27th HKCC Annual Scientific Congress
ACC-HKCC Joint Symposium: Advances in Cardiology

Latest Updates on Stroke Prevention in Atrial Fibrillation

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ACC/AHA/HRS: Focused Update on AF

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the Society of Thoracic Surgeons

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- **Twice annual review by the joint Taskforce on Practice Guidelines.**
- **Publication of RCTs or non-randomized trials with safety or efficacy implications.**
- **Approval of new drugs, devices or applications by FDA that have an impact on care**

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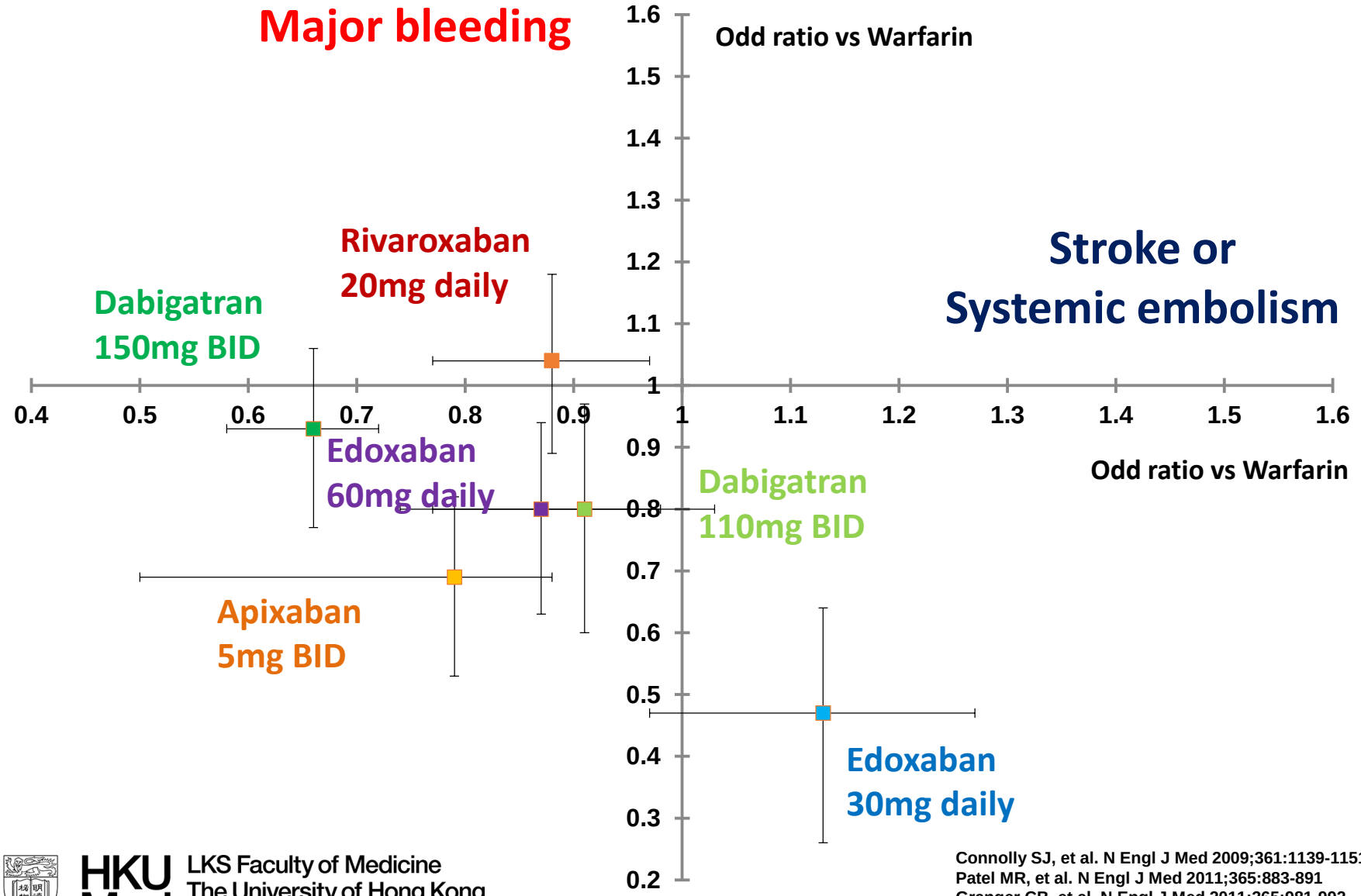
Recommendations for Selecting an Anticoagulant Regimen—Balancing Risks and Benefits
Referenced studies that support new or modified recommendations are summarized in Online Data Supplements 1 and 2.

COR	LOE	Recommendations
I	A	1. For patients with AF and an elevated CHA_2DS_2-VASc score of 2 or greater in men or 3 or greater in women, oral anticoagulants are recommended. Options include: • Warfarin (LOE: A) (S4.1.1-5–S4.1.1-7) • Dabigatran (LOE: B) (S4.1.1-8) • Rivaroxaban (LOE: B) (S4.1.1-9) • Apixaban (LOE: B) (S4.1.1-10), or • Edoxaban (LOE: B-R) (S4.1.1-11) **MODIFIED**: This recommendation has been updated in response to the approval of edoxaban, a new factor Xa inhibitor. More precision in the use of CHA_2DS_2-VASc scores is specified in subsequent recommendations. The LOEs for warfarin, dabigatran, rivaroxaban, and apixaban have not been updated for greater granularity as per the new LOE system. (Section 4.1. in the 2014 AF Guideline) The original text can be found in Section 4.1 of the 2014 AF guideline. Additional information about the comparative effectiveness and bleeding risk of NOACs can be found in Section 4.2.2.2.
	B	
	B	
	B-R	
I	A	2. NOACs (dabigatran, rivaroxaban, apixaban, and edoxaban) are recommended over warfarin in NOAC-eligible patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve) (S4.1.1-8–S4.1.1-11). **NEW**: Exclusion criteria are now defined as moderate-to-severe mitral stenosis or a mechanical heart valve. When the NOAC trials are considered as a group, the direct thrombin inhibitor and factor Xa inhibitors were at least noninferior and, in some trials, superior to warfarin for preventing stroke and systemic embolism and were associated with lower risks of serious bleeding.

Edoxaban is now included in the guideline as on the NOAC

NOACs are preferable over warfarin

Safety and Efficacy of NOACs in RCT



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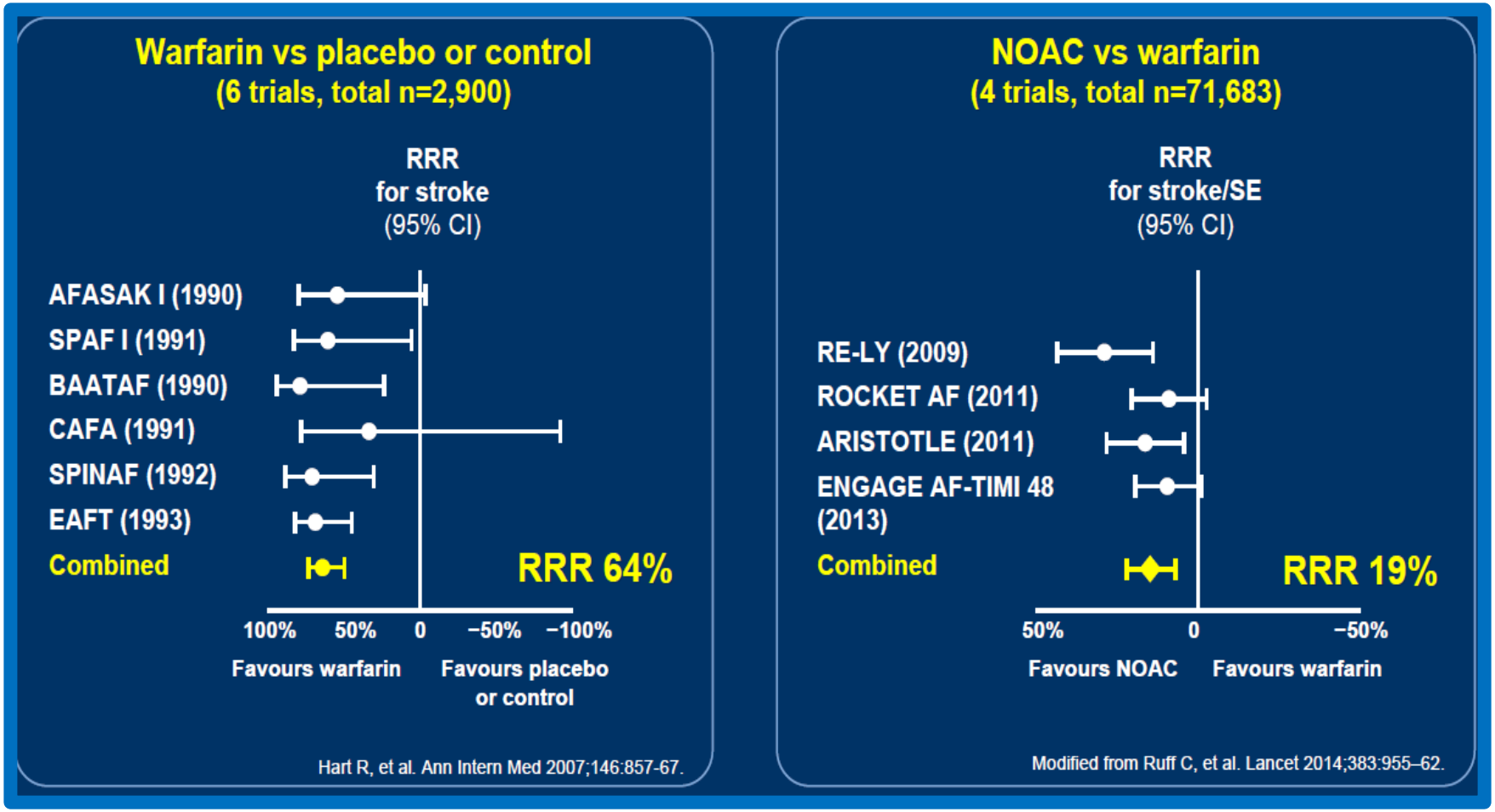
Connolly SJ, et al. N Engl J Med 2009;361:1139-1151
Patel MR, et al. N Engl J Med 2011;365:883-891
Granger CB, et al. N Engl J Med 2011;365:981-992
Giugliano RP, et al. N Engl J Med 2013; e-pub ahead of print
DOI:10.1056/NEJMoa1310907

Incremental Benefit of Stroke Prevention with NOAC vs VKA in NVAF



NVAF= Exclude mechanical heart valves and mod-severe mitral stenosis

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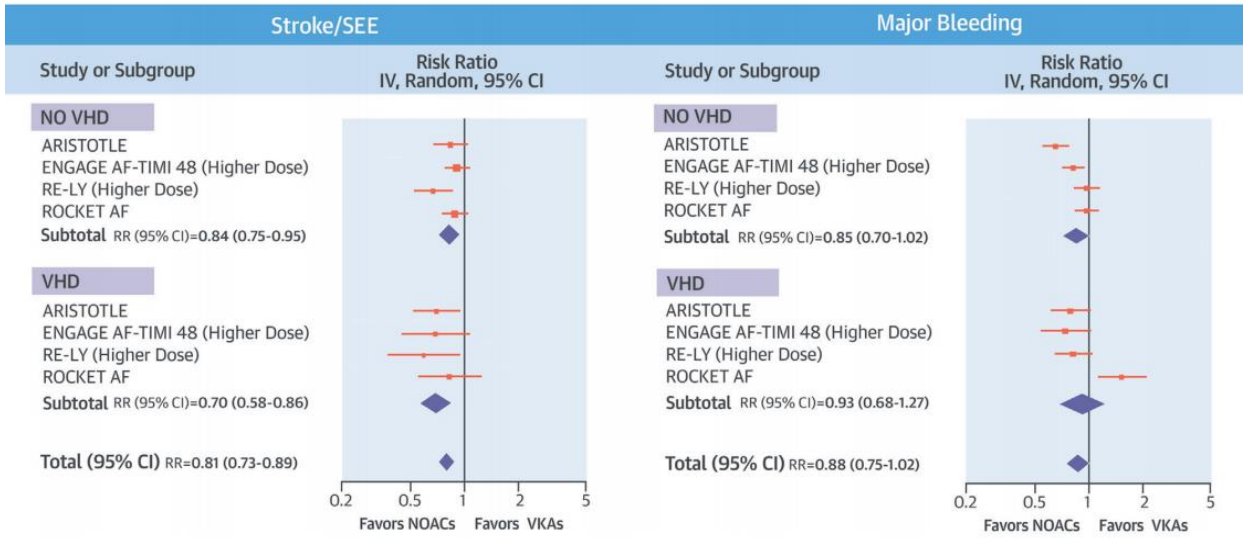
I	B	4. In patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve), the CHA_2DS_2-VASc score is recommended for assessment of stroke risk (S4.1.1-5–S4.1.1-7). **MODIFIED**: Exclusion criteria are now defined as moderate-to-severe mitral stenosis or a mechanical heart valve. Patients with AF with bioprosthetic heart valves are addressed in the supportive text. (Section 4.1. in the 2014 AF guideline)
I	B	5. For patients with AF who have mechanical heart valves, warfarin is recommended (S4.1.1-15–S4.1.1-19). **MODIFIED**: New information is included in the supportive text.



