



# Clinical Impact of Residual Leaks Following Left Atrial Appendage Occlusion: Insights from LAAO Registry

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# Disclosures

The study was funded by a grant from Boston Scientific.

The sponsor had no role in the design of the study or the interpretation of the data

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# Left Atrial Appendage Occlusion; a Misnomer?

## PROTECT AF <sup>1</sup>

- ❑ Any Leak: **40.9%** at 45 day (32.1% at 1 year)
- ❑ Large (>3mm) leak: **13.3%** at 45 day (11.8% at 1 year)

## ACP Registry <sup>2</sup>

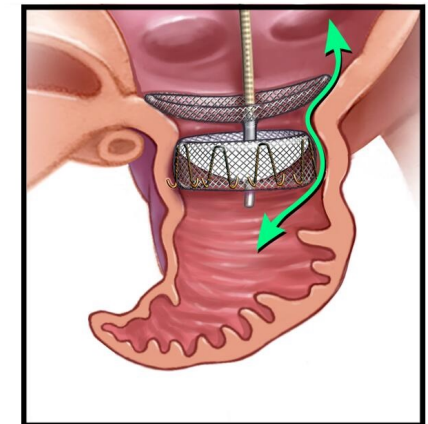
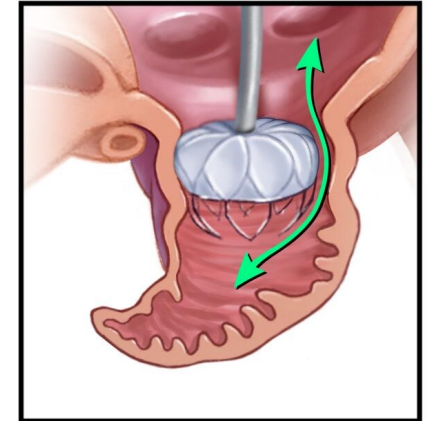
- ❑ Any leak: **12.5%** at median f/u 134 days

## PINNACLE FLX Trial <sup>3</sup>

- ❑ Any Leak: **7.4%** at 45 day (10.5% at 1 year)
- ❑ Large (>5mm) leak: **0%**

## AMULET IDE Trial <sup>4</sup>

- ❑ Any Leak: **50.8%** Watchman; **35.8%** Amulet
- ❑ Large (>5mm) leak: **3.2%** Watchman; **1.1%** Amulet



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- <sup>1</sup> Viles-Gonzalez et al. JACC 2012;59:923–9
- <sup>2</sup> Saw et al. JACC Intv 2017;10:391–9
- <sup>3</sup> Kar et al. Circulation. 2021;4;143(18):1754-1762
- <sup>4</sup> Lakkireddy et al. Circulation. 2021;9;144(19):1543-1552

# Residual leaks after LAAO; Do They Matter?

## PROTECT AF <sup>1</sup>

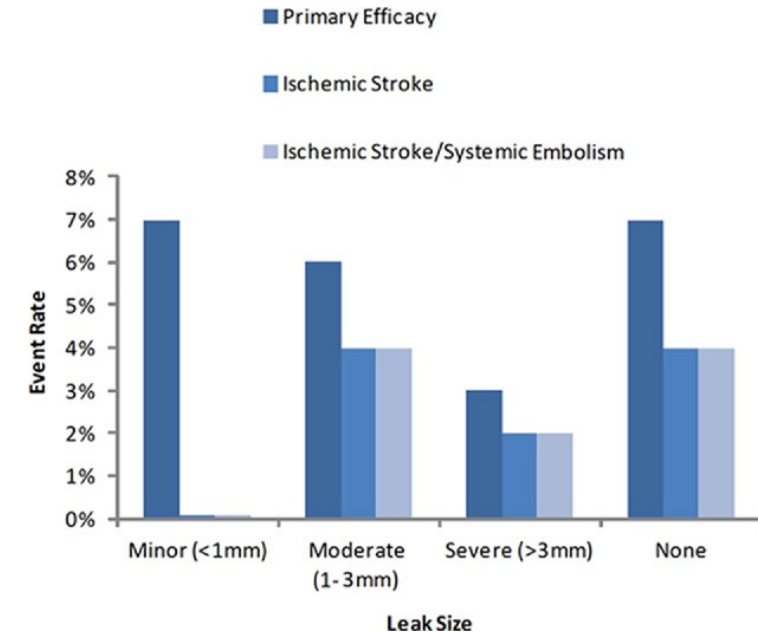
- ❑ No association with thromboembolic events (n=16)

## ACP Registry <sup>2</sup>

- ❑ No association with thromboembolic events (n=7)

## Vanderbilt Registry <sup>3</sup>

- ❑ The combined endpoint (failure to stop OAC, TIA or stroke, DRT, need for leak closure) was higher in patients with leaks >3 mm 69% vs 34%; p=0.002



<sup>1</sup> Viles-Gonzalez et al. JACC 2012;59:923–9

<sup>2</sup> Saw et al. JACC Intv 2017;10:391–9

<sup>3</sup> Afzal et al. JACC Clin Electrophysiol .2022;8(1):15-25.

