NCDR Left Atrial Appendage Occlusion (LAAO) Registry: Review Of The First 3 Years

James V. Freeman, MD, MPH, MS
Associate Professor, Cardiac Electrophysiology
Director, Yale Atrial Fibrillation Center
Yale University School of Medicine

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Disclosures

- Research funding/ Salary support
  - NHLBI/NIH
  - American College of Cardiology (ACC)
- Advisory board/ Consulting- modest
  - Medtronic
  - Boston Scientific
  - Janssen Pharmaceuticals
  - Biosense Webster

NCDR LAAO Registry

- WATCHMAN approved in March 2015
- LAAO Registry developed through a collaboration
  - ACC, SCAI, FDA, CMS, Boston Scientific
- LAAO Registry launched late December 2015
- Enrollment began in January 2016
- Mandated for CMS reimbursement
- Supports post-market FDA surveillance study

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LAAO Registry

- Hospitals are encouraged to submit data on all WATCHMAN
  - ~90% of hospitals do
  - Includes Lariat procedures; can support additional devices
- Data elements
  - 220 for index hospitalization
  - 60 per follow-up visit
  - 15 to support adverse event (AE) adjudication
- Adjudication performed using electronic algorithm and clinical events committee for some events
- Active follow-up for AEs and medical therapy though 2 years
- CMS claims for collection of AEs in years 3-4

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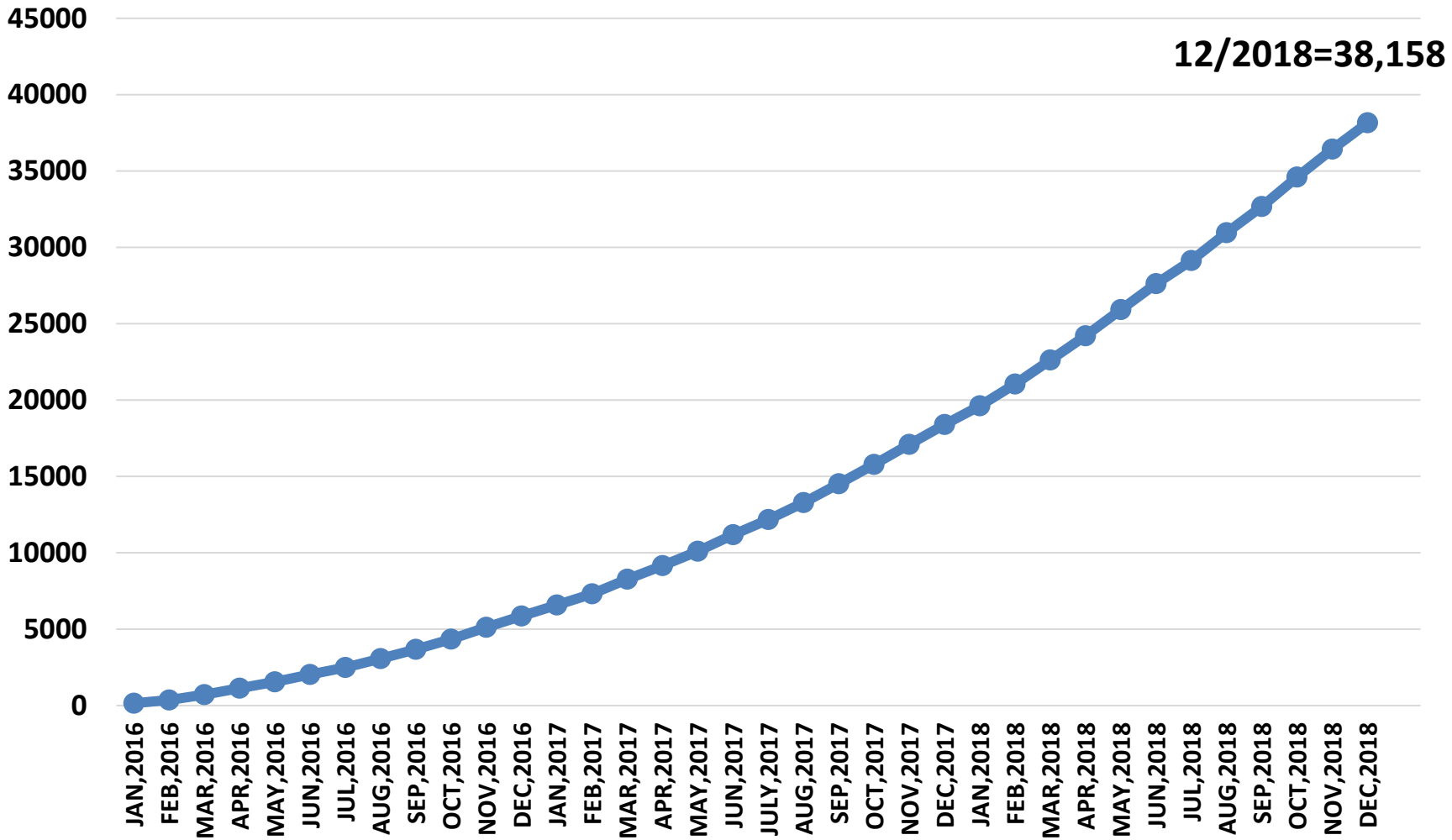
Cumulative Procedures



