

Between a Rock and a Hard Place

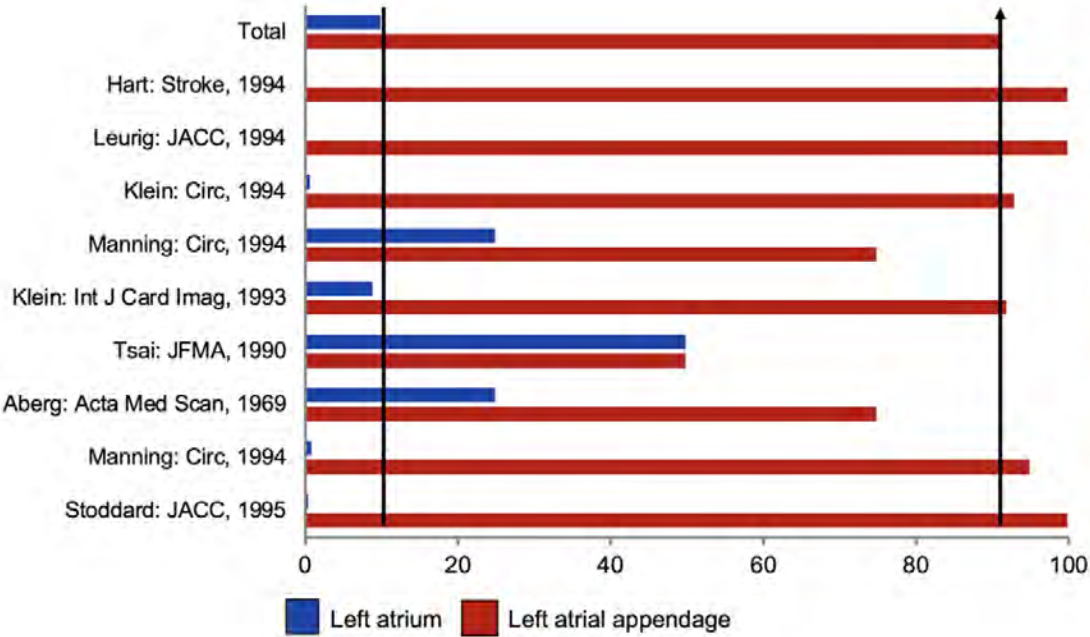
2023 Heart & Vascular Conference

Jason Payne, MD

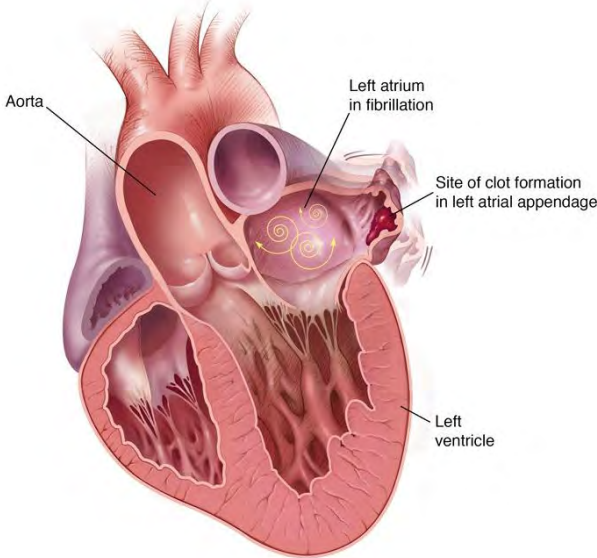
Assistant Professor

Left Atrial Appendage Thrombus

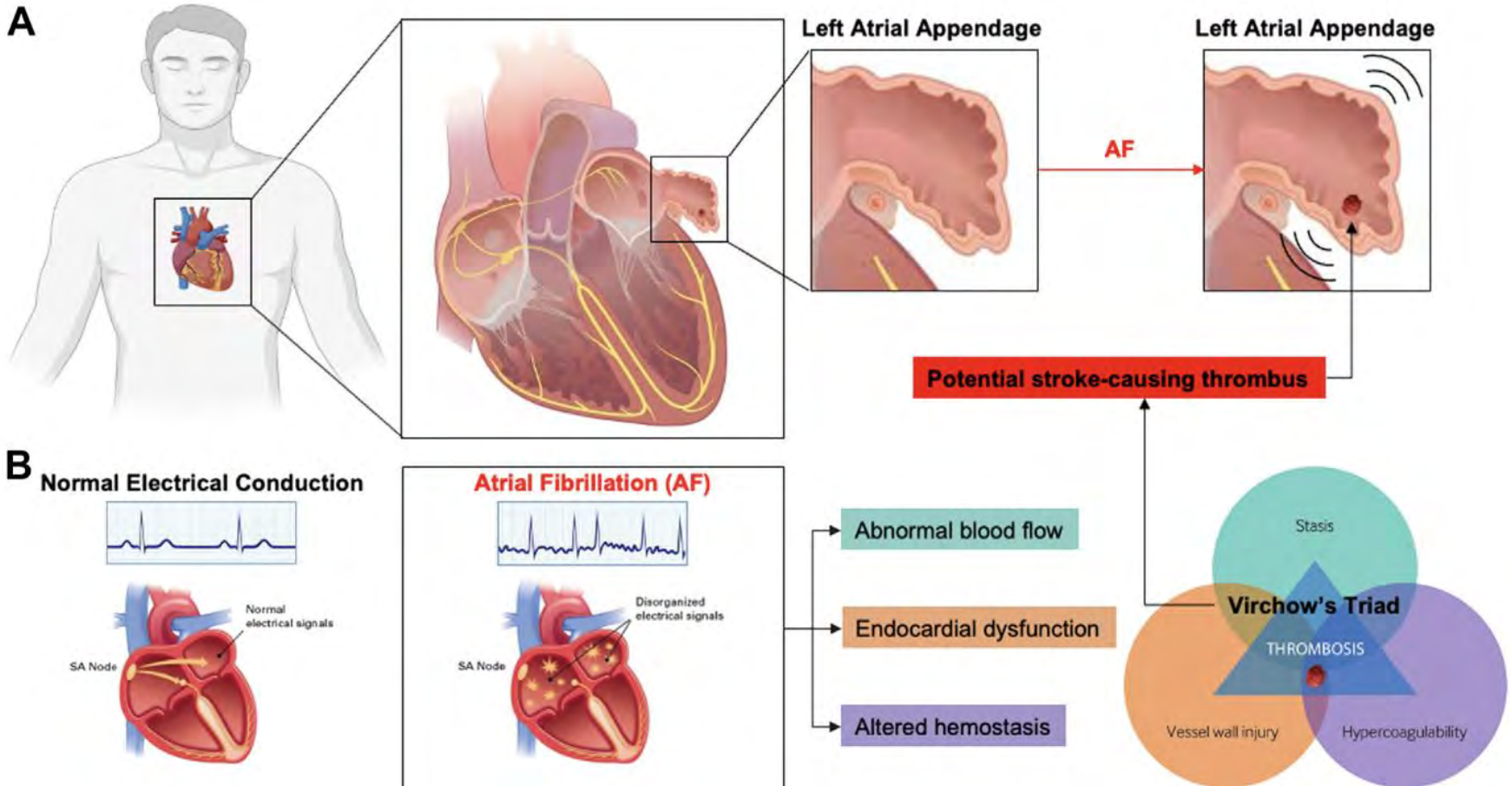




91% in LAA



Pathophysiology 101



We know anticoagulation works

A Study, Year (Reference)

Adjusted-dose warfarin compared with placebo or control

AFASAK I, 1989 (2); 1990 (3)

SPAF I, 1991 (5)

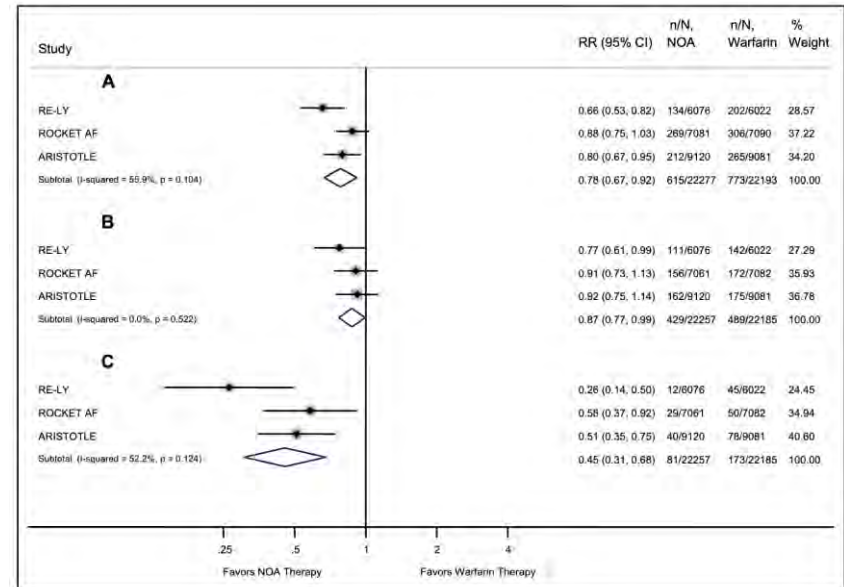
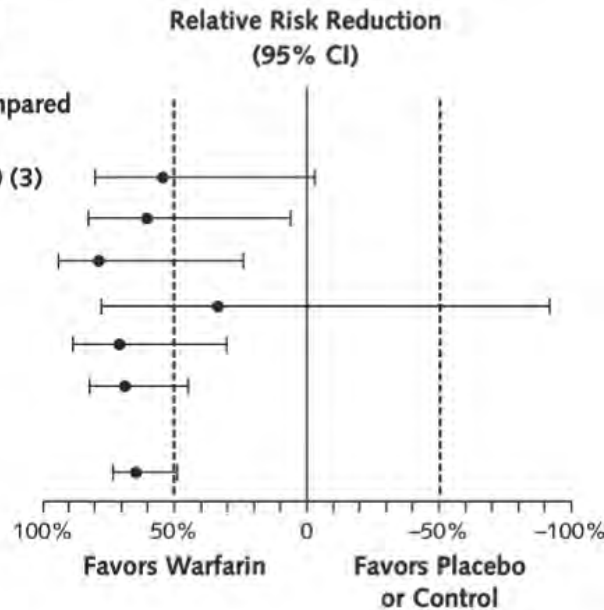
BAATAF, 1990 (4)

CAFA, 1991 (6)

SPINAF, 1992 (7)

EAFT, 1993 (8)

All trials (n = 6)



1. Hart RG, Pearce LA, Aguilar MI. Meta-analysis: antithrombotic therapy to prevent stroke in patients who have nonvalvular atrial fibrillation. *Ann Intern Med.* 2007 Jun 19;146(12):857-67. doi: 10.7326/0003-4819-146-12-200706190-00007. PMID: 17577005.

2. Miller, C. S., Grandi, S. M., Shimony, A., Fillion, K. B. & Eisenberg, M. J. Meta-Analysis of Efficacy and Safety of New Oral Anticoagulants (Dabigatran, Rivaroxaban, Apixaban) Versus Warfarin in Patients With Atrial Fibrillation. *Am J Cardiol* **110**, 453–460 (2012).



So, who then, is the LAAO Candidate?

Patients with an indication for stroke prevention due to atrial fibrillation

Suitable for OAC

Elevated bleeding risk

- Patients with
1. HAS-BLED ≥ 3
 2. Elevated bleeding risk outside HAS-BLED-Score, e.g., tumour, thrombocytopenia
 3. Need for prolonged or repetitive triple therapy, e.g., severe CAD and stenting
 4. Renal failure (severe) as contraindication to NOAC

Patients with individual and specific risk constellation for stroke

1. Inefficient OAC: "stroke on warfarin"
2. Electrically isolated LAA post ablation (indication for LAA occlusion controversial)

Patient unwilling or unable to take OAC

Contraindication to oral anticoagulation

Advise NOAC

NOAC

Individual risk-benefit analysis of OAC vs LAA occlusion


OAC
(NOACs/Vit-K-antagonists)

LAA occlusion*
(may require antiplatelet therapy)

*Note: In case of strict contraindication to antiplatelet therapy, patient may not be eligible for LAA occluder implantation but for epicardial LAA occlusion or thoracoscopic LAA clipping.