High-dose NOACs provide overall efficacy and safety similar in AF patients with or without VHD.

Renda G, et al. JACC 2017

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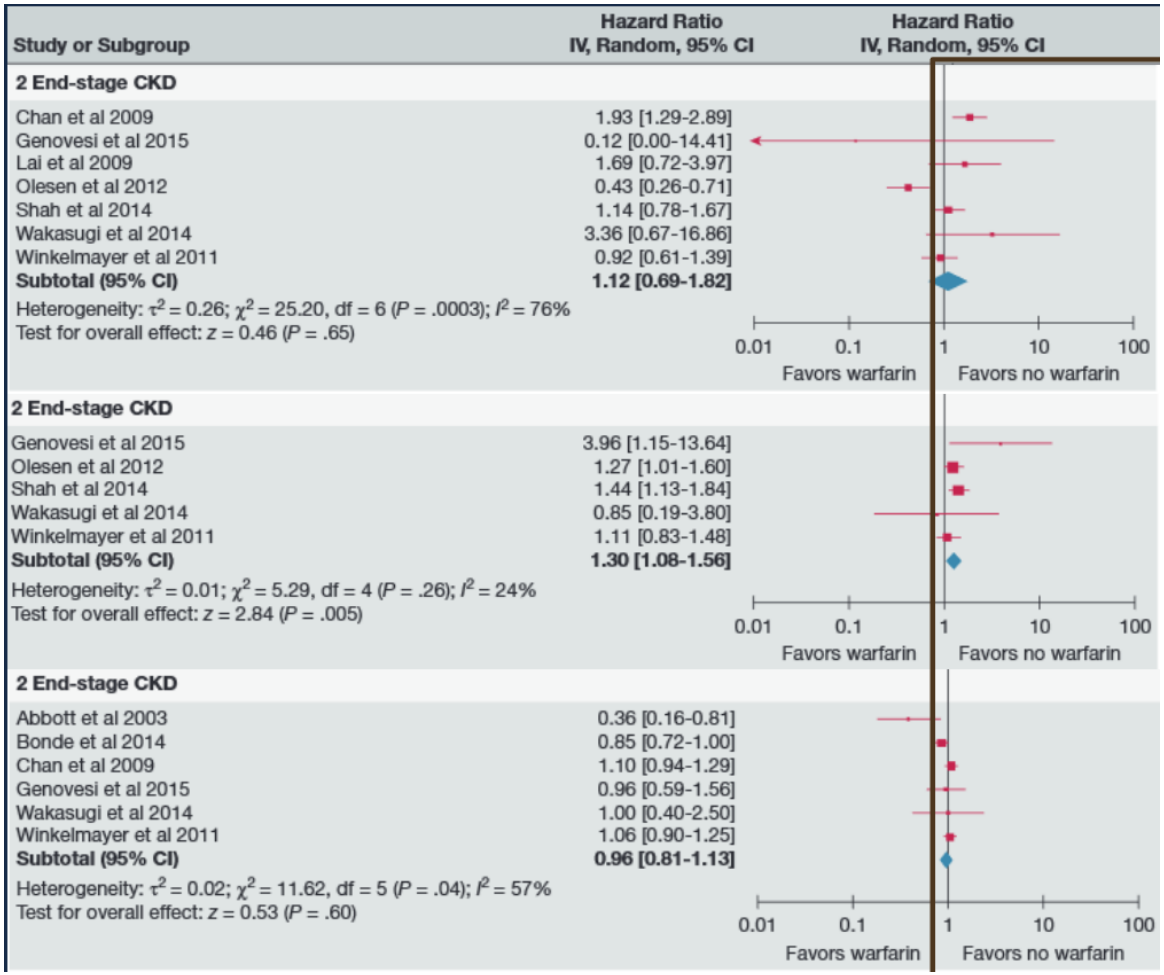
IIb	B-NR	13. For patients with AF who have a CHA_2DS_2-VASc score of 2 or greater in men or 3 or greater in women and who have end-stage chronic kidney disease (CKD; creatinine clearance [CrCl] <15 mL/min) or are on dialysis, it might be reasonable to prescribe warfarin (INR 2.0 to 3.0) or apixaban for oral anticoagulation (S4.1.1-26, S4.1.1-29, S4.1.1-30). **MODIFIED**: New evidence has been added. LOE was updated from B to B-NR. (Section 4.1. in the 2014 AF Guideline)

III: No Benefit	C-EO	16. In patients with AF and end-stage CKD or on dialysis, the direct thrombin inhibitor dabigatran or the factor Xa inhibitors rivaroxaban or edoxaban are not recommended because of the lack of evidence from clinical trials that benefit exceeds risk (S4.1.1-8–S4.1.1-11, S4.1.1-36–S4.1.1-38). **MODIFIED**: New data have been included. Edoxaban received FDA approval and has been added to the recommendation. LOE was updated from C to C-EO. (Section 4.1. in the 2014 AF Guideline)

Warfarin Use in AF with ESRD



Ischemic Stroke/TE:
Warfarin had no effect (HR 1.12; 95% CI 0.69-1.84, P=0.65)

Major Bleeding:
Warfarin increased the risks of major bleeding (HR 1.30; 95% CI 1.08-1.56, P=0.005)

Mortality:
Warfarin had no effect on mortality (HR 0.96; 95% CI 0.81-1.13, P=0.6)

Dahal K, et al. Chest 2016

Efficacy and Safety Profiles of NOACs: Renal Impairment

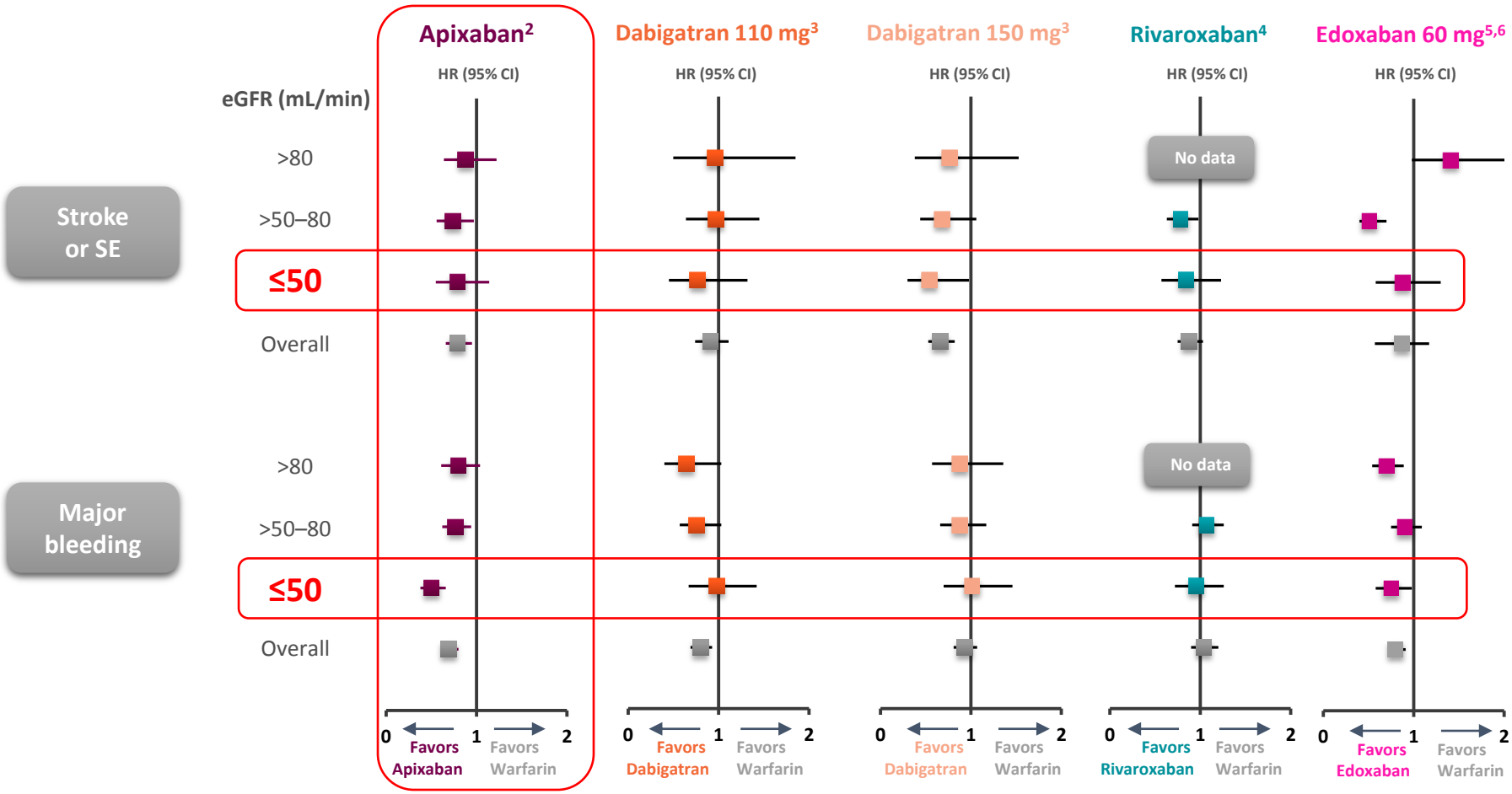


Figure created using the data from the references

There are no head-to-head trials comparing NOACs

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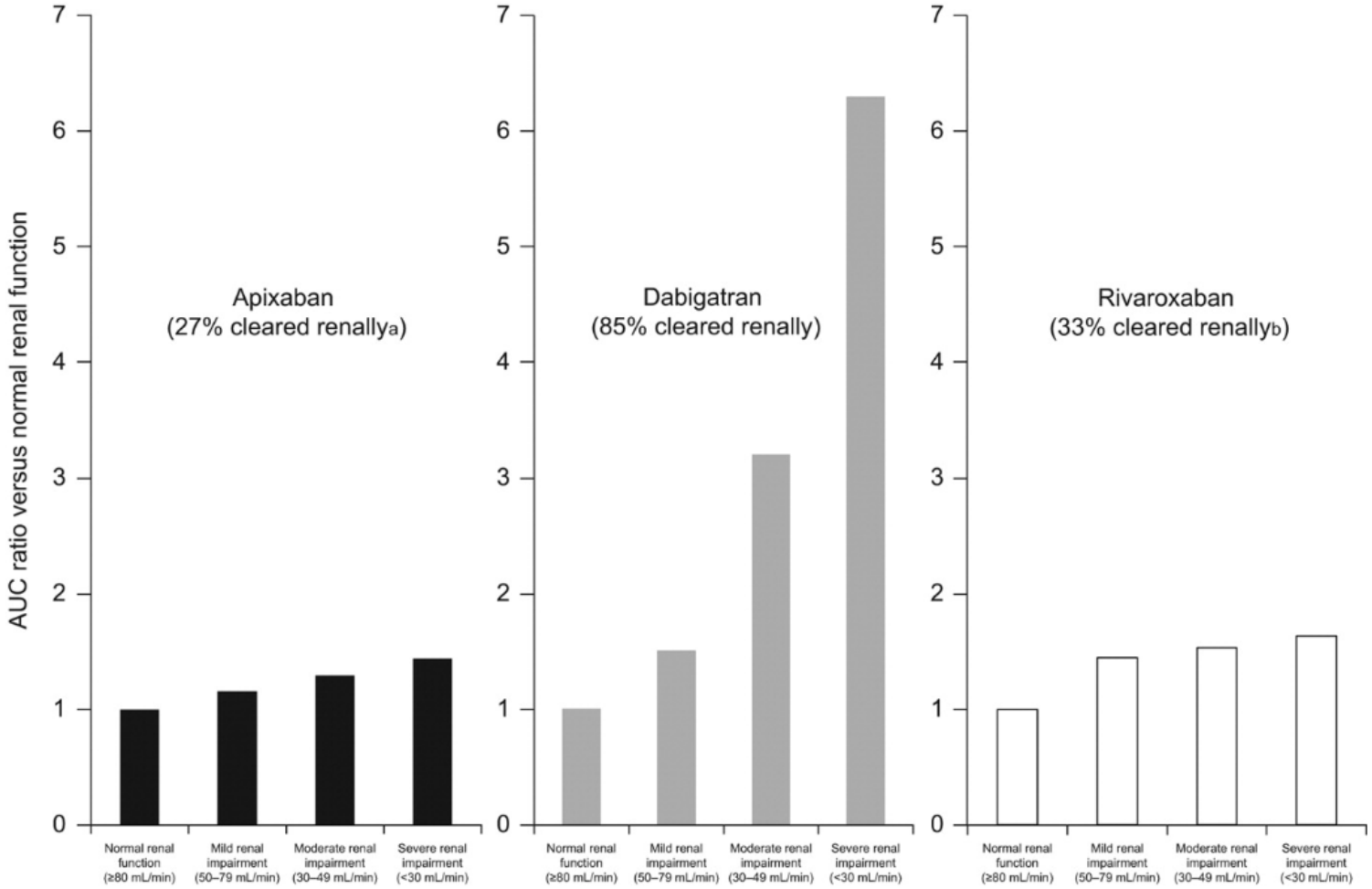
eGFR=estimated glomerular filtration rate.