# Residual leaks after LAAO: Insights from NCDR

## Study Design

### LAAO Registry

#### Inception & Timeline

- ❑ January 2016 – Registry Launched
- ❑ February 2016 - CMS NCD
- ❑ April 2016 – Mandate to Submit to LAAO

#### Data Collection & Utilization Process

- ❑ Data collected at 45-day, 6-month, 1 & 2 years
- ❑ Automated ± manual adjudication
- ❑ Audits 5% of the sites annually\*
  - 93.3% agreement with source documentation
  - 100% agreement with billing information
- ❑ Utilized for research via NCDR R&P process <sup>1,2</sup>
- ❑ Currently >120,000 LAAO cases recorded

Patients Undergoing LAAO in the US

N= 86,761

#### Excluding

- ❑ Discharged after 2019 (n=19,598)
- ❑ No data on LAAO Device (n=2,724)
- ❑ Device not deployed (n=2,028)
- ❑ Missing TEE or Leak Data (n=11,078)

Final Study Cohort

N=51,333

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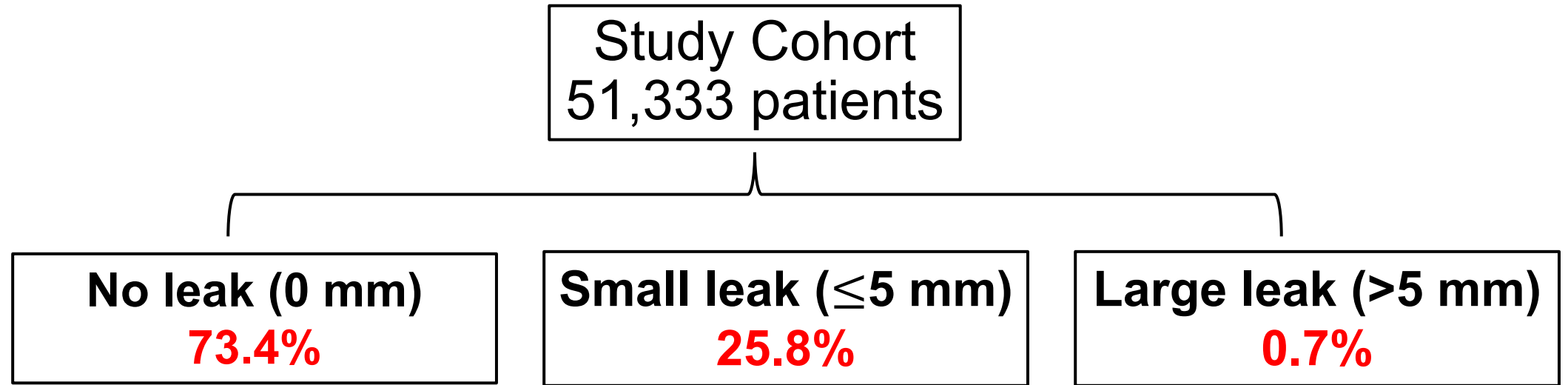
<sup>1</sup> Freeman et al. JACC. 2020;7;75(13):1503-1518

