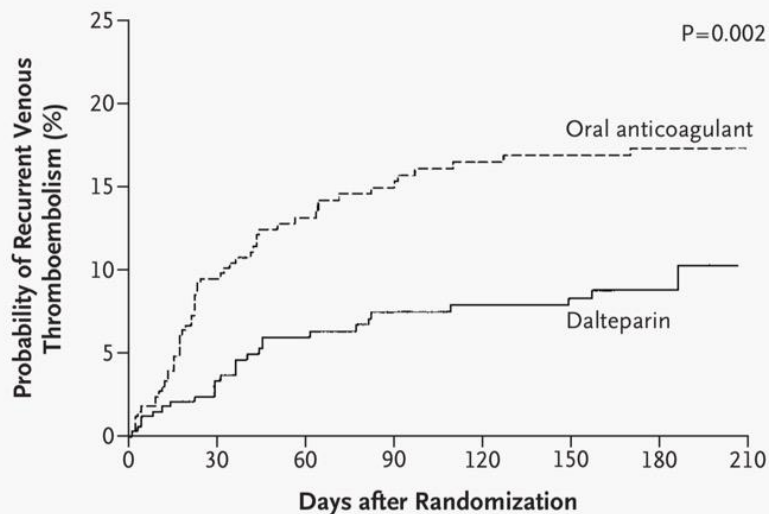
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Cancer-associated VTE: LMWH vs. Warfarin