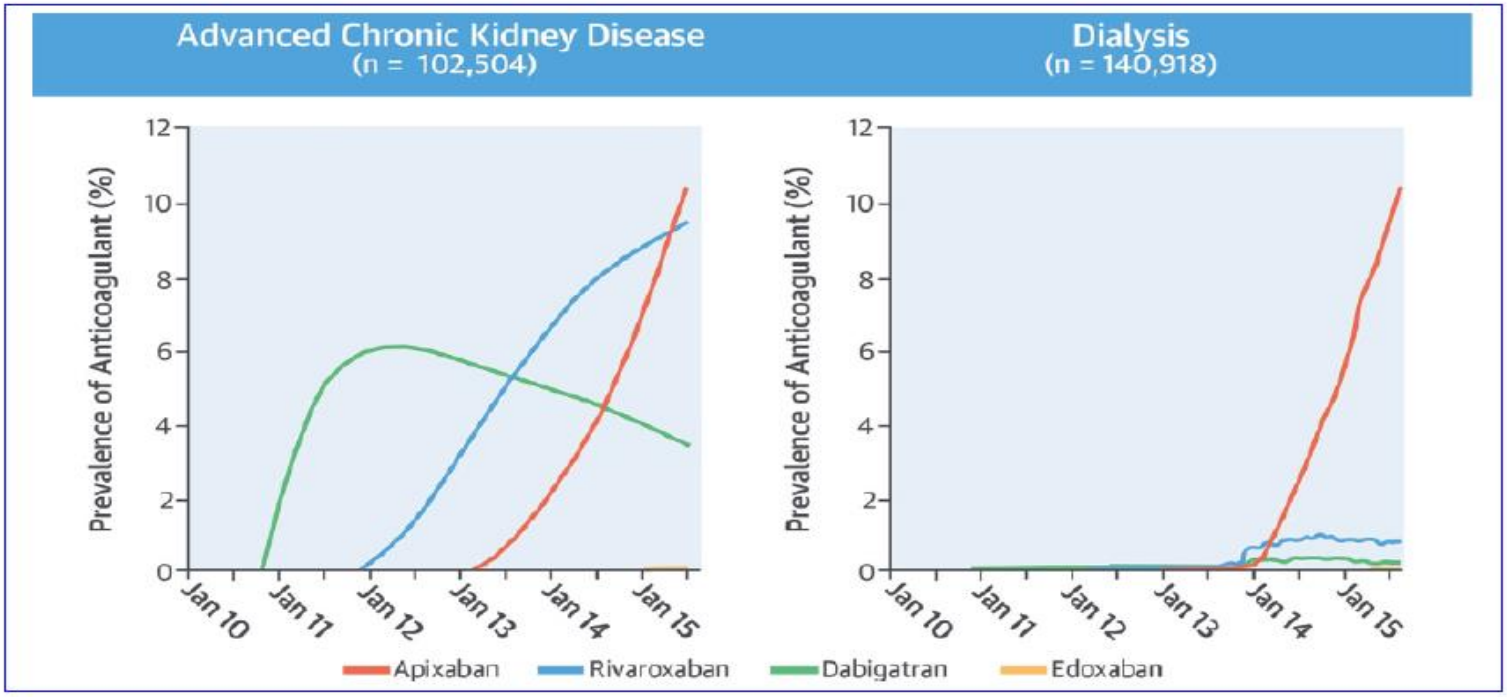
1. Capranzano P et al. *Expert Rev Cardiovasc Ther.* 2013;11:959-973; 2. Granger CB et al. *N Engl J Med.* 2011;365:981-992; 3. Connolly SJ et al. *N Engl J Med.* 2009;361:1139-1151; 4. Patel MR et al. *N Engl J Med.* 2011;365(10):883-891; 5. Giugliano RP et al. *N Engl J Med*; 2013;369: 2093-2104; 6.Edoxaban Prescribing Information. 2015.

Renal Clearance of NOAC in Patient with Renal Impairment



Cox JL. Ann Med 2015

NOAC in Patients with Advanced CKD or Dialysis



Advanced CKD: CrCl < 30 m1/min

- **>25000 patients with AF, Medicare**
- **Real-world AF pts with ESRD**
- **Standard dose of apixaban 5mg BD) is associated with lower risks of stroke and death vs, reduce dose apixaban or warfarin**

Chan KE, et al. JACC 2016
Siontis KC, et al. Circulation 2018

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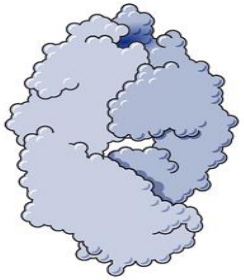
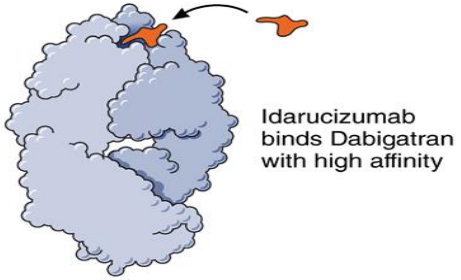
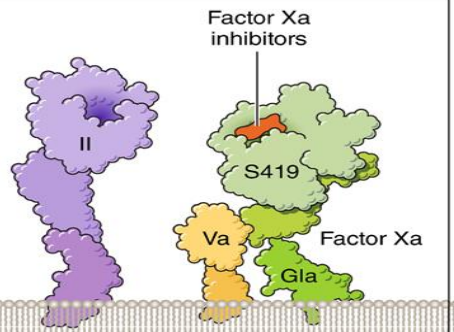
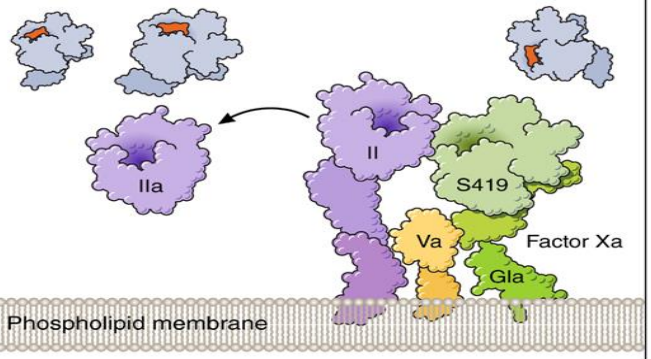
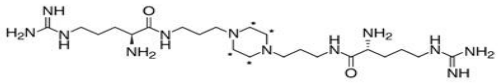
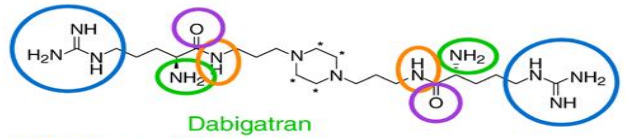
Recommendations for Interruption and Bridging Anticoagulation Referenced studies that support new or modified recommendations are summarized in Online Data Supplement 3.		
COR	**LOE**	**Recommendations**
I	C	**1. Bridging therapy with unfractionated heparin or low-molecular-weight heparin is recommended for patients with AF and a mechanical heart valve undergoing procedures that require interruption of warfarin. Decisions on bridging therapy should balance the risks of stroke and bleeding.**
I	B-R	**2. For patients with AF without mechanical heart valves who require interruption of warfarin for procedures, decisions about bridging therapy (unfractionated heparin or low-molecular-weight heparin) should balance the risks of stroke and bleeding and the duration of time a patient will not be anticoagulated (S4.3-1).** **MODIFIED**: LOE was updated from C to B-R because of new evidence. (Section 4.1. in the 2014 AF Guideline)
I	B-NR	**3. Idarucizumab is recommended for the reversal of dabigatran in the event of life-threatening bleeding or an urgent procedure (S4.3-2).** **NEW**: New evidence has been published about idarucizumab to support LOE B-NR.
IIa	B-NR	**4. Andexanet alfa can be useful for the reversal of rivaroxaban and apixaban in the event of life-threatening or uncontrolled bleeding (S4.3-3, S4.3-4).** **NEW**: New evidence has been published about andexanet alfa to support LOE B-NR.

Reversal Agents for NOACs

NOAC reversal agent	Target	Mechanism
 Idarucizumab	 Dabigatran	 Idarucizumab binds Dabigatran with high affinity
 Andexanet alpha	 Factor Xa inhibitors; II; S419; Va; Factor Xa; Gla	 IIa; II; S419; Va; Factor Xa; Gla; Phospholipid membrane
 Ciraparantag (PER977)	Apixaban Argatroban Edoxaban Dabigatran Rivaroxaban UFH LMWH Fondaparinux	 Edoxaban Dabigatran Rivaroxaban UFH/LMWH Fondaparinux; Dabigatran Rivaroxaban Apixaban Argatroban UFH/LMWH Fondaparinux; Dabigatran Rivaroxaban UFH/LMWH Fondaparinux; Edoxaban Apixaban Computer-aided energy minimization modeling predicts 8 non-covalent binding sites on ciraparantag for NOACs or heparins

Ruff et al. Circulation 2016

Reversal Agents for NOACs

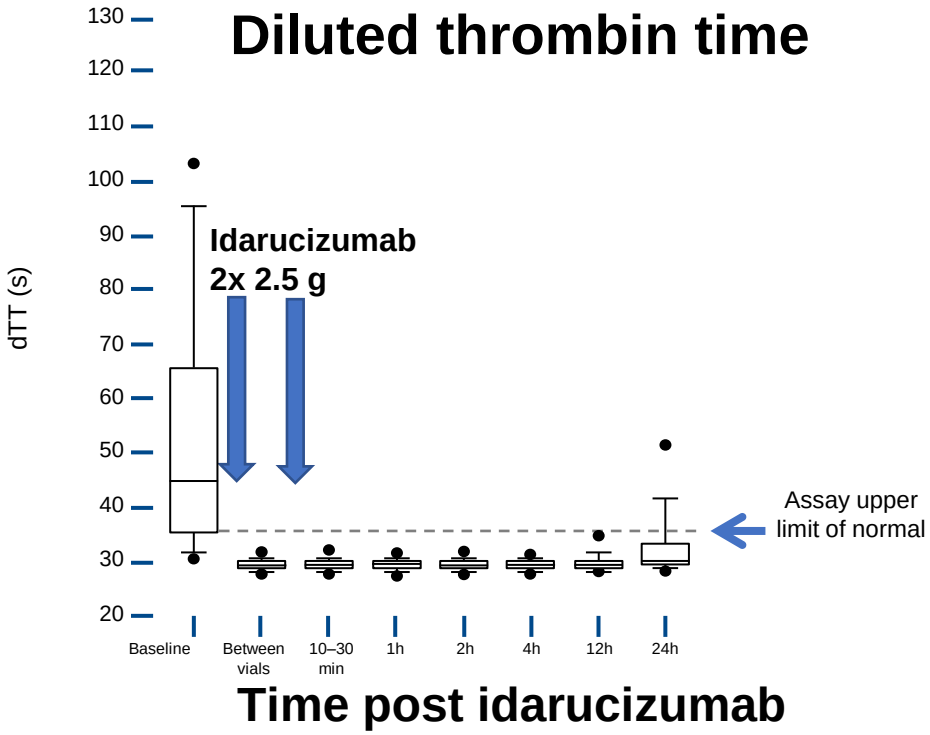
	Idaracizumab	Andexanet alfa	Ciraparantag
Alternate names	aDabi-Fab, BI655075	PRT064445	Aripazine, PER977
Company	Boehringer Ingelheim	Portola Pharmaceuticals	Perosphere Inc.
Chemical structure	Humanized monoclonal antibody fragment	Recombinant truncated human factor Xa variant (decoy)	Synthetic water-soluble cationic small molecule consisting of 2 L-arginine units connected with a piperazine-containing linker chain
Molecular mass	47 766 Da	39 000 Da	512 Da
Binding	Noncompetitive binding to dabigatran	Competitive binding to direct factor Xa inhibitors or to indirect factor Xa inhibitor–activated antithrombin	Covalent hydrogen bonding
Target affinity	≈350× greater affinity for dabigatran than factor IIa	Affinity for direct factor Xa inhibitors similar to that of native factor Xa	Not reported
Onset	<5 min	2 min	5–10 min
Half-life	Initial: 47 min	Terminal: ≈6 h	Duration of action 24 h
	Terminal: 10.3 h		
Elimination	Kidney (protein catabolism)	Not reported	Not reported
Anticoagulant(s) reversed	Dabigatran	Direct and indirect factor Xa inhibitors*	Dabigatran
			Argatroban
			Low-molecular-weight heparins
			Unfractionated heparin
			Oral and parenteral factor Xa inhibitors
Route and dose in clinical studies	5 g administered as 2 doses of 2.5 g IV over 5–10 min, 15 min apart (repeat dosing can be considered if recurrent bleeding or require second emergent procedure if elevated coagulation parameters)	400–800 mg intravenous bolus (30 mg/min) followed by infusion of 4–8 mg/min†	100–300 mg intravenous bolus
Storage	Refrigerated	Refrigerated	Room temperature