<sup>2</sup> Darden et al. JAMA Cardiol. 2021;1;6(11):1275-1284

\* Prior NCDR data audits

# Residual leaks after LAAO: Insights from NCDR

## Study Population & Endpoints



**1° Endpoint:** a composite of stroke, TIA, or systemic embolization

**2° Endpoint:** major bleeding, death, major adverse events



# Residual leaks after LAAO: Insights from NCDR

## Baseline Characteristics

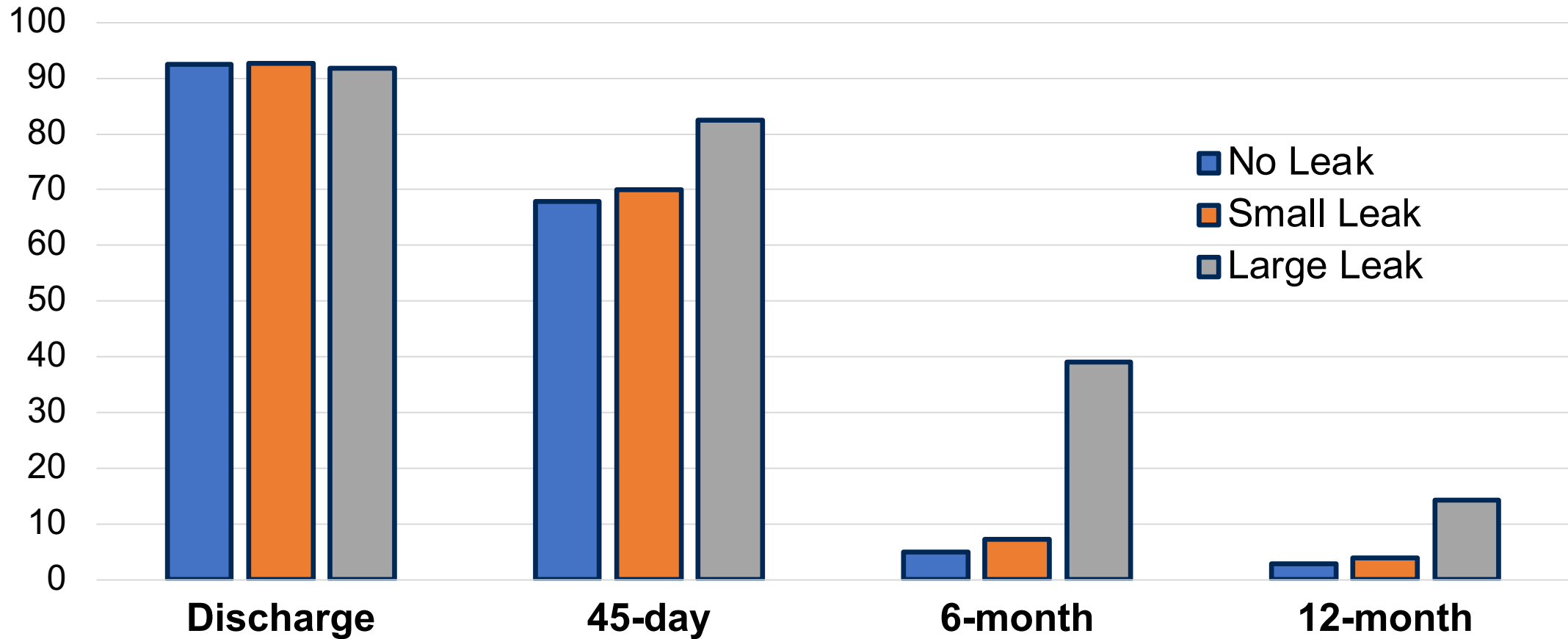
- ❑ Modest but statistically significant differences in baseline profile
- ❑ No difference in moderate sedation or ICE usage, case duration, contrast volume, or in-hospital complications

Patient Characteristics	No Leak	Small Leak	Large Leak	P value
Non-Paroxysmal AF	43.3%	48.2%	53.8%	<.001
Cardiomyopathy	19.8%	22.1%	24.0%	<.001
LAA orifice diameter	21.1±4.2	22.3±4.3	23.7±4.4	<.001