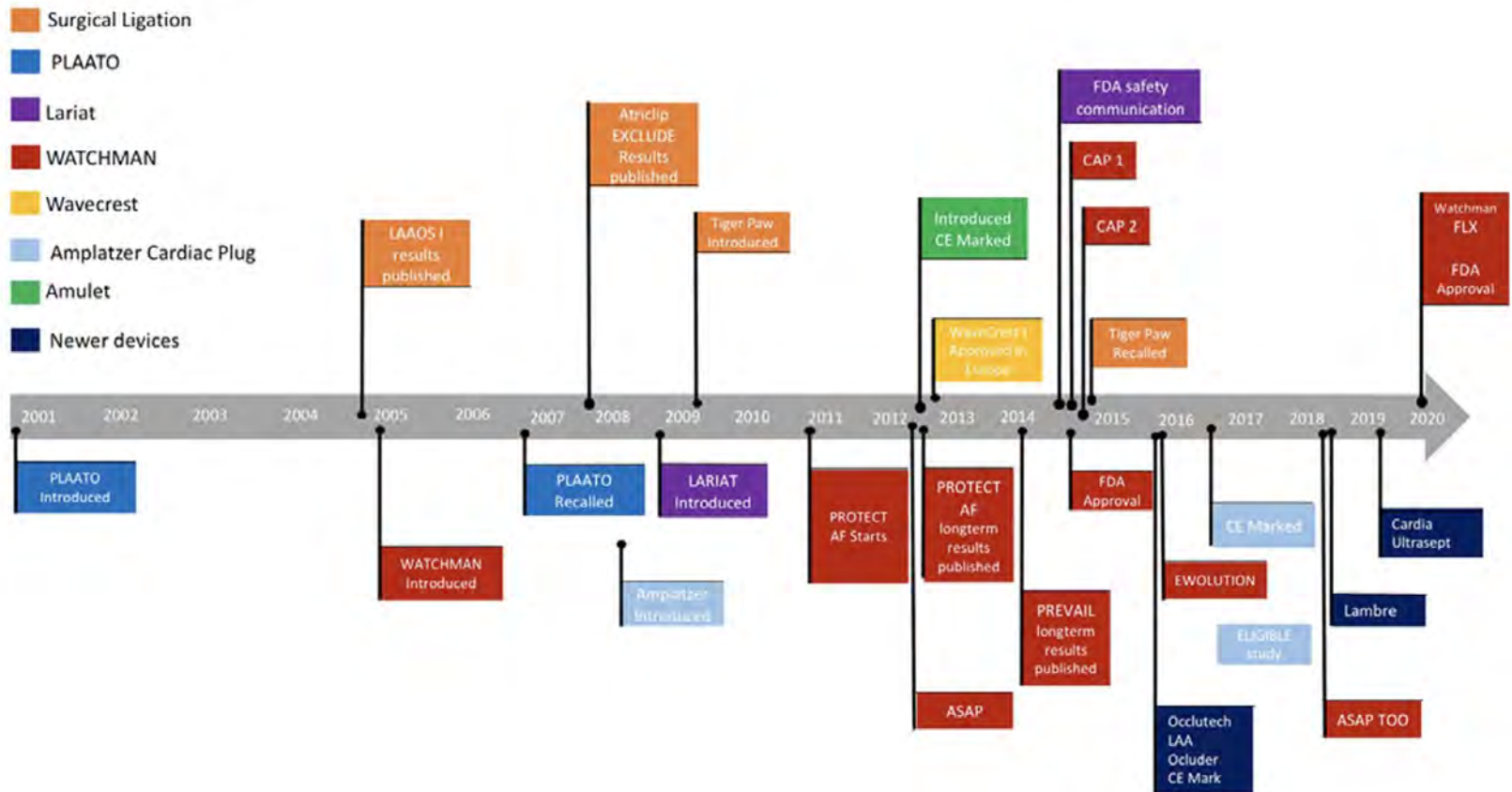


Noncompliant patients or patients unwilling to take OAC.

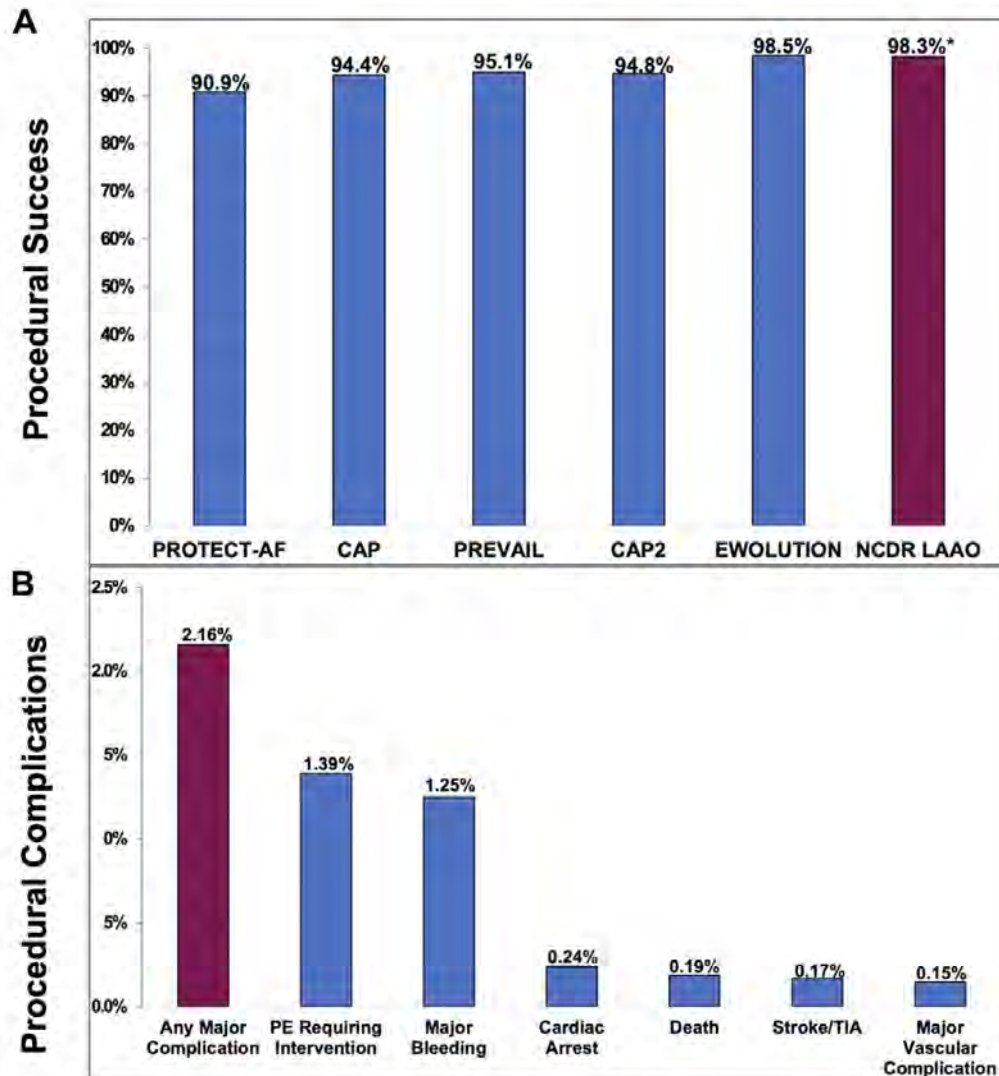
Clinical situation and therapeutic concept	Consensus statement	Icon
Any AF patients with an increased risk for stroke and embolism and no contraindication for OAC should receive personal and detailed advice that according to current evidence long-term OAC treatment is the preferred prophylactic strategy.	"Should do this"	
In AF patients with a high risk score for stroke and embolism who refuse OAC even after personal and detailed advice, LAA occlusion may be considered	"May do this"	
In patients with documented non-compliance, LAA occlusion can be discussed as a therapeutic alternative after attempts to resolve the reasons for non-compliance	"May do this"	
In patients who are opposed to chronic drug intake, LAA occlusion is currently not offered as a simple and equally effective treatment alternative	"Should not do this"	



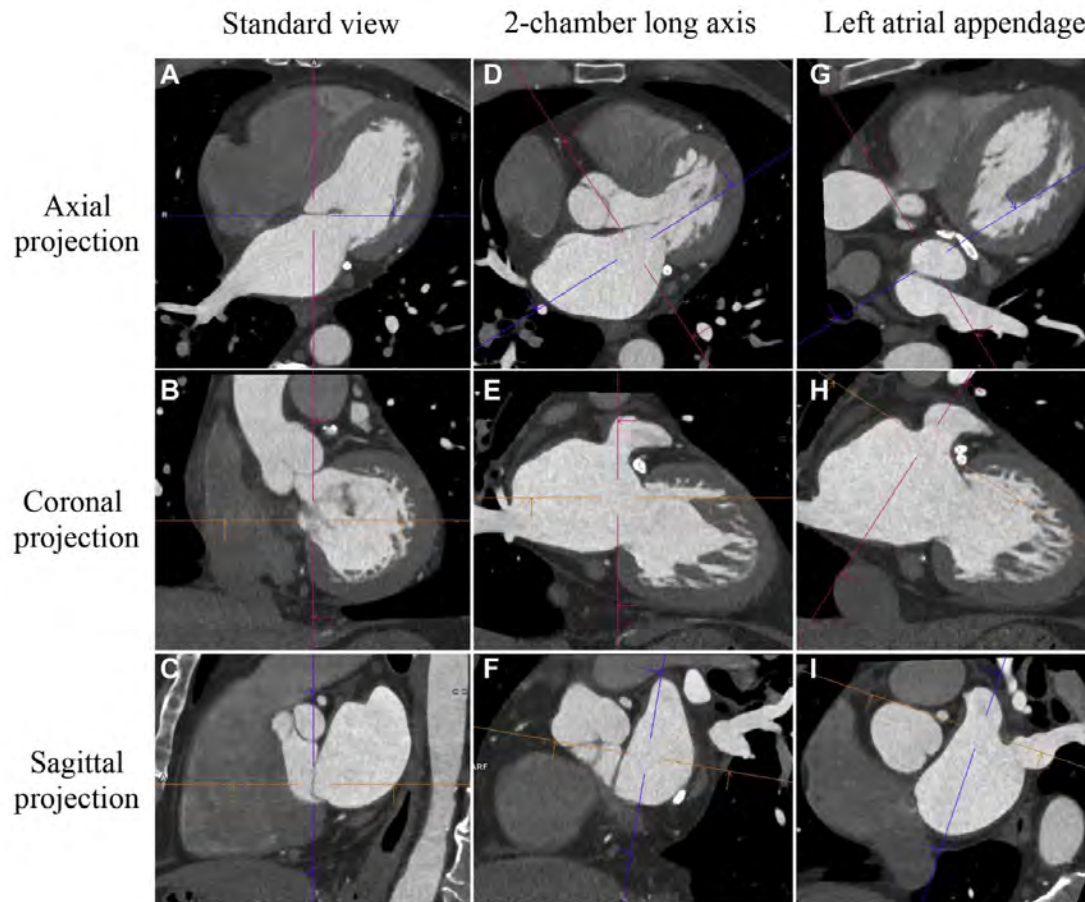
Timeline showing important dates of left atrial appendage occlusion trials and US FDA milestones in the United States.



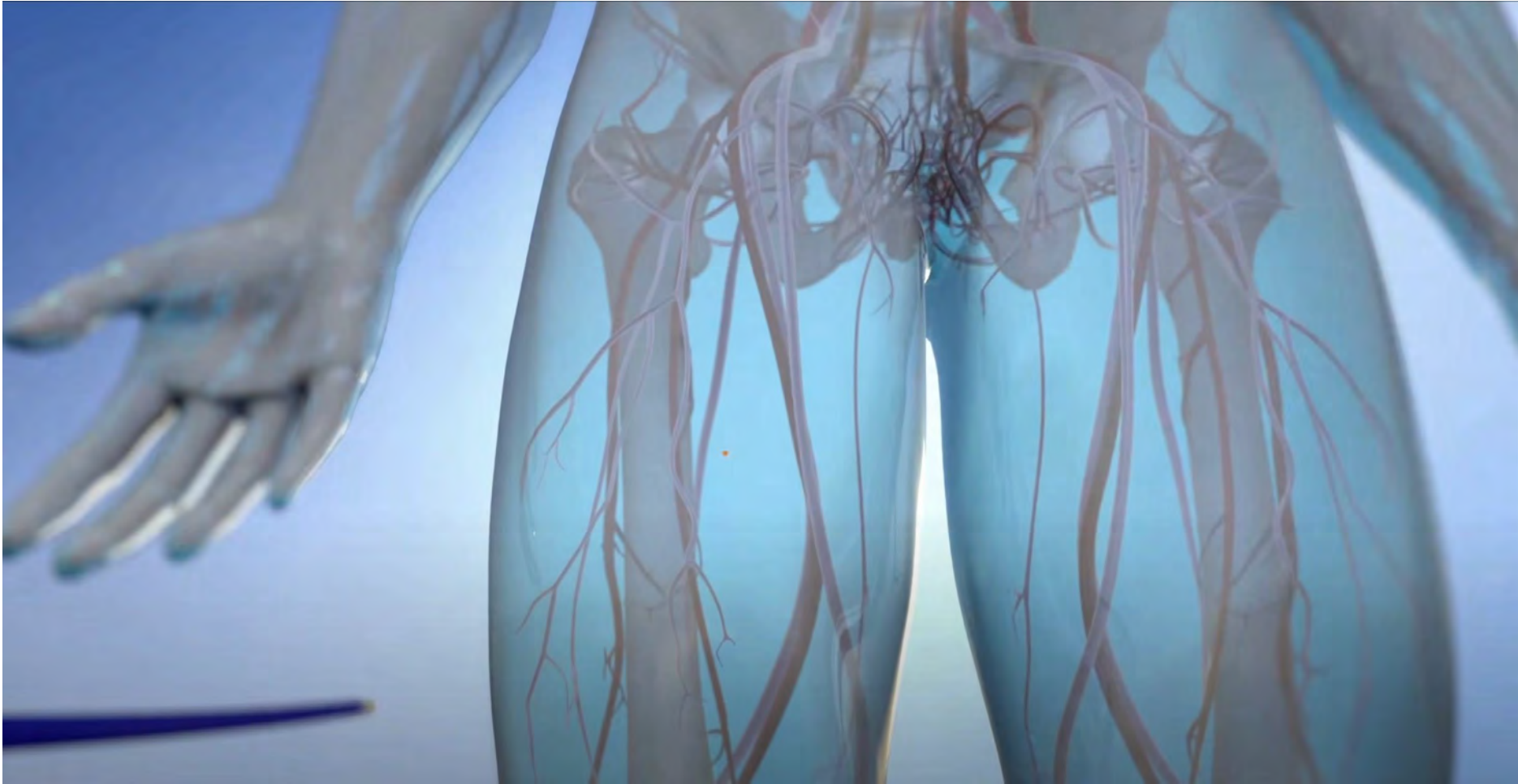
Procedural Outcomes in the NCDR LAAO Registry

