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# Tricuspid Valve Dysfunction After Leadless Versus Transvenous Pacemakers: The LEADLESS-TR

Kerollos Abdelsayed, Nadira Hamid, Ali Bahbah, Mariam Tarek Desouki, Dawn Witt, Emily Halvorson, Melanie Kapphahn-Bergs, Edwin Zishiri, Scott Sharkey, Robert Hauser, Joao Cavalcante, and Jay Sengupta

Heart Rhythm Science Center, Minneapolis Heart Institute Foundation, Minneapolis, MN, USA

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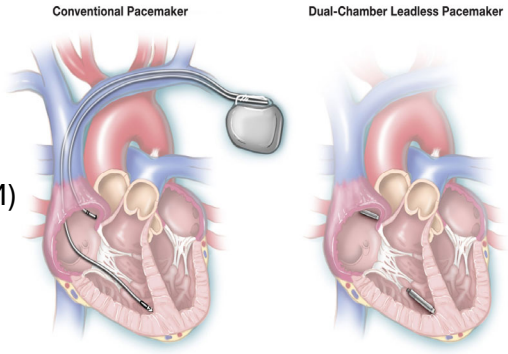
## Disclosures

- None



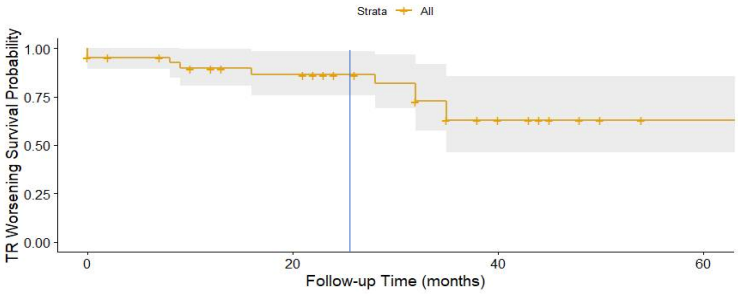
## Background

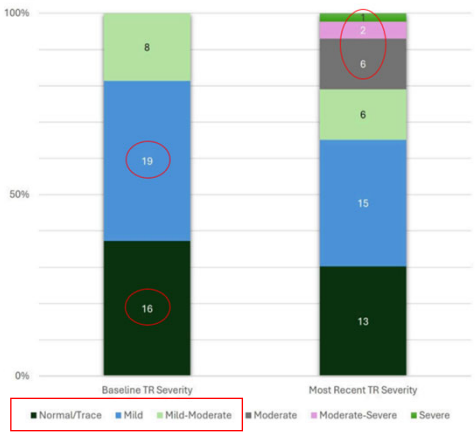
- Leadless pacemakers (LPM) emerged as a valuable alternative to transvenous pacemakers to avoid complications of transvenous permanent pacemakers (TV-PPM)
- LPM impact on long-term tricuspid valve (TV) dysfunction remains conflicting



## Preliminary analysis

- 43 first-time Micra LPM patients with non-significant baseline TR
- 23.3% incidence on new TR Worsening ≥2 grades

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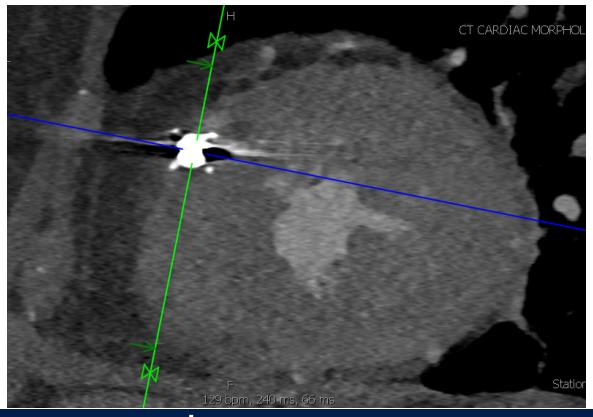
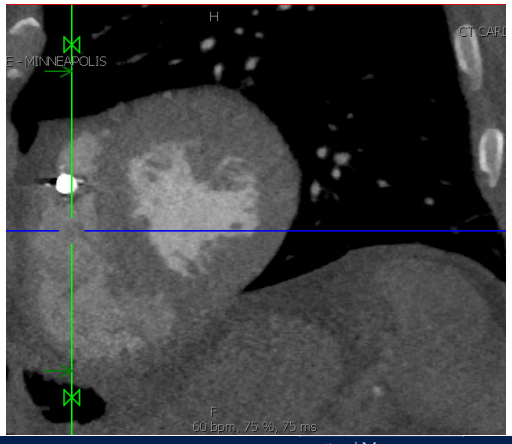
## Preliminary analysis

Evidence of device location discrepancy on CT scan

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## Aims

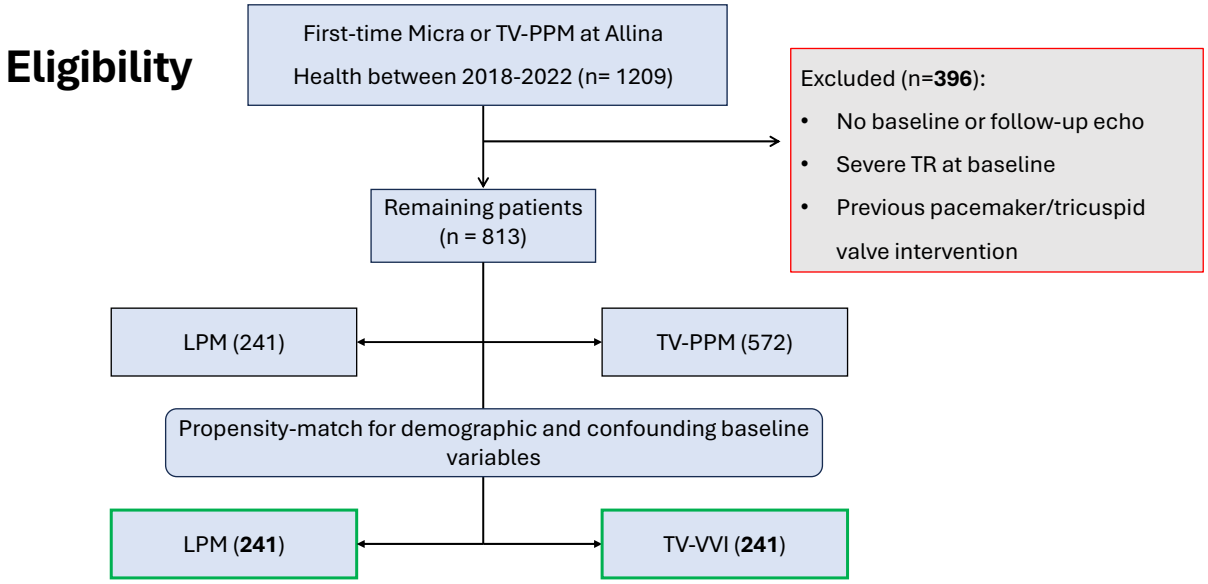
1. Compare progression of TV Dysfunction between LPM versus dual chamber TV-PPM
2. Explore the progression in LV Dysfunction and MACE