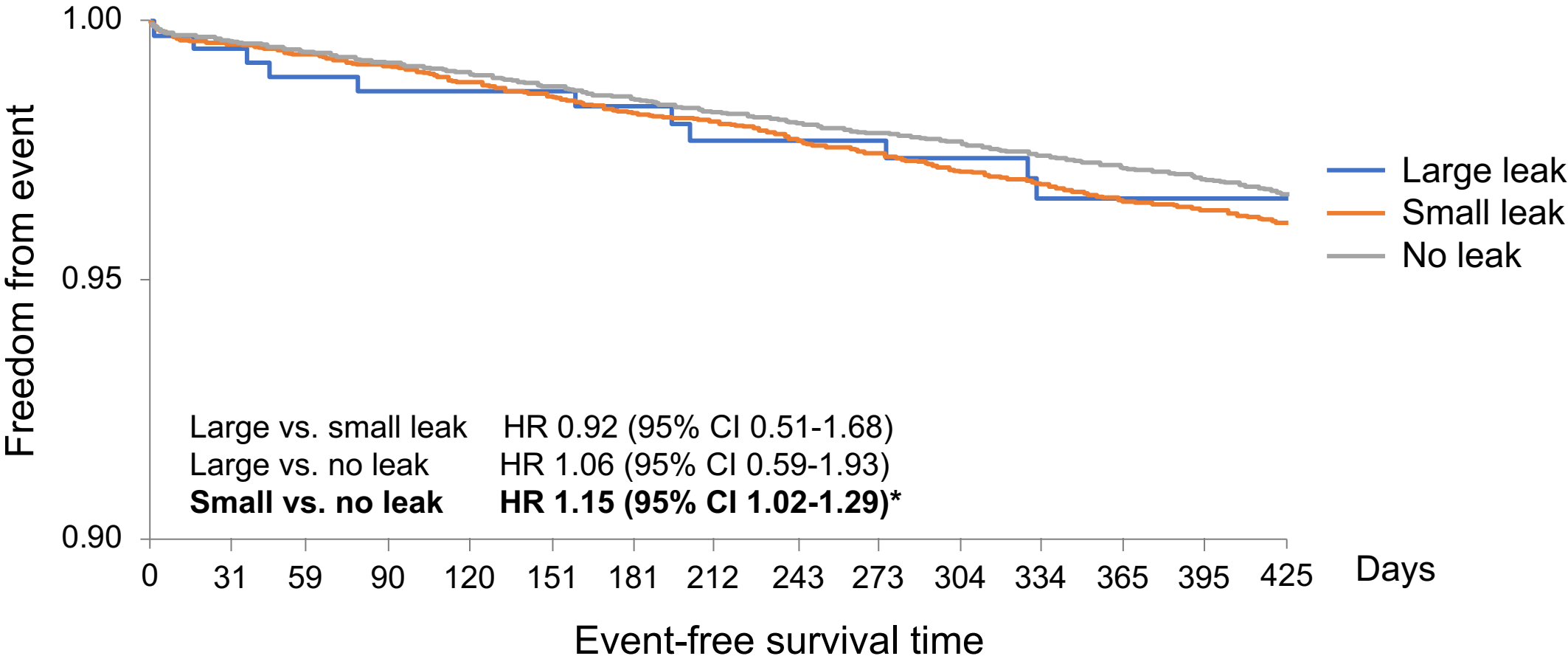
# Residual leaks after LAAO: Insights from NCDR

## Post-LAAO Anticoagulation



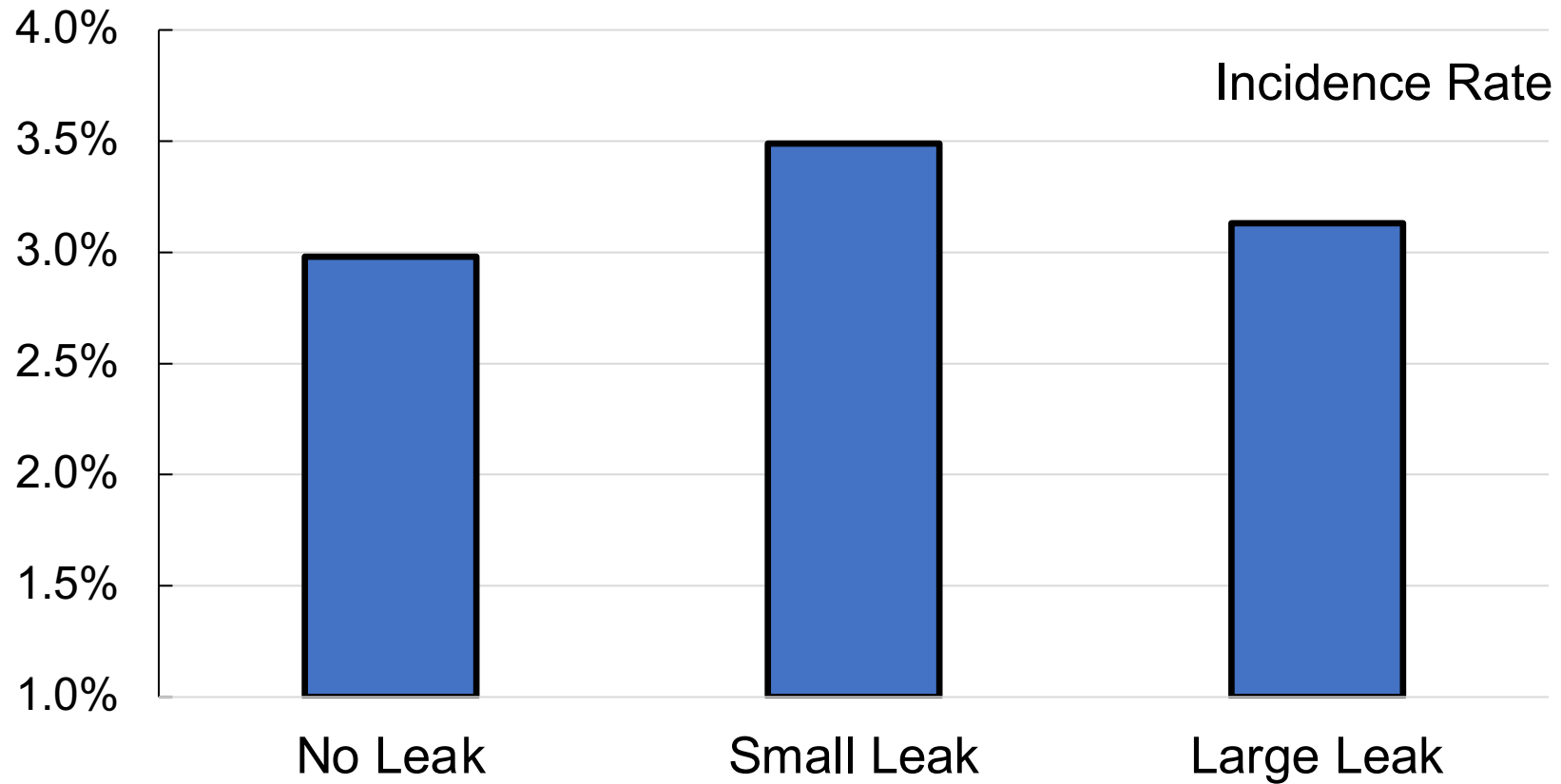
# Residual leaks after LAAO: Insights from NCDR