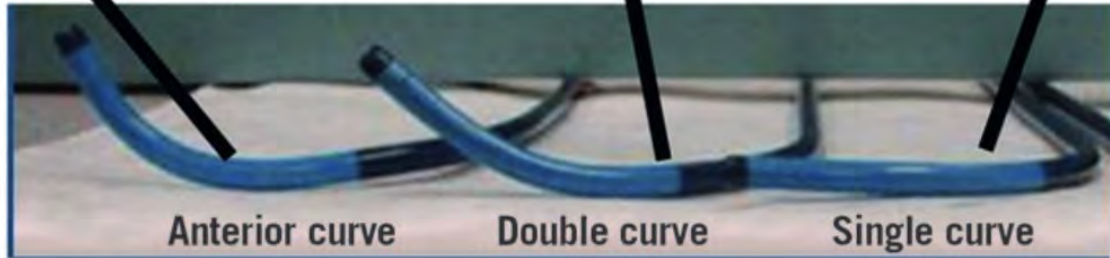
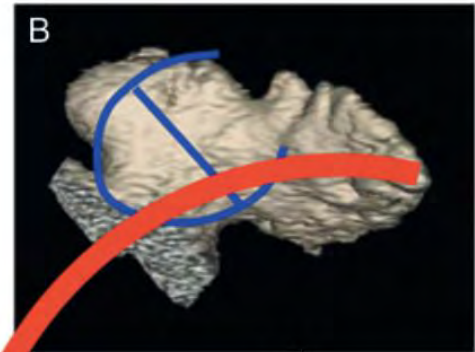
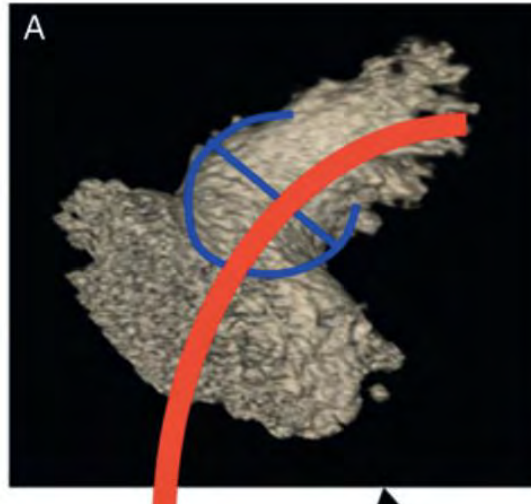
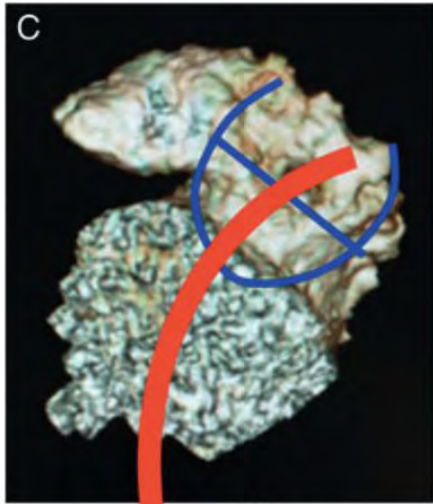


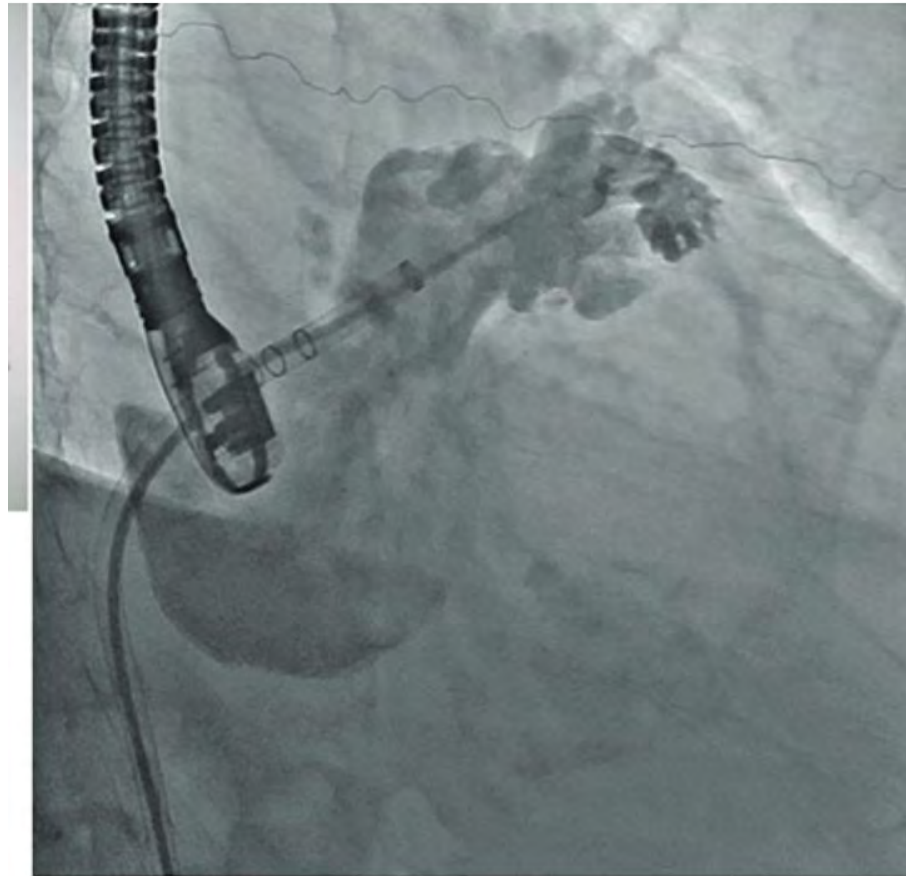
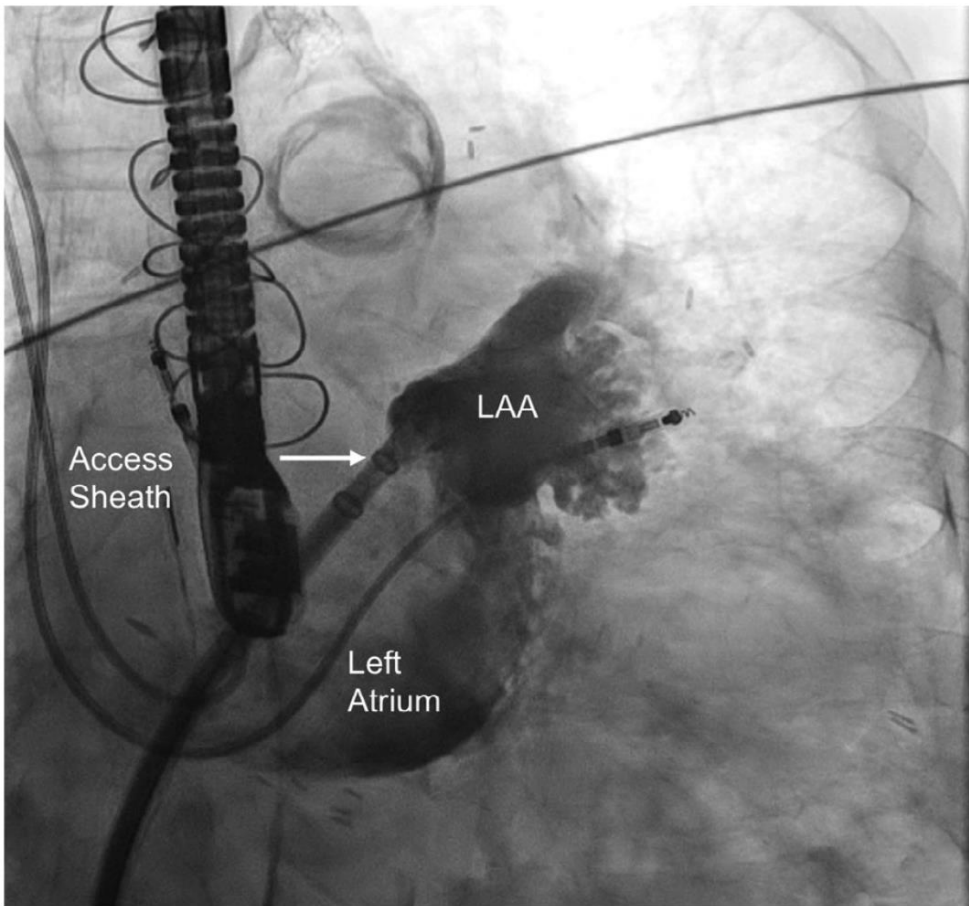
Imaging Analysis of Cardiac Computed Tomographic Images for Left Atrial Appendage Occlusion