Freeman, JACC, 2020.

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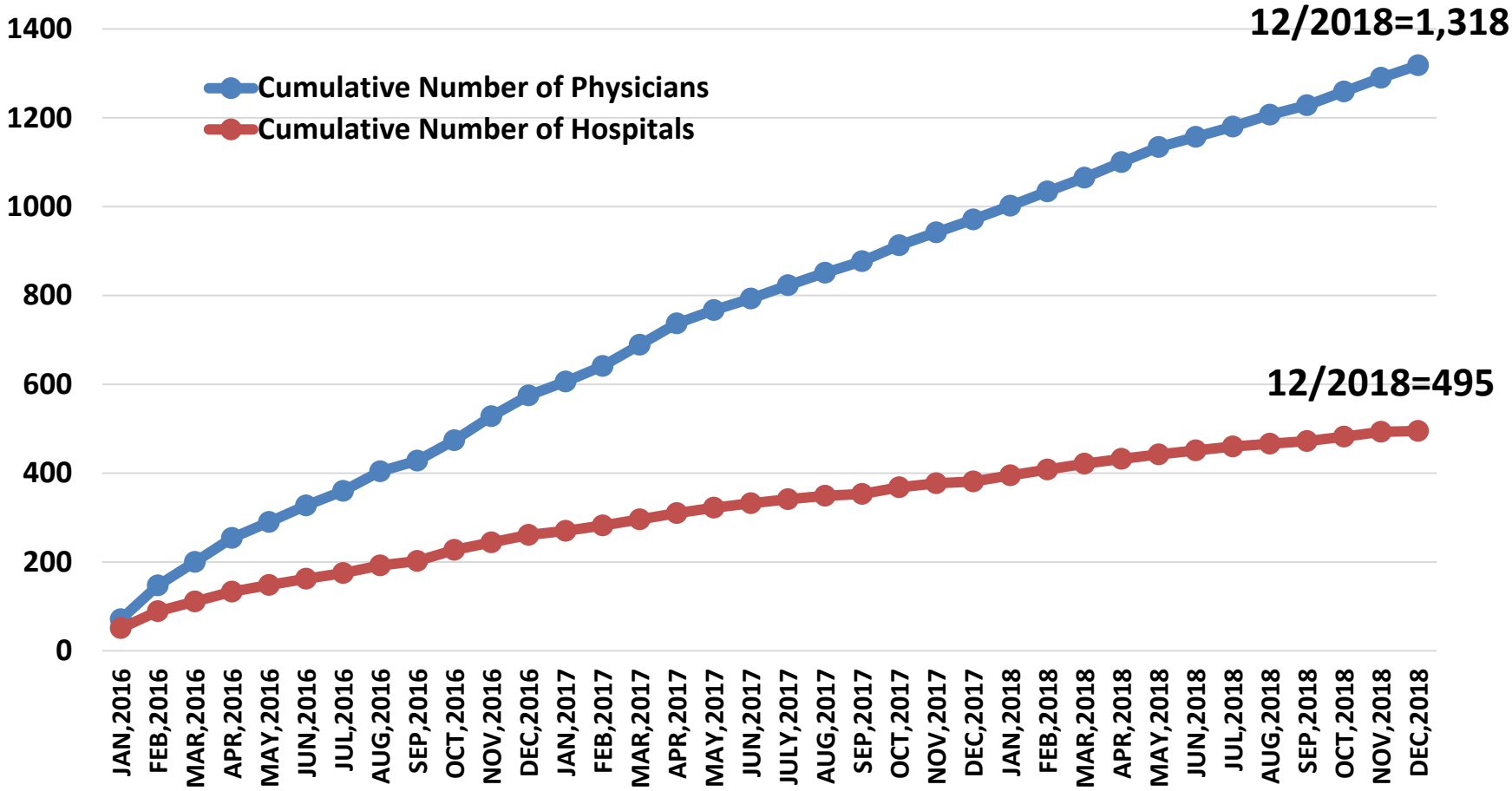
Participating Physicians and Hospitals