Ruff et al. Circulation 2016

Reversal Agents for NOACs

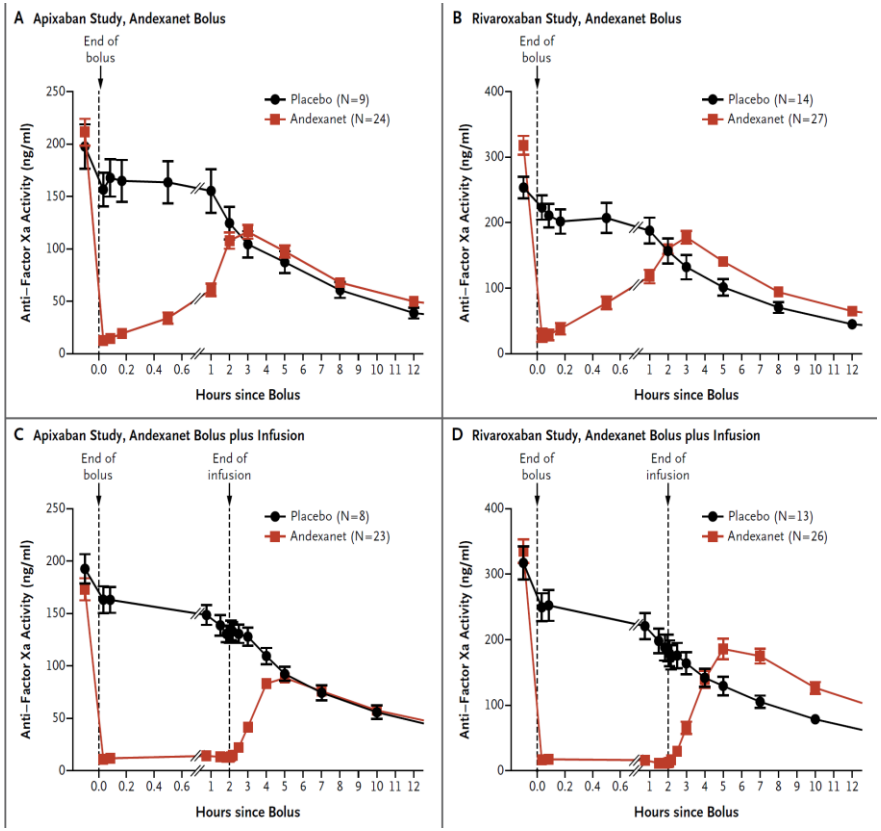
Idarucizumab

Reversal of dabigatran



Andexenet apla

Reversal of Xa



Pollack C, et al. NEJM 2015; 373: 511-520

Siegal DM, et al. *NEJM* 2015

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Recommendation for Percutaneous Approaches to Occlude the LAA

Referenced studies that support the new recommendation are summarized in Online Data Supplement 4.

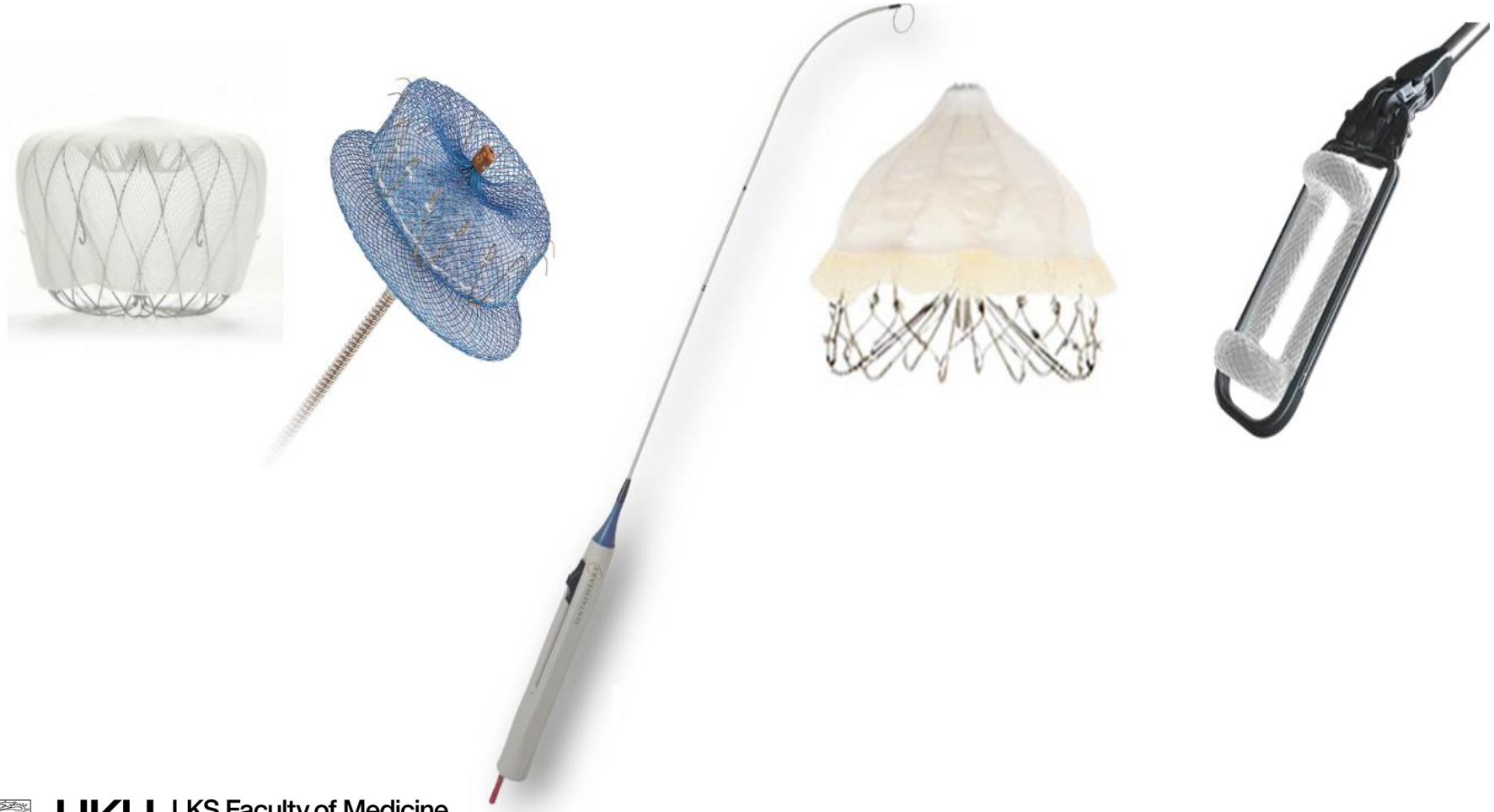
COR	LOE	Recommendation
IIb	B-NR	**1. Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (S4.4.1-1–S4.4.1-5).** **NEW**: Clinical trial data and FDA approval of the Watchman device necessitated this recommendation.

Recommendation for Cardiac Surgery—LAA Occlusion/Excision

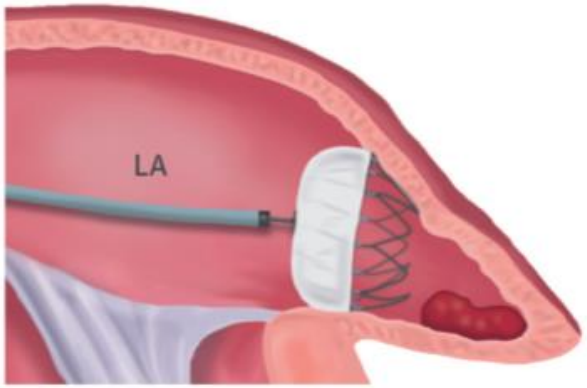
Referenced studies that support the modified recommendation are summarized in Online Data Supplement 5.

COR	LOE	Recommendation
IIb	B-NR	**1. Surgical occlusion of the LAA may be considered in patients with AF undergoing cardiac surgery (S4.4.2-1), as a component of an overall heart team approach to the management of AF.** **MODIFIED**: LOE was updated from C to B-NR because of new evidence.

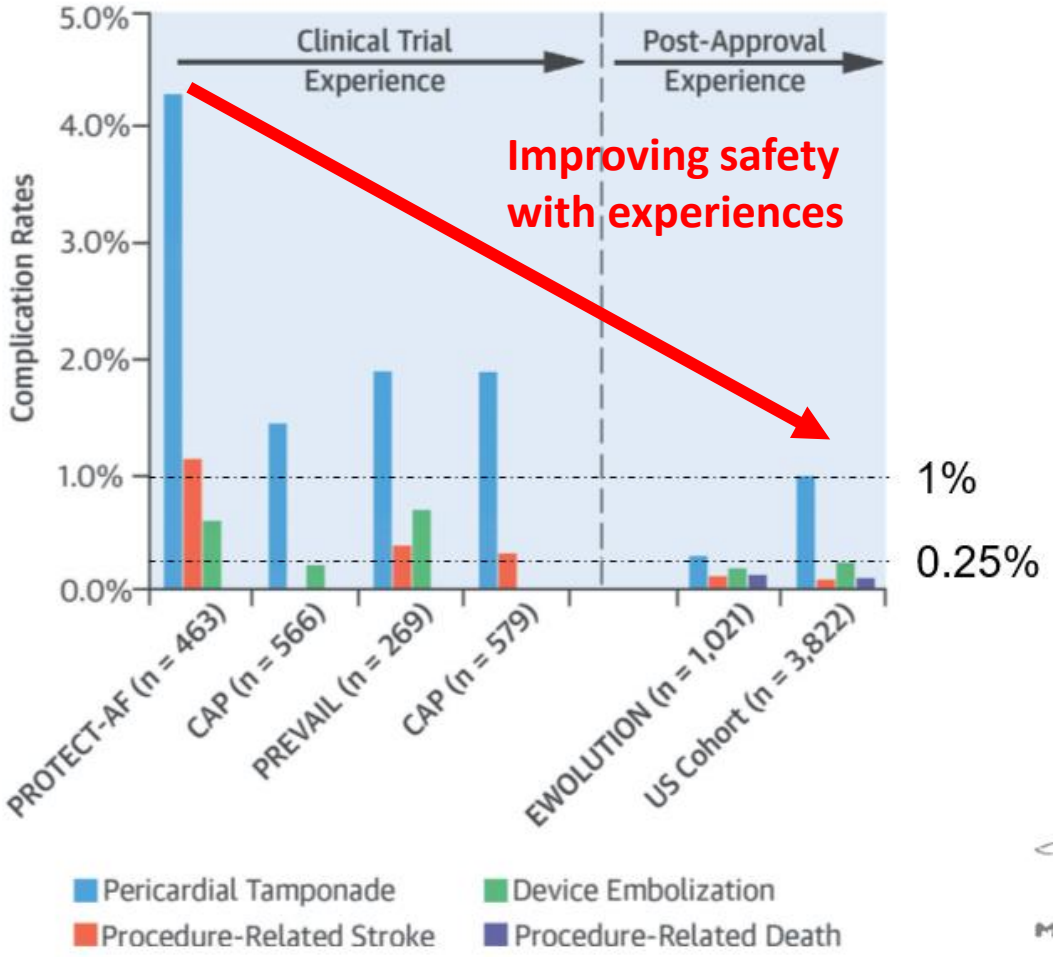
Percutaneous LAAO Device



Safety of LAAO



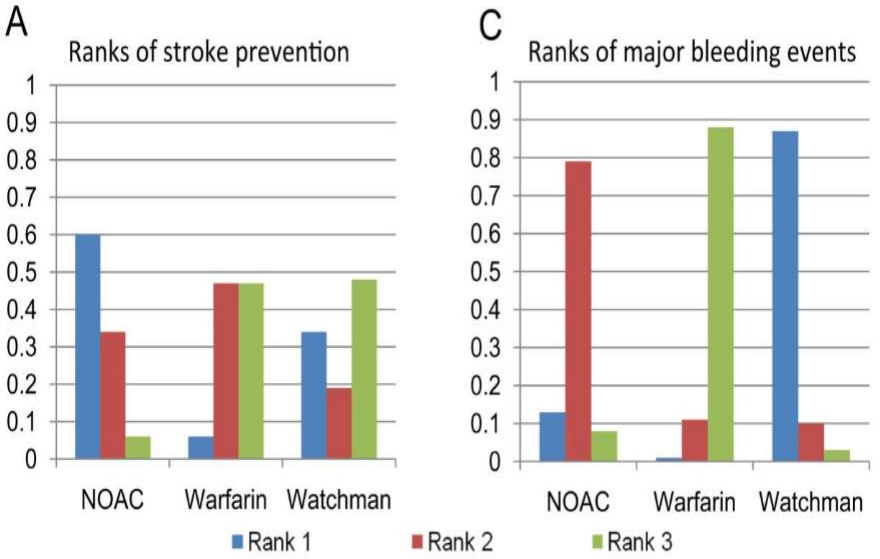
Procedural Parameters	Aggregate Clinical Data
Number of Procedures	6,720
Implantation Success, %	94.9%
Complication Rates	
Pericardial Tamponade	1.24%
Procedure-Related Stroke	0.18%
Device Embolization	0.25%
Procedure-Related Death	0.06%