## Methods

- **LEADLESS-TR** was a retrospective multicenter study
- First Micra or dual-chamber TV-PPM implantation (2018-2022) at one of the three Allina Health Hospitals (Abott, United, Mercy)
- A baseline and ≥1 follow-up echocardiogram within 5.5 years
- Up to moderate baseline TR severity with no history of TR interventions
- Follow-up: 5.5 years or death, pacemaker inactivation, or a valve intervention

## Eligibility



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## Baseline Characteristics

- 1:1 Nearest Neighbor Propensity Score Match

1. Age at implant
2. Sex
3. Implant year
4. Baseline LVEF

| Characteristic | Overall N = 482 | TVP N = 241 | MICRA N = 241 | p-value |
|---|---|---|---|---|
| Age (years) | 78 (72, 84) | 78 (72, 83) | 78 (72, 84) | 0.2 |
| Females | 177 (37%) | 86 (36%) | 91 (38%) | 0.6 |
| Baseline LVEF | 60 (55, 65) | 60 (55, 65) | 60 (55, 65) | 0.9 |
| BMI | 29 (25, 33) | 28 (25, 32) | 29 (25, 35) | 0.12 |
| CKD | 223 (46%) | 91 (38%) | 132 (55%) | **<0.001** |
| DM | 158 (33%) | 62 (26%) | 96 (40%) | **<0.001** |
| Follow-up time (years) | 2.63 (1.15, 3.92) | 2.43 (1.11, 3.33) | 2.96 (1.19, 4.78) | **<0.001** |



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## Outcomes

**TR was graded as:**
0= None/Trace
1= Mild
2= Moderate
3= Severe

1. TR worsening ≥1 grade
2. LVEF Worsening >10% reduction
3. MACE (a composite of cardiac death or heart failure hospitalization)

**Multivariate Cox Models** adjusted for BMI, CKD, diabetes, and baseline TR



## TR worsening >1 grade

| Characteristic | HR | 95% CI | p-value |
|---|---|---|---|
| Pacemaker Type | | | |
| **TV-PPM** (~22%) | — | — | |
| **MICRA** (~25%) | 1.17 | 0.87, 1.57 | 0.3 |
| BMI | 0.98 | 0.96, 1.00 | 0.10 |
| CKD | 0.87 | 0.65, 1.17 | 0.3 |
| DM | 1.87 | 1.33, 2.61 | **<0.001** |
| Baseline TR | | | |
| Normal | — | — | |
| Mild | 0.79 | 0.57, 1.08 | 0.13 |
| Moderate | 0.86 | 0.53, 1.39 | 0.5 |

# LVEF worsening >10%

| Characteristic | HR | 95% CI | p-value |
|---|---|---|---|
| Pacemaker Type | | | |
| **TV-PPM** | — | — | |
| **MICRA** | 0.86 | 0.57, 1.31 | 0.5 |
| BMI | 1.01 | 0.98, 1.04 | 0.5 |
| CKD | 0.99 | 0.66, 1.49 | >0.9 |
| DM | 1.41 | 0.93, 2.15 | 0.11 |
| Baseline LVEF | 0.99 | 0.97, 1.02 | 0.6 |



# MACE

| Characteristic | HR | 95% CI | p-value |
|---|---|---|---|
| Pacemaker Type | | | |
| **TV-PPM** | — | — | |
| **MICRA** | 1.08 | 0.79, 1.49 | 0.6 |
| BMI | 1.00 | 0.97, 1.02 | 0.8 |
| CKD | 1.89 | 1.36, 2.62 | **<0.001** |
| DM | 1.79 | 1.28, 2.49 | **<0.001** |

## Limitations

- Retrospective observational analysis
- Relatively small sample size
- No account for TR improvement or temporary changes
- LPMs were followed slightly longer than TV-PPM
- Potential inter-observer variability



## Comparability

University of Amsterdam
**43% worsening**


Circulation: Arrhythmia and Electrophysiology

CURRENT ISSUE | ARCH

RESEARCH ARTICLE | Originally Published 7 May 2019 | Check for updates

Impact of Leadless Pacemaker Therapy on Cardiac and Atrioventricular Valve Function Through 12 Months of Follow-Up

Niek E.G. Beurskens, MD, Fleur V.Y. Tjong, MD, PhD, Rianne H.A. de Bruin-Bon, BsC, Kosse J. Dasselaar, MD, Wichert J. Kuijt, MD, Arthur A.M. Wilde, MD, PhD, and Reinoud E. Knops, MD, PhD | AUTHOR INFO & AFFILIATIONS

UCSD: **22% Micra** vs **26% TV-PPM**, p=0.192


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Circulation

CURRENT ISSUE | AR

Meeting Abstract: Abstracts From the American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium

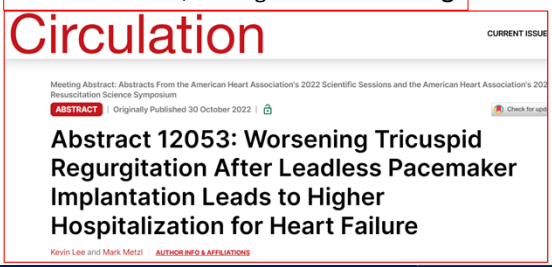
ABSTRACT | Originally Published 11 November 2024 | Check for updates

Abstract 4138230: Incidence of Worsening Tricuspid Regurgitation Following Implantation of Leadless versus Dual-Chamber Pacemakers

Omar Aldaas, MD, Jesus Gil, BS, Gordon Ho, MD, and Ulrika Birgersdotter-Green, MD AUTHOR INFO & AFFILIATIONS

Circulation • Volume 150, Number Suppl_1 • https://doi.org/10.1161/circ.150.suppl_1.4138230

NorthShore Univ, Chicago: **38% worsening**


Circulation

CURRENT ISSUE

Meeting Abstract: Abstracts From the American Heart Association's 2022 Scientific Sessions and the American Heart Association's 202 Resuscitation Science Symposium

ABSTRACT | Originally Published 30 October 2022 | Check for upd

Abstract 12053: Worsening Tricuspid Regurgitation After Leadless Pacemaker Implantation Leads to Higher Hospitalization for Heart Failure

Kevin Lee and Mark Metzl AUTHOR INFO & AFFILIATIONS

## Could it be possible?

- Challenges in device deployment:
  1. Biplane fluoroscopy
  2. Delivery system and procedure complexity
  3. Suboptimal septal pacing with the need to reposition



## Could it be possible?

- Device location and stability
  - More septal -> TV interaction
  - More apical/free wall -> LV dyssynchrony
  - Interaction with sub-valvular apparatus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Circulation: Arrhythmia and Electrophysiology CURRENT ISSUE

REVIEW ARTICLE | Originally Published 17 May 2021 | Check for updates

Close Proximity of Leadless Pacemaker to Tricuspid Annulus Predicts Worse Tricuspid Regurgitation Following Septal Implantation