LAAO implant Procedure







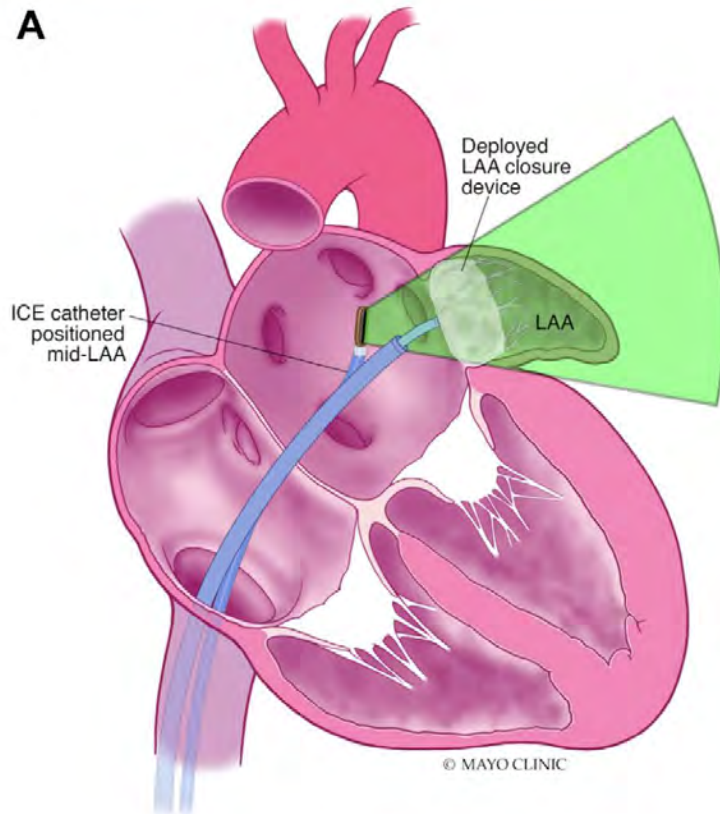


RAO cranial

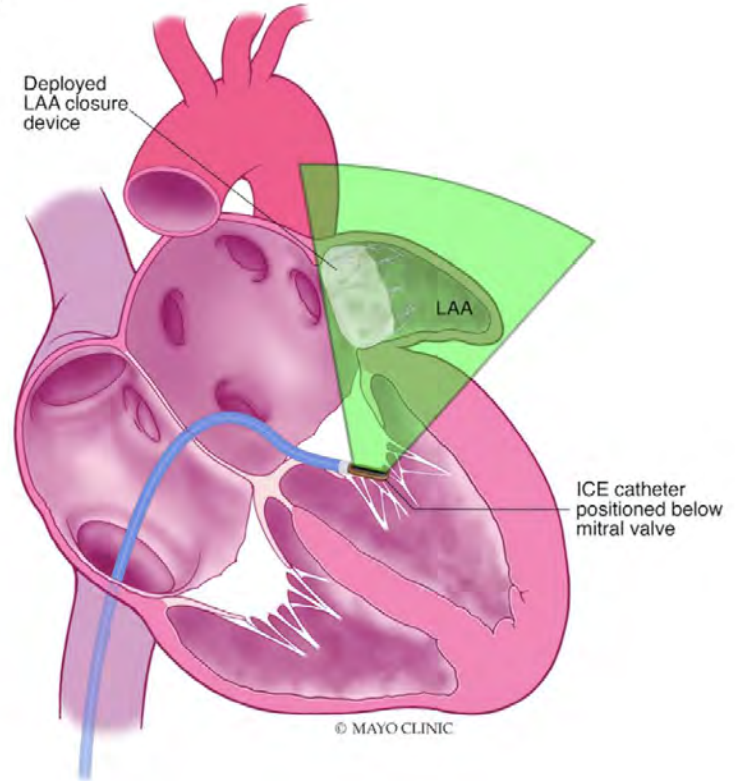


Simplified Imaging Protocol for ICE-Guided LAAO

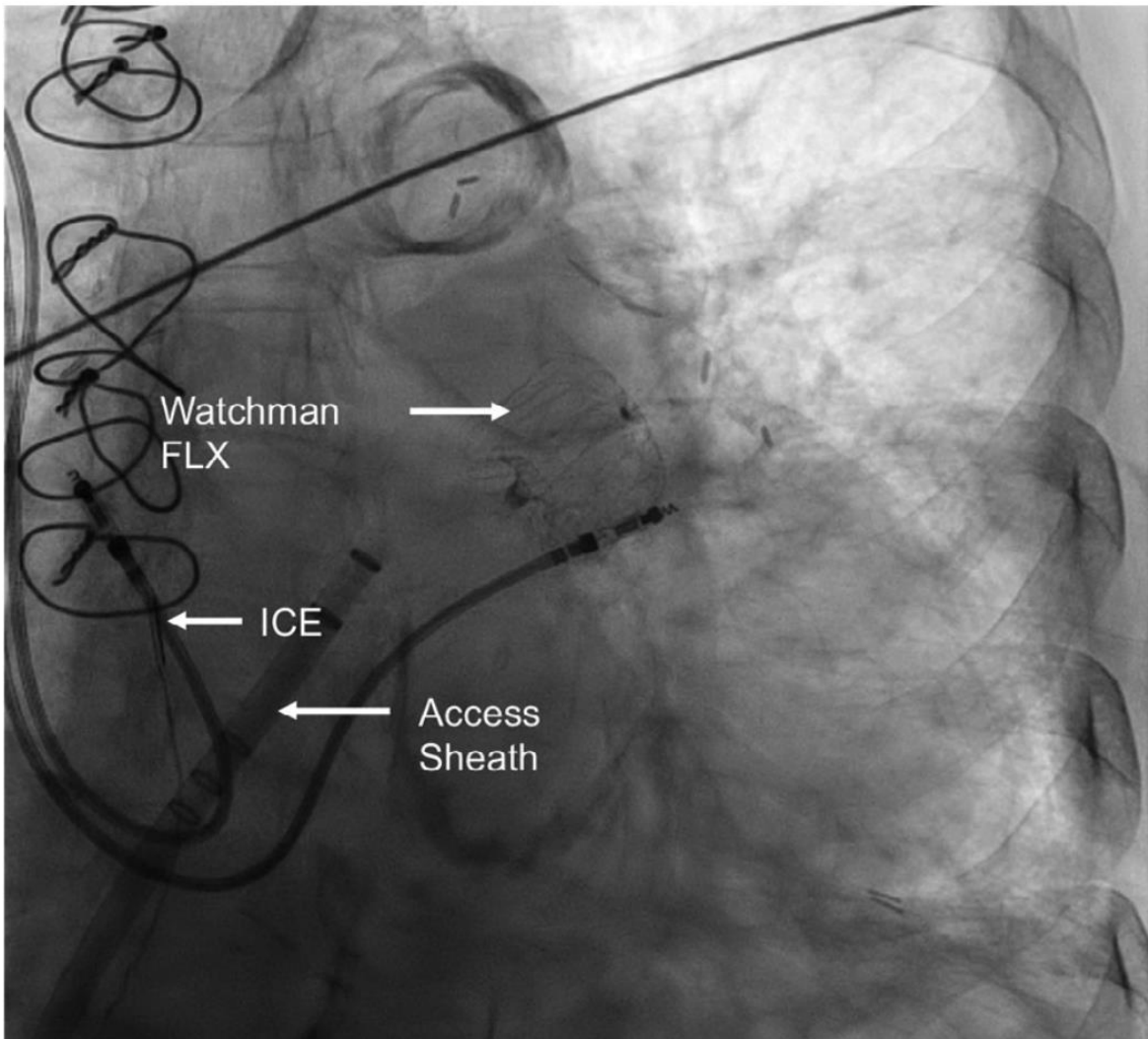
A



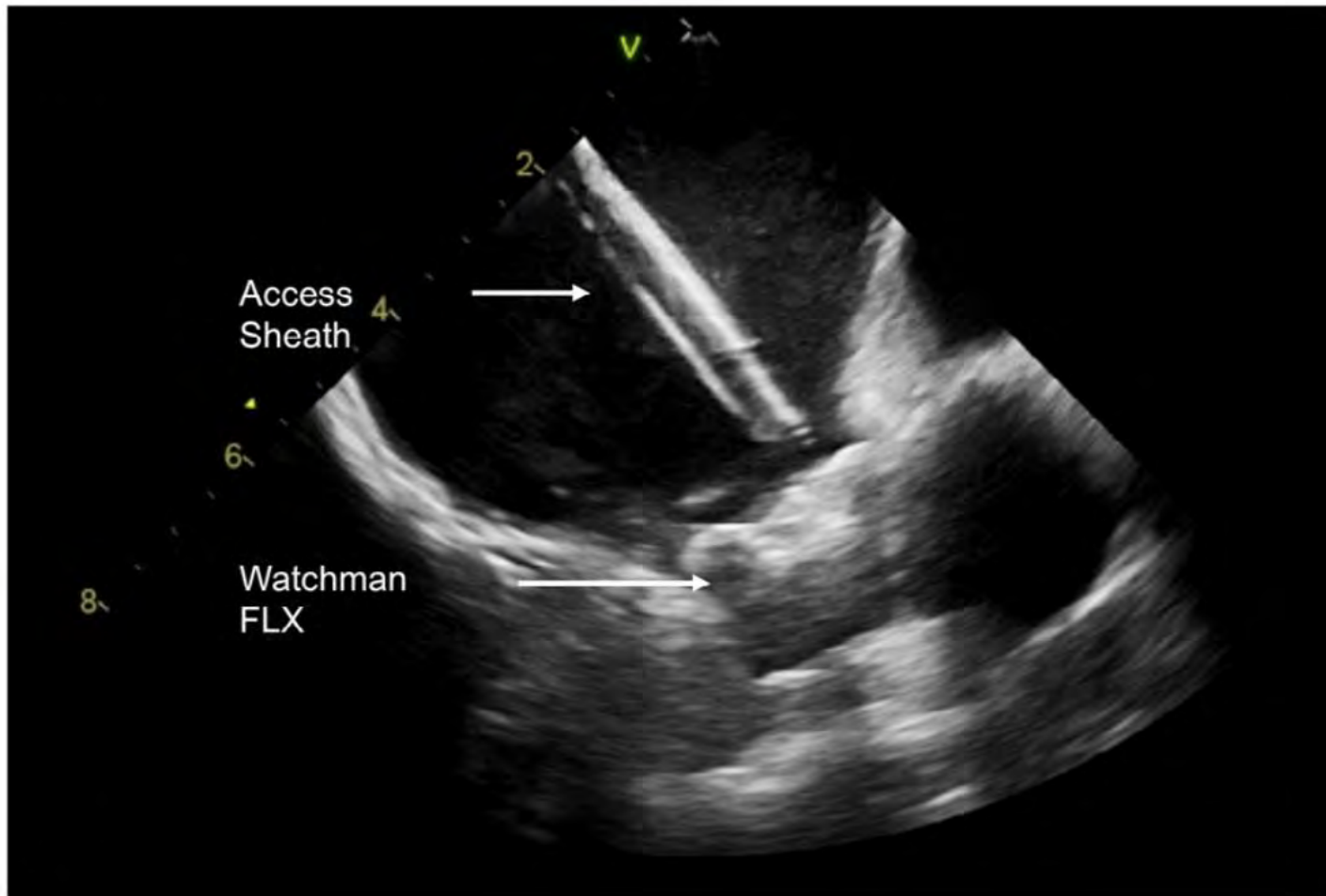
B



Fluoroscopic image of a Watchman FLX device released using intracardiac echo guidance (ICE)



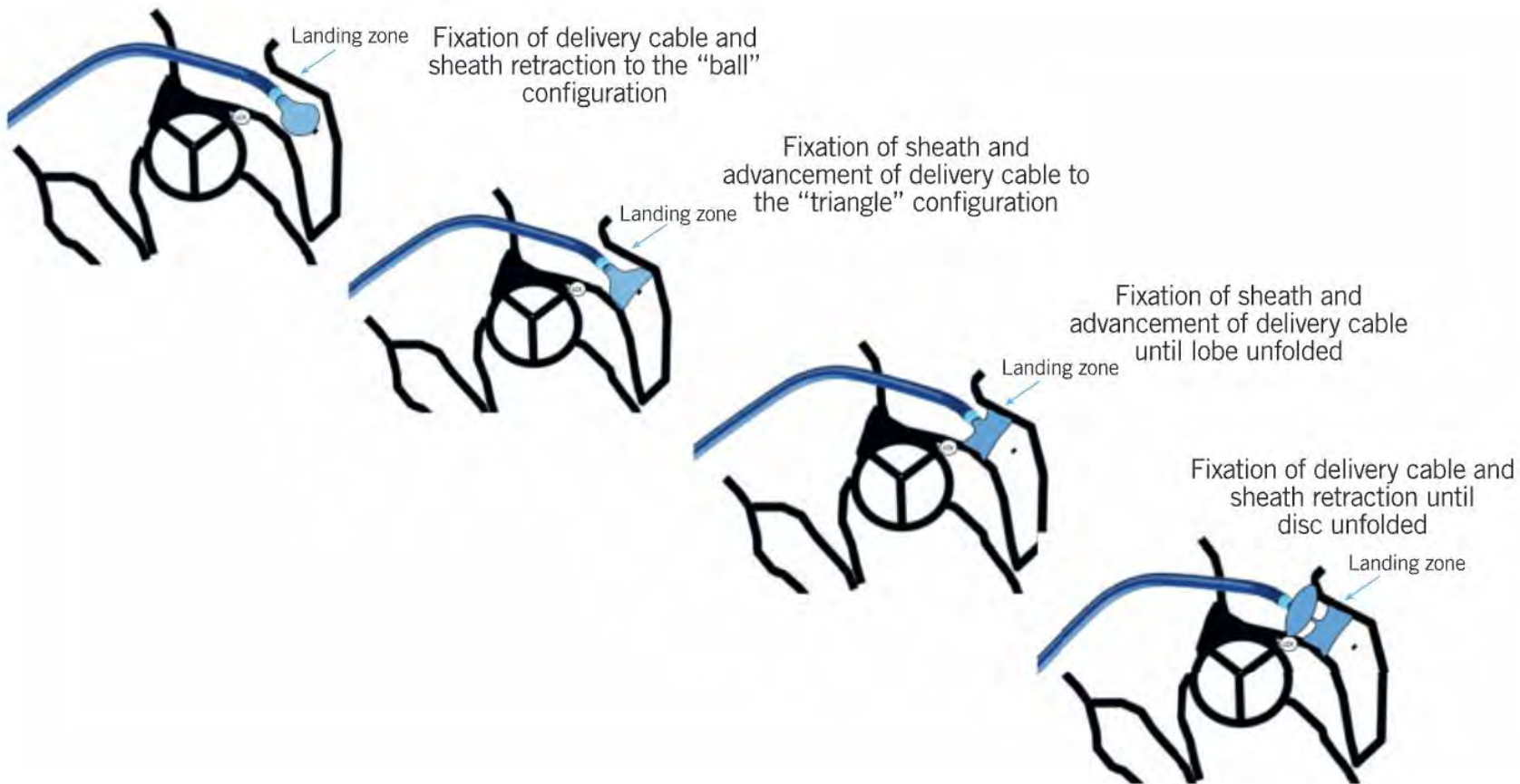
Intracardiac echocardiogram image of a deployed Watchman FLX device