VY.Reddy, et al, J Am Coll Cardiol 69:253–61 (2017)

Efficacy of LAAO

LAAO- More safe but less efficacy in high risk population



B

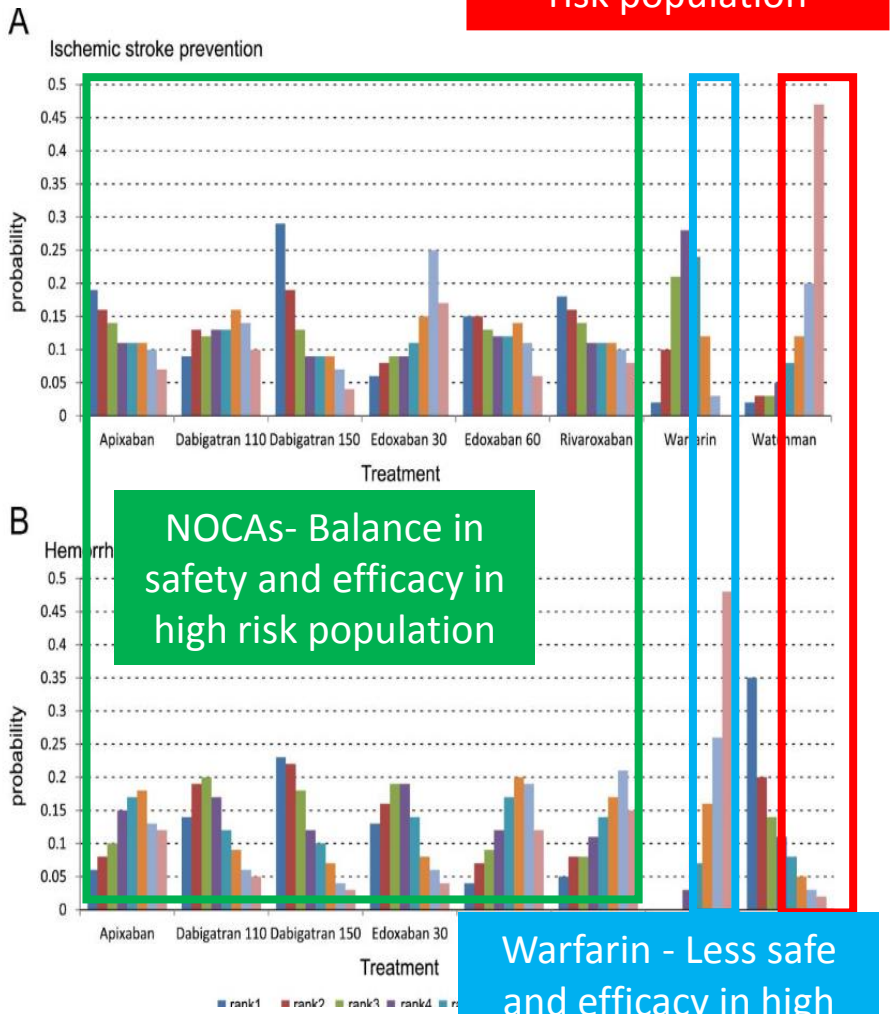
ORs of stroke prevention

NOAC	**1.17** (0.85,1.67)	**1.16** (0.57,2.97)
0.86 (0.60,1.18)	Warfarin	**0.99** (0.52,2.28)
0.86 (0.34,1.75)	**1.01** (0.44,1.94)	Watchman

D

ORs of major bleeding events

NOAC	**1.27** (0.84,1.88)	**0.66** (0.29,1.45)
0.79 (0.53,1.19)	Warfarin	**0.52** (0.26, 1.06)
1.52 (0.69,3.42)	**1.93** (0.94,3.89)	Watchman



NOCAs- Balance in safety and efficacy in high risk population

Warfarin - Less safe and efficacy in high risk population

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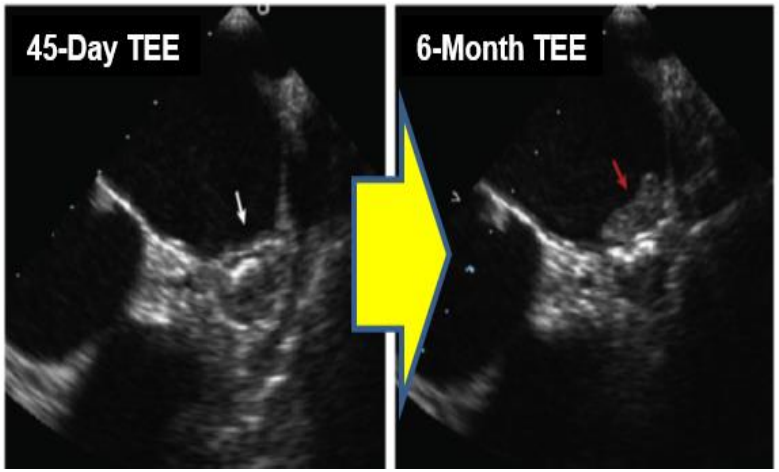
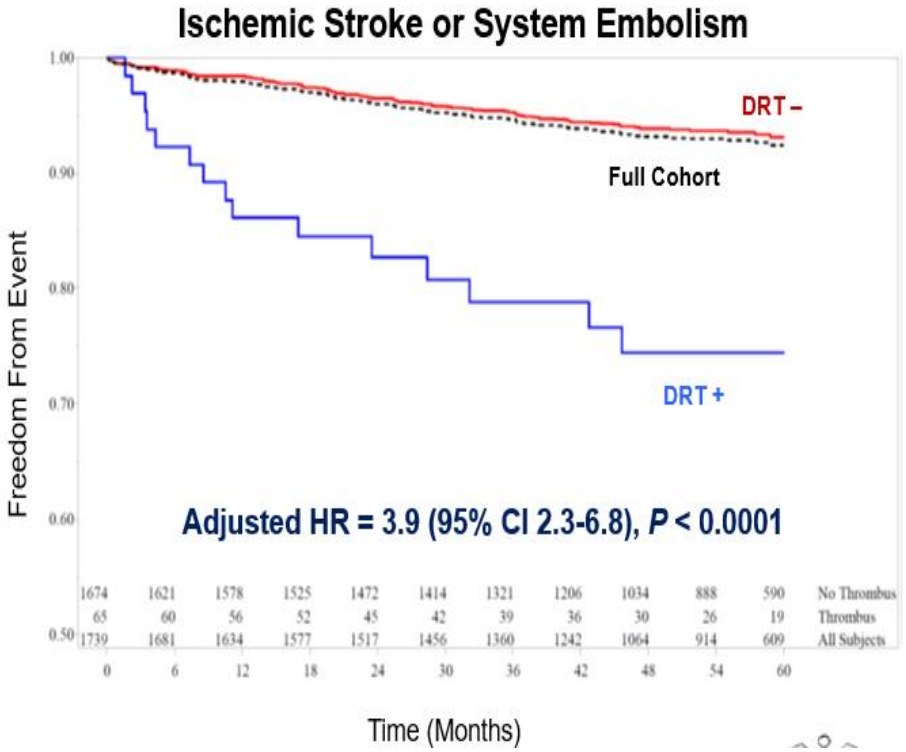
Li et al. Heart Rhythm 2016

Device-Related Thrombus after LAAO

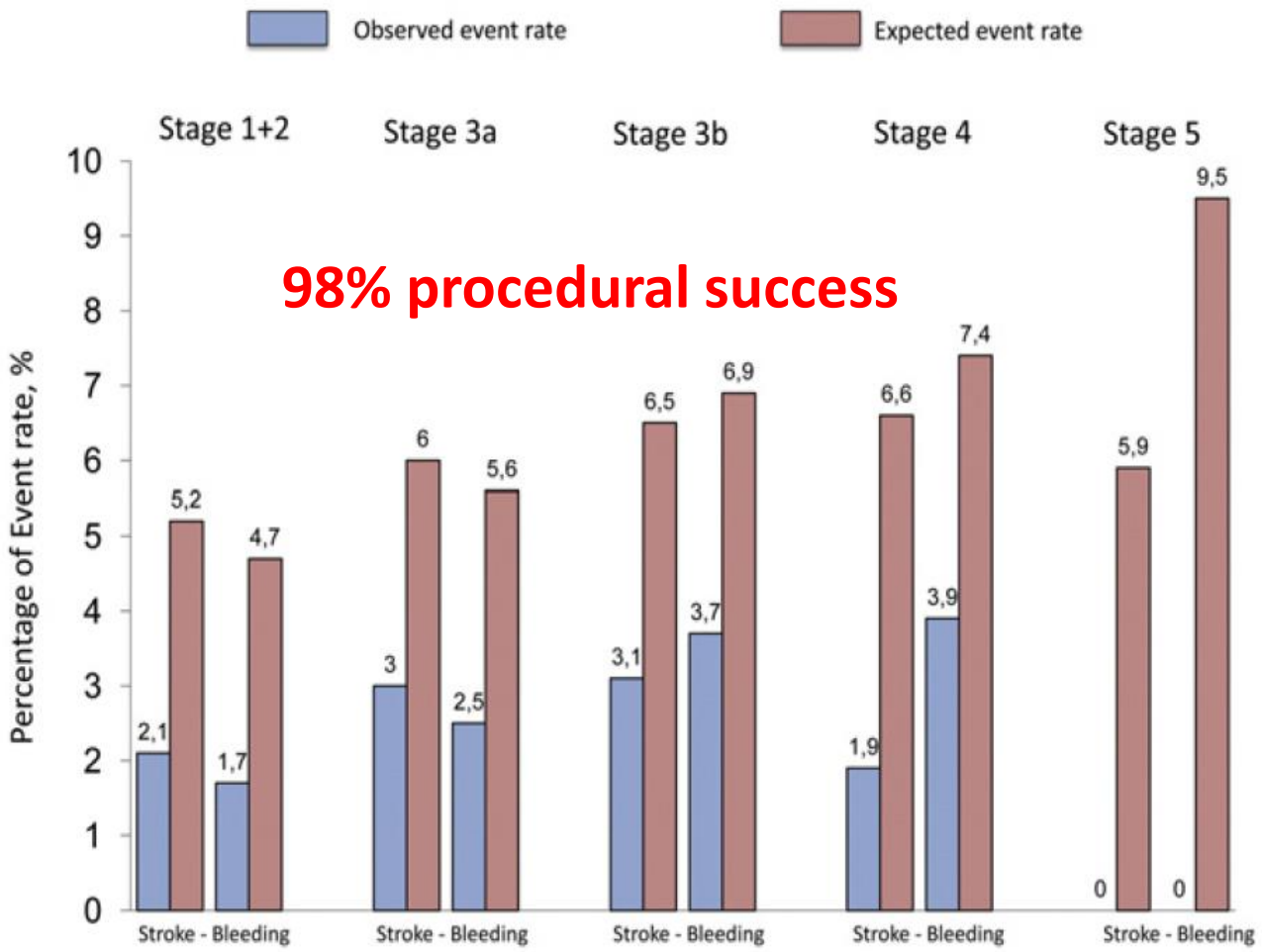
- Watchman Implants from 4 FDA Trials
- Patient Cohort: 1,739 pts (7,159 pt-yrs)
  - Mean age: 73.8±8.4 yrs (34% women)
  - CHA_2DS_2-VASc=4.0 ± 1.5 & HAS-BLED=2.0±1.0
  - 28% Hx Stroke/TIA