Jo-Jo Hai, MBBS, Yankai Mao, MD, Zhe Zhen, PhD, Jonathan Fang, MBBS, Chun-Ka Wong, MBBS, Chung-Wah Siu, MD, Kai-Hang Yiu, MD, Chu-Pak Lau, MD, and Hung-Fat Tse, MD, PhD AUTHOR INFO & AFFILIATIONS

Circulation: Arrhythmia and Electrophysiology • Volume 14, Number 5 • https://doi.org/10.1161/CIRCEP.120.009530

## Biplane Fluoroscopy

PACE
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DEVICES | Full Access

**Leadless pacemaker implantation sites confirmed by computed tomography and their parameters and complication rates**

Hirofumi Arai MD, Akira Mizukami MD, Yoshihiro Hanyu MD, Takuya Kawakami MD, Yuki Shimizu MD, Jiro Hiroki MD, Kenji Yoshioka MD, Hirofumi Ohtani MD, Maki Ono MD, PhD ... See all authors

First published: 03 January 2022 | https://doi.org/10.1111/pace.14437 | Citations: 3

53.8% unintentional non-septal implantation

JACC Journals › JACC: Clinical EP › Archives › Vol. 8 No. 12

FREE ACCESS | Research Letter | 28 September 2022

**Echocardiogram-Guided Leadless Pacemaker Implantation**

Authors: Rahul Bhardwaj, Jakrin Kewcharoen, Tahmeed Contractor, Srishti Nayak, Saif Ai, Uoo Kim, Ravi Mandapati, and Jalaj Garg | AUTHORS INFO & AFFILIATIONS

Publication: JACC: Clinical Electrophysiology • Volume 8, Number 12

40.7% RV Free wall

JOURNAL ARTICLE

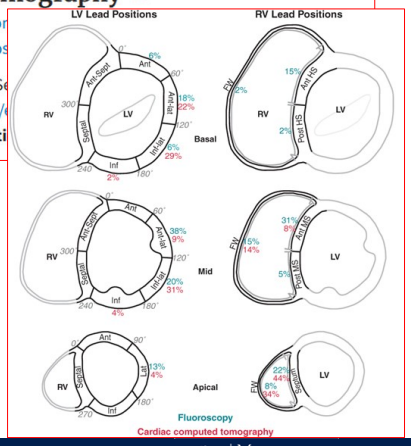
**Left and right ventricular lead positions are imprecisely determined by fluoroscopy in cardiac resynchronization therapy: a comparison with cardiac computed tomography** FREE

Anders Sommer, Mads Brix Kron, Peter Thomas Mortensen, Jens Cos

*EP Europace*, Volume 16, Issue 9, Se

https://doi.org/10.1093/europace/

**Published:** 30 March 2014 Arti

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## Implications

- Future research should confirm those observations, and if confirmed, investigate the mechanisms behind

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ORIGINAL ARTICLE

**A Dual-Chamber Leadless Pacemaker**

Authors: Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D., Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D., Robert Canby, M.D., +10, for the Aveir DR iZi Study Investigators* Author Info & Affiliations

Published May 20, 2023 | N Engl J Med 2023;388:2360-2370 | DOI: 10.1056/NEJMoa2300080 | VOL. 388 NO. 25

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PHYSIOLOGICAL PACING · Volume 22, Issue 8, P2010-2017, August 2025 · Open Access | Download Full Issue

**First-in-human study of a leadless pacemaker system for left bundle branch area pacing**

Vivek Y. Reddy, MD [1,2] · Devi G. Nair, MD, FHRS [3] · Shephal K. Doshi, MD [4] · ... · Leyla Sabet, PhD [6] · Chunlan Jiang, PhD [6] · Petr Neuzil, MD, PhD [2] ... Show more

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## Conclusion

1. With the study limitations in mind, LPMs showed no significant advantage over TV-PPMs in preserving the TV function, LVEF, or reducing MACE
2. Prospective head-to-head studies with advanced imaging should be performed to investigate any potential device-valve interactions and guide more accurate device deployment



# Thank you!

# A Regional Partnership Model for VA-ECMO Initiation and Transfer from Remote Centers Using Air Medical Transport

Maroun Chedid, MD
Katarzyna Hryniewicz, MD
10/27/2025

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## Background

- Partnership between MHI and Bismarck Air Medical (BAM)
- Goal is to provide comprehensive training in all types of mechanical circulatory support (MCS), mainly VA ECMO
- Collaboration includes:
  - Education through lectures held virtually every 2 months
  - Hands-on simulation for the flight team
  - 24/7 cardiogenic shock hotline for consultation on VA-ECMO candidacy
  - Real-time management support once ECMO is initiated

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Patient identified as a candidate for VA ECMO

Transfer supervisor nurse informed

Thread created between outside site staff and on call Heart Failure specialist at MHI

Assess candidacy for VA ECMO

Initiate Transfer Protocol



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CARDIOVASCULAR EMERGENCIES

## Pre-Transport Checklist - Patient on ECMO

### Goals for Transport:

- MAP 50-90mmHg on 3 or less vasoactive medications
- Mechanical Ventilation: Volume control with TV 4-6 ml/kg, PEEP 10, and RR<14
- ECMO: sweep at 2.5 LPM -VA; sweep at 1.0 LPM -VV (avoiding rapid correction of PaCo2)
  - SaO2 >90% in RUE ABG is a qualifying marker of adequate support
- Patient is sedated
- 2 units of packed red blood cells (PRBC) available for transport (4 packs in bleeding patient)
- Cannulas sutured to skin AND secured with stat lock device

**If your patient is outside of the above criteria please notify Heart Failure Provider for VA and Intensivist for VV**

### Additional Guidelines:

- Stabilize cannula site bleeding prior to transport
- If Hgb < 9, consider transfusion of PRBC
- If pH <7.2 from metabolic acidosis, consider bicarb (draw from right radial/brachial arterial line)
- If iCa <1.2, give 1 gram calcium gluconate
- If chatter is present in ECMO tubing, give 500 ml 5% albumin
- Venous or drainage cannula tip should be above intrahepatic IVC on X-ray
- Rule out increased intrathoracic pressure such as pneumothorax, hemothorax, etc.
- Inspect cannula for dislodgement, obstructon or kinking prior to transport

### For Further Assistance

VV ECMO contact Tele Intensivist at 612-775-9999

VA ECMO contact Advanced Heart Failure line at 612-246-9460

Allina Health



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- Bismarck Air Medical provides a Critical Care Registered Nurse with ICU or ER experience along with a specialty trained Paramedic
- MHI perfusionist accompany the flight team to manage the ECMO pump during interfacility air transport

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# Patient Characteristics and Outcomes


ND: Altru Grand Forks; Essentia Fargo; Sanford Bismarck; St Alexius Bismarck.
SD: Aberdeen Medical Center Aberdeen; Sanford Sioux Falls

| Total | N= 15 patients |
|---|---|
| Male | 80% |
| Age, Median (Q1-Q3) | 60 (49-68) |
| Indication | STEMI 73.3%, PC Shock 26.7% |
| Distance, average | 323 miles (520 kilometers) |
| Time to arrival, Median (Q1-Q3) | 14.7 hours (11.7–18.9). |
| Time on ECMO, Median (Q1-Q3) | 94 hours (87–122) |
| Survival to decannulation | 66.7% |
| Survival to discharge | 53.3% |

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# Ablation of atypical flutter using a dual energy lattice-tip focal catheter and integrated mapping system: addressing target tissue-form factor mismatch.