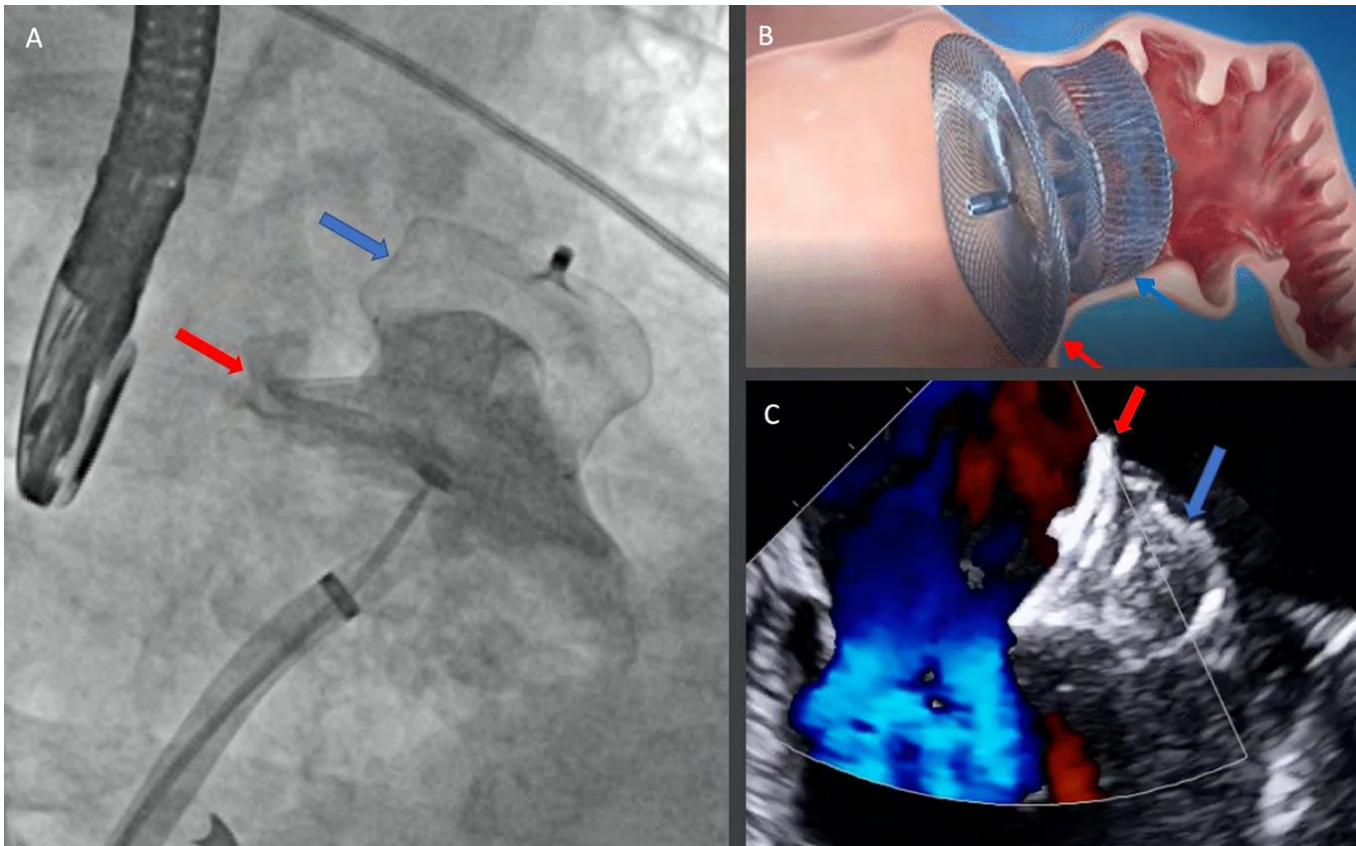
PASS criteria for device release

- Position: The proximal shoulders of the device are at or just distal to the LAA ostium and span the entire breadth of the LAA ostium.
- Anchor: The device does not shift and the device and LAA move together when the deployment knob is gently withdrawn and released.
- Size: There is adequate device compression according to the maximal shoulder-to-shoulder diameter of the device by TEE (see [Table 1](#)).
- Seal: All lobes are distal to the shoulders of the device and are sealed (defined by ≤ 5 -mm jet on TEE).

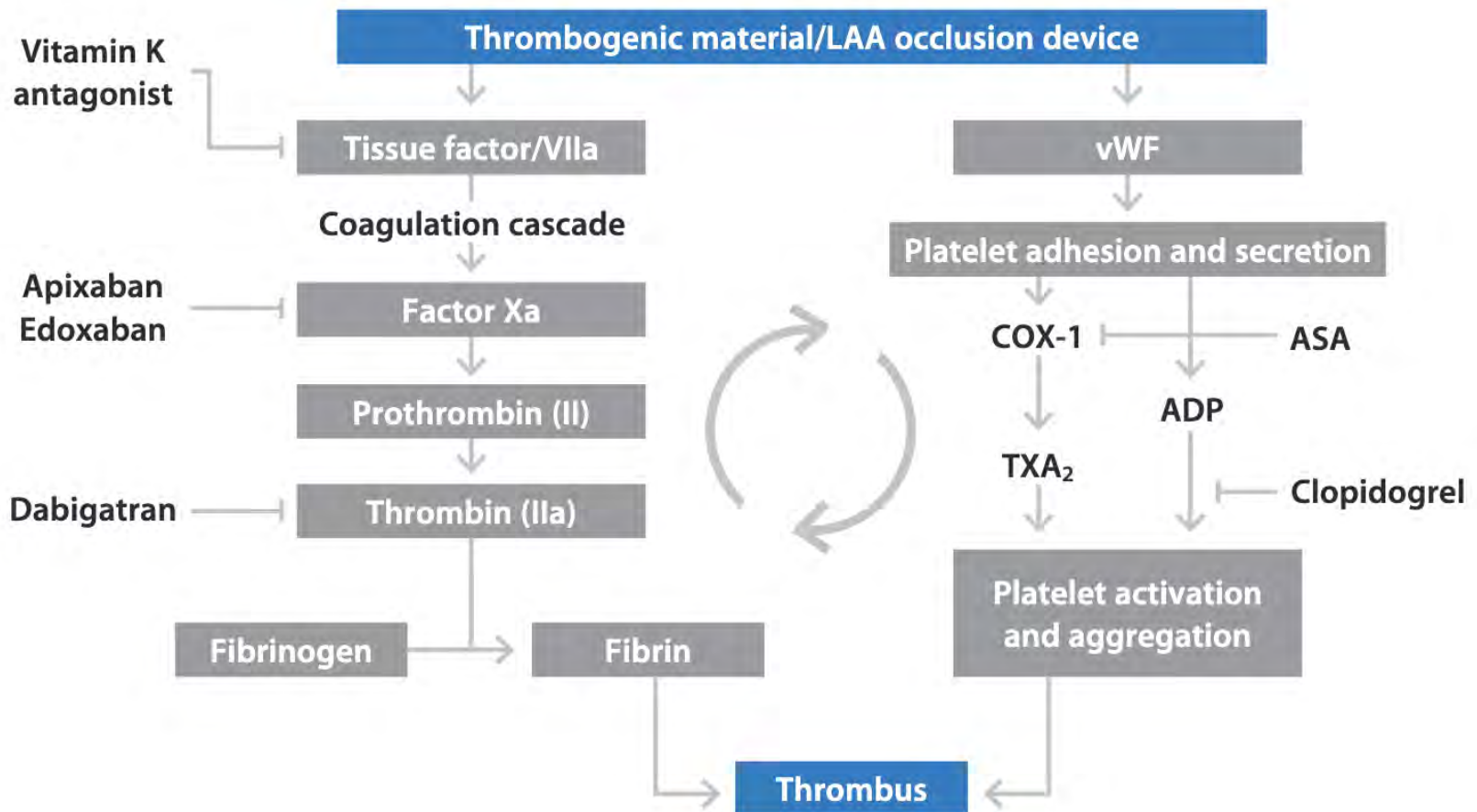




Amulet device

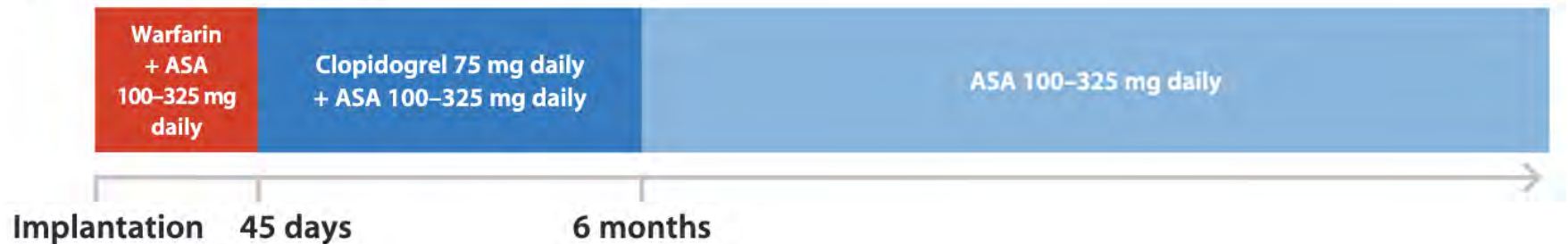


Short Term OAC is necessary

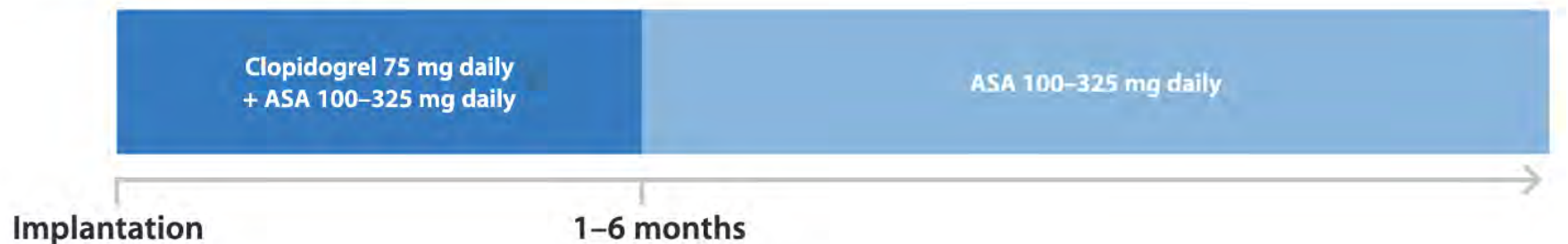


Timeline of antithrombotic treatment after LAA occlusion with the Watchman device