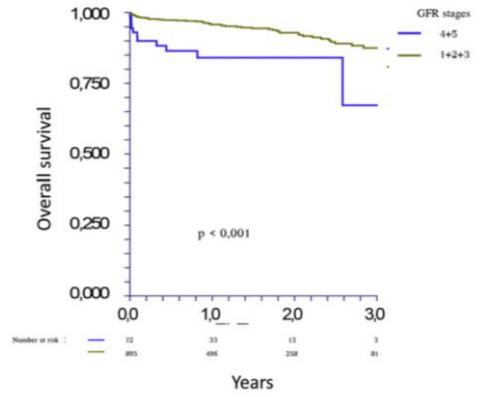


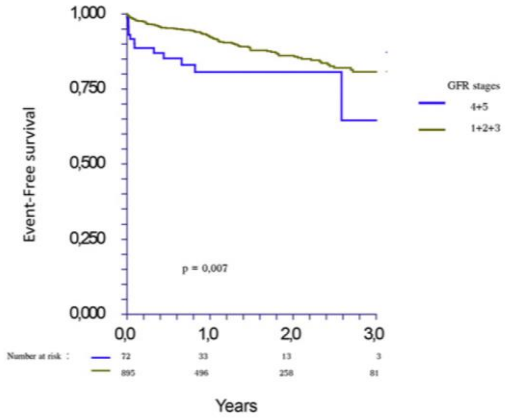


Dukkipati S, et al. Circulation 2018

LAAO in Patients with ESRD







LAAO offers a reduction of stroke/TIA and bleeding rate in all stages of CKD

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Kefer J, et al. Int J Cardiol 2016

LAAO in Patients with ESRD

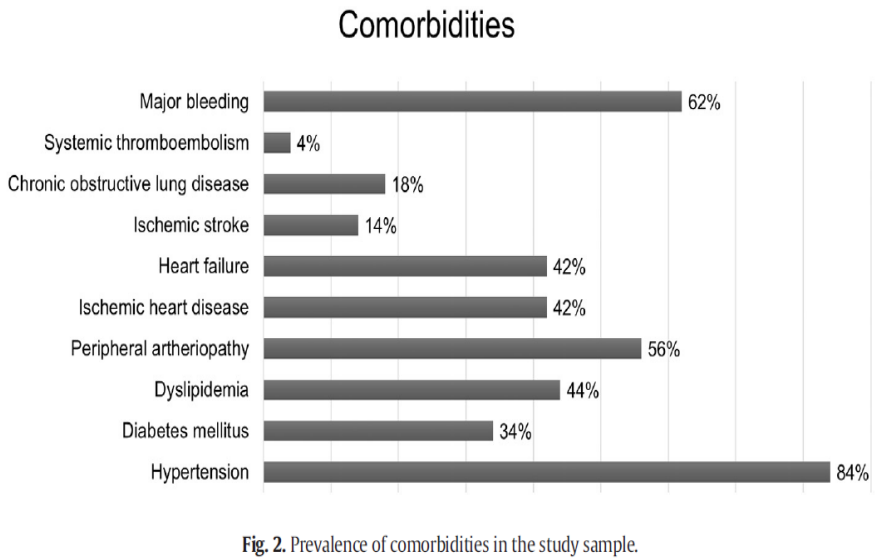
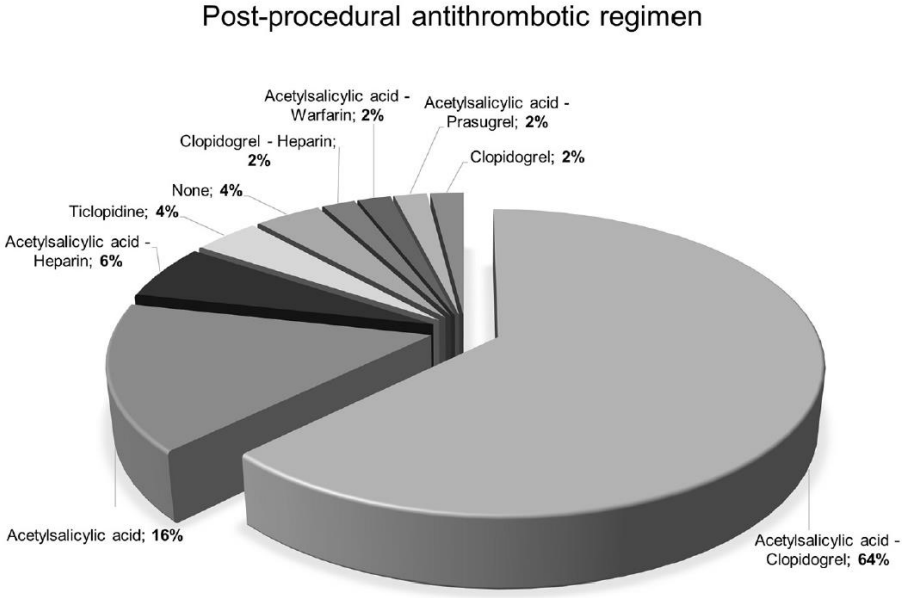


Fig. 2. Prevalence of comorbidities in the study sample.



- **50 pts on HD underwent LAA occlusion between 2014-2017**
- **All devices were implanted successfully.**
- **No deaths or major adverse events were reported during a 30-day FU.**
- **Our preliminary data suggest the feasibility and safety of LAAO in HD pts.**

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Genoversi S, et al. Int J Cardiol 2018

LAAO in Patients with ICH

Table 2 Initiation of anticoagulation prior to device implantation

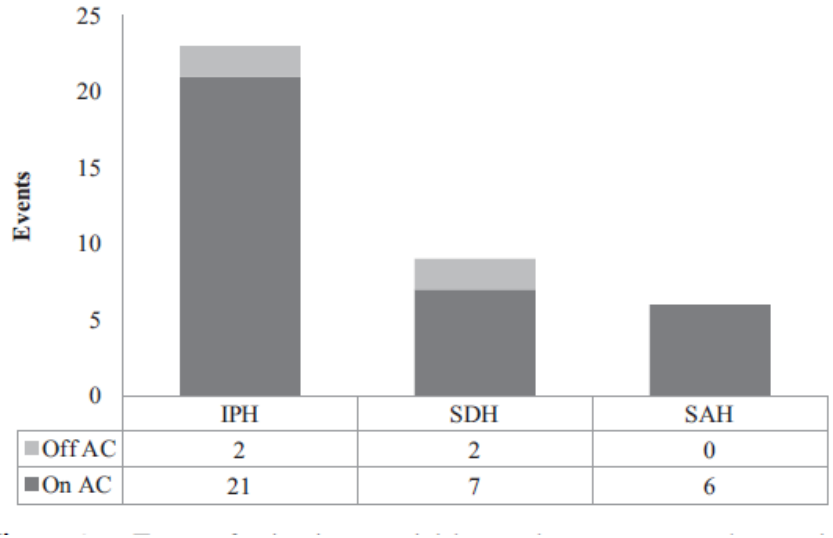
AC initiation prior to procedure	n (%)
>1 month prior to procedure	14 (37)
1 month prior to procedure	7 (18)
7–30 days prior to procedure	4 (11)
3–7 days prior to procedure	4 (11)
1–2 days prior to procedure	9 (23)

AC = anticoagulation.

Table 3 Outcomes of study population

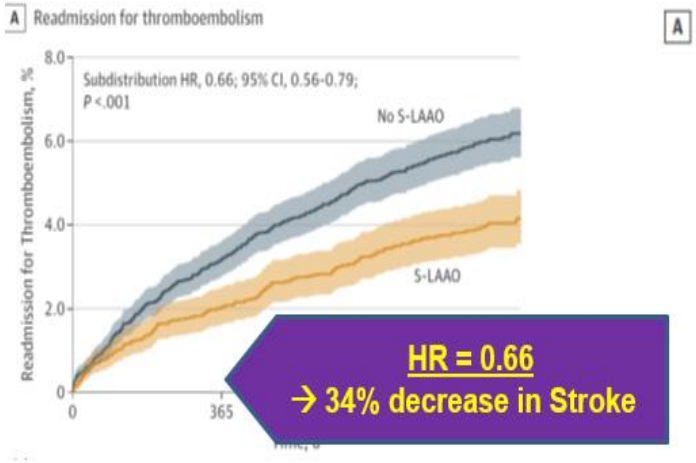
Outcome	No. of events
Minor bleeding	1 (traumatic hematoma of lower extremity)
Major bleeding	0
Device-related thrombosis	1 (filamentous material, resolved with longer AC)
Peridevice leak >5 mm	0
Stroke	0
Death	0

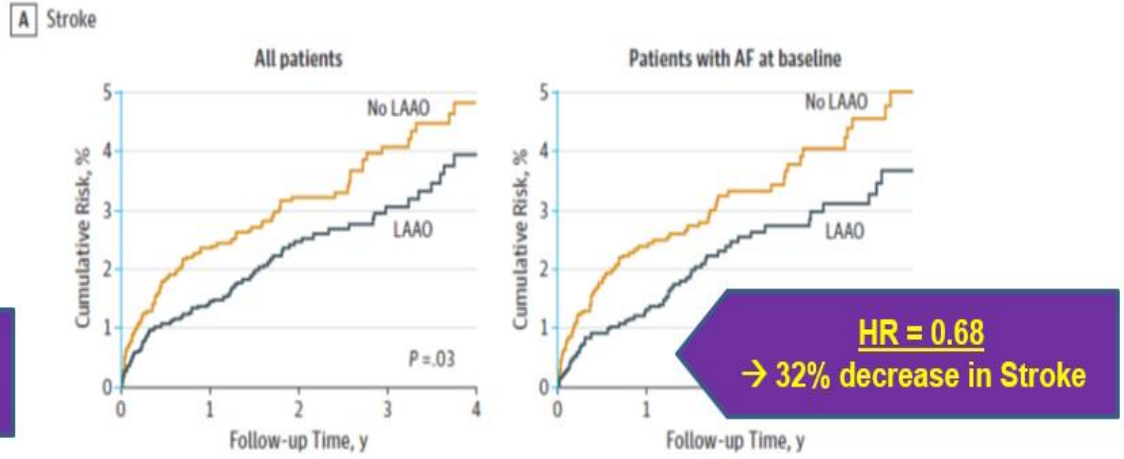
- 38 pts on ICH underwent LAA
- All devices were implanted successfully.
- Short-term OAC seems to be safe and effective after LAAO