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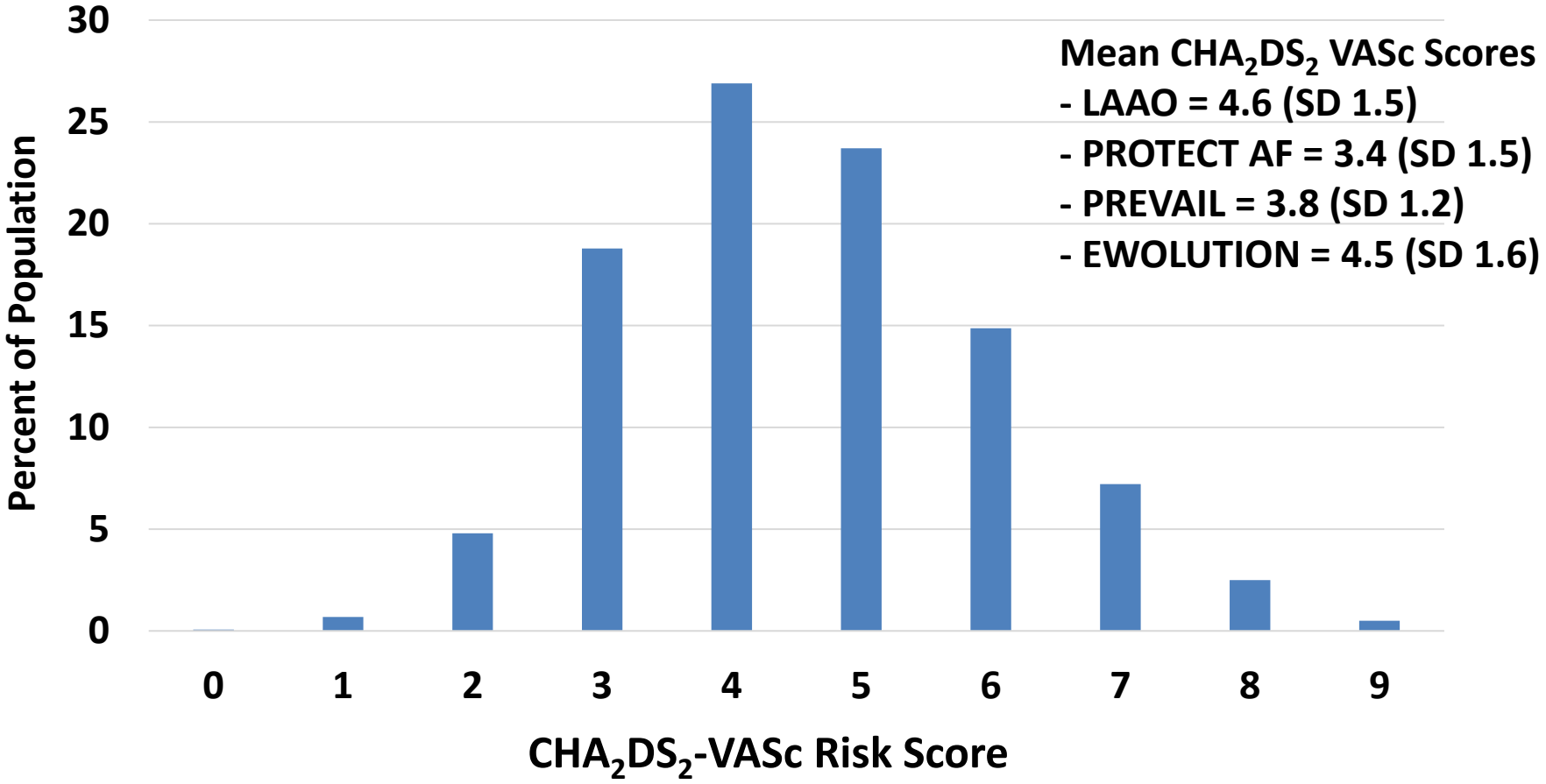
Patient Characteristics