LOW BLEEDING RISK



HIGH BLEEDING RISK



All Options Include Low-Dose Aspirin for Minimum of 12 Months

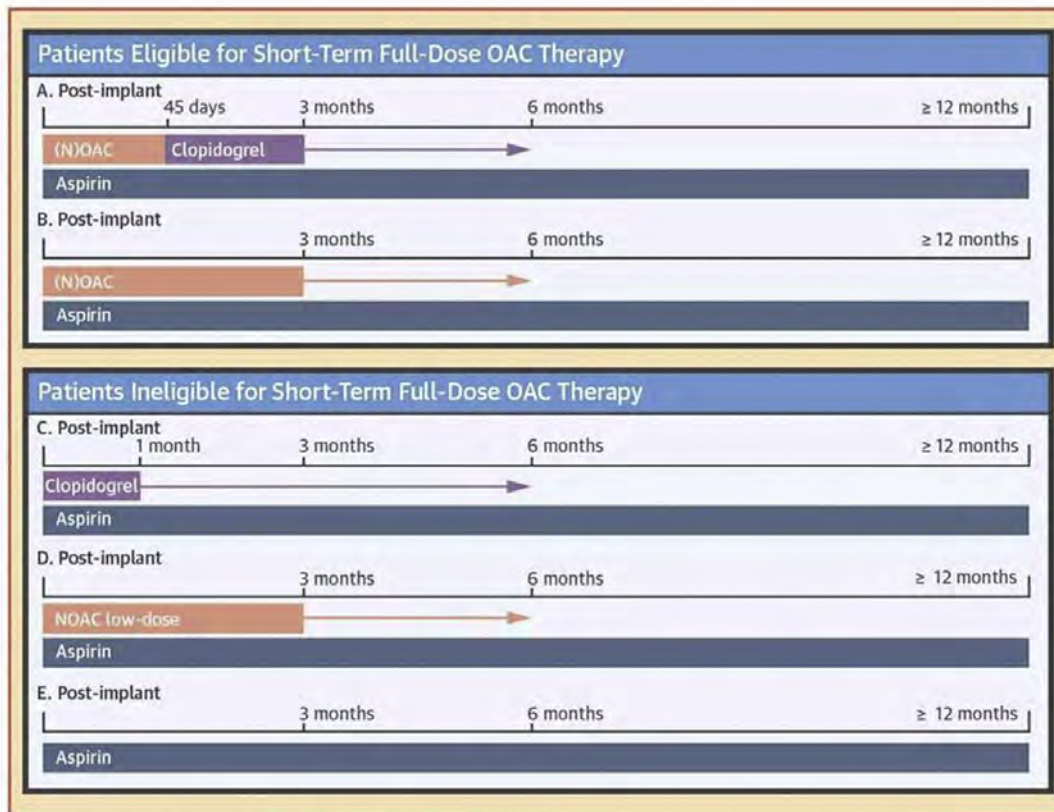


TABLE 2 Potential Risk Factors for Device-Related Thrombus

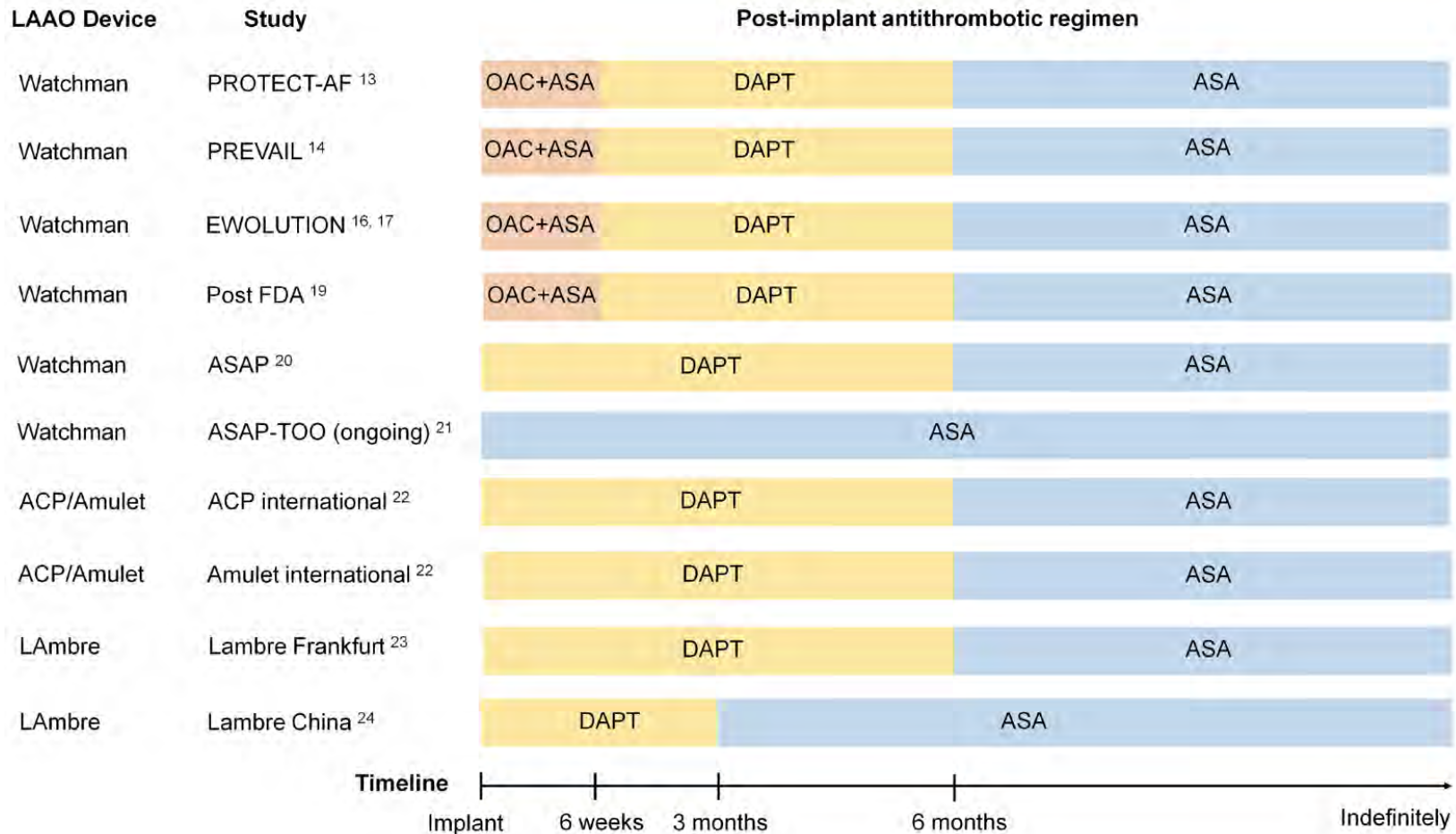
Category	Mechanism	Specific Details
Unmodifiable patient factors	Increased clot formation	Echocardiographic parameters <ul style="list-style-type: none"> • LVEF <40% • Spontaneous echocardiographic contrast • Low LAA peak emptying velocity Hematological: relative platelet count elevation Female sex High CHA ₂ DS ₂ -VASc score
	Reduced clot dispersion Slow device endothelialization	Medication responsiveness Medication acceptability (bleeding) Unmeasurable/unpredictable even at young age
Post-procedural medication	Potency of strategy Compliance	Choice of SAPT, DAPT, direct OAC, OAC, or LMWH <ul style="list-style-type: none"> • Subtherapeutic INR • Noncompliance • Early medication discontinuation
Mechanical factors	Implantation result	Deep implantation, forming neoappendage Failure of disc apposition Residual leak
	Device	Intracardiac vs. extracardiac devices Exposed screw
	Periprocedural	Thrombus on device/wire during implantation

INR = international normalized ratio; LAA = left atrial appendage; LMWH = low-molecular weight heparin; LVEF = left ventricular ejection fraction; other abbreviations as in Table 1.

Saw, J. et al. J Am Coll Cardiol Intv. 2019;12(11):1067-76.



Antithrombotic regimens

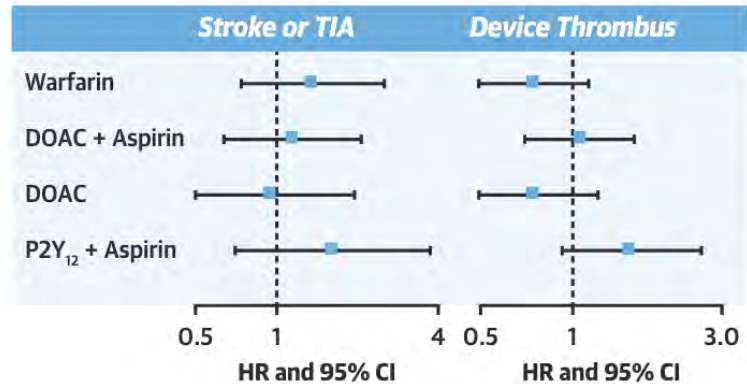
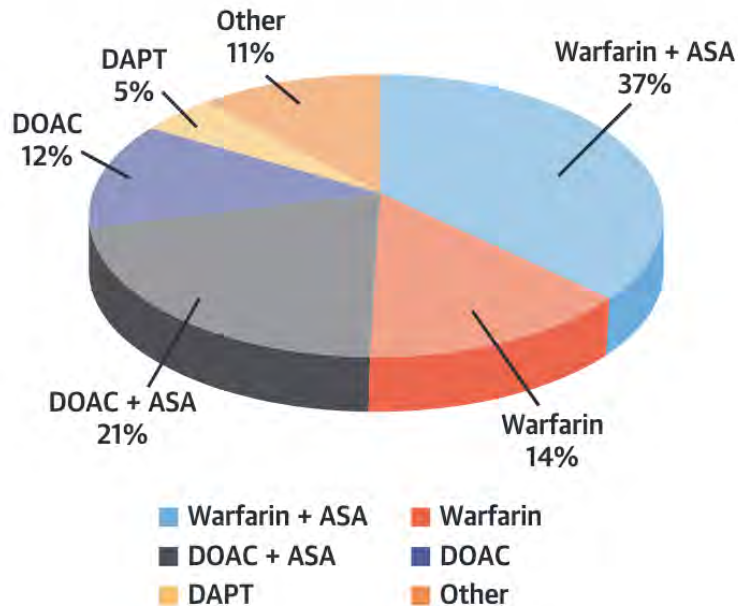


Registry Data

NCDR LAAO Registry: 31,994 Patients With Watchman Implants

Most Common Discharge Antithrombotic Strategies

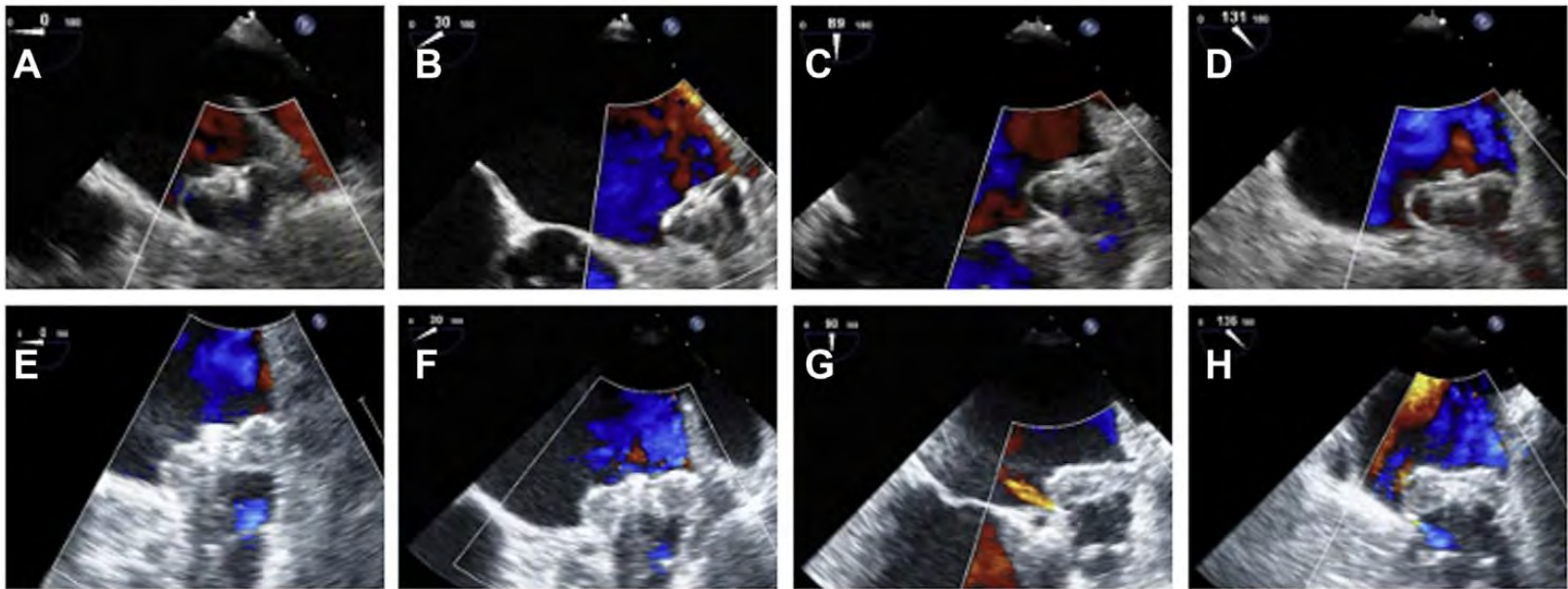
• Only 12.2% received FDA-approved postimplant regimen