## 1° Endpoint: Stroke, TIA, or SE



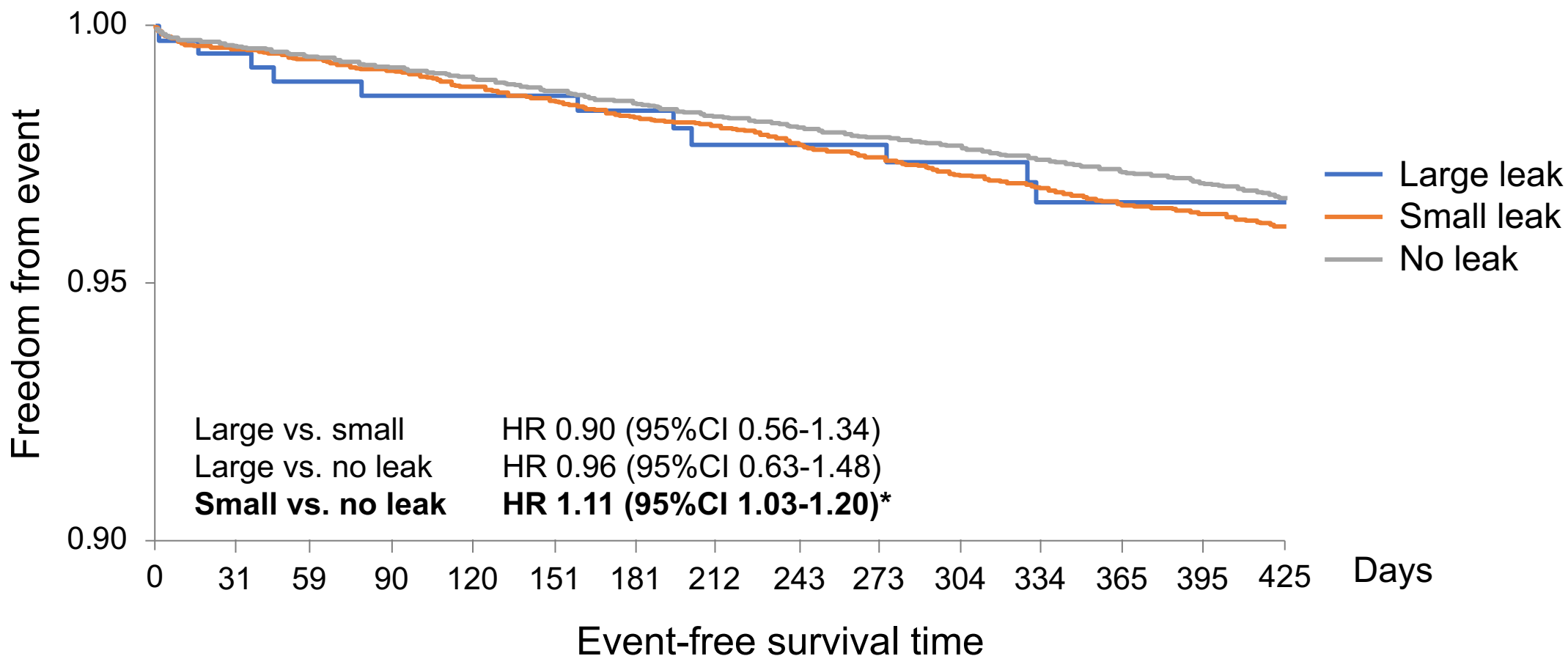
# Residual leaks after LAAO: Insights from NCDR