Characteristic	LAAO Registry 2016-2018 (N=38,158)	PROTECT AF trial 2005-2008 (N=463 implants)	PREVAIL trial 2011-2013 (N=269 implants)	EWOLUTION Registry 2013-2015 (N=1025)
Demographics				
Age, mean (SD), year	76.0 (8.1)	71.7 (8.8)	74.0 (7.4)	73.4 (8.9)
Women, N (%)	15,672 (41.1)	137 (29.6)	87 (32.3)	411 (40.1)
Race, N (%)				
White/European	35,345 (92.6)	425 (91.8)	253 (94.1)	NA
Black/African American	1768 (4.6)	6 (1.3)	6 (2.2)	NA
Asian/Pacific Islander	670 (1.8)	5 (1.1)	1 (0.4)	NA
Hispanic ethnicity, N (%)	138 (0.4)	25 (5.4)	6 (2.2)	NA
Medical History				
Prior ischemic stroke/TIA, N (%)	10,425 (29.8)	82 (17.7)	74 (27.5)	312 (30.5)
Prior congestive heart failure, N (%)	14,266 (37.4)	124 (26.8)	63 (23.4)	350 (34.2)
Prior diabetes mellitus, N (%)	14,396 (37.7)	113 (24.4)	91 (33.8)	304 (29.7)
Prior hypertension, N (%)	35,148 (92.1)	413 (89.2)	238 (88.5)	885 (86.4)
Prior intracranial bleeding, N (%)	4550 (11.9)	NA	NA	155 (15.1)
Prior clinical bleeding, N (%)	26,466 (69.4)	NA	NA	396 (38.7)

LAAO Registry: CHA_2DS_2 VASc Scores



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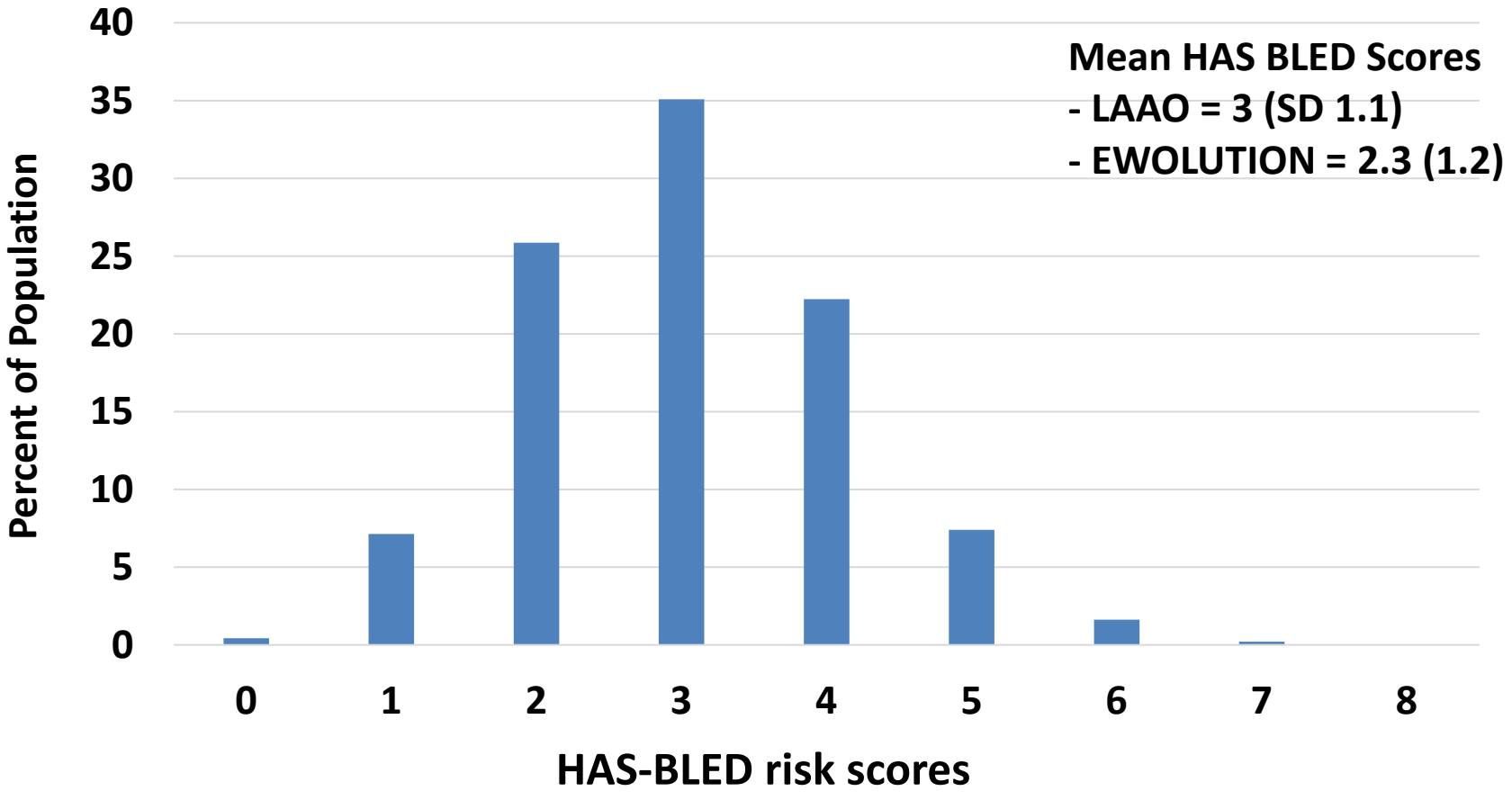
HAS BLED Score Distribution