Mariam Tarek Desouki, MD[1]; Ali Bahbah, MD[1,2]; Kerollos Abdelsayed, MD[1]; Evan Walser-Kuntz, MS[3]; Tesfatsiyon Ergando, MD[4]; Emily Halvorson[1], Melanie Kapphahn-Bergs, RN[1]; Dawn Witt, PhD[1]; Edwin Zishiri, MD[1]; John Zakaib, MD[1]; JoEllyn C. Moore, MD[1]; Raed H. Abdelhadi, MD[1]; Robert G.Hauser, MD[1]; Jay Sengupta, MD[1].

[1]The Joseph F. Novogratz Family Heart Rhythm Science Centre, Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, USA.
[2]Department of Medicine, University of California San Francisco, Fresno Program.
[3]Minneapolis Heart Institute Foundation, Minneapolis, Minnesota, USA.
[4]Minneapolis Heart Institute and Hennepin Health.

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## Disclosures

- None

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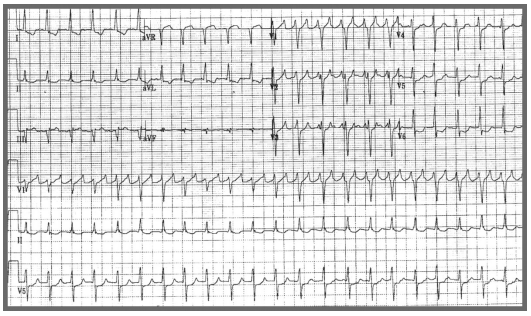
## Background

Challenges encountered with atypical atrial flutter

- Comorbid patients with > 2 prior ablation procedures
- Extra-PV sites of origin
- Co-existence of atrial myopathy and extensive fibrosis
- Requirement of complex electro-anatomical mapping
- High recurrence rate



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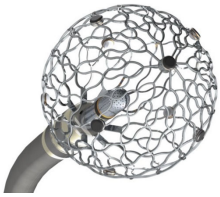
## Background

- Wide area focal design
- Dual-energy source
- Bidirectional steering = more precision
- Integrated mapping and ablation = zero exchange work-flow
- Real time temperature feedback
- High density mapping



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# Background

| | Radiofrequency ablation | Fara wave pulse ablation | Affera Pulse ablation |
|---|---|---|---|
| |  |  |  |
| **Energy form** | Thermal energy | Non-thermal energy | Both thermal and non-thermal energy |
| **Tissue selectivity** | No | Yes | Yes |
| **Device diameter** | 4-10 mm | 31-35 mm | 9 mm |

Urbanek L, Bordignon S, Schaack D, Chen S, Tohoku S, Efe TH, et al. Pulsed Field Versus Cryoballoon Pulmonary Vein Isolation for Atrial Fibrillation: Efficacy, Safety, and Long-Term Follow-Up in a 400-Patient Cohort. Circ Arrhythm Electrophysiol. 2023 Jul;16(7):389–98.

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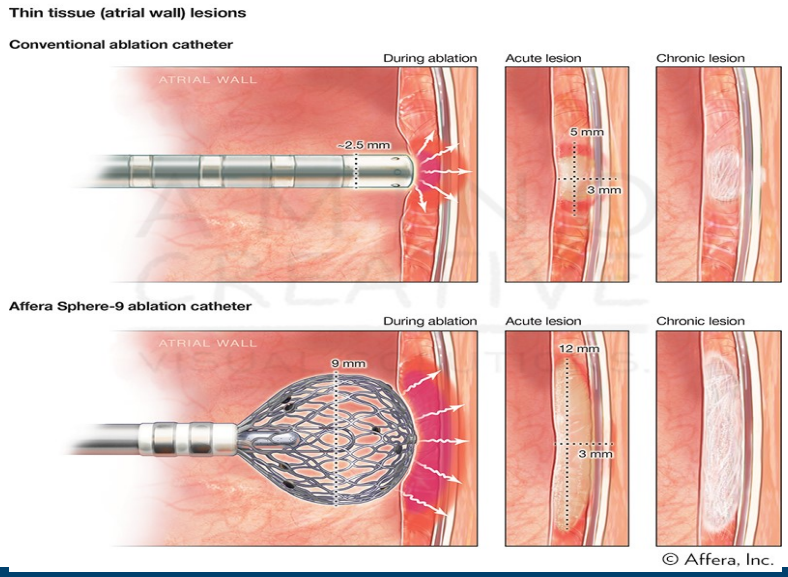


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## Aim

- To determine the safety, intra-procedural efficacy, and short-term outcomes of Sphere 9 catheter in the treatment of patients with atypical atrial flutter (AAFL).

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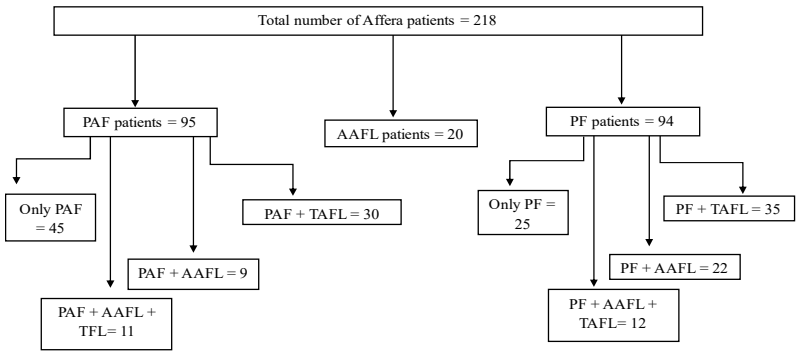
**Fig. 1:** Overview of Affera cohort according to the type of atrial arrhythmia targeted during the ablation




PAF = Paroxysmal atrial fibrillation, TAFL= Typical atrial flutter, PF = Persistent atrial fibrillation, AAFL = atypical atrial flutter.

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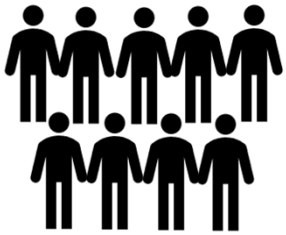
# Methods

Single-Center Retrospective study



Patients diagnosed with AAFL, defined as atrial flutter originating from a site other than cavotricuspid isthmus.

Presented to our EP clinic from January 2025 to July 2025.