## 1<sup>o</sup> Endpoint: Stroke, TIA, or SE



# Residual leaks after LAAO: Insights from NCDR

## 2° Endpoint: Major Bleeding\*



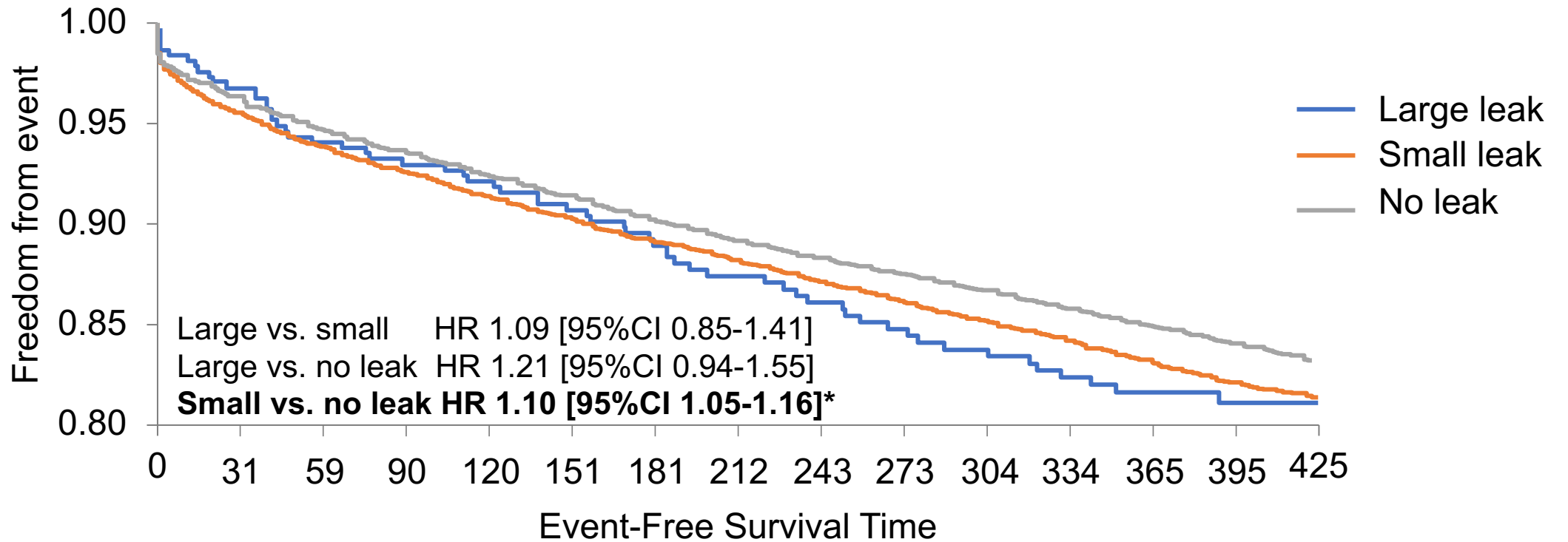
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\* Major bleeding was defined as: access bleeding or hematoma, GI bleeding, retroperitoneal bleeding, other non-intracranial bleeding or hemothorax requiring hospitalization and/or causing >2 gram/deciliter decrease in hemoglobin and/or requiring transfusion