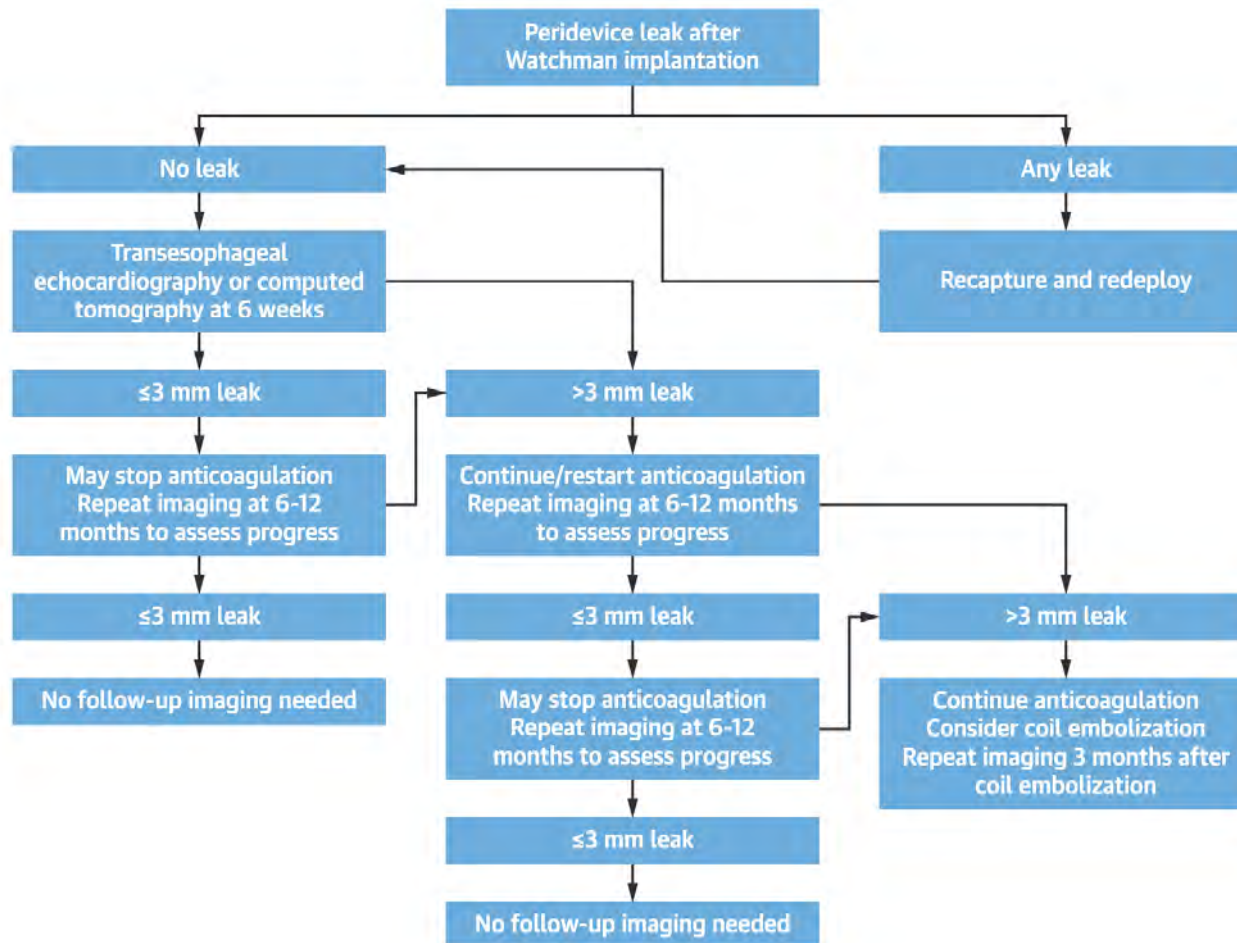
Freeman JV, et al. J Am Coll Cardiol. 2022;79(18):1785-1798.







Identification of PDL Using TEE Imaging



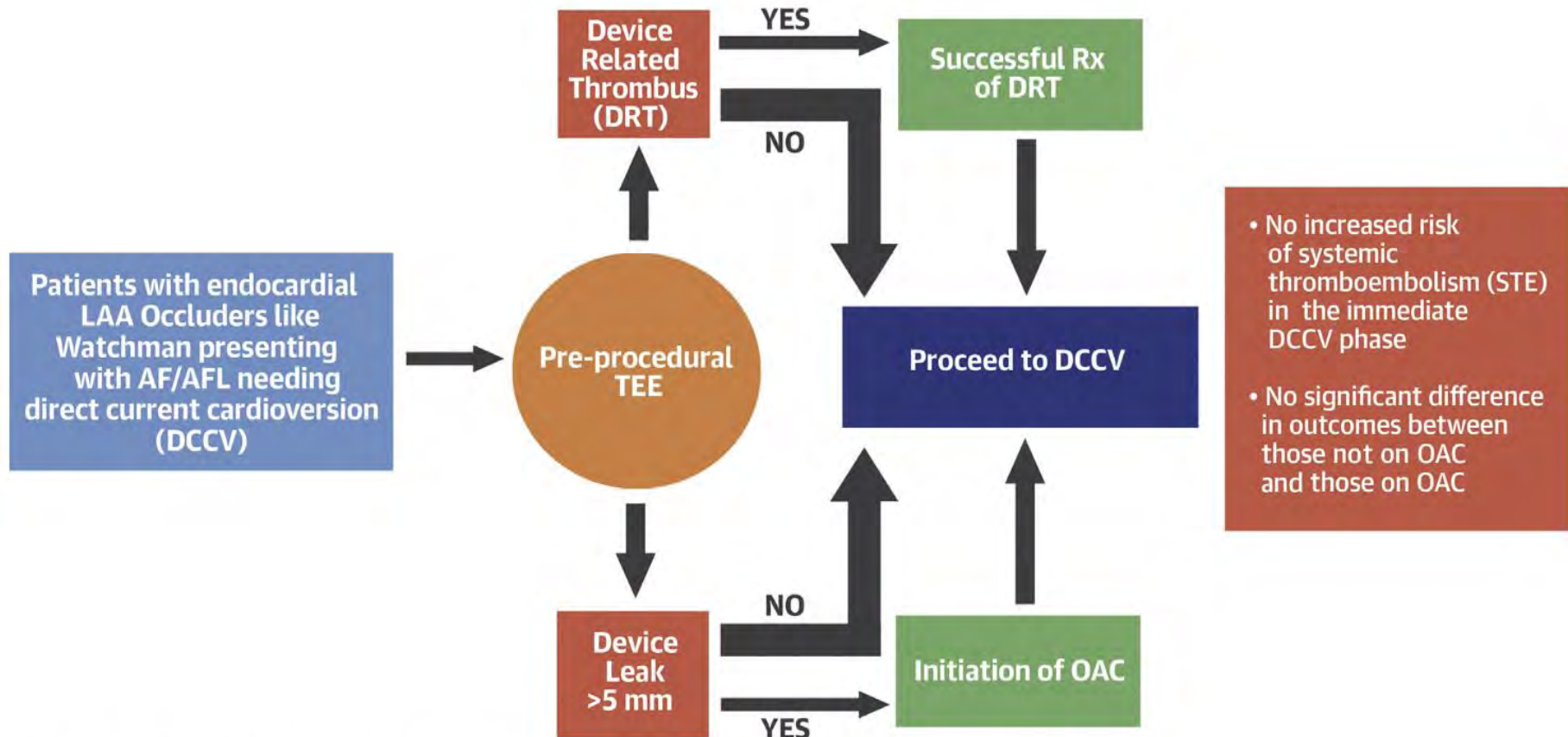
Proposed Strategy to Manage Peridevice Leak



<p>Minor PDL < 3 mm</p> 	<p>Small PDL $\geq 3 - < 5$ mm</p> 	<p>Moderate PDL $\geq 5 - 9$ mm</p> 	<p>Large PDL ≥ 10 mm</p> 
<ul style="list-style-type: none"> • Presumed low risk for stroke • No clear indication for closure • Discontinue OAC 	<ul style="list-style-type: none"> • Unclear risk for stroke • Options: <ul style="list-style-type: none"> - Discontinue OAC - Continue OAC - PDL closure 	<ul style="list-style-type: none"> • Persistent risk for stroke • Options: <ul style="list-style-type: none"> - Continue OAC - PDL closure 	<ul style="list-style-type: none"> • Persistent risk for stroke • Options: <ul style="list-style-type: none"> - Continue OAC - PDL closure
<p>No indications or data to support PDL closure</p>	<p>Endovascular Coils & Endovascular Plugs</p>		<p>LAA Closure Device</p>



Direct Current Cardioversion in Patients With Left Atrial Appendage Occlusion Devices



Sharma, S.P. et al. J Am Coll Cardiol. 2019;74(18):2267-74.



Left atrial appendage occlusion (LAAO) devices can be successfully placed with some procedural modifications in patients with persistent left atrial appendage (LAA) thrombus

Persistent LAA thrombus despite adequate oral anticoagulation

OR

Contraindication to oral anticoagulation

LAAO devices can be successfully implanted with some modifications in standard procedure such as

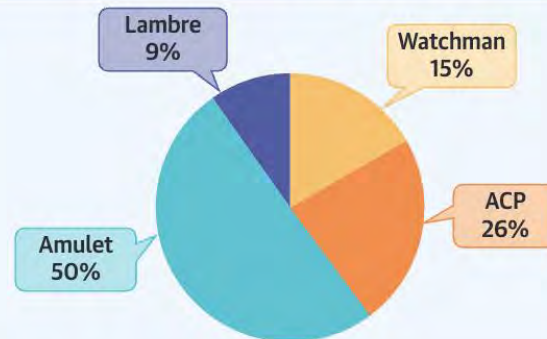
- limited LAA angiography
- minimal or no touch technique
- consideration for cerebral protection device

Amulet, ACP, and Watchman FLX have distinct advantages over Watchman

Current evidence mostly limited to distally located thrombus



TYPES OF LAAO DEVICES USED

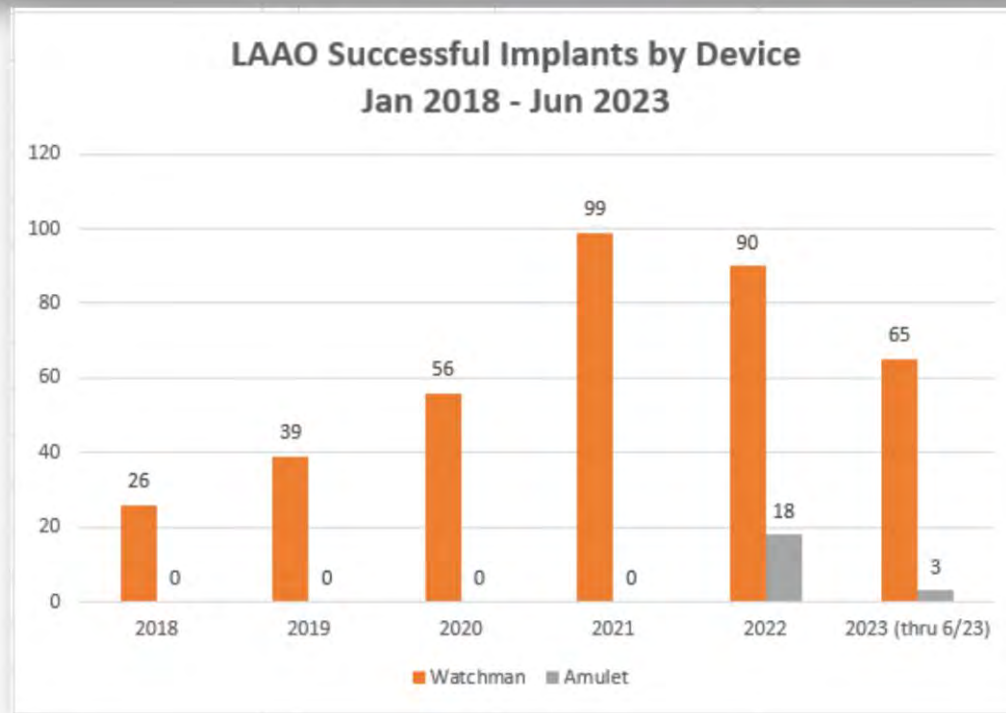


Sharma, S.P. et al. J Am Coll Cardiol EP. 2020;6(4):414-24.