Procedural end points like fluoroscopy time, fluoroscopy dose, procedural time, and acute procedural success

1. Post-procedural safety outcomes like MACCE, and acute kidney injury.
2. Recurrence rate >3 month after the procedure.

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**Table 1.** Baseline characteristics of atypical flutter patients included in our cohort.

| Characteristic | Overall N = 74[1] | Ablation-naive patients N = 25[1] | Previously ablated patients N = 49[1] | P-value[2] |
|---|---|---|---|---|
| **Age** | 72 (63,78) | 72 (57,78) | 73 (64,77) | 0.6 |
| **BMI (kg/m²)** | 30 (26,35) | 28 (24, 30) | 31 (28, 35) | 0.024 |
| **Race (Caucasian)** | 73 (99%) | 24 (96%) | 49 (100%) | |
| **Gender (male)** | 41 (55%) | 16 (64%) | 25 (51%) | 0.3 |
| **Dyslipidemia** | 48 (66%) | 16 (64%) | 32 (67%) | 0.8 |
| **Hypertension** | 46 (62%) | 14 (56%) | 32 (65%) | 0.4 |
| **Diabetes Mellitus** | 12 (16%) | 2 (8.3%) | 10 (20%) | 0.3 |
| **Valvular heart disease** | 21 (28%) | 6 (24%) | 15 (31%) | 0.6 |
| **Congenital heart disease** | 6 (8.1%) | 1 (4%) | 5 (10%) | 0.7 |
| **Echocardiography parameters** | | | | |
| **Left ventricular ejection fraction (%)** | 60 (55,65) | 57 (54,60) | 60 (55,65) | 0.2 |
| **Left atrial size** | 4.30 (3.90, 4.80) | 4.20 (3.60, 4.40) | 4.40 (3.90, 5.00) | 0.2 |
| **Left atrium volume index** | 41 (33,50) | 33 (28,51) | 41 (36, 48) | 0.3 |

[1]Median (Q1, Q3); n (%)
[2]Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

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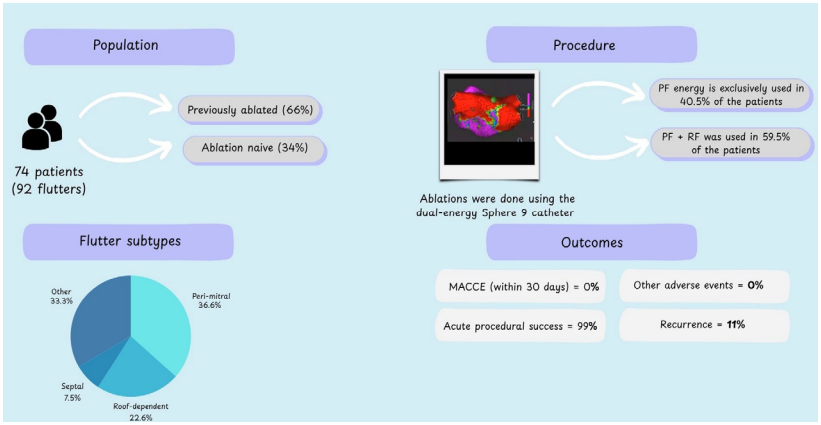
# General overview

**Central illustration.** Descriptive overview of the atypical atrial flutter patients undergoing Affera catheter ablation

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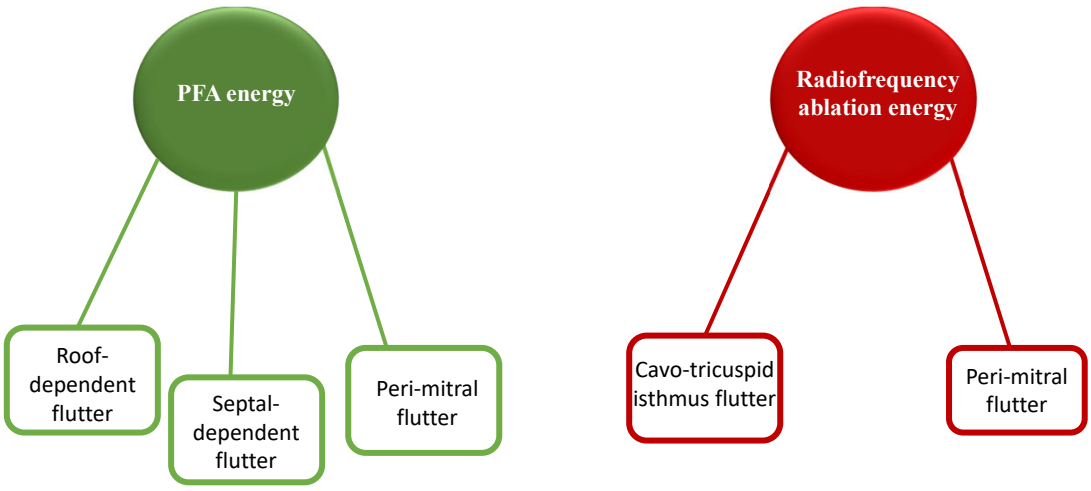
# Results

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# Results

**Table 2.** Procedural characteristics of atypical flutter patients included in our cohort.

| Characteristic | Overall N = 74[1] | Ablation-naive patients N = 25[1] | Previously ablated patients N = 49[1] | P-value[2] |
|---|---|---|---|---|
| **Procedural success** | | 99 % | | |
| **Procedure time, min** | 94 (81, 117) | 90 (78, 115) | 97 (83, 118) | 0.6 |
| **Trans-septal left atrial pressure (mmHg)** | 14.0 (11.0, 17.5) | 14.5 (11.0, 17.0) | 14.0 (11.0, 18.0) | 0.9 |
| **Fluoroscopy time, min** | 2.5 (0.0, 5.5) | 0.0 (0.0, 3.2) | 3.1 (0.0, 5.6) | 0.062 |
| **Fluoroscopy dose, mGy** | 3 (0, 13) | 0 (0, 3) | 9 (0, 16) | 0.027 |
| **Total ablation time, milliseconds** | 317 (211, 483) | 471 (413, 534) | 276 (191, 418) | <0.001 |

[1]Median (Q1, Q3); n (%)
[2]Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

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# Results

## Comparative procedural success within our cohort

82 %

99 %

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# Results

**Comparative procedural success within the existing literature**

85.2 %[1]

85.4 %[2]

99 %

[1]La Fazia VM, Mohanty S, Gianni C, Zito E, Pierucci N, Stifano G, et al. Feasibility and Safety of Pulsed Field Ablation for Coronary Sinus and Left Atrial Appendage Isolation and Mitral Isthmus Ablation: Acute and Chronic Findings. Circ Arrhythm Electrophysiology Available from: https://www.ahajournals.org/doi/10.1161/CIRCEP.125.014026
[2]Demian J, Younis A, Wazni OM, Santangeli P, Mdaihly M, Watfa A, et al. Pulsed-Field Ablation of Atrial Flutter. JACC: Clinical Electrophysiology. 2025 Aug;S2405500X25005560.