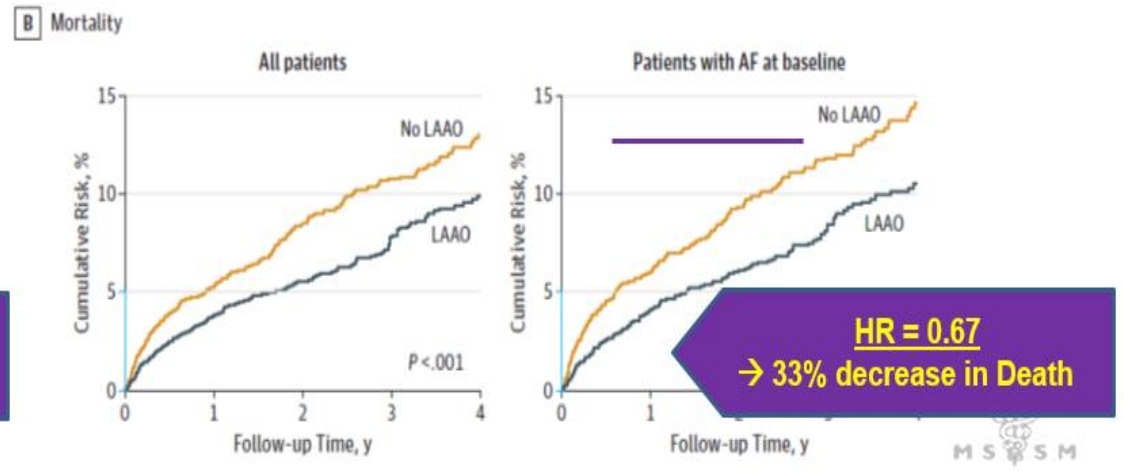


Hutt E, et al. Heart Rhythm 2019

Concomitant Surgical LAAC







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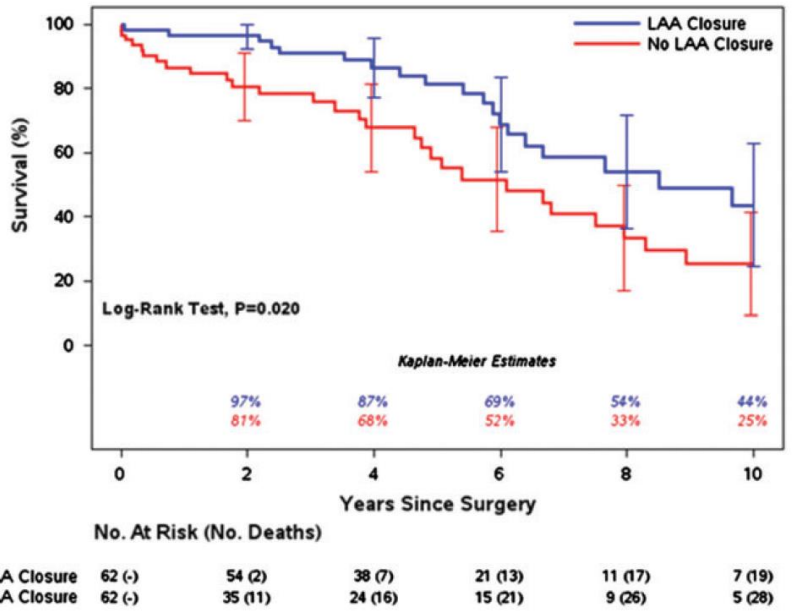
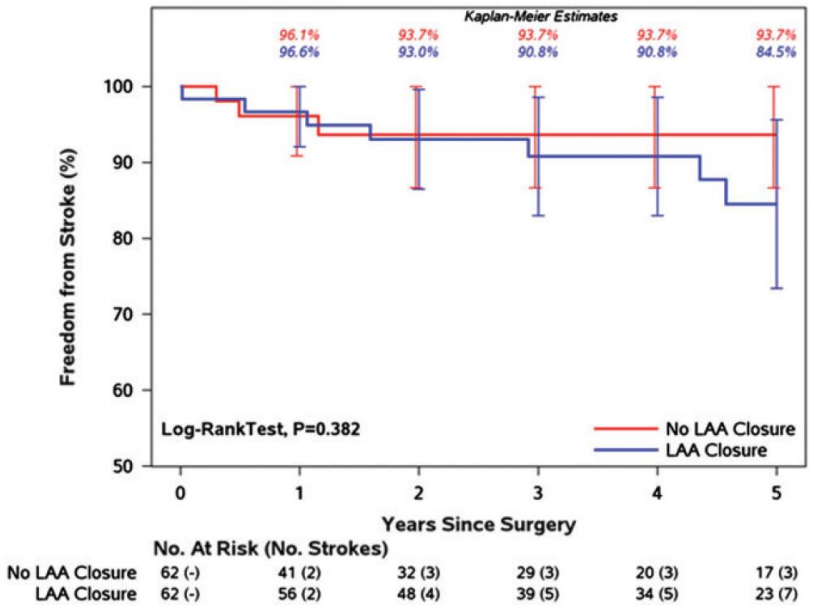
DJ.Friedman, JP.Piccini, T.Wang et al, *JAMA* 319:365-374 (2018)
X.Yao, BJ.Gersh, DR.Holmes et al, *JAMA* 319:2116-2126 (2018)

Use of OAC after Surgical LAAC





Variable	Model 1HR (95% CI)	P	Model 2HR (95% CI)	P
LAA closure, case:control	2.02 (0.61, 6.70)	0.250	1.95 (0.58, 6.52)	0.277
OAC at discharge, yes:no	0.19 (0.06, 0.59)	0.004	0.15 (0.04, 0.66)	0.012
Time-varying OAC use, yes:no	–		1.41 (0.34, 5.91)	0.635

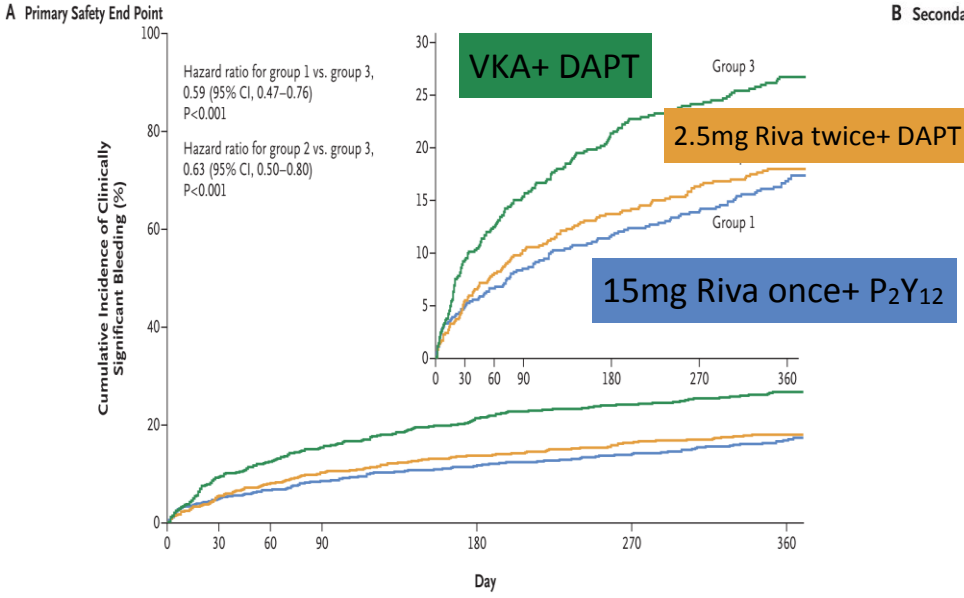
- **LAA exclusion did not appear to reduce early or late stroke.**
- **Only OAC was associated with a reduction in stroke risk, underscoring the need for continued anticoagulation in high-risk patients**

Johnsrud DO, et al. Clin Cardiol 2018

ACC/AHA/HRS: Focused Update on AF

Recommendations for AF Complicating ACS Referenced studies that support new or modified recommendations are summarized in Online Data Supplement 8.		
COR	**LOE**	**Recommendations**
IIa	**B-R**	**5. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with a $P2Y_{12}$ inhibitor (clopidogrel or ticagrelor) and dose-adjusted vitamin K antagonist is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-3, S7.4-6–S7.4-8).** **NEW**: New RCT data and data from 2 registries and a retrospective cohort study are available.
IIa	**B-R**	**6. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with $P2Y_{12}$ inhibitors (clopidogrel) and low-dose rivaroxaban 15 mg daily is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-2).** **NEW**: New published data are available.
IIa	**B-R**	**7. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with a $P2Y_{12}$ inhibitor (clopidogrel) and dabigatran 150 mg twice daily is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-1).** **NEW**: New published data are available.

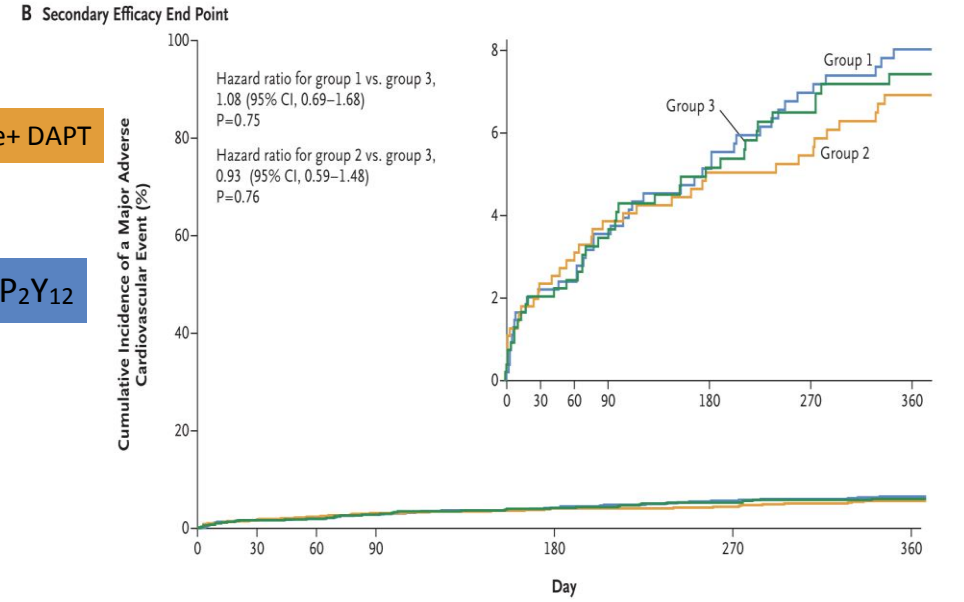
Safety and Efficacy of Rivaroxaban for AF and ACS



VKA+ DAPT

2.5mg Riva twice+ DAPT

15mg Riva once+ P_2Y_{12}



- **Efficacy not even powered for non-inferiority**
- **15mg Rivaroxaban not being tested for stroke prevention**
- **Np correction for multiple testing**

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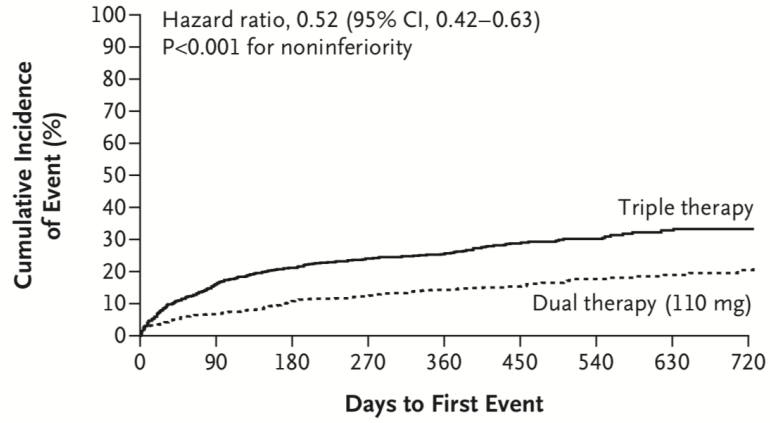
Gibson et al. 10.1056/nejmoa1611594

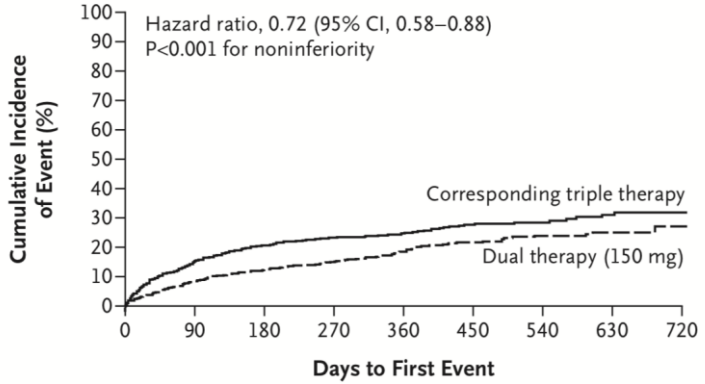
Safety and Efficacy of Dabigatran for AF and ACS

A Primary End Point in Dual-Therapy Group (110 mg) vs. Triple-Therapy Group



No. at Risk									
Dual therapy (110 mg)	981	898	834	671	538	384	258	162	86
Triple therapy	981	800	719	580	453	302	205	124	63

B Primary End Point in Dual-Therapy Group (150 mg) vs. Triple-Therapy Group



No. at Risk									
Dual therapy (150 mg)	763	694	640	514	404	278	182	113	65
Corresponding triple therapy	764	630	562	446	349	222	152	88	47

End Point	Dual Therapy with Dabigatran, 110 mg (N=981)	Triple Therapy with Warfarin (N=981)	Hazard Ratio (95% CI)	P Value†	Dual Therapy with Dabigatran, 150 mg (N=763)	Corresponding Triple Therapy with Warfarin (N=764)	Hazard Ratio (95% CI)	P Value†
	no. (%)				*no. (%)*			
Primary end point: ISTH major or clinically relevant nonmajor bleeding	151 (15.4)	264 (26.9)	0.52 (0.42–0.63)	<0.001 (<0.001 for noninferiority)	154 (20.2)	196 (25.7)	0.72 (0.58–0.88)	0.002 (<0.001 for noninferiority)