Progress

	Year	Watchman	Amulet
375	2018	26	0
Total Watchman	2019	39	0
21	2020	56	0
Total Amulet	2021	99	0
	2022	90	18
	2023 (thru 6/23)	65	3

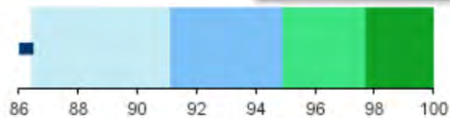


Successful Implants



4 - Proportion of successful LAO procedures

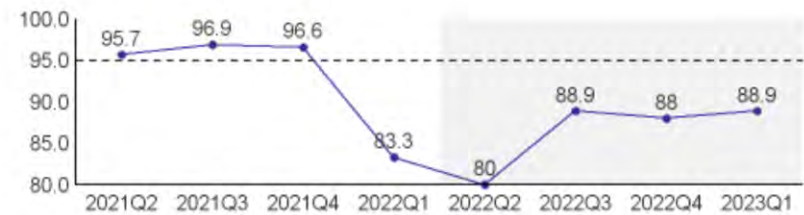
86.5%
My R4Q Performance



(90/104)

10th	25th	50th	75th	90th
86.4	91.1	94.9	97.7	100

US Hospital R4Q Performance Distribution for 2023Q1

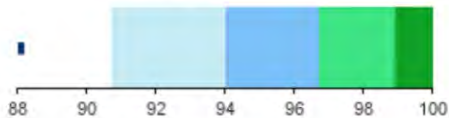


Performance Trend



5 - Proportion of successful LAO procedures excluding canceled procedures

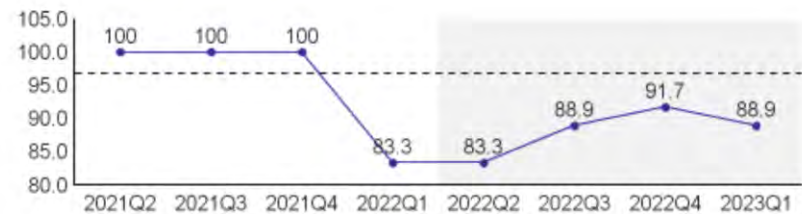
88.2%
My R4Q Performance



(90/102)

10th	25th	50th	75th	90th
90.7	94	96.7	98.9	100

US Hospital R4Q Performance Distribution for 2023Q1

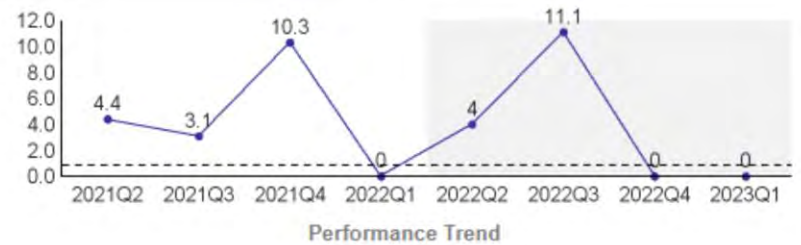


Performance Trend

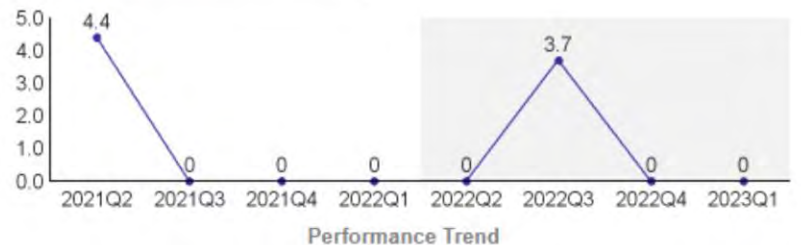


Major Complications and Life-threatening Bleeds

6 - Proportion of patients with a major complication either intra or post procedure and prior to discharge

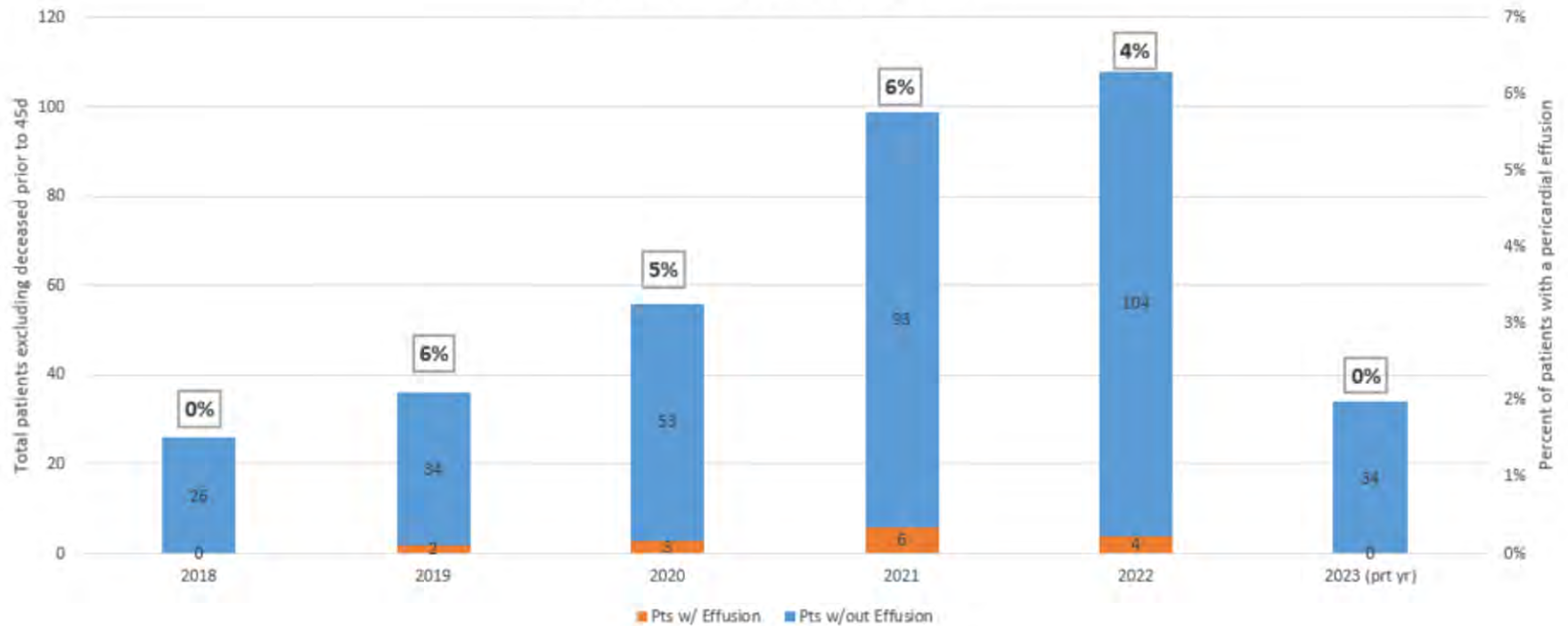


7 - Proportion of patients experiencing a disabling or life threatening bleeding event intra or post procedure and prior to discharge

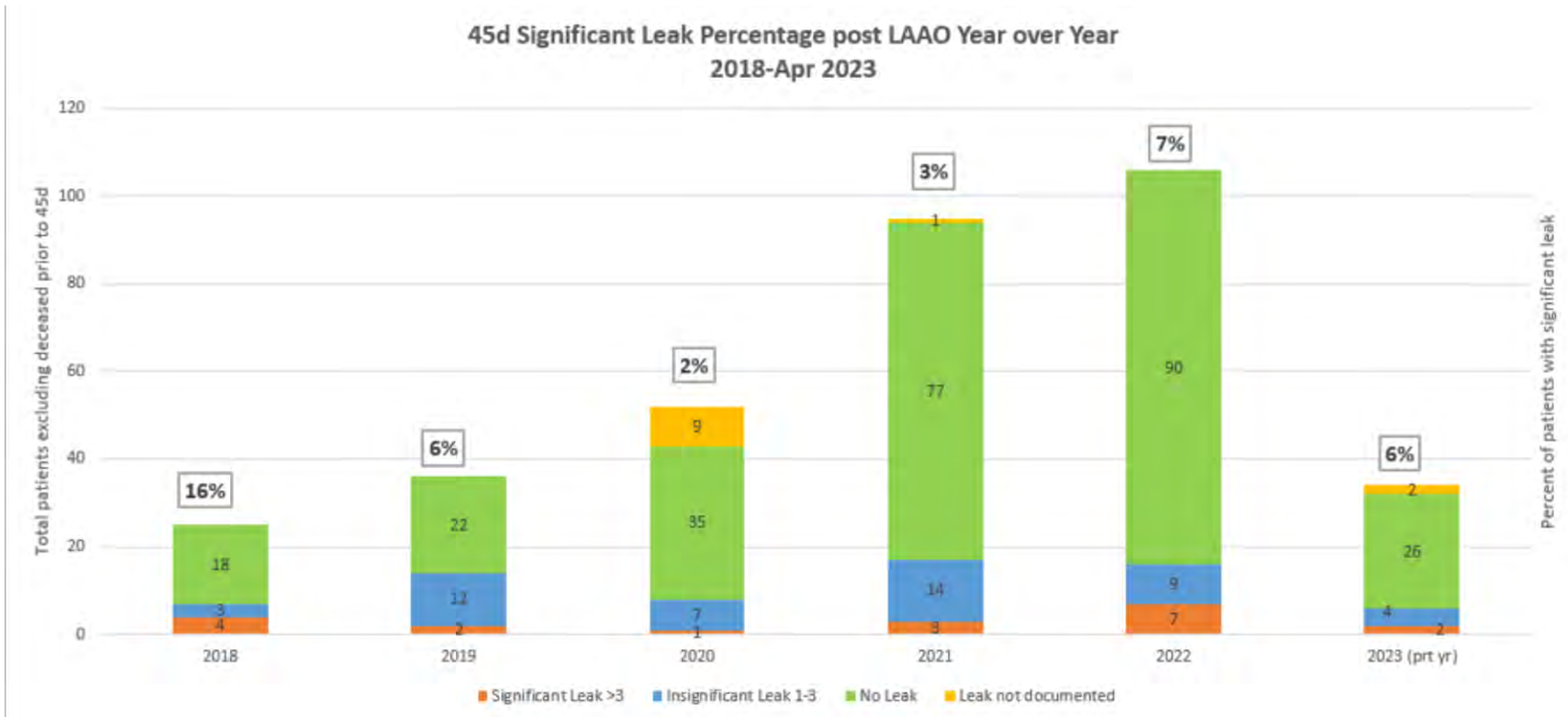


Pericardial Effusions

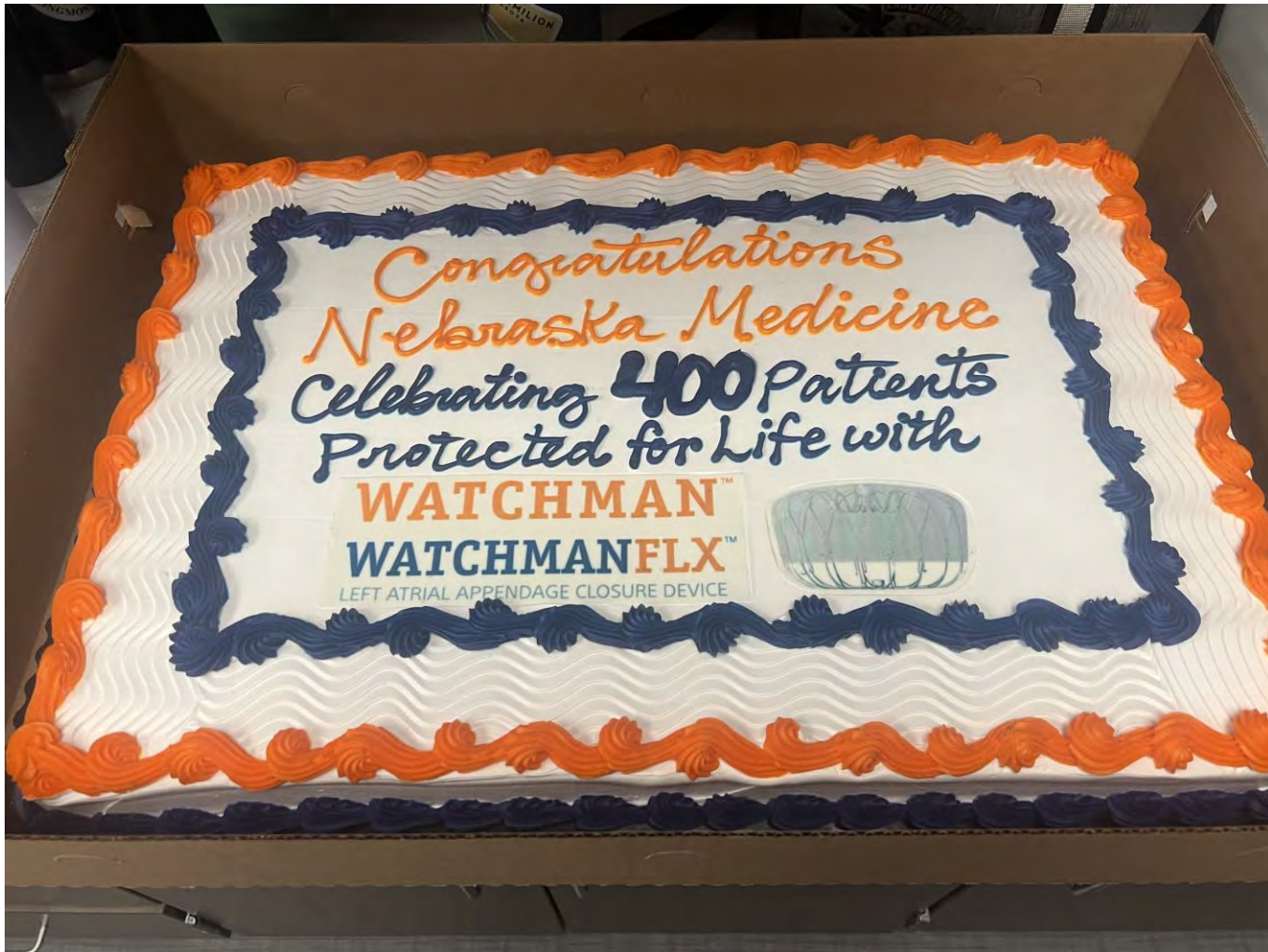
Post Procedure Pericardial Effusion



Peri-device Leaks



Congrats 400!



The Team!



Implanters