# Residual leaks after LAAO: Insights from NCDR

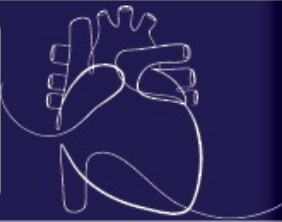
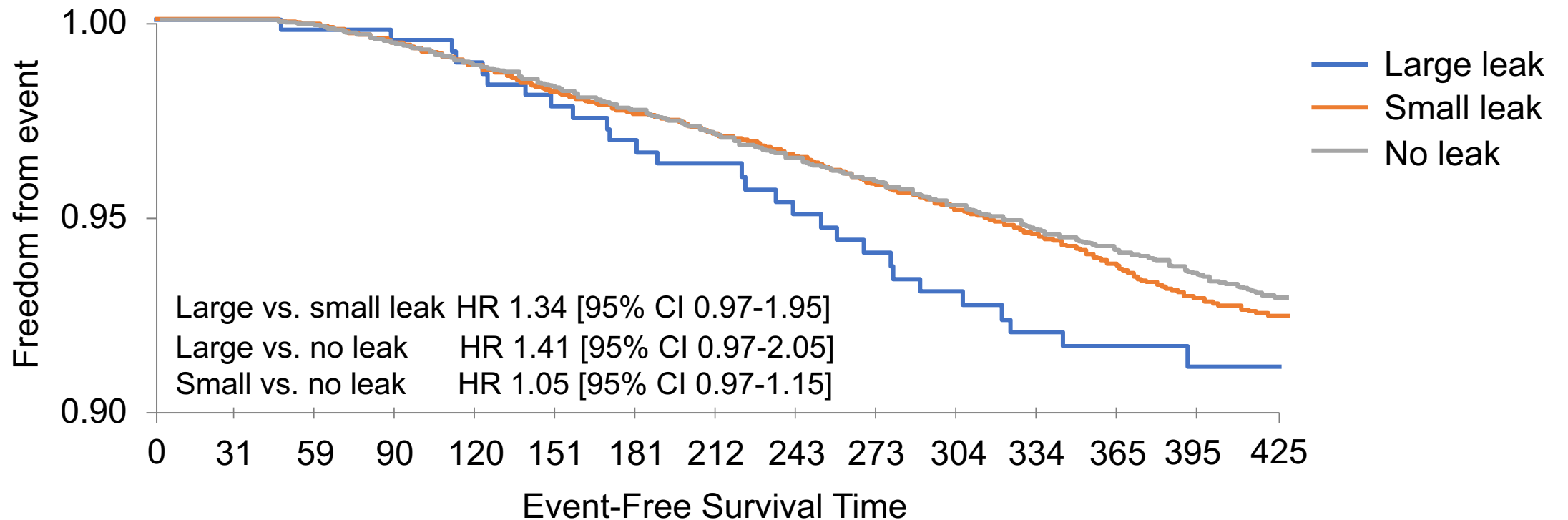
## 2° Endpoint: Major Adverse Events\*



\* Major adverse events included death; cardiac arrest; stroke; TIA; SE; major bleeding; major vascular complication, MI, pericardial effusion requiring intervention, or device embolization

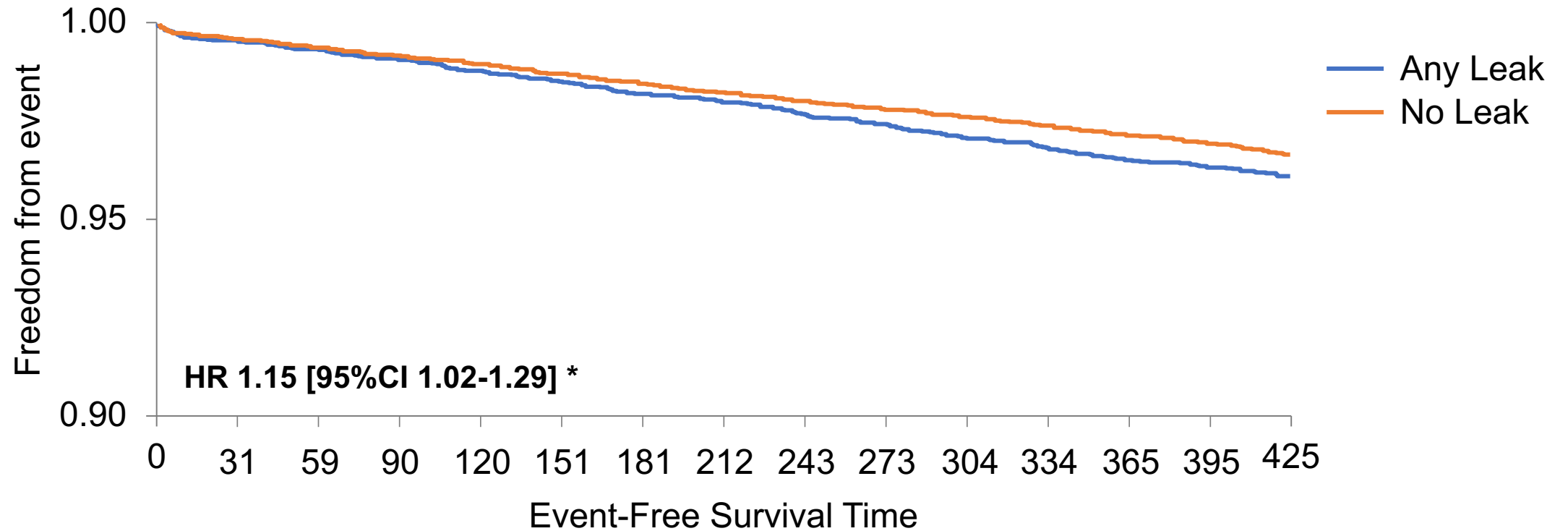
# Residual leaks after LAAO: Insights from NCDR