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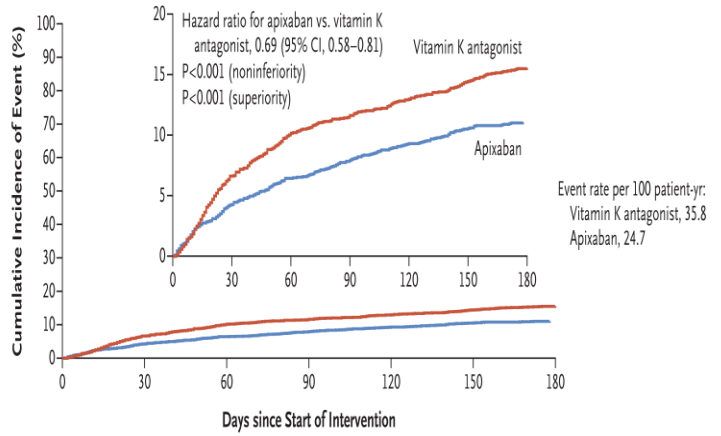
Cannon C et al. 10.1056/NEJMoa1708454

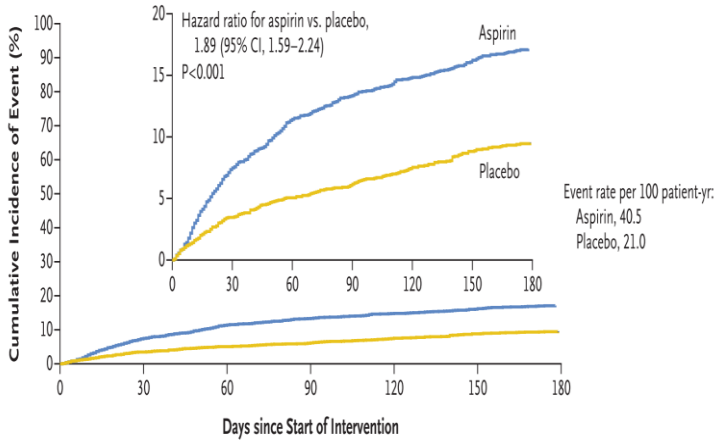
Safety and Efficacy of Apixaban for AF and ACS

A Primary Outcome — Apixaban vs. Vitamin K Antagonist



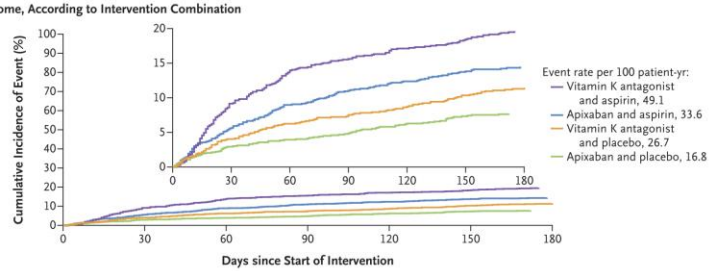
No. at Risk							
Vitamin K antagonist	2259	1984	1861	1795	1736	1686	1079
Apixaban	2290	2110	2019	1957	1902	1858	1037

B Primary Outcome — Aspirin vs. Placebo



No. at Risk							
Aspirin	2277	2003	1863	1789	1717	1674	962
Placebo	2279	2095	2006	1941	1880	1824	1079

C Primary Outcome, According to Intervention Combination



No. at Risk							
Vitamin K antagonist and aspirin	1123	962	881	838	800	776	467
Apixaban and aspirin	1145	1036	975	937	903	880	485
Vitamin K antagonist and placebo	1126	1007	947	917	883	851	528
Apixaban and placebo	1143	1075	1044	1007	975	947	536

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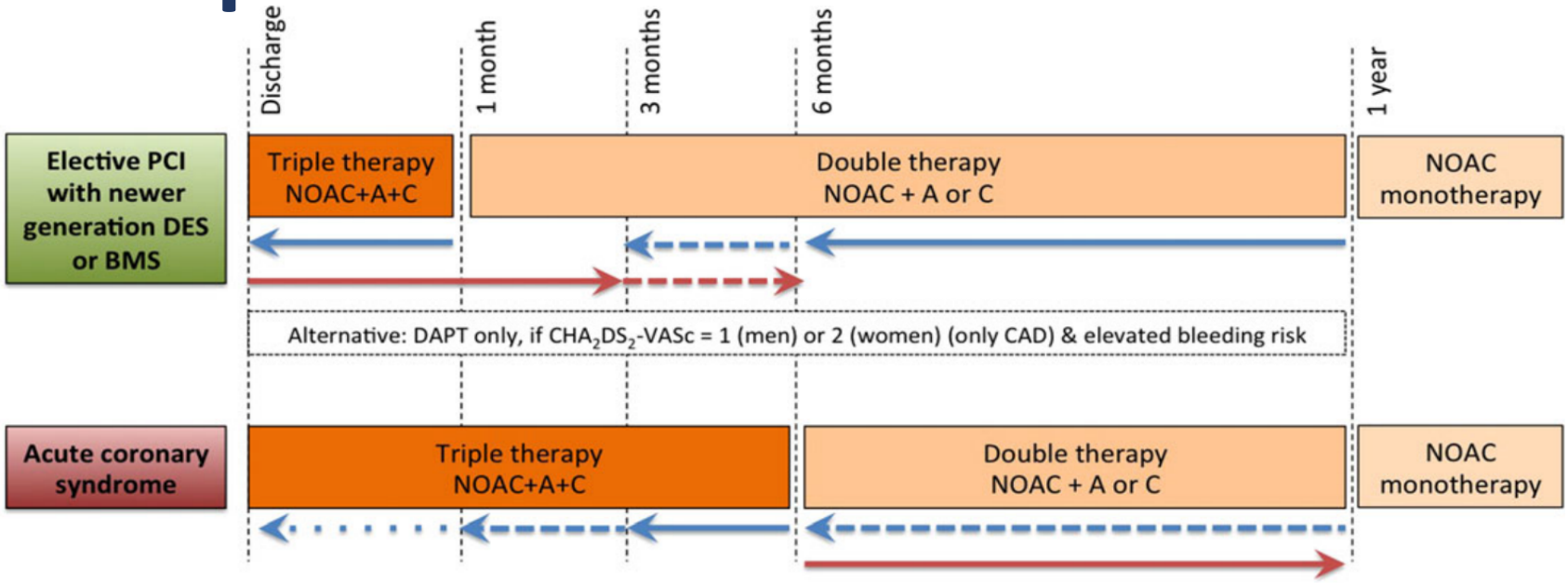
Lopes R et al. 10.1056/NEJMoa1817083

European Guideline for AF and CAD



Factors to shorten combination therapy

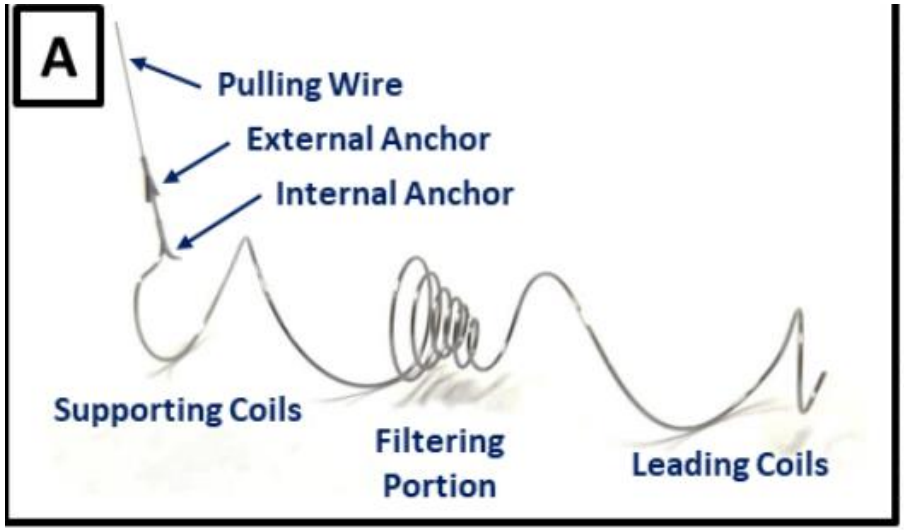
- (Uncorrectable) high bleeding risk
- Low atherothrombotic risk (by REACH or SYNTAX score if elective?; GRACE <118 if ACS?)

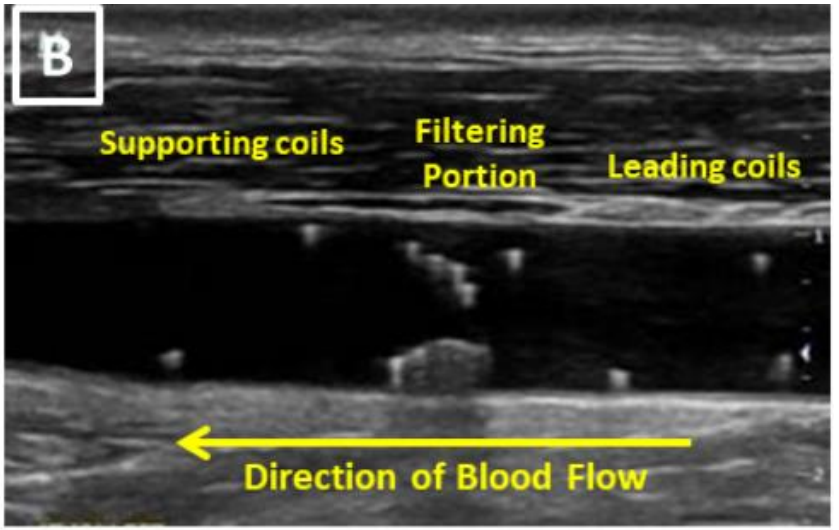
Factors to lengthen combination therapy

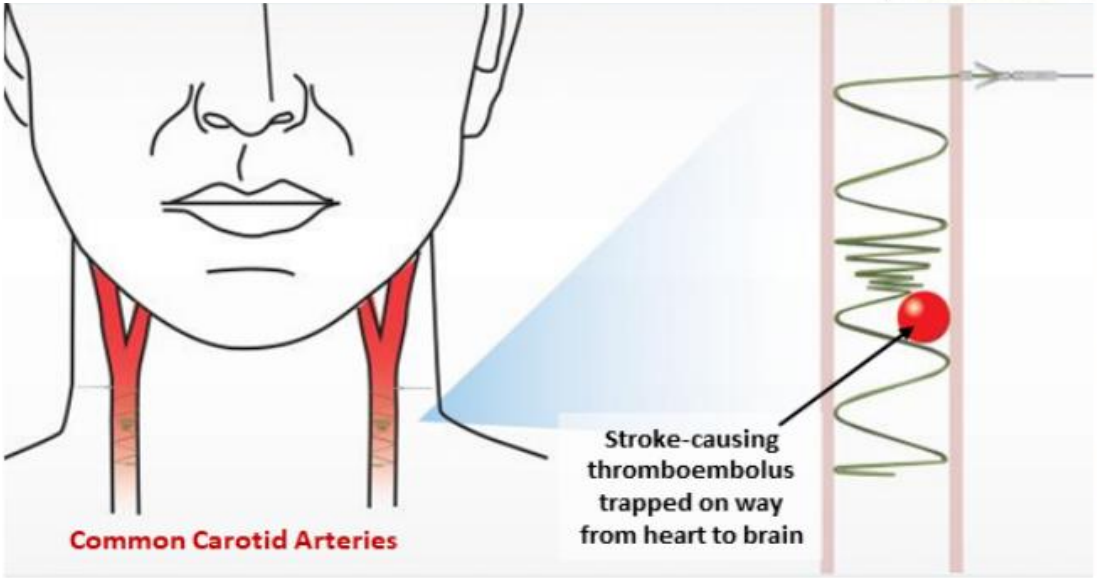
- First-generation DES
- High atherothrombotic risk (scores as above ; stenting of the left main, proximal left anterior descending, proximal bifurcation; recurrent MIs; etc.) and low bleeding risk

Heidbüchl et al. 10.1093/eurheartj/ehw058

The First-in-Human CAPTURE Trial







First-in-Human *CAPTURE* Trial

Trial enrolled 25 patients:

- CHA_2DS_2-VASc = 4.4
- Prior embolism in 48%
- Multiple prior strokes in 12%

Successful bilateral filter deployment in 92%

Major procedure/device adverse events in 0%

After 6 months mean follow-up:

- No in situ thrombus formation
- Six captured emboli in 4 patients
- In 1 patient, 2 minor strokes involving non-carotid territory

Reddy VY, et al. JACC 2019

Latest Updates on SPAF.....

- 4 NOACs have been approved for clinical uses, including selected pts VHD
- Use of Apixaban or LAAO in ESRD
- Applications of LAA occlusion or closure for SPAF
- Development of reversal agents for NOACs
- Antiplatelet therapy and OAC in AF pts with CAD
- New approaches for SPAF is under development