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# Results

- 7 patients experienced recurrence of atrial arrhythmia within 90 days of ablation requiring cardioversion.
- 5 of 7 had a history of at least 1 prior catheter ablation.
- In 5 patients, a different arrhythmia occurred, and in 2 it was not possible to tell if the arrhythmia was different based on ECG interpretation.

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# Results

**Table 3.** Safety outcomes of atypical flutter patients included in our cohort.

| Characteristic | Overall N = 74[1] | Ablation-naive patients N = 25[1] | Previously ablated patients N = 49[1] | P-value[2] |
|---|---|---|---|---|
| Stroke | 0 (0%) | 0 (0%) | 0 (0%) | |
| Congestive heart failure | 0 (0%) | 0 (0%) | 0 (0%) | |
| Atrial fibrillation requiring DCCV | 0 (0%) | 0 (0%) | 0 (0%) | |
| Atrial flutter requiring DCCV | 2 (2.7%) | 1 (4%) | 1 (2.04%) | 1.0 |

[1] n (%)

[2]Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test



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# Results

## Comparative complications rate within the existing literature

3-8.89%[1,3,4]

0%

[1]La Fazia VM, Mohanty S, Gianni C, Zito E, Pierucci N, Stifano G, et al. Feasibility and Safety of Pulsed Field Ablation for Coronary Sinus and Left Atrial Appendage Isolation and Mitral Isthmus Ablation: Acute and Chronic Findings. Circ Arrhythm Electrophysiology Available from: https://www.ahajournals.org/doi/10.1161/CIRCEP.125.014026
[3]Akhtar T, Daimee UA, Sivasambhu B, Boyle TA, Arbab-Zadeh A, Marine JE, et al. Ablation outcomes for atypical atrial flutter versus recurrent atrial fibrillation following index pulmonary vein isolation. Cardiovasc electrophysiol. 2021 June;32(6):1631–9.
[4]Michał P, Bartosz K, Kacper R, Michał M, Cezary M, Karolina M, et al. Atypical atrial flutter ablation: follow-up and predictors of arrhythmia recurrence. Heart Vessels. 2024 Nov;39(11):949–57.



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# Results

- 46 had a follow-up duration of more than 3 months, out of which 5 patients (11%) presented with recurrent atrial arrhythmia beyond 90 days .
- Based on ECG adjudication, no patient had recurrence of the same AAFL.



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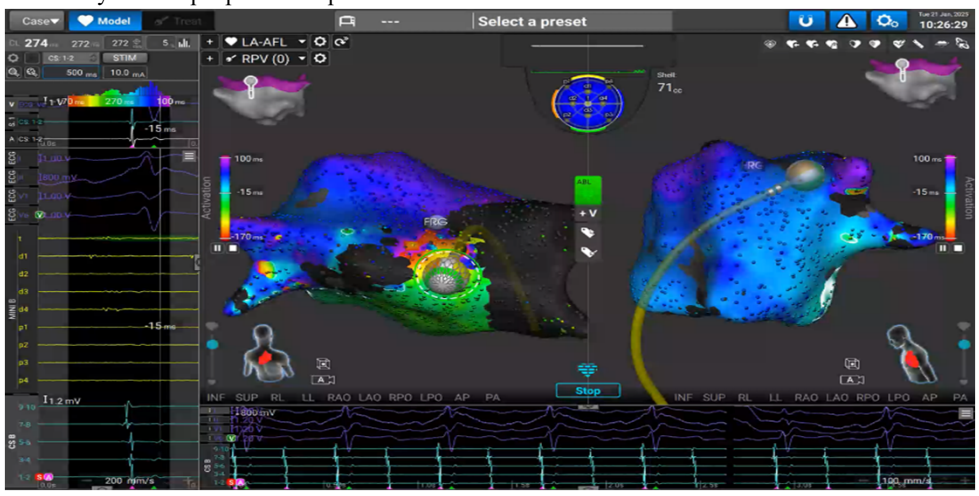
# Results

**Figure 2. A.** Demonstration of the successful mapping of roof-dependent atypical atrial flutter refractory to multiple prior RFA procedures.



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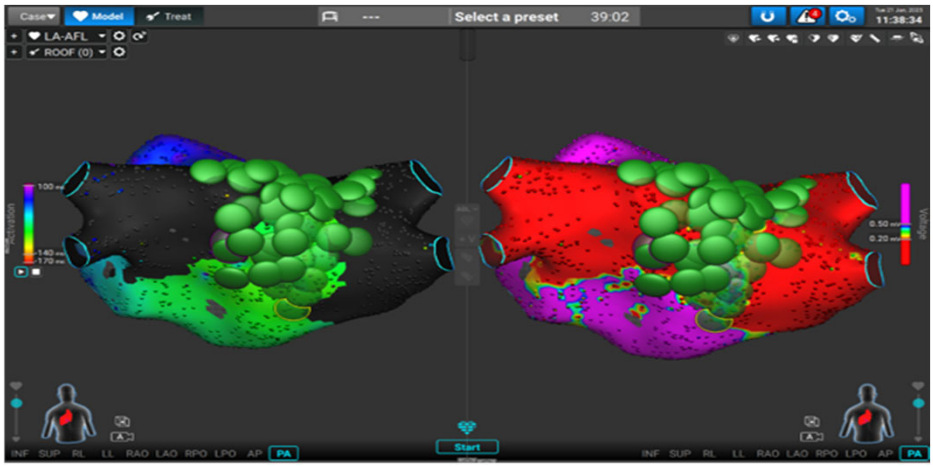
# Results

**Figure 2. B.** Demonstration of the final PFA lesion set following the ablation.

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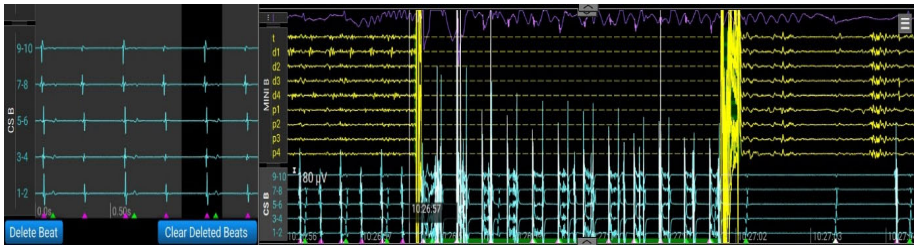
# Results

**Figure 2. C.** A closer look at the intra-cardiac electrograms from Sphere 9 where the cycle length is covered and the atypical atrial flutter is terminated.

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## Conclusions

- Catheter ablation of atypical atrial flutter using the Sphere 9 catheter and Affera mapping system demonstrated excellent intra-procedural success.
- Improved short term clinical outcomes with no post-procedural major cerebrovascular and cardiovascular events within 30 days.
- An extended follow-up duration with a larger sample size of patients is needed to determine long-term efficacy in the reduction of atypical flutter recurrence.