LMWH > Warfarin for VTE Recurrence

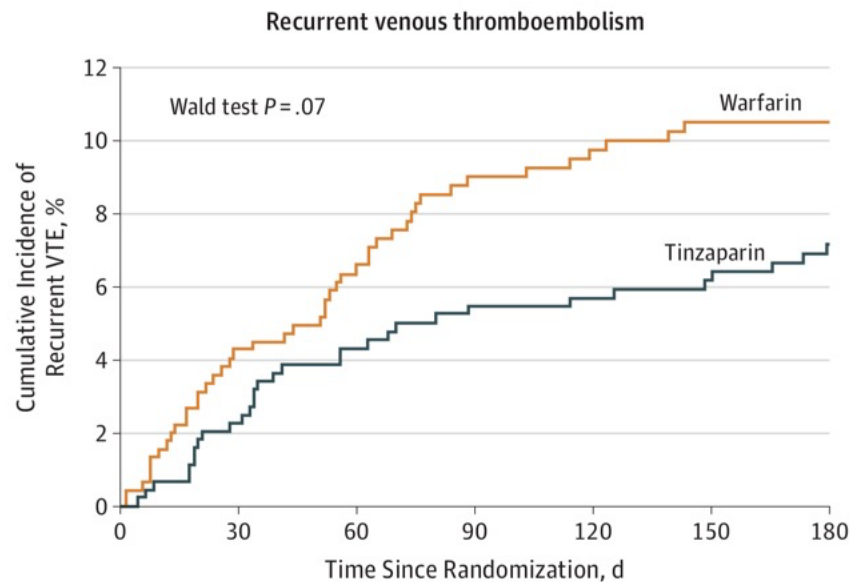
CLOT Trial



No. at Risk

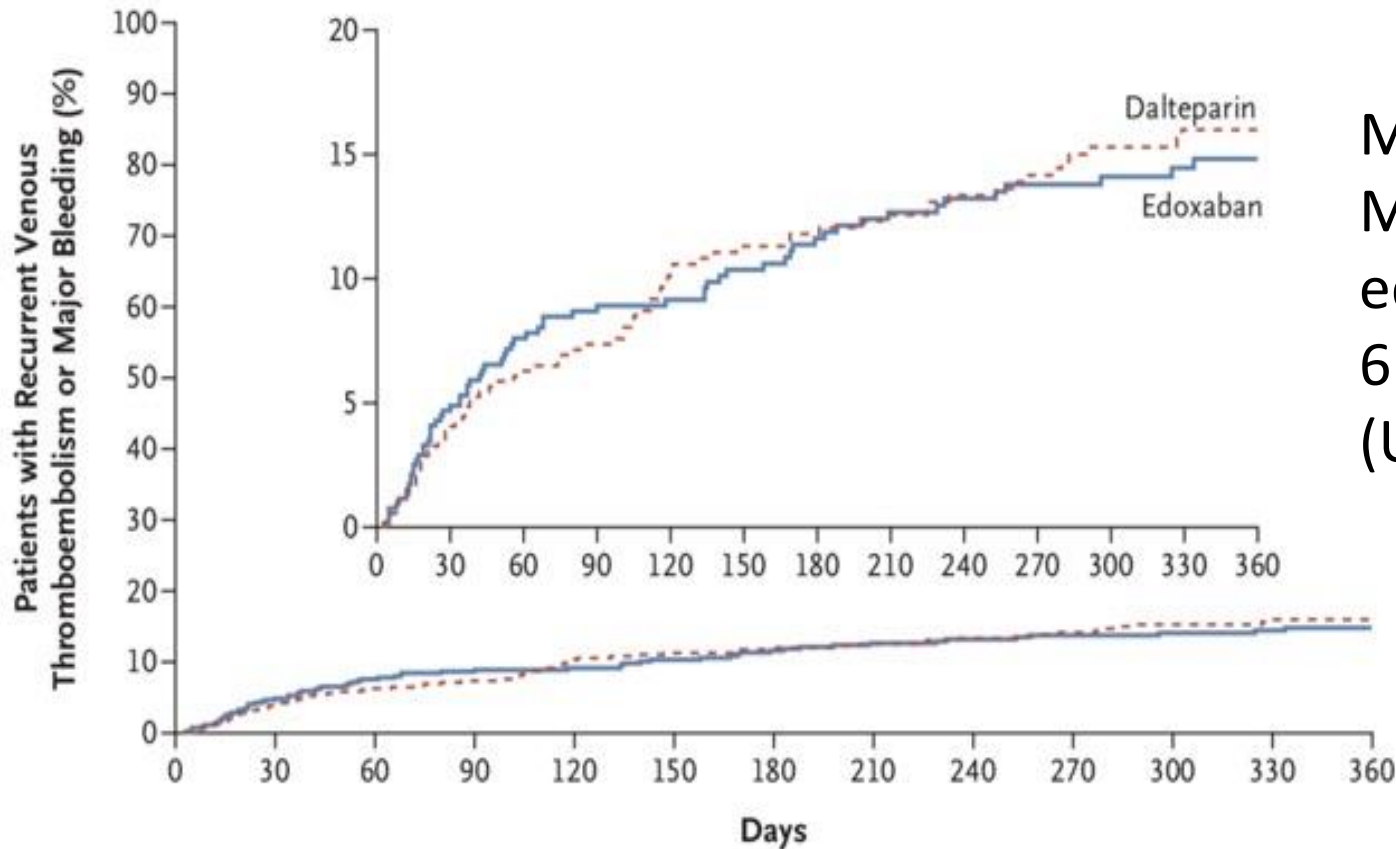
Dalteparin	336	301	264	235	227	210	164
Oral anticoagulant	336	280	242	221	200	194	154

CATCH Trial



Treat Cancer-VTE: Hokusai VTE Study

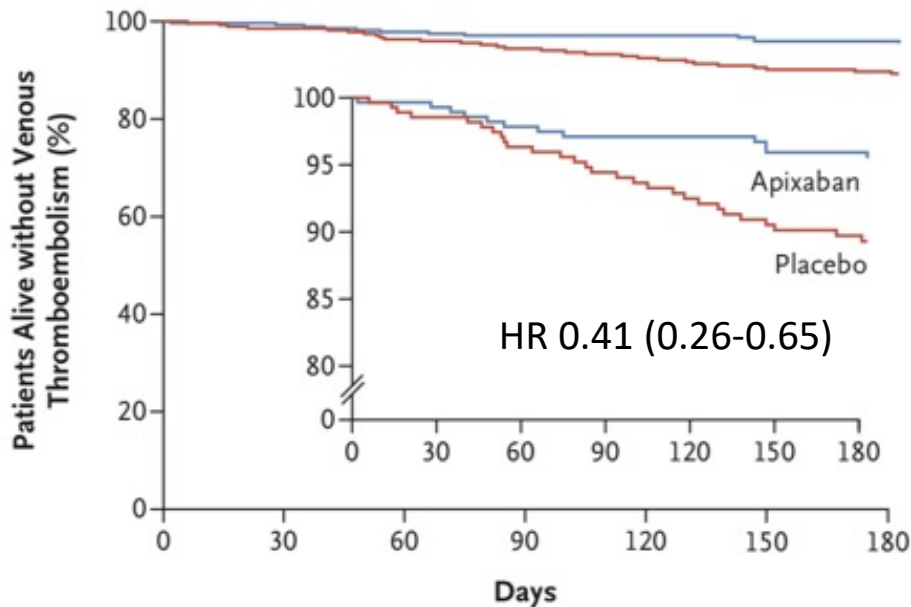
Primary Outcome: Recurrent VTE or Major Bleed



