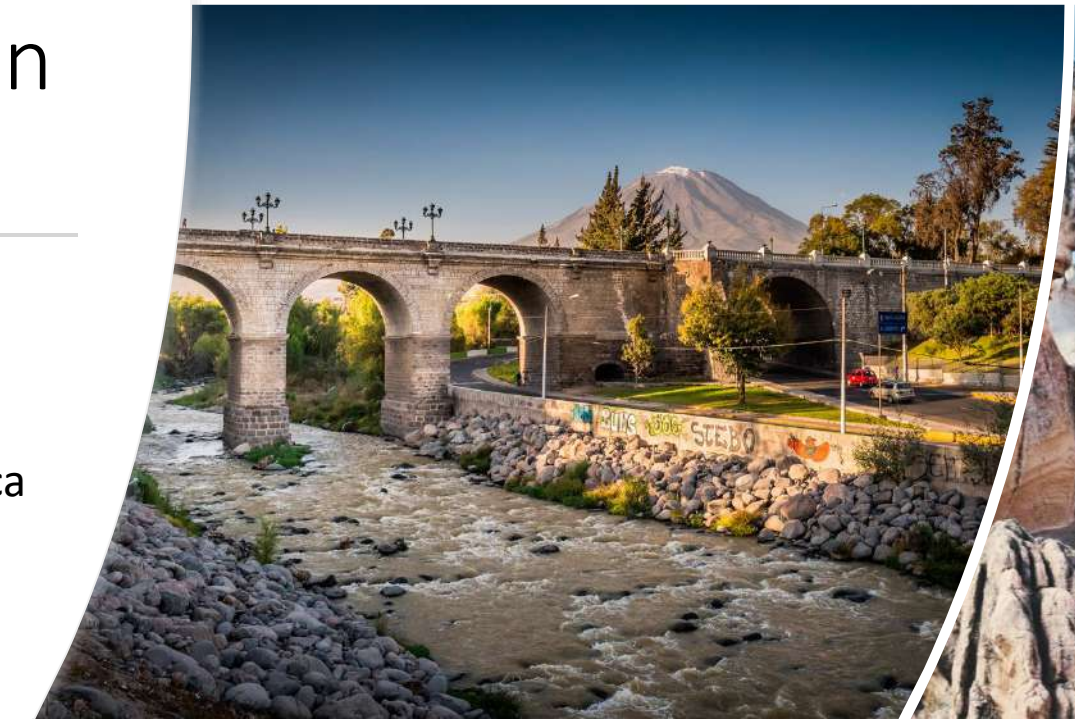
Cierre de Orejuela ¿Qué pacientes se benefician de esta intervención



CLÍNICA San Juan de Dios
AREQUIPA | PERÚ

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Coordonador de Cardiologia Clinica San Juan de Dios – Arequipa

Non-Valvular Atrial Fibrillation (NVAF), Stroke and Current Treatment Options

AF Creates Environment for Thrombus Formation in the Left Atrium

Stasis-related LA thrombus is a predictor of TIA[1] and ischemic stroke[2].

In non-valvular AF, > 90% of stroke-causing clots that come from the left atrium are formed in the LAA[3]

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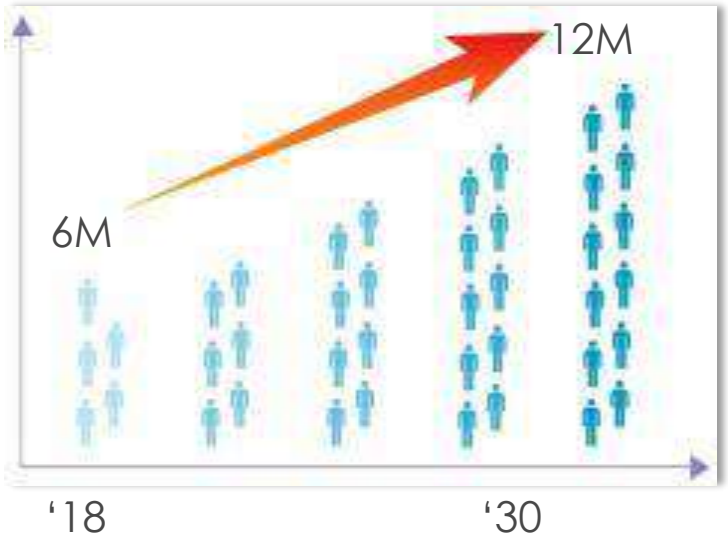
[1]Stoddard et al. Am Heart J. 2003; 145(4): 676-682. [2]Goldman et al. J Am Soc Echocardiography. 1999: 12(12):1080-.1087. [3]Blackshear JL., Odell JA. Annals of Thoracic Surg. 1996; 61: 755-759