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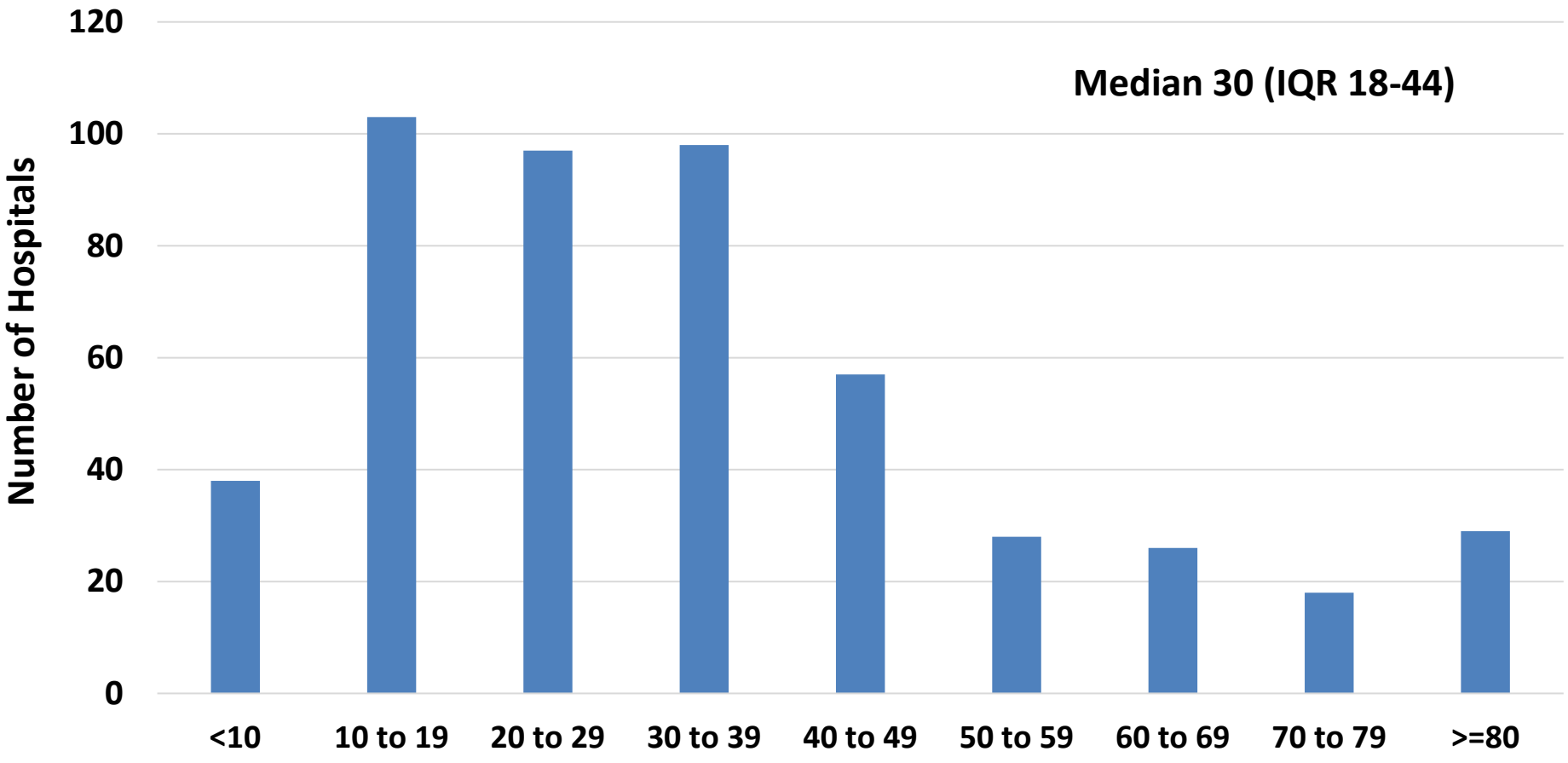
Annual Hospital Volume