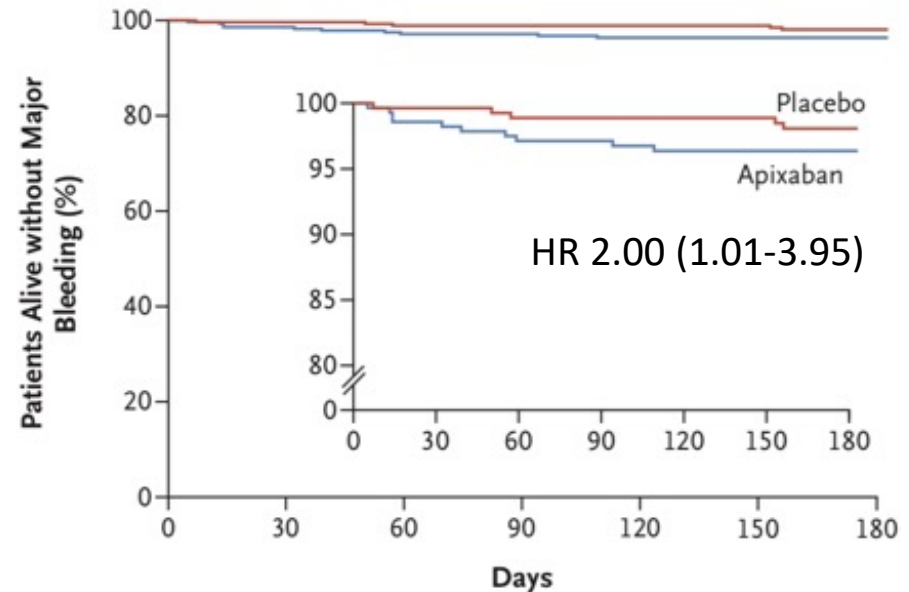
Modest increase in
Major Bleed with
edoxaban:
6.9% vs. 4.0%
(Upper GI Cancer)