Atrial Fibrillation: An Independent Risk Factor for Stroke



~6M

people with AF in U.S., estimated to double by 2030[1]

AF **5X** increased risk of stroke for AF patients[2]

1 in 6 strokes occur in patients with AF[3]

47% of AF patients experiencing a stroke will **suffer a second stroke** within 6 months[4]

~2X greater likelihood of stroke recurrence in AF patients (within 6 months)[4]

1. Benjamin, EJ et al., Heart Disease and Stroke Statistics—2018 Update: A Report From the American Heart Association. Circulation. 2018; 137: e67-e492.
2. Holmes DR, Atrial Fibrillation and Stroke Management: Present and Future, Seminars in Neurology 2010;30:528–536
3. Hart RG, Halperin JL. Atrial fibrillation and thromboembolism: a decade of progress in stroke prevention. Ann Intern Med. 1999.
4. Wolf PA et al, Duration of Atrial Fibrillation and the Imminence of Stroke: The Framingham Study, Stroke 1983; 14:664-667

AF-Related Strokes are Debilitating

Stroke

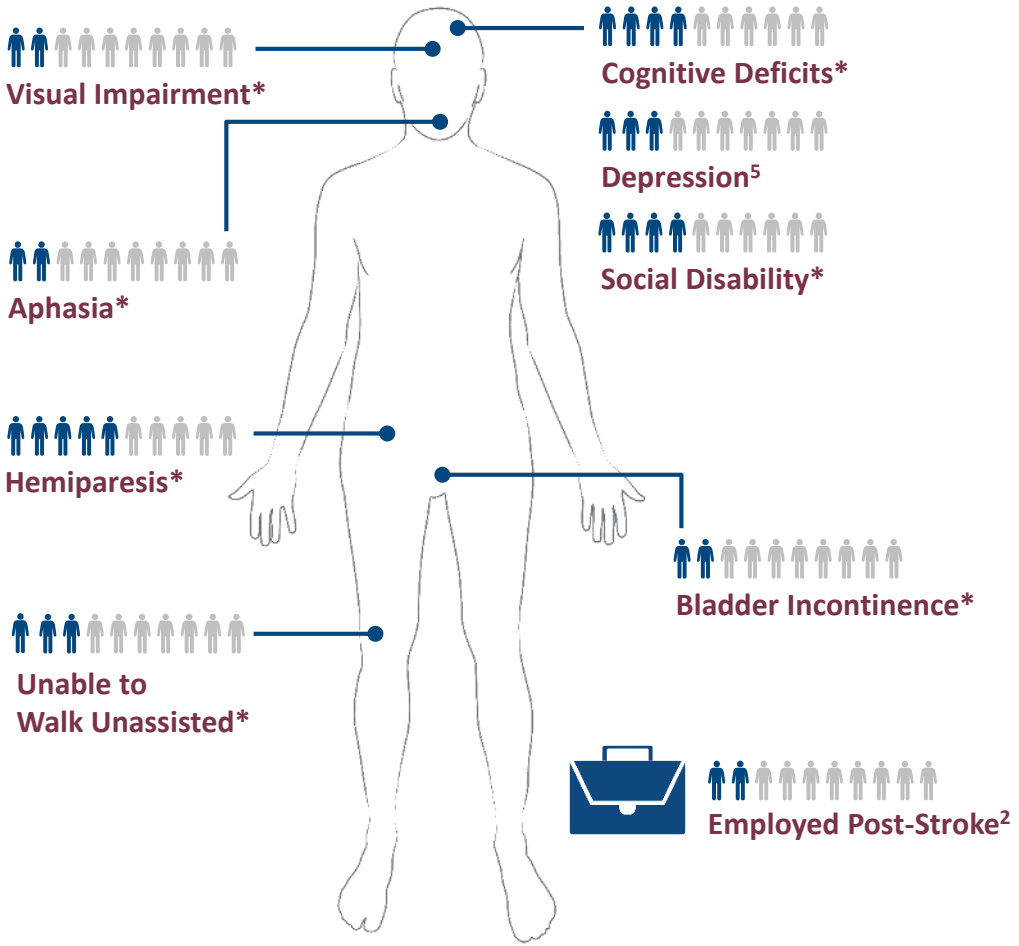
#1 cause of **adult disability** worldwide[1]