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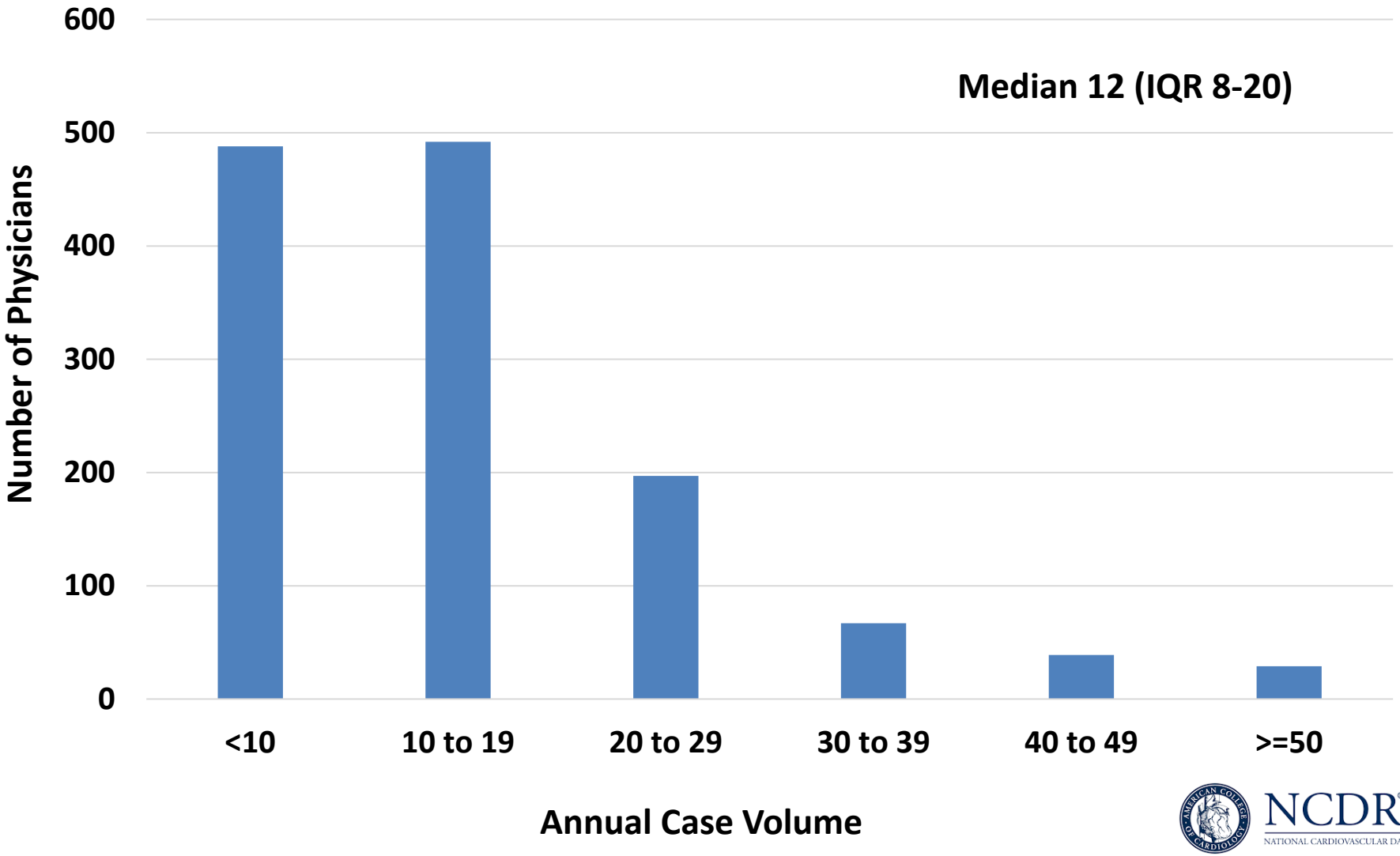
Annual Physician Volume



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Cancelled and Aborted Procedures

- Device deployed in 93% of procedures attempted
  - 3% cancelled prior to venous access
  - 4% aborted after access but before deploying device
- Approximately 50% of cancelled procedures due to LAA thrombus detected on day of procedure
- Rates of major AEs significantly higher among those who had cancelled or aborted procedures