Preventing Cancer-associated VTE: The AVERT Trial

Prevent VTE

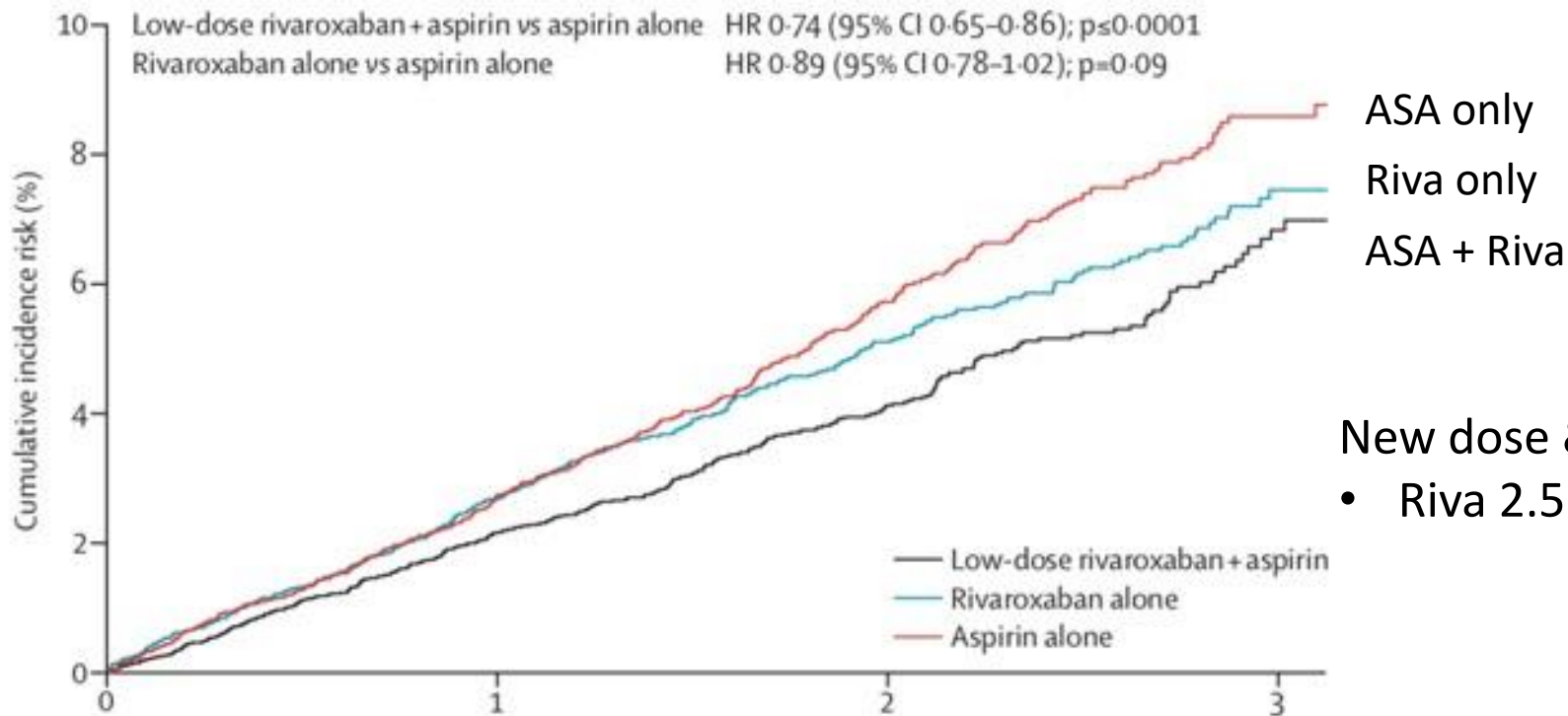


Avoid Bleeding



Anticoagulation for CAD/PAD?

Stable CAD or PAD



- New dose & indication
- Riva 2.5mg BID

DOAC Reversal Agents

	Idarucizumab	Andexanet Alpha	Ciraparantag
Drug Reversed	Dabigatran	Rivaroxaban, Apixaban, Edoxaban (non-FDA), LMWH (non-FDA)	Dabigatran, Xa Inhibitors LMWH, UFH
Mechanism	Monoclonal Ab <ul style="list-style-type: none"> • Binds Dabigatran • Frees Thrombin 	Recombinant Factor Xa <ul style="list-style-type: none"> • High affinity for Xa Inhibitors 	Covalent bonds to drugs
Published Clinical Studies	Bleeding Patients & Emergent Reversal	Healthy Volunteers & Bleeding Patients	Healthy Volunteers
FDA Approval	Approved!	Approved!	TBA

Recent Advanced in Anticoag

- New indications
 - Cancer-VTE treatment
 - Cancer-VTE prevention
 - Stable CAD & PAD
- New doses
 - Rivaroxaban 2.5mg BID (similar to apixaban)
- Specific DOAC Reversal agents
 - \$\$\$\$
 - Potential thrombotic risk?

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National Patient Safety Goals

- “To reduce the likelihood of patient harm associated with the use of anticoagulant therapy”
- Effective July 1, 2019
- 8 new elements of performance
- All Joint Commission-accredited hospitals, nursing care centers, and medical centers (ambulatory health care program)



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Anticoagulation
FORUM



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Comprehensive Resources

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Anticoagulation
Center of
Excellence

2017 - 2019

Concepts of Care Home Health
Lafayette, LA

Welcome to Anticoagulation Centers of Excellence

The Anticoagulation Centers of Excellence program was created in 2012 to help healthcare professionals provide the highest level of care and achieve the best possible outcomes for their patients on antithrombotic medications. Through access to evidence-based guidelines and constantly researched and updated best practices, tools and information, healthcare professionals will be able to improve outcomes through active participation in their patients' care. The Anticoagulation Centers of Excellence program offers a roadmap to achieving consistent, sustainable excellence in patient care.

There are two essential components to the Centers of Excellence program - an

Why Become a Center of Excellence?

The landscape of anticoagulation is advancing, evolving and changing. Until now, there has not been a comprehensive standard to define ideal practices for an anticoagulation service.

[Learn More >](#)

Resources



Anticoagulation Toolkit

(Version 1.9)

A Consortium-Developed Quick Reference for
Anticoagulation

Element of Performance 1: Protocols for Anticoag Therapy

Address the following issues:

- Medication selection
- Dosing
 - Adjustment for age and renal/liver function
- Drug-drug interactions
- Drug-food interactions
- Other applicable risk factors

Element of Performance 1: Protocols for Anticoag Therapy

- Areas to cover
 - Acute care
 - Transitions of care
 - Ambulatory care
- Who is responsible?
 - MD
 - RN
 - Pharmacist
- Multidisciplinary Oversight Group
 - P&T committee?
 - Physician & Pharmacists

Element of Performance 1: Protocols for Anticoag Therapy

- Initiation (Hospital and Ambulatory)
 - Indications & Contraindications
 - Baseline renal & liver function assessment
 - Screen for drug-drug interactions
 - Protocol for dosing
- Follow up (Ambulatory)
 - Need for continued anticoagulation (VTE)?
 - Renal and Liver function (frequency?)
 - Drug-drug interactions
 - Bleeding risk