## 2° Endpoint: All-cause death



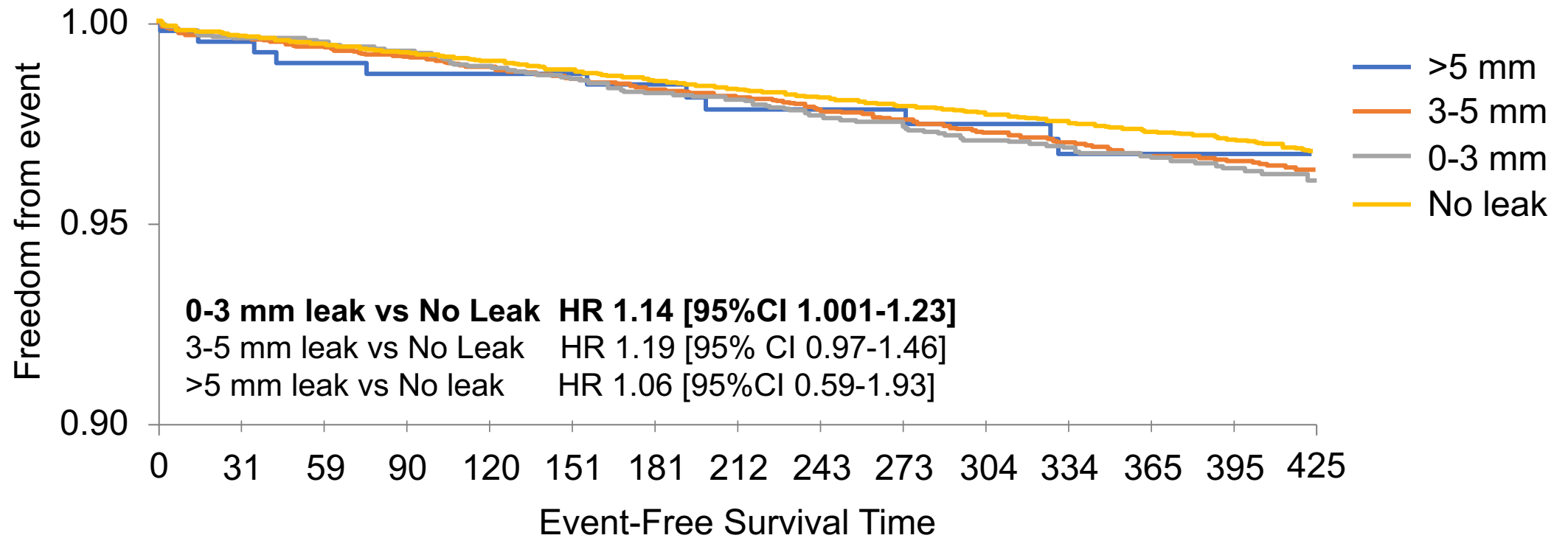
# Residual leaks after LAAO: Insights from NCDR

## Secondary Analysis: Stroke, TIA, SE



# Residual leaks after LAAO: Insights from NCDR

## Secondary Analysis: Stroke, TIA, SE



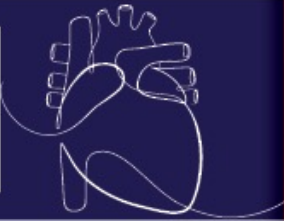
# Limitations

- ❑ Observational registry
- ❑ Imaging for leak >45 day uncommon in practice
- ❑ Variation in peri-device leak size measurement
- ❑ Only the first-generation Watchman device included
- ❑ Data on interventional leak management not available
- ❑ Follow up limited to 1 year



# Conclusions

- ❑ Peri-device leak at follow up is observed in ~25% of patients undergoing LAAO with the Watchman 2.5 device
- ❑ The leak was small  $\leq 5\text{mm}$  in  $>99\%$  of patients
- ❑ Small leaks were associated with a modest (~10-15%) increase in 1-year risk-adjusted rates of thromboembolic and bleeding complications



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