Title

Atrial fibrillation after patent foramen ovale device closure: Protecting from one embolic stroke etiology but causing another?

Journal

Catheterization and Cardiovascular Interventions, 100(5)

ISSN

1522-1946

Authors

Mojaddedi, Sanaullah
Esmati, Saliman
Patel, Nimesh K
et al.

Publication Date

2022-11-01

DOI

10.1002/ccd.30330

Received: 27 June 2022 | Accepted: 2 July 2022

DOI: 10.1002/ccd.30330

LETTER TO THE EDITOR

WILEY

Atrial fibrillation after patent foramen ovale device closure: Protecting from one embolic stroke etiology but causing another?

To the Editor,

We read with interest the recent article by Krishnamurthy et al.[1] In an observational study, 35 patent foramen ovale (PFO) closure patients had an implantable loop recorder placed before device closure, without prior documentation of atrial fibrillation (AF), and had ≥1 month of monitoring postclosure. At a mean monitoring duration of 54.6 ± 39.4 weeks post-PFO closure, the authors determined that AF occurred in 13/35 (37%) of the cohort, predominantly in older patients. The investigators found that nearly all of the initial AF events (12/13 [92%]) occurred within 4 weeks of device closure, consistent with a postimplant inflammatory mechanism, and no recurrent strokes occurred during the loop recorder monitoring period. We commend the authors for their work and would like to shed more light on the data regarding post-PFO closure AF.

To date, six randomized trials have demonstrated an excellent safety profile with percutaneous PFO closure for the treatment of PFO-associated stroke. All studies revealed no significant difference in the incidence of serious adverse events, including major bleeding, vascular complications, or deaths, when PFO closure was compared to medical therapy.[2–7] Although published trials reported a 2%–6.6% incidence of new-onset AF following PFO closure,[2–7] it is highly encouraging that most AF cases entailed a single isolated event, occurred periprocedurally or <30 days after the procedure, and rarely led to recurrent stroke (~0.1% incidence [5 out of 1889 patients in the device arm]).[8] Of these five recurrent stroke cases that were attributed to device-associated AF, three occurred with the STARFlex device, a device that was later found to be thrombogenic and is no longer manufactured.[6] Moreover, most of these new-onset AF cases did not require long-term anticoagulation in the trials; for example, 70% of patients in the CLOSE trial who developed device-associated AF eventually had their anticoagulation discontinued.[5] On the basis of one observational study, only 3.8% of post-PFO closure AF events progress to permanent AF.[9]

Although the study by Krishnamurthy et al.[1] demonstrated that the incidence of post-PFO closure AF was likely grossly underestimated in the clinical trials by approximately ninefold, we agree with their conclusion that the high incidence of post-closure AF can be attributed to postimplant inflammation; these AF cases carry a minimal risk of recurrent stroke as confirmed by their study and data from the randomized trials. The REDUCE trial recently published 5-year outcomes data on PFO closure for stroke prevention.[10] At a 5-year follow-up, the number needed to treat to prevent one stroke was as low as 25. Moreover, the two study arms (i.e., device vs. medical therapy) continued to show no difference in the incidence of serious adverse events, deaths, major bleeding, venous thromboembolism, fractures, thromboses, or embolizations of the device, nor were there cardiac erosions, during the extended follow-up period. These findings confirm that percutaneous PFO closure is efficacious and safe, with many experts considering the procedure to be the safest therapeutic interventional cardiology procedure performed.[11,12]

CONFLICT OF INTEREST

Dr. Jonathan M. Tobis has served as a consultant for St. Jude Medical (now Abbott) and W. L. Gore, has served as a proctor for Cardiac Dimensions, was a coinvestigator of the RESPECT trial, and was on the steering committee for the PREMIUM trial. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Sanaullah Mojaddedi MD[1]
Saliman Esmati MD[2]
Nimesh K. Patel MD[1]
Jonathan M. Tobis MD[3]
Mohammad K. Mojadidi MD[1]

[1]*Division of Cardiology, Department of Medicine, Virginia Commonwealth University, Richmond, Virginia, USA*
[2]*Department of Medicine, Jamaica Hospital Medical Center, Queens, New York, USA*
[3]*Division of Cardiology, Department of Medicine, University of California, Los Angeles, Los Angeles, California, USA*

Correspondence
Mohammad K. Mojadidi, MD, Division of Cardiology, Department of Medicine, Virginia Commonwealth University (VCU Health), 1250 E Marshall S, Richmond, VA 23219, USA.
Email: mkmojadidi@gmail.com

ORCID

Nimesh K. Patel http://orcid.org/0000-0001-7549-9422
Jonathan M. Tobis http://orcid.org/0000-0003-2462-3459
Mohammad K. Mojadidi http://orcid.org/0000-0002-4574-4287

REFERENCES

1. Krishnamurthy Y, Ben-Ami J, Robbins BT, Sommer RJ. Incidence and time course of atrial fibrillation following patent foramen ovale closure. *Catheter Cardiovasc Interv*. 2022. doi:10.1002/ccd.30247
2. Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *New Engl J Med*. 2017;377:1022-1032.
3. Sondergaard S, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *New Engl J*. 2017;377:1033-1042.
4. Lee PH, Song JK, Kim JS, et al. Cryptogenic stroke and high-risk patent foramen ovale: the DEFENSE-PFO trial. *J Am Coll Cardiol*. 2018;71(20):2335-2342.
5. Mas JL, Derumeaux G, Guillon B, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *New Engl J Med*. 2017;377:1011-1021.
6. Furlan A, Resman M, Massaro J, et al. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med*. 2012;366:991-999.
7. Meier B, Kalesan B, Mattle HP, et al. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med*. 2013;368:1083-1091.
8. Elgendy AY, Elgendy IY, Mojadidi MK, et al. New-onset atrial fibrillation following percutaneous patent foramen ovale closure: a systematic review and meta-analysis of randomised trials. *EuroIntervention*. 2019;14:1788-1790.
9. Staubach S, Steinberg DH, Zimmerman W, et al. New onset atrial fibrillation after patent foramen ovale. *Catheter Cardiovasc Interv*. 2009;74:889-895.
10. Kasner SE, Rhodes JF, Andersen G, et al. Five-year outcomes of PFO closure or antiplatelet therapy for cryptogenic stroke. five-year outcomes of PFO closure or antiplatelet therapy for cryptogenic stroke. *Engl J Med*. 2021;384:970-971.
11. Windecker S, Meier B. Interventional PFO closure: what we see is but the tip of the iceberg. *Catheter Cardiovasc Interv*. 2000;50:199.
12. Mojadidi MK, Zaman MO, Elgendy IY, et al. Cryptogenic stroke and patent foramen ovale. *J Am Coll Cardiol*. 2018;71:1035-1043.