Element of Performance 2: Protocols for Bleeding Management

- Different reversal mechanisms
 - Heparin
 - Warfarin
 - Dabigatran
 - Apixaban, Rivaroxaban, Edoxaban, Betrixaban
- Assess severity of bleeding
- Select appropriate therapy
 - Stop anticoagulant
 - Use of clotting factors
 - Use of specific reversal agent

Element of Performance 2: Protocols for Bleeding Management

- Order sets & Decision-support tools
- Labs for DOAC-related bleeding management
- Guidance for managing high INR without bleeding (warfarin)

Element of Performance 2: Protocols for Bleeding Management

- Anticoagulation Reversal
 - Vitamin K protocol for high INR if no bleeding (outpatient)
 - Reversal strategy for warfarin, Factor Xa inhibitor, Direct Thrombin Inhibitor (hospital/ED)
- Management of Bleeding
 - Patient education on nuisance bleeding (outpatient)
 - Nose bleeding
 - Bruising

Element of Performance 3: Protocols for Periop Management

Address the following issues:

- Should anticoagulant be stopped?
- Need for bridging anticoagulation (warfarin)
- When to stop
- When to restart
- What dose to restart

Element of Performance 3: Protocols for Periop Management

- Need for bridging anticoagulation
 - Very few warfarin patients (<10%?)
- Use visual tools
 - What day to take/not take medication
- Neuraxial anesthesia
 - When to stop anticoagulation pre-procedure?

Element of Performance 3: Protocols for Periop Management

- Interruption – Yes/No?
 - Dental, dermatologic, endoscopic → No
- When to stop anticoag pre-procedure
 - Warfarin → 5 days
 - DOAC → 2-3 days for most
- When to restart
 - Usually defer to procedural team
- What dose to restart
 - DOAC is effective within 1-3 hours
 - Warfarin takes 5-10 days
- Is bridging necessary?
 - DOAC → never
 - Warfarin → few patients

Element of Performance 4: Policy for Laboratory Testing

Address the following issues:

- Baseline and follow up labs
 - INR (warfarin)
 - Renal/Liver function (DOAC)
- When and how to adjust dose

Element of Performance 4: Policy for Laboratory Testing

- Clinical staff
 - When to check labs
 - Which labs to check
- Include laboratory staff on development team
- Baseline labs
 - Rule out coagulopathy
 - Select best anticoagulant & dose
 - CBC, PT/INR, PTT, Creatinine

Element of Performance 4: Policy for Laboratory Testing

- Hospital Protocol
 - Renal function at baseline (DOAC)
 - INR at baseline (warfarin)
- Ambulatory Protocol
 - Check INR goal (most 2-3 or 2.5-3.5)
 - INR-based dosing algorithm
 - Standardize INR documentation process

Element of Performance 5: Adverse Drug Events

Address the following issues:

- Establish a process to identify, respond to, and report ADEs
- Evaluate & take action around safety practices in a timely manner

Element of Performance 5: Adverse Drug Events

- Identify responsible individual(s)/teams
 - Review ADE case
 - Assess for patterns and gaps in care
 - Facilitate change

Element of Performance 6: Patient/Family Education

Address the following issues:

- Importance of medication adherence
 - Dose and schedule
- Importance of follow up appointments/labs
- Potential drug-drug & drug-food interactions
- Potential adverse drug reactions
 - Bleeding (especially minor)

Element of Performance 6: Patient/Family Education

- Provide key information
 - Contact for anticoagulation clinic/provider
 - “Emergencies” vs. “non-emergencies”
- Use teach back with patient/family
 - Confirm understanding
- Consider group education

Element of Performance 6: Patient/Family Education

- Documentation
 - What was taught
 - How it was taught (handout, teachback, group session)
 - When it was given

Element of Performance 7: Hospital Med Delivery

Use only the following (when available):

- Oral unit-dose products
- Prefilled syringes
- Premixed infusion bags

Note: Unchanged from prior version

Element of Performance 7: Hospital Med Delivery

- Develop a process for potential drug shortages
- Avoid multiple concentrations of medication
- Note: pediatric pre-filled syringe must be specifically designed for children

Element of Performance 8: Hospital Med Delivery IV Heparin

Intravenous Heparin Administration:

- Use programmable pumps

Note: Unchanged from prior version

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Advice from Joint Commission

- Process > Content
 - Be sure you can follow protocols
- Documentation is critical
- Staff/Provider knowledge is key

Thank You!



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