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# Significance of peri-device leak detected by cardiac computed tomography after percutaneous left atrial appendage occlusion

Matthew Katsiyiannis[1], Melanie Kapphahn-Bergs[1], Sue Casey[1], Dawn Witt[1], Kerollos Abdelsayed[1], Mariam Desouki[1], Emily Halvorson[1], Robert Hauser[1], Jay Sengupta[1], Ali Bahbah

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# Disclosures

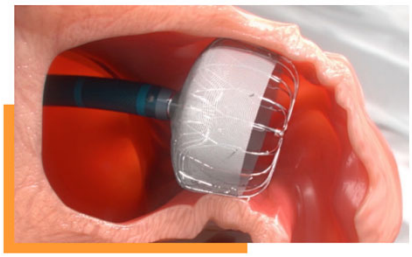
- None

# Percutaneous Left Atrial Appendage Occlusion (p-LAAO)

**Purpose:** Reduce stroke risk in patients with NVAF who cannot tolerate long-term OAC.

**Mechanism:** Sealing off the LAA – where clots commonly form in NVAF.

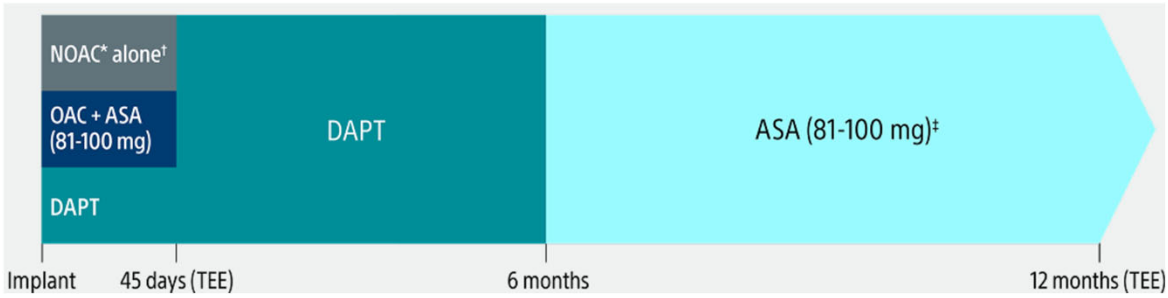
**Device:** Performed via a minimally invasive catheter procedure using the Watchman device.



WATCHMAN Physician Site



# Percutaneous Left Atrial Appendage Occlusion (p-LAAO)

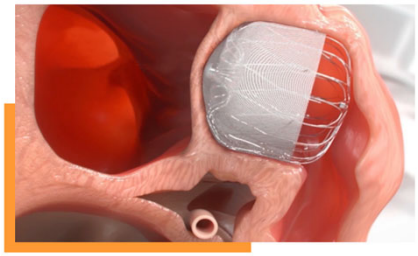



WATCHMAN Physician Site

# Percutaneous Left Atrial Appendage Occlusion (p-LAAO)

**Ideal:** Device becomes endothelialized leading to a complete seal

**Limitations:** Device related thrombosis and peri-device leak



WATCHMAN Physician Site



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# Cardiac Computed Tomography with Angiography (CCTA)

- Has evolved as a sensitive and **non-invasive** tool for the assessment of implanted LAAO device
- 45-day post-procedural imaging is recommended in many practice-guidelines for the assessment of adequate seal
- **CCTA is increasingly being used as follow-up imaging after p-LAAO**

Cardiac Computed Tomography Angiography (CCTA) | American Heart Association



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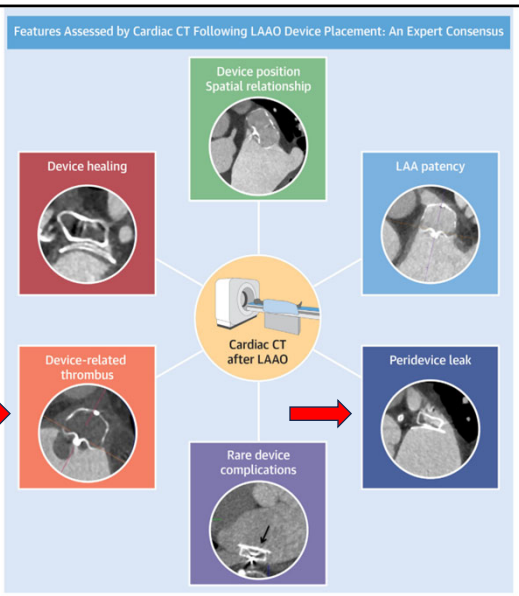
# Background

STATE-OF-THE-ART REVIEW

## Position Statement on Cardiac Computed Tomography Following Left Atrial Appendage Occlusion

Kasper Korsholm, MD, PhD,[a] Xavier Iriart, MD,[b] Jacqueline Saw, MD,[c] Dee Dee Wang, MD,[d] Sergio Berti, MD,[e] Roberto Galea, MD,[f] Xavier Freixa, MD, PhD,[g] Dabit Arzamendi, MD,[h] Ole De Backer, MD, PhD,[i] Anders Kramer, MD,[a] Filippo Cademartiri, MD,[e] Hubert Cochet, MD, PhD,[b] Jacob Odenstedt, MD, PhD,[j] Adel Aminian, MD,[k] Lorenz Räber, MD, PhD,[f] Ignacio Cruz-Gonzalez, MD, PhD,[l] Philippe Garot, MD,[m] Jesper Møller Jensen, MD, PhD,[a] Mohamad Alkhouli, MD,[n] Jens Erik Nielsen-Kudsk, MD, DMSc[a]

> procedural evaluation, CCT offers several advantages, including noninvasive acquisition of isotropic high-resolution images.[3-25] This allows detailed evaluation without patient discomfort and sedation requirements.[22] A standard-



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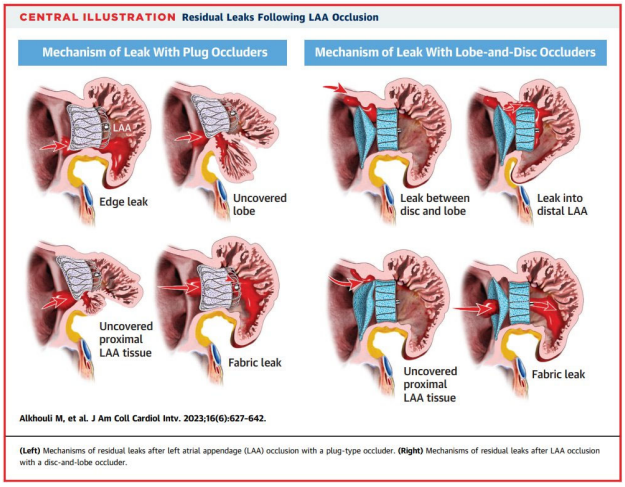
# Peri-Device Leak (PDL)

- Peri-device leak (PDL) is a widely known **limitation** to the procedure
- Incomplete endothelization allowing **continued communication** between LAA and LA
- Several studies have shown links between PDL and **adverse events**




[10] Alkhouli M, De Backer O, Ellis CR, Nielsen-Kudsk JE, Sievert H, Natale A, Lakkireddy D, Holmes DR. Peridevice Leak After Left Atrial Appendage Occlusion: Incidence, Mechanisms, Clinical Impact, and Management. JACC Cardiovasc Interv. 2023 Mar 27;16(6):627-642. doi: 10.1016/j.jcin.2022.12.006. PMID: 36990553.