AF-related Stroke

1.5X higher **disability**[3**]

2X higher **mortality**[3**]

70% result in **death or permanent disability**[6]



*at 6 months post-stroke[4]

**compared with stroke patients without AF

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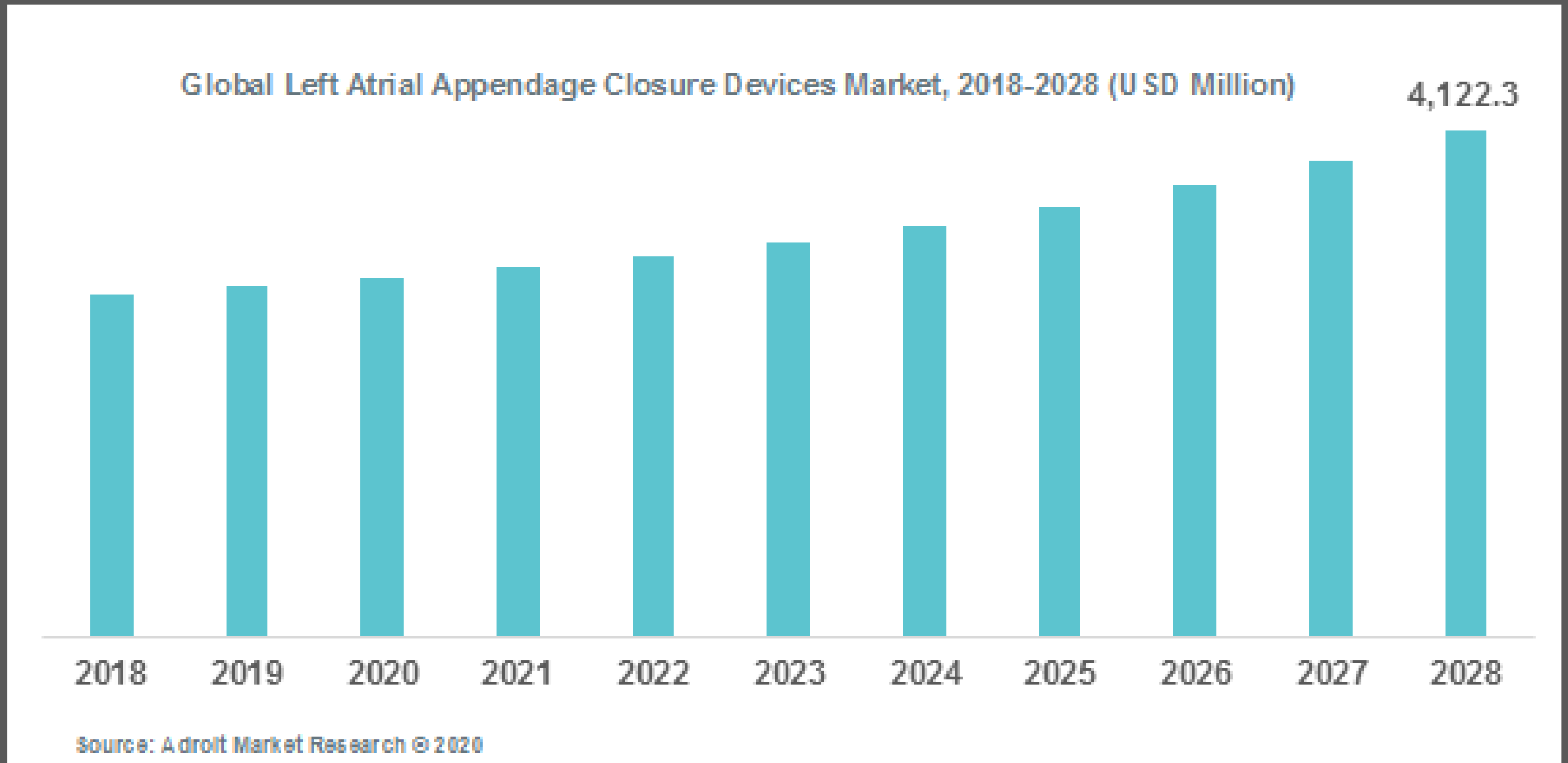
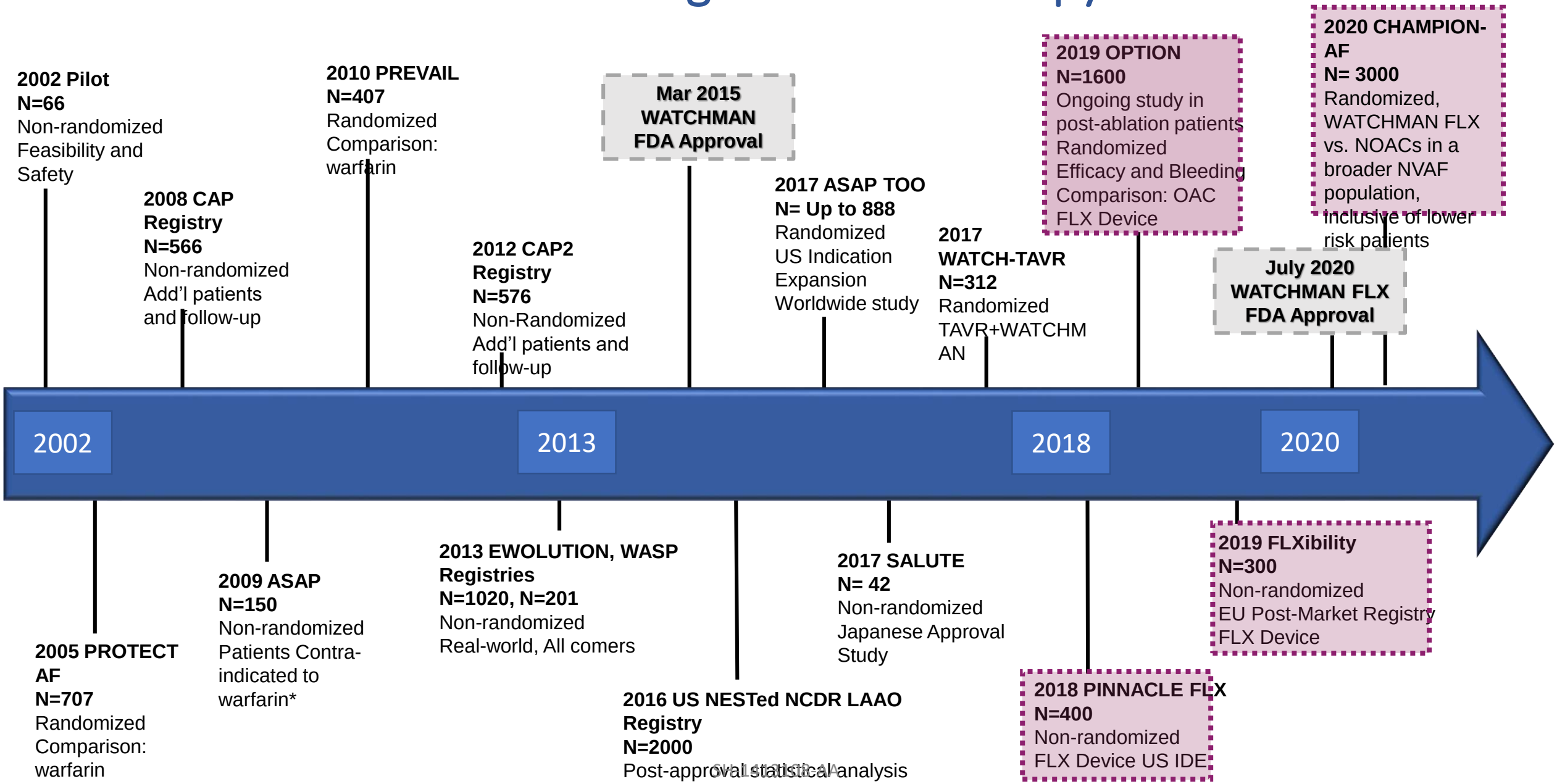
[1]Chee and Tan. Med J Malaysia 69.3 (2014): 119-23. [2]Sreedharan et al. Journ of the neurological sciences 332.1 (2013): 97-101. [3]Lamassa et al. Stroke 32.2 (2001): 392-398.[4]Kelly-Hayes et al. Journ of Stroke and Cerebrovascular Diseases 12.3 (2003): 119-126. [5]Loo and Gan. International Journ of Stroke 7.2 (2012): 165-167. [6]Holmes DR, Seminars in Neurology 2010;30:528–536.