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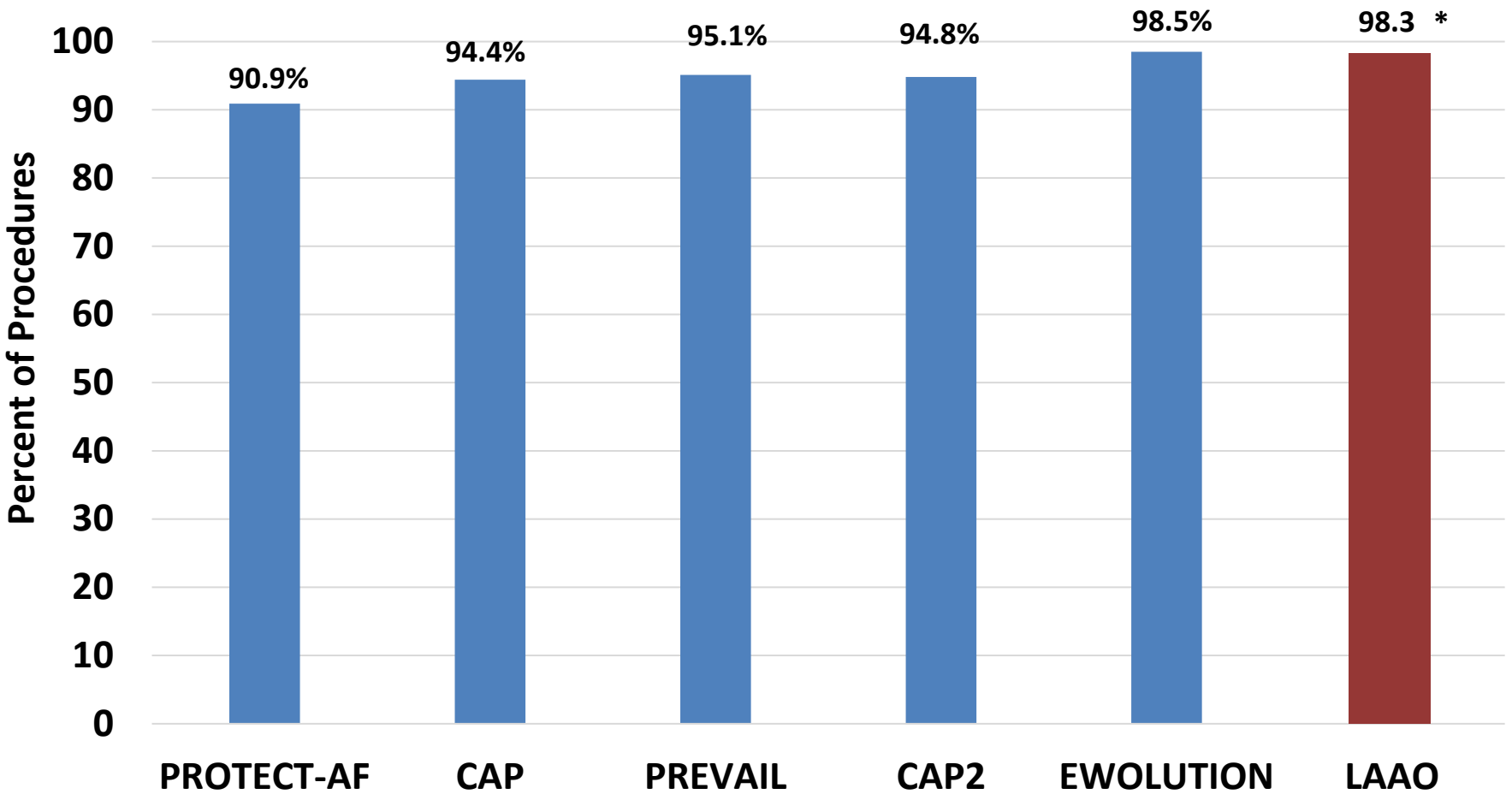
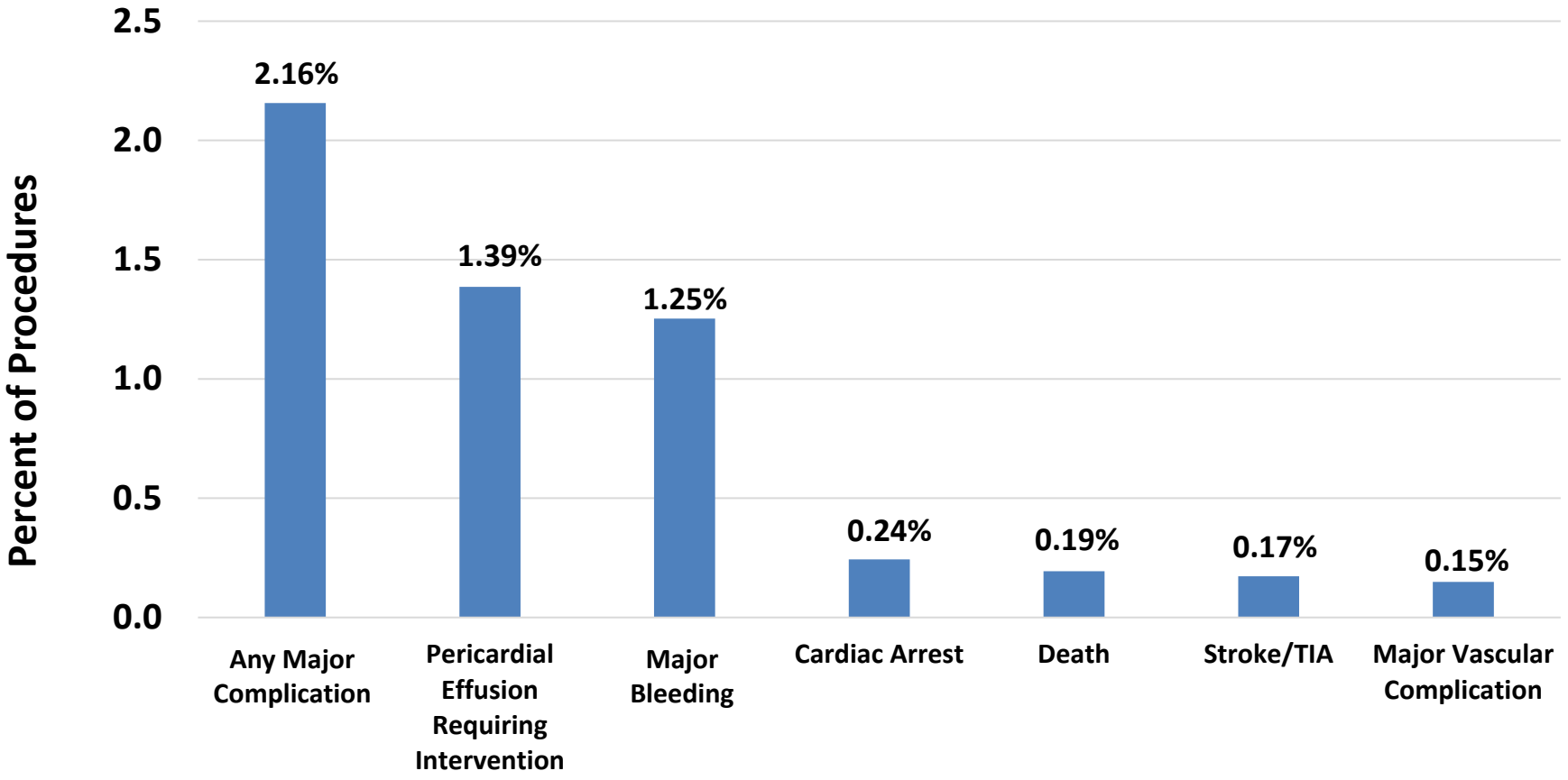
Procedural Success