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# Background

**Impact of Peridevice Leak on 5-Year Outcomes After Left Atrial Appendage Closure**

Srinivas R. Dukkipati, MD,[a] David R. Holmes, Jr., MD,[b] Shephal K. Doshi, MD,[c] Saibal Kar, MD,[d] Sheldon M. Singh, MD,[e] Douglas Gibson, MD,[f] Matthew J. Price, MD,[f] Andrea Natale, MD,[g] Moussa Mansour, MD,[h] Horst Sievert, MD,[i] Vicki M. Houle, PhD,[j] Dominic J. Allocco, MD,[j] Vivek Y. Reddy, MD[a]

Though complete sealing of the LAA is desirable, incomplete occlusion can occur in up to 32% of implants.[8] This is in large part due to the anatomic mismatch that occurs between the device and the LAA ostium. The LAA morphology is highly variable, and the ostium is elliptical with variable lengths and diameters,[9,10] whereas the Watchman device is cir-

ESC European Society of Cardiology
European Heart Journal (2024) 45, 214–229
https://doi.org/10.1093/eurheartj/ehad828

META-ANALYSIS
*Interventional cardiology*

**Residual leaks following percutaneous left atrial appendage occlusion and outcomes: a meta-analysis**



**Transoesophageal echocardiography examination**

The presence of any reported TEE-based PDL was significantly associated with almost two-fold increased odds of thromboembolism (pooled OR 2.04, 95% CI: 1.52–2.74; $I^2 = 28\%$; see Supplementary data online, *Figure S4*), compared with the absence of PDL. Regarding the secondary study outcomes, PDL presence was also significantly associated with increased all-cause mortality (pooled OR 1.16, 95% CI: 1.08–1.24; $I^2 = 0\%$; see Supplementary data online, *Figure S5A*) and major bleeding rates (pooled OR 1.12, 95% CI: 1.03–1.22; $I^2 = 0\%$; see Supplementary data online, *Figure S5B*), compared with absence of TTE-based PDL.



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# Background

**Clinical Impact of Residual Leaks Following Left Atrial Appendage Occlusion**

Insights From the NCDR LAAO Registry

Mohamad Alkhouli, MD,[a] Chengan Du, PhD,[b] Ammar Killu, MD,[a] Trevor Simard, MD,[a] Peter A. Noseworthy, MD,[a] Paul A. Friedman, MD,[a] Jeptha P. Curtis, MD,[b] James V. Freeman, MD,[b] David R. Holmes, MD[a]

nificant leaks Current guidelines use an arbitrary cut-off of >5 mm to classify leaks as significant vs nonsignificant, but cutoffs of >3, ≥3, or ≥5 mm have also been suggested in published reports.[10] In addition, data on the association between peri-device leaks and thromboembolic events are sparse and often contradictory.[10-13] Hence, we sought to use the largest

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**Standards and Guidelines**

2025 SCAI/HRS Clinical Practice Guidelines on Transcatheter Left Atrial Appendage Occlusion

7. In adults with NVAF who have a PDL of any size after undergoing LAAO, should OAC be prescribed over no OAC?

7.1 The SCAI/HRS guideline panel makes no recommendation regarding the use of OAC in adults with a PDL after LAAO (knowledge gap).



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# Research Question

What is the association of peri-device leak (of any size) as detected by CCTA with major thromboembolic events post percutaneous left atrial appendage occlusion?



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# Methodology

**Study Design**

Single-system multicenter retrospective study

Patients with documented atrial fibrillation and a **clinical indication for p-LAAO** based on $CHA_2DS_2$-VASc score.

Underwent successful Watchman implantation at Allina systems hospitals (**2016-2023**). Underwent CCTA post implantation

**Primary endpoint:** Major thromboembolic events; a composite of stroke, TIA, or systemic embolism.

**Secondary endpoint:** Device-related thrombosis

Pariwise comparison between patients whose **CCTA revealed PDL and those whose did not**



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# Results: Patient Demographics

| Characteristic | N=100 | Size (mm) |
|---|---|---|
| Age (years) | 77 (72, 84) | |
| Gender (female) | 51 (51%) | |
| Follow-up (years) | 2.25 (1.4, 3.5) | |
| $CHA_2DS_2VAS_C$ | 4 (3, 5) | |
| HASBLED | 3 (2, 4) | |
| CCTA (days) | 57 (48, 340) | |
| PDL | 22 (22%) | 4 (2, 5) |
| DRT | 4 (4%) | 2 (2, 2.2) |
| DOAC | 90 (90%) | |
| Primary endpoint | 9 (9%) | |



# Results: Pairwise Comparison

| | Well-seated Device | PDL | |
|---|---|---|---|
| Characteristic | N=78[1] | N=22[1] | p-value[2] |
| Gender (male) | 37 (47%) | 12 (55%) | 0.7 |
| Age (years) | 76 (9) | 77 (10) | 0.9 |
| OAC at discharge | 71 (91%) | 19 (86%) | 0.8 |
| Follow up (years) | 2.75 (1.68) | 2.56 (1.52) | 0.6 |
| DRT on CCTA | 1 (1.3%) | 3 (14%) | 0.046 |
| Stroke/TIA/S.E | 7 (9%) | 2 (9.1%) | >0.9 |
| All cause mortality | 10 (13%) | 4 (18%) | 0.8 |
| [1]n (%); Mean (SD) | | | |
| [2]Pearson's Chi-squared test; Two Sample t-test | | | |

# Results: Outcomes

| | All | PDL | Well seated |
|---|---|---|---|
| Total | N=100 | N=22 | N=78 |
| Death | 14 (14%) | 4 (18%) | 10 (13%) |
| TIA | 2 (2%) | 1 (4.5%) | 1 (1.3%) |
| Systemic embolism | 2 (2%) | 0 (0%) | 2 (2.6%) |
| Major bleeding | 17 (17%) | 6 (27%) | 11 (14%) |
| Stroke | 5 (5%) | 1 (4.5%) | 4 (5.1%) |



# Results: PDL and DRT

| Antithrombotic Regimen | PDL (mm) | DRT (mm) | Primary Endpoint |
|---|---|---|---|
| DAPT | 2 | **2.8** | No |
| Apixaban/Aspirin | 4 | **2** | No |
| Apixaban | 0 | **2** | Stroke |
| Apixaban | 1 | **2** | No |

# Limitations

This study was limited by:

- Small cohort size
- Retrospective design
- Single system



# Conclusions

- PDL (of any size) as detected by CCTA **was common after p-LAAO (22%).**
- PDL was associated with a modestly **significant higher incidence of DRT (p=0.046).**
- PDL was not significantly associated with a higher incidence of thromboembolic events.

# Thank you!!

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