Global Left Atrial Appendage Closure Devices Market, 2018-2028 (USD Million)
4,122.3
2018
2019
2020
2021
2022
2023
2024
2025
2026
2027
2028
Source: Adroit Market Research © 2020

BSC's Commitment to Advancing the LAAC Therapy



*Not US Indication

Atrial Fibrillation Guidelines

2014 ACC/AHA/HRS Treatment Guidelines to Prevent Thromboembolism in Patients with AF & 2019 Focused Update

Assess stroke risk with CHA_2DS_2-VASc score

- Score 1 in men & 2 in women: Annual stroke risk 1%-2%, oral anticoagulants or aspirin **may be considered**
- Score ≥2 in men & ≥3 in women: Annual stroke risk 2%-15%, oral anticoagulants **are recommended**

&

Balance stroke risk reduction benefit vs. bleeding risk

CHA_2DS_2-VASc Score in Men	CHA_2DS_2-VASc Score In Women	Recommendation
0	0	No anticoagulant
1	2	Aspirin (81-325 mg daily) or oral anticoagulants may be considered*
≥ 2	≥ 3	Oral anticoagulants are recommended**

** WATCHMAN and WATCHMAN FLX labeling updated to 81-100 mg ASA in 2020.*

***DOACS (dabigatran, rivaroxaban, apixaban, and edoxaban) recommended over warfarin in DOAC-eligible patients.*

January, CT. et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation. JACC. 2014; doi: 10.1016/j.jacc.2014.03.022
January CT, Wann LS, Calkins H, et al. 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. Journal of the American College of Cardiology 2019; 74(1): 104-132.

WATCHMAN included in AF Guidelines

2019 ACC/AHA/HRS Focused Update on Atrial Fibrillation

4.4. Nonpharmacological Stroke Prevention

4.4.1. Percutaneous Approaches to Occlude the LAA

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.

"Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with AF and elevated stroke risk. However, **for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence)**, the Watchman device provides an alternative."

January CT, Wann LS, Calkins H, et al. 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. Journal of the American College of Cardiology 2019; 74(1): 104-132.

Difficult to Strike a Balance in Stroke and Bleeding Risk

CHA_2DS_2-VASc Score	Annual % Stroke Risk
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7

HAS-BLED Score	Annual % Bleed Risk
0	0.9
1	3.4
2	4.1
3	5.8
4	8.9
5	9.1

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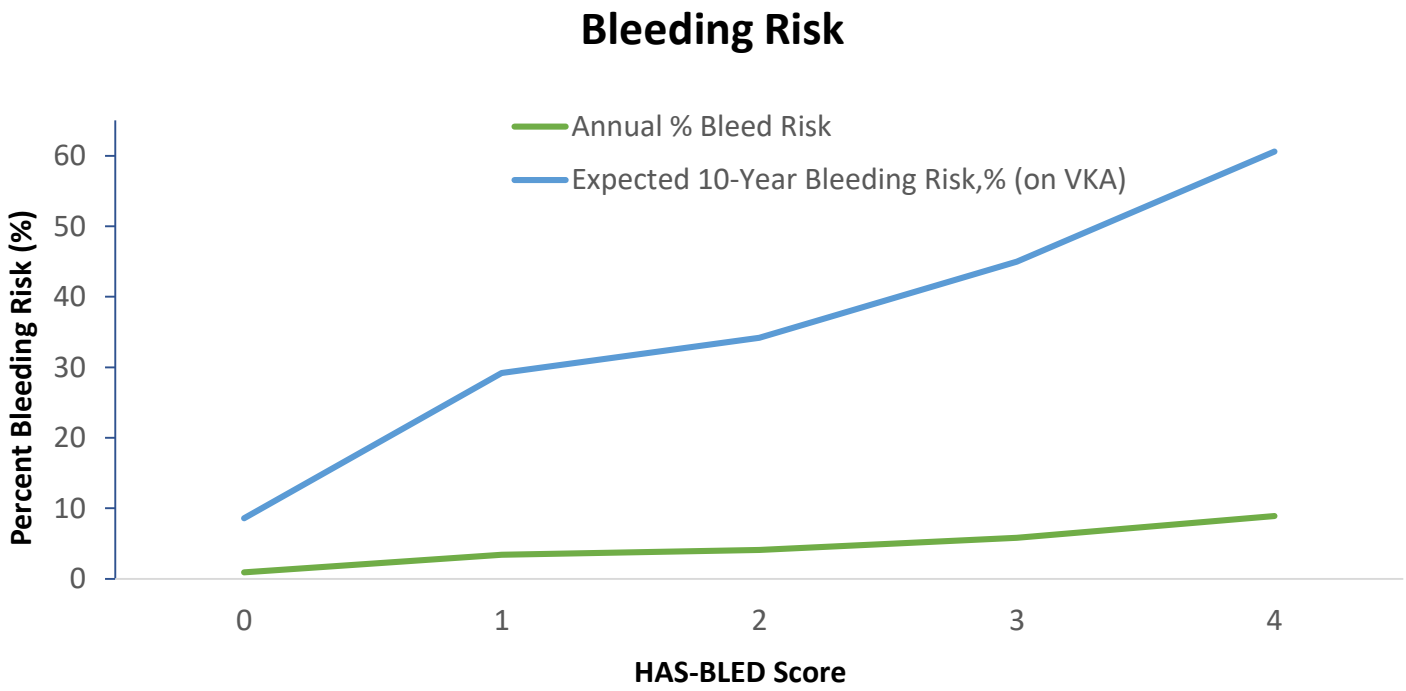
[1]2014 AHA/ACC/HRS Guidelines. [2]Lip. JACC . 2011; 57(2): 173-180