*Acute procedural success= rate of success among procedures in which a device was deployed.

Among those with an acutely successful procedure 70 (0.2%) had device margin residual leak ≥5mm

Major In-hospital AEs



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Major In-hospital AEs

Overall	38158	100.00
Adverse Event Type	N	%
Neurologic Events		
Ischemic Stroke	45	0.12
Hemorrhagic Stroke	3	0.01
Undetermined stroke	2	0.01
TIA	16	0.04
Intracranial Hemorrhage	3	0.01
Systemic Arterial Embolism	1	<0.01
Myocardial Infarction	14	0.04
Device Embolization	30	0.07

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Adverse Events Compared with Prior Studies

- Major in-hospital AEs (2.16%) lower than those reported in the pivotal trials at 7 days
  - PROTECT AF
    - Pericardial effusion requiring surgery or pericardiocentesis 4%
    - Major bleeding 3.5%
    - Procedure-related stroke 1.1%
    - Device embolization 0.4%
  - PREVAIL
    - Pericardial effusion requiring surgery or pericardiocentesis 1.9%
    - Procedure-related stroke 0.7%
    - Device embolization 0.7%

Adverse Events Compared with Prior Studies

- EWOLUTION Registry
  - 7-day procedure related AEs 2.8%
  - 1-day procedure related adverse event rates
    - Pericardial effusion 0.5%
    - Major bleeding 0.7%
    - Device embolization 0.2%

Conclusions

- NCDR LAAO Registry the largest registry of percutaneous LAAO procedures
- Over 38,000 WATCHMAN procedures between 2016-2018
- Hospital and physician procedure volumes were generally low to moderate but vary substantially

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Conclusions

- Patients were higher risk for stroke and bleeding than prior studies
  - Most with prior clinically relevant bleeding
- Despite this, procedural characteristics and safety compared favorably with the pivotal trials
- LAAO Registry demonstrates the value of national registries to evaluate technology as adopted in clinical practice

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Thank you

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