Bleeding Risk Compounds Over Patients' Lifetime

CHA_2DS_2-VASc* Score	Annual % Stroke Risk		HAS-BLED Score [1]	Annual % Bleed Risk[1]	Estimated 10-Year Bleeding Risk (%)*
0	0		0	0.9	8.6
1	1.3		1	3.4	29.2
2	2.2		2	4.1	34.2
3	3.2		3	5.8	45.0
4	4.0		4	8.9	60.6
5	6.7		5	9.1	61.5



*Assumes constant risk despite increasing age, and bleeding risk is independent from bleeding risk in previous years.

CHA2DS2-VASc score – Congestive heart failure=1, Hypertension (SBP >160)=1, Age > 75 yrs=2, Diabetes mellitus=1, Prior stroke, TIA, or thromboembolism=2, Vascular disease (PAD, MI)=1, Age 65-74 yrs=1, Sex category (female)=1.

HAS-BLED score – Hypertension=1, Abnormal renal/liver function (1pt each)=1 or 2, Hemorrhagic stroke=1, Bleeding history or disposition=1, Labile INRs=1, Elderly=1, Current drugs (medication) or alcohol use (1 pt each)=1 or 2.

The HAS-BLED scoring system predicts a patient's risk of major bleeding while on warfarin.

1. Lip GYH, et al. Comparative Validation of a Novel Risk Score for Predicting Bleeding Risk in Anticoagulated Patients with Atrial Fibrillation: The HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) Score. JACC. 2011; 57(2):173-180.

Finding Your WATCHMAN™ Patients

WATCHMAN™ Patient Criteria

1. Patient has Non-Valvular Atrial Fibrillation (NVAF)
2. Patient has an increased risk for stroke and is recommended for oral anticoagulation (OAC)
3. Patient is suitable for short-term anticoagulation therapy but deemed unable to take long-term OAC
4. Patient has an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy.

CMS Decision Memo for Percutaneous LAAC Therapy (page 91)

Explore the Broad Range of Patients Suitable for WATCHMAN

Examples of factors that may warrant seeking a non-pharmacologic alternative to anticoagulation therapy:

1. History of bleeding
2. Increased bleeding risk based on HAS-BLED score or other factors (e.g. thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)
3. History or risk of falls
4. Documented poor compliance with OAC therapy
5. Inability or difficulty maintaining therapeutic range
6. Occupation that puts patient at an increased bleeding risk
7. Lifestyle or hobby that puts patient at an increased bleeding risk
8. Severe renal failure – medical condition for which OAC inappropriate
9. Avoidance of triple therapy after PCI or TAVR
10. Other situations for which OAC is inappropriate
11. Drug or medication regimen not compatible with oral anticoagulant therapy

WATCHMAN Therapy Candidates

What type of LAAC candidates are you referring today?

Drug Interactions	Bleeder	Future Bleeder	Non-Compliant	Lifestyle & Occupation
Not suitable for long-term anticoagulation therapy use due to other medical treatment needs	History of major and/or non-major bleeding	No prior bleeds but high-risk / include fall risk	Tolerant, but not taking OAC	Patient prefers device over OAC

GRACIAS

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